

1 UNITED STATES FOOD AND DRUG ADMINISTRATION  
2 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
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8 Scientific Data and Information about Products  
9 Containing Cannabis or Cannabis-Derived Compounds  
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11 Part 15 Public Hearing  
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14 DATE: Friday, May 31, 2019  
15 TIME: 8:00 a.m.  
16 LOCATION: U.S. Food and Drug Administration  
17 White Oak Campus, Building 31  
18 10903 New Hampshire Avenue  
19 Silver Spring, MD 20993  
20 JOB No.: 3406507  
21 REPORTER: KeVon Congo  
22

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2 Amy Abernathy, MD, PhD</p> <p>3 Principal Deputy Commissioner</p> <p>4 U.S. Food and Drug Administration</p> <p>5 Nick Alexander</p> <p>6 Director, Intergovernmental Affairs</p> <p>7 Office of Policy, Legislation and International</p> <p>8 Affairs</p> <p>9 U.S. Food and Drug Administration</p> <p>10 Dayle Lewis Cristinzio</p> <p>11 Director, Stakeholder Engagement</p> <p>12 Office of External Affairs</p> <p>13 U.S. Food and Drug Administration</p> <p>14 Jarilyn Dupont</p> <p>15 Director, Regulatory Policy</p> <p>16 Office of Policy</p> <p>17 U.S. Food and Drug Administration</p> <p>18 Randall Gnatt</p> <p>19 Regulatory Counsel</p> <p>20 Center for Veterinary Medicine</p> <p>21 U.S. Food and Drug Administration</p> <p>22</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES</p> <p>2 Sherene Sepehri</p> <p>3 Associate Chief Counsel</p> <p>4 Office of the Chief Counsel</p> <p>5 U.S. Food and Drug Administration</p> <p>6 Ned Sharpless, MD</p> <p>7 Acting Commissioner of Food and Drugs</p> <p>8 Douglas Throckmorton, MD</p> <p>9 Deputy Director for Regulatory Programs</p> <p>10 Center for Drug Evaluation and Research</p> <p>11 U.S. Food and Drug Administration</p> <p>12</p> <p>13 ORAL COMMENTS WITHOUT SLIDE DECK</p> <p>14 ACADEMIA</p> <p>15 Peter Pitts</p> <p>16 Center for Medicine in the Public Interest</p> <p>17 Tory Spindle, PhD</p> <p>18 Johns Hopkins University School of Medicine</p> <p>19</p> <p>20 AGRICULTURE (NON-GOVERNMENT)</p> <p>21 Jason Amatucci</p> <p>22 Virginia Industrial Hemp Coalition</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES</p> <p>2 Rebecca Goldberg</p> <p>3 Associate Chief Counsel</p> <p>4 Office of the Chief Counsel</p> <p>5 U.S. Food and Drug Administration</p> <p>6 Sharon Mayl</p> <p>7 Senior Advisor for Policy</p> <p>8 Office of Foods and Veterinary Medicine</p> <p>9 U.S. Food and Drug Administration</p> <p>10 Erik Mettler</p> <p>11 Assistant Commissioner for Partnerships and Policy</p> <p>12 Office of Regulatory Policy</p> <p>13 U.S. Food and Drug Administration</p> <p>14 Timothy Schell, PhD</p> <p>15 Director, Office of Surveillance and Compliance</p> <p>16 Center for Veterinary Medicine</p> <p>17 U.S. Food and Drug Administration</p> <p>18 Lowell Schiller</p> <p>19 Principal Associate Commissioner for Policy</p> <p>20 Office of Policy</p> <p>21 U.S. Food and Drug Administration</p> <p>22</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES</p> <p>2 Hunter Buffington</p> <p>3 Hemp Feed Coalition</p> <p>4 Jonathan Miller</p> <p>5 U.S. Hemp Roundtable</p> <p>6 Jonathan Vaught, PhD</p> <p>7 Front Range Biosciences</p> <p>8</p> <p>9 CONSUMERS</p> <p>10 Susan Cromer</p> <p>11 LilyHemp</p> <p>12 Pamela McColl</p> <p>13 Smart Approaches to Marijuana Canada</p> <p>14 Sally Schindel</p> <p>15 Marijuana Victims Alliance</p> <p>16</p> <p>17 HEALTH PROFESSIONALS</p> <p>18 Anne Hassel</p> <p>19 Holyoke Visiting Nurse Association</p> <p>20 Russell Kamer, MD</p> <p>21 Partners in Safety</p> <p>22</p>

Page 6	Page 8
<p>1 APPEARANCES</p> <p>2 Ashley Morgan, DVM</p> <p>3 American Veterinary Medical Association</p> <p>4</p> <p>5 MANUFACTURERS</p> <p>6 Philip Blair, MD</p> <p>7 Elixinol LLC</p> <p>8 Charles Jolly</p> <p>9 Baker Donelson</p> <p>10 James Shults</p> <p>11 WMI Consulting - Wildflower Brands</p> <p>12 David Spangler</p> <p>13 Consumer Healthcare Products Association</p> <p>14 Stuart Titus, PhD</p> <p>15 Medical Marijuana</p> <p>16 Julian Wright</p> <p>17 Science &amp; Recreation</p> <p>18</p> <p>19 OTHER</p> <p>20 William Bookout</p> <p>21 National Animal Supplement Council</p> <p>22</p>	<p>1 APPEARANCES</p> <p>2 David Rodman</p> <p>3 The Rodman Law Group LLC</p> <p>4 Zoe Sigman</p> <p>5 Project CBD</p> <p>6 Andy Snyder</p> <p>7 Manward Press</p> <p>8 Monica Weldon</p> <p>9 Bridge the Gap - SYNGAP Education and Research</p> <p>10 Foundation</p> <p>11 Anna Williams</p> <p>12 A2LA</p> <p>13</p> <p>14 PATIENTS</p> <p>15 Keith Fargo, PhD</p> <p>16 Alzheimer's Association</p> <p>17 Keith Chapman, MD</p> <p>18 American Epilepsy Society</p> <p>19 Kari Rosbeck</p> <p>20 Tuberosus Sclerosis Alliance</p> <p>21</p> <p>22</p>
Page 7	Page 9
<p>1 APPEARANCES</p> <p>2 Betsy Booren, PhD</p> <p>3 Grocery Manufacturers Association</p> <p>4 Aubrey Adams* (for James Childs, MD)</p> <p>5 Childs Dermatology Clinic</p> <p>6 Robert Discordia, PhD</p> <p>7 Corbus Pharmaceuticals</p> <p>8 Kristina Garcia</p> <p>9 Women Grow</p> <p>10 Gabriel Giancaspro, PhD</p> <p>11 US Pharmacopeia</p> <p>12 Karen Howard</p> <p>13 Organic &amp; Natural Health Association</p> <p>14 Rod Kight</p> <p>15 Kight Law Office PC</p> <p>16 Andrew Kline</p> <p>17 National Cannabis Industry Association</p> <p>18 Michael McGuffin</p> <p>19 American Herbal Products Association</p> <p>20 Megan Olsen</p> <p>21 Council for Responsible Nutrition</p> <p>22</p>	<p>1 APPEARANCES</p> <p>2 PUBLIC SAFETY</p> <p>3 Patrick Bird</p> <p>4 PMB BioTek Consulting</p> <p>5</p> <p>6 RETAILERS/DISTRIBUTORS</p> <p>7 Crystal Guess</p> <p>8 NuLeaf Naturals, LLC</p> <p>9 David Heldreth</p> <p>10 True Terpenes</p> <p>11 Peter Matz</p> <p>12 Food Marketing Institute</p> <p>13</p> <p>14 STATE/GOVERNMENT OFFICIALS/ENTITIES</p> <p>15 Pam Miles</p> <p>16 Virginia Department of Agriculture</p> <p>17 Brenda Morris</p> <p>18 Florida Department of Agriculture and Consumer</p> <p>19 Services</p> <p>20 Joseph Reardon</p> <p>21 North Carolina Department of Agriculture &amp;</p> <p>22 Consumer Services</p>

Page 10	Page 12
<p>1 APPEARANCES</p> <p>2 Erin Bubb</p> <p>3 Pennsylvania Department of Agriculture</p> <p>4</p> <p>5 FORMAL PRESENTATIONS WITH SLIDE DECK</p> <p>6 ACADEMIA</p> <p>7 Barry Gidal, PharmD</p> <p>8 University of Wisconsin-Madison</p> <p>9 Igor Grant, MD</p> <p>10 Center for Medicinal Cannabis Research, University</p> <p>11 of California, San Diego</p> <p>12 Bill Gurley, PhD</p> <p>13 University of Arkansas for Medical Sciences</p> <p>14 Rick Kingston, PharmD</p> <p>15 University of Minnesota; SafetyCall International</p> <p>16 PLLC</p> <p>17 Igor Koturbash, MD, PhD</p> <p>18 Center for Dietary Supplements Research,</p> <p>19 University of Arkansas</p> <p>20 Michelle Peace, PhD</p> <p>21 Virginia Commonwealth University</p> <p>22</p>	<p>1 APPEARANCES</p> <p>2 Yael Ossowski</p> <p>3 Consumer Choice Center</p> <p>4</p> <p>5 HEALTH PROFESSIONALS</p> <p>6 Ann Allworth, PhD</p> <p>7 Cannabis Education Solutions</p> <p>8 Jerry Bryant</p> <p>9 Vyripharm Biopharmaceuticals</p> <p>10 Najla Guthrie</p> <p>11 KGK Science</p> <p>12 Sue Sisley, MD</p> <p>13 Scottsdale Research Institute</p> <p>14 Lucille Vega, MD</p> <p>15 Vega Direct Medical Family Practice</p> <p>16</p> <p>17 MANUFACTURERS</p> <p>18 Justin Blehar</p> <p>19 Genco Pura Oil Company, LLC</p> <p>20 Richard Brumfield</p> <p>21 Full Spectrum Omega, Inc.</p> <p>22</p>
Page 11	Page 13
<p>1 APPEARANCES</p> <p>2 Ryan Vandrey, PhD</p> <p>3 Johns Hopkins University</p> <p>4 Larry Walker, PhD</p> <p>5 University of Mississippi, National Center for</p> <p>6 Natural Products Research</p> <p>7 Elise Wertz, PhD</p> <p>8 Johns Hopkins Medicine; The College on Problems of</p> <p>9 Drug Dependence</p> <p>10</p> <p>11 AGRICULTURE (NON-GOVERNMENT)</p> <p>12 Cameron Cane</p> <p>13 Deutsche Process</p> <p>14</p> <p>15 CONSUMERS</p> <p>16 Jaclyn Bowen</p> <p>17 International Association for Cannabis Testing</p> <p>18 David Evans</p> <p>19 Cannabis Industry Victims Educating Litigators</p> <p>20 Lisa Gill</p> <p>21 Consumer Reports</p> <p>22</p>	<p>1 APPEARANCES</p> <p>2 Rola Mazloun* (for Guy Chamberland, PhD)</p> <p>3 Tetra Bio-Pharma Inc.</p> <p>4 Josh Epstein</p> <p>5 Socati</p> <p>6 Bill Grubb* (for Scott Warner)</p> <p>7 Noramco</p> <p>8 Deb Kimless, MD</p> <p>9 Pure Green</p> <p>10 Douglas MacKay, ND</p> <p>11 CV Sciences</p> <p>12 Ray Mannion</p> <p>13 Zynerva Pharmaceuticals, Inc.</p> <p>14 Rosemary Mazanet, MD, PhD</p> <p>15 Columbia Care Inc.</p> <p>16 Alice Mead</p> <p>17 Greenwich Biosciences</p> <p>18 Marwan Moheyeldien</p> <p>19 Maryland Packaging LTD</p> <p>20 Stephen Mueller</p> <p>21 Mile High Labs</p> <p>22</p>

<p style="text-align: right;">Page 14</p> <p>1 APPEARANCES</p> <p>2 Aaron Secrist</p> <p>3 NOW Health Group, Inc.</p> <p>4 James Sharkey, PhD</p> <p>5 Therabis, LLC</p> <p>6 Priyanka Sharma, PhD</p> <p>7 Kazmira LLC</p> <p>8 Pulak Sharma</p> <p>9 Kazmira LLC</p> <p>10 Thuy Vu</p> <p>11 Hammer Enterprises</p> <p>12</p> <p>13 OTHER</p> <p>14 Aubree Adams</p> <p>15 Moms Strong</p> <p>16 Susan Audino, PhD</p> <p>17 S.A. Audino &amp; Associates, LLC</p> <p>18 James Beck, PhD</p> <p>19 Parkinson's Foundation</p> <p>20 Scott Coates</p> <p>21 AOAC Research Institute, AOAC INTERNATIONAL</p> <p>22</p>	<p style="text-align: right;">Page 16</p> <p>1 APPEARANCES</p> <p>2 Matt Sica</p> <p>3 ANSI National Accreditation Board</p> <p>4 David Steinberg</p> <p>5 Steinberg &amp; Associates, Inc.</p> <p>6</p> <p>7 PATIENTS</p> <p>8 James Werline, PharmD</p> <p>9 H-E-B</p> <p>10</p> <p>11 PUBLIC SAFETY</p> <p>12 Heather Despres</p> <p>13 Americans for Safe Access</p> <p>14 John Redman</p> <p>15 Community Alliances for Drug Free Youth</p> <p>16 Denise Valenti, OD</p> <p>17 IMMAD, LLC</p> <p>18</p> <p>19 RETAILERS/DISTRIBUTORS</p> <p>20 Howard Baxter, PhD</p> <p>21 Daye</p> <p>22</p>
<p style="text-align: right;">Page 15</p> <p>1 APPEARANCES</p> <p>2 Daniel Fabricant, PhD</p> <p>3 Natural Products Association</p> <p>4 Jacqueline French, MD</p> <p>5 Epilepsy Foundation</p> <p>6 Jeffrey Gitto</p> <p>7 Vanguard Legal PLLC</p> <p>8 Garrett Graff</p> <p>9 Hoban Law Group</p> <p>10 Shawn Hauser</p> <p>11 Vicente Sederberg LLC</p> <p>12 Youn Lee, PhD</p> <p>13 RTI International</p> <p>14 Brian Malkin</p> <p>15 Arent Fox LLP</p> <p>16 Steve Mister</p> <p>17 Council for Responsible Nutrition</p> <p>18 Robert Morgan</p> <p>19 ASTM International</p> <p>20 Sheri Orlowitz</p> <p>21 Artemis Holdings / MPP</p> <p>22</p>	<p style="text-align: right;">Page 17</p> <p>1 APPEARANCES</p> <p>2 Craig Brand</p> <p>3 Folium Biosciences</p> <p>4 Dana McMurchy</p> <p>5 Harvard CBD Health Center, Oklahomans for Health</p> <p>6 Valentina Milanova</p> <p>7 Daye</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>

Page 18		Page 20	
1	CONTENTS	1	PROCEEDINGS
2	PAGE	2	OPENING REMARKS
3	Welcome & Overview	3	MS. CRISTINZIO: -- to the Food and Drug
4	Dayle Cristinzio 20	4	Administration's scientific data and information about
5	Opening Remarks	5	products containing cannabis or cannabis-derived
6	Ned Sharpless, MD 26	6	compounds public hearing.
7	Oral Comments without Slide Deck	7	I am Dayle Cristinzio, director of
8	Academia 37	8	stakeholder engagement within the Office External
9	Agriculture (Non-government) 42	9	Affairs, and I will be moderating today's hearing.
10	Consumers 53	10	For today's agenda, we will hear from Dr. Ned
11	Health Professionals 58	11	Sharpless, FDA's acting commissioner, who is right
12	Manufacturers 66	12	here next to me. And then, we will proceed with the
13	Other 83	13	oral comment, without slides, portion of the hearing.
14	Patients 135	14	Afterwards, we will proceed with a group of
15	Public Safety 145	15	state presentations and then finish with about six
16	Retailers/Distributors 147	16	hours of formal presentations with slides. There are
17	Oral Comments & Formal Presentations with Slide Deck	17	printed copies of the detailed agenda at the back of
18	State/Government Officials/Entities 156	18	the room and at the registration desk with more
19	Formal Presentations with Slide Deck	19	information about the flow of the day.
20	Academic 176	20	Before we begin, I would like to ask our
21	Agriculture (Non-government) 227	21	distinguished panel members seated at this table next
22	Consumers 235	22	to me to introduce themselves, except for Dr.
Page 19		Page 21	
1	CONTENTS	1	Sharpless. Please state your name, your position and
2	PAGE	2	office and center.
3	Health Professionals 259	3	MR. SCHILLER: Good morning. My name is
4	Manufacturers 287	4	Lowell Schiller. I'm the principal associate
5	Other 373	5	commissioner for policy here at FDA. I also co-chair
6	Patients 456	6	FDA's internal CBD working group
7	Public Safety 461	7	DR. ABERNATHY: Good morning. Amy Abernathy,
8	Retailers/Distributors 481	8	principal deputy commissioner, and I also co-chair the
9	Closing Remarks 501	9	CBD working group.
10		10	MS. MAYL: Good morning. My name is Sharon
11		11	Mayl, and I am the senior advisor for policy in FDA's
12		12	Office of Food Policy and Response in the
13		13	commissioner's office and I co-chair the marijuana
14		14	working group at FDA.
15		15	DR. THROCKMORTON: And I'm Doug Throckmorton.
16		16	I'm the deputy director for regulatory programs in the
17		17	Center for Drug Evaluation and Research at the FDA,
18		18	and I am the other co-chair for the marijuana working
19		19	group.
20		20	MR. METTLER: Good morning. Erik Mettler. I
21		21	am the assistant commissioner for partnerships and
22		22	policy in the Office of Regulatory Affairs.

Page 22	Page 24
<p>1 MR. ALEXANDER: Good morning. I'm Nick 2 Alexander. I'm the director of intergovernmental 3 affairs in the Office of Policy, Legislation and 4 International Affairs in the Office of the 5 Commissioner.</p> <p>6 MS. GOLDBERG: Good morning. I'm Rebecca 7 Goldberg. I'm an attorney in the FDA's Office of the 8 Chief Counsel.</p> <p>9 MS. SEPEHRI: Good morning. Sherene Sepehri, 10 associate chief counsel in the Office of the Chief 11 Counsel.</p> <p>12 DR. SCHELL: And I'm Tim Schell. I'm the 13 director of the Office of Surveillance and Compliance 14 for the Center for Veterinary Medicine.</p> <p>15 MS. CRISTINZIO: And now, I have a few 16 general announcements to go over before we begin. In 17 addition to the hundreds of people we are expecting to 18 attend today's session in person, today's hearing is 19 also being webcast and transcribed.</p> <p>20 Public hearings are public administrative 21 proceedings and are subject to FDA policy and 22 procedures for electronic media coverage.</p>	<p>1 approach panelists during the hearing. Also, please 2 silence your cellphones -- mine is silenced -- and 3 other electronic devices at this time and be 4 respectful of the speakers and move outside of the 5 room if you need to have a side conversation during 6 today's session.</p> <p>7 Lunch and refreshments are available for 8 purchase just outside the Great Room throughout the 9 day. If you are planning to purchase lunch, please 10 consider filling out a lunch form and paying in 11 advance during the morning break in order to help us 12 get lunches distributed to this large number of people 13 as quickly as possible.</p> <p>14 Restrooms are located just outside the Great 15 Room to the right. Just ask any of the staff outside 16 and they will help direct you to them.</p> <p>17 For our speakers, please be mindful of all 18 your fellow presenters' time and do not go over your 19 allotted amount. We have an ambitious agenda today, 20 with over 113 speakers, and must stay within the time 21 limitations in order to end on time.</p> <p>22 Please also pay attention to the agenda which</p>
<p>Page 23</p> <p>1 Representatives of the electronic media are permitted, 2 subject to certain limitations to videotape, film or 3 otherwise record FDA public procedures, including the 4 presentations of the speakers today.</p> <p>5 The hearing will also be transcribed and 6 copies of the transcript can be ordered through the 7 docket or accessed on our website approximately 30 8 days after the hearing. In addition, the webcast of 9 the hearing will be recorded and a copy of that 10 recording should be available on our website by the 11 end of next week.</p> <p>12 No participant can interrupt the presentation 13 of any other participant and only FDA panel members 14 will be allowed to question the presenters. The press 15 contact for today's meeting is Mr. Michael Felberbaum. 16 If you are media and haven't checked in with him yet, 17 please do so as soon as possible. I believe he is at 18 the back of the room waving his hand at us.</p> <p>19 I would like to remind everyone that members 20 of the public and the press are not permitted in the 21 panel area, which is the area beyond the speaker's 22 podium towards the front of this room. Please do not</p>	<p>Page 25</p> <p>1 will be projected throughout the day and make your way 2 to the podium before your time slot so that we do not 3 lose valuable time between presentations. In order to 4 help the transcribers identify who is speaking, please 5 be sure to clearly state your name and affiliation at 6 the beginning of your remarks.</p> <p>7 Also, there is a colored light system on the 8 podium microphone that will guide you through your 9 allotted time. It will change from green to yellow 10 when you have one minute remaining. And when the 11 light changes to red, your time is up.</p> <p>12 If you have not concluded your remarks by the 13 time the light turns red, I apologize in advance, but 14 I will interrupt you and ask you to stop, very nicely.</p> <p>15 And I will be emphasizing this throughout the 16 day. Your comments and presentations today will be 17 included in the public docket. But if you run out of 18 time and don't get to complete your remarks, please 19 submit additional information to the public docket for 20 consideration.</p> <p>21 And with that, I'd now like to introduce our 22 distinguished acting commissioner, Dr. Ned Sharpless,</p>

<p style="text-align: right;">Page 26</p> <p>1 for opening remarks.</p> <p>2 Dr. Sharpless has been with the agency for a</p> <p>3 few months now, but is certainly not new to public</p> <p>4 health or the FDA. He has a long and distinguished</p> <p>5 career in public service, most recently serving as</p> <p>6 director of the National Cancer Institute at NIH.</p> <p>7 He is also a world-renowned oncologist who</p> <p>8 was the director of the UNC Lineberger Comprehensive</p> <p>9 Cancer Center and served on the faculty of UNC School</p> <p>10 of Medicine as well as Harvard Medical School. Please</p> <p>11 join me in welcoming Dr. Sharpless to the podium.</p> <p>12 (Applause.)</p> <p>13 OPENING REMARKS</p> <p>14 DR. SHARPLESS: Thank you, Dayle. Good</p> <p>15 morning, everyone. Thank you for joining the FDA</p> <p>16 today for this public hearing titled "Scientific Data</p> <p>17 and Information about Products Containing Cannabis or</p> <p>18 Cannabis-Derived Compounds."</p> <p>19 I'm pleased to see that there's so much</p> <p>20 interest in this topic. We have over 500 people</p> <p>21 registered to attend in person. We expect more than</p> <p>22 800 people registered to join us remotely and over a</p>	<p style="text-align: right;">Page 28</p> <p>1 At the same time though, some relevant laws</p> <p>2 have changed. First, some states have changed their</p> <p>3 laws to allow for medical use of marijuana or CBD and</p> <p>4 others have begun allowing for recreational marijuana</p> <p>5 use or decriminalized recreational marijuana</p> <p>6 possession.</p> <p>7 Moreover, certain federal laws have changed</p> <p>8 as well. Part of the cannabis sativa plant have been</p> <p>9 controlled under the federal Controlled Substances</p> <p>10 Act, or the CSA, since 1970 under the drug class</p> <p>11 marijuana.</p> <p>12 Marijuana is included in Schedule 1 of the</p> <p>13 CSA, the most restrictive schedule, due to its</p> <p>14 potential for abuse, largely attributable to the</p> <p>15 psychoactive effects of THC and the absence of a</p> <p>16 currently acceptable medical use in the United States.</p> <p>17 Last year, the federal scheduling of cannabis</p> <p>18 changed. The Agricultural Improvement Act of 2018,</p> <p>19 otherwise known as the farm bill, removed hemp,</p> <p>20 meaning cannabis or derivatives of cannabis with a</p> <p>21 very low THC content. And that's below 0.3 percent by</p> <p>22 dry weight -- from -- so hemp was removed from the CSA</p>
<p style="text-align: right;">Page 27</p> <p>1 hundred speakers on today's very packed agenda and</p> <p>2 lots of interest from the media.</p> <p>3 We encourage all stakeholders, presenters,</p> <p>4 attendees and those unable to participate in today's</p> <p>5 meeting to submit comments to our docket, which is</p> <p>6 open and will be open until July 2, 2019. Docket</p> <p>7 comments will help inform the FDA as we consider the</p> <p>8 important policy options related to the regulation of</p> <p>9 products containing cannabis or cannabis-derived</p> <p>10 compounds.</p> <p>11 It's important to note that the FDA's role in</p> <p>12 the regulation of products containing cannabis is not</p> <p>13 new. Cannabis contains more than 80 biologically</p> <p>14 active chemical compounds, including the best known</p> <p>15 compounds, -9-tetrahydrocannabinol, or THC, and</p> <p>16 cannabidiol, or CBD.</p> <p>17 If one of these compounds or the plant itself</p> <p>18 is added to a food or cosmetic, marketed as a drug or</p> <p>19 otherwise added to an FDA-regulated product in</p> <p>20 interstate commerce, then it falls within FDA's</p> <p>21 jurisdiction. As I said, this is nothing new for the</p> <p>22 FDA.</p>	<p style="text-align: right;">Page 29</p> <p>1 definition of marijuana. As a result, while marijuana</p> <p>2 remains a Schedule 1 drug, hemp is no longer a</p> <p>3 controlled substance under federal law.</p> <p>4 As these laws have changed, FDA's authorities</p> <p>5 have therefore become more relevant. The 2018 farm</p> <p>6 bill explicitly preserved the FDA's authority to</p> <p>7 regulate products containing cannabis or cannabis-</p> <p>8 derived compounds.</p> <p>9 In doing so, Congress recognized FDA's</p> <p>10 important public health role with respect to all of</p> <p>11 these products that it regulates, including when those</p> <p>12 products are or contain cannabis ingredients.</p> <p>13 FDA treats substances derived from cannabis</p> <p>14 just like we do any other substance and they are</p> <p>15 subject to the same authorities as any other</p> <p>16 substance. Under FDA's authorities, the relevant</p> <p>17 legal requirements vary depending on which type of</p> <p>18 product we're talking about.</p> <p>19 For example, if a product is being marketed</p> <p>20 as a drug, meaning that it's intended to have a</p> <p>21 therapeutic effect such as treating a disease or</p> <p>22 affecting the body's structure or function, then it's</p>



<p style="text-align: right;">Page 30</p> <p>1 regulated as a drug and it generally cannot be sold 2 without FDA approval. 3 FDA has approved several products that 4 contain compounds found in cannabis as drugs. These 5 include Epidiolex, which contain CBD for the treatment 6 of certain kinds of pediatric seizures, and Marinol 7 and Syndros, which contain dronabinol, a synthetic 8 version of THC, that's used for the treatment of 9 anorexia, for example, in patients with AIDS. 10 These drugs have important therapeutic value 11 and it is critical that we continue to do what we can 12 to support the science needed to develop new drugs 13 from cannabis. 14 Food, including dietary supplements, is 15 regulated differently, but with the same overarching 16 goals throughout the FDA of protecting consumers and 17 the public health. We know that American consumers 18 depend on FDA to help make sure that the food they eat 19 and that they serve to their families is safe. We do 20 this through a number of requirements. 21 For example, while we don't generally require 22 foods to be approved by FDA before coming to market,</p>	<p style="text-align: right;">Page 32</p> <p>1 both substances that have been approved as drugs as 2 well as compounds for which substantial clinical 3 investigation have been instituted. Similarly the law 4 excludes these products from the statutory definition 5 of a dietary supplement. 6 Based on the information available to the 7 FDA, we have concluded that these provisions apply to 8 CBD and THC. And while there is an exception when the 9 substance was marketed as a food or dietary supplement 10 before it was studied as a drug, we have concluded 11 that that is not the case for CBD or THC. 12 What that means is that under current law, 13 CBD and THC cannot lawfully be added to food or 14 marketed as a dietary supplement 15 Although the new law says that FDA could 16 issue regulations to create new exceptions to these 17 statutory provisions, FDA has never issued a 18 regulation like that for any substance. So if we were 19 thinking about doing that for a substances like CBD, 20 well, that would be new terrain for the FDA. 21 There are important reasons to generally 22 prohibit putting drugs in the food supply. When FDA</p>
<p style="text-align: right;">Page 31</p> <p>1 we do require that a new food additive be approved as 2 safe by FDA before being put in the food supply, 3 unless that substance is generally recognized as being 4 safe, or GRAS. 5 This requirement applies to cannabis-derived 6 ingredients just as it does to any other substance. 7 Americans deserve to know that substances being added 8 to their food are safe, regardless of the source. 9 I will note that several cannabis-derived 10 substances have already come to market through the 11 GRAS pathway. In December, FDA announced that we 12 completed our evaluation of GRAS noticed for three 13 hemp seed ingredients and had no objection to their 14 being marketed in human foods for certain uses without 15 approval, provided they comply with all other 16 requirements. 17 As I mentioned earlier however, some 18 compounds found in cannabis, specifically CBD and THC, 19 have been studied and even approved as drugs. It's 20 important to note that the federal Food, Drug and 21 Cosmetics Act prohibits adding drugs to human or 22 animal food in interstate commerce. That includes</p>	<p style="text-align: right;">Page 33</p> <p>1 approves a drug, we carefully evaluate the risks and 2 benefits of a specific formulation, dosage form and 3 strength for a particular population. Often we 4 conclude that to be safely used, it requires a 5 prescription or other medical supervision to help 6 protect against potential dangerous misuse. THC and 7 CBD are no exception. 8 There are real risks associated with both 9 substances and critical questions remain about the 10 safety of their widespread use in foods and dietary 11 supplements, as well as other consumer products like 12 pet food and cosmetics, which are subject to a 13 separate regulatory framework. 14 And given the new interest in marketing 15 cannabis products across a range of areas that the FDA 16 regulates, we will need to carefully evaluate how all 17 these pieces fit together in terms of how consumers 18 might access cannabis products. 19 Nowhere is this truer than with CBD. While 20 we've seen an explosion of interest in products 21 containing CBD, there is still much that we don't 22 know. Prior to the 2018 farm bill, population-based</p>

<p style="text-align: right;">Page 34</p> <p>1 research mostly included cannabis-focused observations  2 in aggregate. There still -- rather than specific to  3 CBD.  4       When hemp was removed as a controlled  5 substance, this lack of research and therefore lack of  6 evidence to support CBD's broader use in FDA-regulated  7 products, including in food and dietary supplements,  8 has resulted in unique complexities for its  9 regulation, including many unanswered questions  10 related to its safety.  11       For example, how much CBD is safe to consume  12 in a day? What if someone applies a topical CBD  13 lotion, consumes a CBD beverage or candy and also  14 consumes some CBD oil? How much is too much? How  15 will it interact with other drugs the person may be  16 taking? What if she's pregnant?  17       What if children access CBD products like  18 gummy edibles? What happens when someone chronically  19 uses CBD for prolonged periods? These and many other  20 questions represent important and significant gaps in  21 our knowledge.  22       To help us evaluate these questions as well</p>	<p style="text-align: right;">Page 36</p> <p>1 CBD products. There are lots of questions we will  2 need to answer to ensure that FDA is taking an  3 appropriate well-informed and science-based approach  4 to the regulation of cannabis and cannabis  5 derivatives, including CBD.  6       We hope that this meeting and the comments  7 submitted in our public docket will help us as we try  8 to approach this in a science-based way. This hearing  9 is an important step in our continued evaluation of  10 cannabis and cannabis-derived compounds in FDA-  11 regulated products.  12       Now, that was a lot to go through quickly.  13 So I will be tweeting the text of this speech as well  14 as a link to where you can submit comments for the  15 docket from the FDA commissioner account later today.  16       I thank you all for taking the time to join  17 us today and your contributions toward this important  18 topic. And as mentioned, we have a very fully agenda.  19 So I'll leave it at that. Thank you this morning.  20       (Applause.)  21       MS. CRISTINZIO: Thank you, Dr. Sharpless.  22 Now we are going to begin the open public comment</p>
<p style="text-align: right;">Page 35</p> <p>1 as potential pathways for CBD products, FDA has formed  2 an internal working group to address these data gaps  3 specifically, and you will be hearing more from this  4 group in the months to come.  5       FDA is aware that some companies appear to be  6 marketing products containing cannabis and cannabis-  7 derived compounds in ways that violate the law. FDA  8 has issued warning letters to companies selling  9 unapproved CBD products.  10       Our biggest concern is the marketing of  11 products that put the health and safety of consumers  12 at risk, such as those claiming to prevent, diagnose,  13 mitigate, treat or cure serious diseases such as  14 cancer in the absent of requisite approvals.  15       Selling unapproved drug products with  16 unsubstantiated therapeutic claims is a violation of  17 the law and puts patients at risk. Patients and other  18 consumers may be influenced not to use approved  19 therapies to treat serious and even fatal diseases if  20 they're confused.  21       That being said, the agency does not have a  22 policy of enforcement discretion with respect to any</p>	<p style="text-align: right;">Page 37</p> <p>1 period, or oral comment period of our program this  2 morning. Those people on the agenda will have two  3 minutes each to present.  4       Hopefully when you checked in outside, you  5 were told that you were given a number. We'll have a  6 numeric order for speakers. And they're organized by  7 segment, how you identified yourself. Some of you  8 identified yourself as academic first, and that is the  9 first category that is up.  10       First, I have Peter Pitts, from the Center  11 for Medicine in the Public Interest, as our first  12 speaker. And if you all know your numbers, please  13 make your way to the line behind him so that we can  14 move quickly in between. Peter, you may begin.  15 <b>ORAL COMMENTS WITHOUT SLIDE DECK</b>  16 <b>ACADEMIA</b>  17       MR. PITTS: Thank you. Good morning. My  18 name is Peter Pitts. I'm the president of the Center  19 for Medicine in the Public Interest. The absence to  20 date of advanced regulatory thinking relative to CBD  21 has resulted in a maelstrom of false claims and shoddy  22 quality standards. Nature abhors a vacuum.</p>

<p style="text-align: right;">Page 38</p> <p>1 What's the relevant messages for the nascent,  2 but swiftly growing CBD industry? First, that  3 aggressive and misleading marketing campaigns need to  4 be put on hold now that the FDA has stepped up to the  5 plate. Next, as with all FDA-regulated products,  6 manufacturing quality and labeling integrity are  7 joined at the hip.</p> <p>8 Many in the CBD community think this issue is  9 one of regulatory creep on the part of the FDA. But  10 waving away as "Big Brotherism" the important public  11 health role of the FDA doesn't make the agency's  12 position or authority any less real or relevant.</p> <p>13 It's time for the proponents of CBD,  14 including many highly vocal patients, physicians,  15 pharmacists, manufacturers and distributors to become  16 part of the solution.</p> <p>17 Some key issues include, one, no current  18 standard in quality of production. We mustn't repeat  19 the tragic flaws of limiting FDA's hand via outdated  20 DSHEA legislation. Quality must always trump  21 corporate convenience. Two, no dosing standard. When  22 patients are prescribed any FDA-approved medication,</p>	<p style="text-align: right;">Page 40</p> <p>1 Spindle from Johns Hopkins University School of  2 Medicine.</p> <p>3 DR. SPINDLE: Hi, everyone. My name is Tory  4 Spindle, and I'm a cannabis researcher at Johns  5 Hopkins University. I'm not speaking on behalf of  6 Johns Hopkins today, and these are my own views.</p> <p>7 Although I now specialize in cannabis  8 research, I did my PhD work conducting research to  9 inform product regulations for electronic cigarettes.  10 From this research, I learned there's a lot of moving  11 parts with e-cigarettes that will make it very  12 difficult to regulate nicotine dosage and delivery.</p> <p>13 But I've grown to realize from my cannabis  14 research that regulating dosage for cannabis products  15 will be exponentially more difficult. If you remember  16 one thing from my talk today, remember that for  17 cannabis, a dose is not necessarily a dose.  18 Importantly, the same dose of cannabis can have very  19 different effects on a person depending on the route  20 of administration.</p> <p>21 We recently published a paper in JAMA Network  22 Open showing that the same dose of cannabis can</p>
<p style="text-align: right;">Page 39</p> <p>1 they are given a dosing schedule by the doctor telling  2 them how much to take, how to take it and how often.</p> <p>3 When people are told to use CBD by  4 physicians, pharmacists, friends or Internet experts,  5 they are not given any peer-reviewed guidelines about  6 how they should take it or in what amounts, something  7 that should never happen.</p> <p>8 Three, potential for help and harm through  9 chronic use. What does serious research tell us?  10 Hardly anything. And the plural of anecdote isn't  11 data. We mustn't repeat the mistakes that led to the  12 opioid epidemic.</p> <p>13 Four, legalization changes public opinion.  14 If you can't measure it, then it doesn't count.  15 Quantifying CBD's therapeutic and manufacturing bona  16 fides for pain treatment isn't the end of the debate.  17 It is only the beginning.</p> <p>18 Now you must develop ways to measure its  19 effectiveness and develop ways to capture the real-  20 world evidence that must drive evolving best practice  21 and reimbursement policies. Thank you.</p> <p>22 MS. CRISTINZIO: Thank you. Next up is Tory</p>	<p style="text-align: right;">Page 41</p> <p>1 produce stronger drug effects and greater impairment  2 if it's inhaled with a cannabis vaporizer compared to  3 with a smoked method.</p> <p>4 When cannabis is inhaled, users can feel the  5 drug effects within minutes. However, when cannabis  6 is orally ingested, it can take up to 45 minutes for a  7 person to feel a drug effect and often peak effects  8 don't occur until hours after ingestion. This delayed  9 onset of effects makes it difficult for someone to  10 titrate their dosage, which can lead to acute  11 overdose.</p> <p>12 Beyond these products, there are many other  13 routes of administration that are becoming popular,  14 including transdermal or topical cannabis products,  15 sublingual sprays, lozenges and cannabis  16 suppositories. But given the regulatory barriers to  17 conducting cannabis research, we have very little  18 scientific evidence available to inform regulation of  19 these emerging products.</p> <p>20 Just like the research currently being done  21 to inform regulations for tobacco products, we  22 desperately need to conduct cannabis regulatory</p>

<p style="text-align: right;">Page 42</p> <p>1 science to inform appropriate product standards for  2 the various forms of cannabis that are available today  3 or that might become available tomorrow. Researchers  4 need a streamlined, regulatory pathway that can  5 facilitate research on the spectrum of commercially  6 available products.</p> <p>7 Clinical research studies have barely  8 scratched the surface when considering the vast array  9 of cannabis products available to consumers. The risk  10 of retail cannabis products harming public health must  11 be mitigated by swift and evidence-based regulatory  12 action. Thank you all for allowing me to speak today.</p> <p>13 MS. CRISTINZIO: Thank you. The next speaker  14 is from the agriculture category. Jason Amatucci.  15 AGRICULTURE (NON-GOVERNMENT)</p> <p>16 MR. AMATUCCI: Good morning. My name is  17 Jason Amatucci. I founded the Virginia Industrial  18 Hemp Coalition in 2012 and since that time I've been  19 assisting with the crafting of legislation and policy  20 for the Virginia and United States hemp industry. I  21 want to thank the FDA for holding this public hearing  22 on the subject of cannabis-derived products.</p>	<p style="text-align: right;">Page 44</p> <p>1 Currently farmers who grow crops on land  2 where hemp also does well, such as corn, soybeans and  3 tobacco, are being hit with multiple downward  4 pressures. The recent popularity of hemp products  5 have shown great economic promise in providing some  6 hope for farmers and agribusiness in places where  7 there currently is little hope to be found.</p> <p>8 It is our request that the FDA strongly  9 considers the new economic opportunities that farmers  10 and agribusiness have when forming regulations. We  11 recommend that you regulate hemp products as food and  12 dietary supplements and give them all GRAS  13 designation.</p> <p>14 We wholeheartedly agree with the FDA that  15 food and dietary supplement safety for the public is  16 of the utmost importance. And the hemp industry has  17 shown that it will work, as it has already started to,  18 to self-regulate, to provide safe products and  19 consumer products.</p> <p>20 What we need from the FDA right now is clear  21 communication as quickly as possible so that all  22 stakeholders can get on the same page so that the</p>
<p style="text-align: right;">Page 43</p> <p>1 I'd like to begin this morning by making a  2 connection between safe, non-intoxicating hemp  3 products being produced currently throughout America  4 and the relationship to farmers and agribusiness in  5 those states.</p> <p>6 Today, as many of you know, the American  7 farmer is facing some of the toughest times in recent  8 history. In my home state of Virginia, agriculture is  9 the largest private industry by far. Nothing else  10 comes a close second.</p> <p>11 It has an economic impact of \$70 billion  12 annually and provides more than 334,000 jobs for our  13 state. In neighboring Kentucky last year, hemp  14 processors reported \$58 million in gross product sales  15 and they paid Kentucky farmers \$18 million for  16 harvested hemp materials. Hemp processors also spent  17 \$23 million in capital improvements in the state,  18 while creating many new jobs in the process.</p> <p>19 I truly believe the United States hemp  20 industry is poised to take off. But to do so, we  21 cannot have legal uncertainty which can hinder the  22 growth in confidence in our industry.</p>	<p style="text-align: right;">Page 45</p> <p>1 American hemp industry can thrive to boost the  2 economy, create jobs and give Americans safe and  3 effective products for a better quality of life.  4 Thank you for your time.</p> <p>5 MS. CRISTINZIO: Thank you. Next, we have  6 Hunter Buffington, from Hemp Feed Coalition.</p> <p>7 MS. BUFFINGTON: Good morning. I'm Hunter  8 Buffington, program director for the Hemp Feed  9 Coalition, a group of farmers, processors, feed  10 experts, researchers, animal nutritionists from across  11 the United States and Canada.</p> <p>12 Our goal is the legal approval of hemp as an  13 animal feed ingredient, focusing on hempseeds and  14 their byproducts. However, there is an opportunity to  15 utilize flour grown commonly for CBD as forage and  16 silage and significant interest in the nutritional  17 value of post-extracted cannabinoid pulp material for  18 the animal feed market as well.</p> <p>19 Preliminary data shows that this is a  20 valuable material with high levels of protein and  21 omega fatty acids, including linoleic acid. This  22 material is currently considered waste and accumulates</p>

<p style="text-align: right;">Page 46</p> <p>1 in warehouses instead of providing a much needed 2 secondary revenue stream for farmers and a high 3 protein feed source for animal, poultry and fish 4 producers. 5 Hemp is one of the oldest crops known to 6 mankind and American farmers must be given the 7 opportunity to have an additional cash crop to replace 8 dwindling commodity prices. 9 Currently China produces 50 percent of the 10 world's cannabis supply, a threat to cannabis 11 interests around the world and particularly the U.S. 12 market, as reported by Forbes. Not only is this a 13 threat to small farmers and livestock producers, this 14 introduces low quality and potentially harmful 15 products into the U.S. market and to American 16 consumers. 17 We need to ensure that the economic benefits 18 of the emerging hemp industry start on the family farm 19 with American-grown and processed feeds. Healthier 20 feeds create healthier animals and in turn leads to 21 healthier Americans. 22 We ask that the FDA and its commissioner do</p>	<p style="text-align: right;">Page 48</p> <p>1 industry. We're comprised of members from more than 2 60 firms from across the country who are involved in 3 each link of the hemp supply and sales chain, as well 4 as grassroots leaders such as the Hemp Industries 5 Association. 6 Over the past several weeks, we have worked 7 with members of Congress on the drafting of 8 legislation that, if necessary, could provide a more 9 efficient pathway for CBD while FDA considers 10 rulemaking to allow the use of CBD in food and dietary 11 supplements. 12 We believe Congress clearly intended on 13 having hemp-derived products available to consumers as 14 foods and dietary supplements when it passed the 2018 15 farm bill. There is an urgent need for an efficient 16 regulatory framework for CBD as we continue to see a 17 great deal of confusion among consumers and state and 18 local regulators surrounding the lawfulness of hemp- 19 derived products. 20 The roundtable appreciates the FDA's 21 willingness to work with stakeholders. But we 22 strongly believe that the FDA has all the tools</p>
<p style="text-align: right;">Page 47</p> <p>1 not utilize a lack of data and research, considering 2 we've only had access to cannabis for the last three 3 years, as a reason to implement a ban or incorrectly 4 label it a drug. 5 Instead, we recommend the following steps: 6 include data and research from qualified international 7 sources and open research opportunities to private 8 companies instead of a small group of universities. 9 Identify a pathway for the production of hemp-derived 10 foods and reconsider designation of a dietary 11 supplement for products that contain CBD and other 12 useful phytochemicals. 13 Your agreement to this shows a commitment to 14 help farmers and animal producers to keep American 15 agriculture competitive. Thank you. 16 MS. CRISTINZIO: Thank you. The next 17 speaker, number five, is Jonathan Miller, U.S. Hemp 18 Roundtable. 19 MR. MILLER: Good morning. The U.S. Hemp 20 Roundtable is the hemp industry's leading business 21 advocacy organization committed to fostering 22 regulatory discussions and building an accountable</p>	<p style="text-align: right;">Page 49</p> <p>1 necessary to make a change expeditiously. Multiple 2 reviews, including the World Health Organization's 3 June 2019 critical review of cannabidiol and ones from 4 the FDA itself have found that CBD is safe, with a 5 growing body of scientific research which demonstrates 6 CBD's potential benefits. 7 Although hemp-derived CBD is safe, our 8 members are not just relying on the current scientific 9 literature; but rather, we are also investing millions 10 of dollars to conduct our own safety studies. 11 Moreover, the U.S. Hemp Authority's certification 12 program is our industry's initiative to provide high 13 standards, best practices and self-regulation, giving 14 confidence to consumers and law enforcement that hemp 15 products are safe and legal. 16 This effort, led by the roundtable, HIA top 17 tier testing laboratories and quality assessors, 18 provides comprehensive guidance for growers and 19 processors of hemp to help ensure the safety and 20 quality of hemp-derived products, including CBD. 21 We welcome the opportunity to discuss this 22 important initiative with the FDA and use what we've</p>

<p style="text-align: right;">Page 50</p> <p>1 learned to help the agency establish measures of 2 quality, safety and transparency for the entire 3 industry. Thank you.</p> <p>4 MS. CRISTINZIO: Thank you. Panelists, do 5 you have any questions? Okay. Our next speaker is 6 Jon Vaught, from Front Range Biosciences.</p> <p>7 DR. VAUGHT: My name is Jon Vaught. I have a 8 PhD in organic chemistry from the University of 9 Colorado at Boulder and I'm CEO and founder of Front 10 Range Biosciences. We're an agricultural company that 11 supports farmers of high value crops such as hemp and 12 coffee.</p> <p>13 Before Front Range, I spent 15 years 14 developing technology platforms in human diagnostics 15 that generated validated clinical data supporting the 16 FDA drug approval process. I have a deep 17 understanding of FDA regulations for taking drugs to 18 market and the scientific rigor required to ensure 19 safety and efficiency for consumers.</p> <p>20 I strongly support the FDA's mission of 21 ensuring public safety when it comes to bringing new 22 products to market and am thankful for the role it</p>	<p style="text-align: right;">Page 52</p> <p>1 Second, the economic impact of cannabis 2 products is massive and it's important that 3 regulations don't create a monopoly for any one 4 segment of the industry. The current market in the 5 U.S. hit over \$10 billion last year, generating a 6 billion dollars in tax revenue for state governments 7 and representing over 200,000 jobs in the United 8 States. That's more jobs than coal or textile 9 manufacturing.</p> <p>10 It has huge potential impact for agricultural 11 regions in the U.S., providing opportunities that can 12 raise the economic status of many farming communities 13 that have been beaten down economically.</p> <p>14 It's important we focus on a regulatory 15 framework for cannabinoid-based products that ensures 16 public safety, but provides the opportunity for not 17 just one, but multiple segments of the industry to 18 thrive, pharmaceuticals, dietary supplements, food 19 additives, cosmetics and even animal feed.</p> <p>20 MS. CRISTINZIO: Thank you.</p> <p>21 PANEL MEMBER: Quick question. Are you 22 willing to submit your data to the public docket so</p>
<p style="text-align: right;">Page 51</p> <p>1 plays, despite frequent criticism from the public. I 2 can imagine it's not an easy job to do.</p> <p>3 There are two key points: first, that 4 cannabis-derived ingredients have an incredible safety 5 profile compared to many over-the-counter products and 6 FDA-approved drugs on the market. Besides it's 7 measured therapeutic ratio, cannabis is 400 times 8 safer than caffeine and 200 times safer and aspirin.</p> <p>9 In published Epidiolex studies, doses as high 10 as 10 mg/kg, or 70 milligrams a day for a normal 11 adult, were well tolerated, with only 2.7 percent of 12 the trial participants discontinuing treatment due to 13 severe adverse events such as mild liver toxicity and 14 sleepiness.</p> <p>15 Given the last decade of state-regulated 16 legal programs which have not created a public health 17 crisis, in recent clinical data from the Epidiolex 18 trials, there is more than enough evidence showing 19 cannabis is generally at safe limits where it's 20 marketed and regulated at the state level as a 21 supplement or a wellness product, typically 10 to 30 22 mg per dose.</p>	<p style="text-align: right;">Page 53</p> <p>1 that it can be reviewed?</p> <p>2 DR. VAUGHT: Absolutely. I'll do it by July 3 2nd.</p> <p>4 PANEL MEMBER: Thank you.</p> <p>5 MS. CRISTINZIO: Thank you. Our next 6 speakers in the consumer category, Susan Cromer from 7 LilyHemp.</p> <p>8 CONSUMERS</p> <p>9 MS. CROMER: Thank you for taking the time to 10 address this very important issue. I am Susan Cromer, 11 founder and CEO of LilyHemp, a boutique and gourmet 12 retail, wholesale and e-commerce business, cofounder 13 of Women in Hemp, a 501(c)(3) dedicated to the 14 education and support of women in the industry and I 15 am a board member of the Virginia Industrial Hemp 16 Coalition.</p> <p>17 As a retailer, it is paramount to me to offer 18 safe, effective, top quality products. This can 19 easily be achieved by following the guidelines 20 currently in place for supplements and for ingredients 21 in foods. Additionally, require clear, truthful 22 labeling, the implementation of good manufacturing</p>

<p style="text-align: right;">Page 54</p> <p>1 practices and determination of shelf stability.</p> <p>2       These are all systems the FDA already has in</p> <p>3 place to keep us safe. You got this. Just use them</p> <p>4 for CBD. Science has proven with the discovery of the</p> <p>5 endocannabinoid system that CBD is beneficial to</p> <p>6 humans and animals alike. The World Health</p> <p>7 Organization has deemed CBD safe. Much credible</p> <p>8 research and a multitude of anecdotal evidence attest</p> <p>9 that CBD has many positive effects.</p> <p>10       Personally I have been privileged, awed and</p> <p>11 at times brought to ears by the positive changes CBD</p> <p>12 has brought to my customers' lives. My clients and</p> <p>13 thousands, if not hundreds of thousands of others,</p> <p>14 have felt the difference CBD can make.</p> <p>15       Overregulation will simply drive consumers to</p> <p>16 the black market, costing our economy and tax base a</p> <p>17 projected revenue stream of many billions of dollars.</p> <p>18 The ending of prohibition of hemp with the 2018 farm</p> <p>19 bill was monumental for our country. I ask you not to</p> <p>20 repeat history by once again demonizing any part of</p> <p>21 this wondrous plant. We the people deserve and I</p> <p>22 daresay demand no less than safe and unfettered</p>	<p style="text-align: right;">Page 56</p> <p>1 alcohol or something like that, just seemed like the</p> <p>2 age that people usually use for substances.</p> <p>3       PANEL MEMBER: Thank you.</p> <p>4       MS. CROMER: That is just a safety guideline.</p> <p>5 There is no -- I know there is no set thing. But I</p> <p>6 know that other states that have -- I'm from Virginia.</p> <p>7 We really don't have any guideline for that.</p> <p>8       But I know that other states have used 21.</p> <p>9 So we just did it as kind of a safety net. No</p> <p>10 particular -- just think that's a good idea. You guys</p> <p>11 can tell us. We'd appreciate that.</p> <p>12       PANEL MEMBER: Thank you.</p> <p>13       MS. CROMER: Thank you.</p> <p>14       MS. CRISTINZIO: Thank you. Our next speaker</p> <p>15 is Sally Schindel, from the Marijuana Victims</p> <p>16 Alliance, speaker number eight.</p> <p>17       MS. SCHINDEL: Sally Schindel, Marijuana</p> <p>18 Victims Alliance. My son was the consumer. My son's</p> <p>19 suicide note: "Marijuana killed my soul, plus ruined</p> <p>20 my brain." In the end, Andy understood the dangers of</p> <p>21 marijuana. And I have to ask do you understand.</p> <p>22       What we need is our federal government</p>
<p style="text-align: right;">Page 55</p> <p>1 access. Thank you.</p> <p>2       PANEL MEMBER: Could I ask, as a retailer,</p> <p>3 what steps are you taking relating to youth access to</p> <p>4 cannabis products?</p> <p>5       MS. CROMER: As to what?</p> <p>6       PANEL MEMBER: Youth access.</p> <p>7       MS. CROMER: Youth access? We do not allow</p> <p>8 anyone under 21.</p> <p>9       PANEL MEMBER: Within the store premises?</p> <p>10       MS. CROMER: Correct. Well, I don't -- yeah,</p> <p>11 I mean, we don't sell to anyone under 21 personally.</p> <p>12 And I guess if parents decide they want to have them</p> <p>13 using, that's up to them. But, I mean, I can't</p> <p>14 control that obviously, nor can anybody.</p> <p>15       PANEL MEMBER: Okay. Thank you.</p> <p>16       MS. CROMER: With anyone, any subject -- I</p> <p>17 mean, any product.</p> <p>18       PANEL MEMBER: And how was the age 21</p> <p>19 selected?</p> <p>20       MS. CROMER: Pardon me?</p> <p>21       PANEL MEMBER: How did you select the age 21?</p> <p>22       MS. CROMER: Just because of thinking of like</p>	<p style="text-align: right;">Page 57</p> <p>1 enforcing federal laws. We need limits on THC</p> <p>2 potency. We need product safety warning labels. I</p> <p>3 have with me Andy's death certificate, Andy's medical</p> <p>4 marijuana card, Andy's dispensary frequent purchaser</p> <p>5 card.</p> <p>6       And I took all of this to the dispensary and</p> <p>7 I asked the manager to save the next kid to appeared</p> <p>8 to abuse the drug. She told me marijuana does not</p> <p>9 cause addiction or death. I asked that she share</p> <p>10 Andy's warning with others. She refused, saying Andy</p> <p>11 must have used other drugs. He did not. His</p> <p>12 toxicology confirmed that.</p> <p>13       Andy had been a kid with dreams. Join the</p> <p>14 army. Go to college. Get married. Have kids. He</p> <p>15 worked hard. He achieved some of that. He served</p> <p>16 with the 82nd Airborne. He earned two degrees. But</p> <p>17 by age 25, he was in a downward spiral of severe</p> <p>18 cannabis use disorder, serious mental illness, locked</p> <p>19 up in psych units, multiple suicide attempts, court-</p> <p>20 ordered mental healthcare.</p> <p>21       I want you to understand the devastation</p> <p>22 marijuana brought to our family. And sadly, ours is</p>

<p style="text-align: right;">Page 58</p> <p>1 not an isolated story. I can tell you of other                  2 tragedies directly linked to marijuana, a list of                  3 stories that goes on and on and keeps getting longer.                  4 Many families I work with find it too painful to be                  5 public about the harms this drug brought into their                  6 lives.                  7 And even now, it still hurts me. But I am                  8 mad. So I speak for those other families. And I am                  9 sad. So I speak for my Andy, that his message and                  10 warning will be heard.                  11 We need FDA to be more involved and take a                  12 leading role in marijuana research and policy                  13 formation. Being proactive, we can save other                  14 families the agony from a loss that so many of us have                  15 had. Thank you.                  16 (Applause.)                  17 MS. SCHINDEL: Thank you.                  18 HEALTH PROFESSIONALS                  19 MS. CRISTINZIO: Thank you for your comments.                  20 Our next category is health professionals. Our                  21 speaker number nine, Corey Burchman, is up next. All                  22 right. We will move on to speaker number 10, Nasser</p>	<p style="text-align: right;">Page 60</p> <p>1 environments exposed to biological toxins and harmful                  2 chemicals.                  3 The marijuana industry is self-policing and                  4 self-reporting. The state is woefully incapable of                  5 effectively regulating marijuana to ensure patient and                  6 worker health and safety. Health hazards were                  7 reported to the state by a group of concerned workers.                  8 After two years, we are still awaiting a response, no                  9 response despite the fact I have documents to support                  10 my toxic exposure and heavy metal poisoning.                  11 My state issued a waiver for testing of heavy                  12 metals and pesticides in marijuana products. I was                  13 fortunate to wake up to the harms of why marijuana is                  14 a medicine, cease consuming it, quit an industry more                  15 focused on profit over people and seek medical                  16 attention for my exposure.                  17 The trusting patient population is assuming                  18 that medical marijuana is safe, as I did. What the                  19 states are allowing the medical marijuana industry to                  20 do is dangerous, wrong and a great threat to public                  21 health. The FDA needs to step in. You must create                  22 rigorous controls over the purity of marijuana</p>
<p style="text-align: right;">Page 59</p> <p>1 Hassan, CanDiscPharma, Incorporated. Nasser? Moving                  2 on to speaker number 11, Anne Hassel, Holyoke Visiting                  3 Nurse Association.                  4 MS. HASSEL: My name is Anne Hassel. I am a                  5 physical therapist who was once a strong believer in                  6 medical marijuana and also an employee in the                  7 industry. I worked as a budtender in a Massachusetts                  8 medical marijuana dispensary for a year-and-a-half and                  9 learned this has nothing to do with public health,                  10 just profit.                  11 I witnessed unethical and dangerous practices                  12 harmful to patients' physical and mental health. I                  13 saw and trimmed moldy marijuana plants at the                  14 cultivation center. I saw and sold moldy marijuana to                  15 dispensaries -- to patients at the dispensary who                  16 truly believed we were taking good care of them,                  17 looking out for their health. I was wrong.                  18 Management policy was to mask moldy marijuana                  19 by dunking it into barrels of caustic hydrogen                  20 peroxide, an industry standard, all for the purpose of                  21 making a sale and a profit. This industry also has a                  22 lack of concern for its employees who work in</p>	<p style="text-align: right;">Page 61</p> <p>1 products and especially levels of high potency THC in                  2 these products to protect the public. I am willing to                  3 provide additional information, answer any health-                  4 related questions. Thank you.                  5 PANEL MEMBER: May I ask which state was the                  6 facility that you worked at located in?                  7 MS. HASSEL: Massachusetts.                  8 PANEL MEMBER: Thank you.                  9 MS. CRISTINZIO: Thank you. The next speaker                  10 is speaker number 12, Lily Jin, from DataRevive.                  11 Lily? Moving on to number 13, Amy Jones, from the                  12 Toxicology and Risk Assessment Consulting. Any Jones?                  13 All right. We're on to speaker number 14, Russell                  14 Kamer, Partners in Safety.                  15 DR. KAMER: Good morning. My name is Russell                  16 Kamer, from Partners in Safety. Despite the lack of                  17 FDA approval, this plant-based substance was legalized                  18 for medicinal use by 27 states.                  19 The FDA associate commissioner, Dr. Stuart                  20 Nightingale, wrote, "Unfortunately, the lack of                  21 scientific evidence about the drug and the views of                  22 responsible orthodox spokespersons were viewed as of</p>



<p style="text-align: right;">Page 62</p> <p>1 no consequence by state legislators and the public.                  2 Consumer groups were notably silent on this major                  3 public health issue." Of course, I am talking about                  4 Laetrile, the bogus cancer cure that swept the nation                  5 40 years ago.                  6 Once again, the FDA's authority to protect                  7 the public is being challenged. This time, it is in                  8 the form of cannabis-derived products, both THC and                  9 CBD.                  10 THC products are sold as medical marijuana in                  11 the manner described by Anne, the budtender, this                  12 morning. And that is just a small bit of what                  13 happened at that so-called dispensary. CBD is sold in                  14 even less regulated way, if that's even possible.                  15 As a practicing primary care physician, I can                  16 vouch for the extent of the CBD craze. Every day --                  17 every day, I see a patient who has taken CBD. Some                  18 patients get it from drugstores or chiropractors while                  19 others purchase it online, at gas stations or even at                  20 flea markets. They think they are getting a THC-free,                  21 safe product. In two cases, they are providing CBD to                  22 their children.</p>	<p style="text-align: right;">Page 64</p> <p>1 that potential realized.                  2 There are FDA-approved cannabis products for                  3 human use that veterinarians may use in an extra-label                  4 fashion. However, we ultimately desire products for                  5 use in animals that come with the assurance                  6 veterinarians need that they are of good and                  7 consistent quality and that they are efficacious and                  8 safe for use in our patients.                  9 Currently products intended for use in                  10 animals may be animal drugs, food or feed or food or                  11 feed additives. The FDA should clearly articulate                  12 where the various cannabis-derived and cannabis-                  13 related products fall and what may or may not be                  14 included in the promotional and labeling materials for                  15 these categories.                  16 There are many companies in the marketplace                  17 today selling unapproved cannabis-derived products for                  18 dogs, cats and horses, some of which make what clearly                  19 appear to be therapeutic claims. And while we know                  20 that DSHEA doesn't apply to products intended for use                  21 in animals, other manufacturers say that they are                  22 making no therapeutic claims or are simply selling</p>
<p style="text-align: right;">Page 63</p> <p>1 Most of these products have no independent                  2 lab analysis. Ones that do, for a 20 mg CBD tablet,                  3 there was 1 mg of THC. A person taking two or three                  4 of these tablets would be getting a significant                  5 exposure to THC.                  6 As Dr. Nightingale said 40 years ago,                  7 experience tells us a successor to Laetrile is almost                  8 surely on the horizon, if not in our midst. It is                  9 hoped that those of us in medicine and science, in and                  10 out of government, would be able to meet the next                  11 challenge of quackery.                  12 While the role of a drug regulatory agency                  13 may be limited, submission of scientific data should                  14 be encouraged. Thank you.                  15 MS. CRISTINZIO: Thank you. The next speaker                  16 is number 15, Ashley Morgan, from the American                  17 Veterinary Medical Association.                  18 DR. MORGAN: Thank you. Good morning. I am                  19 Dr. Ashley Morgan, with the American Veterinary                  20 Medical Association. We believe there is therapeutic                  21 potential in the development of cannabis-derived and                  22 cannabis-related compounds, and we would like to see</p>	<p style="text-align: right;">Page 65</p> <p>1 supplements or nutraceuticals for veterinary use.                  2 As justification, they ask rhetorically what                  3 is the difference between CBD and a glucosamine                  4 supplement intended to support joint health. Given                  5 known gaps in quality, limited information about these                  6 products' efficacy in veterinary patients and emerging                  7 concerns about their safety, AVMA believes FDA must                  8 seriously consider the need for efficacy and safety                  9 data when therapeutic claims are made or implied for                  10 these products.                  11 To facilitate the development of such                  12 products for veterinary use, it is imperative that FDA                  13 provide a pathway that assures regulatory clarity and                  14 predictability and the economic viability of the                  15 industry.                  16 Further the agency must make its enforcement                  17 policies known and then consistently and intentionally                  18 act on these priorities. Otherwise we will continue                  19 to face the Wild West and invariably greater numbers                  20 of therapeutic failures and toxicoses in our patients.                  21 Thank you for the opportunity to comment.                  22 PANEL MEMBER: I have a -- I have --</p>

<p style="text-align: right;">Page 66</p> <p>1 PANEL MEMBER: Do you have views on the use  2 of cannabis products in feed-producing animals and the  3 impact on human food?  4 DR. MORGAN: We definitely have concerns  5 about that and would like to see the data and ensure  6 that those products are safe, particularly, like you  7 mentioned, as they're going to go into the food  8 supply. We are going to be submitting additional  9 comments by the July 2nd date.  10 PANEL MEMBER: Okay. Thank you.  11 PANEL MEMBER: Sorry. One more question,  12 please. Is the veterinary community currently  13 prescribing or using these products?  14 DR. MORGAN: No. Well, not legally.  15 PANEL MEMBER: Okay.  16 MS. CRISTINZIO: All right. Well, we are  17 moving onto our next category of speakers in the  18 manufacturer category. Number 16 is Robert Allen.  19 Robert, from Celtic Wind Crops? Now we're moving on  20 to number 17, Phillip Blair, from Elixinol.  21 MANUFACTURERS  22 DR. BLAIR: Hello. I am Dr. Philip Blair,</p>	<p style="text-align: right;">Page 68</p> <p>1 effects indicative of any substance abuse. And to  2 date, there is no evidence of any recreational CBD use  3 or any public health-related problems associated with  4 use of CBD.  5 So in summary, high quality, full spectrum,  6 hemp-derived CBD has an absolutely safe for all of my  7 patients over the last five years while providing  8 immeasurable levels of benefit. I'll be submitting my  9 written comments with scientific data to support my  10 testimony forthwith.  11 PANEL MEMBER: Please also include the  12 mechanism through which you collected the data and the  13 protocols or anything else you used. That would be  14 great.  15 DR. BLAIR: Yes, ma'am.  16 PANEL MEMBER: Thank you.  17 PANEL MEMBER: Also, you used the term full  18 spectrum CBD derived from hemp. And I'm wondering if  19 you could elaborate on the term full spectrum and what  20 you meant by that.  21 DR. BLAIR: So a legal hemp plant that fits  22 all the categories that have been designated: less</p>
<p style="text-align: right;">Page 67</p> <p>1 MD, and I represent Elixinol, a hemp CBD manufacturer  2 out of Colorado. I'm also a retired U.S. Army colonel  3 and a veteran of the Gulf War.  4 I've been helping patients with hemp-derived  5 CBD for over five years in all ages. None have  6 experienced any significant adverse effects. On the  7 contrary, CBD has protected many of my patients from  8 the complications of cancer chemo and radiation  9 therapies.  10 Patients with addictions to opioids and  11 benzodiazepines and THC had no increase in physical or  12 cognitive sedation, but instead rapidly reduced or  13 discontinued these drugs, including Suboxone.  14 With respect to laboratory indicators, on  15 patient has reported any adverse result. Yet many  16 showed striking improvements in MRIs, retinal scans,  17 PSAs and liver function tests, unlike Epidiolex.  18 Despite the concern for drug interactions,  19 full spectrum CBD derived from hemp in my use has not  20 caused any significant adverse effects or injuries. I  21 also want to note that the 2018 WHO expert committee  22 on drug dependence said, in humans, CBD exhibits no</p>	<p style="text-align: right;">Page 69</p> <p>1 than 0.3 percent THC and deriving the substances from  2 that as a full distillate and derivative. And in  3 fact, there are very, very low levels of THC from the  4 Elixinol products specifically.  5 PANEL MEMBER: In your submitted comments,  6 we'd also appreciate it if you could provide  7 information on how you determine dosing and what  8 amount if safe or unsafe for a particular patient.  9 DR. BLAIR: Yes, sir.  10 PANEL MEMBER: Thank you.  11 PANEL MEMBER: And the characteristics of the  12 patients, including age, would be really helpful.  13 DR. BLAIR: Yes, ma'am.  14 PANEL MEMBER: And --  15 DR. BLAIR: Thank you very much for your  16 time.  17 PANEL MEMBER: Oh, sorry. I was just curious  18 too. You mentioned that you hadn't seen any  19 significant adverse effects. I'm curious if there are  20 lesser, more mild side effects that you sometimes  21 observe in your patients.  22 DR. BLAIR: There are sometimes mild side</p>

<p style="text-align: right;">Page 70</p> <p>1 effects from perhaps too heavy a dosing. The                  2 variability of a patient's response to CBD is                  3 considerable so that a standard serving that would be                  4 on a bottle is too much for some, but far too little                  5 for others.                  6 PANEL MEMBER: So what sorts of side effects                  7 do you see of the milder sort?                  8 DR. BLAIR: You may see a mild, temporary                  9 headache. You might see -- the most common side                  10 effect that I've experienced for my clients has been                  11 fatigue.                  12 PANEL MEMBER: Thanks.                  13 MS. CRISTINZIO: Thank you.                  14 DR. BLAIR: Again, thank you -- again, thank                  15 you very much.                  16 MS. CRISTINZIO: We are now on speaker number                  17 18, David Holmes, from Plant Life Group. David?                  18 Okay. Moving on to speaker number 19, Charles Jolly,                  19 from Baker Donelson.                  20 MR. JOLLY: Good morning. My name is Charles                  21 Jolly. I'm an attorney with the Baltimore office of                  22 Baker Donelson. My firm represents a number of</p>	<p style="text-align: right;">Page 72</p> <p>1 We believe the NDI system with a master file                  2 is the proper device for regulating CBD as a dietary                  3 supplement. The NDI submission would permit                  4 limitations on THC, 3 percent or less, mold, heavy                  5 metals, pesticide residues and other issues.                  6 Enforcement of the NDI must be extended beyond FDA in                  7 order to make it effective. Thank you very much for                  8 the opportunity to participate in this important                  9 discussion.                  10 MS. CRISTINZIO: Thank you. Our next speaker                  11 is speaker number 20, James Shults, from WMI                  12 Consulting.                  13 MR. SHULTS: Hello. My name is James Shults.                  14 I'm here representing Wildflower Brands today. We                  15 make infused beauty and wellness products.                  16 Before I begin, I'd like to thank you all for                  17 allowing me to speak at this historic point in                  18 American history. It's through efforts like today's                  19 hearing that we can begin to take an honest and                  20 evidence-based approach to truly understanding the                  21 productive potential of this plant. So, thank you.                  22 Fundamentally Wildflower is a health and</p>
<p style="text-align: right;">Page 71</p> <p>1 clients interested in various ways in the cannabis-                  2 derived compound CBD and dietary supplements.                  3 It's beyond debate that hemp and its                  4 constituents, including CBD, have been part of the                  5 human dietary for centuries.                  6 Given the legal status of CBD in this                  7 country, there's a surprisingly strong body of                  8 information that supports the notion that the                  9 digestion of CBD enables the body, utilizing the                  10 cannabinoid receptor system, to better cope with                  11 inflammation, anxiety, sleeplessness and possibly                  12 other circumstances. This is a classic definition of                  13 a dietary supplement -- a dietary ingredient impacting                  14 on human structure function.                  15 If CBD is a dietary supplement can play even                  16 a small role in addressing these public health issues,                  17 the benefits would be huge. Because CBD is coming,                  18 whether as a matter of intrastate commerce or                  19 otherwise, with or without FDA, I would submit that                  20 the question is simple. Is the public health better                  21 served with FDA strongly regulating it or staying out?                  22 And I would submit they should strongly regulate.</p>	<p style="text-align: right;">Page 73</p> <p>1 wellness company committed to providing premium                  2 holistic products. While we recognize that CBD has                  3 demonstrable medical use when highly refined and used                  4 in a controlled clinical setting, we also believe                  5 there is sufficient evidence to safely regulate plant                  6 extracts containing CBD in a dietary supplement or                  7 cosmetic.                  8 Wildflower understands that the best approach                  9 to establishing public safety and trust in our                  10 products is through the FDA regulating CBD for use in                  11 a dietary supplement or cosmetic.                  12 As this industry begins to take shape                  13 globally, the public needs to trust that the products                  14 they are buying are safe, are made with the                  15 ingredients that are promised and don't contain any                  16 misleading information about its benefits or uses.                  17 To begin this process, I'll be submitting a                  18 citizen petition requesting -- or excuse me,                  19 requesting a regulation allowing the use of CBD in a                  20 dietary supplement or cosmetic and I encourage fellow                  21 stakeholders to collaborate and do the same.                  22 At Wildflower, we have personally seen the</p>

<p style="text-align: right;">Page 74</p> <p>1 public interest in CBD increase exponentially and it's 2 only through -- and it's only getting started. 3 Through evidence-based regulation and guidance, the 4 FDA can ensure safe and accurate CBD products are 5 available to the public and that the industry can grow 6 with clear expectations of what good manufacturing 7 looks like. 8 Thank you for your time. I truly appreciate 9 the opportunity to speak here today and look forward 10 to being part of this conversation as we develop this 11 exciting new industry. 12 PANEL MEMBER: Could I ask what you view as 13 the functional purpose of CBD in a beauty product? 14 MR. SHULTS: Personally I don't have a 15 collection of the evidence to give you a hard claim on 16 that. 17 We've had a lot of interactions with 18 customers that it's simply more effective as a beauty 19 product when we include that ingredient. I'm not -- 20 yeah, I'm just not a hundred percent on the scientific 21 reasoning. 22 PANEL MEMBER: And when you say effective,</p>	<p style="text-align: right;">Page 76</p> <p>1 Healthcare Products Association. 2 MR. SPANGLER: I'm David Spangler, speaking 3 on behalf of the Consumer Healthcare Products 4 Association. We represent over 65 manufacturers of 5 OTC medicines or dietary supplements. 6 Four points. Point one, FDA speaks 7 frequently about three priorities for both OTC 8 medicines and supplements: public safety, product 9 quality and informed consumers. We share these 10 priorities and agree they apply to hemp-derived and 11 CBD products. 12 Second point, we support the status quo for 13 medicines. The existing new drug approval process 14 provides a pathway for sponsors to develop data to 15 bring cannabis-derived products to market once shown 16 safe and effective. 17 Point three, we all see the intense consumer 18 and commercial interest in CBD and hemp-derived 19 products more broadly. But with little regulatory 20 oversight, the marketplace offers a vast array of 21 products of varying degrees of quality, an array of 22 unapproved drug claims and even fraudulent products.</p>
<p style="text-align: right;">Page 75</p> <p>1 what do you mean by that? 2 MR. SHULTS: It delivers a more -- a higher 3 sense, you know, of personal attraction, you know, 4 increasing -- it's more desirable to the product, not 5 through clinical definitions but, you know, through a 6 consumer-based opinion. 7 PANEL MEMBER: Can I follow up on that about 8 that? Do you have any information about the 9 absorption of CBD from your products? 10 MR. SHULTS: Personally, no. I am -- so as 11 part of my citizen petition, I'm collecting evidence 12 and presenting it, you know, to the FDA, exactly. 13 Getting additional information about the routes of 14 access, specifically topical or ingested and things 15 like that. We make, you know, both. 16 So yeah, no, that is at root of what we're 17 trying to figure out and present to you to provide a 18 clear grounds for why this is -- you know, why you can 19 safely regulate this as those products. Okay. Thank 20 you very much. 21 MS. CRISTINZIO: Thank you. We are now on 22 speaker number 21, David Spangler, from the consumer</p>	<p style="text-align: right;">Page 77</p> <p>1 While FDA is charting a course forward, 2 enforcement needs to increase. For instance, more 3 consumer alerts and follow-ups beyond morning letters 4 on enforcement actions would be important steps. 5 Finally, point number four, beyond 6 enforcement, dietary supplements need a path to bring 7 CBD-containing products to market. One way to do that 8 is for FDA to exercise its authority to exempt forms 9 of CBD from the prior IND, prior new drug approval 10 exception in the law's dietary supplement definition. 11 Please do that this year. 12 Supplement makers would still need to file 13 NDI notifications for CBD under this approach. Those 14 NDIs would still need to meet the same legal standard 15 of sufficient information to provide reasonable 16 assurance the ingredient does not pose a significant 17 or unreasonable risk. We appreciate this opportunity. 18 MS. CRISTINZIO: Thank you. Moving on to 19 speaker number 22, Stuart Titus. 20 DR. TITUS: Good morning. My name is Stuart 21 Titus. I'm the chief executive officer of Medical 22 Marijuana, Inc., which was founded in March of 2009.</p>

<p style="text-align: right;">Page 78</p> <p>1 In spite of our name, we are not engaged in the 2 production, manufacture or sale of either recreational 3 or medical marijuana. 4       Instead, we're focused on nutraceutical sales 5 of botanical, hemp-based products containing CBD 6 through our four operating divisions. We brought the 7 first nutraceutical hemp-based CBD products to U.S. 8 markets in 2012. 9       In our view, most American diets do not 10 contain an adequate amount of CBD and other non- 11 psychoactive cannabinoids, leaving most of us 12 cannabinoid-deficient and lacking support for a key 13 system in our body, our endogenous cannabinoid system. 14       Our belief was that fully botanical hemp- 15 based CBD nutraceutical supplements would support 16 health and wellness. The belief appears well-founded 17 within the medical literature. There are 2,281 18 studies available PubMed with the term endocannabinoid 19 in the title and there are another 10,000 other 20 studies that mention the endocannabinoid system in 21 their abstracts. 22       In addition, the National Institutes of</p>	<p style="text-align: right;">Page 80</p> <p>1 overall better levels of health and wellness. 2 Certainly we don't make any medical claims. 3       But I think the anecdotal evidence is 4 overwhelming, the public support. People are just 5 seeing tremendous benefit. Anecdotally we see people 6 less stressed. 7       We see people sleeping better. We see less 8 brain fog, many other great anecdotal evidence that 9 we're slowly accumulating. We'll certainly look 10 forward in our written comments to showing more of 11 this data to you. 12       PANEL MEMBER: A follow-up question. If I 13 understood you, you're saying you believe that 14 cannabidiol is non-psychoactive? 15       DR. TITUS: We have seen in the literature, 16 particularly a U.S. government patent mentioning that 17 it is non-psychoactive. We believe it does reduce 18 anxiety. Thus, it may have anxiolytic effects. But 19 we do believe, unlike THC, it is non-intoxicating. So 20 that may be a better distinction. 21       PANEL MEMBER: If you had evidence to support 22 what you just said, it'd be useful to see that when</p>
<p style="text-align: right;">Page 79</p> <p>1 Health appear supportive of our viewpoint, having 2 mentioned the benefit of non-psychoactive cannabinoids 3 in its 507 patent awarded in 2003. It also should be 4 noted that on the NIH dietary supplement label 5 database, a CBD product is already listed as a dietary 6 supplement. 7       Accordingly we believe that non-psychoactive 8 hemp products containing CBD and other cannabinoids as 9 they support our endogenous cannabinoid system are an 10 essential nutritional supplement for optimal health, 11 just as is vitamin C. In addition, botanical hemp 12 products containing CBD are safe and extremely well 13 tolerated. 14       Given these facts, there is widespread public 15 and legislative support for botanical CBD. Thank you 16 for allowing this opportunity before you today. We 17 will submit more in our written comments. 18       PANEL MEMBER: Question. What do you believe 19 are the health benefits of hemp and CBD? 20       DR. TITUS: Well, we believe they do support 21 this large self-regulatory system, the endogenous 22 cannabinoid system and that helps move people to</p>	<p style="text-align: right;">Page 81</p> <p>1 you submitted your comments. 2       DR. TITUS: Very good. We'll do that. Thank 3 you. 4       MS. CRISTINZIO: Thank you. Moving onto our 5 next speaker, Julian Wright, from Science &amp; 6 Recreation. 7       MR. WRIGHT: Good morning. My name is Julian 8 Wright. I am the founder of Science &amp; Recreation. 9 It's an honor to attend today's proceedings and 10 present the FDA with oral comments regarding products 11 containing cannabis or cannabis-derived compounds. 12       Hemp was made legal at the federal level by 13 signing into law the 2018 farm bill, with the FDA 14 retaining control over regulation of products 15 containing cannabis. 16       It is my understanding, based upon publicly 17 available information, that a substance that has been 18 approved by the FDA as an active ingredient in a 19 prescription drug -- in this case, CBD -- is precluded 20 from being a food additive. But in order for a 21 substance to be an active ingredient in a prescription 22 drug, the active ingredient must be a controlled</p>

<p style="text-align: right;">Page 82</p> <p>1 substance.</p> <p>2 But being that industrial hemp and its</p> <p>3 derivatives are no longer controlled substances, they</p> <p>4 should enjoy the same range of use as any other legal</p> <p>5 commodity.</p> <p>6 Confusion regarding the status of CBD has</p> <p>7 negatively impacted responsible and legal uses of CBD</p> <p>8 post 2018 farm bill, resulting in detrimental effects.</p> <p>9 Grandmothers are being arrested at Disneyworld and by</p> <p>10 the TSA. National couriers are not accepting lawful</p> <p>11 shipments, thereby stifling commerce. Distribution</p> <p>12 and advertising channels are limited due to lack of</p> <p>13 clarity.</p> <p>14 Hemp stakeholders need certainty and clarity.</p> <p>15 Hemp represents potentially the largest boon to the</p> <p>16 agricultural community since tobacco. The 2018 farm</p> <p>17 bill was passed, banking on that promise. Yet without</p> <p>18 a vibrant CBD market, American farmers will lag behind</p> <p>19 the rest of the hemp-producing world.</p> <p>20 Our competitive advantage is in producing</p> <p>21 hemp which is high in CBD. This advantage allows</p> <p>22 farmers to realize crops that can return \$60,000 per</p>	<p style="text-align: right;">Page 84</p> <p>1 considered approved drugs as opposed to compounds</p> <p>2 extracted from or derived from the whole plant or</p> <p>3 parts of the Cannabis sativa L plant containing broad</p> <p>4 spectrum constituents, including CBD, terpenes, trace</p> <p>5 THC and other cannabinoids. We would ask the agency</p> <p>6 to clearly define the meaning of CBD concentrates and</p> <p>7 isolates. We fully support THC levels of less than</p> <p>8 0.3 percent.</p> <p>9 Risk to animals. Consistent with the</p> <p>10 agency's risk-based approach, NASC provides visibility</p> <p>11 to regulators from our database which we believe is</p> <p>12 the most advanced in the world for animal supplements.</p> <p>13 In addition to product labels, specific data</p> <p>14 regarding hemp-derived products are. There are 149</p> <p>15 products currently in the marketplace. They've been</p> <p>16 in the market for over 10 years. There have been nine</p> <p>17 adverse events reports, none serious and over 18</p> <p>18 million administrations in dogs, cats and horses.</p> <p>19 While more research is certainly needed, we</p> <p>20 believe the data at this time suggests these compounds</p> <p>21 provided by responsible companies do not pose undue</p> <p>22 risk to animals and the species cited. We support the</p>
<p style="text-align: right;">Page 83</p> <p>1 acre when compared to hemp sold for fiber at \$750 per</p> <p>2 acre. This difference is stunning and should be</p> <p>3 paramount as the FDA considers crafting regulations</p> <p>4 regarding CBD. A strong CBD market means a stronger</p> <p>5 American economy. Thank you.</p> <p>6 MS. CRISTINZIO: Thank you. We are moving</p> <p>7 onto our next category, which was titled "Other."</p> <p>8 Sorry for that. Number 24 is William Bookout.</p> <p>9 OTHER</p> <p>10 MR. BOOKOUT: Thank you. My name is Will</p> <p>11 Bookout. I'm the president of the National Animal</p> <p>12 Supplement council. On behalf of the members of NASC,</p> <p>13 we appreciate the opportunity to comment regarding</p> <p>14 cannabis-containing products for dogs, cats and</p> <p>15 horses. I'll be highlighting key points in the verbal</p> <p>16 comments. However, a more complete response will be</p> <p>17 submitted in writing.</p> <p>18 We have three primary points. First, the</p> <p>19 regulatory agencies, as well as the industry need</p> <p>20 clearly defined and viable pathways for marketing of</p> <p>21 these products. FDA needs to provide clear guidance</p> <p>22 and definitions delineating compounds that would be</p>	<p style="text-align: right;">Page 85</p> <p>1 agency's position of taking regulatory action against</p> <p>2 companies for egregious violation in terms of claims</p> <p>3 and irresponsibly marketed products. In fact, we are</p> <p>4 disappointed that more action has not been taken</p> <p>5 against irresponsible participants.</p> <p>6 Finally, solutions taking two to three years</p> <p>7 are simply not realistic or acceptable. NASC has</p> <p>8 initiated the formation of a taskforce of industry</p> <p>9 experts that we believe will provide a clearly defined</p> <p>10 comprehensive pathway that's both viable and</p> <p>11 responsible for all stakeholders. We'll be reaching</p> <p>12 out to FDA CVM for further discussion and we thank you</p> <p>13 for the opportunity to comment.</p> <p>14 PANEL MEMBER: I have a question for you.</p> <p>15 MR. BOOKOUT: Yes, sir.</p> <p>16 PANEL MEMBER: On the 0.3 percent you</p> <p>17 mentioned --</p> <p>18 MR. BOOKOUT: Yes.</p> <p>19 PANEL MEMBER: -- do you have data that</p> <p>20 supports that use?</p> <p>21 MR. BOOKOUT: Yes. Our threshold is less</p> <p>22 than 0.3 percent. We do have data, and we'll be</p>

<p style="text-align: right;">Page 86</p> <p>1 submitting that to the docket.</p> <p>2 PANEL MEMBER: Okay. Thank you. And what do</p> <p>3 you see as the intended use of this?</p> <p>4 MR. BOOKOUT: We're consistent with intended</p> <p>5 use with 201(g)(1)(C), non-nutritional benefits,</p> <p>6 occasional discomfort, cognitive function, immune</p> <p>7 support, similar structure and function examples.</p> <p>8 PANEL MEMBER: Thank you.</p> <p>9 PANEL MEMBER: Just one other question.</p> <p>10 MR. BOOKOUT: Yes, sir.</p> <p>11 PANEL MEMBER: Do you have any data also on</p> <p>12 either swine or bovine as well?</p> <p>13 MR. BOOKOUT: We don't.</p> <p>14 PANEL MEMBER: Okay.</p> <p>15 MR. BOOKOUT: Our focus is dogs, cats and</p> <p>16 horses only, not production animals.</p> <p>17 PANEL MEMBER: All right. Thank you.</p> <p>18 PANEL MEMBER: One last question. The safety</p> <p>19 database that you -- it'd be really useful to have a</p> <p>20 little more information about it.</p> <p>21 MR. BOOKOUT: Yeah.</p> <p>22 PANEL MEMBER: I assume it's spontaneous, as</p>	<p style="text-align: right;">Page 88</p> <p>1 every single day.</p> <p>2 GMA advocates for rational, uniform</p> <p>3 regulatory frameworks that are informed by risk-based</p> <p>4 science, promote choice and build consumer trust</p> <p>5 across the sectors we represent, which is personal</p> <p>6 care, to household, to food and beverage.</p> <p>7 We applaud this effort by FDA for holding</p> <p>8 this public meeting as the first step of stakeholder</p> <p>9 engagement. We support the opportunity for additional</p> <p>10 stakeholder discussions as both stakeholders and FDA</p> <p>11 and other federal agencies share the common goal of</p> <p>12 providing consumers safe, trustworthy and reliable</p> <p>13 products.</p> <p>14 As consumers' interest for food and beverage</p> <p>15 and personal care and household products containing</p> <p>16 cannabis and cannabis derivatives, the necessity for</p> <p>17 nationally uniform regulatory frameworks that protect</p> <p>18 public health is of a critical importance.</p> <p>19 The potential patchwork of laws at the state</p> <p>20 and local level promotes confusion among consumers.</p> <p>21 We need clear, simple, consistent, national</p> <p>22 regulations informed by risk-based science that will</p>
<p style="text-align: right;">Page 87</p> <p>1 opposed to a required reporting and things like that,</p> <p>2 for instance.</p> <p>3 MR. BOOKOUT: It is required reporting.</p> <p>4 PANEL MEMBER: It is required?</p> <p>5 MR. BOOKOUT: Yes.</p> <p>6 PANEL MEMBER: So that kind of information</p> <p>7 would be really helpful to us.</p> <p>8 MR. BOOKOUT: It's a condition of membership,</p> <p>9 and we've made the information available to CVM. In</p> <p>10 fact, we've conducted training sessions with the</p> <p>11 Division of Surveillance at CVM and we work very</p> <p>12 closely with the agency. Thank you.</p> <p>13 MS. CRISTINZIO: Thank you. We are now on</p> <p>14 speaker number 25, Betsy Booren.</p> <p>15 DR. BOOREN: Good morning. I'm Betsy Booren.</p> <p>16 I'm senior vice president for science and technology</p> <p>17 for the Grocery Manufacturers Association. GMA</p> <p>18 represents the world's leading consumer packaged goods</p> <p>19 companies.</p> <p>20 The CPG industry plays a unique role as the</p> <p>21 single largest U.S. manufacturing sector, delivering</p> <p>22 products vital to the wellbeing of people's lives</p>	<p style="text-align: right;">Page 89</p> <p>1 enhance the consumer trust in these products and</p> <p>2 reduce frictions within the supply chain. FDA and</p> <p>3 other relevant agencies must provide this leadership.</p> <p>4 We support a transparent regulatory process</p> <p>5 for stakeholder engagement, including comment and</p> <p>6 rulemaking, development of risk management strategies,</p> <p>7 development of any research action plans.</p> <p>8 This will ensure that all stakeholders have</p> <p>9 an opportunity to provide insights to agencies during</p> <p>10 the development of this regulatory framework. Only</p> <p>11 with this type of transparency will effective and</p> <p>12 durable, long-lasting regulations be developed. Thank</p> <p>13 you.</p> <p>14 PANEL MEMBER: Thanks for your comments. I</p> <p>15 was wondering if, given your broad representation of</p> <p>16 food and consumer products, if there are thoughts on</p> <p>17 how to deal with risks of cumulative exposure across</p> <p>18 many products if these substances are now allowed</p> <p>19 outside the drug context.</p> <p>20 DR. BOOREN: Sure, and thank you for your</p> <p>21 question. I think that is one of interest whereas the</p> <p>22 branded national companies that we represent start</p>

<p style="text-align: right;">Page 90</p> <p>1 diving into this space, that they would need to take 2 into that.</p> <p>3 We don't have any clear evidence at this 4 time. But as we indicated, I think that that's part 5 of the discussions we should have in the stakeholder 6 process to make sure we're collecting the right data 7 to protect public health.</p> <p>8 PANEL MEMBER: And one other question, which 9 is as other markets, significantly Canada, open up and 10 many of your members sell products in that country, 11 are you thinking about ways to collect additional data 12 and information as those products might be sold 13 legally in other jurisdictions?</p> <p>14 DR. BOOREN: I think there's some 15 opportunities for that. I think GMA is uniquely 16 positioned to gather a lot of consumer information in 17 our current framework of better understanding what 18 consumers want, need and what they expect of these 19 products. I think that's something that we would look 20 at.</p> <p>21 The market and the indications of what 22 consumers want from these innovation processes or</p>	<p style="text-align: right;">Page 92</p> <p>1 Internet taught him that marijuana was medicine. This 2 past Thanksgiving, the day after, he found his son 3 cutting his hand. He took him to the hospital. He 4 was admitted into a psych unit and only testing 5 positive for THC and diagnosed with psychosis.</p> <p>6 He was discharged. His family put him in an 7 outpatient program. On the fourth day of that 8 program, it was December the 5th, David Childs came 9 home. He went to the woods behind his house. He 10 smoked marijuana. Then he came back into the house 11 and he shot himself in the head. David was 19.</p> <p>12 MS. CRISTINZIO: Thank you for telling that 13 story. Any questions from the panel?</p> <p>14 MS. ADAMS: Thank you.</p> <p>15 MS. CRISTINZIO: Speaker number 27, Robert 16 Discordia.</p> <p>17 DR. DISCORDIA: Thank you. My name is Dr. 18 Robert Discordia. I'm vice president of 19 pharmaceutical development and manufacturing at Corbus 20 Pharmaceuticals, where we are developing medicines 21 that target the endocannabinoid system to treat rare, 22 life-threatening autoimmune and genetic disorders.</p>
<p style="text-align: right;">Page 91</p> <p>1 products is really indicative of the market to grow. 2 Our inherent issue is making sure we have the strong 3 legitimate regulatory framework which you all provide. 4 Thank you.</p> <p>5 MS. CRISTINZIO: Thank you. We are moving 6 down our agenda to speaker number 26, James Childs.</p> <p>7 MS. ADAMS: I have a question. He was not 8 allowed to be here. He couldn't make it. But I have 9 -- (off mic) -- thoughts to the docket.</p> <p>10 MS. CRISTINZIO: Approach, so we can hear 11 you.</p> <p>12 MS. ADAMS: I'm sorry. I'm sorry. I just 13 have a question. Dr. Childs was not able to be here. 14 He did upload his comments to the docket. May be just 15 briefly tell his story?</p> <p>16 MS. CRISTINZIO: Sure.</p> <p>17 MS. ADAMS: Okay. Dr. Childs --</p> <p>18 MS. CRISTINZIO: Two minutes, please. And 19 please state your name.</p> <p>20 MS. ADAMS: Oh, my name is Aubrey Adams. And 21 Dr. Childs has a son -- had a son named David Childs. 22 He started smoking marijuana at the age of 16. The</p>	<p style="text-align: right;">Page 93</p> <p>1 Under IND from FDA, treatment with our novel 2 oral investigational drug called Lenabasum has been 3 associated with improvement in efficacy outcomes in 4 multiple Phase II studies in diseases such as 5 scleroderma, dermatomyositis and cystic fibrosis. It 6 has been granted both orphan and fast track 7 designations. Two Phase III pivotal multinational 8 studies are underway and over 700 patients have been 9 dosed, some for longer than three years.</p> <p>10 Lenabasum is not medical cannabis nor is it a 11 cannabis-derived substance and it does not involve 12 cannabis-derived compounds in its synthesis. It is a 13 rationally designed NCE specifically designed to avoid 14 interaction with cannabinoid receptors in the brain 15 and purposefully focuses on immune system outside the 16 brain.</p> <p>17 And yet, because Lenabasum is categorized as 18 a cannabinoid, we face obstacles that other drug 19 developers targeting the same indications with non- 20 cannabinoid experimental drugs do not because we fall 21 under the Controlled Substances Act as a Schedule 1 22 whose restrictions have delayed our clinical trials</p>



<p style="text-align: right;">Page 94</p> <p>1 only in the U.S., Canada and Australia, but not 27  2 other countries in which our trials are conducted.  3 We're here in the interest of public health  4 as a drug developer that experiences unnecessary  5 delays in this field. It is no exaggeration to state  6 that had we not been obliged to comply with Schedule  7 1, we would be one year closer to completing our  8 studies and potentially closer to making available our  9 orphan drug to patients who have no approved medicines  10 to treat their devastating conditions.  11 We respectfully urge FDA to develop a  12 transparent, consistent, fair and practical framework  13 to support the investigation and development of drugs  14 targeting the endocannabinoid system.  15 Specifically for compounds that are not  16 potent brain-penetrating CB1 agonists, to have a  17 clinical development pathway mirroring as closely as  18 possible that of other investigational drugs without  19 the need for onerous regulatory hurdles. I thank you  20 for the opportunity.  21 PANEL MEMBER: One question. How does the  22 availability of CBD or other cannabis derivatives in</p>	<p style="text-align: right;">Page 96</p> <p>1 cofounder of magnolia Partners, an agency devoted to  2 providing strong foundations to early stage companies  3 both in and outside of the cannabis landscape. I'm a  4 new mother to a four-month-old baby boy and my husband  5 is an army vet and an operating engineering in Local  6 825.  7 Through my role in the industry, I've had the  8 privilege to hear many personal stories from patients  9 whose lives have been transformed and even saved due  10 to cannabis and hemp products.  11 I was also privy to clinical studies of  12 equine, canine and feline patients using full spectrum  13 both cannabis and hemp oils with positive results for  14 conditions from anxiety to skin cancer.  15 I also hear from business owners who make  16 quality products which undergo vigorous testing, yet  17 are frustrated with their cheaper competitors who  18 cannot claim the same exhaustive research.  19 While walking in a grocery store earlier this  20 week, I came upon a shelf of no less than 10 products  21 ranging from cookies to tinctures to gummies and the  22 shelf was directly across from the pharmacy counter.</p>
<p style="text-align: right;">Page 95</p> <p>1 the marketplace potentially incentivize or  2 disincentivizes your drug development?  3 DR. DISCORDIA: I don't think it actually has  4 an effect since we're not phytocannabinoids. We're  5 not derived from cannabis. I think that because of  6 the regulations though, mostly DEA, we have to -- we  7 have to follow strict guidelines in accounting for  8 every milligram of the material. I'm sorry if I --  9 did I answer your question or --  10 PANEL MEMBER: You got it. Thanks. That's  11 all.  12 DR. DISCORDIA: Thank you very much.  13 MS. CRISTINZIO: Next on the agenda, we are  14 on speaker number 28, Kristina Garcia.  15 MS. GARCIA: Good morning. I'm Kristina  16 Garcia, former CEO and current board member of Women  17 Grow, an international women's networking organization  18 dedicated to the cannabis industry.  19 I also serve on the advisory board of Green  20 Check, a Connecticut company based on meeting the  21 banking and compliance needs of cannabis companies and  22 the financial institutions that serve them. I'm a</p>	<p style="text-align: right;">Page 97</p> <p>1 As an expert in the industry, I have the knowledge to  2 differentiate between those products and it's still a  3 challenge. And I know that some of those brands are  4 quality and some of those are not.  5 The consumers that are currently seeking out  6 or stumbling upon these products in the marketplace do  7 not have my expert knowledge or that of a trusted  8 medical professional behind them. They're desperate  9 for help and they don't have anybody to turn to.  10 In May of 2018, then commissioner Gottlieb  11 said that it was crucial that we provide clear  12 expectations so that the industry can meet them. It's  13 just as important for consumers to be able to  14 effectively use updated labels.  15 And we're launching a major educational  16 campaign for consumers to help them better understand  17 the new information that they'll be seeing in the  18 marketplace. That was regarding the food labels and  19 that same information and application can work here.  20 So I ask that you demand that suppliers have  21 their products tested by reputable labs and that those  22 test results be readily available to consumers prior</p>

<p style="text-align: right;">Page 98</p> <p>1 to purchase. Implement clear and concise labeling                  2 rules and encourage businesses to provide educational                  3 information for medical professionals.                  4       And I ask that you move with purpose, as the                  5 marketplace is already active and the federal courts                  6 have also, as recently as yesterday, asked the DEA to                  7 seriously consider the de-scheduling of cannabis in an                  8 expeditious manner. Thank you.                  9       MS. CRISTINZIO: Great. We are now on number                  10 29 on the agenda, Gabriel Giancaspro.                  11       DR. GIANCASPRO: Good morning. My name is                  12 Gabriel Giancaspro. I'm the vice president for                  13 dietary supplements and herbal medicines at the                  14 science division at USP.                  15       On behalf of USP, I would like to thank the                  16 agency for allocated time for us to offer comments on                  17 the value of robust science-based, quality standards                  18 for products containing cannabis and cannabis-derived                  19 compounds.                  20       USP is an independent scientific nonprofit                  21 public health organization devoted to improving health                  22 through the development of standards for medicines,</p>	<p style="text-align: right;">Page 100</p> <p>1 therefore include specifications for the content of                  2 active constituents and limits for contaminants such                  3 as pesticide residue, microbial load, aflatoxin level,                  4 elemental contaminants based on reliable scientific                  5 information.                  6       USP is committed to bringing our public                  7 health mission and expertise in this developing area                  8 through publications and information sharing. We've                  9 made significant progress to define suitable quality                  10 specifications for this plant material and we plan to                  11 publish our work in a scientific paper to disseminate                  12 this knowledge to the community.                  13       We look forward to continuing the dialogue                  14 for exploration of the science-based standards that                  15 help prevent harm and protect public help once the                  16 regulatory status and path forward for these products                  17 are clear, USP stands ready, as appropriate, to work                  18 with the agency and other interested parties to                  19 develop reliable quality standards and make them                  20 available for use by manufacturers and regulators                  21 alike. Thank you.                  22       PANEL MEMBER: Could you remind -- do you</p>
<p style="text-align: right;">Page 99</p> <p>1 foods and dietary supplements. The organization                  2 publishes two legally recognized official compendia of                  3 the United States.                  4       Additionally, one of USP's areas of expertise                  5 and focus is the development of the standards for                  6 articles of botanical origin, including analytical                  7 procedures and acceptance criteria to help ensure                  8 their identity, purity and strength.                  9       Regardless of product category, the purpose                  10 of a public standard is to help regulators protect                  11 public health and by providing scientifically                  12 validated tests to ensure identity, constituent                  13 composition and strength of a product. The standards                  14 also help monitor product quality so adulterants and                  15 contaminants are absent or below the level of concern.                  16       Public standards are essential to help                  17 prevent harm to patients and consumers. The facility                  18 -- they facilitate the production of non-contaminated,                  19 non-adulterated trials and help limit exposure to                  20 toxic substances, pathogenic microorganisms and                  21 harmful additives.                  22       A robust standard in this area should</p>	<p style="text-align: right;">Page 101</p> <p>1 have -- I believe you've put out some materials on                  2 marijuana standards to date separate from cannabidiol.                  3 Is that right?                  4       DR. GIANCASPRO: Yes.                  5       PANEL MEMBER: And do you have a date when                  6 you anticipate that the cannabidiol might be released,                  7 the product might?                  8       DR. GIANCASPRO: Our net process for                  9 developing quality standards requires the sponsor for                  10 the manufacturer that is approved by the agency. We                  11 contacted the manufacturer to supply the information.                  12 Unfortunately the manufacturer was not willing to                  13 supply the information for us to construct the public                  14 monitoring at this time.                  15       Should the path forward for dietary                  16 supplements is clear or other path forward different                  17 from drug approval, we may have alternatives to                  18 develop quality standards. Thank you.                  19       MS. CRISTINZIO: Thank you. Our next speaker                  20 is number 30 on the agenda, Karen Howard, from the                  21 Organic &amp; Natural Health Association.                  22       MS. HOWARD: Good morning. My name is Karen</p>

<p style="text-align: right;">Page 102</p> <p>1 Howard. I'm the CEO of the Organic &amp; Natural Health  2 Association. We're a trade association whose  3 decisions are rooted primarily in transparency and  4 traceability and the quality of products provided to  5 consumers and their interests.  6       Based on the FDA definition of a drug,  7 Organic &amp; Natural concludes that CBD is not precluded  8 from use as a dietary supplement.  9       Hemp extract is not approved or investigated  10 for the intended use of treating a disease. Hemp  11 extract does not resemble the drug Epidiolex to which  12 it is being compared to. For us, the issue is whether  13 hemp extracts are equivalent to the drug, and it is  14 not.  15       Hemp extracts will be proven safe, are safe  16 and can be demonstrated as such, whether by an NDI or  17 through GRAS. That said, Organic &amp; Natural does have  18 concerns related to enforcement and we appreciate the  19 viral nature of how CBD has hit the marketplace.  20       With that, there are always going to be  21 problems related to things like contamination and  22 toxins, especially as it relates to the presence of</p>	<p style="text-align: right;">Page 104</p> <p>1 require an NDI or whether it would require GRAS. We  2 believe that at the end of the day, either will  3 support those conclusions in recognition that some  4 people will choose to go the NDI route while others  5 will partake in the GRAS process.  6       PANEL MEMBER: Yeah. I would just encourage  7 any safety data that you have be put into the record  8 by July 2nd, if you have it.  9       MS. HOWARD: Thank you.  10       PANEL MEMBER: Thank you.  11       MS. CRISTINZIO: Thank you. I believe the  12 next number on the agenda, Loren Israelsen, was an  13 early cancellation this morning. I just thought I'd  14 check before I move on. Okay. Number 32, Rod Kight,  15 from Kight Law Office, is the next on the agenda.  16       MR. KIGHT: Good morning. My name is Rod  17 Kight. Thank you for allowing me this opportunity to  18 speak. I'm an attorney who represents cannabis  19 businesses.  20       Numerous studies have found that CBD is safe.  21 According to the World Health Organization, it is  22 nontoxic, non-addictive and non-intoxicating. People</p>
<p style="text-align: right;">Page 103</p> <p>1 any THC or heavy metals, which I believe you will hear  2 more about this afternoon. Those would be our  3 concerns. We remain in support of CBD safety.  4       PANEL MEMBER: A question. You're referring  5 to hemp extract. Could you explain what exactly you  6 mean by that?  7       MS. HOWARD: Well, we do mean CBD. But we  8 also know that there are different derivatives that  9 can be derived from the hemp plant.  10       I think our real issue is that hemp extract,  11 hemp CBDs and all of the derivatives from the hemp  12 plant are simply not related to the product that it's  13 being compared to, which is the pharmaceutical.  14       PANEL MEMBER: You stated that the hemp  15 extract has been demonstrated that it would be safe  16 under the NDI and GRAS standard. And I'm wondering if  17 you're putting in any data and information into the  18 record on that regard.  19       MS. HOWARD: We have members of our  20 organization that are currently working on safety data  21 related to it. Our position is that there has been  22 discussion in the industry as to whether this would</p>	<p style="text-align: right;">Page 105</p> <p>1 who use CBD should have helpful guidance and  2 reasonable regulations that will allow them to  3 produce, sell and safely use CBD products.  4       The FDA's approval of a CBD seizure drug last  5 year has created a complex legal scenario under  6 section 301(ll) of the Food, Drug and Cosmetic Act.  7       Fortunately there are at least two paths  8 forward. The first path is hemp extract. Section  9 301(ll) prohibits a drug being added to food only if  10 the substance is intended to diagnose, cure, mitigate,  11 treat or prevent disease through its use in food, as  12 shown objectively by marketing and labeling  13 representations and is the exact same moiety as the  14 active ingredient in an approved drug and is added to  15 the food in the same dosage range as authorized by the  16 new drug approval.  17       Hemp extract as a food is an exception to  18 this rule, notwithstanding that it contains CBD. This  19 is because CBD is a constituent inherent in hemp which  20 has been marketed and used at least since the Civil  21 War.  22       The prohibition on marketing a drug in food</p>

<p style="text-align: right;">Page 106</p> <p>1 applies only to a substance that is added to food and  2 does not apply to a substance that is in food, even  3 when the substance is identical to an approved drug.  4 Additionally, hemp extract contains dozens of  5 compounds and is not the same moiety as the FDA-  6 approved CBD drug.</p> <p>7 The second path is for CBD itself. The mere  8 chemical identify of an approved drug does not -- or  9 with an approved drug does not render a substance a  10 drug in the absence of marketing claims.</p> <p>11 Section 301(ii) excepts from its prohibition  12 a drug that was marketed in food before any approval  13 of the drug or before substantial clinical  14 investigations involving the drug were instituted.</p> <p>15 Marketed in food simply means that the  16 substance has been present in food that has been  17 marketed, regardless of whether or not it has been  18 separately promoted.</p> <p>19 Once a substance has been marketed in food as  20 an inherent natural constituent, as with CBD, it  21 remains within the marketed in food exemption, even if  22 that constituent is later isolated and added to food.</p>	<p style="text-align: right;">Page 108</p> <p>1 demand and the industry is eagerly awaiting FDA's  2 regulatory framework for these products. We strongly  3 recommend that FDA act quickly to clarify the  4 regulatory environment because there is significant  5 confusion in the market. Businesses don't know who is  6 legally permissible -- what is legally permissible,  7 and some are making health claims in the absence of  8 clear regulatory guidance.</p> <p>9 Most significantly, banks and payment  10 processors don't currently understand the regulatory  11 landscape and as a result many CBD companies are at  12 risk of losing essential financial services. Because  13 of this, it is critical for FDA to advance regulations  14 in an expedited fashion.</p> <p>15 The second point I'd like to drive home is  16 the significance of the economic impact of this  17 nascent industry. Current research indicates that at  18 present, about 7 percent of all adult Americans, or 22  19 million people, use CBD as a supplement.</p> <p>20 The current market size is estimated at  21 upwards of \$2 billion. This current economic activity  22 supports nearly 12,000 direct full-time jobs. A five-</p>
<p style="text-align: right;">Page 107</p> <p>1 Thank you.</p> <p>2 MS. CRISTINZIO: Thank you. We are on number  3 33, Andrew Kline, the National Cannabis Industry  4 Association.</p> <p>5 MR. KLINE: Good morning. My name is Andrew  6 Kline, and I'm the lead -- the lead of public policy  7 of the National Cannabis Industry Association,  8 otherwise known as NCIA.</p> <p>9 Today NCIA represents nearly 2,000 members,  10 including CBD-related commercial manufacturers as well  11 as cannabis and ancillary business leaders. Recently  12 we formed a coalition of well over a hundred CBD  13 entrepreneurs, scientists, medical professionals and  14 food and drug lawyers to provide comments to FDA.  15 Yesterday that coalition submitted more than 60 formal  16 written pages on FDA's website.</p> <p>17 We encourage interested parties to review our  18 written submission, which can also be found on our  19 website at <a href="http://thecannabisindustry.org">thecannabisindustry.org</a>.</p> <p>20 I'd like to quickly drive home five important  21 points today. The first is that time is of the  22 essence. Hemp-derived CBD is in very high consumer</p>	<p style="text-align: right;">Page 109</p> <p>1 year projection shows a multiple of eight. We need to  2 get this right. But we need to get this done as  3 quickly as possible before we lose market share to  4 Canada, China and other international players.</p> <p>5 The third point I'd like to drive home is  6 that CBD products are safe. There is no higher  7 calling in government service than public safety and  8 we applaud FDA's efforts to make certain that  9 consumers are safe. The bottom line is this. An  10 overwhelming preponderance of evidence indicates that  11 cannabis and cannabis-derived compounds present  12 minimal safety concerns.</p> <p>13 Sorry. My pages are stuck. To address any  14 potential safety concerns, we believe FDA should  15 mandate that all cannabis products are tested in a  16 licensed analytical laboratory to ensure that  17 dangerous levels of potential contaminants are absent  18 from products that are consumed. In July of 2018, we  19 issued a report on lab testing. That report can be  20 found on our website.</p> <p>21 A fourth point I'd like to drive home is that  22 we need consensus industry standards to get this</p>

<p style="text-align: right;">Page 110</p> <p>1 right. While we know that CBD is safe, we also know 2 that universal standards have worked in other 3 industries to help protect the public from health and 4 safety risks.</p> <p>5 MS. CRISTINZIO: Sir, are you almost done? 6 MR. KLINE: Yes.</p> <p>7 MS. CRISTINZIO: You're beyond your time. 8 MR. KLINE: Finally, of course, it's 9 important that consumers be informed of any potential 10 risks. In February of 2019, NCIA released a report on 11 packaging and labeling. You can also find that on our 12 website. Thank you.</p> <p>13 PANEL MEMBER: One just quick remark. 14 Anything that you would like us to consider, we would 15 encourage you to put those reports and studies into 16 the docket before July 2nd. Thank you.</p> <p>17 MR. KLINE: We will. Thank you. 18 PANEL MEMBER: Just one other quick question. 19 You mentioned the domestic industry and you briefly 20 mentioned international. Any data that you have from 21 the international industry would be greatly 22 appreciated as well.</p>	<p style="text-align: right;">Page 112</p> <p>1 conventional foods.</p> <p>2 AHPA notes that these provisions should not 3 preclude use of hemp-derived ingredients containing 4 naturally occurring quantities of CBD and urges FDA to 5 -- excuse me -- publicly acknowledge this important 6 distinction.</p> <p>7 FDA's position on CBD has resulted in 8 significant marketplace confusion, many companies now 9 selling foods and supplements containing CBD have the 10 mistaken impression that FDA does not currently 11 regulate them. Others have chosen to stay out of the 12 market.</p> <p>13 Based on FDA's position to fully implement 14 the congressional intent to allow access to products 15 that contain hemp-derived CBD and to further AHPA's 16 and FDA's shared goal of ensuring safe and well- 17 manufactured supplements and foods, AHPA requests that 18 FDA promptly take one of the two following actions. 19 FDA should use its authority under the FD&amp;C 20 Act to issue a regulation possibly as an interim final 21 rule with an accelerated effective date permitting CBD 22 as a lawful ingredient in supplements and foods. Of</p>
<p style="text-align: right;">Page 111</p> <p>1 MR. KLINE: I can get that for you. 2 PANEL MEMBER: Perfect. Thank you. 3 MR. KLINE: Thank you.</p> <p>4 MS. CRISTINZIO: Thank you. We are now on 5 speaker number 34, Ken Maciora. I'm sorry. I'm 6 butchering your name, if you're here -- from the 7 Empire Relations Group. Next on the agenda is speaker 8 number 35, Michael McGuffin, the American Herbal 9 Products Association.</p> <p>10 MR. MCGUFFIN: Good morning. My name is 11 Michael McGuffin and I am president of the American 12 Herbal Products Association, or AHPA. Aside from my 13 statement here, AHPA will submit detailed written 14 comments to the docket.</p> <p>15 AHPA understands that the 2018 farm bill 16 reflected the intent of Congress to allow broad access 17 to hemp and products derived from hemp, including 18 those containing CBD.</p> <p>19 Even prior to the farm bill's enactment, FDA 20 stated its position with which AHPA has neither agreed 21 nor disagreed that provisions of the FD&amp;C Act prohibit 22 marketing CBD dietary supplements and adding CBD to</p>	<p style="text-align: right;">Page 113</p> <p>1 course this regulation would still require compliance 2 with all other applicable federal regulations.</p> <p>3 Alternately, and especially if FDA cannot 4 issue this requested regulation promptly, FDA should 5 issue guidance to state the agency's intent to 6 exercise formal enforcement discretion with respect to 7 the provisions of the FD&amp;C Act on which FDA bases its 8 position that CBD-containing supplements and foods are 9 unlawful.</p> <p>10 AHPA would support conditioning this exercise 11 of enforcement discretion also on full compliance with 12 all other regulations applicable to these categories.</p> <p>13 FDA has previously acknowledged its authority 14 to create a lawful pathway for marketing CBD- 15 containing supplements and foods, and the agency 16 should act promptly to use this authority. Thank you.</p> <p>17 PANEL MEMBER: Yes. I was wondering, you 18 mentioned products with naturally occurring levels, 19 right, of CBD.</p> <p>20 Is that -- if you could say a bit more about 21 that, is that like in the proportion that you would 22 usually see within the plant or sort of explain a</p>

<p style="text-align: right;">Page 114</p> <p>1 little bit more what you mean about it --</p> <p>2 MR. MCGUFFIN: Sure.</p> <p>3 PANEL MEMBER: -- and also what sorts of</p> <p>4 levels you tend to see.</p> <p>5 MR. MCGUFFIN: Correct. That is what I mean.</p> <p>6 I mean the proportion in a plant. So, for example, if</p> <p>7 a product came to the marketplace that was simply the</p> <p>8 plant packaged in a tablet or a capsule, then the</p> <p>9 naturally occurring presence of CBD should not be</p> <p>10 interpreted by FDA as the restriction under the</p> <p>11 provisions of the Food, Drug and Cosmetic Act.</p> <p>12 I think also simple products, tinctures,</p> <p>13 extracts that do not deliberately concentrate up the</p> <p>14 level of CBD, those also should be acknowledged as not</p> <p>15 affected by those provisions of the Food, Drug and</p> <p>16 Cosmetic Act.</p> <p>17 PANEL MEMBER: So what sorts of levels do you</p> <p>18 tend to see in those products and does it depend if</p> <p>19 it's a derivative from only part of the plant? Is</p> <p>20 that still within what you're talking about?</p> <p>21 MR. MCGUFFIN: I'd have to get back to you,</p> <p>22 and we will submit comments to clarify that detail.</p>	<p style="text-align: right;">Page 116</p> <p>1 is the leading trade association representing dietary</p> <p>2 supplement and functional food companies. CRN is here</p> <p>3 today to present comments about CBD use in supplements</p> <p>4 and foods, specifically to urge FDA to use its</p> <p>5 rulemaking authority as quickly as possible to create</p> <p>6 a legal pathway for CBD use in supplements and food.</p> <p>7 Despite FDA's current position on the</p> <p>8 legality of CBD, the CBD food and supplement</p> <p>9 marketplace is exploding. For dietary supplements</p> <p>10 alone, hemp-derived CBD sales were over \$200 million</p> <p>11 in 2018 and are expected to grow to over \$300 million</p> <p>12 by the end of 2019.</p> <p>13 Driving these sales is an intense consumer</p> <p>14 demand in hemp-derived CBD. Research suggests that a</p> <p>15 third of U.S. adults are current CBD users and nearly</p> <p>16 half of all U.S. adults have used CBD at some point.</p> <p>17 Lack of FDA oversight for these products leaves this</p> <p>18 growing consumer base vulnerable.</p> <p>19 Without FDA oversight, consumers lack</p> <p>20 assurance that products labeled as CBD are safe.</p> <p>21 Consumers cannot trust that the products are</p> <p>22 manufactured in an appropriate manner or actually</p>
<p style="text-align: right;">Page 115</p> <p>1 But -- and there is also a range. There are different</p> <p>2 cultivars that have different levels. I don't know</p> <p>3 the numbers right now. But we'll make sure that we</p> <p>4 provide that information in our comments. Thank you.</p> <p>5 PANEL MEMBER: One other thing that would be</p> <p>6 useful, when you submit that comment, is you had two</p> <p>7 proposed solutions.</p> <p>8 I'm not sure if you're -- if there's a dose</p> <p>9 of cannabidiol that you believe should be considered</p> <p>10 safe or were there some higher level of cannabidiol</p> <p>11 that shouldn't be allowed under one or the other of</p> <p>12 those proposals.</p> <p>13 MR. MCGUFFIN: We will definitely address</p> <p>14 that issue in our comments. Thank you for that</p> <p>15 question. I think it's a very important element of</p> <p>16 this whole discussion. Thank you.</p> <p>17 MS. CRISTINZIO: Great. We are now on</p> <p>18 speaker number 36, Megan Olsen, from the Council for</p> <p>19 Responsible Nutrition.</p> <p>20 MS. OLSEN: Thank you. I'm Megan Olsen. I'm</p> <p>21 the assistant general counsel for the Council for</p> <p>22 Responsible Nutrition. CRN, based in Washington, DC,</p>	<p style="text-align: right;">Page 117</p> <p>1 contain the amount of CBD listed on the label or any</p> <p>2 CBD at all. Therefore FDA does not have the luxury of</p> <p>3 time. They must act quickly to address a market that</p> <p>4 is out of control. Three to five years at a minimum</p> <p>5 for rulemaking is too long.</p> <p>6 In fact, CRN was alarmed by the suggested</p> <p>7 timeframe and comments by FDA leadership, including</p> <p>8 former FDA commissioner, Dr. Gottlieb. CRN</p> <p>9 understands and respects FDA's concerns about safety</p> <p>10 of CBD products. But as CRN will expand on in further</p> <p>11 comments by CRN CEO Steve Mister, we do not believe</p> <p>12 that the safety debate has to impede rulemaking at</p> <p>13 that stage.</p> <p>14 There is already a regulatory framework in</p> <p>15 place that is proven to ensure the safety of dietary</p> <p>16 supplements in food, one that will automatically be</p> <p>17 implemented should FDA develop a regulation permitting</p> <p>18 CBD use in food and supplements.</p> <p>19 To be clear, FDA is not asking -- or CRN is</p> <p>20 not asking FDA to abdicate a safety review. Rather,</p> <p>21 CRN is asking FDA to address safety as the Food, Drug</p> <p>22 and Cosmetic Act intended. In the fact-specific</p>

<p style="text-align: right;">Page 118</p> <p>1 context of how a product will be marketed, intended to  2 be used, its form, dosage and other unique  3 considerations that apply once a product is considered  4 a supplement or food.  5 Americans deserve access to safe quality  6 supplements and food, as well as protection from  7 supplements and food that pose risk. FDA under  8 current law has the authority to achieve both goals  9 for CBD and we strongly urge the agency to use this  10 authority as quickly as possible.  11 PANEL MEMBER: I'm going to ask you the same  12 question I think that I asked the previous speaker,  13 which is if you have information about safe dosages of  14 these products or use in supplements, that would be  15 very useful, including information about whether those  16 dosages or recommended serving sizes would change  17 based upon the intended effect.  18 MS. OLSEN: Yes, and CRN is intending to  19 submit written comments. And we will take that into  20 consideration with our written comments.  21 PANEL MEMBER: Okay. Thank you.  22 MS. CRISTINZIO: Thank you. We are now on</p>	<p style="text-align: right;">Page 120</p> <p>1 Ladies and gentlemen, the genie is out of the  2 bottle here and it is probably impossible to force it  3 back inside. Accordingly, I encourage FDA to take  4 prompt action to address this unique regulatory  5 situation. A more comprehensive exposition of my  6 suggestions are contained in my written comment.  7 But in brief, my suggested actions include,  8 one, allowing low dose CBD products to be sold as  9 dietary supplements and/or food additives. The  10 prescribing guidelines for Epidiolex establish the  11 dose range between 700 mg and 1.4 g per day.  12 Most of the CBD products currently in the  13 customer marketplace have less than 500 mg in their  14 entire container and are generally intended to last  15 about a month. This is a difference of several orders  16 of magnitude.  17 The significant differential in dosages  18 suggests the current consumer CBD products should be  19 placed in an entirely different category than  20 pharmaceutical products. The logical category for  21 this is that of dietary supplements.  22 Two, enact a policy stating FDA will not</p>
<p style="text-align: right;">Page 119</p> <p>1 speaker number 37, David Rodman.  2 MR. RODMAN: Good morning. My name is Dave  3 Rodman, and I am here on behalf of The Rodman Law  4 Group. I'd like to thank FDA for hosting this hearing  5 and for having the foresight to address these  6 important issues in a proactive manner.  7 My firm has been representing and advising  8 companies in the cannabinoid space for the past five  9 years and we have seen the industry as a whole grow at  10 a blistering pace.  11 Even with this unprecedented expansion as a  12 baseline, the CBD sector stands out due to its  13 exponential growth. Yet this proliferation has  14 occurred almost entirely outside any well-defined or  15 widely enforced regulatory regime.  16 To my knowledge, no compound has ever been  17 removed from Schedule 1. But CBD achieved mass  18 adoption practically overnight, even before hemp-  19 derived CBD was removed from the CSA. Now FDA is  20 faced with the daunting task of attempting to regulate  21 an unprecedented billion-dollar industry that shows no  22 signs of slowing its growth.</p>	<p style="text-align: right;">Page 121</p> <p>1 prioritize enforcement of the FD&amp;C Act against CBD  2 operations that follow established enforcement  3 priorities.  4 Soon after states like Colorado began to  5 legalize cannabis, the Department of Justice issued  6 the Cole memo, which basically stated that the DOJ  7 would not enforce the CSA in states where cannabis has  8 been legalized, provided that the state legal cannabis  9 activities did not violate eight established  10 enforcement priorities.  11 FDA could take a page from DOJ's playbook and  12 issue guidance similar to the Cole memo with respect  13 to the FD&amp;C Act. Suggested enforcement priorities  14 could include, A, strictly limiting claims about CBD  15 to structure or function claims only; B, not marketing  16 CBD to children; and, C, adherence to certain  17 packaging, labeling and testing standards to ensure  18 quality and accuracy of ingredients.  19 I should note that much of the industry has  20 already voluntarily participated in rigorous testing  21 programs and it would not be hard to codify such  22 testing. And much of the industry would support it</p>

<p style="text-align: right;">Page 122</p> <p>1 immediately.</p> <p>2 I know I'm a little bit over time. My last</p> <p>3 suggestion would be to expedite the creation of a CBD</p> <p>4 OTC monograph. And I'm not going to read all of that</p> <p>5 because I'm about a minute late. Thank you.</p> <p>6 MS. CRISTINZIO: Please submit the rest of</p> <p>7 your comments to the docket. Next on the agenda is</p> <p>8 Zoe Sigman.</p> <p>9 MS. SIGMAN: Good morning. My name is Zoe</p> <p>10 Sigman, and I'm the program director at Project CBD,</p> <p>11 an educational nonprofit focused on cannabis science</p> <p>12 and medicine. Ten years ago, we introduced CBD to the</p> <p>13 medical cannabis community in California. It spread</p> <p>14 like wildfire and has become the hugely popular</p> <p>15 phenomenon that it is today.</p> <p>16 There are occasions when public health</p> <p>17 priorities and pharmaceutical priorities are not</p> <p>18 equivalent. That is, we believe that this is the case</p> <p>19 with CBD and cannabis. We urge the FDA to maintain</p> <p>20 public health at the core of your decision-making</p> <p>21 process.</p> <p>22 CBD is a nontoxic, non-intoxicating, non-</p>	<p style="text-align: right;">Page 124</p> <p>1 health officials.</p> <p>2 Contraindications and drug interactions are</p> <p>3 easily manageable. Project CBD has published an</p> <p>4 extensive report on cannabinoid drug interactions,</p> <p>5 noting few problems, except with high doses of CBD</p> <p>6 isolates.</p> <p>7 Project CBD advocates banning artificial</p> <p>8 thinning agents and flavor additives from cannabis oil</p> <p>9 vape cartridges unless these additives are proven safe</p> <p>10 when heated and inhaled. None have been. Let's</p> <p>11 regulate CBD to promote public health. Let's make the</p> <p>12 most of this historic opportunity. Thank you.</p> <p>13 PANEL MEMBER: Thank you for your comments.</p> <p>14 You did again mention a few -- a study on pregnancy</p> <p>15 and a report on drug interactions.</p> <p>16 MS. SIGMAN: Yes.</p> <p>17 PANEL MEMBER: And I'm hoping that you will</p> <p>18 submit those to the docket before July 2nd.</p> <p>19 MS. SIGMAN: Absolutely.</p> <p>20 PANEL MEMBER: I do have a question for you.</p> <p>21 It sounds like your group is sort of coordinating a</p> <p>22 lot of efforts on CBD. Have you made any efforts to</p>
<p style="text-align: right;">Page 123</p> <p>1 habit-forming neuroprotective antioxidant. What's not</p> <p>2 to like? Given CBD's intrinsic safety and many</p> <p>3 potential benefits, it should be legally available</p> <p>4 without a prescription.</p> <p>5 Sensible regulations can assure product</p> <p>6 safety without going through expensive, time-consuming</p> <p>7 clinical trials. The goal should be public access to</p> <p>8 diverse cannabis product options that are subject to</p> <p>9 rigorous manufacturing and compliance oversight.</p> <p>10 Towards this end, we propose the formation of</p> <p>11 a committee for traditional herbal medicinal products</p> <p>12 to assist in implementing regulations for CBD,</p> <p>13 cannabis and other medicinal plants. Project CBD will</p> <p>14 provide a detailed account of the committee's</p> <p>15 responsibilities in a written submission to the FDA.</p> <p>16 For those interested, I have a list of the resources</p> <p>17 that informed that idea here today.</p> <p>18 A few closing comments. Regarding pregnancy,</p> <p>19 when confounding variables like alcohol and cigarettes</p> <p>20 are accounted for, there is no science that</p> <p>21 demonstrates harm to the fetus from cannabis, as</p> <p>22 Project CBD documented in a report for California</p>	<p style="text-align: right;">Page 125</p> <p>1 monitor any adverse events or consumer complaints</p> <p>2 related to these products? And, if so, are there</p> <p>3 reports that you could submit to the docket?</p> <p>4 MS. SIGMAN: Absolutely, yeah. We have a</p> <p>5 research survey that over a thousand people have</p> <p>6 filled out. So we will. Thank you.</p> <p>7 MS. CRISTINZIO: great. Thank you. We are</p> <p>8 now on agenda number 39, Andy Snyder.</p> <p>9 MR. SNYDER: Good morning. My name is Andy</p> <p>10 Snyder. I'm the founder and publisher of Manward</p> <p>11 Press, and I'm not just here today on behalf of our</p> <p>12 200,000 readers and their families. I'm here on</p> <p>13 behalf of my family, friends and every American</p> <p>14 listening and watching today online.</p> <p>15 Our nation is at a crossroads, one that</p> <p>16 should be clear to everyone in this room today. While</p> <p>17 the evidence supporting both the safety and efficacy</p> <p>18 of CBD continues to pile up, response at the federal</p> <p>19 level has been slow at best and nonexistent at worse.</p> <p>20 Today most Americans are under the impression</p> <p>21 that the research on CBD is insufficient. But that's</p> <p>22 merely a projection of the mainstream perception. The</p>



<p style="text-align: right;">Page 126</p> <p>1 truth is there are more than 150 active clinical 2 trials registered with the U.S. National Library of 3 Medicine as I speak to you right now. 4 In fact, multiple published studies in the 5 U.S. National Library of Medicine confirm the safety 6 profile and efficacy of CBD. 7 One recent review of 132 studies found that 8 not only is CBD safe, it's a powerful antioxidant that 9 is more effective than vitamin C or E at protecting 10 the human brain. 11 Make no mistake. This is just scratching the 12 surface of CBD's potential for mainstream, widespread 13 application in human health optimization. 14 I believe that if the folks charged with 15 liberating CBD from its shackles make the right 16 decisions, CBD is just a few years away from being 17 perceived by the average American no differently than 18 vitamin C or any other common drugstore vitamin. The 19 main difference will be that, unlike vitamin C, the 20 average American will be able to experience 21 significant tangible benefits from CBD. 22 For many, CBD has already become the go-to</p>	<p style="text-align: right;">Page 128</p> <p>1 into our hands. Thank you. 2 PANEL MEMBER: Are you familiar with data 3 regarding the safety of CBD use in children? 4 MR. SNYDER: Not personally, no. 5 PANEL MEMBER: Are you supportive of that? 6 MR. SNYDER: In children? I'm a publisher. 7 So I don't have the research on that. Based on what 8 I've heard, no, I wouldn't give my son or my daughter 9 CBD. 10 PANEL MEMBER: Would you give your son or 11 daughter vitamin C? 12 MR. SNYDER: I would. 13 PANEL MEMBER: Okay. 14 PANEL MEMBER: I'm curious just to ask you to 15 speculate a little bit about the impact of expanding 16 the availability of cannabidiol in the foods and 17 dietary supplements based on study of cannabidiol 18 formally and in the kinds of trials that you mentioned 19 on clinicaltrials.gov. Do you think that would help 20 that or in any way hinder it by potentially removing, 21 you know, some incentives for that? 22 MR. SNYDER: You're asking if getting rid of</p>
<p style="text-align: right;">Page 127</p> <p>1 natural solution for a variety of concerns, like one 2 of my readers, Frank B. Frank wrote in to tell me 3 about his experience with CBD. 4 Here's just a short example of what he wrote 5 me: I'm an old guy that still works pretty hard. My 6 friends are all older farmers, loggers and equipment 7 operators that are still working because we enjoy it. 8 We are using CBD oils and rubs to get through the 9 aches and pains that come from that kind of work. 10 This stuff makes it so we can going without the pain. 11 Ladies and gentlemen, we're talking about a 12 safe, natural compound with seemingly endless benefits 13 for users, one with very little, if any, risk of 14 significant downside. For my money, CBD may be one of 15 God's greatest gifts to mankind in the pursuit of 16 health. 17 It's outrageous that corporate greed and red 18 tape have forced most Americans to spend the last 19 eight decades in the dark. Today is our chance to 20 learn from past mistakes, open our eyes to the 21 compelling scientific and anecdotal evidence and 22 harness the power of nature to put our health back</p>	<p style="text-align: right;">Page 129</p> <p>1 the regulations on food supplements would help? 2 PANEL MEMBER: If it was more broadly 3 available in that way. Would that -- what effect 4 would that have on sort of additional scientific 5 research? 6 MR. SNYDER: I think what we need to do is 7 clear up the confusion. Anything -- any regulations 8 we make need to be simple, clear. Our readers -- I 9 hear it every day. They think there's opportunity out 10 there. They just don't know what to do. 11 As we've heard today, there's a lot of shady 12 characters in the market. There's some really good 13 characters out there. And clearing that up with 14 smart, commonsense regulation is what's needed. Thank 15 you. 16 MS. CRISTINZIO: Thank you. We are now on 17 speaker number 40, Ian Spotts. Ian? Okay. We are 18 moving onto speaker 41, Monica Weldon 19 PANEL MEMBER: WSWA, whatever that is. 20 MS. WELDON: Hi. Thank you. Thank you. I'm 21 Monica Weldon, and I'm president and CEO of bridge the 22 Gap, SYNGAP Education Research Foundation. Imagine</p>

<p style="text-align: right;">Page 130</p> <p>1 being told there is no FDA-approved product for your                  2 child. Picture watching your children suffer from a                  3 rare genetic disorder that physicians barely                  4 understand, marked by seizures, mood disorders, the                  5 inability for your child to communicate due to their                  6 being nonverbal. Put yourself in the shoes of a                  7 parent or a caregiver who is disparate for their child                  8 -- to treat their child's challenges, even just to                  9 find out what's wrong.</p> <p>10 Now insert CBD. With all its confusing                  11 descriptions, derivative products, vague dosage                  12 recommendations, the cure-all marketing and then you                  13 create a legal environment of ambiguity around it and                  14 now you've just created the Wild West of CBD.</p> <p>15 Like many pediatric rare disease advocates,                  16 we are particularly sensitive to new emerging                  17 therapies that are going to help our children.</p> <p>18 Patients and their families look to us for                  19 guidance and trusted educational materials on                  20 potential treatments, especially as we work closely                  21 with researchers to develop targeted therapies for                  22 SYNGAP1. We have no approved targeted therapy for our</p>	<p style="text-align: right;">Page 132</p> <p>1 substandard and fake products.</p> <p>2 We need to know exactly what we are                  3 consuming, especially if we are feeding it to our                  4 children. We need to feel confident that the products                  5 we are using are held to the highest safety standards.                  6 SYNGAP1 patients, along with other rare pediatric                  7 disease patients, need to have access to safe and                  8 effective therapies to improve their quality of life.                  9 Thank you.</p> <p>10 MS. CRISTINZIO: Thank you. I just want to                  11 note we're running a little bit behind. We're about                  12 10 minutes behind schedule. So I'm going to try and                  13 stick to the lights a little bit more vigorously. We                  14 are on number 42, Anna Williams.</p> <p>15 MS. WILLIAMS: My name is Anna Williams, and                  16 I'm the main point of contact at the American                  17 Association for Laboratory Accreditation, otherwise                  18 known as A2LA, for their cannabis and hemp programs.                  19 Established in 1978, A2LA is a nonprofit,                  20 third party accreditation body with over 3,500                  21 actively accredited certificates representing all 50                  22 states. We offer training and services to public and</p>
<p style="text-align: right;">Page 131</p> <p>1 children. So therefore we are focused on short-term                  2 repurposing of drugs and natural medications to                  3 mitigate SYNGAP1 symptoms.</p> <p>4 CBD-based pharmaceuticals and OTC CBD                  5 products come up in conversations all the time. Our                  6 greatest challenge as an organization is how to                  7 address them. At this stage, we need further                  8 scientific research when it comes to safety, efficacy,                  9 product integrity, drug interactions, further CBD                  10 research will answer many of our questions.</p> <p>11 In addition to our patient community, they                  12 have expressed appropriate dosing, potential                  13 interactions with other pharmaceuticals, where to                  14 purchase products free of harsh chemicals and                  15 pesticides.</p> <p>16 In addition, we support regulations on                  17 standards of labeling of CBD products so that patients                  18 and caregivers can easily understand what they are                  19 consuming and compare labels for different products.                  20 We need regulatory shielding from predators and                  21 opportunists in the consumer product space looking to                  22 capitalize off CBD's popularity by peddling</p>	<p style="text-align: right;">Page 133</p> <p>1 private testing laboratories, proficiency testing                  2 providers, reference material producers and product                  3 certifiers.</p> <p>4 In the U.S., both government regulators and                  5 consumers seek assurance that products and commerce                  6 conform to specific quality attributes and/or                  7 regulatory requirements. This is generally                  8 accomplished via testing of the product by a competent                  9 analytical laboratory.</p> <p>10 The same is true for products containing                  11 cannabis and cannabis-derived compounds and both the                  12 neat, plant and process materials should be testing                  13 for unacceptable levels of contaminant and                  14 adulterants.</p> <p>15 The challenges at present are there few                  16 multi-laboratory validated test dates or realistically                  17 nationally available proficiency testing programs.                  18 This circumstance places the requirement on the lab to                  19 develop, validate and run their own internal methods                  20 without these necessary tools that laboratories in                  21 other industries have access to.                  22 Assurance of laboratory competence is most</p>

<p style="text-align: right;">Page 134</p> <p>1 often accomplished through ISO 17025 accreditation  2 process. Accreditation uses criteria and procedures  3 specifically developed for the assessment of technical  4 competence of the laboratory and depends on multiple  5 factors including qualifications and training of  6 staff, correct equipment, adequate quality assurance  7 procedures, properly statistical-based sampling  8 practices, appropriate and valid testing procedures  9 and methods, traceability of measurements to national  10 standards, accurate recording and reporting procedures  11 and suitable testing facilities.</p> <p>12 Expert technical assessors conduct a thorough  13 evaluation of a laboratory's management process,  14 affecting the production of analytical test data and  15 through being accredited laboratories demonstrate that  16 these quality requirements have been and continue to  17 be met.</p> <p>18 Accreditation bodies themselves are also  19 periodically evaluated and are part of international  20 laboratory accreditation cooperation. It is through  21 this process that assurance is provided to regulators  22 and the public of technical competence of this testing</p>	<p style="text-align: right;">Page 136</p> <p>1 Agency for Healthcare Research and Quality, in its  2 recent draft report on the diagnosis and treatment of  3 Alzheimer's, determined that there is insufficient  4 evidence to draw conclusions about the efficacy or  5 safety of cannabinoids for treatment of Alzheimer's, a  6 determination with which the Alzheimer's Association  7 agrees.</p> <p>8 At this time, cannabis is essentially an  9 untested drug for use in Alzheimer's disease and  10 dementia. And like any untested drug, it cannot be  11 responsibly recommended for human use.</p> <p>12 Only large, randomized, controlled clinical  13 trials can provide reliable evidence of efficacy or  14 safety of any drug for human use. And to date, this  15 has simply not happened with cannabis in relationship  16 to Alzheimer's and dementia.</p> <p>17 This lack of evidence creates substantial  18 risks for individuals and their families. Simply put,  19 there is currently no robust consistent clinical trial  20 data to support the use of cannabis for treatment of  21 Alzheimer's or dementia.</p> <p>22 The Alzheimer's Association believes that</p>
<p style="text-align: right;">Page 135</p> <p>1 laboratory.</p> <p>2 In summary, it is the position of A2LA that  3 any outcome of the FDA's request for information  4 inform any future regulations to include language that  5 requires proficient -- or excuse me, participating  6 analytical testing laboratories to be accredited to  7 ISO 17025 by a signatory accreditation body. Thank  8 you.</p> <p>9 MS. CRISTINZIO: Thank you. We are on number  10 43, Tiffany Wilson. Tiffany? So we are going to go  11 on to the patient category. We have number 44, Keith  12 Fargo.</p> <p>13 PATIENTS</p> <p>14 DR. FARGO: Hi. Good morning. My name is  15 Keith Fargo. I'm the director of scientific programs  16 and outreach for the Alzheimer's Association.</p> <p>17 Although the chemical components of cannabis  18 have been studied in relationship to Alzheimer's and  19 dementia, most of this research has been conducted in  20 in animal models and cell culture and not in people.</p> <p>21 Furthermore, research findings to date have  22 been inconclusive and contradictory. Accordingly, the</p>	<p style="text-align: right;">Page 137</p> <p>1 more research in this area is needed, and we applaud  2 the FDA's commitment to protecting the health and  3 safety of individuals until such evidence becomes  4 available. Thank you.</p> <p>5 PANEL MEMBER: How do you view the commercial  6 availability of cannabis and CBD and other cannabis  7 derivatives as affecting incentives for research in  8 Alzheimer's?</p> <p>9 DR. FARGO: That's a great question. I don't  10 know that it directly affects the incentive to do  11 further research in Alzheimer's. I just don't know  12 that I have a good answer to that question. All  13 right. Thanks.</p> <p>14 MS. CRISTINZIO: Thank you. We are now on  15 speaker number 45, Kevin Chapman.</p> <p>16 DR. CHAPMAN: Good morning. Good morning.  17 My name is Dr. Kevin Chapman, and I'm a pediatric  18 epilepsy specialist in Colorado speaking on behalf of  19 the American --</p> <p>20 MS. CRISTINZIO: Can you speak a little  21 louder, please?</p> <p>22 DR. CHAPMAN: Sorry.</p>

<p style="text-align: right;">Page 138</p> <p>1 MS. CRISTINZIO: Or move closer to the mic.</p> <p>2 DR. CHAPMAN: My name is Dr. Kevin Chapman,</p> <p>3 and I'm a pediatric specialist in Colorado speaking on</p> <p>4 behalf of the American Epilepsy Society, representing</p> <p>5 over 4,400 health professionals who focus on the care</p> <p>6 of patients with epilepsy from neonates to the</p> <p>7 geriatric population.</p> <p>8 We have significant concerns about the</p> <p>9 current status quo for cannabis products and advocate</p> <p>10 for regulation of cannabis products as drugs under the</p> <p>11 purview of the FDA.</p> <p>12 The current patchwork of state and federal</p> <p>13 regulations has led to an array of products with</p> <p>14 variable phytocannabinoid content and potential</p> <p>15 impurities such as pesticides. By classifying these</p> <p>16 compounds and drugs, the FDA can assure consistency</p> <p>17 and safety of these poorly regulated compounds.</p> <p>18 We strongly encourage the FDA and United</p> <p>19 States Pharmacopeia to create standard assays to</p> <p>20 evaluate content and purity, as well as quality</p> <p>21 standards for cannabis-containing products that are</p> <p>22 currently unregulated yet may be marketed and sold for</p>	<p style="text-align: right;">Page 140</p> <p>1 these compounds as drugs under the complete</p> <p>2 jurisdiction of the FDA. We also advocate for</p> <p>3 ongoing, well-designed studies into the safety and</p> <p>4 efficacy of cannabis drugs. We commend the FDA for</p> <p>5 tackling this complex problem of public safety, and I</p> <p>6 appreciate your time.</p> <p>7 PANEL MEMBER: Question for you.</p> <p>8 DR. CHAPMAN: Yes, ma'am.</p> <p>9 PANEL MEMBER: Have you found any -- are you</p> <p>10 aware of patients using unapproved CBD products as</p> <p>11 opposed to Epidiolex, which has been approved?</p> <p>12 DR. CHAPMAN: Yes. I am aware of that.</p> <p>13 There are quite a few.</p> <p>14 PANEL MEMBER: And do you know why they are</p> <p>15 doing that?</p> <p>16 DR. CHAPMAN: At this point, Epidiolex is</p> <p>17 limited to a very small segment of our population.</p> <p>18 There's two current approvals, Dravet syndrome and</p> <p>19 Lennox-Gastaut syndrome, which is a fairly small but</p> <p>20 serious epilepsy syndrome.</p> <p>21 And so, all of the patients that are outside</p> <p>22 of that are not covered. And the cost of the</p>
<p style="text-align: right;">Page 139</p> <p>1 the treatment of various medical conditions such as</p> <p>2 epilepsy, pain or migraine headache.</p> <p>3 Studies of Epidiolex, an FDA-approved</p> <p>4 prescription CBD product, have raised concerns about</p> <p>5 hepatotoxic effects of CBD and interactions with other</p> <p>6 medications if taken outside of medical supervision.</p> <p>7 Clear warning labeling of cannabis-derived</p> <p>8 compounds is necessary to educate about potential</p> <p>9 adverse effects and help offset the common belief that</p> <p>10 these products are, quote, "more natural," end quote,</p> <p>11 and therefore safer than pharmaceutical products.</p> <p>12 Many questions remain regarding the long-term</p> <p>13 consequences of cannabis compounds whose underlying</p> <p>14 mechanism of action remains unknown.</p> <p>15 We have specific concerns about the unknown</p> <p>16 effects of these compounds on the complex pathways of</p> <p>17 the developing brain in children. We also have</p> <p>18 concerns about the potential long-term effects on</p> <p>19 adults who regularly consume these products.</p> <p>20 We support reducing regulatory barriers to</p> <p>21 research of cannabis-derived compounds. We strongly</p> <p>22 encourage -- we strongly urge the FDA to classify</p>	<p style="text-align: right;">Page 141</p> <p>1 medication is about 430,000 per year, whereas families</p> <p>2 can go to a dispensary and pick up something, you</p> <p>3 know, on the order of \$100 per month or so.</p> <p>4 PANEL MEMBER: And how are they choosing</p> <p>5 dose?</p> <p>6 DR. CHAPMAN: They're making it up as they go</p> <p>7 along.</p> <p>8 PANEL MEMBER: (Off mic.)</p> <p>9 DR. CHAPMAN: Sorry. Sorry. They're just</p> <p>10 sort of making it up as they go along.</p> <p>11 PANEL MEMBER: I'll just follow up on that,</p> <p>12 given that answer. Do you find that most of these</p> <p>13 patients are being monitored in some way by their</p> <p>14 physicians for adverse events like liver toxicity and</p> <p>15 others that were identified in the approval of the</p> <p>16 Epidiolex drug?</p> <p>17 DR. CHAPMAN: It's an excellent question. I</p> <p>18 mean, so this has really been kind of an issue for</p> <p>19 five years. Since this WEEDS program in August of</p> <p>20 2013, especially in Colorado, we had an influx of</p> <p>21 patients. And early on, we definitely did not know</p> <p>22 what to expect from these compounds.</p>

<p style="text-align: right;">Page 142</p> <p>1 We instituted, you know, trying to evaluate  2 drug interactions, hepatotoxic effects, aplastic  3 anemia, those types of things, with sort of  4 standardized -- at least some attempt at  5 standardization of blood testing and things like that.  6 It's a bit variable because, you know, some  7 families were getting -- we felt as physicians within  8 Colorado we could not make recommendations about non-  9 FDA-approved products because, at the time, we were  10 worried for other regulatory reasons whether it may  11 affect our ability to do research and things such as  12 that.  13 So we have really -- there's so much  14 variability within the CBD products and I think that's  15 one of the biggest concerns that we have.  16 MS. CRISTINZIO: Great. Thank you. Our next  17 speaker is Kari Rosbeck, number 46.  18 MS. ROSBECK: My name is Kari Luther Rosbeck,  19 and I'm president and CEO of the Tuberous Sclerosis  20 Alliance, an advocacy organization for people with  21 tuberous sclerosis complex, or TSC.  22 About 85 percent of those with TSC will</p>	<p style="text-align: right;">Page 144</p> <p>1 compromised if investigators are unable to control and  2 verify dietary intake of cannabinoids which might lead  3 to increased variability and apparent placebo effects.  4 In summary, without a wide safety margin to  5 avoid accidental exposure of people with TSC to levels  6 of cannabinoids which are known to interact with their  7 medications, we urge the FDA to prohibit the inclusion  8 of cannabis-based additives in any FDA-regulated  9 products other than drugs as defined and approved  10 under the FD&amp;C Act.  11 Please refer to our written public comments  12 for more information. Thank you on behalf of the TS  13 Alliance and the TSC community.  14 PANEL MEMBER: Sorry. Do your written  15 comments include the information you mentioned about  16 drug interactions?  17 MS. ROSBECK: Yes. Yes, they do.  18 PANEL MEMBER: Okay. Thank you.  19 MS. ROSBECK: Thank you.  20 MS. CRISTINZIO: Great. Okay. We are moving  21 on to the next category of public safety. We have  22 number 47, Patrick Bird.</p>
<p style="text-align: right;">Page 143</p> <p>1 experience epilepsy. So accessing effective seizure  2 medications is critically important for our community.  3 In fact, a recent Phase III clinical trial reported  4 efficacy of Epidiolex, a purified and standardized  5 formulation of cannabidiol, for treating drug-  6 resistant seizures in TSC, which we hope will lead to  7 an FDA approval for broader use in epilepsy associated  8 with TSC.  9 The TS Alliance recognizes the importance of  10 taking an evidence-based approach to discovery,  11 development and clinical application of cannabis and  12 derivatives. Multiple drug cannabinoid interactions  13 with commonly used anti-seizure medications are well-  14 documented, including clobazam, valproate and others.  15 Risks of unexpected drug-drug interactions  16 may occur if cannabinoid enters the bloodstream due to  17 its inclusion in food, cosmetics and other products.  18 Therefore we believe labeling of identified drug  19 interactions should be required on any cannabis-  20 derived or cannabis-containing products since people  21 may be exposed to these products in multiple ways.  22 Clinical trial results could also be</p>	<p style="text-align: right;">Page 145</p> <p>1 PUBLIC SAFETY  2 MR. BIRD: Good morning. My name is Patrick  3 Bird. And I'm the owner of PMB BioTek Consulting,  4 which works to develop analytical methods and rapid  5 detection platforms for analytical testing  6 laboratories. I'm also the co-chair of the  7 microbiology working group for AOAC International's  8 cannabis analytical science program.  9 The complete lack of a federal regulatory  10 scheme for cannabis generally, including both hemp and  11 marijuana, has left cannabis decades behind other food  12 and agricultural testing. And now, the FDA that must  13 bring a plant that has been used by humans for  14 millennia into a 21st century paradigm for food  15 safety.  16 The FDA is responsible for protecting the  17 public health by ensuring the safety of products  18 millions of Americans consume every day.  19 In developing a new regulatory framework for  20 hemp-derived products, the FDA, in partnership with  21 industry groups like AOAC and testing laboratories  22 like Titan Analytical, should look to two primary</p>

<p style="text-align: right;">Page 146</p> <p>1 sources to guide its efforts: state cannabis                  2 regulations and federal food safety regulations.                  3 First, the FDA should closely examine the                  4 regulatory schemes implemented by states with mature                  5 medical and adult use cannabis markets; namely                  6 California, Illinois and Colorado.                  7 Although these states' regulatory structures                  8 have different ends, their policy goals are congruent                  9 because the same baseline safety issues are present                  10 regardless of whether a cannabis plant, hemp or                  11 marijuana is grown in accordance with or in                  12 contravention of federal law.                  13 The cannabis plant is a bioaccumulator,                  14 acting as a sponge for a wide range of environmental                  15 and microbiological contaminants. By establishing                  16 baseline regulations for pesticides, metals,                  17 bacteriological agents and other key target analytes                  18 in hemp-derived products for human consumption, the                  19 FDA can continue to fulfill its responsibility to                  20 protect public health.                  21 Second, the FDA should incorporate aspects of                  22 federal food safety regulations like FSMA such as</p>	<p style="text-align: right;">Page 148</p> <p>1 where there are a lot of people that are trying to                  2 provide this medicine to consumers.                  3 But they are being held and their hands are                  4 being tied because they have no ability to take                  5 payment, whether it's online or face-to-face. The                  6 banking -- so we just -- we're asking for more clarity                  7 from the FDA to give -- to make these people feel a                  8 little bit more confident in approaching the banks and                  9 being able to get those approvals.                  10 When it comes to labeling, I think, you know,                  11 when we have -- we're hearing some stories of people,                  12 that -- you know, when it comes to labeling, they                  13 don't know what they're getting when it comes to full                  14 spectrum versus isolate. We're getting questions                  15 about what is this, what's the clarity on that.                  16 There are companies out there that are saying                  17 we're full spectrum, and yet it's 99 percent CBD                  18 spiked with 1 percent terpenes and they're putting                  19 these out there.                  20 And so, there needs to be a little bit more                  21 clarity, I think maybe some sort of seal on the label                  22 saying this is full spectrum and a table of</p>
<p style="text-align: right;">Page 147</p> <p>1 HACCP, FSVP and preventative control planning that                  2 will adequately ensure product safety. Consumers                  3 should expect, if not demand the same levels of                  4 safety, traceability and recall readiness that the FDA                  5 already requires of food manufacturers. Hemp products                  6 should be treated no differently. Thank you.                  7 MS. CRISTINZIO: Thank you. We are on a new                  8 category, retailers and distributors. Number 48,                  9 Crystal Guess.                  10 RETAILERS/DISTRIBUTORS                  11 MS. GUESS: Good morning. My name is Crystal                  12 Guess, and the comments that I am making today are my                  13 own and do not represent the company or any                  14 individual. I would like to speak to the 2018 farm                  15 bill, being that it now regulates hemp as any other                  16 agricultural crop, just like corn, wheat, rye, barley,                  17 potatoes.                  18 I can walk into a Safeway and I can buy                  19 potato chips and buy those potato chips with a credit                  20 card. I can then -- Safeway can they deposit those                  21 funds into a national bank. We are having some very -                  22 - we are having some issues with now in the industry</p>	<p style="text-align: right;">Page 149</p> <p>1 definitions as to what full spectrum means, what is                  2 isolate so that consumers are educated and they're not                  3 left in the dark as to what is this, what is this.                  4 When it comes to dosing, this is a very                  5 complicated topic because everybody is different and                  6 every body is different. There's no magical chart                  7 that we can point to that says, oh, a woman aged this                  8 to this that has this condition takes this much CBD.                  9 We don't have that.                  10 We have to educate the public as to how to                  11 titrate themselves and so on and so forth. And a lot                  12 of these things can be addressed I believe through                  13 labeling, through obviously education.                  14 And we need to also have the ability to hold                  15 companies and individuals that are making these false                  16 promises to the public, we need to have a place to go                  17 where we can hold these people accountable, so that we                  18 can raise the flags and so that we aren't having                  19 people come up and saying my -- you know, this                  20 happened to my son or my cousin and they didn't know.                  21 So it really does boil down to consumer                  22 education, labeling as well as opening the doors to a</p>

<p style="text-align: right;">Page 150</p> <p>1 little bit more clarity we are asking from the FDA in  2 regards to --  3 MS. CRISTINZIO: Your time is up.  4 MS. GUESS: -- states that -- yeah, that are  5 a little confused as to what they can and cannot do.  6 MS. CRISTINZIO: Sorry for the interruption.  7 We're running behind.  8 MS. GUESS: That's okay.  9 MS. CRISTINZIO: Thank you. Next we have  10 David Heldreth from -- I'm not even going to try and  11 pronounce it.  12 MR. HELDRETH: I'll handle that for you.  13 Good morning. My name is David Heldreth. I'm the  14 chief -- excuse me, chief science officer for True  15 Terpenes. With a little bit of time, let me get to  16 the heart of the matter.  17 While the majority of this hearing is  18 focusing on things related to CBD, I believe there are  19 other issues that we can address with less  20 controversy. CBG, CBC, CBN, these are cannabinoids  21 which are legalized under the farm bill, but don't  22 require the regulatory hurdles that CBD and THC face</p>	<p style="text-align: right;">Page 152</p> <p>1 our food system.  2 In fact, True Terpenes has our own such  3 system that we deemed True Grade that we would love to  4 provide you information on. As I previously stated,  5 terpenes as an entire class have been demonstrated  6 safe in GRAS panels and are used in innumerable  7 household foods, drinks and other products.  8 Further, there are manufacturing techniques  9 such as steam distillation that are able to  10 selectively pull terpenes while leaving behind things  11 such as cannabinoids that are creating these  12 difficulties.  13 In closing, True Terpenes and myself hope the  14 FDA can see an easy way forward to create more access  15 for safe, sane hemp food products. Please, I  16 recommend you visit our website for more information,  17 trueterpenes.com, and I would love to provide some of  18 this information for you in the future.  19 PANEL MEMBER: Just a quick follow-up  20 question about your comment about selectively I assume  21 concentrating specific terpenes. Any data you have  22 available on the safety of those higher concentration</p>
<p style="text-align: right;">Page 151</p> <p>1 with the drug approvals.  2 Even easier would be things like terpenes and  3 products like hemp leaf foods which will provide low  4 hanging fruit for the FDA to create allowances while  5 avoiding again CBD and other issues.  6 Imagine hemp leaf salads and terpene  7 dressings, hemp and terpene-flavored sodas or your  8 favorite beer with a skunky hemp note. Terpenes are  9 responsible for the taste and aroma of cannabis, in  10 addition to hops, lavender and almost every scented  11 plant on Earth.  12 When these compounds are found in hops or  13 lavender, they're considered generally regarded as  14 safe by the FDA. However, these identical molecules,  15 when sourced from the hemp plant, are not allowed to  16 be used in food, drinks, supplements or even alcohol  17 due to TTB and FDA regulations.  18 True Terpenes is considered the industry  19 expert by those sourcing terpenes from non-cannabis  20 plants and we would relish the opportunity to help the  21 FDA and Congress establish the safety and  22 manufacturing requirements for hemp terpenes to enter</p>	<p style="text-align: right;">Page 153</p> <p>1 of individual terpenes found in hemp would be really  2 useful to have submitted to the docket.  3 MR. HELDRETH: We would love to. And again,  4 most of that data has also been shown safe in GRAS  5 panels. But we would love to provide that for you.  6 MS. CRISTINZIO: Great. Thank you. Our  7 final speaker in this category is Peter Matz, from the  8 Food Marketing Institute.  9 MR. MATZ: Good morning. I'm pleased to be  10 closing out the first batch of comments and I  11 appreciate the opportunity to provide comment today on  12 behalf of the Food Marketing Institute, the trade  13 association for the supermarket industry, including  14 roughly 33,000 grocery stores and 12,000 pharmacies  15 across the country.  16 I am here first and foremost to convey the  17 seriousness of the regulatory ambiguity facing our  18 member companies and their customers each day as  19 consumer demand for products containing hemp and hemp  20 derivatives continue to grow, along with the  21 commercial availability of such products, especially  22 those which count CBD as an ingredient.</p>

<p style="text-align: right;">Page 154</p> <p>1 While most of the stakeholders participating 2 today understand the farm bill did not alter FDA's 3 authority over the use of such ingredients in FDA- 4 regulated products, there is mass confusion in the 5 marketplace for the public, for suppliers and 6 retailers and also for state regulators.</p> <p>7 From ingestible products including foods, 8 beverages and dietary supplements to topical items 9 such as creams and lotions, the demand for CBD 10 products for both human and animal use is already 11 staggering and growing rapidly.</p> <p>12 In fact, just last month, a Consumer Reports 13 survey found that more than a quarter of Americans say 14 that they've tried CBD, while one out of seven of 15 those people said they use it every day.</p> <p>16 Because of the consumer interest in this 17 emerging market and the desire of our members to 18 provide products which their customers are seeking, 19 we're fielding more and more questions from companies 20 that are understandably seeking clarity about the 21 current regulatory framework for the sale and labeling 22 of products containing CBD in particular.</p>	<p style="text-align: right;">Page 156</p> <p>1 ORAL COMMENTS &amp; FORMAL PRESENTATIONS WITH SLIDE DECK 2 STATE/GOVERNMENT OFFICIALS/ENTITIES</p> <p>3 MS. MILES: Good morning. I'm Pam Miles, and 4 I'm the past president of the Association of Food and 5 Drug Officials, AFDO. AFDO has been working toward 6 uniformity in food and drug laws since 1896. AFDO 7 represents federal, state and local food and medical 8 products regulators primarily in the United States. 9 Thank you for the opportunity to present at this 10 public hearing.</p> <p>11 Across the United States, state and local 12 regulators have been confronted with the huge 13 onslaught of CBD in food products and cosmetics being 14 sold in all types of venues, from farmers markets, 15 convenience stores up to some of the largest retailers 16 and we also have standalone CBD stores opening in many 17 states.</p> <p>18 Recently a national quick service restaurant 19 chain served CBD-infused sandwiches as part of a 20 promotion. Currently states are struggling with a 21 lack of sound, scientific research available on CBD 22 and long-term health impacts of ingestion, including</p>
<p style="text-align: right;">Page 155</p> <p>1 And while we want to be in full compliance 2 with all of FDA's requirements, we also want to ensure 3 our members have appropriate assurances that the 4 products they're merchandising are both safe and being 5 sold appropriately.</p> <p>6 Having said that, FMI sees the regulatory 7 challenges surrounding the legal and appropriate sale 8 of hemp and hemp-derived products as a critically 9 important policy issue. And given the prevalence of 10 these products in the marketplace, we respectfully 11 urge FDA to move swiftly to provide additional clarity 12 and establish a pathway forward.</p> <p>13 In conclusion, please know that our industry 14 would welcome the opportunity to be a resource to the 15 agency throughout this regulatory process and we look 16 forward to working with FDA, USDA and Congress as 17 things move forward. Thank you very much.</p> <p>18 MS. CRISTINZIO: Thank you. Now we are 19 moving onto our next panel of speakers that are 20 representatives from state and government officials 21 and entities. Our first speaker is Pam Miles, for two 22 minutes.</p>	<p style="text-align: right;">Page 157</p> <p>1 those to children.</p> <p>2 Nearly all peer-reviewed research has been 3 based on the usage of CBD as a drug. Most 4 manufacturers are approaching CBD as if it is as safe 5 as food ingredients that have had substantial amounts 6 of long-term research.</p> <p>7 Further, new reports across the United States 8 have documented that food products purporting a 9 specific quantity of CBD frequently are not adequate. 10 Further, with the widespread distribution and usage of 11 CBD across the U.S., it's making it very difficult for 12 state and local regulators to continue with our stance 13 that CBD cannot be used in food products.</p> <p>14 AFDO is hopeful that FDA will begin to 15 provide significant leadership as it relates to CBD, 16 including research related to its health impacts. 17 Thank you again for the opportunity to participate 18 today. AFDO looks forward to collaborating with FDA 19 on this important regulatory issue. Thank you.</p> <p>20 PANEL MEMBER: Hi. Also I think AFDO is in 21 sort of a unique position with state governments. And 22 I'm wondering if there's -- if you're aware or have</p>



<p style="text-align: right;">Page 158</p> <p>1 submitted to the document any systematic collection of  2 adverse events associated with cannabis products or  3 CBD products specifically.  4 MS. MILES: We do not have that right now. I  5 believe we did do a national survey with all of our  6 states and we're collecting the information that we  7 are going to be making comments, written comments.  8 PANEL MEMBER: Any idea of when that might be  9 finished or available?  10 MS. MILES: It is finished.  11 PANEL MEMBER: Oh, it is finished?  12 MS. MILES: I'm not sure. And I don't know  13 if Brenda has -- Brenda's going to speak next. I  14 don't know how many states have replied.  15 PANEL MEMBER: Okay.  16 MS. MILES: And we've been reaching out. But  17 we have quite a few replies. And we're actually  18 putting together that information right now.  19 PANEL MEMBER: Okay.  20 MS. MILES: And our executive director will  21 be sending written comments.  22 PANEL MEMBER: All right. Thanks, Pam.</p>	<p style="text-align: right;">Page 160</p> <p>1 For states that are not allowing CBD, most  2 all acknowledge they have insufficient resources to  3 effectively end the sales of CBD in food and cosmetics  4 in their state. Of the 20 responding states where CBD  5 sales is not legal, only eight states were considering  6 any sort of enforcement action on those with clear  7 health claims and even when there are clear health  8 claims, many states are not taking any action.  9 Many of the states noted they are struggling  10 with the appropriate approach given the lack of  11 federal participation in this process.  12 FDA began hosting 50 state meetings in 1998  13 and two key statements that were made by FDA at those  14 early meetings were the vision for the future is an  15 integrated food safety that focuses on preventing harm  16 before it happens and food safety reform at the  17 federal level will be incomplete and insufficient  18 unless it strengthens state and local roles and builds  19 true partnerships across all levels of government.  20 With the legislation of hemp as part of the  21 farm bill, most every state legislature in this  22 country considered and many will enact some type of</p>
<p style="text-align: right;">Page 159</p> <p>1 MS. MILES: Thank you.  2 MS. CRISTINZIO: Thank you. Next up is  3 Brenda Morris.  4 MS. MORRIS: Thank you. I'm Brenda Morris,  5 and I'm president-elect and representing the  6 Association of Food and Drug Officials. Currently a  7 patchwork of laws exist for CBD across the nation,  8 with very little consistency or uniformity in  9 regulations, which is creating a Wild West type  10 atmosphere where nothing -- anything is allowed.  11 CBD products in foods and cosmetics are being  12 shipped in interstate commerce and this is clearly  13 within FDA's regulatory authority. As of last week in  14 a survey that AFDO has conducted in which we had 33  15 responses, 13 of the states that responded have legal  16 CBD sales.  17 Over half are using 21 CFR 117 as their  18 primary regulatory authority with a portion of those  19 also applying parts of the dietary supplement  20 regulations. The remainder states are using the  21 retail food code and a few relying on GMPs under  22 either 110 or 117.</p>	<p style="text-align: right;">Page 161</p> <p>1 state hemp growing bill in 2019, increasing CBD  2 production. AFDO looks forward to collaborating with  3 FDA on this very important regulatory issue. Thank  4 you so much for allowing us to speak.  5 PANEL MEMBER: And the results of that survey  6 of the states you'll be putting on the docket?  7 MS. MORRIS: Yes, we will.  8 PANEL MEMBER: Thanks so much.  9 MS. CRISTINZIO: Great. Thank you. Next, we  10 have Joseph Reardon, speaker number 53.  11 MR. REARDON: Thank you very much for the  12 opportunity to be here today. Again, my name is Joe  13 Reardon. I serve as the assistant commissioner for  14 consumer protection at the North Carolina Department  15 of Agriculture and Consumer Services. I want to thank  16 FDA today for this opportunity to bring these comments  17 forward.  18 North Carolina, like many other states, has a  19 rapidly growing industrial hemp industry. As of this  20 year, we have over 1,000 growers licensed in the state  21 of North Carolina, 12,000 acres of product that is  22 being grown and 4.9 million square feet that's being</p>

<p style="text-align: right;">Page 162</p> <p>1 grown in greenhouses. We have 601 registered  2 processors just in the state of North Carolina alone.  3 The farmers in North Carolina have invested  4 over a hundred million dollars in this current crop.  5 We know that CBD is being sold across the nation in  6 dietary supplements in food and drink and there's no  7 regulatory framework for that to be done.  8 Due to the availability of these products in  9 the marketplace, we've done some survey work to better  10 understand the availability of these products in the  11 marketplace. We've also sent letters out to our  12 industry in our state informing them of the  13 information that Dr. Gottlieb provided last year and  14 earlier this year of FDA's position on these products.  15 We have done some market survey to understand  16 the prevalence of these products in the marketplace to  17 give us a more informed position here.  18 And in doing so and better understanding the  19 prevalence of these products in North Carolina and the  20 future production of those products, North Carolina  21 will be seeking and will now ask our state legislature  22 to give us the authority to have a regulation in place</p>	<p style="text-align: right;">Page 164</p> <p>1 products to enter the marketplace. I want to thank  2 you for the opportunity today to provide these  3 comments.  4 We are hearing from some states that they  5 would like to extend the written comment period from  6 July to August. We think with the amount of people  7 here today and the interest in this, you want to get  8 all the feedback you can. So it may be in the FDA's  9 interest to extend that written comment period. Thank  10 you very much.  11 PANEL MEMBER: I have a question about your  12 market survey.  13 MR. REARDON: Yes.  14 PANEL MEMBER: I know it's a big agricultural  15 crop, particularly in your state. But when you did  16 the market survey, do you have a sense of the  17 synthetic market as well? There's a lot of synthetic  18 CBD products out there as well.  19 MR. REARDON: We didn't look at that in our  20 survey. We looked at the prevalence of it being sold  21 in foods, what types of foods. Are they the  22 traditional gummies that are being marketed to</p>
<p style="text-align: right;">Page 163</p> <p>1 for the production of these products.  2 We will use the FDA's 21 CFR 111 as the  3 foundation of writing those regulations. We believe  4 with the support of our industry there and the input  5 of our industry, we will be able to put a regulatory  6 framework in place for the production of those  7 products to ensure the suitability of those products  8 going into the marketplace.  9 We believe a uniform and consistent approach  10 is critical to consumer safety and long-term viability  11 of this emerging industry. Consumers and industry  12 alike benefit from a regulatory framework we believe  13 to ensure the identity, the purity, the strength and  14 the composition of those products.  15 The one thing I do want to say though, to be  16 clear, without the FDA's guidance and leadership,  17 individual states may carve out their own regulatory  18 exceptions for CBD, creating a patchwork approach  19 which will hinder the nationwide growth of this  20 industry and endanger consumers.  21 We urge FDA to resolve the statutory issues  22 and properly establish a legal pathway for CBD</p>	<p style="text-align: right;">Page 165</p> <p>1 children? We wanted to understand the prevalence of  2 health claims on those products as well, understand  3 the prevalence of smokables, which is wide in the  4 market today.  5 So we really wanted to understand what was in  6 the marketplace, what the compliance level was on that  7 and what information they need from the federal  8 government or others to better understand what the  9 legal framework is.  10 PANEL MEMBER: Yeah. That would be great to  11 see that data if you could submit that to the docket.  12 That would be great.  13 My other question is when you're  14 contemplating a regulatory scheme at the state level,  15 are you thinking about restrictions on retail, age  16 limitations or labeling or other types of  17 restrictions?  18 MR. REARDON: We're not. We're simply  19 looking for a regulatory framework on the extraction,  20 production and reconstitution of CBD or cannabinoid-  21 related compounds, including terpenes and other  22 constituents that may be in the hemp plant.</p>

<p style="text-align: right;">Page 166</p> <p>1 We are really, like other states, looking for 2 that guidance, and the industry in our state is as 3 well from FDA to show that we have a uniform and 4 consistent platform. What we're hearing from our 5 industry, and you've heard it today, is they want a 6 legal pathway to bring these products to market. So 7 we look forward to partnering with you. Thank you.</p> <p>8 MS. CRISTINZIO: Thank you. Our next speaker 9 is William Tilburg, number 54. William? William's 10 not here? All right. I'm going to welcome to the 11 podium Erin Bubb, number 55, from the Pennsylvania 12 Department of Agriculture. Erin is our first speaker 13 to present for five minutes with slides.</p> <p>14 MS. BUBB: Good morning, and thank you. I'm 15 here today to represent the Association of American 16 Feed Control Officials, known as AFCO.</p> <p>17 AFCO is a voluntary membership organization 18 of the states and federal government agencies, as well 19 as government agencies from other countries, 20 responsible for the execution of laws and regulations 21 pertaining to the production, labeling, distribution 22 and sale of animal feed and feed ingredients.</p>	<p style="text-align: right;">Page 168</p> <p>1 ingredient has a standard of identity and has been 2 evaluated for safety and efficacy for its intended 3 use.</p> <p>4 This route has served regulatory officials, 5 the regulated industry and the public well by 6 providing consistency to the animal feed ingredient 7 approval process.</p> <p>8 AFCO's and CVM's primary concern is the 9 safety of the ingredient. AFCO awaits the industry's 10 scientific evaluation of the safety of hemp-derived 11 products in order to bring these ingredients legally 12 into the market.</p> <p>13 The AFCO process does take time. If 14 additional resources could be allocated to CVM to more 15 quickly complete their technical review, the entire 16 process could be completed sooner.</p> <p>17 Hemp seed oil, hemp seed meal or seed cake 18 and whole hemp seeds are products expected to be 19 reviewed by AFCO and CVM for use in animal feed when 20 industry completes the safety studies. Materials and 21 products that are CBD or phytocannabinoid-infused need 22 to be treated as drugs and kept separate from other</p>
<p style="text-align: right;">Page 167</p> <p>1 Many states' laws or regulations reference 2 the official terms and definitions of the AFCO 3 official publication. This is the most comprehensive 4 list of approved feed ingredients. There are three 5 ways for an ingredient to make its way into the 6 publication: through a food additive petition, a 7 definition request to AFCO or a generally recognized 8 as safe, also known as GRAS, voluntary notification to 9 FDA.</p> <p>10 All three routes include a safety and utility 11 review done by FDA's Center for Veterinary Medicine. 12 All three routes result in the ingredient being 13 published in the AFCO official publication and 14 accepted by the states as ingredients in animal feed 15 and pet food products.</p> <p>16 Let's see. I'm not advancing. But I'm going 17 to continue. Okay. AFCO and FDA have a longstanding 18 MOU that allows FDA to accept animal feed ingredients 19 that have come through the AFCO ingredient definition 20 process.</p> <p>21 During this process, CVM reviews the 22 ingredient submission packet to ensure the new</p>	<p style="text-align: right;">Page 169</p> <p>1 hemp products used in animal feed or pet food as there 2 is currently no nutritional basis for these compounds 3 to be allowed in animal feed or pet food.</p> <p>4 AFCO is ready to participate in getting hemp 5 products into the animal feed market as nutritional 6 sources. We are waiting on the industry to complete 7 the safety studies.</p> <p>8 Lastly, I also respectfully request a 30-day 9 extension for written comments to August 1st. Ah, 10 there's my last slide. If there are any questions, 11 folks are welcome to visit the afco.org website, 12 generalinquiries@afco.org and those that are 13 interested in ingredient definitions and providing a 14 submission through AFCO can use the general email of 15 definitions@afco.org. Thank you.</p> <p>16 PANEL MEMBER: A quick question. When you do 17 your evaluation of feed ingredients, do you consider 18 residues that might be left in the tissues of food- 19 producing animals?</p> <p>20 MS. BUBB: That is absolutely one of the 21 evaluations that would be conducted. And that is the 22 information that is needed in a submission,</p>

<p style="text-align: right;">Page 170</p> <p>1 absolutely.</p> <p>2 PANEL MEMBER: Can you characterize for me</p> <p>3 what you see on the state level in the use of these</p> <p>4 products in animals?</p> <p>5 MS. BUBB: Currently states are not</p> <p>6 recognizing the legality of hemp-derived products in</p> <p>7 animal feed. What we are seeing personally, in</p> <p>8 Pennsylvania, we are seeing CBD-infused products, pet</p> <p>9 treats especially. And we are issuing regulatory</p> <p>10 actions on such products in the marketplace. We are</p> <p>11 issuing stop sale orders, withdrawal from marketplace.</p> <p>12 We do have a burgeoning, growing hemp</p> <p>13 industry in Pennsylvania. We want to see it succeed.</p> <p>14 They're very, very interested in hemp-derived products</p> <p>15 for the use in animal feed.</p> <p>16 And we are educating them and supporting them</p> <p>17 in their efforts for study and research so that hemp-</p> <p>18 derived products such as hemp seed oil, hemp seed</p> <p>19 cake, meal could be used for nutritional purposes in</p> <p>20 animal feed. Okay.</p> <p>21 PANEL MEMBER: To what extent are you seeing</p> <p>22 the use of CBD in the feed of food-producing animals?</p>	<p style="text-align: right;">Page 172</p> <p>1 fiber ingredient yet in animal feed. I do know that</p> <p>2 again there's been some limited research. I know Penn</p> <p>3 State and University of Pennsylvania have been</p> <p>4 involved in some limited studies. They've talked</p> <p>5 about them on some different podcasts and some</p> <p>6 different outlets. There's been, you know, not a lot</p> <p>7 of information released yet.</p> <p>8 PANEL MEMBER: Right. But not sort of</p> <p>9 widespread usage of those parts of the plants that</p> <p>10 might be used for other areas?</p> <p>11 MS. BUBB: No. I am not familiar with that</p> <p>12 at all, no.</p> <p>13 PANEL MEMBER: Okay. Thank you.</p> <p>14 MS. BUBB: Okay.</p> <p>15 MS. CRISTINZIO: Great. Thank you, Erin.</p> <p>16 And sorry for the technical difficulties. We have now</p> <p>17 a break on the schedule and we are still going to take</p> <p>18 the break, even though we are running a little bit</p> <p>19 behind because I know everyone could use a little</p> <p>20 stretch. We will begin again at 10:45. Thank you.</p> <p>21 (Whereupon, the foregoing went off the</p> <p>22 record.)</p>
<p style="text-align: right;">Page 171</p> <p>1 MS. BUBB: Could you repeat that?</p> <p>2 PANEL MEMBER: To what extent are you seeing</p> <p>3 CBD in the feed of food-producing animals?</p> <p>4 MS. BUBB: We have not seen anything like</p> <p>5 that yet. We do look for that type of product in the</p> <p>6 marketplace through inspections. We have not come</p> <p>7 upon that yet. The CBD-infused products are mainly</p> <p>8 being found -- wholly being found in pet treats and</p> <p>9 more of the treat/supplement world, maybe even for</p> <p>10 horses.</p> <p>11 But right now, food production animals, they</p> <p>12 have not really crossed that line to put CBD into</p> <p>13 those food-producing animals at this time, although</p> <p>14 there's talk about it. There's interest. They would</p> <p>15 like to do it.</p> <p>16 PANEL MEMBER: Okay, and one other question</p> <p>17 sort of on that regard. Are you seeing -- because we</p> <p>18 have heard and seen news stories about this, sort of</p> <p>19 the stalks of cannabis and hemp plants being used for</p> <p>20 animal feed like other grains are being used.</p> <p>21 MS. BUBB: Okay. Have not seen anything like</p> <p>22 stalks, leaves or anything like that as forage or as a</p>	<p style="text-align: right;">Page 173</p> <p>1 MS. CRISTINZIO: Please sit down. We're</p> <p>2 about to begin. We have someone joining us via phone</p> <p>3 for a two-minute presentation. Thank you, everyone.</p> <p>4 Hopefully you had a nice break. We have one person</p> <p>5 who has joined us via phone for an oral comment. She</p> <p>6 is a consumer. Her name is Pamela McColl and she is</p> <p>7 on the line. Pamela, you are up for two minutes.</p> <p>8 MS. MCCOLL: Hi. Thank you. Good morning,</p> <p>9 everyone. I am a social historian and I've been</p> <p>10 active on the marijuana file in Canada for over seven</p> <p>11 years and I have the following to say.</p> <p>12 The public is up against a narrative that is</p> <p>13 at war with science. The marijuana lobby deceives by</p> <p>14 saying consuming has no lasting negative impacts.</p> <p>15 They deceive by denying cannabis hyperemesis syndrome</p> <p>16 and addiction. The DSM-5 establishes clearly</p> <p>17 marijuana is highly addictive.</p> <p>18 Every week, patients on MJ enter the Denver</p> <p>19 Health Center ER and must be restrained so as not to</p> <p>20 harm themselves or others. In casual users, THC can</p> <p>21 disrupt working memory and focus for 24 hours, says</p> <p>22 Harvard researchers. The true believers of</p>

<p style="text-align: right;">Page 174</p> <p>1 cannabinoids, there can be placebo effect.</p> <p>2 But it is critical that all be informed with</p> <p>3 the risk associated with CBD and THC. This includes</p> <p>4 pregnant women and the risks to the fetus, including</p> <p>5 developmental damage and DNA damage.</p> <p>6 In 20 years of research on human cells, I</p> <p>7 have never found any other drug, including heroin,</p> <p>8 which comes close to the DNA damage caused by</p> <p>9 marijuana, Dr. Hugh Davis, at Health Canada. Even</p> <p>10 minuscule amounts of THC are not safe for human</p> <p>11 consumption.</p> <p>12 Health Canada warns men not to use MJ if they</p> <p>13 wish to have children. MJ products put young adult</p> <p>14 males at risk of the most aggressive type of</p> <p>15 testicular cancer. The FDA must respond to the</p> <p>16 malevolent billionaire's marijuana experiment that has</p> <p>17 medical professionals and states in extreme anxiety</p> <p>18 over the damage industry profiteering has inflicted on</p> <p>19 the public.</p> <p>20 For Epidiolex, the only FDA-approved CBD</p> <p>21 product approved for Dravet's and LGS, package</p> <p>22 warnings include suicidal ideation, driving impairment</p>	<p style="text-align: right;">Page 176</p> <p>1 of the billionaires and the industry that have</p> <p>2 influenced public sentiment and dictated a very</p> <p>3 deceitful campaign. So with that, I conclude. I</p> <p>4 applaud the FDA for looking into this and I beg them</p> <p>5 to not reclassify THC or CBD. Thank you very much.</p> <p>6 MS. CRISTINZIO: Thank you, Pamela. All</p> <p>7 right. I want to make just one brief announcement. I</p> <p>8 think we have a number of people waiting for seats in</p> <p>9 overflow. And I believe that we have enough space to</p> <p>10 pull them into the room.</p> <p>11 I just want to make people aware, if you have</p> <p>12 a bag on a seat or you're saving a seat, that we would</p> <p>13 like everyone have a seat in the room. Thank you.</p> <p>14 All right. Our next speaker represents</p> <p>15 academia. We're moving onto the formal presentations</p> <p>16 with slide deck part of the day. And we have Barry</p> <p>17 Gidal.</p> <p>18 FORMAL PRESENTATIONS WITH SLIDE DECK</p> <p>19 ACADEMIA</p> <p>20 DR. GIDAL: Good morning. Barry Gidal,</p> <p>21 University of Wisconsin School of Pharmacy. My theme</p> <p>22 today is to discuss potential unintended consequences</p>
<p style="text-align: right;">Page 175</p> <p>1 and hepatocellular injury, requiring liver function</p> <p>2 testing before starting. Are there such warnings for</p> <p>3 CBD products being sold at Walgreen's today? Are</p> <p>4 consumers buying Whoopi Goldberg and Maya's CBD THC</p> <p>5 rubs informed of these risks?</p> <p>6 With 3,000 marijuana studies and high potency</p> <p>7 product research enter biomedical literature,</p> <p>8 reclassification is but an attempt to access the U.S.</p> <p>9 banks. We changed the conversation. Now we've</p> <p>10 changed the laws, boast the lobbyists. The FDA must</p> <p>11 take back this conversation and protect the public.</p> <p>12 I would encourage you to call Dr. Hugh Davis</p> <p>13 from Health Canada, who in the late 1990s did a risk</p> <p>14 assessment of THC and found that even minuscule</p> <p>15 amounts were not safe. He was fired. That science</p> <p>16 was shredded. And the Canadian government lied to the</p> <p>17 United States government in saying that they had no</p> <p>18 risk assessment on this drug.</p> <p>19 The subversion of truth and science and</p> <p>20 what's gone on in North America should cause everyone</p> <p>21 great concern and reason to pause and do risk</p> <p>22 assessments on these drugs and analyze the influence</p>	<p style="text-align: right;">Page 177</p> <p>1 that may arise from our gaps in our knowledge base.</p> <p>2 Now, as has been alluded to by other speakers</p> <p>3 this morning, CBD is a complicated molecule. It has a</p> <p>4 complicated biotransformation pathway, as you can see</p> <p>5 from my slide, being metabolized by a variety of</p> <p>6 cytochrome p450 enzymes to at least one active</p> <p>7 metabolite, at least active in a seizure model.</p> <p>8 CBD also has a complicated pharmacokinetic</p> <p>9 profile. We've talked about dosing and the</p> <p>10 variability of dosing this morning. CBD exposure can</p> <p>11 vary by route of administration, whether or not this</p> <p>12 drug is taken with food or on an empty stomach and may</p> <p>13 vary by other patient-specific variables such as liver</p> <p>14 function.</p> <p>15 Now, one of the things that I want to talk</p> <p>16 about some knowns and unknowns. And I first need to</p> <p>17 emphasize that we've known for a while, looking at the</p> <p>18 scientific and the metabolic literature, the enzyme</p> <p>19 literature for a while, that CBD as well as some other</p> <p>20 cannabinoids such as THC have the potential to cause</p> <p>21 drug interactions, specifically enzyme inhibition of a</p> <p>22 variety of different important drug-metabolizing</p>

<p style="text-align: right;">Page 178</p> <p>1 enzymes.</p> <p>2 But I want to emphasize it really wasn't</p> <p>3 until the Epidiolex clinical development, the FDA-</p> <p>4 approved preclinical and clinical development program</p> <p>5 that we began to really appreciate and understand the</p> <p>6 clinical ramifications of these potential drug</p> <p>7 interactions.</p> <p>8 Now, we know again, if you harken back to my</p> <p>9 previous slide, because of the metabolism of CBD,</p> <p>10 there may be impacts of other enzyme-inducing drugs</p> <p>11 that may alter the exposure of this drug. We simply</p> <p>12 don't know enough yet.</p> <p>13 And there's more importantly perhaps the</p> <p>14 effect of CBD on other drugs that may be used that</p> <p>15 maybe go beyond the anti-seizure drugs that have been</p> <p>16 studied so far and that's what I hope to emphasize</p> <p>17 today.</p> <p>18 Now, let me talk about some knowns that came</p> <p>19 out of the Epidiolex clinical development program. We</p> <p>20 know that an important drug, clobazam, which is used</p> <p>21 in epilepsy, part of its metabolism can be inhibited</p> <p>22 by CBD. Clobazam is active. It's metabolized by</p>	<p style="text-align: right;">Page 180</p> <p>1 metabolized by P450 2C9.</p> <p>2 Why is this important? Data that came out of</p> <p>3 the University of Alabama group recently showed again,</p> <p>4 as we broadened our use of CBD, in a patient receiving</p> <p>5 warfarin, which is a very narrow therapeutic index</p> <p>6 drug, in fact the anticoagulation potential of this</p> <p>7 drug as measured by INR went up dramatically when CBD</p> <p>8 was added. Now, this could have serious health</p> <p>9 implications.</p> <p>10 Now, one of the other things, I want to get</p> <p>11 back to what I mentioned about clobazam. Clobazam is</p> <p>12 metabolized by an enzyme called cytochrome P450 3A4.</p> <p>13 We know from the clinical development program of</p> <p>14 Epidiolex that there was no interaction with clobazam.</p> <p>15 We also know from published literature that</p> <p>16 there is no inhibition of metabolism of a probe drug</p> <p>17 for at least one isoform of P450 for midazolam.</p> <p>18 However, a report that just came out in the clinical</p> <p>19 literature from Rita Alloway and colleagues at</p> <p>20 University of Cincinnati looking at tacrolimus, which</p> <p>21 is an important and potentially toxic</p> <p>22 immunosuppressive drugs. It's used in a variety of</p>
<p style="text-align: right;">Page 179</p> <p>1 cytochrome P450 3A4.</p> <p>2 Interestingly enough, clobazam levels don't</p> <p>3 really change. I'll get back to why I think that's</p> <p>4 important in a few moments. But the active</p> <p>5 metabolite, the N-desmethyloclobazame levels, have been</p> <p>6 shown quite consistently to go up. And this may in</p> <p>7 fact be responsible for some of the adverse effects</p> <p>8 that we see such as sedation in the clinical trial</p> <p>9 program.</p> <p>10 Now, let me talk about some other things that</p> <p>11 maybe are less well recognized. This graph may be a</p> <p>12 little bit difficult to read. This is some work from</p> <p>13 a few years ago of looking at the effect of not just</p> <p>14 CBD but also THC and other drug-metabolizing enzyme</p> <p>15 systems such as cytochrome P450 2C9.</p> <p>16 Now why am I telling you? Why is this</p> <p>17 important? Let's go beyond the anti-seizure</p> <p>18 development program or anti-seizure co-medication. I</p> <p>19 think many in this room are familiar with the drug</p> <p>20 warfarin. Warfarin also has a complicated</p> <p>21 pharmacokinetic profile. The more active enantiomer</p> <p>22 of warfarin, the s-warfarin, is extensively</p>	<p style="text-align: right;">Page 181</p> <p>1 regimens, including transplantation.</p> <p>2 In fact, if you look at this data, a patient</p> <p>3 had been stabilized on tacrolimus, was part of also</p> <p>4 this CBD, the Epidiolex program. And within the label</p> <p>5 doses of Epidiolex, had a dramatic increase in the</p> <p>6 plasma levels of tacrolimus, necessitating drug</p> <p>7 reduction.</p> <p>8 So again, why is this important? There's a</p> <p>9 lot of things we know. There's a lot of things we</p> <p>10 don't know. There is the potential for multiple drug</p> <p>11 interactions from CBD. The exposure-concentration</p> <p>12 relationship is still unclear. And in fact, some</p> <p>13 patients may be at risk if we don't have adequate</p> <p>14 oversight and involvement of healthcare practitioners</p> <p>15 when using this drug. Thank you.</p> <p>16 MS. CRISTINZIO: Thank you. Our next speaker</p> <p>17 is number 58, Igor Grant.</p> <p>18 DR. GRANT: Thank you very much.</p> <p>19 MS. CRISTINZIO: Give us one second to pull</p> <p>20 up your presentation.</p> <p>21 DR. GRANT: Sorry about that. I didn't hear</p> <p>22 what was just said. Okay. My name is Igor Grant.</p>

<p style="text-align: right;">Page 182</p> <p>1 Thank you very much for allowing me to speak. I'm  2 professor of psychiatry and director of the Center for  3 Medicinal Cannabis Research at the University of  4 California. That center was established about 20  5 years ago by the legislature of the state of  6 California as perhaps the first of the national  7 centers to actually address medicinal cannabis per se.  8 There are a couple of points I would like to  9 make today beyond the fact that there is emerging  10 science suggesting that THC, CBD and potentially other  11 cannabinoids may have medicinal value.  12 We have some challenges facing us, including  13 research that is limited by the availability of the  14 increasing number of products that patients are  15 consuming in states where cannabis or medicinal  16 cannabis laws exist.  17 We also have some viscosity, shall I say, or  18 I use the term barriers. It's not really barriers.  19 Nobody's trying to prevent research obviously. But  20 there is a kind of slowness in the process of doing  21 research that perhaps could be improved. And that  22 includes the fact that many federal agencies need to</p>	<p style="text-align: right;">Page 184</p> <p>1 administration, in particular because these do  2 influence how patients are able to tolerate these  3 drugs. The other is expanding to the range of  4 conditions and the third is to focus much more on  5 cannabidiol, which is a focus of this meeting.  6 We know that the route of administration  7 matters. People have seen these curves before. I  8 won't dwell on them.  9 One thing that was very interesting in some  10 of our early studies with the THC-based products from  11 NIDA is that actually rather small doses of THC seem  12 to produce benefit in neuropathic pain.  13 And these were doses that were much, much  14 less than people would typically consume if they  15 wanted to get a high. So this idea of the therapeutic  16 window needs to be explored further, and that may bear  17 also on safety considerations such as for driving.  18 So I'd like to spend the last minute on just  19 suggesting some paths forward to consider. One of  20 course is that we obviously need more studies and  21 including, as I've mentioned, routes of  22 administration, different kinds of products people are</p>
<p style="text-align: right;">Page 183</p> <p>1 opine and regulate this research.  2 This is consequential because, in our view,  3 we are rapidly getting behind the curve in terms of  4 what is happening in the real world and what patients  5 are utilizing. And we need to take steps to catch up  6 and to provide the public with correct scientific  7 information, including positives and negatives.  8 Now, as far as the CMCR center, we early on  9 completed a number of studies, mostly focused on  10 neuropathic pain and these used the NIDA's THC-based  11 products. These all showed in the short term, in  12 limited studies, positive results and these findings  13 have been also confirmed many times by other  14 investigators and by the National Academies report. I  15 don't have to go through that again.  16 Just by way of summary as far as THC-based  17 products and neuropathic pain, the efficacy seems to  18 be comparable to other used drugs and the toxicities  19 certainly are no worse.  20 Currently the CMCR is moving in new  21 directions and these include, first of all, in the  22 case of THC-based products, to look at modes of</p>	<p style="text-align: right;">Page 185</p> <p>1 using, products to put on their skin and so forth. We  2 have no idea if these products are absorbed or are  3 affected by those routes.  4 I said before we need to get ahead of the  5 curve of what's going on in the public. Otherwise,  6 the public will continue to use these products without  7 appropriate information. But we need to get the  8 information out in a more nimble fashion.  9 So what does that nimbleness suggest?  10 Perhaps permit research exemptions such as envisioned  11 in the Schatz-Feinstein bill, not requiring detailed  12 pharmacology for all new cultivars if DEA approves  13 manufacturing and if the FDA still requires all these  14 toxicology studies, we'll be in a problematic area.  15 And I've listed some of the other factors that I think  16 should be considered. Thank you very much for your  17 attention.  18 PANEL MEMBER: I have a question. I saw that  19 you had -- you talked about how routes of  20 administration matter and you talked about inhaled  21 versus edible. And I wondered if there was any data  22 on sort of absorption through the skin as would be</p>

<p style="text-align: right;">Page 186</p> <p>1 received through a cosmetic.</p> <p>2 DR. GRANT: I am not aware of it. Maybe</p> <p>3 there are data out there. But that's exactly the</p> <p>4 point I was trying to make, that we need to look at</p> <p>5 these modes of administration.</p> <p>6 People claim that, you know, putting some</p> <p>7 kind of salve on your elbow helps with arthritis.</p> <p>8 Maybe it does. Maybe it doesn't. But we just don't</p> <p>9 know. An that's the kind of study that needs to be</p> <p>10 done.</p> <p>11 PANEL MEMBER: And in addition to differences</p> <p>12 in efficacy with different routes of administration,</p> <p>13 have you found any differences in safety?</p> <p>14 DR. GRANT: No, because we are now doing an</p> <p>15 actual comparison of an oral product, which is</p> <p>16 dronabinol, to a NIDA THC product. So we'll know more</p> <p>17 about that.</p> <p>18 What we know from the literature of course</p> <p>19 is, because of the different pharmacokinetics, the</p> <p>20 onset of action is much delayed through oral</p> <p>21 administration and so forth. But in terms of long-</p> <p>22 term tolerability, I don't know that we have data on</p>	<p style="text-align: right;">Page 188</p> <p>1 right. Very good.</p> <p>2 All right. Again, thank you for the</p> <p>3 opportunity to speak. My name is Bill Gurley. I'm a</p> <p>4 professor of pharmaceutical sciences at the University</p> <p>5 of Arkansas for Medical Sciences College of Pharmacy</p> <p>6 and I'm also a principal scientist at the National</p> <p>7 Center for Natural Products Research. I've also been</p> <p>8 doing research in botanical dietary supplements for</p> <p>9 the past 23 years.</p> <p>10 My talk this morning is entitled "Content v.</p> <p>11 Label Claim: A Survey of CBD Content in Commercially</p> <p>12 Available Products from the State of Mississippi."</p> <p>13 And in short, this study provides a snapshot of CBD</p> <p>14 product quality or lack thereof and is likely</p> <p>15 representative of the fraudulent nature of many, if</p> <p>16 not most CBD products currently sold in the U.S.</p> <p>17 market. I'll skip that slide.</p> <p>18 Now, for conventional medications regulated</p> <p>19 by the FDA, product labels must accurately reflect the</p> <p>20 content of active ingredients within a container. For</p> <p>21 dietary supplements however, especially botanical</p> <p>22 dietary supplements regulated by the FDA under the</p>
<p style="text-align: right;">Page 187</p> <p>1 that.</p> <p>2 PANEL MEMBER: Has your program found value</p> <p>3 in looking at real-world datasets to support some of</p> <p>4 your questions? So electronic health records, claims</p> <p>5 data, any other aspects?</p> <p>6 DR. GRANT: We are in fact moving in that</p> <p>7 direction and particularly wanting to work with</p> <p>8 institutions within California itself to do that. But</p> <p>9 as of yet, we have not don't that.</p> <p>10 MS. CRISTINZIO: Great. Thank you so much.</p> <p>11 DR. GRANT: Thank you.</p> <p>12 MS. CRISTINZIO: continuing in the academia</p> <p>13 category, we have number 59, Bill Gurley.</p> <p>14 DR. GURLEY: Thank you very much for the</p> <p>15 opportunity to speak this morning at this public</p> <p>16 hearing.</p> <p>17 MS. CRISTINZIO: Can you move the microphone</p> <p>18 up a little?</p> <p>19 DR. GURLEY: Yeah, that's a -- us tall guys</p> <p>20 have a tough time with this. That's about it. Sorry.</p> <p>21 I'm taking up all my time playing around with the damn</p> <p>22 microphone. All right. So can you hear me now? All</p>	<p style="text-align: right;">Page 189</p> <p>1 dietary supplement Health and Education Act, it's not</p> <p>2 uncommon for a product's contents to differ markedly</p> <p>3 from its label claim.</p> <p>4 Content versus label claim discrepancies are</p> <p>5 especially prevalent for dietary supplements marketed</p> <p>6 for weight loss, exercise performance enhancement and</p> <p>7 sexual performance enhancement. And so, the question</p> <p>8 is are CBD-containing products also subject to</p> <p>9 significant discrepancies between actual content and</p> <p>10 label claim.</p> <p>11 All right. So a survey of CBD-containing</p> <p>12 products was conducted by investigators in the</p> <p>13 National Center for Natural Product Research to</p> <p>14 compare CBD as well as THC content to label claims for</p> <p>15 CBD. And there's 25 various CBD-containing products</p> <p>16 that were purchased from retailer vendors in the state</p> <p>17 of Mississippi and submitted for analysis by law</p> <p>18 enforcement officials from the Mississippi Bureau of</p> <p>19 Narcotics.</p> <p>20 Product label claims ranged from either no</p> <p>21 label claim to as much as 1,500 mg per container. And</p> <p>22 products were analyzed by gas chromatography with</p>



<p style="text-align: right;">Page 190</p> <p>1 flame ionization detection as well as mass  2 spectrometry for both CBD and THC content as well as  3 the presence of synthetic cannabinoids.  4       Now the data from the first 13 products  5 represented in this table and the second column is the  6 product label for CBD. Column three is the quantity  7 of CBD detected within the product. The fourth column  8 is the percent label claim. The fifth column  9 indicates those products whose THC content exceeded  10 0.3 percent and the last column indicates products  11 containing synthetic cannabinoids.  12       Now, in most instances, product label claims  13 misrepresented the actual CBD content within the  14 product. Percent label claims ranged from  15 indeterminate values -- in other words, there was no  16 claim for CBD -- to products that contained very  17 little CBD to others that far exceeded the label  18 claim.  19       In one instance, the CBD content was almost  20 23 times greater than the quantity claimed on the  21 label. In three instances, THC content exceeded 0.3  22 percent, with one product containing 45 percent THC.</p>	<p style="text-align: right;">Page 192</p> <p>1 have little or no relation to any potential benefits  2 of CBD itself and pose a range of risks to consumers  3 from both fraud to serious health dangers.  4       The public demand and potential abuses in  5 this unique market sector warrant special attention to  6 regulation of such products in terms of label claim  7 restrictions, good manufacturing practice enforcement  8 and monitoring for potential adulterants. Thank you.  9       MS. CRISTINZIO: Thank you. Our next speaker  10 is number 60, Rick Kingston.  11       DR. KINGSTON: Good morning. My name is Rick  12 Kingston, and I'm a clinical professor of pharmacy at  13 the University of Minnesota, an adjunct professor at  14 the University of Mississippi in the National Center  15 for Natural Product Research and lastly I'm president,  16 regulatory and scientific affairs at SafetyCall  17 International. My comments today will dovetail  18 comments made by my colleagues, Dr. Gurley, Koturbash  19 and Walker at the University of Mississippi.  20       At SafetyCall, we have the distinction of  21 being the only academically affiliated,  22 multidisciplinary healthcare practice providing third</p>
<p style="text-align: right;">Page 191</p> <p>1 An even more disconcerting finding was the fact that  2 one product was adulterated with synthetic  3 cannabinoid.  4       The second table depicts results from the  5 next 12 products. Once again, percent label claims  6 ranged from indeterminate values to values that were  7 either far below label claim or, thankfully, in one  8 case, exactly matched the label claim. In four  9 instances -- in four instances, little to no CBD was  10 detected. Yet three of these products, all of which  11 were vaping oils, were adulterated with synthetic  12 cannabinoids.  13       So in summary, a small sampling of CBD  14 products acquired from retailers in the state of  15 Mississippi demonstrated marked variability in actual  16 CBD content versus product label claims. Several  17 products had no CBD while others contained  18 significantly more than label claims.  19       One product contained only THC while others  20 exceeded the 0.3 percent limit on THC. Several vaping  21 products contained CBD but were adulterated with  22 synthetic cannabinoids. So clearly many CBD products</p>	<p style="text-align: right;">Page 193</p> <p>1 party post-market surveillance for both human and  2 animal product categories. That includes conducting  3 post-market surveillance for medical cannabis programs  4 in multiple states, including Minnesota, where we are  5 the sole provider of safety surveillance for all  6 medical cannabis companies and the dispensaries in the  7 state.  8       First, I wanted to comment on the pet side of  9 the cannabis safety issue and echo some of the  10 concerns raised by Dr. Gurley regarding issues of  11 product integrity for many CBD-containing products in  12 the marketplace.  13       Our pet poison helpline has documented  14 cannabis exposures in pets for over a decade and more  15 recently for CBD-containing products where adverse  16 effects reported after pet exposures to such products  17 is oftentimes resulted in clinical effects that are  18 uncharacteristic for what we would expect for CBD such  19 as significant ataxia, lethargy, vomiting and, in some  20 cases, significant cardiovascular effects.  21       In fact, for CBD exposures, up to 45 percent  22 of the incidents require veterinarian intervention.</p>

<p style="text-align: right;">Page 194</p> <p>1 This suggested to us many of these exposures may be                  2 secondary to adulterated CBD products that contain                  3 other potentially toxic compounds.                  4 As for information regarding properly                  5 manufactured cannabis products such as those found in                  6 medical cannabis products in the medical cannabis                  7 program in Minnesota, I believe components of that                  8 program could be considered as part of a framework for                  9 an FDA-regulated program for CBD.                  10 This would include establishing GMPs, sharing                  11 of consumer clinical experiences and implementing                  12 robust mandatory adverse event reporting -- monitoring                  13 and reporting such as required in Minnesota.                  14 In fact, in the Minnesota program, there are                  15 requirements for 24/7 access to medical professionals                  16 for fielding any safety issues, including reports of                  17 adverse events.                  18 Regarding post-market surveillance for other                  19 cannabis products, we are already providing standard                  20 of care pharmacovigilance to best practice companies                  21 that manufacture both CBD, THC and CBD combination THC                  22 products.</p>	<p style="text-align: right;">Page 196</p> <p>1 safety information for CBD. We believe tapping into                  2 the programs mentioned here would be a good start and                  3 also allow access to safety data and clinical                  4 experience with cannabis-containing products,                  5 including CBD-only products.                  6 We would specifically recommend initiating                  7 data-sharing with the Minnesota program, where there                  8 are currently more than 16,000 patients enrolled in                  9 their program where clinical experiences are being                  10 prospectively documented.                  11 As for a potential regulatory framework for                  12 CBD, we think a model with components similar to                  13 Health Canada's natural health product regulatory                  14 framework might be considered, which would include GMP                  15 development, product registration and a post-market                  16 surveillance process including submission of adverse                  17 event data along with comprehensive adverse event data                  18 analysis for signal detection and investigation into                  19 any potential safety issues.                  20 This could also include a conditional                  21 registration process for companies that adhere to a                  22 variety of best practices for safety confirmation and</p>
<p style="text-align: right;">Page 195</p> <p>1 In these circumstances, these companies have                  2 us provide 24/7 access to medical professionals to                  3 field any safety issue, including reports of adverse                  4 effects and documentation of such data for analysis                  5 and benchmarking to aid in safety profiling and                  6 conducting surveillance for safety signals.                  7 Quite simply, in a market where such products                  8 are not currently regulated at a federal level, these                  9 companies seek to distinguish themselves from                  10 companies that do not adhere to best practices to                  11 protect their consumers.                  12 We also have worked very closely and                  13 collaborated with the National Center for Natural                  14 Product Research at the University of Mississippi                  15 regarding investigations into botanical adulterants                  16 where proper characterization of botanicals including                  17 cannabinoids. This includes our mutual efforts to                  18 support the American Botanical Council and their                  19 botanical adulterants prevention program, known as                  20 BAPP.                  21 So in summary, the question is what would be                  22 a path forward for FDA to gather or develop solid</p>	<p style="text-align: right;">Page 197</p> <p>1 product stewardship. Thank you very much.                  2 PANEL MEMBER: Excuse me. Just a follow-up                  3 question. I hope that you submit some of the details                  4 about the Minnesota experience to the docket. This is                  5 a rich source of information and I think we'd really                  6 appreciate that help. Just I wanted to clarify, these                  7 are data on both pet exposures and human exposures?                  8 DR. KINGSTON: That's correct. We have two                  9 sides of our practice. One is our human toxicology                  10 staff and then we have a whole veterinary team of                  11 experts. And so, our pet poison helpline collects                  12 information from the general public as an animal                  13 poison control center.                  14 But we also do it for companies that actually                  15 market products. So we have information from both                  16 areas to compare and contrast. And maybe in comment                  17 to your question about access to the Minnesota data, I                  18 would strongly encourage FDA to reach out to Minnesota                  19 where we could share information with the patients                  20 that we're collecting that clinical experience because                  21 the spontaneous reporting of adverse events which                  22 we're documenting is then integrated within their</p>

<p style="text-align: right;">Page 198</p> <p>1 system of clinical experience. So I think it's a very  2 rich program and we'd certainly like to see some  3 collaboration there.</p> <p>4 PANEL MEMBER: Thank you. So you're  5 contributing data to that other system now too?</p> <p>6 DR. KINGSTON: Yes. We're the sole supplier  7 of all the spontaneous reported adverse events from  8 our 24/7 call center.</p> <p>9 That information is then given to the state  10 of Minnesota and the medical cannabis program within  11 the Minnesota department of health. And so, we  12 collaborate on conducting safety surveillance and  13 signal detection.</p> <p>14 PANEL MEMBER: Thank you.</p> <p>15 PANEL MEMBER: So I just have one more  16 question for you. Sorry. Do you have any estimate on  17 the relative size of the market related to the  18 frequencies that you're seeing these experiences?</p> <p>19 DR. KINGSTON: The size of the market?  20 You're talking about in general?</p> <p>21 PANEL MEMBER: Yeah, and you mentioned that -  22 - you mentioned that you have the data for specific</p>	<p style="text-align: right;">Page 200</p> <p>1 is.</p> <p>2 DR. KINGSTON: Right. Okay. So there's a  3 couple of answers to that. One is if you look at it  4 big picture and having the experience from the public  5 poison center perspective, as previously being a  6 director in that area, it's probably got one of the  7 lowest incident rates that I've seen for a marketed  8 product. It's rare that we get significant adverse  9 effects, especially for these companies that engage  10 us. So I think they have a higher quality product.</p> <p>11 PANEL MEMBER: Okay. Thanks.</p> <p>12 MS. CRISTINZIO: Thank you. Our next speaker  13 is number 61, Igor Koturbash.</p> <p>14 DR. KOTURBASH: Ladies and gentlemen, it's  15 both a pleasure and honor being here today. My name  16 is Igor Koturbash. I'm a faculty at the University of  17 Arkansas for Medical Sciences and I'm also co-director  18 of the Center for Dietary Supplements Research.</p> <p>19 The mission of our center is actually to  20 provide industry, regulatory agency and public with  21 credible information, assessments and experts opinions  22 about the safety of dietary supplements and various</p>
<p style="text-align: right;">Page 199</p> <p>1 companies. So I would suspect that you would know  2 relative to their marketing amount how much -- what  3 the frequency is for reporting.</p> <p>4 DR. KINGSTON: I'd say the frequency for  5 reporting in the general market is pretty small, to be  6 honest with you.</p> <p>7 PANEL MEMBER: Okay.</p> <p>8 DR. KINGSTON: I think that there's a small  9 number of companies that are ahead of the curve and  10 are actually engaging organizations like ours to do  11 third party assessment and investigations into  12 potential adulteration and monitor the experience of  13 their products.</p> <p>14 PANEL MEMBER: But I guess my question is  15 more on the actual adverse events related to a  16 particular product.</p> <p>17 Would it be -- you know, you mentioned 50  18 percent of these need veterinary care and I guess I'm  19 thinking if I'm a company and I have a product and  20 you're taking all my adverse events for it, then I  21 know how much I'm marketing and you know how many  22 adverse events I have. So I know what that frequency</p>	<p style="text-align: right;">Page 201</p> <p>1 phytochemicals.</p> <p>2 As cannabidiol falls into the category of  3 phytochemicals, it is of our interest and especially  4 because there is, as you know, about -- based on  5 clinical data, about 5 to 20 percent of patients who  6 receive Epidiolex during the clinical trial develop  7 elevated liver enzymes. And if you pay attention to  8 the warning label on Epidiolex, it clearly states the  9 potential for hepatocellular liver injury -- for  10 hepatocellular injury.</p> <p>11 Therefore, we performed a series of studies  12 within the last few years at our center and I would  13 love really to share some of the highlights of our  14 studies.</p> <p>15 First of all, aspect number one, that  16 cannabidiol, or we use cannabidiol rich cannabis  17 extract that had 57.9 percent of cannabidiol in it.  18 It cannot really cause liver injury. If for single  19 administration case, you really need relatively high  20 dose to achieve it.</p> <p>21 In the context of repeated dose, then you  22 have to use very low dose actually to cause liver</p>

<p style="text-align: right;">Page 202</p> <p>1 injury evident as elevated liver enzymes, spiking  2 levels of bilirubin and histomorphological changes.  3 Aspect number two I would like to point your  4 attention to is a very high potential for CBD drug  5 interaction, as has been mentioned today by various  6 speakers. Of particular concern of course is CYP2B10  7 in mouse, which is CYP2B6 in humans, responsible for  8 metabolism of the majority of endostatins as well as  9 CYP2E1 which is a major cytochrome for metabolism of  10 mostly frequently used make human antibiotics like  11 ethanol and acetaminophen.  12 Furthermore our concern is in regards to the  13 so-called biphasic response when various doses of  14 cannabidiol can cause differential gene expression.  15 For example, high dose will cause downregulation but  16 low dose will cause upregulation, right? So that's  17 why you may face really very differential responses on  18 cannabidiol.  19 And the third concern of course is the  20 potentiation of drug-induced liver injury. In the  21 study, when we used the nontoxic doses of cannabidiol  22 and mice received up to that one single administration</p>	<p style="text-align: right;">Page 204</p> <p>1 Our call is that clearly further research is needed to  2 further understand the safety and drug interaction  3 potential for CBD and CBD-containing products.  4 And we are looking forward to working with  5 the regulatory agencies, with the industry and  6 certainly with public to further understand this.  7 Thank you for your attention.  8 MS. CRISTINZIO: Thank you. Next we have  9 speaker number 62, Michelle Peace.  10 DR. PEACE: All right. Good morning. First,  11 thank you for the opportunity to present our findings  12 on the analysis of CBD products intended to be used in  13 electronic cigarettes. I will also be submitting  14 comments to the docket regarding laboratory testing  15 standards before the deadline.  16 My name is Michelle Peace. I'm associate  17 professor in the department of forensic science at  18 Virginia Commonwealth University. My subject matter  19 expertise is forensic toxicology and I do have a  20 relevant scientific story for you.  21 I have been funded by the National Institute  22 of Justice since 2014 to study the manipulation and</p>
<p style="text-align: right;">Page 203</p> <p>1 of acetaminophen which was capable only to cause  2 transient elevation in liver enzymes, when you cord  3 administer them, we observed significant liver injury.  4 It was a so-called sinusoidal obstruction  5 syndrome like if you would pay attention to the slide  6 and we did 10 mg/kg CBD + APAP. It is a classical  7 picture of the toxic destruction of sinusoidal and  8 endothelial cells with further hemorrhage into the  9 liver tissue.  10 We published some of our data. There are  11 several more manuscripts at various stages under  12 review to preparation and we certainly continue  13 working in this field.  14 The three major points once again that  15 cannabidiol, at least in the form of the cannabidiol-  16 rich cannabis extract, can cause liver injury. It has  17 a very significant potential for drug interaction and  18 can further exacerbate other agents inducing  19 hepatotoxicity.  20 So in my understanding, we just really are  21 only scratching the top of the surface and it's like  22 we're really just observing the tip of the iceberg.</p>	<p style="text-align: right;">Page 205</p> <p>1 use of electronic cigarettes to vape drugs other than  2 nicotine and the impact on the criminal justice  3 system.  4 We have certainly seen an increase in the  5 submission of e-cigarettes and e-liquids into crime  6 labs for analysis as evidence in criminal justice  7 cases. With regards to CBD products, law enforcement  8 is generally very confused about what they need to do  9 about these products in terms of confiscating them and  10 submitting them to crime labs. And there is deep  11 concern about clogging the system that is already has  12 tremendous workload.  13 To set the stage here, what is an e-liquid.  14 The predominant components are the humectants that  15 create the cloud, propylene glycol and vegetable  16 glycerin mixed in some kind of ratio. We know that  17 there are thousands of flavor profiles and that the  18 most predominant drug is nicotine.  19 However, my lab focuses on drugs other than  20 nicotine. We have evaluated herbal substances like  21 blue lotus and kratom and dietary supplements. But  22 our main focus is on designer drugs, legal novel</p>

<p style="text-align: right;">Page 206</p> <p>1 psychoactive substances and drugs scheduled by the 2 FDA.</p> <p>3       What most people say about vaping drugs other 4 than nicotine is that people know what they're vaping 5 or they know they're vaping something that will make 6 them high. We have been monitoring this website and 7 similar websites for years. Companies do not list 8 what drugs the e-liquids contain. But the 9 descriptions in the user reviews will say this will 10 get you high or this will create hallucinations for 11 you or it will make you mellow.</p> <p>12       The e-liquids are usually generally very 13 expensive compared to nicotine e-liquids. In some 14 cases, like you see here, they range from \$30-ish to 15 \$2,000. You can also see the shoddy product 16 packaging. In this particular instance, we found a 17 dangerous synthetic cannabinoid, MDMB-FUBINACA and 18 frankly nobody was surprised.</p> <p>19       Shortly after publishing this finding, I 20 received a call from a young man who was vaping CBD 21 products and he had a really hard high that scared 22 him. He wanted to know if CBD is supposed to do that</p>	<p style="text-align: right;">Page 208</p> <p>1 store. We have seen a rash of reports nationwide of 2 people being poisoned from taking CBD products that 3 they purchased. In these particular headlines from 4 North Carolina, dozens of soldiers went to the 5 emergency room after taking CBD products purchased in 6 brick-and-mortar stores outside of their military 7 bases.</p> <p>8       We began monitoring drug forms specifically 9 regarding consumers who had bad reactions after taking 10 CBD products. They don't know where to turn for help. 11 They are embarrassed or afraid to report having had a 12 bad reaction.</p> <p>13       We have received more than 50 emails from 14 consumers after we reported the adulteration of CBD 15 products purchased directly from the manufacturer. In 16 all cases, the consumer purchased what they believed 17 was CBD.</p> <p>18       Mostly people are afraid of the short-term 19 and potential long-term symptom. They are afraid of 20 losing their jobs and/or embarrassed to admit they 21 took something that made them high. Convincing them 22 to send me the sample is difficult. But many have.</p>
<p style="text-align: right;">Page 207</p> <p>1 or if he just had a bad reaction. We told him to send 2 it to us for analysis and also purchased a number of 3 the same e-liquid products directly from the 4 manufacturer.</p> <p>5       You can see here that the products appear 6 professionally produced and the website is high 7 quality and they proclaim 100 percent CBD extracts. 8 Upon analysis, we found CBD in all of the products. 9 We also found 5-fluoro ADB in the young man's sample 10 and in what we acquired from the manufacturer. 5- 11 fluoro ADB has sent thousands of people to the 12 emergency rooms and been attributed to overdose deaths 13 in the United States and Europe.</p> <p>14       Several CBD samples we purchased from the 15 manufacturer also contained dextromethorphan, the 16 active ingredient in over-the-counter cough syrups. A 17 consumer wanting to purchase CBD because they want to 18 relieve pain or manage seizures has no idea of the 19 chance of buying something that also contains 20 dangerous drugs.</p> <p>21       This is the case whether someone purchases 22 from the Internet or walks into a brick-and-mortar</p>	<p style="text-align: right;">Page 209</p> <p>1       To highlight this problem, just two weeks 2 ago, we received two CBD samples from the family of a 3 79-year-old woman who was convinced to take CBD by her 4 grandchildren to relieve pain from rheumatoid 5 arthritis. After not hearing from her for a few days, 6 they did a wellness check. They found her 7 hallucinating and still trembling days after taking 8 it. Seventeen of the 18 samples we received contained 9 a dangerous synthetic cannabinoid.</p> <p>10       This unregulated industry with no -- with 11 high public demand and no requirements in oversight 12 for quality that is skirting the edge of legality has 13 ample room for nefarious activity. Clinics will not 14 find these kinds of drugs when they just do drug 15 testing.</p> <p>16       So we have significant concern with those who 17 are reporting hallucinations or adverse effects are 18 probably just going to say it was just THC when it was 19 likely something else. Thank you for your time.</p> <p>20       (Applause.)</p> <p>21       MS. CRISTINZIO: Thank you. Our next speaker 22 is number 63, Ryan Vandrey.</p>

<p style="text-align: right;">Page 210</p> <p>1 DR. VANDREY: Okay. Good morning. So I want 2 to just try to highlight a couple of things that I 3 think are important and I want to note that although I 4 work for Johns Hopkins, I'm here representing myself 5 and not the university. 6 So from a regulatory perspective as a 7 researcher, we know that CBD is the predominant 8 byproduct of hemp and that's what most people have 9 been talking about today. 10 From a research standpoint, it's confusing 11 from a regulatory perspective because CBD is both 12 currently unscheduled if it's derived from hemp. It's 13 Schedule 5 under the CSA at Epidiolex. And it's 14 Schedule 1 if it's synthetically derived. So that 15 causes problems for us doing research. 16 Also, as mentioned by the gentleman from true 17 Terpenes earlier today, it's not just CBD that can be 18 derived from hemp. There are a number of other 19 cannabinoids and non-cannabinoids that can be 20 extracted. And those products can come to market. 21 There are some on the market already. Minor 22 cannabinoids like CBG, CBN, we have no controlled</p>	<p style="text-align: right;">Page 212</p> <p>1 controlled administration studies and showed that 2 vaporization of cannabis produces a stronger drug 3 effect and a greater impairment compared with smoking 4 it. Smoking and oral dosing produce comparable peak 5 drug effects. But the time course is very different. 6 We found that the blood cannabinoid 7 concentration correlates poorly with subjective drug 8 effects and impairment and that's important as a 9 consideration for evaluation of these products. And I 10 want to also highlight -- and things got wonky with 11 the transition from Mac to PC again these days. 12 But even though these figures are a little 13 bit hard to see, I'll describe an ongoing study that 14 we have where we're acutely administering cannabidiol 15 as a pure substance as well as cannabis containing a 16 high concentration of cannabidiol and a low 17 concentration of THC. 18 What we found is that when CBD by itself is 19 orally administered, we don't see much in the way of 20 subjective drug effects or impairment. When it's 21 vaporized, we see a discriminable drug effect. It's 22 not THC-like and does not produce cognitive</p>
<p style="text-align: right;">Page 211</p> <p>1 research on what these do pharmacologically in humans. 2 MS. CRISTINZIO: Can you move your microphone 3 up a bit? 4 DR. VANDREY: Yes. Sorry. So in addition to 5 CBD and some of these other minor cannabinoids, THC is 6 an important constituent that is allowable in hemp 7 products. Hemp is defined as 0.3 percent THC. But 8 that's a percentage and not a total amount in a 9 product. 10 A study conducted by my friend and colleague, 11 Marcel Bonn-Miller, found that CBD oils sold on the 12 Internet contained up to 6.4 mg of THC per milliliter 13 of liquid. 14 And to kind of put that in perspective, 15 laboratory studies that we've done at Hopkins have 16 shown that oral doses of 10 mg of THC can produce mild 17 to moderate drug effects and can impair cognitive 18 performance. So the data there show 10 in a 25 mg 19 dose orally administered and showing significant 20 impairment on a working memory task. 21 In addition, route of administration is 22 important. And so, we've conducted a number of</p>	<p style="text-align: right;">Page 213</p> <p>1 impairment. But to consider CBD non-psychoactive I 2 think is inappropriate. 3 Additional research -- this is with 100 mg 4 dose of CBD. Higher doses administered at the 5 University of Wollongong in Australia by Nadia Solowij 6 have shown some mild cognitive impairment with a 7 higher dose of CBD. 8 We found no THC in blood after administration 9 of pure CBD, which kind of addresses the potential for 10 conversion there. What we do see is difference in CBD 11 in blood when THC is co-administered. 12 I also want to point out that when we did 13 urine drug testing, two of our six participants had 14 positive drug tests with a dose of about 4 mg of THC 15 in this product. So the amount -- again, the amount 16 of THC in the product is going to be important as 17 these retail products come out. 18 So points that I want to make outside of the 19 laboratory studies we've done is that standards for 20 quality control testing and contaminants is urgently 21 needed and while we know a lot about acute effects, we 22 don't know much in terms of systematic evaluation of</p>

<p style="text-align: right;">Page 214</p> <p>1 long-term health effects of chronic use of hemp or CBD 2 products. 3 We need to have better data on special 4 populations such as pregnancy, psychiatric 5 populations, elderly and other at-risk populations. 6 And I encourage the FDA to engage in a formal 7 pharmacovigilance program as these products come to 8 market. Labeling should clearly disclose the amount 9 of THC, CBD and any other detectable cannabinoids. 10 And so, what I would encourage the FDA to do 11 is to establish regulations immediately for content, 12 for quality control and for labeling and to consider 13 the use of existing CGMP regulations for drugs and 14 supplements but also to urgently fund cannabis 15 regulatory science and provide a pathway for 16 researchers to better do what we need to do to help 17 inform you guys. Thank you. 18 PANEL MEMBER: I have a question. You said 19 that CBD has a drug effect, a psychoactive drug effect 20 but not like THC. Can you elaborate on what you mean 21 by that? 22 DR. VANDREY: Sure. So when we've</p>	<p style="text-align: right;">Page 216</p> <p>1 DR. VANDREY: They had used it in the past, 2 but not in the prior month. 3 PANEL MEMBER: Okay, and second, like many 4 other comments that have been made, we'd really 5 appreciate any data that you could submit to the 6 docket or make available, you know, in that way to us. 7 Thanks. 8 DR. VANDREY: Certainly. 9 MS. CRISTINZIO: Thank you. Our next 10 speaker, number 64, is Larry Walker. 11 DR. WALKER: Thank you very much for the 12 opportunity. I represent the University of 13 Mississippi. And just some -- it's a little off- 14 center, but just a quick pointers on some background, 15 we've had a program for several years with CFSAN for 16 botanical ingredients research, a center of excellence 17 there, not cannabis-related. 18 We also have been the contractor for many, 19 many years for the NIDA drug supply program for 20 cannabis and cannabinoids. We're a partner in the 21 botanical adulterants prevention program of the 22 American Botanical Council and have now ongoing a</p>
<p style="text-align: right;">Page 215</p> <p>1 administered pure CBD in the laboratory, people report 2 discriminable drug effects. They on a drug effect 3 scale report feeling a drug effect. But when we look 4 at adjectives that are THC-like effects, do you get 5 the munchies, do you feel impaired, do you feel high, 6 and they say no to that. So the things that we 7 typically see with THC administration we don't see 8 with CBD. 9 PANEL MEMBER: So what do they describe as 10 the drug effect? 11 DR. VANDREY: They've had a difficult time 12 articulating exactly what they feel and it's been 13 different from different people. The most common is 14 relaxing, calm, somewhat sedating. 15 PANEL MEMBER: Excuse me. One other thing. 16 I just -- just to clarify, I assume those studies were 17 done in healthy volunteers. 18 DR. VANDREY: These were healthy adults who 19 were non-cannabis -- non-frequent-cannabis users at 20 the time. So they were all -- had tested negative for 21 THC. 22 PANEL MEMBER: But had used it in the past?</p>	<p style="text-align: right;">Page 217</p> <p>1 current expanded access IND for CBD extract in 2 refractory childhood epilepsy at the University of 3 Mississippi Medical Center with Dr. Ingram as the PI. 4 It's been touched on already here that in 5 addition to the risk with cannabis smoking and 6 presumably THC-related that there are also a number of 7 potential CBD safety issues, product quality issues 8 particularly, but maybe others as well that need to be 9 considered. 10 In our program in Mississippi, which is just 11 a small extended access IND, but I believe the first 12 that was done in the, quote, "restricted" THC states 13 on a CBD extract and the findings were, you know, so 14 far generally it's well tolerated and the patients and 15 the families seem to be happy. 16 But we have had, even with fairly low doses, 17 significant side effects and especially in the drug 18 interaction realm. So these are certainly things that 19 need to be further studied and monitored. 20 A possible path forward it seems to us is 21 prudent to have a multitrack approach with these 22 products that are cannabis-related. In fact, we</p>

<p style="text-align: right;">Page 218</p> <p>1 already have in some respects some of these programs                  2 existing. Dr. Sharpless mentioned the GRAS program                  3 already existing.                  4 Our thinking would be that in the supplement                  5 world, some type of program with a special focus,                  6 limits on CBD and special focus on the NDI                  7 notifications, GMPs, adverse event surveillance, that                  8 we need to be able to gather this data and maybe some                  9 type of conditional registration for manufacturers                  10 that might participate in a quality stewardship --                  11 safety and quality stewardship program.                  12 There's also also ready the track for the                  13 development of botanical drugs under the botanical                  14 drug route or single chemical entity. And we're very                  15 much proponents and very much in favor of this.                  16 But one of the key issues is how do we relax                  17 the restrictions on the availability of plant-derived                  18 material for clinical research. This has been a major                  19 issue for us in Mississippi and all other state                  20 programs that I'm aware of, how do we work under the                  21 federal guidelines with those types of materials. How                  22 do we source those? Even though we are the contractor</p>	<p style="text-align: right;">Page 220</p> <p>1 for cannabinoid quality and standardization. You can                  2 see what the product picture looks like. A national                  3 adverse event reporting program for whatever products                  4 are out there and rapid response program for products                  5 where there are serious incidents. We need analytical                  6 backup on many of these things where serious incidents                  7 have occurred. And then, finally, if possible, to                  8 gather research outcomes in these state medical                  9 programs. Thank you very much.                  10 (Applause.)                  11 MS. CRISTINZIO: Great. Finishing out our                  12 academia category, we have Elise Weerts.                  13 DR. WEERTS: I'm actually here on behalf of                  14 the college on the problems of drug dependence. And                  15 this is one of the longest standing scientific                  16 organizations focused on the problems of drug abuse                  17 and dependence and empirical data for its treatment.                  18 I'm presenting also for Margaret Haney, who                  19 is the acting president this year, and I am the                  20 incoming president. Both of us study cannabis in                  21 laboratory studies.                  22 So medical cannabis -- important in the</p>
<p style="text-align: right;">Page 219</p> <p>1 for NIDA for this, it's not been easy for us.                  2 And then, I think just it's been touched on                  3 by my colleagues, but about these state medical                  4 marijuana programs, although this is obviously out of                  5 the FDA bailiwick, so to speak, but I really think                  6 gathering data from those programs in some type of                  7 coordinated national way would really be very helpful                  8 for us in the future going forward.                  9 And so, I would just mention these in                  10 summary. We need a lot more clinical research. We                  11 need a lot more clinical research on well-defined                  12 products, whether they're under controlled substances                  13 or not. This necessitates some relaxation of the                  14 restrictions for producing these materials for                  15 legitimate clinical researchers.                  16 It would be outstanding I think if the FDA                  17 could conduct some basic studies in this realm. It's                  18 a national need. It impacts so broadly that I think                  19 it's very unique. We need to extend some of the                  20 animal work that's been presented here to look at                  21 NOELs, you know, very carefully.                  22 We need I believe a national testing program</p>	<p style="text-align: right;">Page 221</p> <p>1 discussion, is it marketing or science. This slide                  2 shows you the proliferation of advertising that's out                  3 there and convincing people that there's some medical                  4 benefit. It's very polarizing.                  5 At the same time, the states have enacted                  6 laws that have so-called approved medical conditions.                  7 Up to 51 so far have been approved in the different                  8 states. And they're not even consistent in which                  9 things are being approved. So, for example, like New                  10 York could approve an antibiotic for the treatment of                  11 an infection and then Kansas could approve it for                  12 epilepsy.                  13 We need science to inform policy. Is                  14 cannabis good or bad? The answer is actually it's a                  15 little of both. So it's pharmacologically complex.                  16 It has multiple constituents. And it can have medical                  17 benefit in some cases and then also have problematic                  18 use.                  19 The cannabinoid receptor in the brain is                  20 widely spread. We're just starting to learn about                  21 what it does for your health. It was only discovered                  22 in the 1990s. The plant itself has over a hundred</p>



<p style="text-align: right;">Page 222</p> <p>1 unique cannabinoids. Unfortunately research has been  2 limited primarily to two of them, THC and cannabidiol.  3 And that's because of access.  4       We're in a vacuum right now. We really do  5 need randomized placebo controlled trials of testing  6 products that have known composition. Right now, they  7 are marketed and they're not tested under FDA-approved  8 strategies for safety and efficacy. The public  9 opinion is guiding how we're treating a number of  10 disorders.  11       There's also little regulatory oversight.  12 Recent testing of compounds that are obtained online  13 or from dispensaries of edibles and other things that  14 are cannabinoid-based have shown that they're not  15 accurately labeled and that less than a third actually  16 contain even some of the products that they say they  17 do.  18       What about the GMP and purity and how about  19 dose? And how do we take it? This all effects  20 whether it's going to do anything.  21       And then, the big question, is cannabis  22 addictive? Yes. There's a lot of data in the</p>	<p style="text-align: right;">Page 224</p> <p>1 using the same amount as men.  2       Now, to switch sides, Margaret Haney has done  3 a number of laboratory studies looking at benefit. So  4 she did some studies in HIV-positive patients and  5 showed that these individuals who often have problems  6 eating and lose weight, when you give cannabis, it  7 actually improves those symptoms. So there's reduced  8 GI distress and the increase of caloric intake.  9       She also did a laboratory pain model where  10 smoked cannabis and oral THC dose dependently reduced  11 pain sensitivity and then load opioids that don't  12 produce any amount of analgesia or pain relief when  13 combined with small amounts of cannabis actually do  14 have a benefit.  15       However, again, women appear less sensitive  16 to these effects than men. So it may not be  17 beneficial for women.  18       There's also the National Academy of Sciences  19 review that covered a lot of the different literature  20 that's out there to look for medical benefit. Only  21 three of the things that were examined actually proved  22 to be beneficial.</p>
<p style="text-align: right;">Page 223</p> <p>1 scientific literature showing that 30 percent of  2 regular users will come to have a cannabis use  3 disorder and about 300,000 treatment admissions occur  4 each year. And why do people seek treatment? They've  5 having problems with functioning. They're having an  6 inability to stop using. They're smoking more than  7 they intend. They have memory deficits. They go  8 through withdrawal and they have other health  9 concerns.  10       Few patients that seek treatment actually are  11 able to abstain, only about 20 percent. The treatment  12 options are not that good.  13       So what does withdrawal look like? Well,  14 typically you see increase in anxiety, irritability,  15 craving and restlessness. They have decreases in food  16 intake and sleep quality.  17       This withdrawal emerges after 24 hours when  18 you stop and it continues for weeks. And a really  19 important point is that women seem to be more  20 vulnerable. They have an accelerated trajectory for  21 developing problems and they also experience more  22 withdrawal and have worse outcomes, even when they're</p>	<p style="text-align: right;">Page 225</p> <p>1       So more research is needed. We need to  2 increase research because legalization and acceptance  3 is increasing use. So there's an escalation that's  4 well documented in adolescents and adults, including  5 pregnant women, that's rising. We need to understand  6 how this is affecting health.  7       There's also no regulatory pathway for all  8 these constituents and we really don't know anything  9 about them. The idea that they've been said to be  10 safe is ridiculous. It hasn't been done. And then  11 also we need to evaluate the health claims. But we  12 can't do that if research can't access these  13 compounds.  14       And then, I give you a list of things that we  15 need to research and, you know, you can look at that  16 online. But we need to understand the risks and  17 benefits. There's clearly both. And then, there's  18 some recommendations here for the regulatory outcomes,  19 about streamlining the process, particularly for  20 interactions between the DEA and the FDA because  21 that's very long.  22       And INDs, we need to accelerate the INDs so</p>

<p style="text-align: right;">Page 226</p> <p>1 we can actually study these things in clinical trials.  2 If you would like copies of the slides or you want  3 more information, well, that was my email that was up  4 there that went away. Thank you. Questions?  5 MS. CRISTINZIO: Thank you.  6 PANEL MEMBER: I have a question for you, for  7 just -- so you comment about the need to have a  8 streamlined availability of products for  9 investigation. Could you comment what you think the  10 impact of the farm bill removing cannabidiol --  11 DR. WEERTS: For a researcher --  12 PANEL MEMBER: -- and other hemp-based  13 products --  14 DR. WEERTS: For a researcher --  15 PANEL MEMBER: For research purposes, yeah.  16 DR. WEERTS: It has no impact.  17 PANEL MEMBER: Please elaborate just a little  18 bit.  19 DR. WEERTS: So I have a DEA Schedule 1  20 license to study cannabinoids. My 21-year-old son can  21 walk into a store and buy it and I cannot. That's  22 really it in a nutshell. I cannot purchase, store or</p>	<p style="text-align: right;">Page 228</p> <p>1 pharmaceuticals, cosmetics, a lot that deal with the  2 general cannabis and CBD space. We work with majority  3 of the largescale LPs out of Canada as well as some of  4 the major producers here domestically for CBD  5 production.  6 We're here to talk about a little bit today  7 about some of the misinformation on just general  8 compliance in the agricultural community as well as  9 the general processing capabilities in order to  10 hopefully, you know, create a more compliant product  11 and a more simple pathway for compliance in the  12 industry.  13 So, you know, that being said, obviously  14 there's -- in the agricultural community, there has  15 been a lot of information as far as, you know, the  16 federal tolerance for THC and the actual plant itself.  17 You know, in certain states, in certain varieties of  18 the plant, it's kind of irrelevant of the actual  19 content of the THC.  20 States like -- we're in North Carolina. And  21 the state of North Carolina, we almost had full  22 compliance last year for THC products or CBD products</p>
<p style="text-align: right;">Page 227</p> <p>1 test that product. It is illegal for me to do so  2 because I am following the regulations of the DEA and  3 I'm following the regulations of the FDA, which  4 anything that I test has to go through an IND and meet  5 all those requirements and go through our IRB.  6 It's a very circular process and can take  7 months and months. But it does bother me that my 20-  8 year-old kid can now get it and, you know, take it and  9 I can't even touch it, unless I was a consumer. Any  10 other questions?  11 MS. CRISTINZIO: Thank you.  12 (Applause.)  13 MS. CRISTINZIO: We are now onto a new  14 segment called agriculture. And we have Cameron Cane  15 up next, number 66.  16 AGRICULTURE (NON-GOVERNMENT)  17 MR. CANE: How are we doing? My name is  18 Cameron Cane. I'm with Deutsche Process. We are a  19 largescale industrial scale sanitary process equipment  20 company.  21 We work in a variety of different food,  22 beverage-related industries as well as nutraceuticals,</p>	<p style="text-align: right;">Page 229</p> <p>1 devoid of THC in there. In states like Nevada, same  2 plant varieties, almost 40 percent compliance, a 60  3 percent noncompliant product. But Nevada has a gray  4 market where, you know, they can push their products  5 to. There was no real reason other than just grow  6 mediums and the actual locations and the timing of  7 harvest of that compliance that actually had that.  8 If that was the case in North Carolina, you  9 would have had farmers who unfortunately would have  10 been forced to burn their crops, submit insurance  11 claims, which currently there are no federal crop  12 insurance for that.  13 But what is unknown about the process,  14 regardless of what the THC content is in the field,  15 once you go through a processing facility, you process  16 this stuff and you concentrate the full spectrum  17 extract down to a concentrate, as you can see from the  18 pictograph here.  19 Through the concentration process, nearly  20 all, 90 percent plus of all the concentrate itself  21 will be federally noncompliant. There are processes  22 in order to mitigate that, in order to effectively</p>

<p style="text-align: right;">Page 230</p> <p>1 delete THC from those compounds. You know, as you see  2 on here, you go through a purification step once you  3 pass through that concentration.  4 You know, purification is the crystallization  5 of the CBD compounds, generated in an isolate product.  6 You'll then be left with a high THC, what is called  7 the mother liquor. In that product, you will have a  8 variety of other compounds in there as well.  9 And you can take that through several  10 different steps, whether that's hydrogenation or  11 reduction of that THC compound to essentially  12 effectively delete the lucid chemical that is  13 obviously the stigma in the industry.  14 By taking these very simple steps, which are  15 readily available -- you know, we are not the company  16 that created, you know, isolate production or  17 hydrogenation processes. There are multiple  18 hydrogenation processes that have patents out there  19 currently.  20 We are also creating multiple other  21 hydrogenated processes in conjunction with one of our  22 partners, Canopy Growth, in order to, you know,</p>	<p style="text-align: right;">Page 232</p> <p>1 there's no need for that.  2 If we had an audited choke point being the  3 processing facilities, you don't have to worry about  4 THC. You don't have to worry about mycotoxins. You  5 don't have to worry about pesticides because when it  6 comes out of these audited facilities, you know it is  7 100 percent compliant and there is no question in the  8 industry and there goes the stigma as well. I  9 appreciate your time.  10 (Applause.)  11 PANEL MEMBER: I have one question for you.  12 What other byproducts would come out of this process?  13 Is there a waste stream that comes out?  14 MR. CANE: There is. And that's -- you would  15 hydrogenate the waste stream or you'd take that  16 through another purification process of you'd throw it  17 away.  18 You know, there are -- the isolation process,  19 the crystallization and isolation process is roughly,  20 you know, 50 to 60 percent effective, you know, as far  21 as an efficiency standpoint. And you take that  22 byproduct, the waste stream from that, which is the</p>
<p style="text-align: right;">Page 231</p> <p>1 develop more products that are marketable for a, you  2 know, mainstream use down -- you know, without the  3 problem of THC in the marketplace.  4 You know, how do we regulate this and how do  5 we make sure, you know, this is kind of the pathway?  6 You know, in our opinion, again, what's being  7 regulated right now is the agricultural community.  8 It's not processing. It's not the white label CPG  9 manufacturers.  10 The simple choke point here is absolutely  11 from a compliance standpoint. Is our process in  12 compliance? And speaking with our clients, they want  13 to be a compliant, a regulated industry that has  14 transparency and, you know, has the ability to make  15 all of us feel very safe in what we're doing.  16 You know, being able to have an audited --  17 you know, a federal audited compliance checkpoint, you  18 know, through our processing facilities is certainly  19 the way to make it easy from a capacity standpoint  20 from federal regulators and so we know what is going  21 into -- you know, when I listened to the lady from VCU  22 and you see these products, it's scary. You know,</p>	<p style="text-align: right;">Page 233</p> <p>1 mother liquor that has THC in it, and you take that  2 through a hydrogenation process in order to  3 essentially reform that molecular compound that was  4 THC.  5 PANEL MEMBER: Quick question for you. In  6 North Carolina, what do you think the proportion of  7 hemp growers are moving then their hemp for CBD  8 specifically versus other purposes for hemp growth in  9 North Carolina?  10 MR. CANE: I'm not sure I understood the  11 question.  12 PANEL MEMBER: Among farmers who are farming  13 hemp in North Carolina, how many of them are farming  14 hemp for CBD production versus for other purposes?  15 MR. CANE: Nearly all. There is -- you know,  16 when you talk about an economic driver, another  17 gentleman said it today, you know, you can make  18 \$30,000 to \$60,000 an acre on CBD product. You can  19 make \$700 an acre on fiber. Nearly all of it is CBD  20 production. That's globally.  21 PANEL MEMBER: Thanks.  22 PANEL MEMBER: Can I ask a question real</p>

<p style="text-align: right;">Page 234</p> <p>1 quickly? I want to follow up on the waste stream. So  2 we heard this morning about full spectrum  3 phytocannabinoids and things like that. Do these --  4 they come out of this same process as the  5 hydrogenation change what ends up in what you would  6 call full spectrum or --  7 MR. CANE: So your full spectrum, you would  8 take that through the isolation process, first and  9 foremost.  10 And that would isolate the CBD compounds and  11 leave out the rest of your other compounds, fats,  12 waxes, lipids, amino acids, your THC, the mycotoxins,  13 anything else that might -- you know, some of the  14 pesticides, heavy metals, things like that. You know,  15 they don't get crystallized during that process.  16 And, you know, once that happens, you know,  17 you take that through the hydrogenation process. We  18 have done testing on selective hydrogenation. They  19 have been varied results, not very good. It is more  20 of a blunt force trauma of hydrogenation where we're  21 hydrogenating all of the compounds that are in that  22 mother liquor stream.</p>	<p style="text-align: right;">Page 236</p> <p>1 what we do is we're a consumer advocacy organization  2 focused on bringing truth and transparency to consumer  3 product labeling. More specifically, what we concern  4 ourselves with is what's not on the labels. Marketing  5 departments can do an effective job at selling comfort  6 and security. So for us, in data and science we  7 trust.  8 So what we do is we go out to the marketplace  9 and I simulate the consumer shopping experience. I go  10 out. I actually buy the products from the -- be it  11 websites or local, national retailers. The only  12 difference is instead of taking them and putting them  13 in my pantry, I take them to an analytical chemistry  14 lab to see what's actually inside.  15 So why did we test the CBD category? Really  16 because of a lot of the great work that FDA has  17 already been doing over the past several years.  18 You've already called it. There have been systemic  19 quality control issues that have been identified. And  20 we see this coming out in other media, academic  21 studies that have been taking place.  22 So for us, we also wanted to validate that.</p>
<p style="text-align: right;">Page 235</p> <p>1 And you know, we're still very actively  2 testing in real time. But there are, you know, THC  3 compounds that are patented -- hydrogenated compounds  4 that are patented out there with, you know, good  5 results that do have ancillary revenue streams or you  6 just take it down and reduce that down to CBN. Thank  7 you.  8 MS. CRISTINZIO: Thank you. Our next  9 speaking category is consumers. And we have Jaclyn  10 Bowen, number 67.  11 CONSUMERS  12 MS. BOWEN: Hi. Thank you. I'm Jaclyn  13 Bowen. I'm the executive director of Clean Label  14 Project, the international association for cannabis  15 testing is a division of Clean Label Project.  16 I'm a food safety and quality systems  17 engineer. So before coming to Clean Label Project,  18 for 15 years I worked on different activities related  19 to standards development, certification, compliance  20 and enforcement mechanisms within food and consumer  21 product safety.  22 Specifically for us at Clean Label Project,</p>	<p style="text-align: right;">Page 237</p> <p>1 The samples that we selected were the ones that were  2 out in the marketplace between January and February of  3 this year.  4 So a little bit more about the study. How  5 did we test the study? We were inspired by the  6 Amazon.com bestseller's list as well as an Internet  7 search of different types of consumer blogs of popular  8 CBD products that consumers were buying.  9 We used, like I mentioned before, consumer  10 chain of custody rather than relying on certificates  11 of analysis as disclosed by brands. We went out into  12 the marketplace, procured the samples ourselves just  13 like a consumer would and took it to an analytical  14 chemistry lab. Had it validated by another lab as  15 well.  16 What did we look at? Over 400 analytes --  17 heavy metals, pesticide residues, plasticizers,  18 potency, THC as well as mycotoxins. And we tested  19 America's bestselling CBD products.  20 So three key findings that we found. The  21 first one is highly variable potency and  22 contamination. We tested for over 400 analytes. The</p>

<p style="text-align: right;">Page 238</p> <p>1 average of top 10 brands based on what they disclose  2 on their website is about 14 different tests. What we  3 found within our testing, and I'll show more details  4 to this, is that you see over 30 percent of products  5 are plus or minus 20 percent of the CBD value that's  6 listed on the label.</p> <p>7 We see on average 34 parts per billion of  8 lead, which is the highest amount of any consumer  9 product or food category that we've ever tested. The  10 pesticides that we see, the total pesticides, nearing  11 41 parts per million. The most common pesticide hits  12 listed here. Average phthalates, which I was really  13 surprised about, nearly 1,100 parts per billion. I'm  14 not exactly sure where that's coming from.</p> <p>15 Overall what we see is a general disconnect  16 between brand-reported certificates of analysis and  17 what's actually showing up on retail store shelves.  18 What happens is this elevated level of detection  19 coming from certificates of analysis listing a bunch  20 of non-detects results in unsuspecting brands and  21 consumers getting a false sense of comfort, security  22 and compliance.</p>	<p style="text-align: right;">Page 240</p> <p>1 If someone chooses to make a THC-free claim,  2 well then what exactly what does that mean? In terms  3 of my sensitivity, we tested down to 0.2 parts per --  4 or sorry, 0.2 parts per million. So it was one where  5 we did not see anything that exceeded this 0.3  6 percent.</p> <p>7 But I think what's important to note is the  8 0.3 percent THC is based on dry weight in hemp and the  9 limit is being applied to manufactured products. But  10 there's no rule or regulation as to how much THC can  11 be present in a concentrate or manufactured product.  12 Thank you.</p> <p>13 (Applause.)</p> <p>14 MS. CRISTINZIO: Thank you. Our next speaker  15 is David Evans, number 68.</p> <p>16 MR. EVANS: And how do I advance the slides?  17 MS. CRISTINZIO: You should be able to do it  18 with your clicker?</p> <p>19 MR. EVANS: That's the advance? Oh, okay. I  20 am the senior counsel to the Cannabis Industry Victims  21 Educating Litigators. We are a legal education  22 organization that trains lawyers in how to sue the</p>
<p style="text-align: right;">Page 239</p> <p>1 So, number two key finding, the CBD content  2 varies widely based with the values listed on the  3 label. What's I think so interesting here and aligned  4 with my friend over in Arkansas is I think that's the  5 same product we tested that was exactly 100 percent  6 accurate with the other one.</p> <p>7 We see products that had zero CBD. We had  8 another one that I didn't include on here that had 700  9 percent of the claim. But it wouldn't fit on my  10 chart.</p> <p>11 And then, you know, another question is, you  12 know, I see a fair amount of CBD washing. To be able  13 to kind of command this market premium, it's almost  14 something where it has very, very low levels of CBD,  15 but it's still really marketing that.</p> <p>16 Finally another question would be we see a  17 lot of THC-free claims. So what exactly does it mean  18 to be THC-free? It's interesting because, for me, I  19 look at words like FDA-provided guidance on gluten-  20 free. And that meant if you chose to make a claim of  21 gluten-free, then that means that you have to be less  22 than 20 parts per million.</p>	<p style="text-align: right;">Page 241</p> <p>1 marijuana industry. We've spent the last year doing  2 research on that. This year we're rolling it out.</p> <p>3 So if a lawyer wants to sue somebody in the  4 marijuana industry, we give them a suit to nuts legal  5 guide on how to do it, the law, the science, a model  6 complaint, model responses to motions, model  7 interrogatory questions and so forth.</p> <p>8 Right now, we have about a thousand lawsuits  9 against the opioid industry. And if our dreams come  10 true, we'll have the same thing going against the  11 marijuana industry in a year or two or maybe a little  12 bit more.</p> <p>13 Now, who are the marijuana industry?  14 Basically it's anybody that's selling marijuana as a  15 medicine or as a food that has been approved by the  16 FDA. They have set themselves up in various  17 associations and industry associations.</p> <p>18 The reality is these people are criminals.  19 They are doing this in violation of the federal  20 Controlled Substances Act and also the criminal  21 penalties within the Food, Drug and Cosmetic Act.  22 They're criminals. And the federal government has</p>

<p style="text-align: right;">Page 242</p> <p>1 allowed this to go on for a long, long time.</p> <p>2 I have no sympathy for them. I don't respect</p> <p>3 them. I have seen the widespread damage that they are</p> <p>4 affecting on this country. We advocate for the</p> <p>5 victims of the marijuana industry, children with birth</p> <p>6 defects, developmental problems. We'll provide you</p> <p>7 all the science on it. We've got a lot of science.</p> <p>8 Talk to Dr. Howard (ph) at the National</p> <p>9 Institute on Drug Abuse. She's written papers on the</p> <p>10 damage to unborn children.</p> <p>11 We also advocate for marijuana consumers.</p> <p>12 Marijuana products are full of contamination. We have</p> <p>13 papers documenting all this, even in the so-called</p> <p>14 regulated states such as Massachusetts and California.</p> <p>15 Colorado is now a narco-state. The state</p> <p>16 government there has been grossly irresponsible in</p> <p>17 dealing with this issue. And if somebody from one of</p> <p>18 those states wants to give you a tour, come to us and</p> <p>19 we'll give you our tour. We'll show you what's really</p> <p>20 going on there in the ERs and every place else.</p> <p>21 Marijuana is very dangerous. I have given</p> <p>22 three copies of a book by Alex Berenson, a New York</p>	<p style="text-align: right;">Page 244</p> <p>1 organizations have put in damage reports about</p> <p>2 marijuana. The science is clear. It's not debatable.</p> <p>3 There is no regulatory ambiguity. You guys have said</p> <p>4 don't sell this stuff. It's illegal.</p> <p>5 Now I'm just going to ask you a question.</p> <p>6 These people have been operating for years, okay? And</p> <p>7 they have ignored you. What makes you think if you</p> <p>8 come out with something now that the situation is</p> <p>9 going to be any different? The only way it's going to</p> <p>10 be different is if you enforce it. And you have not</p> <p>11 been doing that.</p> <p>12 And in all my years in government -- I used</p> <p>13 to work for the New Jersey Department of Health --</p> <p>14 this is the most negligent, damaging thing I've ever</p> <p>15 seen a government agency do, the FDA's negligence in</p> <p>16 not dealing with marijuana and cannabinoids.</p> <p>17 You've seen very good science here and I urge</p> <p>18 you clean it up. Redeem yourselves and go after this</p> <p>19 criminal industry that's damaging our children.</p> <p>20 This is not a states' rights issue. The U.S.</p> <p>21 Supreme Court has determined that regulation of</p> <p>22 medical marijuana is a medical issue. I've got a</p>
<p style="text-align: right;">Page 243</p> <p>1 Times reporter, who has looked into marijuana-induced</p> <p>2 mental illness and violence. A great deal of violence</p> <p>3 is being caused by high-potency marijuana. Read his</p> <p>4 book. You've got three copies of it there.</p> <p>5 Mental illness, physical disease and</p> <p>6 addiction to marijuana. Now, is there a demand for</p> <p>7 marijuana products? You bet your lives there is.</p> <p>8 These folks in the marijuana industry have created the</p> <p>9 demand, primarily by lying to people about the</p> <p>10 addictive qualities and the dangers of marijuana.</p> <p>11 We've probably all gotten things on the Internet about</p> <p>12 CBD, that it's the wondrous plant.</p> <p>13 And by the way, this meeting has been very</p> <p>14 helpful to me on a personal level. I am an anxious,</p> <p>15 combative individual and I have come -- and I have</p> <p>16 come to realize that my problem is I have a</p> <p>17 cannabinoid deficiency. And I'm going to -- my wife</p> <p>18 is driving me home. That's the first thing I'm going</p> <p>19 to tell her, is sweetheart, I've figure out what's</p> <p>20 wrong with me finally. I don't have enough of this</p> <p>21 stuff.</p> <p>22 Now, who agrees with me? All of these</p>	<p style="text-align: right;">Page 245</p> <p>1 minute left and I've got other points. But I want to</p> <p>2 just spend a few minutes looking at some people's</p> <p>3 children. Every one of these people is dead, except</p> <p>4 for one. And their parents all say that their deaths</p> <p>5 were caused by marijuana. This is the only one of</p> <p>6 these folks that's alive. They committed suicide,</p> <p>7 they overdosed or they died as a result of their</p> <p>8 marijuana use.</p> <p>9 So you have a tremendous responsibility.</p> <p>10 You're going to meet with a lot of smooth talking</p> <p>11 lobbyists here, okay, who are going to spin a lot of</p> <p>12 bullshit to you about their products. Keep these</p> <p>13 people in mind. Their photographs are on my office.</p> <p>14 I look at them every day. Thank you.</p> <p>15 (Applause.)</p> <p>16 MS. CRISTINZIO: Thank you. Next, we have</p> <p>17 Lisa Gill.</p> <p>18 MS. GILL: Hello. I'm Lisa Gill. I am a</p> <p>19 health and medicine investigative reporter for</p> <p>20 Consumer Reports. I have been as a journalist</p> <p>21 covering prescription and over-the-counter drugs now</p> <p>22 for the better part of 20 years. And I've spent about</p>

<p style="text-align: right;">Page 246</p> <p>1 11 of those at Consumer Reports. Hang on here. Let's  2 figure out -- okay.  3 CBD for me personally represented a compound  4 that I had never really come across before, both in  5 terms of how people used it, why people used it, how  6 they purchased it, how it's regulated or not.  7 Consumer Reports had very similar feelings about it  8 and started to take a great interest in this product  9 about a year-and-a-half ago when we started seeing the  10 market flooded with products, the retail market and  11 online.  12 At the same time, we became quite concerned  13 by some of the safety problems uncovered by the FDA as  14 well as good researchers like Michelle Peace and Ryan  15 Vandrey and others.  16 At the same time, we also started to hear  17 stories of individual consumers telling us though that  18 CBD was actually very helpful to them. And so, we  19 took a deeper dive into this topic and the  20 organization made substantial investments in trying to  21 understand what was happening in the marketplace and  22 what was happening with consumers.</p>	<p style="text-align: right;">Page 248</p> <p>1 that I'm very delighted to show you today.  2 First off, number one, many adults use CBD.  3 The second, a majority of people told us that they  4 found it effective though for the thing that they were  5 trying to treat. And the third is that consumers may  6 assume that CBD is safe.  7 All right. So the first thing here, many  8 adult consumers, basically one out of every four adult  9 Americans told us that they had tried CBD at least  10 once in the last 24 months. About 70 percent of those  11 told us that they had taken the product more than  12 once.  13 One out of seven said that they take it on a  14 regular basis. If you're wondering, 26 percent of  15 adult Americans represents about 64 million people,  16 which is a lot. We also broke it down by age. You  17 can see it's concentrated mostly in the people under  18 the age of 44. But all generations are represented.  19 Okay. We also asked, hey, why do you use  20 this stuff? Number one reason, to reduce stress and  21 anxiety. Also joint pain. Eleven percent told us  22 they use it for fun or recreation. And I think that's</p>
<p style="text-align: right;">Page 247</p> <p>1 Now, you may know Consumer Reports as an  2 organization that -- nonprofit, that tests things like  3 cars and washing machines and washers and dryers and  4 even lawnmowers. But we have a long, 83-year history  5 in the area of consumer health and safety.  6 And I have to say I have no conflicts of  7 interest to report. Part of that is because Consumer  8 Reports does not accept any kind of advertising or  9 sponsorship or partnerships of any kind. We are  10 supported entirely by consumer members, millions of  11 them, and consumer donors.  12 We actually buy every product that we test  13 and we sell it back to people like me, employees, who  14 purchase those products. I've personally purchased a  15 number of coffeemakers on my own.  16 So part of the substantial investment that  17 Consumer Reports made in this space was a national  18 representative survey just this past January of 4,355  19 adults, adult Americans, a telephone survey asking  20 people all kinds of questions. Do you take CBD?  21 Where'd you get it from? Why did you buy it? Did it  22 work? And there were three really important takeaways</p>	<p style="text-align: right;">Page 249</p> <p>1 where we get into a whole other category. Ten percent  2 said they did it to help with their sleep. Not  3 surprisingly, millennials said they use it to treat  4 anxiety. Baby-boomers said that they use it to help  5 with their joint pain.  6 Also we asked, you know, what form do you use  7 it in. the top three that I think are really  8 important, particularly for this meeting, they told us  9 the top way they got it, they drink CBD or they eat it  10 or, second way, they use drops or oil sprays or they  11 vape it. I think that's important considering a lot  12 of the vaping research that's been done. There's  13 other ways as well.  14 Then we asked, you know, where do you guys  15 buy this stuff, just out of curiosity. So I was very  16 surprised to see that 40 percent get it from a  17 dispensary. That beat out 34 percent that said they  18 were getting it at a retail store. And please take  19 note here. One out of every four said they were  20 buying it online.  21 All right. Then we asked, well, is it  22 helpful for the thing you're trying to treat. A</p>

<p style="text-align: right;">Page 250</p> <p>1 majority here, for the people who said they were  2 treating it for stress or anxiety, I'd like you to  3 look at this column here. Sixty-three percent that it  4 was extremely or very effective.  5 The column on the right shows when people  6 said that it was slightly or not effective at all.  7 That was 16 percent. You can see that it helped 38  8 percent with joint pain.  9 Twenty-four percent were satisfied with how  10 they felt after using it for fun or recreation. And  11 half of them said that it helped with their sleep.  12 But taken in total, about half said that CBD was very  13 or extremely effective for them.  14 And this is the slide I'd like you to --  15 everybody should put down the phones and close the  16 computers because there are three stats on here that  17 are extremely important.  18 And the first one is that when we asked  19 people, hey, did you use your CBD to replace it with  20 any medication that you were taking, one out of every  21 five told us that they stopped taking a medication as  22 a result. And of that, a third said that they stopped</p>	<p style="text-align: right;">Page 252</p> <p>1 what are your top concerns, that the product wasn't  2 safe, only 13 percent told us that. They were  3 actually much more concerned that CBD would be too  4 expensive.  5 If you have any comments or questions, I  6 would love to hear it. If you think we're wrong about  7 anything or you'd like us to take a look at something,  8 let me know. I'm at Lisa, or lgill@consumer.org.  9 Thank you.  10 (Applause.)  11 PANEL MEMBER: Did you ask if they had given  12 it to pets?  13 MS. GILL: You know, we did not. But we have  14 done a couple -- or at least one story on pets. And  15 we do know that it is a growing area and that a lot of  16 people are very interested in how CBD might be able to  17 help their household pets. Thank you.  18 MS. CRISTINZIO: Thank you. Next, we have  19 speaker number 70, Yael Ossowski. Sorry.  20 MR. OSSOWSKI: Hey, you got it the second  21 time. Thank you. Good afternoon, FDA. Pleasure to  22 speak with you all. So I'm here on behalf of the</p>
<p style="text-align: right;">Page 251</p> <p>1 using their opioid prescriptions, and that includes  2 things like Percocet and OxyContin, Vicodin --  3 (Applause.)  4 MS. GILL: The other number that was  5 important and much higher than I expected, 30 percent  6 said that they were taking their CBD along with  7 medication, which is important. We did not ask them  8 if they did this with their doctor's advice or not.  9 That would hopefully be a follow-up survey.  10 All right. We also asked about side effects.  11 The majority told us no. But the 26 percent who did  12 said that they experienced a change in appetite or  13 fatigue. And don't forget, fatigue might be something  14 that they actually are looking for.  15 And in terms of the area of safety, most  16 important, half of the people told us that they were  17 extremely or very confident that there was a  18 regulation in place that required their CBD to be  19 tested for safety and accuracy by outside labs. But  20 we know if you get it at a retail store in most states  21 or online, that is absolutely not true.  22 It was also asking about safety, when we said</p>	<p style="text-align: right;">Page 253</p> <p>1 Consumer Choice Center. We are a consumer advocacy  2 group, ab it different than the previous speaker.  3 We're the group that is actually supporting lifestyle  4 freedom, innovation, privacy, science and consumer  5 choice. We are active around the world, though our  6 base is here in Washington, DC.  7 And the main policy areas that we focus on  8 are digital, mobility, we look a lot at lifestyle and  9 consumer goods and health and science. And it's in  10 that last category that we focus on cannabis and  11 specifically CBD.  12 We've worked on this issue internationally.  13 We've done a lot, particularly in Canada where  14 cannabis is now legal recreationally, and also in many  15 local jurisdictions throughout the United States and  16 also now in Luxembourg, which is to be the next  17 European country that will legalize recreationally.  18 So our goal is to promote smart cannabis  19 policy. The idea that you're going to promote  20 competition, that you're going to promote safety and  21 you're going to eradicate black markets.  22 I believe the previous speaker mentioned a</p>



<p style="text-align: right;">Page 254</p> <p>1 lot of issues before. I think that really comes  2 because of the black markets because there is no  3 regulation and it's left only where there is no  4 regulation, there are no rules and there's no way for  5 consumers especially to have good products or to know  6 what the products are.</p> <p>7 So I'm going to go through some of our points  8 here, things that are very important for us, looking  9 at smart regulation. Number one is going to be clear  10 labeling standards. I think that's probably one of  11 the most important things.</p> <p>12 It sounds as if there are many consumers in  13 the house who've been to some CBD shops or stores.  14 They've been able to see what some of the products are  15 there. But we don't necessarily know the exact  16 percentage.</p> <p>17 And as a consumer, how are you supposed to  18 know exactly what to take, how much to take, at what  19 cost? This is the thing that's very important to  20 know, is that as old as the cannabis industry or  21 cannabis use has been, everyone is new to the new  22 legal CBD market. Therefore we need to have great</p>	<p style="text-align: right;">Page 256</p> <p>1 Next is age restriction. I know that this is  2 important for a lot of people here. I know that there  3 are probably going to be a lot of people advocating  4 for 21. When it comes to the smokable products,  5 obviously an 18 age restriction we think is very  6 appropriate.</p> <p>7 But because of the oils and the edibles and  8 this entire new industry that's coming about, that's  9 something to where the age restrictions might not be  10 as necessary and assuming that we have clear laws and  11 standards, should be addressed in the right way.</p> <p>12 But to have a total 18-plus or 21-plus even  13 age restriction on all CBD products, we don't really  14 think that's going to be helpful, particularly to the  15 medical consumers who are going to need that.</p> <p>16 Next is the benefits and the side effects.  17 Obviously as many researchers have pointed out, there  18 is a need for more research, for more information.  19 But we don't need to allow the companies that are  20 marketing. As consumers, we need to be able to know  21 what are the health claims. Can they prove them? And  22 they should be allowed to testify that and to include</p>
<p style="text-align: right;">Page 255</p> <p>1 clarity and great labeling as to how much CBD is in  2 this, how much THC is in this. That's very important  3 for consumers. Otherwise they have no idea exactly  4 what they're taking and the effect that will be on  5 them.</p> <p>6 The second point is to allow branding and  7 advertising of CBD goods. I know this is already  8 happening. So we're just kind of regulating after the  9 fact. But we have to allow companies and brands to  10 exist because that's the only way the consumers are  11 going to be able to differentiate between good  12 products and bad products. We allow that with every  13 other product.</p> <p>14 Unfortunately in Canada, there they've plain-  15 packaged a lot of their cannabis products. So there  16 is no branding necessarily. You can't really tell the  17 differences between brands. And because consumers  18 don't have that option, they're not really able to  19 establish loyalty. They can't figure out exactly  20 which product is meant for them and they can't figure  21 out if it's a bad company and a product that they  22 don't want to use.</p>	<p style="text-align: right;">Page 257</p> <p>1 that in their promoting and in their branding.  2 As a consumer, it's very important to know  3 that what the side effects are going to be, what the  4 benefits are going to be. We think that's very  5 important and something that should be upheld.</p> <p>6 And lastly, harm reduction. So the idea is -  7 - and the mistakes that were made in Canada when it  8 came to cannabis legislation is they actually  9 legalized the flower and the oils first.</p> <p>10 So if you wanted to consume cannabis, you  11 could only smoke it. You couldn't have any brownies  12 or chocolates or food or drink. And that's been very  13 bad for many people who would like to take these  14 products and not have that additional harm.</p> <p>15 So we need to allow CBD to be infused in many  16 of these products and allow consumers to ingest them  17 in the least harmful way possible. And I have some  18 testimonials of people who do use CBD that is  19 available and you can follow us, Consumer Choice  20 center. Thank you very much.</p> <p>21 (Applause.)  22 PANEL MEMBER: I have a question.</p>

<p style="text-align: right;">Page 258</p> <p>1 MR. OSSOWSKI: Yes, ma'am.</p> <p>2 PANEL MEMBER: I have a question for you.</p> <p>3 What evidence do you have about the different routes</p> <p>4 of administration that causes you to have a</p> <p>5 distinction of age restrictions between different</p> <p>6 types of infused products?</p> <p>7 MR. OSSOWSKI: That's been done in some</p> <p>8 states, in some markets. Again, this is --</p> <p>9 PANEL MEMBER: But in terms of its effect on</p> <p>10 the body, why would it -- do you have evidence that</p> <p>11 shows that some routes are different than others that</p> <p>12 would justify having different age limits for</p> <p>13 different routes of administration?</p> <p>14 MR. OSSOWSKI: In that case, we're mostly</p> <p>15 talking about medical uses and because if you have the</p> <p>16 blanket ban, then you have exceptions, then we're just</p> <p>17 carving out laws that's carving out laws. It has to</p> <p>18 be as general as possible so it can be applied.</p> <p>19 Ideally if there's going to be any age</p> <p>20 restriction, we talk about 18. Ideally there wouldn't</p> <p>21 be perhaps. That's to be determined by obviously your</p> <p>22 agency. So thank you very much. Any other questions?</p>	<p style="text-align: right;">Page 260</p> <p>1 evidence that I'm going to share with you today</p> <p>2 relative to the need for de-scheduling cannabis.</p> <p>3 What do we know about cannabis as medicine?</p> <p>4 Conservatively, it's estimated that more than 60,000</p> <p>5 doctors are practicing cannabis medicine and there are</p> <p>6 more than 3 million registered medical marijuana</p> <p>7 patients. The stories these docs tell are variations</p> <p>8 of miraculous cures in patients who found no relief</p> <p>9 from conventional medicine.</p> <p>10 Some examples. A young teen whose 70 chest</p> <p>11 tumors disappeared. A two-year-old with brain cancer</p> <p>12 not expected to live three months is now six-and-a-</p> <p>13 half. Dramatic decreases in opioid use, helping to</p> <p>14 resolve this heinous health crisis. Veterans who</p> <p>15 experienced horrible PTSD experiencing powerful</p> <p>16 relief.</p> <p>17 These stories are not miracles. They're</p> <p>18 empirical evidence that cannabis is potent medicine.</p> <p>19 It works when approved medicines do not. And it works</p> <p>20 for a wider range of conditions than any medicine</p> <p>21 known.</p> <p>22 Here is a composite of the -- of all the</p>
<p style="text-align: right;">Page 259</p> <p>1 Okay. Thank you.</p> <p>2 MS. CRISTINZIO: Thank you. Now we are</p> <p>3 moving onto the health professionals category.</p> <p>4 Speaker number 71, Ann Allworth?</p> <p>5 HEALTH PROFESSIONALS</p> <p>6 DR. ALLWORTH: I've got to get this down.</p> <p>7 There we go. Hello, everyone. I'm Dr. Ann Allworth</p> <p>8 and I'm very grateful to have this incredible</p> <p>9 opportunity to share the reasons why I, like thousands</p> <p>10 of other scientists and doctors, believe that the</p> <p>11 endocannabinoid system is scientific proof that</p> <p>12 cannabis is medicine.</p> <p>13 I'm a cell biologist who studied, researched</p> <p>14 and taught various aspects of the human body for over</p> <p>15 35 years. Cells, medical school gross anatomy, breast</p> <p>16 and ovarian cancer, innate intelligence, the critical</p> <p>17 role diet has to human wellbeing. And over these</p> <p>18 years, I've acquired much wisdom about human health,</p> <p>19 which has led me here today.</p> <p>20 We need to know -- we know the needed</p> <p>21 cannabis research cannot be done. So please give</p> <p>22 strong consideration to the fundamental empirical</p>	<p style="text-align: right;">Page 261</p> <p>1 qualifying conditions that are in the legal states.</p> <p>2 There are more than 75 of them. And these conditions</p> <p>3 are as disconnected as autism is to pancreatitis as</p> <p>4 cancer is to multiple sclerosis.</p> <p>5 There's no time to read all of these. These</p> <p>6 slides are here to emphasize their number and range of</p> <p>7 beneficial effects this medicine provides for</p> <p>8 conditions in every single system of the body.</p> <p>9 Some of you might ask, well, just how</p> <p>10 effective is this medicine. Let's look at three of</p> <p>11 the commonly treated ailments: migraines, epilepsy and</p> <p>12 chronic pain. Dr. Patricia Frye, of Takoma Park</p> <p>13 Alternative Care in Maryland, saw a 60 to 75 percent</p> <p>14 decrease in opioid use in 80 percent of her patients</p> <p>15 with chronic pain. And in patients with migraines and</p> <p>16 chronic headaches, 66 percent showed definite</p> <p>17 improvement.</p> <p>18 Dr. Dustin Sulak in Maine, Russell Saneto in</p> <p>19 Washington and Bonni Goldstein in California published</p> <p>20 a very important paper in Epilepsy Behavior using</p> <p>21 pooled data on epilepsy patients treated with</p> <p>22 artisanal whole-plant cannabis. In 272 patients with</p>

<p style="text-align: right;">Page 262</p> <p>1 medically refractory epilepsy, 86 percent had some 2 decrease in the number of their seizures. 3 Clearly cannabis is effective medicine. But 4 how is it that cannabis can fix 75 very diverse 5 ailments? The answer is the endocannabinoid system, a 6 critically important body system, a system that 7 regulates every system in our body, and when it's 8 disrupted, can manifest as the very conditions we just 9 saw. 10 So let's take a quick look at the components 11 of the system, the ECS. Receptors include CB1, CB2, 12 CB3. We have endocannabinoids AEA and 2-AG which we 13 make in our body that our body uses to maintain 14 balance. We have the enzymes that synthesize them, 15 the enzymes that degrade them. 16 So what does the ECS have to do with cannabis 17 as medicine? The simple answer is everything. And 18 though empirical, it is important fundamental 19 knowledge that needs to be recognized. Just look at 20 the relationship of the endocannabinoid system to 21 other body systems. 22 Our systems include the reproductive, the</p>	<p style="text-align: right;">Page 264</p> <p>1 Bryant. I'm president of -- and managing member of 2 Vyripharm Biopharmaceutical. We're located in 3 Houston, Texas in the medical center and we -- we're 4 located in the Texas Medical Center and we work with 5 several institutions within the medical center. 6 Vyripharm is focused on diagnostic and 7 therapeutic application in the area -- in the areas of 8 neurological disorders and cancer. The focus was to 9 present the company where we can integrate medicinal 10 cannabis with traditional medicine. So medical 11 cannabis integrated with traditional medicine was sort 12 of the platform. 13 We had to ask several questions. The 14 question that we had to ask is, is medical cannabis a 15 medicine. Did it have uniformity in the sector? 16 Diagnostic application, meaning the dosing issues as 17 well as the biodistribution. Also the treatment 18 outcome, how can be quantitate? Do we have -- can it 19 fall into the category of personalized medicine and 20 IP, intellectual property? 21 We were able to develop a collaboration with 22 the University of Texas MD Anderson Cancer Center.</p>
<p style="text-align: right;">Page 263</p> <p>1 urinary, the digestive, the respiratory, the 2 endocrine, the circulatory, the nervous, lymphatic 3 immune, skeletal, muscular. 4 So where does the ECS fit into this picture? 5 It literally coexists with cells in all systems of the 6 body. It is everywhere. It maintains balance in 7 every system and between systems. Research, primarily 8 animal studies, shows that disruptions of ECS 9 components are seen in many conditions. 10 Conventional medicine is never effective 11 because it's not treating the real issue. Cannabis 12 resolves a broad spectrum of issues because it fixes 13 the disrupted endocannabinoid system. And it is the 14 only medicine that can do this. All of this is 15 fundamental evidence demonstrating that cannabis is in 16 fact actual medicine which should be de-scheduled. 17 Thank you. 18 (Applause.) 19 DR. ALLWORTH: Any questions? 20 MS. CRISTINZIO: Thank you. Now we're moving 21 onto speaker number 72, Jerry Bryant. 22 MR. BRYANT: Thank you. My name is Jerry</p>	<p style="text-align: right;">Page 265</p> <p>1 And lo and behold, we studied some of the malignant 2 lymphoid cell lines. We were able to use medical 3 cannabis to treat and look at the efficacy of the -- 4 and cytotoxicity of those cells. And we determined 5 that medical cannabis is a drug. 6 The work that's been done by companies such 7 as Vyripharm can only deliver its true benefit to the 8 public if the federal government takes the lead in 9 developing a uniform and comprehensive approach 10 towards cannabis products. Uniformity means the 11 federal government must resolve inconsistencies in 12 state and local approaches. Comprehensive means 13 guidelines, effective testing, QC/QA and clear and 14 consistent product labeling. 15 Let me move to the next slide here. There we 16 go. As you can see from this slide, we have pure 17 chaos. In the absence of federal regulation, dozens 18 of states have legalized medical and recreational 19 cannabis products that have been left to their own 20 devices. 21 According to the study performed by the 22 Center for Public Health Law Research at Temple</p>

<p style="text-align: right;">Page 266</p> <p>1 University in the area of health policy, states are  2 serving as laboratory democracies.  3 But the exercise is only productive if  4 research, which we have done, and partnered in Texas  5 Medical Center, step up to rigidly evaluate the impact  6 on state innovation.  7 We largely have no idea about how well these  8 laws protect patients and the public. The FDA really  9 need to integrate and help this industry with  10 guidelines on standardization. Uniformity is a  11 necessity when it comes to the development of safe and  12 effective medicine. It is only through uniform  13 standards that regulators, sellers and customers can  14 learn about what actually makes one product different  15 from the other.  16 And so, you get some normalcy and  17 differentiation in this whole process. And that's one  18 thing that Vyripharm has really designed platform to  19 maybe assist the FDA in establishing.  20 Accessibility is critical. In addition of  21 uniform standards, information collected must be under  22 a universal, recognizable, usable platform and the</p>	<p style="text-align: right;">Page 268</p> <p>1 cause right now. But every day the federal government  2 delays in taking the need puts more consumers at risk  3 and puts the true benefits of these medical products  4 out of the grasp. We look forward to partnering with  5 FDA and other regulatory officials in this important  6 issue. Thank you for the opportunity to speak.  7 MS. CRISTINZIO: Thank you.  8 MR. BRYANT: Thank you.  9 MS. CRISTINZIO: We have two more speakers  10 before we break for lunch. Next up is Najla Guthrie,  11 speaker number 73.  12 MS. GUTHRIE: Thank you. Good afternoon.  13 I'm Najla Guthrie, CEO and president of KGK Science, a  14 global health and wellness contract research  15 organization.  16 KGK Science has been designing and conducting  17 clinical trials for over 22 years to support clients  18 with product development claims, claim substantiation  19 and new dietary ingredient notifications. KGK Science  20 is a subsidiary of Oxley Cannabis Group, operating in  21 Canada and abroad.  22 The volume -- sorry. The volume of</p>
<p style="text-align: right;">Page 267</p> <p>1 status quo, which we have now, different states use  2 different testing protocols.  3 Tests have different components, track  4 products differently and do not share information with  5 each other. However, the entire supply chain needs to  6 have access to the best and most consistent  7 information.  8 What we have learned at Vyripharm means  9 embracing what new technology has to offer. For  10 example, we have developed an interface and database  11 using block chain technology that allows access to  12 extensive product information down to the strain  13 source, genotype, phenotype and particular plant that  14 you can correlate with a patient.  15 If we actually think that medical cannabis is  16 a medicine, well, let's treat it as medicine. We do  17 hold tremendous medical potential. Then we must treat  18 this medicine as medicine. Consumers of medicine in  19 our country know and they can rely on the information  20 of medical labeling because we have to build a uniform  21 and comprehensive platform.  22 Companies like Vyripharm are leading this</p>	<p style="text-align: right;">Page 269</p> <p>1 unsubstantiated claims being made on CBD products is a  2 clear abuse of the rules set forth by FDA and FTC.  3 CBD foods are not permitted to make disease or  4 therapeutic drug claims.  5 CBD has been marketed for multiple broad  6 areas besides rare epilepsy in children. It has been  7 marketed for its neuroprotective, anxiolytic,  8 antipsychotic, analgesic, anti-inflammatory and anti-  9 asthmatic properties, as well as combatting hypoxic  10 ischemia.  11 FDA has asked what systems are in place to  12 ensure adverse events are collected to mine toxicology  13 signals and about margins of exposure. Dietary  14 supplements are the only food commodity which there is  15 a mandatory reporting requirement for serious adverse  16 events.  17 CBD is a new dietary ingredient. NDI  18 notifications must provide the basis for reasonable  19 expectations of safety, which should include the NOEL.  20 FDA asks about margin of exposure. Knowing the margin  21 of exposure is a critical component of the NDI  22 evaluated by the NDI review team at FDA CFSAN.</p>

<p style="text-align: right;">Page 270</p> <p>1 There are clear gaps in safety. But FDA has  2 an established NDI process to receive and evaluate  3 those concerns. There are two main intercellular  4 targets for CBD, namely CB1 and CB2 receptors. They  5 are located in the central nervous system and some  6 expression in peripheral tissues on cells with immune  7 function and in the GI tract.</p> <p>8 However, a pharmacologist might ask -- or  9 might say that CBD is a dirty rather than a clean  10 compound, not because of where it acts or any bad  11 connotation. It acts on a wide array of intercellular  12 targets. Therefore it is not surprising that there is  13 a diverse array of purported uses.</p> <p>14 CBD is considered to have low toxicity. In  15 clinical trials and research studies, CBD is  16 administered orally as either a capsule or dissolved  17 in an oil solution. It can also be administered  18 through sublingual or intranasal routes.</p> <p>19 A wide range of oral doses have been reported  20 in the literature, from 100 up to 800 mg per day. It  21 is used in Epidiolex at up to 20 mg/kg daily with some  22 concern in patients with hepatic impairment. This is</p>	<p style="text-align: right;">Page 272</p> <p>1 concentrations.</p> <p>2 In terms of unique populations such as  3 pregnant women and elderly, one should consider  4 undertaking safety studies for NDI notification or  5 other safety dossier. There is a clear knowledge gap  6 in our understanding of CBD which should be addressed  7 in the future if products are to be intended for these  8 sensitive populations.</p> <p>9 The Epidiolex dosing guidelines indicate that  10 with severe hepatic impairment, dosing should vary  11 between 1 and 4 mg/kg/day. A significant difference  12 however is that Epidiolex is exclusively directed to  13 pediatric patients, which are not considered smaller  14 versions of adults.</p> <p>15 CBD in foods is typically marketed to healthy  16 adults and should never be marketed to those with  17 hepatic impairment. In addition, there should  18 probably be a voluntary black box warning on all CBD  19 food products, conventional food or dietary supplement  20 that they should not be used in the setting of liver  21 disease.</p> <p>22 And to conclude, the recommendations for</p>
<p style="text-align: right;">Page 271</p> <p>1 not surprising, given its liver metabolism.</p> <p>2 Studies on CBD show no effect on embryonic  3 development. CBD has no effect on a wide range of  4 physiological and biochemical parameters unless  5 administered at extremely high doses.</p> <p>6 CBD has no mutagenic potential, based upon  7 Ames, comet and micronucleus assays. In rats, CBD at  8 low doses does not change the threshold for  9 intracranial cell stimulation. At higher doses, CBD  10 actually raises the threshold, meaning that it  11 interferes in reward behavior. This is the exact  12 opposite of what drugs of abuse do, like cocaine and  13 opioids. Drugs of abuse lower the threshold.</p> <p>14 In human clinical research, CBD was not  15 associated with abuse potential or addiction. Unlike  16 THC, CBD showed no physiological changes on heartrate,  17 psychotic symptoms or anxiety.</p> <p>18 In terms of food, nutraceutical and drug  19 interaction, there is only potential for CBD to be  20 associated with drug interactions through inhibition  21 of some cytochrome P450 enzymes. However it is not  22 yet clear whether these effects occur at physiological</p>	<p style="text-align: right;">Page 273</p> <p>1 labeling and claims for dietary supplements containing  2 hemp-derived CBD extracts is to remove the inclusion  3 clause in 201(ff) for CBD products to permit  4 eligibility as dietary ingredients. Issue a  5 regulation approving as a food substance under section  6 301(ii).</p> <p>7 Enforce the regulations from the Dietary  8 Supplement, Health and Education Act of 1994 and the  9 1990 Nutritional Labeling and Education Act. This  10 would require an NDI notification within 75 days of  11 marketing, would require GRAS affirmation and NDI  12 status will allow lawful companies to make  13 scientifically validated health claims regarding  14 nutrient content, structure function and qualified  15 claims.</p> <p>16 And amend the labeling regulations to include  17 separate identity statement and standardized hemp-  18 derived CBD symbol. And thank you for allowing me the  19 opportunity to speak today.</p> <p>20 (Applause.)</p> <p>21 PANEL MEMBER: Quick question. As a CRO in  22 this space, how many CBD-related studies do you</p>

<p style="text-align: right;">Page 274</p> <p>1 currently have ongoing?</p> <p>2 MS. GUTHRIE: We've got I believe around nine</p> <p>3 of 10 studies now going on and a number of them are</p> <p>4 looking at the pharmacokinetic properties of CBD and</p> <p>5 THC being located in Canada where we're able to look</p> <p>6 at both of those, as well as other indications.</p> <p>7 So we're looking at indications such as</p> <p>8 sleep, anxiety, pain are some of the indications we're</p> <p>9 looking at.</p> <p>10 PANEL MEMBER: Thank you.</p> <p>11 MS. GUTHRIE: And we plan to submit written</p> <p>12 comments as well.</p> <p>13 MS. CRISTINZIO: Great. Thank you. We have</p> <p>14 one last speaker before we break for lunch, Lucille</p> <p>15 Vega.</p> <p>16 DR. VEGA: Hello, and thank you for allowing</p> <p>17 me to speak today. My name is Dr. Lucille Vega. I</p> <p>18 have a degree in biology at University of Irvine --</p> <p>19 University of California, Irvine. I went to medical</p> <p>20 school at Dartmouth Medical School, Brown University</p> <p>21 for residency and also I have been on concierge</p> <p>22 private practice, private practice for the last 19-</p>	<p style="text-align: right;">Page 276</p> <p>1 the CBD drip, or the EcoDrop now, 88.7 percent would</p> <p>2 recommend the EcoDrop to their fellow friends or</p> <p>3 family members.</p> <p>4 Other witnessed benefits that I have seen,</p> <p>5 there's a list here. You've seen more today I'm sure.</p> <p>6 But PTSD, that one really surprised me. I was very</p> <p>7 excited to see that. As far as concussions and</p> <p>8 diabetic neuropathy, wow, I'm impressed. PMS, sure.</p> <p>9 And then, high blood pressure, wow, I'm lowering blood</p> <p>10 pressures right inside the office. That's fantastic.</p> <p>11 Other benefits of the EcoDrop oil I saw,</p> <p>12 arthritis in canines and separation anxiety. There's</p> <p>13 a full list. Not enough room on this slide. Other</p> <p>14 CBD products I use is PainQuench cream and also</p> <p>15 FreshLeaf edibles.</p> <p>16 Again, I did not believe this stuff would</p> <p>17 work. PainQuench cream, I was surprised that folks</p> <p>18 were coming to me and saying, hey, it works for my</p> <p>19 psoriasis patches. Plantar fasciitis, diabetic</p> <p>20 neuropathy. What? I did not understand. Wow.</p> <p>21 Second degree burns, you kidding me? Wow.</p> <p>22 Acne. And then, as far as the edibles, a lot of</p>
<p style="text-align: right;">Page 275</p> <p>1 and-a-half years.</p> <p>2 When I first heard about CBD, I did not</p> <p>3 believe it worked. I thought it was snake oil. Oh,</p> <p>4 come on. This is from the medieval times. Are you</p> <p>5 kidding me? I would have learned this in medical</p> <p>6 school, right?</p> <p>7 Well, since then, I have done a trial with</p> <p>8 EcoDrop oil. Since it's full spectrum, it has the</p> <p>9 CBD, CBG, CBC and that trace amount of THC, less than</p> <p>10 0.3 percent. In my trial, the first question -- let's</p> <p>11 do this here. In my trial, the first question is</p> <p>12 pain: 65.5 percent dropped their pain scale by two</p> <p>13 points. Pretty significant in my book.</p> <p>14 Number two, sleep question. Let's get back</p> <p>15 to that sleep question: 43.1 percent gained more than</p> <p>16 two hours of sleep. Here's the abdominal question.</p> <p>17 To save time, here's a quick review of the results.</p> <p>18 Also for my headaches and migraine question as well.</p> <p>19 Moving along, buckle up, folks. We have a</p> <p>20 lot more to go. Anxiety, 75.3 percent had a reduction</p> <p>21 of their anxiety symptoms or the intensity of it. And</p> <p>22 then, my last question, would other people represent</p>	<p style="text-align: right;">Page 277</p> <p>1 people came to me and said the anxiety and the sleep,</p> <p>2 it really helped with that. Again, I'm always about</p> <p>3 minimal effective dosing. I remember in medical</p> <p>4 school, first do no harm.</p> <p>5 Here we have PTSD trigger prophylaxis.</p> <p>6 People are using it at 7.5 mg per dose, two to three</p> <p>7 times a day. You may see these as low numbers. But</p> <p>8 with the full spectrum oil, it doesn't require as --</p> <p>9 I'm noticing it doesn't require as much CBD isolate.</p> <p>10 Okay. Post-concussion, people are using it</p> <p>11 10 mg. We usually do it three times a day for a week</p> <p>12 and then twice a day. Autism, seeing a lot of good</p> <p>13 results in adults with 37.5 mg, all using this EcoDrop</p> <p>14 oil because it's full spectrum.</p> <p>15 Most common side effects, it's too relaxing.</p> <p>16 Perhaps that's dose-dependent, which I believe it is.</p> <p>17 Next, my thoughts about safety, I prefer sublingual</p> <p>18 dosing.</p> <p>19 Why? One, I didn't get many complaints in</p> <p>20 the medications interactions because they're my</p> <p>21 primary care patients. I know what they're writing.</p> <p>22 And do I write for pain medication? Absolutely. And</p>

<p style="text-align: right;">Page 278</p> <p>1 I'm here to testify, to say, look, I want to be part 2 of the solution. 3       Okay. We had Coumadin and dialysis patients. 4 Again, no major interactions. In fact, there were no 5 interaction complaints in that trial. Also I didn't 6 have to worry about that first pass effect with the 7 sublingual dosing. That's why as a physician I prefer 8 sublingual dosing. 9       Oral consumption, the minimal dose necessary, 10 I have no complaints at the -- I had no complaints at 11 the 50 mg or less at one to two times a day. Topical 12 application, of course not for open wounds. On dry 13 skin. 14       Last thing, my thoughts about public safety 15 issues. Definitely lab results need to be found 16 online or easy in the packaging for consumer. I would 17 prefer as a physician also product testing, which 18 we've heard before today, heavy metals, 19 organophosphates, pesticides, to name a few. 20       We need more research. We need more 21 research. We need more education for physicians. 22 Why? Because people are coming to me, coming to the</p>	<p style="text-align: right;">Page 280</p> <p>1       PANEL MEMBER: -- or are you talking about 2 actually consuming a fresh leaf? 3       DR. VEGA: it is a brand name of a product, 4 correct. 5       PANEL MEMBER: Okay. Thank you. 6       DR. VEGA: Sorry about that. 7       PANEL MEMBER: So it's a processed product. 8       DR. VEGA: Mm-hmm. (Affirmative.) 9       PANEL MEMBER: Not a fresh -- okay. 10       DR. VEGA: A processed product, edible. 11       PANEL MEMBER: Thank you. 12       PANEL MEMBER: And when you're recommending a 13 specific -- when you're recommending a patient use CBD 14 for a specific use, you had several on your slide, how 15 have you determined what dose to recommend for each 16 use? 17       DR. VEGA: So I always start with sublingual 18 because, to me, I don't have to worry as much about 19 the medications that they're taking. 20       I figure most people over 55 are probably one 21 some type of anti-hypertensive, cholesterol medication 22 and such. So I always start with 1 mg and let's see</p>
<p style="text-align: right;">Page 279</p> <p>1 ER asking us physicians what do I do. I need to know 2 what's online. Or if you're putting out a product, 3 what do you have in there. What am I concerned about, 4 so I can start to assess this patient. 5       Labeling. My biggest pet peeve as a 6 physician, seeing these CBD companies put out 1,000 mg 7 in a bottle. I want to know what's the milligram per 8 smallest dose unit, per drop, per edible, et cetera. 9 Also, definition, broad spectrum, full spectrum, we 10 should probably get a consensus on it, possibly a new 11 language considering how many cannabinoids are in this 12 particular product. There are one, two, three, four 13 cannabinoids. 14       It looks like the FDA may have to bring me 15 back for some more information on my study. And thank 16 you all for listening and being here today and 17 testifying. Thank you. 18       PANEL MEMBER: I have a quick question. I 19 saw on your slides you said something about a 20 FreshLeaf edible. And I wasn't -- is that a brand 21 name of a product -- 22       DR. VEGA: It is.</p>	<p style="text-align: right;">Page 281</p> <p>1 how you do, the lowest dose possible. 2       PANEL MEMBER: Are there any conditions for 3 which you are screening patients before recommending 4 use of CBD? So liver issues or things like that? 5       DR. VEGA: I actually take that into 6 consideration with the liver. That's why I start with 7 the very lowest dose, possibly maybe half a milligram 8 and see how we do. 9       But on the other end, I know what I'm 10 prescribing them for their blood pressure, their 11 cholesterol and such. And so, that's constantly in 12 the back of my mind. 13       Every person I see, I always want to know 14 what's your kidney function, what's your liver 15 function and what's your blood pressure. Absolutely. 16 Thank you very much. 17       MS. CRISTINZIO: Thank you. 18       (Applause.) 19       MS. CRISTINZIO: We are now going to take a 20 break. Unfortunately we went a little over and we're 21 going to have to take some of that time out of the 22 lunch. We will reconvene at 1:30. Thank you.</p>

<p style="text-align: right;">Page 282</p> <p>1 (Whereupon, the foregoing went off the 2 record.) 3 MS. CRISTINZIO: Sue, on the line, give us 4 one more minute. 5 DR. SISLEY: Sure. 6 MS. CRISTINZIO: Okay. We are ready to begin 7 our afternoon program. The good news is we're about 8 halfway through our speakers. We have joining us on 9 the phone, continuing our health professionals 10 segment, Sue Sisley from Scottsdale Research 11 Institute. And she's going to tell us verbally when 12 to move the slides forward. Thank you. Go ahead, 13 sue. 14 DR. SISLEY: Okay. Wonderful. I'm Sue 15 Sisley. I'm an internal medicine physician from 16 Arizona and I'm the head of Scottsdale Research 17 Institute. You can see on the next slide our mission 18 is to strive to evaluate the safety and efficacy of 19 smoked and vaporized cannabis flower. So we're 20 striving to put flower through the entire FDA drug 21 development process. 22 On the next slide you'll see we just</p>	<p style="text-align: right;">Page 284</p> <p>1 Next slide you'll see, you know, we were 2 somewhat optimistic to see that the DEA announced on 3 the Federal register back in 2016 that they would 4 finally license other growers for research. 5 And on the next slide, you'll see that even 6 though the DEA received almost 30 applications from 7 potential growers that wanted to provide cannabis for 8 clinical trials, the DEA has not processed any of 9 these applications. And despite members of Congress 10 repeatedly urging the DEA to either process the apps 11 or explain the delay, we've gotten no response to 12 these letters. 13 And the next slide shows you a good example 14 of one of the -- of one of over a dozen bipartisan 15 letters that was sent to DEA asking for an 16 explanation, and nothing. 17 So you'll see, next slide, shows you that the 18 real issue for us is the fact that we don't have 19 flower to use for FDA Phase III trials. So right now, 20 you know, the FDA of course requires that whatever 21 drug you use in Phase III, it's a drug that you would, 22 you know, go to market with later.</p>
<p style="text-align: right;">Page 283</p> <p>1 completed an FDA Phase II trial looking at four 2 different varieties of cannabis for military veterans 3 with PTSD. And on the next slide, you'll see why this 4 study took us 10 years to get through, you know, to 5 navigate all of the regulatory hurdles. 6 And this schematic really demonstrates the 7 excessive layers of government red tape involved in 8 trying to study efficacy of cannabis through the -- 9 you know, the regular drug development process. 10 The next slide, you'll see these are some 11 examples of pictures from investigators who used NIDA 12 study drug in the past. The top ones were from a few 13 years ago. The bottom picture is our most recent 14 shipment from NIDA and on the next slide you'll see we 15 were one of the first scientists to ever do secondary 16 independent testing on the cannabis from NIDA. 17 And we sent this to Schedule 1 licensed 18 laboratories in the U.S. to do proper testing. And we 19 did three rounds of testing that all showed 20 excessively high levels of mold in all the batches 21 that would not have passed state testing in any of 22 these regulated markets that mandates testing.</p>	<p style="text-align: right;">Page 285</p> <p>1 And NIDA cannabis is not authorized, you 2 know, to be available for sale as a prescription FDA- 3 approved medicine. So there's currently no way to put 4 flower through the entire FDA process unless we use 5 flower from a foreign manufacturer. 6 So next slide, you'll see here are just our 7 final points for the FDA, things that we hope you can 8 address. We'd like to see the paradigms with 9 botanical medicine become different than the paradigms 10 we use for standard pharmaceutical prescriptions. 11 Like we hope that eventually you'll allow, embrace the 12 idea of patient self-titration. 13 We're using that in the recent study we just 14 completed. Patient self-titration was an optimal way 15 of administering smoked cannabis flower because it 16 allows for small variations in the potency of the 17 flower and it enables patients to discover a much 18 lower therapeutic dose and avoid a lot of the adverse 19 events that we see when patients overuse flower. 20 So next slide, you'll see that we also hope 21 that the way you define GMP will evolve to ensure that 22 we're only getting the flowering tops of the plants,</p>



<p style="text-align: right;">Page 286</p> <p>1 not the extraneous plant material, stems, sticks,                  2 leaves, that all, you know, confound the efficacy of                  3 the study drug.                  4       The idea is just flower only and other things                  5 that we agree on that should be GMP, like free from                  6 pesticides, free from microbial and mycotoxins. But                  7 the idea is not so over-processed that it no longer                  8 resembles real world flower. We feel that in this                  9 excessive exuberance to make sure that the cannabis                  10 flower is so standardized, that we lose a lot of the                  11 efficacy of the natural flower.                  12       So finally, the next slide shows you that our                  13 big push here today is to urge you to help us, you                  14 know, work with the DEA to urge them to make good on                  15 their pledge to the public and license other growers                  16 for research so that we can finally put flower through                  17 the Phase III trials because currently there is no                  18 federally legal drug supply for drug that can be used                  19 in Phase III and then sold later as a prescription                  20 medicine.                  21       And the next slide shows you, this is my                  22 final point, that the next clinical trial at our</p>	<p style="text-align: right;">Page 288</p> <p>1 think we'll be bringing up our slide in a minute.                  2 I'll just go ahead and introduce myself to start. I                  3 started -- I'm not a billionaire. I'm not a lobbyist.                  4 I am an owner of a company that I started. I am a 15-                  5 year veteran, served overseas a couple different                  6 deployments, honorably discharged. And my partners                  7 and I had no idea what CBD was a few years ago.                  8       We started looking at what could help, what                  9 would make a positive difference. This is what we got                  10 into looking at vets and trying to have a positive                  11 impact. Since that time, we've become a single point                  12 manufacturer with a large network. We work at all                  13 different levels.                  14       And we'll start with the farms. A lot of the                  15 other stuff has been touched on. But I want to hit a                  16 couple of these points. So one of the things that we                  17 do is working with the farms and the farming co-ops is                  18 these farmers, you have micro farmers, one acre, five                  19 acre plots and then you have these large farmers.                  20       One of the things that wasn't addressed that                  21 is going to be important, there's going to be a                  22 surplus of biomass and there's going to be a limited</p>
<p style="text-align: right;">Page 287</p> <p>1 laboratory will be looking at smoked cannabis flower                  2 compared to fentanyl for late-stage cancer patients                  3 with breakthrough pain.                  4       But lastly because of the -- you know, of                  5 this limitation with the current drug supply, we are                  6 forced to import study drug from a Canadian                  7 manufacturer. And that's disappointing to us. We'd                  8 like to see our own domestic -- you know, a variety of                  9 domestic manufacturers. The point is that researchers                  10 need access to options. Scientists need options to                  11 embolden scientific freedom. And my last slide just                  12 gives you my contact information. Thank you very                  13 much.                  14       MS. CRISTINZIO: Thank you, Sue. All right.                  15 I think we're about to move onto our next category of                  16 speakers. We have next manufacturers up. And the                  17 first one is number 76.                  18       MR. BLEHAR: Is that me?                  19       MS. CRISTINZIO: Number 76, Justin Blehar.                  20 MANUFACTURERS                  21       MR. BLEHAR: Hi, guys. How are you? I'm                  22 Justin Blehar, with Genco Pura Oil Company. And I</p>	<p style="text-align: right;">Page 289</p> <p>1 amount of certified extraction places to make CBD. We                  2 also work with the networks of these labs. These labs                  3 could be anywhere of something like a small corner                  4 area over there that God knows what they're putting in                  5 there in the back of their room, sending out isolate,                  6 broad spec.                  7       Then you have larger facilities that are                  8 doing it properly and there's different types of                  9 processing. These facilities are not -- there's not                  10 enough of them in the U.S. to handle the production                  11 that's going to be coming out. A hundred thousand                  12 acres to 200,000 acres is projected for this year,                  13 2,000 to 3,000 pounds per acre. It's not going to                  14 work.                  15       So you're going to have a surplus. Then                  16 you're going to have farmers that are going to have to                  17 make decisions on whether to burn their crops or not.                  18 And then making those decisions on \$20,000 or \$30,000                  19 of annual income is a big deal.                  20       So just something that I want to bring up.                  21 And having a certification process for the labs or                  22 some type of QA or QM process is something we've been</p>

<p style="text-align: right;">Page 290</p> <p>1 working on and other companies are as well.  2 Cold packaging facilities, we work with pet  3 food manufacturers, cosmetic manufacturers, nutrition  4 and food and beverage. All of them are a little bit  5 sketch and concerned about what's going on in the FDA  6 and how to work with that and how to get people to  7 process stuff in a quality manner and not be dealing  8 in the gray area or the conmen and the Wild West.  9 You also have several small businesses trying  10 to get started right now. They're buying \$500 to  11 \$1,500 at a time every month. They're trying to do  12 the right thing. They want to implement testing.  13 They want to have stuff on the base oil. And they  14 want to be able to move everything through and grow  15 their businesses and have a positive impact.  16 A lot of what I'm hearing is not stuff that  17 allows them to do that. They can't do through any of  18 these new drugs' certifications. You've got the  19 patchwork of states. Utah, for example, people are  20 already having to register as manufacturers. Per SKU  21 can start costing so many hundreds of dollars.  22 So I think overregulation would be a big</p>	<p style="text-align: right;">Page 292</p> <p>1 So the legalities especially, and going back  2 to the farms, you guys brought it up, delata-9 versus  3 THCA. There is a difference and there's a gray area  4 in regulation. If I want to go from a farm in Oregon  5 and drive, you know, 10 truckloads down to California,  6 is my delta-9 at 0.4? Am I now a federal drug  7 trafficker?  8 All right. And then, is everyone done and  9 what happens from that point in our logistics systems?  10 So if I'm a manufacturer and we're licensed, there  11 should be some variance in that and clarification on  12 THCA versus delta-9 so we don't have to work in that  13 area and worry about it.  14 It was already brought up the differences in  15 CBD. Along with academics and research, isolated CBD  16 is different from utilizing full spec CBD at scale  17 with manufacturing processes. This can become an  18 issue. So that's when you get into broad spectrum and  19 distillate, something we can submit later on to you  20 guys as well.  21 Next piece, ability for real research we  22 discussed. Consensus and the benefit to CBD, everyone</p>
<p style="text-align: right;">Page 291</p> <p>1 problem. We're five years into a multibillion dollar  2 industry right now and we're just talking about it  3 with you guys and you guys weren't aware of some of  4 the issues for the researchers to be testing stuff.  5 So it's not a ding on you. I love we're  6 having this convo. But I think the industry should  7 take the lead, utilizing networks, using ISO 9001 2015  8 standards and establishing those processes that the  9 consumers and businesses are already demanding.  10 All right. So sticking with the gray areas,  11 it shouldn't be a fear of the FDA. This should be a  12 conversation that we should be able to have.  13 Companies shouldn't be scared that they're going to  14 get warning letters to come up here and tell you guys  15 some of the issues they're dealing with and other  16 stuff going on.  17 But they're scared because, God forbid, you  18 know, I tell you I'm making a drink line in a few  19 months and it's not ready and it's going to mess up  20 our dollars. We need to move forward in a way that  21 everyone is being safe and can do this, you know, in a  22 constructive manner.</p>	<p style="text-align: right;">Page 293</p> <p>1 sees that overall and acknowledgement, you know, that  2 hey, we do have a patent on this and we've been  3 studying this stuff for over 50, 60 years at least  4 right now. There is a dearth of research. There's  5 meta-analysis, including stuff on dosing. We have  6 enough to move forward overall.  7 All right. Lastly, as we're running short on  8 time, one of the things is I just, you know, always  9 like to stick this out there as far as the benefits of  10 CBD. We can't ignore that. We see it across the  11 world internationally along with in the UK and Israel.  12 We're doing commercial trial arrangements with  13 different people and working logistics. All of them a  14 nightmare.  15 So I'm hoping we can go ahead and move that  16 forward. But that small difference, what CBD can do  17 can make a life-changing impact in people. I'm out of  18 time. Any questions? All right. Thanks so much.  19 MS. CRISTINZIO: Thank you. Next we have  20 speaker number 77, Richard Brumfield.  21 MR. BRUMFIELD: Good afternoon, ladies and  22 gentlemen and panelists. My name is Richard</p>

<p style="text-align: right;">Page 294</p> <p>1 Brumfield. I'm the CEO and founder of Full Spectrum  2 Omega, Incorporated. We are a phytocannabinoid life  3 science company out of California since 2010. We have  4 developed a non-euphoric THC product which has shown  5 benefits in the California medical marijuana group of  6 patients that we are serving in California.  7 Full Spectrum currently has two signed  8 agreement with the United States government to do  9 research in their lab for multiple applications  10 supporting national security and specifically military  11 need.  12 Now, I want to concentrate a little bit on  13 why we're here today. We're here today because we are  14 trying to get our products from California to the  15 federal lab in Maryland and San Antonio, Texas. And  16 our problem is there is no bridge between research and  17 drug development to have our product tested because  18 the product in the industry is my own invention.  19 We discovered the plant that we need. And we  20 are in control of those plants. And we work in a  21 state-sponsored program which is able to allow us to  22 use these products to help patients in different</p>	<p style="text-align: right;">Page 296</p> <p>1 percent -- 0.3 percent. The World Health Organization  2 has got 0.2 percent. FDA has done 0.1 percent. Where  3 is the standard between dietary supplements and a  4 drug? There's no standard. You have no separation.  5 Everything that falls under 0.3 percent and it says  6 under the Controlled Substances Act that it's legal to  7 ship across state lines.  8 But if your source material is cannabis,  9 Schedule 1, how do you cross over once you develop a  10 product that's 0.3 percent? Can that product now  11 cross state lines if it starts with a Schedule 1  12 product?  13 As far as we understand, it cannot. I've  14 been working two years with the FDA, NIH and DoD  15 trying to find that bridge to cross over. And what we  16 have found is that if the FDA and the DEA don't come  17 together and work with these state programs to capture  18 the data that we have, then we aren't even going to  19 get the true information that we need.  20 Let's see here. Next slide. Any drug  21 developer has to control his raw material. I cannot  22 trust my raw material in the hands of someone else to</p>
<p style="text-align: right;">Page 295</p> <p>1 needs.  2 Now, my next slide, going through some  3 discussion points, discussion point one is FDA  4 recommends data and the data is captured by the  5 National Institute of Drug Abuse and locked away where  6 researchers like myself who are in independent states  7 with cannabis programs, we cannot take our product  8 that we didn't develop into research because there's  9 no bridge between a state-sponsored development  10 program to where it could go to the FDA and say, look,  11 we discovered a new benefit.  12 So we need to be able to find a way to bridge  13 that gap where innovators like myself are not  14 handicapped to use a subpar or substandard product to  15 try to prove a point.  16 The next slide is the challenges moving  17 forward. Wait a minute. Hold on. Okay. I hit the  18 wrong button. Discussion point we want to talk about  19 is safety and effectiveness. I just went over that.  20 I'm sorry.  21 Discussion point number two. There are now  22 three definitions for hemp. The farm bill has 3</p>	<p style="text-align: right;">Page 297</p> <p>1 produce a quality product every time I need it. If we  2 don't have control of our raw material, how can we not  3 have a drug shortage later on? So it's imperative  4 that the industry controls its raw materials. And the  5 bulk manufacturer license that's currently being  6 applied don't apply to industry standards. So we need  7 the FDA to help educate Congress on what is a  8 botanical drug development program and what is  9 research.  10 I'm trying to hurry up. Number four, the FDA  11 don't want us to go around using other people's  12 products without it first being tested. But if  13 there's no bridge to go there, how can we get there?  14 Let me hit number five. Number five is the  15 most critical one to me. FDA and DEA allow foreigners  16 to import cannabis products to the United States for  17 research and development. But there are no pathways  18 for American industry to go. That is not right.  19 As Sue Sisley just said, she's fixing to  20 import from Canada. I'm located in California. We  21 are growing. We are processing and we're treating.  22 Now we need the FDA to come in and help us regulate</p>

<p style="text-align: right;">Page 298</p> <p>1 that because we believe the FDA should be the 2 regulatory agent over this process. That's it. 3 This slide will be put up in 72 hours. So if 4 anyone wants to capture the information, it'll be up 5 in 72 hours. And we just want to thank you for 6 allowing us to stand up here and talk to you for these 7 few minutes. Thank you. 8 MS. CRISTINZIO: Thank you. 9 MR. BRUMFIELD: Oh, okay. No questions. 10 MS. CRISTINZIO: Our next speaker is Guy 11 Chamberland, speaker number 78. 12 MS. MAZLOUM: Hi. I'm Rola Mazloum. I think 13 that's okay. Is that okay? 14 PANEL MEMBER: No. We still can't hear you. 15 MS. MAZLOUM: Hi. I'm Rola Mazloum, 16 regulatory affairs director at Tetra Bio-Pharma. 17 MS. CRISTINZIO: You need to move a little 18 closer to the mic so we can hear you. 19 MS. MAZLOUM: Okay. I'm Rola Mazloum, a 20 regulatory affairs director at Tetra Bio-Pharma. I am 21 here to present you the corporate slides on behalf of 22 Dr. Guy Chamberlain. Next. Okay. To date, Tetra</p>	<p style="text-align: right;">Page 300</p> <p>1 THC Cmax reported for Sativex. 2 When we look at the adverse events reported 3 with inhaled cannabis, with smoked cannabis, hundred 4 percent of patients experienced adverse events. There 5 was a dose-related trend that was observed. 6 The most common types of adverse events in 7 single dose were nervous system disorders and multiple 8 dose were euphoria and general disorders. Majority of 9 AEs were mild and considered drug-related. There were 10 some severe adverse events and most common adverse 11 events are listed here. 12 With vaporized cannabis, again, hundred 13 percent of patients experienced adverse events. Most 14 common was euphoric mood, which is the cannabis 15 expected pharmacological effect. Majority of AEs were 16 drug-related and were mild to moderate in severity. 17 In Phase I trial with smoked cannabis, we 18 have also assessed cardiac function following the 19 multiple dose phase. There was a substantial heart 20 rate effect that was observed at five minute time 21 point. That difference ranged between 15.4 and 24.2 22 bpm and it remained elevated 60 minutes post dosing.</p>
<p style="text-align: right;">Page 299</p> <p>1 Bio-Pharma has conducted four clinical trials, three 2 of which were Phase I trials and one Phase II trial. 3 Phase I clinical studies assessed safety, tolerability 4 and PK of single and multiple daily doses of cannabis 5 administered by smoke inhalation, vapor inhalation or 6 orally as cannabis oil capsules. 7 Phase II trial was a randomized, double 8 blind, placebo-controlled pilot study followed by an 9 open label extension phase that assessed safety and 10 efficacy of oral cannabis oil in patients with chronic 11 pain. 12 When we look at the PK parameters obtained 13 from Phase I trials, there's no -- there are no 14 significant differences between smoke and vapor. We 15 see that Cmax for both smoke and vapor is reached 16 between 0.5 and 0.17 hours and this was also achieved 17 for both THC and CBD. Obviously we see that PK 18 parameters for oil are much more different. 19 When we compare the THC Cmax obtained from 20 smoke, it is six to 20 times higher than the THC Cmax 21 reported in Sativex. When we look at the THC Cmax 22 obtained from vapor, it is around 12 times higher the</p>	<p style="text-align: right;">Page 301</p> <p>1 Neurologic adverse events that were reported, 2 we're talking about dizziness, fainting, headaches, 3 fatigue, somnolence, feeling abnormal. Cardiac 4 adverse events and neurologic adverse events were 5 related to Cmax. 6 And now, if we look at the adverse events 7 with oral cannabis oil, after seven day repeated dose, 8 two out of seven patients experienced at least one AE. 9 All AEs were mild. They occurred and resolved on day 10 one and did not reoccur even with higher CBD 11 concentration throughout the study duration, which 12 suggests a mechanism of tolerance. 13 Now if we look at adverse events and safety 14 data obtained from oral cannabis oil from our Phase II 15 study, here the THC/CBD ratio of interest is 120, with 16 5 mg CBD. There are no observed adverse effect levels 17 while at 5 mg CBD, following a daily consecutive 18 intake for six days. The first time an adverse effect 19 was observed was at day seven with 5 mg CBD. 20 Now again with our Phase I trial with smoked 21 cannabis, for the multiple dosing phase, we have 22 applied a program titration where after multiple</p>

<p style="text-align: right;">Page 302</p> <p>1 dosing for seven days, no adverse events classified as  2 nervous system disorders were reported, where also the  3 negative impact on cognition was not evident after  4 seven days of repeated dose, which also suggests the  5 mechanism of tolerance.  6       So to summarize, with inhalation, we have  7 much more neurologic and cardiac adverse events. With  8 single dose, we have much more neurologic adverse  9 events. And with multiple doses, cardiac adverse  10 events are much more important.  11       Another safety issue that we have to address  12 here with cannabis product and cannabis-derived  13 products is the mycotoxin contamination. Tetra Bio-  14 Pharma detected and quantified mycotoxins in three  15 lots of dried cannabis and one lot of cannabis oil.  16 Levels averaged between 1 and 10 mcg/g.  17       Several screening tools were developed and  18 validated to map out the organism growing on a crop  19 and bulk plant supplies. Tetra has developed also and  20 validated assays to quantify multiple known  21 mycotoxins. We also performed assays on all raw  22 materials as well as finished product and all our</p>	<p style="text-align: right;">Page 304</p> <p>1 universally understood.  2       Consumers, and in fact producers, will also  3 expect FDA to be engaged. Some will want FDA to allow  4 only a pharmaceutical pathway for the regulation of  5 hemp extracts. In our view, this will frustrate  6 consumers and bog down the agency without adding  7 appreciably to product safety. Others may call for  8 the barest minimum of an FDA regulation. A lack of  9 regulation has already begun to trigger a race to the  10 bottom in our view, eroding people's trust and  11 consumer safety.  12       We don't want a race to the bottom. We want  13 a race to the top. The starting line is a regulatory  14 framework that sets a high bar for manufacturing,  15 analytical testing and labeling, encouraging  16 investment in quality, choice and innovation.  17       When it comes to CBD, we recommend that the  18 FDA capitalize on its long experience in regulating  19 foods, beverages and supplements, specifically with  20 respect to these three items, the manufacturing,  21 testing and labeling.  22       The model, in our view, represents the</p>
<p style="text-align: right;">Page 303</p> <p>1 supplies of bulk plant material are subject to our  2 monitoring program.  3       Thank you for your attention. I just want to  4 add that complete data will be submitted to the FDA  5 through the confidential path.  6       MS. CRISTINZIO: Thank you. Next we have  7 speaker number 79, Josh Epstein.  8       MR. EPSTEIN: Hello, and thank you. I'm Josh  9 Epstein, from Socati. On screen is a short profile of  10 our company. We're focused on manufacturing broad  11 spectrum hemp extract as an ingredient by investing  12 heavily in science and technology to assure quality  13 and consistency.  14       Consumers rightfully expect CBD-infused  15 products to be made like others they routinely  16 consume, using certified good manufacturing practices  17 and quality standards with validated analytical  18 testing and with enforceable oversight.  19       They rightfully expect labeling that is  20 standardized, accurate, relevant and clear. And they  21 expect important terms such as THC, broad spectrum,  22 full spectrum, isolate to be well defined and</p>	<p style="text-align: right;">Page 305</p> <p>1 goldilocks zone of regulation that's strong enough to  2 ensure consumer safety, clear enough to empower choice  3 and confidence and flexible enough to promote  4 investment and growth.  5       Sorry about that. Allow me to offer some  6 specifics. First, the FDA should narrow the wide  7 variances in the standards for how CBD companies are  8 now making products, certify their processes through  9 third party validation and protect and ensure the  10 transparency of their supply chains.  11       A good start would be requiring CBD producers  12 to demonstrate quality manufacturing through global  13 food safety initiative recognized certifications.  14 This would assure that every stage of production is  15 both validated and auditable.  16       Certainly the use of CBD extract begs the  17 question how do we validate a product as THC-free,  18 which a lot of other people have touched on today, or  19 full spectrum or isolate or broad spectrum. And there  20 is no standard definition of that right at this point  21 in time and no agreed upon approach to measuring it.  22       The FDA should for example establish this</p>

<p style="text-align: right;">Page 306</p> <p>1 threshold for THC-free and a standard analytical  2 laboratory approach to validate it.  3 In short, consumers should be armed with the  4 information they need, including FDA recommendation as  5 to how much CBD can safely be ingested in a 24-hour  6 period and they need answers on whether and how much  7 consumption may trigger a positive drug test.  8 The first important step is being able to  9 accurately identify the content of products.  10 Accordingly, the FDA should also require appropriate  11 analytical testing and exposure of both the desired  12 and undesired components found in CBD products.  13 For the undesired components such as heavy  14 metals, the regulations governing food ingredients may  15 apply. For desired ingredients, consumers and product  16 manufacturers will want to evaluate the synergies and  17 various compounds found in CBD products, whether it's  18 full spectrum or broad spectrum, the synergistic  19 effects commonly known as the entourage effect. But  20 to do so, again, we must know what's in the products.  21 Overall, we believe the FDA can consider a  22 range of analogs from food, beverage and supplement</p>	<p style="text-align: right;">Page 308</p> <p>1 broad spectrum -- start with isolate, and I'm sure  2 there are multiple definitions within this room, quite  3 frankly. But isolate is CBD without any other  4 component that came from the hemp plant.  5 Full spectrum is pulling through all of the  6 synergistic compounds, other cannabinoids that other  7 people have mentioned today, terpenes, et cetera, into  8 an extract. That's full spectrum. Broad spectrum  9 would be that, but with THC removed.  10 PANEL MEMBER: Okay. So full spectrum would  11 include THC?  12 MR. EPSTEIN: The residual amounts, correct.  13 PANEL MEMBER: Got it. And is there any -- I  14 mean, is anything removed or is this, you know,  15 literally just extracted from the plant and you don't  16 do anything else with it or do you do some kind of  17 processing, concentrate some things, remove other  18 things?  19 MR. EPSTEIN: Well then it depends on what  20 the manufacturer is producing. So it could be in a  21 tincture where it's diluted with a carrier oil. It  22 could go into all of the other products that you guys</p>
<p style="text-align: right;">Page 307</p> <p>1 industries to build a regulatory framework and do so  2 with comparative speed. With that, consumers will be  3 well protected and have their expectations well met.  4 In closing, a legal CBD market is projected  5 to grow exponentially in the coming years. Behind  6 wise and timely regulation, the FDA can both protect  7 and empower consumers while galvanizing and  8 appropriately guiding the inevitable growth of a  9 dynamic new industry. Thank you.  10 PANEL MEMBER: I have a question.  11 MR. EPSTEIN: Yes?  12 PANEL MEMBER: Well, actually a couple of  13 questions.  14 MR. EPSTEIN: Okay.  15 PANEL MEMBER: so the first one, you  16 mentioned a couple of different terms, broad spectrum  17 and full spectrum.  18 Are those -- and I know you said they're not,  19 you know, necessarily defined in the industry. But  20 are you using those terms interchangeable or are they  21 the same or different?  22 MR. EPSTEIN: No. They are different. So</p>	<p style="text-align: right;">Page 309</p> <p>1 have seen people present on today.  2 PANEL MEMBER: So the broad spectrum --  3 because you manufacturer a broad spectrum product,  4 right?  5 MR. EPSTEIN: That's what we're primarily  6 focused on, yes.  7 PANEL MEMBER: So what types of levels of CBD  8 do you see in that?  9 MR. EPSTEIN: In the extract, it's a range.  10 It depends on the starting materials in large part.  11 But ultimately, anywhere -- once you do -- once you go  12 through the entire manufacturing process, the CBD  13 content in the oil will be anywhere from 70 to 90  14 percent.  15 PANEL MEMBER: Just a follow-up question to  16 both of those. You can understand the challenge in  17 creating a standard around something that varies like  18 that.  19 MR. EPSTEIN: Absolutely.  20 PANEL MEMBER: If you have ideas for --  21 MR. EPSTEIN: That's part of what we'll be  22 submitting in our comments, yes.</p>

<p style="text-align: right;">Page 310</p> <p>1 PANEL MEMBER: -- it'd be really useful to  2 have you submit those to the docket just so we -- and  3 then, the other thing was just you had mentioned a few  4 other things, THC-free and other people have talked  5 about full spectrum phytocannabinoids or something  6 like that.</p> <p>7 If there's a list of these sorts of terms  8 that you feel would benefit from some kind of a  9 standardization, it'd be just useful if we had a full  10 list of the different terms that people are using  11 today.</p> <p>12 MR. EPSTEIN: Yeah, absolutely.</p> <p>13 PANEL MEMBER: Thanks.</p> <p>14 MR. EPSTEIN: Thank you.</p> <p>15 PANEL MEMBER: Just one last question.</p> <p>16 MR. EPSTEIN: Yeah.</p> <p>17 PANEL MEMBER: You also used -- you talked  18 about CGMPs as well. Are you seeing that most  19 manufacturers are actually following the CGMPs in this  20 space?</p> <p>21 MR. EPSTEIN: No. Thank you.</p> <p>22 MS. CRISTINZIO: All right. Moving onto our</p>	<p style="text-align: right;">Page 312</p> <p>1 More specifically to CBD, as described in our  2 drug master file that's listed up on the screen there,  3 33223, we manufacture CBD synthetically using well-  4 characterized regulatory starting materials. We also  5 test our material with validated analytical methods as  6 described in our DMF on file with the FDA.</p> <p>7 So while our approach does implicitly mean  8 that we're not looking out for pesticides or heavy  9 metals from the soil or plant impurities, I still  10 think that we have a lot of common ground with people  11 that are talking here today related to the principles  12 that should apply to extractors or people who are  13 producing CBD synthetically.</p> <p>14 Some of this has been covered today and so I  15 won't go back through it in quite as much detail as I  16 was planning. But unfortunately there's a lot of  17 mislabeled or misrepresented CBD in the marketplace.</p> <p>18 And so, I selected specifically a reference  19 from 2017, 2018 and 2019, all from peer-reviewed  20 journals or respected government agencies like the CDC  21 to say, you know, that there is a need for specific  22 federal oversight to guarantee consumer safety and to</p>
<p style="text-align: right;">Page 311</p> <p>1 next manufacturer, number 80, Bill Grubb.</p> <p>2 MR. GRUBB: Good afternoon. I'm here this  3 afternoon representing Noramco. We are a CGMP active  4 pharmaceutical ingredient manufacturer. We're  5 registered with the FDA and DEA at our facilities in  6 Wilmington, Delaware and Athens, Georgia.</p> <p>7 We supply around -- materials registered  8 under around 24 U.S. DMFs and then other registrations  9 around the world. We supply our products into 40  10 countries. And again, that's active pharmaceutical  11 ingredient, not drug product.</p> <p>12 For 12 of the -- oh, sorry. For 12 of the 40  13 years that we have been in existence, we've been  14 manufacturing cannabinoids, again under a U.S. DMF.  15 And that's up on my slide, the DMF number. Sorry.  16 Didn't realize it hadn't advanced.</p> <p>17 If you look at Noramco today, we actually  18 produce 30 -- over 30, around 35 individual  19 cannabinoids that are used in pharmaceutical, clinical  20 or analytical testing applications. And again, those  21 are produced using validated analytical methods and  22 procedures described in our SOPs.</p>	<p style="text-align: right;">Page 313</p> <p>1 make sure that frankly people know what they're  2 taking.</p> <p>3 To me, the simplest way to get there -- and  4 this has been covered in some instances today -- is to  5 follow codified CGMPs that exist for foods,  6 supplements and for drugs.</p> <p>7 And Noramco's position and what we're  8 entering in is a comment and we'll upload our  9 information in more detail to the portal is that  10 whether the CBD is extracted or synthesized, whether  11 it's intended as a drug, a food or a supplement and  12 whether -- you know, we're agnostic to the delivery  13 mechanism because that's not our role.</p> <p>14 But if it's oral, topical or inhaled, we  15 believe that CBD -- I mean, CGMP regardless of which  16 one of those is very, very important for public  17 safety.</p> <p>18 Our next comment is that while the  19 Agricultural Improvement Act, or the farm bill, says  20 0.3 percent might be okay for agricultural products,  21 we don't believe that to be true.</p> <p>22 We think that 0.1 percent, as noted in the</p>

<p style="text-align: right;">Page 314</p> <p>1 references that are on the screen, the FDA's own  2 assessment, the World Health organization's expert  3 committee on drug dependence is certainly less than  4 the 0.3.  5 And if you just follow ICH guidelines for  6 control of related substances and impurities, 0.1  7 percent makes sense. And so, that, you know, is  8 something that we really do believe in. And we're  9 able to produce that as are others that have reported  10 today. And so, we feel that it should be adopted as a  11 standard.  12 In practice, as it says on the slide, you  13 know, we're around 10 parts per million, or 0.001  14 percent. And we've submit in our DMF a limit of 0.10.  15 Tightly controlling related substances is  16 very important and I think that whether you're  17 extracting or synthetic, following ICH guidelines for  18 the control of related substances is very important  19 and assures public safety.  20 We ourselves down to a limit of quantitation  21 of 0.02 percent, have five batches that we  22 manufactured this year shown at commercial scale that</p>	<p style="text-align: right;">Page 316</p> <p>1 contaminants. Are you aware of any risks in  2 synthesizing CBD relative to botanicals?  3 MR. GRUBB: No, I'm not. And I'm not because  4 these are -- you know, it's well characterize CBD.  5 It's described in a DMF. It's included in clinical  6 trials. And we're going through validated test  7 methods and procedures to assure that it really is  8 CBD.  9 PANEL MEMBER: What challenges do you  10 encounter in synthesizing it that might be either a  11 barrier to entry or might be a reason why others might  12 not be able to follow suit commercially?  13 MR. GRUBB: Frankly our biggest challenge  14 right now is that if you grow and extract hemp in an  15 unregulated manner, you're not subject to DEA  16 controls, and we are.  17 That is our single biggest challenge is that  18 we're making a very pure product that's under the  19 purview of the FDA and registered facilities and even  20 DEA-registered facilities because both of ours are.  21 But it's not a very level playing field since last  22 December. Thank you.</p>
<p style="text-align: right;">Page 315</p> <p>1 have no detection of total impurities.  2 End product label accuracy, consumer or  3 drugs, depends on a pharmaceutical ingredient that has  4 undergone rigorous stability testing. And again, we  5 test our research and commercial batches under an ICH  6 stability guideline and we report those results in our  7 DMF. I'm showing some publicly here today just to  8 demonstrate the point that very close to the actual  9 melting point of CBD, crystalline solid, 40 degrees  10 Celsius at 75 percent relative humidity, you can have  11 a stable product.  12 Finally and in closing, I've summarized our  13 points here, as well as one I didn't make regarding  14 working with the USP. But we do believe that  15 regardless of the method of production, the intended  16 use for drug, foods or supplements that patients and  17 consumer deserve a CBD that's produced according to  18 GMP and that's tested for identity, purity, quality  19 and strength. Thank you.  20 PANEL MEMBER: You mentioned on slide three  21 several advantages to synthetic CBD compared to  22 botanically derived, less variability, fewer</p>	<p style="text-align: right;">Page 317</p> <p>1 MS. CRISTINZIO: Thank you. Our next  2 speaker, speaker number 81, is Deb Kimless.  3 DR. KIMLESS: So how do we do the slides?  4 MS. CRISTINZIO: Just one second. We're  5 almost there.  6 DR. KIMLESS: There we go. Hello, and thank  7 you for this opportunity to present to you today. My  8 name is Dr. Deborah Kimless, and I'm a 25-year, board-  9 certified anesthesiologist and pain medicine  10 specialist. I'm here on behalf of Pure Green, a  11 licensed medical cannabis processing company in  12 Michigan.  13 I was confident to try sublingual CBD with  14 patients because of Pure Green's processes and  15 procedures. And what I learned is that Pure Green  16 sublingual CBD was safe and effective treatment option  17 for my patients. And while I've presented our  18 clinical data in many scientific forms, never in this  19 short amount of time.  20 So I do regret that I can only present a high  21 level summary to demonstrate that data does exist to  22 help the FDA gain insight into safety and efficacy of</p>



<p style="text-align: right;">Page 318</p> <p>1 sublingual CBD products manufactured under a state-  2 regulated program. And I'll describe how an  3 integrated approach achieves this goal.  4       So the clinical data. Six pilot clinical  5 trials were run in diverse populations with symptoms  6 including PTSD, opioid dependency, insomnia, anxiety  7 and pain and all with positive results. I will report  8 here on one of those trials, the pain trial.  9       So we had a 16-patient trial with mild to  10 moderate chronic pain that was being treated with  11 NSAIDs. The average starting pain scale score was 5.2  12 on a scale of zero to 10.  13       The data demonstrates clinically and  14 statistically significant pain reduction most  15 beginning within eight minutes of taking the  16 sublingual tablet where the average pain scale score  17 dropped by more than 50 percent.  18       Pain relief routinely lasted four to six  19 hours, sometimes over a 24-hour period, without  20 adverse effects. In fact, the one side effect that  21 was reported by the majority of patients was an  22 overwhelming sense of wellbeing. We're currently</p>	<p style="text-align: right;">Page 320</p> <p>1 quality control. Pure Green was one of the first  2 Michigan medical cannabis state licenses and because  3 of this they've obtained pharmacovigilance data in  4 nearly 500,000 dosages in just 10 months.  5       And it can be concluded that this sublingual  6 form of CBD was well tolerated, safe and effective.  7 And in fact, the only two side effects that were  8 reported, one in less than 1 percent of the  9 population, was transient drowsiness and then, from  10 the pain trial, where patients claimed an overwhelming  11 sense of wellbeing. And we're prepared to submit  12 additional proprietary data to aid the agency in  13 deliberations.  14       And here's a picture of a labeled box that  15 contains a similar narrative to what you would see  16 with a traditional over-the-counter pain reliever. We  17 believe that with CBD safety and efficacy, a parallel  18 pat can coexist, the traditional FDA drug path along  19 with the current regulated state programs.  20       We appreciate the FDA considering this CBD  21 presentation and thank you again for your time and  22 consideration.</p>
<p style="text-align: right;">Page 319</p> <p>1 running a follow-up multicenter clinical trial with an  2 n greater than 16 and we're also doing PK tests.  3       The tablet. Patients were given a 5 mg CBD  4 sublingual table that also contains terpenes. The  5 patent-pending formulation renders the tablet water  6 soluble to enhance bioavailability. A 20 mg  7 sublingual CBD iteration of this tablet has been on  8 sale in Michigan because the company Pure Green was  9 granted the first state medical cannabis processor  10 license.  11       The tablet is manufactured under a validated  12 GMP production conditions and each batch is tested by  13 an independent testing lab guaranteeing every batch to  14 have accurate and reliable dosing.  15       The entire tablet processing method and API  16 processes method is fully regulated, meets good  17 manufacturing practices and is tested throughout the  18 production life cycle for potency, residual solvents,  19 heavy metals, microbials and pesticides by the state  20 licensed independent testing laboratories.  21       The vertical integration of the business  22 lines ensures complete beginning to end product</p>	<p style="text-align: right;">Page 321</p> <p>1       PANEL MEMBER: Thank you, and look forward to  2 seeing your data. Out of curiosity, what's  3 overwhelming sense of wellbeing and how is it  4 measured?  5       DR. KIMLESS: It was a statement in the notes  6 section in their -- when they were submitting them on  7 the app. We have a smartphone app that patients who  8 are identified get to enter it in. And in the notes  9 section, many say they had a feeling of wellbeing or  10 overwhelming feeling of wellbeing or incredible sense  11 of wellbeing. Thank you.  12       MS. CRISTINZIO: Thank you. Next up, we have  13 Douglas MacKay.  14       DR. MACKAY: Hi. My name is Douglas MacKay.  15 I'm scenarios vice president, scientific and  16 regulatory affairs, for CV Sciences. I think there's  17 one thing that we can all agree is very clear. You  18 guys have a really tough job ahead of you. It's going  19 to be really hard to manage this diverse set of  20 viewpoints and good luck with that.  21       CV Sciences operates two distinct divisions.  22 The consumer division delivers hemp products through</p>

<p style="text-align: right;">Page 322</p> <p>1 its Plus CBD oil brand and we also have a                  2 pharmaceutical division that's pursuing an FDA-                  3 approved drug. Responsible industry fully embraces                  4 robust FDA regulation.                  5 An appropriate and predictable regulatory                  6 framework protects consumers while allowing a pathway                  7 for companies to lawfully market various types of                  8 cannabis-derived products. Industry applauds FDA for                  9 the significant work done so far to respond to this                  10 rapidly changing environment.                  11 USDA and FDA have been tasked with developing                  12 regulations that separate an agricultural commodity                  13 from a controlled substance. Let me repeat that. You                  14 have to separate an agricultural commodity from a                  15 controlled substance.                  16 Responsible industry strongly encourages that                  17 FDA and USDA closely collaborate to ensure that the                  18 corresponding regulations are synchronized to                  19 efficiently differentiate the hemp and marijuana                  20 supply chains.                  21 International hemp regulatory models apply a                  22 seed licensing and registration scheme that assures</p>	<p style="text-align: right;">Page 324</p> <p>1 companies that want to develop new drugs or new                  2 botanical drugs to treat different diseases. For                  3 supplements, FDA has been clear that highly purified                  4 and isolated CBD can't be added to food or dietary                  5 supplements.                  6 However, scientific and legal experts agree                  7 that a hemp extract containing a full array of                  8 cannabinoids and other plant constituents is a                  9 significantly different article than a highly purified                  10 CBD.                  11 Each has a unique identity and a unique                  12 biological activity. CV Sciences suggests an FDA                  13 guidance that differentiates a hemp extract from a                  14 prescription CBD will allow companies to                  15 confidentially file the requisite NDI notifications.                  16 Today, FDA has made a broad request for data                  17 on cannabis safety. To satisfy this request, one must                  18 first qualify the specific composition of the                  19 cannabis-derived ingredient and, second, the intended                  20 use of the ingredient. Cannabis or hemp product                  21 safety is based on the chemistry of the ingredient and                  22 the intended use.</p>
<p style="text-align: right;">Page 323</p> <p>1 that only appropriate food, fiber hemp cultivars are                  2 used as a raw material source for the hemp-based                  3 industries.                  4 A verified food fiber hemp supply chain                  5 provides a safe, non-intoxicating botanical starting                  6 material. Hemp can be safely regulated by FDA like                  7 other natural ingredients. Current FDA regulations                  8 allow naturally derived ingredients to coexist as                  9 conventional foods, dietary supplements and drugs.                  10 This slide provides examples of different ingredients                  11 derived from the same natural resource being                  12 appropriately marketed in different lanes.                  13 CV Sciences suggests that FDA rulemaking is                  14 not required if FDA provides clear industry guidance                  15 to the type and scope of hemp ingredients allowed in                  16 each FDA-regulated category.                  17 For conventional foods, FDA has completed                  18 three GRAS notices for hemp seed derived ingredients.                  19 The food pathway is clear for companies that want to                  20 use nutrient-rich components of hemp in food or to                  21 develop new ingredients.                  22 The drug regulatory pathway is also clear for</p>	<p style="text-align: right;">Page 325</p> <p>1 FDA regulations, when evaluated holistically,                  2 provide an appropriate framework to regulate cannabis                  3 for different intended uses. A product intended to                  4 treat children with epilepsy is a drug and it should                  5 come with the pre- and post-market rigor of FDA-                  6 approved drugs. However, a food product that provides                  7 nutrition or a supplement that supports a healthy                  8 lifestyle have regulatory paradigms that appropriately                  9 correspond with those uses.                  10 CV Sciences looks forward to submitting                  11 detailed written comments to share our experience                  12 working with hemp. Time constraints will only allow                  13 me to share a few ways that we ensure we provide                  14 consumers with safe and high quality hemp products.                  15 We start with a food fiber hemp cultivar from                  16 a licensed and registered hemp seed. We establish the                  17 identity of our ingredients through technical                  18 analysis. We have published in the peer-reviewed                  19 literature the appropriate toxicology studies on our                  20 ingredient. Those are available on PubMed and I will                  21 submit them to the docket.                  22 We also manufacture in a third party GMP-</p>

<p style="text-align: right;">Page 326</p> <p>1 verified facility and we are compliant with labeling  2 and marketing regulations, as well as adverse event  3 reporting and recordkeeping requirements.  4 In closing, I want to emphasize that  5 responsible hemp companies and FDA have a shared goal  6 of protecting consumers while providing access to  7 appropriate hemp products. Thank you for this  8 opportunity to share our experience and we look  9 forward to providing more substantive written  10 comments, and I'm open to questions.  11 (Applause.)  12 PANEL MEMBER: It's interesting that you sort  13 of outlined three different pathways, which obviously  14 we're familiar with. But -- and the fact that you  15 believe -- seem to believe strongly that they coexist.  16 And I guess one of my questions is do you see  17 any of them disincentivizing sort of the other, in  18 other words, allowing a broader use disincentivizing  19 the ability to complete clinical trials. We've heard  20 a little bit about that today.  21 MR. MACKAY: Yeah. I mean -- yeah. So if --  22 with all due respect, the pharmaceutical companies</p>	<p style="text-align: right;">Page 328</p> <p>1 safety. Those are all guiding principles.  2 I know you're dying for a number. Our  3 product has about 15 mg per soft gel in it and that's  4 what was supported by our safety studies.  5 PANEL MEMBER: In any of your comments, do  6 you explain the taste, aroma, nutritive value or  7 technical effect that these extracts would have in a  8 conventional food?  9 MR. MACKAY: So I have similar questions  10 about the appropriateness in conventional food because  11 of the lack of those properties. There's some  12 indications that CBD does have a bitter taste similar  13 to caffeine.  14 So we might have a taste and there may be  15 some technical effects that might be reasons to add it  16 to food. But I haven't seen frank, clear arguments  17 about how it could be or why it could be a food  18 product. And my company hasn't gone down that pathway  19 for those reasons.  20 MS. CRISTINZIO: Thank you. Our next speaker  21 is number 83, Ray Mannion.  22 MR. MANNION: Good afternoon. My name is Ray</p>
<p style="text-align: right;">Page 327</p> <p>1 have gone through the investment and gotten the drug  2 improved. The provision that is in place that says we  3 can't introduce that to the food supply.  4 So isolated CBD in my humble opinion,  5 isolated CBD and THC are off limits. But we have hemp  6 extracts. And defining a hemp extract, establishing  7 the safety of the hemp extract, understanding the  8 level of cannabinoids and other constituents in that  9 product is what we do in botanical medicine under the  10 current regulatory paradigm -- excuse me, botanical  11 dietary supplements. That was a slip. I didn't mean  12 to say medicine.  13 You know, it's all there is what I'm trying  14 to say. But yes, I think if we allow isolated  15 crystalline CBD to be free-flowing in the food space,  16 it disincentivizes additional research.  17 PANEL MEMBER: And so how are you defining  18 hemp extract and what levels of CBD and THC are you  19 seeing in that?  20 MR. MACKAY: Well, the levels of CBD are  21 depending on not only extraction method, the plant  22 starting material, but also the data we have on</p>	<p style="text-align: right;">Page 329</p> <p>1 Mannion, vice president of manufacturing with Zynerba  2 Pharmaceuticals, located in Devon, Pennsylvania. On  3 behalf of the entire Zynerba team, I'd like to thank  4 FDA for the opportunity to present at today's public  5 hearing.  6 There's an established FDA commitment to  7 quality and safety of cannabinoid products. FDA has  8 previously approved drugs containing CBD and THC,  9 thereby ensuring comprehensive oversight of the  10 products. The 2018 farm bill explicitly preserved  11 FDA's authority to regulate CBD products in  12 furtherance of the agency's mandate to protect the  13 public health.  14 All cannabinoid products should be held to  15 the same rigorous quality, safety and efficacy  16 standards established by FDA to protect the public.  17 The current landscape is marked by, one, proliferation  18 of cannabinoid-containing products and, two, confusion  19 about the legality of distribution and differences  20 between federal and state regulatory oversight of  21 cannabis and cannabinoids.  22 There are established risks with non-FDA-</p>

<p style="text-align: right;">Page 330</p> <p>1 regulated cannabis. Lab analyses demonstrate that  2 some non-FDA-approved, commercially available CBD  3 products do not contain what is listed on their  4 product labels. FDA's independent lab testing has  5 shown similar results.</p> <p>6 In addition, CBD product testing has shown  7 the presence of THC at levels which may be sufficient  8 to produce a negative euphoric effect, particularly  9 among children. Common cannabis contaminants include  10 microbes in the form of bacteria and fungi, heavy  11 metals and pesticides.</p> <p>12 Microbial contamination may occur during  13 improper preparation and storage of cannabis products  14 and can result in infections. Heavy metal  15 contaminants may be attributable to soil fertilizer  16 and/or cross-contamination during processing.  17 Pesticide use in the cultivation of cannabis products  18 is well established.</p> <p>19 FDA should therefore continue to enforce  20 pharmaceutical compliant CGMP processes and testing  21 standards to ensure product quality and safety for all  22 commercially distributed cannabinoid products.</p>	<p style="text-align: right;">Page 332</p> <p>1 Documented manufacturing processes and end  2 process testing are important considerations, as are  3 microbial testing, as is microbial testing to ensure  4 that acceptable levels are not exceeded. And then  5 finally, controlled storage conditions on this aspect  6 can safeguard against the impact of moisture like  7 packaging and oxygen exposure. Product stability and  8 shelf life testing is also a consideration.</p> <p>9 In summary, FDA has a well-established  10 history of protecting the public health. Existing  11 regulations and processes governing the manufacture of  12 pharmaceutical products establish critical controls to  13 ensure necessary quality and safety standards are met.</p> <p>14 This robust framework can and should be  15 leveraged in the regulation of all cannabinoid  16 products. Less stringent manufacturing and quality  17 standards would create an unnecessary public health  18 risk. Thank you. Any questions?</p> <p>19 MS. CRISTINZIO: Thank you very much. We are  20 now on speaker number 84, Rosemary Mazanet.</p> <p>21 DR. MAZANET: Good afternoon. I'd like to  22 tell you a little bit about Columbia Care. Columbia</p>
<p style="text-align: right;">Page 331</p> <p>1 Pharmaceutical product development, evaluation and  2 processes are well defined in FDA and international  3 guidelines.</p> <p>4 Testing limits and controls for each stage of  5 product development are established. Existing  6 pharmaceutical development, manufacturing and quality  7 assurance processes ensure product quality, label  8 accuracy and minimize the risk to public safety.</p> <p>9 FDA should therefore continue to leverage the  10 existing robust regulatory framework in the oversight  11 of cannabinoids. There exists the FDA regulatory  12 oversight guidance, review and inspection and within  13 that, the good manufacturing procedures regulations,  14 the International Conference on Harmonization  15 Guidelines, U.S. Pharmacopeia and national formulary  16 standards and finally drug product track and trace  17 requirements.</p> <p>18 Product quality manufacturing controls ensure  19 product identity, purity, strength, quality and label  20 accuracy. It's important to consider the control of  21 raw materials, solvents, the impurities, herbicides,  22 pesticides and fungicides.</p>	<p style="text-align: right;">Page 333</p> <p>1 Care is U.S.-based medical cannabis company. We're in  2 14 states. We're also in Europe now. We're licensed  3 for medical cannabis. We are largely vertically  4 integrated in each of those states. And the reason  5 why we have always been vertically integrated or made  6 every attempt is to control quality.</p> <p>7 We learned early on that it was really  8 impossible to have a -- to understand what your  9 product really had been through unless you grew it,  10 manufactured it and had sort of chain of custody  11 throughout the whole situation in most states.</p> <p>12 We are in states that largely are regulated.  13 We're in New York. In some states like New York, we  14 have a DEA Schedule I license around our manufacturing  15 plant. In some states like Florida, all of our  16 manufacturing is GMP. So we try to be as compliant as  17 we can with having very high standards for manufacture  18 in the medical cannabis space.</p> <p>19 And the reason for that is because we are  20 undertaking more than a dozen IRB-approved trials in  21 the United States and Europe to try to look at  22 efficacy in these products. And we believe strongly</p>

<p style="text-align: right;">Page 334</p> <p>1 that you have to have the same product. You have to  2 eliminate variables if you're going to do any  3 meaningful research. So we have very formulated  4 products and those are what we test in patients,  5 apples to apples. We're not big fans, as you might  6 imagine, of flower because we feel that it's very hard  7 to have a dosable product.</p> <p>8 So I'm a HEMOC by original training. I  9 actually have done drug development my whole life and  10 I became involved with Columbia Care back in 2013  11 because they were interested in doing clinical trials  12 with formulated dosable products in as many patients  13 as possible in the United States. And that's what  14 we're about.</p> <p>15 But what I'm here today to talk about is  16 hemp, hemp CBD because we believe that that's an  17 important medication. Epidiolex has shown us that it  18 has a lot of potential. We're actually doing trials  19 globally with a high dose CBD formulation in psychosis  20 out of King's College, London. But again, quality is  21 really the issue here that we're concerned about.</p> <p>22 I'm telling you something that you've heard</p>	<p style="text-align: right;">Page 336</p> <p>1 at again not just contaminants. We're not talking  2 about microbes here. We're not talking about heavy  3 metals. We're talking about things that during the  4 manufacturing process, chemicals that got into that  5 product that shouldn't have been there.</p> <p>6 And some of that was dextromethorphan, which  7 really is quite interesting when you think about how  8 that would have gotten into CBD extracted product.  9 Again, there were no quality assurances to make sure  10 that that happened.</p> <p>11 You know, the national news has picked up on  12 this, the Philadelphia Inquirer, some Alabama papers.  13 But again, you know, I think the fact that potentially  14 dangerous CBD is sort of getting into the news is  15 something that should concern us all. Andi think to a  16 large extent that's why we're here today.</p> <p>17 You know, we're trying to make a legitimate  18 business out of the medical products that might be  19 available in the cannabis plant. And so, we need to  20 be credible and we need to get away from some of the  21 fantastic, if you will, things that we read.</p> <p>22 There was a large study done in California</p>
<p style="text-align: right;">Page 335</p> <p>1 all day. I apologize for that. But I'm going to say  2 it again. Okay. We know, going back to 2015, the  3 first publication in JAMA that said that greater than  4 15 percent of the products evaluated had significantly  5 less cannabinoid content than labeled. Okay. You  6 know, that was 2015.</p> <p>7 So we have another publication in 2017 that's  8 more disturbing. Only 31 percent of CBD extracts were  9 labeled correctly. Sixty-nine were labeled -- or 69  10 percent were labeled incorrectly. Forty-three were  11 under-labeled. Twenty-six were over-labeled. And  12 some of those actually had THC in them. So this is  13 pretty alarming if you actually read that JAMA paper.  14 There was THC in a good number of those products that  15 were sold as a CBD extract.</p> <p>16 Now what that shows is just that people are  17 lazy. People will do an extraction of whatever plant  18 they have and they'll sell it. And until somebody  19 tells them that they can't do that, they will continue  20 to do it.</p> <p>21 This past year, Forensic Science  22 International had a study that was published looking</p>	<p style="text-align: right;">Page 337</p> <p>1 recently. I want to point out here that there are two  2 products that had absolutely no CBD in them at all.  3 If I were a parent of a child that had a seizure  4 disorder and I was not eligible for reimbursement to  5 receive Epidiolex and I was buying CBD, this would  6 make me sick. This is just really sad when we think  7 that there are people that rely on these medicines.</p> <p>8 So moving forward, again, I think, you know,  9 singing again to the choir here, that the FDA guidance  10 should protect safety. GMPs should be required.  11 There should be standards for the levels in food and  12 dietary supplements. There should be labeling  13 requirements. And there should be restrictions on  14 disease claims. And thank you for being able to  15 present today.</p> <p>16 PANEL MEMBER: Are you -- is your submission  17 -- does it propose specific levels for food and  18 dietary supplements? And if so, does it take into  19 account exposure across a broader -- a wide array of  20 products?</p> <p>21 DR. MAZANET: We actually have many  22 formulated products that may differ because of that.</p>

<p style="text-align: right;">Page 338</p> <p>1 So I think when we put in some formal comments, I can 2 address that, yes. Thank you.</p> <p>3 MS. CRISTINZIO: Thank you. Next up, we have 4 speaker 85, Alice Mead.</p> <p>5 MS. MEAD: Good afternoon. I'm Alice Mead, 6 from GW Pharmaceuticals. We're here to express our 7 support for a strong and comprehensive regulatory 8 framework that first and foremost further encourages 9 development of cannabis-derived medications for 10 serious and life-threatening illnesses.</p> <p>11 Next, ensures that CBD consumer products can 12 be safely used in a mass market setting that lacks 13 physician oversight. And finally, establishes clear 14 differentiation in dosing and concentration levels 15 between FDA-approved medicines and consumer goods.</p> <p>16 We've seen that cannabis-derived derived 17 medications can change lives. Epidiolex is not only 18 the first cannabis-derived medication approved by the 19 FDA. It's brought new hope to thousands of families 20 with loved ones suffering from two life-threatening 21 forms of epilepsy, Dravet syndrome and Lennox-Gastaut 22 syndrome. And we're just scratching the surface with</p>	<p style="text-align: right;">Page 340</p> <p>1 interactions with other medications like warfarin, a 2 common blood thinner. This can cause these other 3 drugs to have stronger or weaker effects than 4 intended.</p> <p>5 GW and non-GW studies alike tell us that CBD- 6 rich extracts can cause a number of other side effects 7 such as sleepiness, which can be a problem when 8 driving.</p> <p>9 That brings me to the issue of unknowns. 10 There is still so much we do not know about CBD. It 11 has not been tested in a number of vulnerable patient 12 populations such as pregnant women and patients over 13 55. In fact, concerns about fetal toxicity in lab 14 rats prompted FDA to require us to do more studies in 15 fetal toxicity.</p> <p>16 Our research shows that negative side effects 17 from CBD begin to appear at 1 mg/kg of body weight, or 18 about 70 mg per day for an average adult. These side 19 effects appear at relatively low levels probably 20 because CBD affects multiple systems in the body. And 21 people will ingest CBD from multiple sources. And 22 therefore there should be wide safety margins when</p>
<p style="text-align: right;">Page 339</p> <p>1 Epidiolex.</p> <p>2 There's tremendous potential in this plant to 3 treat many more severe illnesses. GW is researching 4 eight different disease areas. We're leading the way. 5 But without greater incentives, few companies will 6 follow us down the FDA pathway.</p> <p>7 So why does FDA approval matter? Because the 8 FDA approval process is the only way to answer 9 important questions about a drug, about the disease it 10 seeks to treat and safety considerations that are 11 unique to the patients who will take the drug.</p> <p>12 For example, no one knew CBD is potentially 13 toxic to the liver until we conducted clinical and 14 preclinical studies. To answer such questions, we've 15 spent the past 20 years researching this plant.</p> <p>16 Along the way, we've built an extremely 17 comprehensive scientific database on CBD. We know 18 that CBD causes drug-induced liver injury. Therefore 19 physicians are instructed carefully to monitor liver 20 function with blood tests when treating patients with 21 Epidiolex.</p> <p>22 We also know that CBD has powerful drug-drug</p>	<p style="text-align: right;">Page 341</p> <p>1 setting concentration limits and daily serving levels.</p> <p>2 That brings me to my last point, which I 3 guess I should have been clicking all this time, 4 shouldn't I? My last point is THC. It's a myth that 5 CBD products will have only trace amounts of THC.</p> <p>6 The 0.3 percent limit from the farm bill 7 could be interpreted to allow, for example, a small 8 gummy bear to have as much as 12 mg of THC. That 9 means that two gummy bears could deliver more THC than 10 smoking an entire marijuana cigarette.</p> <p>11 In closing, we recognize that there are 12 patients suffering from serious ailments outside of 13 Dravet and LGS who feel as though in the absence of an 14 approved cannabis medication, using unapproved 15 cannabis products is their only option. But this is 16 not ideal.</p> <p>17 That's why we support a strong regulatory 18 framework for cannabis products that encourages robust 19 research, maintains the integrity of the FDA approval 20 process for medicines and brings more FDA-approved 21 medicines to patients. Thank you.</p> <p>22 (Applause.)</p>

Page 342

1 MS. CRISTINZIO: So we have a slight change  
 2 in the agenda here, and I'm sorry it's not reflected  
 3 in the printed version that you have. We have number  
 4 85a, as you see, Mr. Marwan Moheyeldien presenting  
 5 from Maryland Packaging next. And then, after him, we  
 6 will resume in numerical order. Thank you.

7 MR. MOHEYELDIEN: Thank you so much. My name  
 8 is Marwan Moheyeldien. I'm the CEO of Maryland  
 9 Packaging and COO of Fuchsia Foods. Maryland  
 10 Packaging is the largest food co-manufacturer in the  
 11 mid-Atlantic. I'm sorry. One second to advance.

12 So we're the largest co-manufacturer in the  
 13 food. We manufacture for Fortune 100 companies. We  
 14 manufacture for startup brands. We've been in  
 15 business since 1983. We produce food and beverage  
 16 that are consumed by millions of consumers on a daily  
 17 basis.

18 Maryland Packaging is PCQI-certified, FDA-  
 19 registered for 20 years without a single violation,  
 20 USDA legend facilities, two of them in the state of  
 21 Maryland, SKF-certified, preventive control program-  
 22 compliant, food defense-compliant, homeland security-

Page 343

1 certified. We are kosher. We're halal. We're  
 2 organic. We're third party-audited. We are HPP  
 3 authority. We are HARPC-compliant, HACCP-compliant  
 4 and certified FSMA-compliant and certified and we are  
 5 GMP-certified. So I think we can say that we are very  
 6 heavily regulated and we're very heavily compliant.

7 We came across CBD because we have a  
 8 tremendous amount of clients that are coming to us to  
 9 be able to start manufacturing products for them with  
 10 CBD. When we looked at the model of being able to  
 11 manufacture for these clients, we started realizing  
 12 very quickly that we have two issues that we have to  
 13 deal with.

14 One of them is how are we going to ensure  
 15 that the product that we are going to manufacture is  
 16 going to be safe. And number two, how are we going to  
 17 make sure that the product that is being received by  
 18 us to manufacture is going to be safe?

19 On our Fuchsia website, which is our own CPG  
 20 brand, we decided that we were going to actually put a  
 21 claimer that says our stand is very clear on CBD. We  
 22 take the same stand as the FDA.

Page 344

1 And we posted the paragraph that the FDA came  
 2 up with stating that it is considered -- if it's being  
 3 sold as any kind of medicinal purpose, it is a drug  
 4 and should be sold as such. And if it's being sold,  
 5 it's basically illegal.

6 So what did we decide on doing to be able to  
 7 make sure that we are compliant? One thing that we  
 8 know is the following. The industry is so large, it's  
 9 right now \$600 -- I'm sorry, it's \$600 million  
 10 industry. And it's going into \$2 billion in the  
 11 retail industry.

12 We've had multiple meetings with the health  
 13 department from the state of Maryland which complies  
 14 for the FDA. The actual meeting with the health  
 15 department when they came and sat with me and they  
 16 said, well, you have to be careful because the FDA has  
 17 not approved for you to manufacture. So when you  
 18 submit the labels, we're going to take the same stance  
 19 with the FDA that you can't manufacture it.

20 And my response to them, well, under Consumer  
 21 Protection Act and as a consumer, I'm going to ask the  
 22 FDA to go in and basically recall anything on the

Page 345

1 shelf in the state of Maryland if you're telling me  
 2 that it's illegal to supply it or illegal to sell it.

3 The response was you're giving us anxiety. Well, you  
 4 know, I'm sure we are.

5 But at the end of the day, if the FDA -- I've  
 6 been down this. We're the largest HPP facility in the  
 7 Mid-Atlantic. And when we started the HPP, we had the  
 8 same arguments with the FDA. Eventually I became the  
 9 foremost authority on HPP in the Mid-Atlantic and I  
 10 became the CASA speaker on behalf of the government as  
 11 well as the FDA.

12 All we are asking for is we are asking for a  
 13 fair, level playing field. We intend -- if we are  
 14 going to use CBD and we're going to manufacture it,  
 15 it's very simple to be able to control it.

16 Our interest is any kind of CBD that we bring  
 17 in to use in our manufacturing, we're going to have it  
 18 tested for pesticides, heavy metal, confirm that it is  
 19 0.3 -- below 0.3 THC, not 0.03. I'm going to have to  
 20 talk to my people -- accurate CBD measurements as  
 21 advertised.

22 Once we find out that the product that we

<p style="text-align: right;">Page 346</p> <p>1 plan on using complies, then we will use it in  2 manufacturing. Before our product is released, our  3 lot number will go to a third party laboratory to be  4 able to confirm the same exact parameters. That COA  5 from the lab would be published on the Internet for  6 inspection by any government agency and any consumer.  7 All we want to do is we want to make sure  8 that we are a responsible manufacturer in the  9 industry. But we have to have a path. We have to  10 know where you guys are going to stand because if we  11 receive a letter telling us that we can't operate  12 under any circumstance, we expect you to do the same  13 thing with every other manufacturer.  14 The last thing is my concern is if we don't  15 have a provisional kind of license allowing  16 manufacturers or responsible manufacturers like us to  17 operate, all the FDA is going to do is going to drive  18 those manufacturers underground and you're going to  19 have a black market to be able to put this product in.  20 You can't control the product on the shelf. And as  21 long as people want it, people are going to  22 manufacture it.</p>	<p style="text-align: right;">Page 348</p> <p>1 committed to and have invested in this industry in a  2 really significant way. We employ more than 130  3 people. We've spent many tens of millions of dollars  4 on hemp that has gone to American farmers. We've  5 spent tens of millions of dollars on equipment and  6 infrastructure.  7 So our company is really focused on  8 manufacturing of CBD ingredients. And that starts  9 with our process expertise and our engineering team.  10 And we've designed and built largescale customized  11 extraction and purification equipment that  12 specifically is tailored to this industry.  13 The second key component of our manufacturing  14 is our commitment to quality and compliance. We  15 manufacture according to GMP standards, 21 CFR parts  16 111 and 117 and we've been audited by third parties  17 for compliance to these GMPs. We have strict  18 specifications on all incoming components and finished  19 products and each material is tested using validated  20 in-house methods for compliance and specification.  21 You know, this has been talked a lot about  22 today. But the size of the CBD market is exploding</p>
<p style="text-align: right;">Page 347</p> <p>1 So my request is to be able to find a path  2 for a provisional license for certain companies that  3 meet certain criteria to be able to manufacture and we  4 will self-police ourselves under the supervision of  5 the FDA or any agency that chooses to regulate us.  6 But we want regulation and we welcome it. So please  7 find a path for us to be able to provide safe products  8 for the consumer.  9 MS. CRISTINZIO: Thank you.  10 MR. MOHEYELDIEN: That's it. Thank you.  11 MS. CRISTINZIO: Next, we have speaker  12 number 86, Stephen Mueller.  13 MR. MUELLER: My name is Stephen Mueller.  14 I'm the founder and CTO of Mile High Labs. Mile High  15 Labs is a largescale hemp extraction and purification  16 company that produces thousands of kilograms of CBD  17 every month. Through our customers, that CBD goes  18 into maybe 10 million products every month.  19 Our production facilities and headquarters  20 are in Colorado. We also have international offices  21 in the UK and New Zealand.  22 You know, we really believe in and are</p>	<p style="text-align: right;">Page 349</p> <p>1 right now. Many other presenters have talked about  2 that today. But it's estimated that up to 64 million  3 Americans have used CBD in the past 24 months. So  4 regardless of the existing regulations, this thing is  5 taking off and we really want to make sure that it's  6 done in a way that's safe for the consumer.  7 You know, here are some of the common issues  8 that we see in the market, and these have kind of been  9 covered as well. Mislabeled products. Some of the  10 presentations I saw today were pretty astounding in  11 terms of just how mislabeled they are. Facilities  12 that aren't operating under GMPs. This is one of the  13 biggest issues that we see out there.  14 If you don't have the proper controls in  15 place per the GMP guidelines, you're really at risk of  16 shipping unsafe product to the consumer. And many  17 manufacturers don't have access to accurate test  18 methods, either in-house or through contract labs.  19 The level of inconsistency that we've see  20 with some of the contract labs and third-party labs is  21 really -- is pretty astounding.  22 So one of the problems today is that a lot of</p>



<p style="text-align: right;">Page 350</p> <p>1 the manufacturers don't actually understand what they  2 need to do to make a safe and consistent product for  3 the consumer. Consumers also don't have confidence in  4 the products themselves and don't understand which  5 manufacturers they can look to, to buy a safe product.  6       And really, our position is that the good  7 manufacturing practices already outlined by the FDA  8 are really the baseline for production of a quality  9 and consistent ingredient and we think that this  10 should be applied to all CBD manufacturers.  11       So new dietary ingredient notification should  12 also be required for all CBD dietary supplements.  13 This is already outlined in FDA guidelines and we  14 think that CBD fits into those existing guidelines.  15       The main focus of the discussion today seems  16 to be around CBD. But a lot of the products on the  17 shelf also contain many other compounds, so other  18 cannabinoids, terpenes, degradants and we think that  19 the FDA should evaluate all of these separately  20 instead of trying to combine all of the non-THC  21 products under one category. I think there's so much  22 variability in the types of products out there that</p>	<p style="text-align: right;">Page 352</p> <p>1 applicability of the method to the sample matrix.  2       Right now most of the industry uses contract  3 labs who are testing products using generic methods  4 that have not been validated for that particular  5 sample matrix. You know, being an agricultural  6 product of hemp, we also need to look at heavy metals  7 and microbial contamination.  8       So I want to commend the FDA for bringing  9 together all of the stakeholders to work together  10 towards a solution. We believe strong regulation  11 enacted quickly will benefit consumers and improve the  12 industry. Thanks for the opportunity. Any questions?  13       PANEL MEMBER: Yeah. Just one follow-up  14 question. So your slide four, you talked about  15 regulating use in dietary supplements, foods and  16 cosmetics at lower strengths.  17       I didn't know if you had an idea for how we  18 would go about identifying that lower strength that  19 would be appropriate for those uses and any thoughts  20 you had with that would be really helpful.  21       MR. MUELLER: So I think you'd need to look  22 at some of the safety data out there in the studies</p>
<p style="text-align: right;">Page 351</p> <p>1 it's very difficult to regulate or to control  2 consistency of the product. We can isolate and purify  3 these compounds and formulate products with them that  4 are more consistent.  5       So the heart of quality control is the  6 ability to characterize and test raw materials and  7 final products. Here's a list of some of the critical  8 quality attributes that we think should be controlled  9 for all of the materials and finished products that  10 CBD manufacturers are dealing with.  11       You know, one thing in particular I want to  12 point at here is using validated test methods, per the  13 GMP guidelines, and really being able to produce  14 accurate test results. This is one of the biggest  15 issues that leads to some of the label claim issues  16 and other problems in the industry.  17       The third-party labs are using generic test  18 methods and the method really should be validated for  19 each sample matrix. It's not appropriate to use a  20 method that was validated for CBD content in hemp and  21 also use that method for testing products containing  22 CBD without performing studies to demonstrate the</p>	<p style="text-align: right;">Page 353</p> <p>1 that have been done. You know, as an ingredient  2 manufacturer, we're not making consumer products that  3 have guidelines on how much can be taken. But you  4 know, we think this is an important route for kind of  5 the broader public outside of pharmaceutical drug  6 applications. Thank you.  7       MS. CRISTINZIO: Thank you. Next we have  8 speaker number 87, Aaron Secrist.  9       MR. SECRIST: Good afternoon. My name is  10 Aaron Secrist. I'm the vice president of quality and  11 regulatory affairs for NOW Health Group. As a  12 responsible manufacturer of legal dietary supplements,  13 NOW Health Group is very concerned about the current  14 state of affairs with regards to hemp and hemp-derived  15 products such as CBD.  16       The current approach taken by FDA, which  17 seems to be best described as unofficial enforcement  18 discretion, does little to promote and protect the  19 public health, the primary mission of the agency.  20       By not enforcing the current statutes, the  21 agency has encouraged irresponsible or, at best,  22 uneducated and uninformed companies to manufacture and</p>

<p style="text-align: right;">Page 354</p> <p>1 market CBD and other hemp-derived products without  2 understanding in many instances the identity of the  3 CBD ingredients or hemp-derived ingredients that  4 they're putting in the products and without any safety  5 studies performed on these ingredients that they use  6 in the products that seem to vary so widely in the  7 marketplace, as we've seen today.</p> <p>8 We respectfully ask the FDA to do one of two  9 things: either enforce the current statutes and hold  10 the companies responsible for manufacturing and  11 marketing these illegal products or we urge the  12 secretary to exercise his authority under current  13 statute to allow hemp-derived products such as CBD to  14 be recognized as legal dietary ingredients, provided  15 that an NDIN is submitted and all other applicable  16 federal laws are met.</p> <p>17 This will encourage responsible companies who  18 follow the law, such as NOW Health Group, to  19 potentially enter the market through the front door  20 and perform the requisite safety studies, method  21 validation, clinical studies and submit an NDIN for  22 agency review to ensure that safe and effective</p>	<p style="text-align: right;">Page 356</p> <p>1 identity of the potentially new dietary ingredient,  2 along with the requisite safety studies necessary to  3 demonstrate to the agency that the ingredient is safe  4 under the conditions of use.</p> <p>5 We do not believe that the agency should  6 accept self-affirmed GRAS as a way to circumvent the  7 NDIN process as it relates to CBD and other hemp-  8 derived ingredients. We also believe that it's very  9 important for the FDA to ensure that there's federal  10 preemption for any pathway forward for hemp-derived  11 ingredients such as CBD as potential new dietary  12 ingredients.</p> <p>13 Varied and often contradictory state law  14 makes it nearly impossible for responsible companies  15 to enter the marketplace, which leads to subpar and  16 possibly unsafe products on the marketplace. Thank  17 you for your time.</p> <p>18 MS. CRISTINZIO: Thank you. Next we have  19 James Sharkey, number 88.</p> <p>20 DR. SHARKEY: Good afternoon. I'm Dr. James  21 Sharkey. A little bit about me, I have a doctorate in  22 biomedical sciences and I am the director of research</p>
<p style="text-align: right;">Page 355</p> <p>1 products are available to the American public. This  2 is in keeping with the FDA's mission and our company's  3 mission and values.</p> <p>4 We also respectfully ask the FDA to ensure  5 that the rule of law is upheld by barring any company  6 illegally marketing CBD or other hemp-derived dietary  7 supplements from submitting an NDIN for a period of  8 time equal to the time that their products have been  9 illegally marketed.</p> <p>10 If the FDA simply opens the door to hemp-  11 derived ingredients and products containing CBD by  12 exercising the secretary's authority without such a  13 provision, then it effectively encourages companies to  14 flout the law in the future, as the only consequence  15 would seem to be a three- to five-year head start in  16 the marketplace over companies who choose to follow  17 the law.</p> <p>18 We also respectfully ask the FDA to continue  19 to explore the idea of master files relative to the  20 NDIN process. We believe that this will help provide  21 some IP protection to the companies that spend the  22 precious resources of time and money to ensure the</p>	<p style="text-align: right;">Page 357</p> <p>1 and development for hemp and CBD products for Dixie  2 Brands and I'm also --</p> <p>3 MS. CRISTINZIO: Can you move closer to the  4 microphone please?</p> <p>5 DR. SHARKEY: I'm sorry.</p> <p>6 MS. CRISTINZIO: That's okay.</p> <p>7 DR. SHARKEY: And I'm also the chief science  8 officer for Therabis, which is a pet supplement brand.  9 My talk today is going to primarily focus on the human  10 supplement aspect of our businesses. But the written  11 comments that we will be providing will also include  12 animals.</p> <p>13 Dixie Brands, we're based out of Denver,  14 Colorado and we were one of the pioneers in the  15 medical cannabis industry, which naturally brought  16 along hemp and CBD products. We've been creating  17 these products since 2009 under the regulatory  18 environment of the Colorado -- state of Colorado,  19 which is one of the most mature hemp and cannabis  20 markets in the United States.</p> <p>21 The reason why I'm employed there, unlike  22 others in the space, is that we are very research-</p>

<p style="text-align: right;">Page 358</p> <p>1 emphasis, very heavy research emphasis and providing  2 products that are safe and have a degree of efficacy.  3       Recently we just announced actually yesterday  4 that we partnered with a major university veterinary  5 school to perform a clinical study on efficacy with  6 safety in canine joint health.  7       So I'm going to proceed to go to -- now,  8 we've heard today that there is a dearth of research  9 in the space, specifically regarding safety. It's  10 true and it isn't true. In the United States, it  11 absolutely is true that very little of this work has  12 been produced in the United States.  13       The majority of this are products from  14 overseas. And I've selected just a few studies to  15 show that we have side effect -- chronicling of side  16 effects in humans, in oral administration since 1973  17 as well as across a broad range of dosages.  18       Now I just learned today from GW  19 Pharmaceutical that they have shown adverse events as  20 low as 1 mg/kg. It's in a bit of conflict and that is  21 not publicly available. So I would strongly encourage  22 that, for the benefit of all of us stakeholders, that</p>	<p style="text-align: right;">Page 360</p> <p>1 we absolutely have to be concerned with because  2 previous mouse work has shown inhibition of cytochrome  3 P450s. And this was with clobazam and valproate.  4 Valproate is known to have hepato -- to damage the  5 liver and clobazam is known to have existing  6 somnolence. As a matter of fact, the CBD of clobazam  7 was predicted and characterized by Geoffrey in 2015.  8       Then earlier today we learned from a previous  9 group about this hepatotoxicity in mice. A lot of  10 hard work has gone into that. But in reality, the  11 test article they did, did not resemble anything that  12 would be seen in a human being in the market.  13       Specifically regarding the THC levels and the  14 fact that the residual solvents weren't characterized  15 to a sufficient degree for a limit of quantitation.  16 So we need some additional data and need to make sure  17 that these studies accurately represent the products  18 we're doing.  19       And then, here are just some conclusions  20 based upon this. The FDA has done a clinical trial, a  21 Phase III clinical trial and approved a drug in a  22 vulnerable patient population of children. That is</p>
<p style="text-align: right;">Page 359</p> <p>1 these type of studies be made publicly available so  2 that we can see and actually produce products, given  3 if it is -- if the FDA does take a path towards a  4 supplement category, that we can actually operate and  5 provide safe products because there are a lot of us  6 out there who do this, do want to ensure safety.  7       So beginning with Carneal, that was a  8 relatively small study. But 40 healthy adult males  9 and a dosage of 15 to 60 mg. So roughly that is sub 1  10 mg/kg. Hollister was 200 to 100. The more  11 interesting one would be Consroe, which was a 15-week  12 study in Huntington disease patients at 10 mg/kg/day  13 that reported no significant side effects.  14       But the more recent data we have is the  15 Epidiolex safety trial and the extended access  16 program. A total of 607 patients were in the safety  17 arm of the extended access program. Dosages got up to  18 between 25 and 50 mg/kg/day and the dose range  19 corresponded to 20 mg/kg/day for the study and 200 mg  20 per day for the maintenance dose in a 10 kg child.  21       Primary findings, it was well tolerated.  22 However, they did show some drug interactions, which</p>	<p style="text-align: right;">Page 361</p> <p>1 the most robust safety trials that exist. Further, we  2 have empirical -- not empirical data, but anecdotal  3 data and a lack of reporting of side effects in the  4 general populace.  5       This lends to a degree that a concentration  6 of 1 to 2.8 mg/kg, which would be the consumer  7 available dose, that these supplements would in fact  8 be relatively safe in an adult -- health adult  9 population. Thank you for your time.  10       MS. CRISTINZIO: Thank you. Speaker number  11 89, Priyanka Sharma?  12       DR. SHARMA: Thank you. Good afternoon to my  13 industry colleagues and distinguished guests. It is  14 truly an honor and a privilege for us to be here  15 today. We'd like to thank the Food and Drug  16 Administration for providing us with this platform  17 today and for hosting this public hearing on cannabis-  18 derived compounds.  19       My name is Dr. Priyanka Sharma, and I'm  20 joined here by Pulak Sharma. We're co-founders of  21 Kazmira. I'm going to be explaining the left-hand  22 side and Pulak will be talking about the remaining</p>

<p style="text-align: right;">Page 362</p> <p>1 information.</p> <p>2 Kazmira is a biotechnology manufacturing</p> <p>3 company operating in Colorado producing THC-free CBD</p> <p>4 raw extracts derived from industrial hemp. Our</p> <p>5 products are consistently free of residual solvents,</p> <p>6 heavy metals, pesticide and microbial contaminants, to</p> <p>7 name a few.</p> <p>8 We develop these raw ingredients for product</p> <p>9 manufacturers who produce finished goods which are</p> <p>10 distributed online and within retail channels. We</p> <p>11 believe that setting high product quality standards</p> <p>12 will enable development of finished products that are</p> <p>13 safe for consumers.</p> <p>14 Industrial hemp manufacturers throughout the</p> <p>15 U.S. have already implemented significant quality</p> <p>16 control and stringent manufacturing standards in the</p> <p>17 current processes of extracting the hemp biomass into</p> <p>18 oils containing a variety of cannabinoids.</p> <p>19 Today we would like to discuss three quality</p> <p>20 metrics already followed closed by hemp-derived</p> <p>21 product manufacturers: consumer safety, quality</p> <p>22 management systems and validated testing.</p>	<p style="text-align: right;">Page 364</p> <p>1 available today to manufacturers where contaminant</p> <p>2 testing is performed on raw materials and finished</p> <p>3 products. Cannabinoid purity analysis, residual</p> <p>4 solvents, heavy metals, pesticides and microbial</p> <p>5 contaminants are among the testing performed currently</p> <p>6 on these products.</p> <p>7 Manufacturers and testing laboratories would</p> <p>8 support a collaboration between industry and federal</p> <p>9 regulatory stakeholders to develop federal compliance</p> <p>10 guidelines and standardized testing methods for CBD</p> <p>11 products.</p> <p>12 MR. SHARMA: Thank you, Priyanka. Performing</p> <p>13 at the highest level of manufacturing and product</p> <p>14 quality standards is going to give us stronger</p> <p>15 consumer safety infrastructure.</p> <p>16 First there will be increased quality</p> <p>17 transparency with consumers being aware of contents of</p> <p>18 their hemp-derived products through updated packaging</p> <p>19 and labeling requirements. This will spark a healthy</p> <p>20 debate that encourages education on product quality.</p> <p>21 Second, enabling a pathway for acceptance of</p> <p>22 CBD oils through the right channels as a dietary</p>
<p style="text-align: right;">Page 363</p> <p>1 With added support from federal regulatory</p> <p>2 agencies, we can continue to create a brighter future</p> <p>3 state for the hemp-derived products industry. At</p> <p>4 Kazmira, we have focused our manufacturing processes</p> <p>5 on meeting the current applicable standards of CBD raw</p> <p>6 materials. This enables our customers to give</p> <p>7 consumers a product with non-detect levels of THC.</p> <p>8 Working with regulatory agencies, we would</p> <p>9 support development of guidelines for consumer product</p> <p>10 specifications.</p> <p>11 Second, current quality management systems</p> <p>12 allow complete traceability from farm to product.</p> <p>13 Many of the manufacturers here today have obtained ISO</p> <p>14 9001 and are working towards self-regulating CGMP</p> <p>15 compliance certifications.</p> <p>16 To further standardize process controls,</p> <p>17 infrastructure to support higher quality control on a</p> <p>18 federal level needs to be provided. We as</p> <p>19 manufacturers would support guidance on obtaining</p> <p>20 FSMA, GFSI or other food safety management compliance</p> <p>21 practices.</p> <p>22 Third, cannabis-testing laboratories are</p>	<p style="text-align: right;">Page 365</p> <p>1 supplement and a food ingredient will create</p> <p>2 accountability with all stakeholders and drive deeper</p> <p>3 transparency and trust with consumers.</p> <p>4 This has been successfully replicated with</p> <p>5 ingredients such as fish oils. As for the CBD</p> <p>6 industry, this model has been defined with successful</p> <p>7 deployment by the Colorado Department of Public Health</p> <p>8 and Environment.</p> <p>9 Finally, ingredient safety will drive the</p> <p>10 conversation of product safety with rigorous process</p> <p>11 control, quality management and high compliance</p> <p>12 standards that enable higher quality products</p> <p>13 consumers can trust. For example, this can be pursued</p> <p>14 through USP monographs for dietary supplements.</p> <p>15 Thank you very much for your valuable time</p> <p>16 and enabling this engagement to start the conversation</p> <p>17 on this important subject. We hope that with the</p> <p>18 presentations today, the regulatory agencies got a</p> <p>19 glimpse of the industry stakeholders' vested interests</p> <p>20 in making processes and standards for consumer safety.</p> <p>21 We look forward to continuing this dialog and</p> <p>22 creating a sustainable pathway for manufacturers to</p>

<p style="text-align: right;">Page 366</p> <p>1 serve consumers with the highest quality and safety  2 standards for cannabis-derived compounds and products.  3 Thank you.  4 MS. CRISTINZIO: Thank you. Our last  5 presentation before the break, number 90, Thuy Vu.  6 MS. VU: Good afternoon. My name is Thuy Vu  7 and I am -- I serve as the director of operations and  8 regulatory affairs for Hammer Enterprises integrated  9 solutions, located in Evergreen, Colorado.  10 Hammer Enterprises is one of the largest  11 vertically integrated industrial hemp companies in  12 Colorado and we serve as a custom white label  13 manufacturer offering a full spectrum of products for  14 oral ingestion, inhalation and absorption.  15 Hammer Enterprises is committed to strict  16 quality control guidelines, ethical standards and high  17 integrity to deliver pesticide-free, chemical-free and  18 preservative-free pesticides -- I'm sorry,  19 preservative-free products. Hammer Enterprises is  20 devoted to setting the highest standards in the  21 industry promoting public health, public safety and  22 environmental stewardship.</p>	<p style="text-align: right;">Page 368</p> <p>1 Colorado has successfully regulated the legal  2 marijuana and industrial hemp program. The Colorado  3 Department of Agriculture regulates the regulation --  4 the registration and cultivation of industrial hemp,  5 requiring all plants cultivated in the registered land  6 area meet the standard identity of no more than 0.3  7 percent THC on dry weight basis, as well as setting  8 forth criteria for pesticide usage.  9 In July of 2017, the Colorado Department of  10 Public Health and Environment announced a new  11 industrial hemp policy recognizing all parts of the  12 industrial hemp plant, including cannabidiol as a food  13 ingredient. CDPHE's industrial hemp policy is the  14 first of its kind in the nation and it's the most  15 progressive program applying current good  16 manufacturing practices to a new food ingredient.  17 Excuse me. Let me get to the right slide.  18 Okay -- as a new food ingredient. CDPHE's industrial  19 hemp policy is the first of its kind in the nation and  20 it's the most progressive program applying current  21 good manufacturing practices to a new food ingredient  22 and for a new emerging industry.</p>
<p style="text-align: right;">Page 367</p> <p>1 My perspective is unique in that I started my  2 career as a lead foodborne illness outbreak  3 investigator for the Denver Department of Public  4 Health and Environment, Public Health Inspections  5 Division.  6 After cannabis legalization in Colorado in  7 2010, I took the initiative to become the first  8 environmental health investigator to specialize in  9 marijuana investigations, spearheading inspections,  10 investigations and enforcement of the Denver marijuana  11 industry, implementing the first food safety recalls  12 of marijuana-infused products and the first foodborne  13 illness outbreak investigation of a licensed marijuana  14 operation in 2014.  15 In addition to my regulatory background, I  16 have five years' experience in the private marijuana  17 industry as well as the industrial hemp industry,  18 specializing in cannabis extraction and refinement  19 processes, concentrated infused products  20 manufacturing, food safety concerns and quality  21 control of cannabis and cannabis derivatives and  22 cannabis-infused products.</p>	<p style="text-align: right;">Page 369</p> <p>1 Hammer Enterprises played a pivotal role in  2 the successful implementation of CDPHE's industrial  3 hemp program, committing to a professional partnership  4 with CDPHE as well as other government and regulatory  5 agencies in efforts to advocate for informed, balanced  6 and fair regulations for the new industry.  7 CDPHE's industrial hemp policy requires all  8 parts of the plant utilized in food to be sourced from  9 a state with an established or approved hemp program  10 or a country that inspects and regulates the commodity  11 to ensure its safety for human consumption.  12 The producer or grower must be in good  13 standing and compliant with the governing laws of the  14 state or the country of origin and the raw material  15 and finished products must be tested to ensure that it  16 meets the standard of identity for industrial hemp and  17 that documentation must be available upon request.  18 The policy also outlines labeling  19 requirements citing all products meet both state and  20 federal labeling guidelines by identifying hemp as an  21 ingredient, the CBD potency, including the statement  22 FDA has not evaluated this product for safety or</p>

<p style="text-align: right;">Page 370</p> <p>1 efficacy, as well as clearly stating that no health                  2 benefit claims are to be made on the label or the                  3 extension thereof.</p> <p>4 In order for these products to be considered                  5 approved sources, CDPHE requires a manufactured foods                  6 registration of all industrial hemp operations. At                  7 Hammer Enterprises, we lead the industry by                  8 voluntarily adhering to the strictest guidelines for                  9 quality control with a robust testing protocol of all                  10 products throughout the extraction, purification and                  11 manufacturing process.</p> <p>12 As a vertically integrated operation, we have                  13 transparent oversight and complete control over every                  14 step of the process, from propagation to cultivation                  15 to extraction, refinement and purification and the                  16 manufacturing of finished products, achieving full                  17 chain traceability.</p> <p>18 All manufactured products are accompanied by                  19 a product specification sheet and a certificate of                  20 analysis, either from our in-house proficiency tested                  21 analytical laboratory or a third-party laboratory.</p> <p>22 While Colorado -- sorry. While Colorado marijuana</p>	<p style="text-align: right;">Page 372</p> <p>1 legitimate regulatory framework to streamline                  2 definitions, standards, required testing and full                  3 chain traceability.</p> <p>4 At Hammer Enterprises, we are setting this                  5 standard by pursuing our ISO 9001, 22000 and 17025                  6 accreditations. We have an onsite PCQI and follow                  7 CGMPs and FSMA guidelines to ensure the safety,                  8 consistency and quality of all manufactured products.</p> <p>9 We conduct -- we conduct batch testing of all                  10 of our raw materials, intermediate ingredients and                  11 finished products for cannabinoid potency, terpene                  12 profiles, residual solvents, mycotoxins, heavy metals,                  13 pesticide residues, moisture analysis, water activity                  14 and microbial, which includes total yeast and mold,                  15 total plate count, total coliform E. Coli and                  16 salmonella.</p> <p>17 We also have preliminary nutritional analyses                  18 of our raw CO2 extract, CO2 extract oil to split                  19 isolate and finished products. Thank you.</p> <p>20 MS. CRISTINZIO: Thank you so much for your                  21 comments. At this time, we are going to take a 15-                  22 minute break. We will see you back here at 3:30.</p>
<p style="text-align: right;">Page 371</p> <p>1 enforcement division has the list of solvents approved                  2 for marijuana extractions, some of which are not                  3 approved solvents for the production of human food.                  4 CDPHE requires the industrial hemp industry use only                  5 approved food solvents.</p> <p>6 These extracts can be further refined into                  7 various forms of concentrates used to produce products                  8 for ingestion, inhalation and absorption.</p> <p>9 Challenges are to be expected in any emerging                  10 industry that has little to no regulatory oversight.                  11 Conflicting regulations from state to state, no                  12 current standardized AOC testing methodologies for the                  13 various matrices allowing for variances in potency                  14 testing results and the lack of guidance from a higher                  15 authority.</p> <p>16 While some markets are still budding and                  17 others like Colorado progressive and radical in its                  18 approach to the regulation of industrial hemp, there                  19 lies one common theme: the desire and duty to ensure                  20 safety, consistency and quality of the manufacturing                  21 products containing cannabis and cannabis-derived                  22 compounds which can be attained by creating a</p>	<p style="text-align: right;">Page 373</p> <p>1 (Whereupon, the foregoing went off the                  2 record.)</p> <p>3 MS. CRISTINZIO: Please take a seat. We're                  4 about to begin. Thank you, everyone. We are ready to                  5 move onto a new category. It is the coveted "Other"                  6 category. First up, we have speaker number 91, Aubrey                  7 Adams. Thank you, Aubree.</p> <p>8 OTHER</p> <p>9 MS. ADAMS: Thank you for this opportunity.                  10 My name is Aubree Adams, and I'm a former Colorado                  11 mom. I moved to Houston, Texas this past summer                  12 because marijuana changed my home.</p> <p>13 My son started using marijuana edibles in the                  14 eighth grade, soon after legalization. He was self-                  15 harming. We did not know he was using marijuana                  16 because the industry makes these products in deceptive                  17 forms to disguise use.</p> <p>18 By February 2015, my son was irrational,                  19 paranoid, repeating things that did not make sense                  20 and, one night, he was so violent towards my younger                  21 son that my younger son ran barefoot through the snow                  22 to get away from him. He attempted suicide and was</p>

<p style="text-align: right;">Page 374</p> <p>1 hospitalized. When he was discharged, he was still  2 suicidal and I took him back to the ER where I was  3 told it's just marijuana and was sent home.  4       Within a few days, my son was hospitalized  5 again in a different town because there were no  6 available beds in our town. He told me he was using  7 dabs and he knew they were making him feel crazy and  8 he was trying to quit. He described dabs as strong  9 marijuana and called them crack weed. Dabs are mass  10 produced, marketed and called medicine.  11       I volunteered my family for crisis  12 intervention with the Department of Social Services  13 because I could not find treatment for marijuana  14 abuse. My son had developed the pediatric disease of  15 addiction. And by the next year, not only was he  16 using marijuana, he was using meth and heroin.  17       Marijuana kills. It's a gateway to more  18 drugs and pharmaceutical drugs. My son allows me to  19 tell his story because he wants the nation to know  20 that marijuana is deadly, harmful and can change you  21 forever with delusional thinking, hallucinations and  22 increased risk for suicide, depression and addiction.</p>	<p style="text-align: right;">Page 376</p> <p>1       Seventy percent of the marijuana shops in  2 Colorado recommend marijuana to pregnant women. So my  3 mom and I hung baby bibs on the marijuana shops in  4 Pueblo that says don't hurt our future, Colorado kids.  5 It's a campaign by the Marijuana Accountability  6 Coalition.  7       These are some of the people that have been  8 killed by the effects of marijuana in the state of  9 Colorado. Marijuana-induced suicides, marijuana-  10 induced psychotic murders and people killed by  11 marijuana-impaired drivers.  12       Here is a quilt from Moms Strong of more  13 people that have been killed by the effects of  14 marijuana, including marijuana psychosis and we even  15 have a marijuana-induced cardiac death.  16       Marijuana industry advertises psychotic  17 experiences as being a bonus. The ad says, ever been  18 so high you've shredded a pizza? We'll take you  19 there. Well, our kids have been so high they've  20 wanted to kill themselves and others.  21       Legalizing marijuana has made it more  22 dangerous than ever. It is now a weaponized assault</p>
<p style="text-align: right;">Page 375</p> <p>1       My husband also allows me to tell his story.  2 He read that marijuana would treat his panic attacks.  3 But marijuana harmed him and now he suffers from  4 severe depression, anxiety and suicidal thoughts.  5       My old community of Pueblo, Colorado has pot  6 scholarships for every high school senior. It's a  7 brilliant marketing plan by the predatory marijuana  8 industry to groom their future users. It's a way to  9 advertise to kids under the radar.  10       One out of three Pueblo high school seniors  11 now uses marijuana and they have a 27.6 chronic  12 absenteeism rate. There is a marijuana head shop next  13 door to an alternative high school where kids can see  14 shiny bongs and pipes and clothing and advertising  15 glorifying and normalizing marijuana. They even have  16 a person waving a sign saying come get your free pipe.  17       The number one cause of death ages 10 to 24  18 in Colorado is suicide. The main drug the victims are  19 testing for is marijuana, ages 10 to 19. In Pueblo,  20 Colorado, we are exposed to marijuana smell and smoke  21 everywhere we go, in schools, in stores, driving down  22 the road, in our own homes and on our own property.</p>	<p style="text-align: right;">Page 377</p> <p>1 on the brains of our loved ones. Colorado has allowed  2 a full criminal organization to flourish with pretty  3 store fronts to sell their poison under the disguise  4 of medicine with false claims, no warning and no  5 accountability.  6       Colorado has allowed products to be marketed  7 in the highest potency levels ever known and Colorado  8 has allowed a predatory industry to profit of our  9 children's demise. For the marijuana industry to  10 survive, they need more and future users. Those users  11 are the youth of our country.  12       Colorado has now turned into a third world  13 country. We have criminal organizations from all over  14 the world living in our neighborhoods. Why have drug  15 dealers been allowed to break federal law for so long?  16       Every day I try to forgive those that have  17 allowed this to happen. Drugs are winning the war on  18 drugs and the war is now in our homes and in our  19 neighborhoods. I am a witness to the fall of America  20 and THC is the weapon of our destruction.  21       I hope -- I hope the House of Representatives  22 in Illinois is listening to the testimonies from the</p>

<p style="text-align: right;">Page 378</p> <p>1 industry. It is very obvious tax and regulation is  2 not working and the people here are poisoning the  3 people of Colorado. And it is my wish that federal  4 law be enforced. Thank you.  5 (Applause.)  6 MS. CRISTINZIO: Thank you.  7 MS. ADAMS: I do have -- I have a minute, so  8 I would like to just keep --  9 MS. CRISTINZIO: No, I'm sorry. You're  10 actually over.  11 MS. ADAMS: Oh, I'm over?  12 MS. CRISTINZIO: Yeah.  13 MS. ADAMS: I'm so sorry.  14 MS. CRISTINZIO: That's okay.  15 MS. ADAMS: Thank you.  16 MS. CRISTINZIO: Next up, speaker number 92,  17 is Susan Audino.  18 DR. AUDINO: Good afternoon. Thank you for  19 the opportunity to address this critically important  20 need to create a regulatory pathway for CBD and other  21 cannabis products.  22 My name is Dr. Susan Audino and my testimony</p>	<p style="text-align: right;">Page 380</p> <p>1 However, to be clear, I do not believe that they  2 should be used freely and at the sole discretion of  3 the public. Rather I believe they need to be  4 introduced and used responsibly and cautiously by all  5 parties -- patients, physicians, the FDA and all other  6 regulatory bodies.  7 All patients, particularly those that are  8 immunocompromised and children, need to be cautious in  9 the adoption of these products and await the results  10 of solid and reputable testing.  11 For example, has science-based testing  12 accurately and precisely analyzed a product's  13 ingredients? Has it evaluated the product's potential  14 therapeutic benefits and risks of toxins or other  15 ingredients causing adverse effects? How do we know  16 how much is in there? How do we know how much is too  17 much or how much is too little?  18 As we know, rigorous testing can answer  19 questions such as these, empowering patients and  20 physicians to make truly informed decisions.  21 As with other products, cannabis-derived  22 products should be developed using and under the</p>
<p style="text-align: right;">Page 379</p> <p>1 here is built upon my expertise as an analytical  2 chemist and in testing methods. I'm also an A2LA lead  3 assessor and an instructor to many ISO standards. I  4 believe you are familiar with A2LA's dedication to  5 quality control testing. And I'm also a board member  6 of the Center for Research on Environmental Medicine  7 here in Maryland.  8 I serve on several expert advisory panels for  9 the cannabis industry and international organizations  10 such as an including AOSC and ASDM. My consulting  11 firm serves chemical and biological laboratories,  12 including those that test cannabis.  13 With that as a background, I'm going to stay  14 in my lane here today and ask you to focus on the role  15 that adequate product testing plays in protecting  16 patient safety. Of course testing and efficacy go  17 hand in hand. We've been hearing that all day.  18 However today I will focus on efficacy only in passing  19 and instead highlight the safety benefits associated  20 with adequate testing.  21 I believe that medical cannabis and cannabis-  22 based products have a place in the lives of patients.</p>	<p style="text-align: right;">Page 381</p> <p>1 processes central to and authorized by the FDA.  2 Product manufacture also requires the scientific  3 integrity of third-party testing labs to ensure that a  4 product meets the expectations displayed on its label  5 and in its marketing efforts.  6 This needs to be demonstrated for every  7 product, on every label, every time. My firm provides  8 scientific and technical guidance to cannabis  9 dispensaries, testing labs, medical personnel and  10 regulatory bodies.  11 We promote active research towards the  12 development of official test methods and we advocate  13 strongly for appropriate clinical research and product  14 development consistently -- consistent within the  15 rigors of the FDA processes.  16 For decades, centuries actually, there have  17 been countless anecdotal reports promoting the  18 benefits of cannabis and cannabis-based materials,  19 although advancing scientific evidence needs to catch  20 up with these attestations. The transparency and  21 openness with which you're conducting today's hearing  22 and soliciting additional testimony is a relief.</p>



<p style="text-align: right;">Page 382</p> <p>1 I say this because now more than ever the 2 public is gambling with its health. Product marketing 3 is far ahead of the science needed to substantiate 4 product claims and the media frenzy around CBD-based 5 products is rapidly expanding the use of unregulated 6 substances that people are ingesting without clear 7 indication of known benefits and risks. 8 This is a very frightening situation. Today 9 there are still many unknowns about the cannabis 10 plants and in particular its interactions with the 11 brain and other organs in order to allow these 12 unregulated CBD products with or without THC to be so 13 easily accessible. 14 Research is slowly emerging from the shadows 15 and must rationally and aggressively continue on. And 16 here are two more facts that could make you lose some 17 sleep. Makers of CBD and cannabis products are 18 susceptible to deception by laboratories that purport 19 to do science-based testing. 20 In fact, some laboratories don't even perform 21 quality control analyses of products for which they 22 are charging the manufacturers.</p>	<p style="text-align: right;">Page 384</p> <p>1 speaker is James Beck, speaker number 93, from the 2 Parkinson's Foundation. 3 DR. BECK: Hi, there. Can everyone hear me? 4 Great. As my slides -- 5 MS. CRISTINZIO: Just one second while we 6 pull your slides up. 7 DR. BECK: Great. No problem. I want to 8 thank you for the opportunity to speak today. I'm 9 James Beck. I'm the chief scientific officer with the 10 Parkinson's Foundation. A little louder? It's 11 deceiving. 12 So while my slides are coming up, the 13 Parkinson's Foundation is the largest community for 14 those living with Parkinson's disease. And there are 15 a number of individuals in the United States have PD. 16 When the slides show up, I'll show you a map 17 of the United States depicting the prevalence of those 18 with Parkinson's disease in the U.S., based upon a 19 current report that we had published recently. 20 MS. CRISTINZIO: Sorry about that. I can see 21 your slide from my desk. But that's not helping 22 anyone else here. Just one second. No? Try again.</p>
<p style="text-align: right;">Page 383</p> <p>1 Second, there are product manufacturers that, 2 when faced with state-mandated requirements, 3 intentionally hire laboratories because of their 4 reputation for doing substandard and ineffective 5 product testing. 6 Patients and other consumers are at greatest 7 risk from this negligent activity, and clearly you 8 know that. Again, I commend you for today's hearing. 9 I close with good news. You have stepped 10 into these waters before. The FDA has created an 11 orderly process that brings benefits to all of 12 society. And the FDA can tame this current Wild West 13 of testing by requiring true quality standards. 14 For that to happen, we need regulators who 15 are well-informed developing regulations that are 16 science-based and consider the intricate 17 interdependencies of accurate and reliable third-party 18 testing, perhaps developing control standards would be 19 a focus of a future FDA hearing. 20 When that day arrives, patients across the 21 U.S. will applaud that effort as well. Thank you. 22 MS. CRISTINZIO: Thank you, Susan. Ur next</p>	<p style="text-align: right;">Page 385</p> <p>1 DR. BECK: Perfect. Okay. Well, I'll start 2 again. So I'm from the Parkinson's Foundation, which, 3 as I mentioned, is the nation's largest community for 4 those living with PD. 5 Nearly a million people live with PD, 6 underlining the urgency for what we do as an 7 organization. This chart of the United States shows 8 deep blue states which have more people with PD than 9 the lighter colored states, based upon a recent report 10 that we published as a group. 11 Many of you on the panel and in the room may 12 not know what Parkinson's disease is. It's a 13 neurodegenerative disease primarily characterized by 14 loss of dopamine neurons that can lead to motor 15 symptoms that include tremor at rest, bradykinesia, 16 which is slowness of movement, or rigidity. 17 Many approved therapies already address these 18 current symptoms. And levodopa shown up there on the 19 right is that green pill is one of the classic 20 examples. However, people with PD have many other 21 symptoms that are not well-addressed by current 22 approved therapies, problems with sleep, cognition,</p>

<p style="text-align: right;">Page 386</p> <p>1 autonomic dysfunction, mood disorders, et cetera,  2 which is why those in our community are seeking  3 alternative ways with which to control these symptoms.  4 And cannabis is not surprisingly one of those  5 choices. And when we surveyed our PD neurologists at  6 our centers of excellence throughout the U.S. and the  7 world, we found that 95 percent of them report being  8 asked about medical cannabis from their patients.  9 That, along with the changing in the  10 legalization in the United States, led to the  11 Parkinson's Foundation to gather key stakeholders in  12 at a meeting in Colorado earlier this spring.  13 The goal here, by bringing together people  14 with Parkinson's disease, neurologists who specialize  15 in PD, epileptologists, people who specialize in MS,  16 is to understand what could cannabis be used for when  17 it came to Parkinson's disease.  18 What are the gaps in knowledge? What are our  19 safety concerns? What are health effects? And the  20 idea here is to guide the patient as we wait for  21 formal guidance from the government and further  22 research and also to develop a research plan for</p>	<p style="text-align: right;">Page 388</p> <p>1 cannabis as a form of treatment.  2 But cannabis is a drug. And like any other  3 drug, it has side effects that we need to be concerned  4 about. Many of the side effects for cannabis are also  5 symptoms of Parkinson's disease itself. So the issue  6 here is that individuals who may utilize cannabis as  7 self-treatment may be making their own PD symptoms  8 worse.  9 Up there are dizziness and low blood pressure  10 or hypotension. If a person with Parkinson's disease  11 who was using cannabis too much led to a fall at the  12 age where people with PD have Parkinson's disease is  13 in the late 60s, early 70s, it could be catastrophic.  14 And that's the last thing we want.  15 The other thing to just point out is that  16 many of these adverse effects or side effects were  17 discovered within a healthy population. It's  18 important to consider a neurodegenerative population  19 when trying to understand how side effects could be  20 different in this community.  21 Routes of administration are a challenge.  22 Inhalation is clearly the most rapid way with which to</p>
<p style="text-align: right;">Page 387</p> <p>1 moving forward with understanding how cannabis can be  2 useful.  3 Key takeaways are, not surprising, that  4 cannabis is unlikely to help the motor aspects. This  5 is the tremor that current approved therapies are able  6 to help.  7 It may be helpful at a targeted level for  8 non-motor symptoms, the sleep, the anxiety issues.  9 Bottom line is we really need more research to  10 understand the utility of cannabis in Parkinson's  11 disease. There's just not a lot known and the quality  12 of research is rather limited that's available.  13 Diving deeper into some of the non-motor  14 aspects, this survey that was again done in 2015  15 asking neurologists what they thought cannabis could  16 be useful for. In blue shows where they think it  17 could be a benefit and orange shows where neurologists  18 thought it could actually cause harm.  19 Superimposed upon this is from a focus group  20 in the patient community identifying their priorities.  21 Pain, anxiety and sleep are issues that people with  22 Parkinson's disease are dealing with and are seeking</p>	<p style="text-align: right;">Page 389</p> <p>1 deliver it. But using raw plant material can lead to  2 difficulties in dosing.  3 Oral forms are great. But they have a  4 delayed effect and it's compounded by the fact that  5 most people with Parkinson's disease have an issue  6 with gastroparesis, which is delayed gastric entering  7 and slow colonic motility, which can further compound  8 any type of titration or even understanding how this  9 can get delivered in an effective way.  10 Our community is concerned about lack of  11 standards that has been talked about here, side  12 effects and whether there's sufficient safety research  13 that accompanies cannabis.  14 Take-home messages from our key stakeholder  15 meeting is that we need objective safety and  16 tolerability assessments at various stages of  17 Parkinson's disease covering the symptoms as well.  18 We need more research within the  19 neurodegenerative community. We need an evidence-  20 based approach for treating and targeting symptoms.  21 And last but not least is what's been brought  22 up before. We need ready access to the study drug for</p>

<p style="text-align: right;">Page 390</p> <p>1 research in human subjects. It's too difficult right  2 now to obtain the medication in order to use for  3 people with Parkinson's disease and other diseases  4 areas. Thank you for your time.  5 PANEL MEMBER: I had a question.  6 DR. BECK: Yes?  7 PANEL MEMBER: When you talk about cannabis  8 use in Parkinson's patients, are you thinking  9 primarily of the higher THC products or of the low  10 THC, higher CBD products?  11 DR. BECK: So it's a mix. The problem is  12 that many people with PD are trying to choose low THC,  13 high CBD is what's often recommended if they're able  14 to get the information because it's less psychoactive.  15 But you go to a dispensary and it could be  16 hit or miss depending on what they could get. And so,  17 people who have high THC cannabis could lead to  18 problems with psychosis or delusions which are already  19 problems with people with PD. Any other questions?  20 Thank you.  21 MS. CRISTINZIO: Thank you. The next speaker  22 is Scott Coates.</p>	<p style="text-align: right;">Page 392</p> <p>1 important function that we serve is that we publish  2 the official methods of analysis.  3 So two years ago, in response to the concern  4 from the states, we responded to regulators and we  5 have taken action to convene experts and approve  6 consensus methods for analysis of cannabis and hemp in  7 feed, food, plant materials.  8 Those would be reference methods that  9 everyone could use so that the testing laboratory and  10 the producer could be using the same validated method.  11 We start by developing standard method  12 performance requirements. We call them SMPRs for  13 short. We started in 2017. We have one for cannabis,  14 cannabinoids and cannabis concentrate and one for  15 dried plant materials, one for chocolates and one for  16 pesticides and cannabis.  17 Those documents give in great detail what  18 cannabinoids and how many of the cannabinoids and at  19 what level we're going to be testing.  20 We use those as a call for methods and we  21 have two official methods now for cannabinoids in  22 dried plant materials.</p>
<p style="text-align: right;">Page 391</p> <p>1 MR. COATES: Thank you. Good afternoon. I  2 am Scott Coates, the senior director for the AOAC  3 Research Institute. That's a division of the AOAC  4 INTERNATIONAL, and I also serve as the program leader  5 for the cannabis analytical science program.  6 Before I start my presentation, I want to  7 make an observation. We've probably had at least a  8 dozen, maybe more, testimonies where there was  9 concerns about label accuracy. And that comes as no  10 surprise to me because we don't have any reference  11 methods.  12 And without having reference methods, we  13 don't know whether the label is accurate or the  14 testing laboratory is accurate. You don't know. So  15 we need to have reference methods. And that's one of  16 the things that I think the analytical science program  17 can help us with.  18 So just a little bit of background on AOAC  19 INTERNATIONAL, we have a long history in food safety  20 and involvement with USDA and FDA. We're consensus  21 builders. We bring people and scientists together to  22 decide on what the correct methods are, and that's an</p>	<p style="text-align: right;">Page 393</p> <p>1 After we did that exercise, we realized that  2 that was too slow. We did two official methods, two  3 reference methods in two years. Too much stuff was  4 going on. So we just decided to develop CASS.  5 So CASS's objective was to facilitate a forum  6 where the science of cannabis analysis could be  7 discussed, develop and publication of cannabis and  8 hemp-specific methods and standards, identify and  9 develop cannabis and hemp reference materials,  10 establish cannabis and hemp proficiency testing  11 programs and provide resources and education to the  12 regulators responsible for establishing rules and laws  13 for hemp.  14 We do have a policy, because it's paid for.  15 We do not advocate for or against the legalization of  16 cannabis. Our mission is consistent with ensuring  17 public health, and we do not accept any funding from  18 any organization involved in the cultivation or  19 manufacturing of cannabis or hemp.  20 We currently have three projects. The first  21 one is microbiology in cannabis and they're focusing  22 on aspergillus. A second one is the cannabinoids as</p>

<p style="text-align: right;">Page 394</p> <p>1 consumables and their initial focus is on  2 cannabinoids, in particular CBD and THC and hemp plant  3 material. They're also missioned to give some kind of  4 recommendations on reporting of total THC and also  5 recommendations on how to calculate dry weight.  6 And a third working group is the one that  7 reviews target limits of quantitation for pesticides.  8 They all currently got started in May and they are  9 doing their work and we expect to have some results by  10 the end of the summer.  11 So those are the first three that we got  12 started with. But we have many particular other  13 options. Potency, pesticide residues, biological  14 contaminants, chemical contaminants, untargeted  15 testing profiles and method validation guidelines.  16 So what AOAC is doing, what we have been  17 doing for 125 years, is set the standards for  18 development of reliable analytical methods and what  19 we're doing now is applying that to supporting  20 programs for cannabis and hemp in food products and  21 plant materials. And we feel that is critical. Thank  22 you.</p>	<p style="text-align: right;">Page 396</p> <p>1 the Food and Drug Administration to be a dietary  2 supplement and therefore legally used.  3 So if the Senate is not getting it right, I  4 think there's a pretty high chance that the rest of  5 America isn't getting it right and there's a lot more  6 that needs to be done in terms of consumer education.  7 So while that's certainly one way to resolve  8 the issue, I think the bigger way is this morning we  9 heard from Dr. Sharpless that this is completely  10 uncharted territory for the agency. That's not  11 exactly accurate.  12 Currently active pharmaceutical ingredients  13 are in nutritional products, dietary supplements,  14 botanicals at levels that are established below an  15 HHE, things like red yeast rice, Monascus purpureus,  16 snake root and those products are allowed to stay on  17 the market as dietary supplements.  18 That would seem to be, at least in the short  19 term, because regulation writing, especially in this  20 environment, and legislative action in this  21 environment, which I think is deemed at best  22 challenging, may be difficult.</p>
<p style="text-align: right;">Page 395</p> <p>1 MS. CRISTINZIO: Any questions from the  2 panel? Thank you so much.  3 MR. COATES: Thank you.  4 MS. CRISTINZIO: Next up, we have speaker  5 number 95, Daniel Fabricant.  6 DR. FABRICANT: Thank you. Good afternoon.  7 I think I may be the only speaker here who was once  8 part of the marijuana taskforce. So, it's good to see  9 some of you again. I don't necessarily miss some of  10 those meetings, and I can't imagine what -- I can't  11 imagine what the next one is going to be like.  12 Now I represent the Natural Products  13 Association, the oldest and largest trade association  14 in the dietary supplement space. We represent about a  15 thousand companies in 10,000 storefronts nationwide.  16 I think looking at how we got here, we've had  17 about 1,500 products come on the market over the past  18 three years. So clearly there's market confusion, so  19 much so that I think we have a letter from a senator,  20 a U.S. senator, which I'll submit for the record,  21 where -- and this man has served since 1993,  22 cannabidiol producer industrial hemp is considered by</p>	<p style="text-align: right;">Page 397</p> <p>1 So FDA can at present, using an HHE process,  2 establish a safe harbor, if you will, until other  3 science comes online. And this isn't completely new  4 territory for the agency. And other agencies have  5 looked at CBD specifically and exposure CBD daily.  6 WHO report has safe use up to 600 mg per day. No  7 place preference and no indication of hepatotoxicity  8 at those levels.  9 Mouse studies indicate somewhere between 8 to  10 10 mg/kg. That's including a safety factor. So for a  11 70 kg human, that would put the dosage range about  12 that 600 level.  13 So currently none of this is happening. And  14 furthermore, products aren't being screened for THC,  15 which is something the agency can do. There's no  16 planned activity code that I'm aware of that the  17 agency is asking for funding to look at THC in  18 products which would seem to be at odds with the  19 public health mission of the agency.  20 So with that, I think it's incredibly  21 important and you've heard from many people that time  22 is of the essence that the agency establish a level</p>

<p style="text-align: right;">Page 398</p> <p>1 via an HHE, allow for something to happen in the  2 interim while a regulation is being written or a  3 statutory solution is being sought.  4 And in the meanwhile, this is, while a  5 confusing issue, it's not an impossible issue. This  6 is food toxicology. I think there's a lot of streams  7 being crossed here. I think when you look at the  8 science, you hear a lot about drugs. You hear a lot  9 about how these interact.  10 But we're talking about food toxicology.  11 These are products that should be used by healthy  12 populations. And so, you saw a recent study that said  13 hepatotoxicity of a cannabidiol-rich cannabis extract  14 in the mouse model. Well, this mouse model actually  15 used a mouse that's used for cancer bioassays. Tumor  16 was not an endpoint of this study.  17 And this mouse is so popular, it's actually -  18 - Dr. Sharpless' lab used to use it at NCI in the  19 mouse bioassay program for cancer. So I think looking  20 at models like this in my time of running the division  21 of dietary supplements and we saw food toxicology  22 routinely on dietary supplements, we never saw any</p>	<p style="text-align: right;">Page 400</p> <p>1 Sharon, you see standard for products with caffeine.  2 Another joy we had at CFSAN. You saw levels for  3 pregnancy, for children, things like that.  4 So I think those are generally labeled away.  5 For adulteration, it's the use specified in the  6 labeling or conditions -- normal conditions of use.  7 So I think that's imparted into 402, into the law.  8 Thank you.  9 MS. CRISTINZIO: Thank you. Next up, we have  10 Jacqueline French, from the Epilepsy Foundation.  11 DR. FRENCH: Good afternoon. Thank you so  12 much for allowing me to make remarks today. I'm Dr.  13 Jaqueline French.  14 I'm the chief medical officer of the Epilepsy  15 Foundation, as well as a professor of neurology at NYU  16 School of Medicine in the epilepsy program and I do  17 see many people with uncontrolled epilepsy. So I come  18 here from both of those perspectives.  19 Next slide, please. I guess I can do it.  20 There we go. So the Epilepsy Foundation is the  21 leading national voluntary health organization that  22 speaks on behalf of the approximately 3.4 million</p>
<p style="text-align: right;">Page 399</p> <p>1 sort of animal models where the animal was already  2 compromised.  3 So I think that that's important to note,  4 that folks aren't getting the issues crossed. We're  5 talking about use in a healthy population and the  6 science should reflect that. And there's quite a bit  7 already in the science that does reflect that.  8 So in closing, again, I think there's plenty  9 of data out there that the agency can already use. A  10 lot of smart people at the agency. A lot of smart  11 people on this panel. A lot of people with background  12 in toxicology.  13 It would seem to be that the exposure level  14 drives this discussion and an unwillingness to set an  15 exposure level doesn't seem to make a lot of sense for  16 an agency charged with the public health. So with  17 that, I'm happy to take any questions.  18 PANEL MEMBER: Hi. I'm wondering if you have  19 any thoughts on labeling issues related to dietary  20 supplements to address some of the risk factors and  21 some of the risks you're seeing.  22 DR. FABRICANT: I mean, I think you --</p>	<p style="text-align: right;">Page 401</p> <p>1 Americans with epilepsy and seizures. We foster the  2 wellbeing of children and adults affected by seizures  3 through research programs, educational activities,  4 advocacy and direct services.  5 Epilepsy, make no bones about it, is a  6 serious and potentially life-threatening disease. And  7 unfortunately, despite all of the therapies that are  8 available right now, one-third of people with epilepsy  9 do not have control of their seizures. Many of these  10 are children. Many of them are young children.  11 Individuals with uncontrolled seizures live  12 with continued risks of serious injuries. There is a  13 condition called sudden unexplained death in epilepsy  14 that can take people's lives. There's also the  15 possibility of status epilepticus, which is continued  16 seizures without stopping that can also be deadly.  17 For these reasons, I think that I speak in a  18 unique position because CBD, we've been told, is not a  19 drug. But we in the epilepsy community, obviously we  20 know it is a drug and it is a lifesaving drug. It's  21 been proven in randomized controlled trials of  22 Epidiolex that CBD in high enough concentrations can</p>

<p style="text-align: right;">Page 402</p> <p>1 stop seizures.</p> <p>2 And people who are in my community know that.</p> <p>3 They've heard that. They understand that and they are</p> <p>4 looking for answers for their uncontrolled seizures.</p> <p>5 So I'm just going to give you a little story,</p> <p>6 Laney's story. Laney was diagnosed with a type of</p> <p>7 epilepsy called juvenile myoclonic epilepsy as an</p> <p>8 adolescent in 2015.</p> <p>9 She had already failed eight other seizure</p> <p>10 medications and had been told that therefore there was</p> <p>11 only about a 1 percent chance of ever getting control</p> <p>12 of her seizures.</p> <p>13 She was started on CBD in September of 2017</p> <p>14 and this is not Epidiolex because Epidiolex is not</p> <p>15 approved for her type of epilepsy. And she stopped</p> <p>16 having convulsions and has not had one since four days</p> <p>17 after starting the product.</p> <p>18 And she is by no means alone. She uses a</p> <p>19 currently unregulated product. And believe me,</p> <p>20 listening to all of the other speakers today, that</p> <p>21 scares the bejesus out of me. But so far, it's been</p> <p>22 successful for her.</p>	<p style="text-align: right;">Page 404</p> <p>1 dietary supplement.</p> <p>2 And in the best case scenario, obviously</p> <p>3 everybody would take the pharmaceutical grade product.</p> <p>4 But they just don't have access for it. It's not</p> <p>5 feasible for everyone.</p> <p>6 So there are many, many people with epilepsy</p> <p>7 that are being medicated and often with their</p> <p>8 physician's assistance with CBD oil from various</p> <p>9 sources. So abrupt removal of CBD from these</p> <p>10 individuals could lead to seizure worsening, injury or</p> <p>11 death.</p> <p>12 And the second thing that I think is very</p> <p>13 important for me to say is that these people are</p> <p>14 unaware of the variability of the drug they may be</p> <p>15 taking, although they look for the best supply. Some</p> <p>16 people seek it out and are unaware of the risk of</p> <p>17 liver injury and the potential for serious drug</p> <p>18 interaction.</p> <p>19 So as the Epilepsy Foundation, we would like</p> <p>20 you to preserve access to CBD for those who need it as</p> <p>21 a lifesaving medication. But it is absolutely</p> <p>22 essential that there is consistency or people</p>
<p style="text-align: right;">Page 403</p> <p>1 So what happens if you, for example, go along</p> <p>2 the lines of what was just suggested and take all of</p> <p>3 the CBD off the market other than what has a low</p> <p>4 concentration? Laney and all the other Laney's in the</p> <p>5 world will suddenly lose access to the product that</p> <p>6 they've been using. And that literally could cause</p> <p>7 her and others to lose their lives.</p> <p>8 So as much as I am afraid of what we have</p> <p>9 now, I am more afraid as a representative of my</p> <p>10 community of losing it. If she needed to get -- to,</p> <p>11 you know, take Epidiolex, it would be \$32,000 per year</p> <p>12 because it would be off-label for her.</p> <p>13 She takes Haley's Hope, which is a form of</p> <p>14 CBD that she gets that's been grown for this very</p> <p>15 purpose. And she pays \$400 a month for that, which is</p> <p>16 still a lot of money, but it's affordable for her</p> <p>17 family.</p> <p>18 So CBD has been proven to be an effective</p> <p>19 treatment for the most severe forms of pediatric</p> <p>20 epilepsy. And I don't know that there's very many</p> <p>21 other circumstances where you have a drug that is</p> <p>22 lifesaving as a medication and also available as a</p>	<p style="text-align: right;">Page 405</p> <p>1 understand the consistency of their product, create</p> <p>2 some manufacturing standards, make sure that the</p> <p>3 horrible other things such as mold that might be in</p> <p>4 there are not in there and also increase availability</p> <p>5 of important information such as the potential side</p> <p>6 effects and drug interactions. And also, I totally</p> <p>7 agree that the access to this product for research is</p> <p>8 extremely important. Thank you.</p> <p>9 PANEL MEMBER: I think you just said that,</p> <p>10 you know, in an ideal world, you would like the</p> <p>11 pharmaceutical quality of an Epidiolex-like drug to be</p> <p>12 more widely available.</p> <p>13 But obviously you're saying preserve -- what</p> <p>14 I'm hearing you say is to preserve the other forms of</p> <p>15 it. And I guess my question for you is how would --</p> <p>16 how does preserving those forms affect companies that</p> <p>17 might want to develop the pharmaceutical.</p> <p>18 DR. FRENCH: Well, the issue is it's a little</p> <p>19 complicated. But there are probably a thousand</p> <p>20 different forms of epilepsy and nobody is ever going</p> <p>21 to have FDA approval for every single one of them.</p> <p>22 And that's true of all the other drugs that are on the</p>

<p style="text-align: right;">Page 406</p> <p>1 market of course.</p> <p>2 And again, I mean, you know, what would</p> <p>3 happen if the other approved drugs -- valproate we've</p> <p>4 heard, clobazam and other things -- were also</p> <p>5 available as a dietary supplement and people were</p> <p>6 taking them? It would be chaos.</p> <p>7 So I didn't -- you know, I'm not saying that</p> <p>8 this situation is the one I would have picked. But,</p> <p>9 you know, if that were true, many of those people</p> <p>10 would be taking it. And if you yanked it away from</p> <p>11 them, they would get horribly worse.</p> <p>12 So the situation is what it is. Many people</p> <p>13 are taking it and they need to have access to it now</p> <p>14 because no matter how many other manufacturers get FDA</p> <p>15 approval, they'll never get approval for everything.</p> <p>16 Thank you.</p> <p>17 MS. CRISTINZIO: Thank you. Our next speaker</p> <p>18 is Jeffrey Gitto, from Vanguard.</p> <p>19 MR. GITTO: Hello. Good afternoon, members</p> <p>20 of the committee. My name is Jeffrey Gitto. I'm an</p> <p>21 active attorney in the cannabis space for about six</p> <p>22 years, which is a very long time in the cannabis space</p>	<p style="text-align: right;">Page 408</p> <p>1 cannabis' long history. We are not speaking of a more</p> <p>2 esoteric version of such back to BCBC eras.</p> <p>3 But specifically the history of the U.S. and</p> <p>4 more specifically the relationship of the plan and</p> <p>5 what was considered to be its beneficial uses in the</p> <p>6 marketplace as an agricultural product, the context</p> <p>7 being you have to clear understand the past to</p> <p>8 understand the future.</p> <p>9 The FDA holds a unique source of power in</p> <p>10 regards to public health. It is important that the</p> <p>11 committee recognizes this beneficial agricultural</p> <p>12 product that has been around for millennia, at least</p> <p>13 outside the confines of a post-prohibitionist</p> <p>14 mentality, alternatively focused on research, product</p> <p>15 accountability, tracking and standardizing consistency</p> <p>16 by the FDA in tandem with the USDA and state oversight</p> <p>17 down to the farm level.</p> <p>18 Data analytics of supply chain is -- as</p> <p>19 everybody has heard the echoing of that -- crucial for</p> <p>20 traceability and safety. Regulating cannabis at a</p> <p>21 distance, at least at the moment, will allow the</p> <p>22 integrity of the currently 33 states and District of</p>
<p style="text-align: right;">Page 407</p> <p>1 for lawyers. Good to see a mix of lawyers on the</p> <p>2 panel too because I'm not going to be high science on</p> <p>3 this one.</p> <p>4 But what I wanted to do was present to the</p> <p>5 committee the legal pathways that, in my opinion,</p> <p>6 would be more an immediate effect for the public to be</p> <p>7 more confident in purchasing these products.</p> <p>8 One is a little more esoteric. I'm actually</p> <p>9 going to go through the three right now and then we'll</p> <p>10 go through them. But there's three, suggesting the</p> <p>11 FDA take a tripartite approach to the regulation of</p> <p>12 cannabis-derived products.</p> <p>13 A public health approach, consistent with the</p> <p>14 FDA core principles of innovation and practical risk</p> <p>15 versus rewards. Two, the duality of market paths</p> <p>16 dietary supplements and prescription-based uses.</p> <p>17 Three is respect state determinations of regulating</p> <p>18 in-state commerce under minimum federal standards.</p> <p>19 I won't get too much into commerce and</p> <p>20 dormant commerce clauses because that might get a bit</p> <p>21 too much. But to start off, number one, a public</p> <p>22 health approach. Here context must be given to</p>	<p style="text-align: right;">Page 409</p> <p>1 Columbia to continue their medical programs, as Mr.</p> <p>2 Fabricant and others have mentioned, the medical THC</p> <p>3 regime that each state has implemented has taken many</p> <p>4 state-specific factors into consideration for both its</p> <p>5 constituents, the state's needs and working within the</p> <p>6 regulated market.</p> <p>7 I put a timeline here, but it's rather</p> <p>8 complicated. But you guys can review it later, of</p> <p>9 course. The second approach is a dual regulatory</p> <p>10 approach similar to alcohol. At least on the</p> <p>11 precipitous of a post-prohibition, the only other time</p> <p>12 the United States has seen this was with alcohol.</p> <p>13 So to subject non-psychoactive cannabis-</p> <p>14 derived products to the two proven regimes that</p> <p>15 already exist.</p> <p>16 Impose similar minimum standards as there is</p> <p>17 upon alcohol and tobacco such as purity, dosage,</p> <p>18 consumer age, known labeling with medical claims,</p> <p>19 health warnings, et cetera, on cannabis-derived</p> <p>20 products, more speaking of non-psychoactive of course.</p> <p>21 And regulate the products under the proven systems</p> <p>22 already in place at the federal and state level.</p>

<p style="text-align: right;">Page 410</p> <p>1 I've heard a few questions from the panel  2 about incentivizations, required prescriptions. I can  3 get into incentivizations if you guys would like my  4 opinion on that.  5 For higher doses purity of cannabinoid and  6 subject such approval to abbreviated review process,  7 thereby increasing incentives for the research which  8 assists in the necessary data collection.  9 With data being collected by the states and  10 Canada, it will not be so much as just proving what  11 may be harmful, the known about the plant, but also  12 the unrealized potentially, the known unknown, if you  13 will.  14 For the moment, farmers should only be able  15 to isolate specific cannabinoids on a prescription  16 dosage purity level with the benefits of insurance,  17 medical industry and FDA support. And the inverse  18 would be social, religious, familial support groups  19 for the people who may abuse that from a dietary  20 supplement aspect.  21 Third is to clarify the confusion. As we all  22 know, having one drug violate the FD&amp;C Act, CBD, and</p>	<p style="text-align: right;">Page 412</p> <p>1 represent quite a few hemp farmers and THC farmers as  2 well as hemp seed cultivars. The industry will be  3 better kept inherently within the states while the FDA  4 and other agencies learn more about the challenges and  5 successes through the states, with the states always  6 being their own experiences in each of themselves.  7 The FDA's workload can be more focused on its  8 current regime of regulatory experience. Each state  9 has agricultural departments that must comply with the  10 USDA. States can regulate and enforce according to  11 minimum federal standards with their own thresholds as  12 they do with other heavily regulated industries like  13 alcohol, tobacco and gambling.  14 Plus they are collecting the tax revenues in  15 order to fund this. Cannabis is actually taxed more  16 than alcohol and tobacco and gambling.  17 MS. CRISTINZIO: Sorry, sir. You're quite  18 over. Can you wrap up, please?  19 MR. GITTO: Oh, am I quite over? Sorry. I  20 was into it.  21 MS. CRISTINZIO: Please don't forget to  22 submit all your comments to the docket.</p>
<p style="text-align: right;">Page 411</p> <p>1 the same drug not violate the act, Epidiolex, in a way  2 that would be understood from an agency level down to  3 the state and federal enforcement departments as well  4 as producers, vendors and consumers.  5 And then three may be controversial to some.  6 It's to allow the states to guide and support state  7 legislation, regulation in tandem with the USDA for  8 the farmers and the FDA. Each state should be allowed  9 to regulate both their respective non-psychoactive and  10 THC cannabis markets while operating under FDA minimum  11 standards and guidelines.  12 The state's commerce may be required to stay  13 within the state to be exempt as a temporary  14 compromise to accommodate this theory. If so,  15 companies who wish to operate in multiple states would  16 need to be based out of each state.  17 If any intrastate pacts are made, transfers  18 of raw plant materials, flower would need to be  19 agriculturally exempt through the act, the  20 agricultural act, in crossing state lines, allowing  21 farmers access to larger out of state markets.  22 I did not mention in the beginning. I</p>	<p style="text-align: right;">Page 413</p> <p>1 MR. GITTO: Absolutely. Thank you so much.  2 MS. CRISTINZIO: Thank you.  3 MR. GITTO: Any questions? I thought I could  4 get into the Tenth Amendment there for a second.  5 Thank you.  6 MS. CRISTINZIO: Maybe another time. Next up  7 we have Brian Malkin.  8 PANEL MEMBER: Garrett Graff, yeah.  9 MS. CRISTINZIO: Sorry about that. I'm ahead  10 of myself. Garrett Graff.  11 MR. GRAFF: No problem at all. Good  12 afternoon, and thank you for allowing us all the  13 opportunity to speak before you here today.  14 My name is Garrett Graff. I am the managing  15 attorney of Hoban Law Group, a Denver-based law firm  16 that almost exclusively serves both the marijuana and  17 the hemp industries.  18 We have been extensively involved for several  19 years now with respect to helping set definitive  20 parameters around regulatory guidance at the state and  21 local levels, as well as at the federal level.  22 So with respect to this afternoon's</p>



<p style="text-align: right;">Page 414</p> <p>1 commentary, four takeaway points. First, to compel  2 and request that the FDA provide interim guidance as  3 it continues to evaluate regulatory schemes in the  4 forthcoming months and years. Second, the need to  5 reconcile and unify existing state regulations.  6       With respect to the 2014 farm bill, perhaps  7 both a good and bad thing is that it encouraged states  8 to create regulatory schemes. But now with federal  9 oversight through the 2018 farm bill, there's great  10 need to reconcile and unify those.  11       Third, in order to so reconcile state and  12 local laws, we can use existing FDA mechanisms to do  13 so. Product classifications, testing, labeling and  14 other standards are all applicable and able to be  15 extrapolated here to hemp products. There is no need  16 to reinvent the wheel.  17       And fourth, for the answers to -- in order to  18 get answers to questions that are yet unanswered, we  19 need to encourage research because to date it's been  20 stifled in many respects by federal agency rhetoric,  21 including that from the DEA.  22       With respect to the existing marketing and</p>	<p style="text-align: right;">Page 416</p> <p>1 implemented regulatory schemes that treat hemp  2 products just as if you're manufacturing any other  3 food or dietary supplement product. Excuse me. The  4 same registration is used. We need not any different  5 registration regulatory scheme, but rather can simply  6 use the same registrations, the same GMP requirements  7 and all of the same typical methods for the existing  8 product types.  9       Next, with respect to the manufacturing of  10 hemp products for public consumption, again, GMPs are  11 in place for foods, supplements, cosmetics and other  12 product types. Solvent-based manufacturing is not  13 new. Plant-based products are not new.  14       There are -- there is no need to specifically  15 regulate hemp differently akin to how vapes or tobacco  16 or other product types have been regulated by FDA in  17 one-off ways in the past. But instead this fits  18 squarely within existing regulatory schemes for  19 products.  20       Testing, there's been commentary so far today  21 with respect to the availability of testing. There  22 are testing companies that are testing food additives</p>
<p style="text-align: right;">Page 415</p> <p>1 sales of hemp products, there again are existing  2 mechanisms already in place. Labeling conventions for  3 foods, supplements, cosmetics and other product types  4 already regulated by the FDA are sensible and provide  5 an appropriate way to disseminate information to  6 consumers.  7       Warnings, such as those for use with  8 medications or when suffering from other medical  9 conditions or when pregnant, many other conventional  10 warnings of those types may be well applicable here  11 too for hemp products as well and can be replicated.  12       Secondly, manufacturers have a great onus in  13 these industries already. So you look at calcium,  14 vitamin C and other supplement manufacturers.  15       In many respects, it's their requirements or  16 their obligation to comply with FDA requirements and  17 to disseminate information to consumers. There should  18 not be any different standards adhered to or applied  19 to hemp product manufacturers.  20       And lastly, as I commented before, we have  21 this great need to reconcile state laws. States like  22 Colorado and their department of health have</p>	<p style="text-align: right;">Page 417</p> <p>1 and dietary ingredients and finished products and have  2 been doing so for decades. And they are applying  3 those same exact standards, knowledge and wherewithal  4 as to hemp products today. For potency, for  5 contaminants, for heavy metals.  6       Now again, I don't expect everything to be  7 perfect. I ordered food this morning at my hotel and  8 there were bits of plastic in it. So clearly not all  9 regulation is perfect. But those same standards can  10 be applied to hemp products in successful way, in a  11 sensible way and in a way that provides confidence and  12 certainty to both consumers and regulators alike.  13       I note on the slide before you with respect  14 to terminology -- and I note that the panel has asked  15 questions about terminology being used. Currently  16 there's approximately four different types -- four  17 different phrases widely used: full spectrum hemp  18 extract, broad spectrum hemp extract, isolate, CBD in  19 this case or perhaps other cannabinoids in other  20 cases, and hemp seed oil for those products derived  21 from hemp seed.  22       Now I also note importantly as well that the</p>

<p style="text-align: right;">Page 418</p> <p>1 panel should not just be considering CBD. That's of  2 course the hot topic for today. But there's over a  3 hundred cannabinoid compounds within cannabis. So  4 these are issues that we're going to have to replicate  5 time and time again or we can take this opportunity to  6 try and handle that for all the different cannabinoids  7 now.</p> <p>8       With respect to those various phrases, full  9 spectrum represents a full representative profile of  10 the entire cannabis plant and the compounds and  11 cannabinoids that are in. Broad spectrum is a broad  12 but not yet full representative profile. Isolates of  13 course mean isolated profiles and hemp seed oils.</p> <p>14       And lastly, with respect to research, you  15 know, obviously there's been a great deal of research  16 presented here today and that's a testament to those  17 that have conducted that research. But yet there are  18 still those that are rejecting the ability to do and  19 conduct research.</p> <p>20       We have clients that have been requesting to  21 do so for years and institutions of higher education  22 that remain -- continue to cite DEA and other rhetoric</p>	<p style="text-align: right;">Page 420</p> <p>1 relationship to cannabis is the New York State Bar  2 Association. I'm the co-chair for the committee on  3 cannabis law. I also am the chair for the food, drug  4 and cosmetic law section and I'm also involved in  5 their activities on legislative affairs. And for the  6 Food and Drug Law Institute, I'm also on a new  7 committee they have, the cannabis-derived products  8 committee.</p> <p>9       So there's increasing interest obviously now  10 with FDA and FDA attorneys looking at how FDA is  11 regulating cannabis. And within cannabis law from  12 such as myself, my current firm, there's a cannabis  13 industry group which we're seeing happening more and  14 more at different law firms as there are more and more  15 products in the space.</p> <p>16       So this is the overview I'm going to talk  17 about today, sort of how I got involved in cannabis  18 and FDA law, what I'm seeing happening in terms of the  19 overlay of cannabis clients and FDA and the  20 interaction there, what that relates to in terms of  21 the questions that are coming up in law firms that  22 have these cannabis industry groups or dealing with</p>
<p style="text-align: right;">Page 419</p> <p>1 saying that IND applications are required. Now, while  2 none of us may agree with that or some of us may not  3 agree with that statement, that rhetoric is still out  4 there. And so, clear and definitive guidance from the  5 FDA that would encourage, not stifle research would  6 answer the questions yet unknown. Thank you for your  7 time this afternoon.</p> <p>8       MS. CRISTINZIO: Thank you.  9       (Applause.)</p> <p>10       MS. CRISTINZIO: Next we have Brian Malkin,  11 from Arent Fox.</p> <p>12       MR. MALKIN: Good afternoon. All right.  13 Good afternoon. My name is Brian Malkin. I'm an  14 attorney. And today I'm not speaking -- I'm speaking  15 on my own behalf. I'm not speaking on behalf of my  16 firm, any client or association.</p> <p>17       I'm a food and drug attorney and an IP  18 attorney. My background's biochemistry. I worked at  19 the agency. I've worked at FDA and IP boutique firms  20 and currently I'm at Arent Fox.</p> <p>21       And one of the things I'm active in now in  22 some bar association where there's a direct</p>	<p style="text-align: right;">Page 421</p> <p>1 cannabis clients and what kind of guidance I would see  2 that's helpful for FDA to spell out as you're looking  3 at lawmaking right now.</p> <p>4       So I got involved back in 2015 as the chair  5 of the food, drug and cosmetic law section. Someone  6 approached me and said, you know, there's a new law  7 within medical marijuana in New York. What kind of  8 program can you do in your FDA group? And I was like,  9 I didn't know. It's not an FDA-regulated product at  10 that moment.</p> <p>11       I said let's do something on ethics of  12 representing cannabis clients because there's a lot of  13 ethics issues that come in which gives the interplay  14 between federal and state laws because federal law was  15 saying it was illegal, state laws were saying it was  16 legal. So we thought that was a good topic to talk  17 about at the time.</p> <p>18       Also what we started seeing is that within  19 our association, there were different programs. Every  20 section was doing it different. They're different  21 legal disciplines. So it's not just food and drug.  22 It's IP. It's labor law. It deals with real estate.</p>

<p style="text-align: right;">Page 422</p> <p>1 You know, there were all these different disciplines  2 that were coming into play.  3 And so, what I saw, there was a need that we  4 had to create some sort of thought leadership in the  5 space of cannabis generally. FDA is just one part of  6 that.  7 And so, back in June 2017, I pitched to the  8 state bar to create a committee and it was approved.  9 And so, now we have a committee on cannabis law. And  10 I'm a co-chair for that. And we also added an  11 academic advisor, the first professor who wrote a  12 textbook for law schools on cannabis law.  13 So this is the mission of our committee and  14 essentially what we're really trying to do is provide  15 good thought leadership within the space for laws as  16 well as advising other lawyers who want to get into  17 the space to properly advise their clients in terms of  18 what's going on in regulatory law. And that's  19 relevant here in terms of what FDA is considering to  20 do for cannabis and CBD-related products.  21 So far we've put on a number of CDLE  22 programs. This is giving a little bit of an overview</p>	<p style="text-align: right;">Page 424</p> <p>1 enter the state friendly markets and then interstate  2 commerce. And that's fine. They're looking for more  3 FDA review and guidance. I want to sort of get  4 actually in terms of -- my time is coming into place -  5 - what kind of questions we see would be helpful for  6 FDA to give guidance on.  7 So a lot of the questions now is like what is  8 legal. We get that question all the time. Is what  9 I'm doing legal? Can I do this? Is it appropriate?  10 We're struggling with definitions about CBD extract,  11 broad, full spectrum, things like we've talked about  12 earlier today.  13 What is hemp extract? Is it from the hemp  14 seed or from the plant? That's not clear all the  15 time. What does THC-free mean? What are these --  16 what kind of laboratory tests are appropriate to use?  17 Are they state testing authorities?  18 Are there some national authorities for that?  19 What kind of intermediary processing comes into play?  20 If your THC level above 0.3 percent in your biomass,  21 what does that mean? Can you transport that in  22 interstate commerce or not?</p>
<p style="text-align: right;">Page 423</p> <p>1 of the ones that had some interplay with FDA and you  2 can take a look at those sort of later.  3 What has happened since 2015 and that initial  4 program, what I'm seeing happening is there's an  5 increasing client base. First there was a lot of  6 international activities going on in regulation  7 because there wasn't a lot of guidance in what you  8 could do in the U.S. Everything was considered  9 illegal.  10 And so, the research had to be done overseas.  11 And there was a lot of frustration. The University of  12 Mississippi was the only source. It was a difficult  13 source to get ahold of the product. It was not a very  14 high quality source for doing cannabis research.  15 And so, and then there's the interplay  16 between whether it was legal or not. And so, again,  17 it was very frustrating and there's banking issues and  18 marketing issues for the products that were very  19 complicated.  20 So now what's happened since the farm bill  21 that came into play is that basically more companies  22 want to enter the market. Their first goal is to</p>	<p style="text-align: right;">Page 425</p> <p>1 And then, what kinds of products can be used  2 in FDA-regulated products? So these are some things  3 where we thought FDA could be helpful with the dosage  4 forms, whether there's need for allergen testing,  5 guidelines for CGMPs that are relevant to cannabis,  6 specific to it.  7 Import/export implications with the Border  8 Patrol and advertising as FDA relates to the THC and  9 developing more uniform labeling standards. Thank  10 you. Any questions? All right. Thank you.  11 MS. CRISTINZIO: Thank you. Next we have  12 speaker number 100, Robert Morgan.  13 MR. MORGAN: That's not mine, no. That's  14 mine. Thank you. Thank you, and good afternoon. My  15 name is Bob Morgan, and on behalf of ASTM  16 International, I would like to thank the FDA for  17 giving us the opportunity to provide some comments  18 concerning our scientific and consensus-based driven  19 efforts to develop technical standards that advance  20 the safety, manufacturing and product quality of  21 cannabis products and processes.  22 ASTM International was established 120 years</p>

<p style="text-align: right;">Page 426</p> <p>1 ago to enable industry, consumers and regulators to  2 work in public and private collaboration in the  3 development of consensus standards that ensure product  4 quality and performance while protecting the consumer  5 and the environment. Over this time, ASTM has  6 developed nearly 13,000 standards for 90 different  7 industry sectors. Over 6,000 ASTM International  8 standards have been adopted or referenced in  9 regulations in the United States and around the world.  10       ASTM standards are known and trusted for  11 their technical quality and relevance because they are  12 developed in an open and transparent form, with all  13 stakeholders having an equal voice in the process.  14       These standards range from ensuring the  15 performance of jet fuel used in airplanes to the steel  16 and concrete used in our infrastructure, as well as  17 for the safety of children's toys.  18       ASTM and the Food and Drug Administration  19 have a long history of working together for the  20 development of standards for all types of medical  21 devices. As an active stakeholder, the FDA  22 contributes its technical and regulatory expertise to</p>	<p style="text-align: right;">Page 428</p> <p>1 transportation have been actively working on standards  2 for their part in this industry.  3       To date, ASTM has developed six full  4 consensus standards addressing water activity,  5 cleaning and sanitation, packaging and labeling, waste  6 management and managing hazard analysis critical  7 control points.  8       Our efforts are already having an impact as  9 U.S. states are working towards referencing the water  10 activity standards, ensuring product stability in the  11 marketplace.  12       In addition to these approved standards, the  13 stakeholders are driving dozens of standard test  14 methods that will impact laboratory testing for  15 pesticides, residual solvents, heavy metals,  16 cannabinoid and terpene analysis, compliance auditing  17 as well as security and transportation processes.  18       Our newest subcommittee on industrial hemp  19 has opened the door for the many issues of hemp as a  20 food supplement and as a construction material.  21       The efforts of ASTM members clearly  22 demonstrate a commitment to raise the bar for this</p>
<p style="text-align: right;">Page 427</p> <p>1 help inform and shape ASTM consensus standards because  2 they can be developed more efficiently by a  3 collaborative effort among regulators, manufacturers  4 and users.  5       They can be more easily updated to reflect  6 changes in technology or new product development and  7 because they can be recognized and utilized globally  8 as international standards.  9       In response to a request for standards from a  10 cannabis cultivator, ASTM met with key industry  11 stakeholders and, in 2017, formed committee D37 on  12 cannabis. The scope of this technical committee is  13 the development and maintenance of standards and  14 guidance materials for cannabis and its products and  15 processes.  16       D37 has grown to 600 members from 14  17 countries representing all aspects and components of  18 the cannabis and hemp industries. Partnerships have  19 been created with key industry organizations bringing  20 in research and stakeholder participation.  21 Subcommittees on cultivation, laboratory testing,  22 quality management, processing and handling and</p>	<p style="text-align: right;">Page 429</p> <p>1 industry through consensus standards that ensure  2 product quality and safety.  3       Moving forward, ASTM committee D37 is eager  4 to work with the FDA and others from state and federal  5 regulatory bodies and all stakeholders on the  6 development of high quality consensus standards that  7 support every step in the production and processes for  8 these emerging class of products.  9       Thank you for this opportunity to share these  10 comments, and I look forward to answering any  11 questions you may have. Thank you.  12       MS. CRISTINZIO: Thank you. Next, we have  13 Sheri Orlowitz, speaker number 101.  14       MS. ORLOWITZ: Good afternoon. I'm Sheri  15 Orlowitz, and I'm honored to be here and I'm pleased  16 to be representing MPP in my role as an officer and  17 board member.  18       I'm a businesswoman. I'm a former Justice  19 Department lawyer who was recruited through the honors  20 program. And I'm a former federal prosecutor who was  21 charged with enforcing the drug laws.  22       We change lives. That's a pretty bold</p>

<p style="text-align: right;">Page 430</p> <p>1 statement. But for the past 25 years, MPP has been  2 working to decriminalize cannabis because cannabis has  3 ruined more lives than people use cannabis today. We  4 need and we welcome the FDA regulation and we suggest  5 that the FDA take note of the state markets and the  6 state regulatory schemes as a starting point.  7 As MPP's legislative counsel said to me, the  8 FDA should pave the cow path. So today, I'm going to  9 give you a little view of the cow path, our broad  10 recommendations and how we might be able to assist.  11 Changing state laws. It's hard to fathom how  12 fast things are changing today. Yesterday 33 states,  13 including 10 states that are adult use cannabis.  14 Today Illinois just passed adult use, 46 against, 66  15 for.  16 The landscape is unbelievable. The reality  17 is cannabis is used by millions of people. One report  18 estimates that close to 25 million people are using  19 cannabis today. They're doctors. They're lawyers.  20 They're legislators. They're Fortune 500 CEOs. In  21 fact, perhaps there are some FDA administrators and  22 some of the most successful people in the world.</p>	<p style="text-align: right;">Page 432</p> <p>1 Regulation now falls largely to the states.  2 And again, that is where MPP has done most of the  3 work. Our knowledge of the state and regulatory  4 schemes that we have helped create over the past few  5 decades is unparalleled.  6 We have been assembling a council of experts  7 which includes scientists, some former FDA, academics,  8 lawyers as well as industry people from outside the  9 U.S. who have no stake in the U.S. regulatory scheme  10 to help us understand the landscape and shape our  11 advocacy work.  12 We've taken great pains to assemble this  13 council so that there are people without conflicts of  14 interest in the current U.S. regulatory scheme.  15 The broad range of products is mindboggling  16 and gives rise to so many dichotomies in the states.  17 Some states allow flower. Some states don't allow  18 flower. Some states allow infused drinks. Some  19 states don't allow infused drinks.  20 Aside from the state and federal illegal  21 dichotomy, I give you an example in California which  22 arose out of an FDA edict which just threw more</p>
<p style="text-align: right;">Page 431</p> <p>1 What we know over the 80 years that cannabis  2 has been illegally -- has been used illegally, there  3 have been few reported incidents of serious adverse  4 effects.  5 To the contrary, they are far outweighed by  6 more and more evidence that cannabis has many  7 legitimate medical and wellness uses, as well as for  8 recreation, with less deleterious effects than  9 alcohol.  10 Unprecedented change. Cannabis moved from  11 the back alleys to beautiful dispensaries and this is  12 an opportunity for oversight and control by the FDA.  13 But we caution against an unduly restrictive scheme  14 that can drive another illegal and unsafe market.  15 That is something we do not want.  16 We have already seen incidents of synthetic  17 CBD using rat poison ingredients which hundreds of  18 people, I've been told, died from. This is something  19 that must stop. No more back alley dealing.  20 Retailers should have confidence in what they are  21 selling and the populace needs to have confidence in  22 what it is buying.</p>	<p style="text-align: right;">Page 433</p> <p>1 confusion into the way. CBD from hemp was illegal for  2 food products. But CBD for marijuana was legal from  3 food products -- in food products, excuse me.  4 Now how can that be enforced? As far as I  5 have researched, there is no test that can discern the  6 difference between CBD from marijuana and CBD from  7 hemp. FDA. FDA looms large over all of the states.  8 These -- wrong page. So we suggest that the FDA work  9 hand in hand with the states and not against the  10 states.  11 Consider we agree with Commissioner  12 Gottlieb's statement in early April. The path that  13 the FD&amp;C allows for such substances to be added to  14 foods or marketed as a dietary supplement is first by  15 the FDA issuing a regulation through notice and  16 comment rulemaking allowing such use and through  17 bifurcating the regulation of cannabis to both drug  18 pathway and supplemental pathway at lower doses, the  19 FDA can provide Epidiolex a protected path and provide  20 for usage for health, wellness and recreational use.  21 As we go forward, MPP is a veteran of the  22 drug war and 25 fighting it has made us experts. We</p>

<p style="text-align: right;">Page 434</p> <p>1 know overregulation created the largest illegal 2 industry and this war has cost more and created more 3 American casualties than all wars combined. So we 4 give the following recommendations. We recommend a 5 dual path be created for cannabis. We recommend -- 6 MS. CRISTINZIO: Briefly, please, because 7 you're over. 8 MS. ORLOWITZ: Okay. Thank you very much. 9 MS. CRISTINZIO: Thank you. 10 PANEL MEMBER: Can I just ask a quick 11 question? You said that you have a vast knowledge of 12 all the state laws and regulations. If you have 13 compilations and analyses or comparisons of those laws 14 that you can put on the record, that would be very 15 useful for us. 16 MS. ORLOWITZ: In fact, we were going to 17 allow -- ask that you allow us to provide a 18 comprehensive report on the state laws along with some 19 recommendations of how to proceed. If you would like, 20 we would be happy to submit such. 21 PANEL MEMBER: Yeah. Thank you. 22 MS. ORLOWITZ: Thank you.</p>	<p style="text-align: right;">Page 436</p> <p>1 is not a safety question, but rather a race to market, 2 or more appropriately, a race to investigate. 3 Even so, Congress gave FDA the discretion by 4 statute to permit an article to be used in food and 5 supplements irrespective of the race to investigate 6 because it foresaw circumstances that might arise that 7 would justify mutual use and deny an indefinite 8 monopoly to a drug company should that article have 9 other intended uses than just the drug claim. 10 So it is worth reiterating that the IND 11 exclusion is not a safety question. FDA has plenty of 12 processes and standards in place to examine the safety 13 of any ingredient and it should use those tools and 14 aggressively demand evidence of safety. But the 15 initial determination of whether CBD is a dietary 16 ingredient is not a safety question. It's a 17 commercial one. 18 FDA needs to trust its own processes for 19 examining safety in due time with respect to the 20 requirements for each of the regulatory channels where 21 CBD would appear, whether food, cosmetic, supplement, 22 OTC drug or prescription medication.</p>
<p style="text-align: right;">Page 435</p> <p>1 MS. CRISTINZIO: Thank you. Next up, speaker 2 number 102, is Steve Mister. 3 MR. MISTER: Good afternoon. I'm Steve 4 Mister, with the Council for responsible Nutrition. 5 CRN is the leading trade association representing the 6 dietary supplement and functional food industry. We 7 start with the acknowledgement that we hear FDA's 8 position. 9 FDA currently considers CBD to be prohibited 10 for use in dietary supplements and foods because of 11 the exclusionary provision of section 321, a provision 12 that's somehow referred to as the IND exclusion. 13 This provision was included in DSHEA to 14 protect the commercial interests of pharmaceutical 15 firms and to incentivize drug development by assuring 16 that years and millions of dollars of research for a 17 drug would not be diminished by allowing food and 18 dietary supplements to come in and use an article if 19 it was first studied as a drug. 20 It's important to realize that this provision 21 is grounded in protecting the commercial interest of 22 pharmaceutical research, a worthy objective. But it</p>	<p style="text-align: right;">Page 437</p> <p>1 One of the advantages of considering the 2 definitional issue first and independent of the safety 3 consideration is that it allows FDA to more quickly 4 clear up the regulatory confusion and then consider 5 safety for each individual product rather than trying 6 to adopt a "one size fits all" broad safety standard 7 dosage ceiling across all of these products. 8 Such a broad safety standard developed at the 9 beginning of the process would be ill-fitted for the 10 vast range of CBD-containing products that are already 11 in the market. 12 It would fail to provide flexibility as new 13 research emerges and it would not take into account 14 the wide range of dosage forms, delivery systems, 15 dosage levels, cautionary level statements and other 16 differences among all of these products that would 17 factor into whether individually they would be 18 considered safe. 19 For FDA and for industry, consumer safety is 20 always job one. But that doesn't mean that 21 sequentially it's the first job we do. Providing a 22 predictable and lawful path to market is.</p>

<p style="text-align: right;">Page 438</p> <p>1 Particularly when it comes to products that are  2 already in the marketplace, FDA needs to act swiftly.  3       The agency must also act boldly to assure  4 that products comply with the rules for whatever  5 regulatory lane they are swimming in. If a CBD-  6 containing product is marketed as a dietary  7 supplement, if it contains a dietary supplement  8 statement of identity on the label, if it carries a  9 supplement facts box, then the marketer of that  10 product has implicitly signaled to FDA and to  11 consumers that it should be held to the regulatory  12 framework for dietary supplements.  13       And so, these products should be made in a  14 facility that is registered with FDA. They should be  15 subject to GMP inspection. The label should comply  16 with all general regulations for supplements. The  17 marketer should have a system in place for reporting  18 adverse events.  19       All CBD-containing supplements should be  20 treated as new dietary ingredients, subject to  21 notification. And then, questions about identity of  22 the product, identity, purity, potency and composition</p>	<p style="text-align: right;">Page 440</p> <p>1 of CBD to be used in the general population without  2 the requirement of the intervention of a health  3 professional. These early studies have found CBD to  4 be well-tolerated and appropriate for use.  5       Ironically if a company submits an NDI  6 notification today to FDA, complete with all of that  7 safety data, it would have the notification returned  8 because the ingredient is not recognized as a  9 legitimate dietary ingredient.  10       But if the FDA creates a predictable path to  11 market, then the safety research that the agency so  12 craves will materialize because then the nutrition  13 community, academia and government agencies like NIH  14 will all join in the symphony of research.  15       So, and then I'm going to provide you with  16 some references to some of those safety data. In  17 summary, CRN urges FDA to act quickly and decisively  18 to resolve the definitional issues by conducting a  19 notice and comment rulemaking to allow hemp and hemp-  20 derived CBD to be used in food and dietary supplements  21 and, in the meantime, to demand that products that are  22 marketed as food or dietary supplements comply with</p>
<p style="text-align: right;">Page 439</p> <p>1 should be addressed with adequate characterization of  2 the product in the NDI notification and then followed  3 up with product testing.  4       And FDA should strongly enforce these  5 category-wide requirements on these CBD requirements  6 as they would for any dietary supplement, using the  7 range of tools provided by DSHEA like warning letters,  8 import alerts, product seizures, mandatory recall and  9 even criminal sanctions to send a clear message.  10       FDA will still have the opportunity to  11 evaluate safety though. And while I will not get into  12 specific safe levels identified in the ongoing  13 research, FDA should find some comfort that well-  14 respected authoritative reviews have already found CBD  15 to be safe.  16       Demanding adherence to the NDI notification  17 requirement in DSHEA will give FDA, in due time, the  18 ample opportunity to insist upon, to analyze and to  19 evaluate the safety data that's specific to each  20 product.  21       Indeed, CBD research has already generated  22 several systematic reviews that support the potential</p>	<p style="text-align: right;">Page 441</p> <p>1 all of the requirements long-established and expected  2 of any product in those channels. Thank you.  3       PANEL MEMBER: Given your knowledge of the  4 dietary supplement industry, I'm curious of your  5 opinion about whether you believe that most of the  6 supplements, particularly the CBD supplements, are  7 produced by companies that already exist.  8       In other words, it's an additional product to  9 an existing facility, or whether you think there'll be  10 numerous additional facilities that will need to be  11 inspected.  12       MR. MISTER: Well, I think that's the irony  13 of the CBD situation in the marketplace that has  14 exploded over the last three years. Typically when a  15 new ingredient comes to market, it comes through  16 existing companies who are already in the dietary  17 supplement space. And as a result, they're well-  18 equipped and familiar with all of those requirements.  19       I believe what's happening in the CBD space  20 is that the majority of these companies who are  21 bringing CBD to market as supplements are not  22 companies that are traditionally in the supplement</p>

<p style="text-align: right;">Page 442</p> <p>1 space. So they're not even aware of the requirements  2 to have an adverse event system in place, where a  3 dietary supplement company that's been in this space  4 knows well that that's been around since 2008. So I  5 think that is creating an added requirement why the  6 agency needs to be aggressive in enforcing the other  7 requirements for supplements.</p> <p>8 PANEL MEMBER: Do you have any estimates of  9 how many additional facilities you think are out there  10 beyond what we're aware of with these existing dietary  11 supplement facilities?</p> <p>12 MR. MISTER: I would have no way of knowing  13 that. Thank you.</p> <p>14 MS. CRISTINZIO: Thank you. Our next speaker  15 is Matt Sica, speaker number 103.</p> <p>16 MR. SICA: I'm Matthew Sica. I'm the  17 accreditation manager at ANAB, responsible for  18 cannabis labs. ANSI National Accreditation Board is a  19 recognized international body that does assessment  20 activities around the world to various standards.</p> <p>21 We're asking that FDA consider the adoption  22 of the international conformity assessment model</p>	<p style="text-align: right;">Page 444</p> <p>1 competence. Accreditation is the formal recognition  2 of competence of the laboratory to carry out specific  3 activities in accordance with the standard as  4 described in a scope of accreditation.</p> <p>5 Accreditation provides the attestation that  6 laboratories offering testing have technical  7 competence and impartiality to check conformity of  8 products to relevant specifications.</p> <p>9 Lab accreditation provides a ready means for  10 customers to identify and select reliable testing  11 services. The competence is determined through an  12 ongoing cycle of assessments, onsite and offsite, by  13 technical competent experts and through participation  14 in proficiency testing on an ongoing basis.</p> <p>15 The conformity assessment model provides  16 several levels of impartiality throughout the process.  17 Regulators may set requirements for specific products.  18 The producers of those products use testing services  19 to determine conformance to specific requirements.</p> <p>20 Conformity assessment bodies, in this case  21 laboratories, test the products where those conformity  22 assessment bodies are assessed for competence by the</p>
<p style="text-align: right;">Page 443</p> <p>1 pertaining to testing activities for the cannabis  2 space. This testing may include aspects such as  3 content of cannabinoids, pesticides, heavy metals and  4 microbiological organisms.</p> <p>5 ANAB encourages the use of accredited  6 laboratories, 217025, the international standard for  7 the general requirements of competence of  8 laboratories. We respectfully ask FDA to consider not  9 using terms such as meeting the requirements of or in  10 compliance with 17025. We stress that conformity  11 assessment and accreditation to 17025 is more  12 appropriate as it includes an independent review of  13 the competence of the laboratory.</p> <p>14 Acting as impartial entities, internationally  15 recognized accreditation bodies evaluate the  16 competence of the lab. The accreditation body  17 approach and assessments provide a credibility to the  18 conformity assessment activities such as testing and  19 that goes beyond a self-declaration of meeting the  20 spirit of the standard.</p> <p>21 The conformity assessment model is structured  22 to give confidence through the attestation of</p>	<p style="text-align: right;">Page 445</p> <p>1 accreditation bodies. This is strengthened when  2 accreditation bodies are peer-evaluated and are  3 members of mutual recognition arrangements among  4 accreditation bodies. In the United States, there are  5 several ILAC signatory accreditation bodies to promote  6 choice through an established competitive market.</p> <p>7 Accreditation is based on the laboratory  8 demonstrating compliance with specified requirements  9 for competence, independence and impartiality.</p> <p>10 Competence is determined through the experience and  11 technical skills of the staff, as well as review of  12 equipment and the methods utilized.</p> <p>13 Independence is determined through a review  14 of the business framework of the accredited body and  15 any related bodies to show autonomy between the  16 laboratory and organizations to which it provides  17 service.</p> <p>18 Impartiality is demonstrated through the  19 absence or management of conflicts of interest with  20 the laboratory to whom they are providing the  21 services.</p> <p>22 Benefits of accreditation include for</p>



<p style="text-align: right;">Page 446</p> <p>1 regulators the use of the conformity assessment model  2 can support implementation of national legislation to  3 confirm compliance with standards and accepted  4 requirements, reduce bureaucracy by eliminating a  5 number of administrative obligations and limit costs  6 and resource needs by reducing the need for regulators  7 to employ their own specialized assessment personnel.  8 For consumers, it can create trust, where  9 consumers have confidence that the market is enhanced  10 knowing that products and services they choose are  11 regularly evaluated and checked by independent and  12 competent third parties.  13 For business, accreditation can boost  14 efficiency where accurate measurement and testing  15 performed in accordance with best practices can help  16 limit errors and control product costs and  17 contributions. By relying on accredited tests,  18 regulators --  19 MS. CRISTINZIO: Sir, please wrap it up.  20 Please wrap up.  21 MR. SICA: Yeah. Regulators obtain  22 independent evaluation which is a transparent process</p>	<p style="text-align: right;">Page 448</p> <p>1 slide up. But no one did. What is CBD? I haven't  2 heard anyone say what it is. I've heard everyone talk  3 about it. CBD is a chemical. It has a CAS number.  4 It's commonly called CBD. It has an IUPAC name. It  5 has a definitive structure right here, which you've  6 already seen.  7 Oh, I went the wrong way. This is what CBD  8 looks like. I don't know how many of you have ever  9 seen pure CBD. Not too many people. It's horrible.  10 I sort of describe it as a mixture of molasses with  11 soft margarine. It is yucky is the best way to  12 describe it. It sticks to everything. As a chemist,  13 it's very difficult to handle.  14 As you know, we've already heard that it has  15 an approved legal use that came out last June. The  16 important comment that I want to make here is on the  17 label it is not stable after being opened for 12  18 weeks. It's available by prescription only.  19 The other term I hear constantly is CBD oil  20 and I have no idea what CBD oil is. Every company  21 that I've asked about what it is, I heard a different  22 story, the term. And I have a typo mistake here. It</p>
<p style="text-align: right;">Page 447</p> <p>1 and allows for the product to go through. Please  2 consider the use of ILAC MRA signatories.  3 MS. CRISTINZIO: Thank you for that. Please  4 submit the rest of your comments to the docket for  5 consideration. Our next speaker is David Steinberg,  6 104.  7 MR. STEINBERG: Okay. I guess I've got the  8 microphone right. I'm David Steinberg. I am the  9 founder of Steinberg &amp; Associates. We are a  10 consulting firm that deals in the chemistry and  11 regulations of cosmetics and topical drugs.  12 I titled my presentation "The Coming Crisis,"  13 and that may give you a slight comment which is to  14 explain why I think it's a crisis and why I'm so  15 concerned.  16 My wife and I have a 38-year-old son who,  17 when he was five months old, was diagnosed with  18 infantile seizures. He outgrew this because he got to  19 be two years old. So it became Lennox-Gastaut  20 syndrome and you've already heard something about  21 this. I'll talk a little bit more about it later.  22 I thought by now someone would have put this</p>	<p style="text-align: right;">Page 449</p> <p>1 should be CBD oil. It has become generic. I've asked  2 manufacturers what is it. Well, it's CBD in oil.  3 Petroleum oil? Mineral oil? Sesame oil? Not  4 disclosed. So this has become a generic term and this  5 has led to some of the crisis that I am concerned  6 about.  7 At the Lennox-Gastaut Foundation meeting  8 three weeks ago in Seattle, I was talking to many  9 parents of children with LGS. And some of them were  10 taking the legal drug and some of them for other  11 reasons were taking the generics, which claim to have  12 the same effect. And their children suffered from it.  13 But they told us it was CBD oil, just like  14 the real stuff.  15 Okay. This, everyone knows the uses of CBD.  16 So what is CBD? Does it have specifications? Do we  17 have solvents present? What is the purity? The  18 sample that I showed you before was measured at about  19 98.2 percent purity. What are the contaminants? Does  20 it have THC in it? What trace contaminants are? And  21 of course we have the unintended use of imitations  22 which have caused all sorts of bad consequences.</p>

<p style="text-align: right;">Page 450</p> <p>1 Okay. My principal chemistry issue with CBD  2 is that it's not stable. Everyone needs to understand  3 it's not stable. It has a maximum temperature of  4 about 25 degrees Celsius, which is 77 degrees  5 Fahrenheit. Above that, it starts to break down or  6 form other compounds. You can't store it cold because  7 below 4 degrees Celsius, around 39 degrees Fahrenheit,  8 you have other problems.</p> <p>9 It is packaged in dark brown glass. We now  10 have a place for recycled beer bottles. It is not pH  11 very stable. It's stable most at about 6.5 to 7.  12 That's not where we want to use it in cosmetics. Most  13 cosmetics are lower than that. The degradation  14 products possible include THC. So stability is a  15 critical question.</p> <p>16 So what I want to say is that the FDA needs  17 to establish specifications for CBD. Get a USP  18 monograph and have that be the law of the land for any  19 use of CBD, whether it's in foods, drugs, cosmetics or  20 in dietary supplements.</p> <p>21 So here it is. Let's have the percent of CBD  22 on the label and also, because of the instability of</p>	<p style="text-align: right;">Page 452</p> <p>1 which severely limits the population surveillance  2 necessary to monitor the population health effects  3 that may occur as a result of some of these products.  4 Furthermore, prior studies show that  5 concurrent use of cannabis and tobacco is prevalent.  6 But less is known about the potential effects of this  7 concurrent use of cannabis with tobacco or nicotine.  8 Such co-use may complicate the regulatory approach  9 needed for such products.</p> <p>10 And finally, there's reason to expect that  11 the use of the range of the available cannabis  12 products varies by subpopulation, in part because of  13 the ease of targeted digital marketing, many brands  14 and retailers can increasingly tailor and target  15 market to specific groups in the population.</p> <p>16 For example, here are a couple of  17 screenshots. You see the brand Kandypens at the top,  18 which I think is clearly positioned to appeal to  19 younger adults. And then below, you have a CBD  20 product line whose ad features older individuals and  21 explicitly markets to what they say seniors and  22 veterans with a discount.</p>
<p style="text-align: right;">Page 451</p> <p>1 it, the date of the manufacture of the CBD raw  2 material on the label. Thank you.</p> <p>3 (Applause.)</p> <p>4 MS. CRISTINZIO: Thank you very much. Our  5 next speaker is Youn Lee, 105.</p> <p>6 DR. LEE: Hi. My name is Youn Ok Lee and I'm  7 a social scientist at RTI International, a nonprofit,  8 independent research institute and I --</p> <p>9 MS. CRISTINZIO: Please move the microphone  10 down a little bit.</p> <p>11 DR. LEE: And I've led many studies in  12 tobacco regulatory science. However, today I'm going  13 to be presenting data from my NIDA-funded study of  14 adult cannabis user behavior. I just wanted to  15 acknowledge my collaborators and funding source.</p> <p>16 And I'll just start by saying what everybody  17 has said before, which there are many, many cannabis  18 products currently available on the market. The  19 degree to which the mode of administration of cannabis  20 may affect both individual and population health risks  21 is currently unknown. And national surveys do not  22 capture this range of cannabis product on the market,</p>	<p style="text-align: right;">Page 453</p> <p>1 So my purpose is threefold. First, I wanted  2 to look at what types of cannabis products are used by  3 consumers, especially those in mature markets.  4 Second, I wanted to know does preferred THC versus CBD  5 concentration vary across sociodemographic groups.  6 And third, I wanted to look at what motives for use  7 are associated with high CBD products compared with  8 high THC products.</p> <p>9 So just very quickly in the interest of time,  10 we collected original data. We surveyed 2,978 past  11 30-day cannabis product users in the legally -- the  12 recreational legal states at the time of survey. We  13 collected this data in November and December of 2018  14 using a protocol approved by the RTI IRB. It was a  15 convenience sample, but we did calibrate based on past  16 30-day cannabis use using the 2016-2017 BRFSS.</p> <p>17 All right. So results. So here you can see  18 the 30-day prevalence of each type of cannabis product  19 that we measured along the bottom. Now one thing to  20 note is that these categories are not mutually  21 exclusive. So they won't total to a hundred percent.  22 But you can see by the percentages that these indicate</p>

<p style="text-align: right;">Page 454</p> <p>1 a high degree of multi-product use. A large                  2 proportion of our adult sample reported using multiple                  3 modes of cannabis administration in the past 30 days.                  4 Overall, if you look at the left side, you                  5 can see that joint, edible, pipe and vape were the                  6 most prevalent reported products, though many current                  7 cannabis users did also use or co-use with tobacco as                  8 well, indicated by the yellow bars.                  9 So we can see evidence of the co-use that's                  10 been reported in prior surveys and show some of the                  11 relative prevalence that may be driving the                  12 introduction of nicotine-cannabis products onto the                  13 market.                  14 Now here we added information about use                  15 frequency, indicated by the orange line. You can see                  16 that shows the average number of days in the past 30                  17 each product type was used. And so, I won't go                  18 through all of the results.                  19 But you can see for pipe, for example, it was                  20 the most frequently reported number of days at 11.5                  21 days of the past 30 compared to 4.3 days of the last                  22 30 for co-vaping with nicotine. But there's a decent</p>	<p style="text-align: right;">Page 456</p> <p>1 the high THC, low CBD, especially you treat a health                  2 problem. You'll see that those scores are higher for                  3 the CBD responses.                  4 So just to wrap up, our data suggests that                  5 regulation of cannabis involves understanding                  6 variation among products and consumers or users.                  7 Protection of public health requires considering                  8 population health in addition to individual health and                  9 this can inform approaches for regulating these                  10 products in the protection of public health.                  11 Thank you. And we look forward to doing more                  12 research like this in support of the decision-making                  13 of you and other stakeholders.                  14 PANEL MEMBER: Just a question. Will those                  15 data be available in the public docket in any greater                  16 detail? That would be really useful information for                  17 us.                  18 DR. LEE: We can submit some summary, I                  19 believe.                  20 PANEL MEMBER: Thank you very much.                  21 MS. CRISTINZIO: Thank you. Our next speaker                  22 is in the "Patient" category. We have James Werline.</p>
<p style="text-align: right;">Page 455</p> <p>1 amount of variation here that should be considered                  2 when assessing the health effects, dose or exposures                  3 of these different modes, certainly when people are                  4 using multi-modes.                  5 So we also wanted to examine cannabis product                  6 type and demographic characteristics. So here you can                  7 see as an example we were comparing people who                  8 reported they usually use a high THC, low CBD product                  9 versus a low THC, high CBD product versus equal                  10 amounts of THC and CBD and we included I don't know                  11 because in this case I think the response of I don't                  12 know can be meaningful because there may be knowledge                  13 gaps in the public that need to be addressed with                  14 proper public education.                  15 We see relatively high percentages compared                  16 to don't know responses to other items in the survey                  17 which suggests that many consumers may not really know                  18 some of these differences.                  19 MS. CRISTINZIO: Please wrap up.                  20 DR. LEE: Oh, all right. Let me go really                  21 quickly then. So finally I just wanted to share some                  22 of the motives and show you that they differ a bit by</p>	<p style="text-align: right;">Page 457</p> <p>1 PATIENTS                  2 DR. WERLINE: Good afternoon. My name is                  3 James Werline. Greenwich Biosciences supported my                  4 travel, but I have not been paid for my time.                  5 I took off of work and traveled here today                  6 from San Antonio, Texas because I feel it is important                  7 for the FDA and the public to understand what an FDA-                  8 approved CBD oil has done for my daughter and family.                  9 I am a husband and father of a child with a                  10 rare disease known as Sturge-Weber syndrome. And I am                  11 also a doctor of pharmacy. So I look at today's                  12 hearing issue, a regulatory pathway for cannabis and                  13 cannabis-derived products, through two lenses, one as                  14 a pharmacist, the other as a dad.                  15 Those two lenses provide me with a single                  16 clear vision for what I believe the FDA must do to                  17 support the needs of people with rare diseases, people                  18 like my daughter, Camilla.                  19 In this photo, my wife Marla is holding                  20 Camilla. We will celebrate her second birthday in                  21 about six weeks. Camilla is as sweet as any little                  22 girl you'll ever see. She's also a fighter. Camilla</p>

<p style="text-align: right;">Page 458</p> <p>1 started having seizures when she was only nine months 2 old.</p> <p>3       When a child has debilitating seizures, the 4 entire family suffers. As time went on, her seizures 5 increased to 20 to 25 attacks every day and were 6 considered drug-resistant. We tried to ease Camilla's 7 suffering and we fought to give her every chance to 8 have a better quality of life through a combination of 9 treatments.</p> <p>10       At one point, we were pumping six medications 11 into our little girl twice a day, every day and still 12 the seizures continued. My worries grew significantly 13 because I didn't know if Camilla's development delays 14 were due to her disease or the medicines prescribed as 15 treatment.</p> <p>16       My wife and I took Camilla to some of the 17 country's leading pediatric neurologists and 18 epileptologists. She underwent all the tests you can 19 imagine. We received three different diagnoses for 20 three different types of epilepsy and we didn't have 21 an answer and neither did the doctors. We even 22 considered a brain surgery that is too complicated and</p>	<p style="text-align: right;">Page 460</p> <p>1 have Camilla her first dose of Epidiolex, which the 2 FDA had recently approved as the only prescription CBD 3 medication. And we watched in wonder as our prayers 4 were being answered right before our own eyes.</p> <p>5       I am forever grateful to the FDA and the 6 company that invested in the clinical trials and 7 manufacturing processes needed to bring a new 8 medication to patients and families like ours.</p> <p>9       I'm not testifying to promote the product. 10 But I have to share that Camilla hasn't had any 11 seizures since she's been on the medication. She's 12 also been able to wean off of five medications and 13 continues to reach new development milestones. Even 14 now, after living her best life for the past six 15 months, it still seems unbelievable.</p> <p>16       FDA determined that the company demonstrated 17 safety and efficacy to the agency's satisfaction and 18 that means that families like ours can have 19 conversations with our doctors to determine if a 20 product is indeed the right drug for the right patient 21 at the right time.</p> <p>22       FDA, I'm asking you to accept your</p>
<p style="text-align: right;">Page 459</p> <p>1 too gruesome to describe during my brief time with you 2 today.</p> <p>3       As the months dragged on, our frustration 4 turned to desperation. About a year ago, my wife and 5 I thought about trying CBD oil on Camilla. We planned 6 to drive from San Antonio to Colorado to buy a CBD 7 product from a dispensary. Desperation can make you 8 do some crazy things.</p> <p>9       For the first time during Camilla's illness, 10 we were considering giving an untested, unproven, 11 unregulated product to our little girl. Sure, there 12 were anecdotal reports of children with epilepsy 13 getting better with CBD.</p> <p>14       But I wouldn't know how to monitor for 15 interactions or how to adjust other medications that 16 she was already taking and who knows what would be in 17 the bottle that we bought and gave to Camilla. Its 18 ingredients and its impurity would be unknown. It 19 could contain THC or toxins or other substances that 20 could worsen her condition. And that is today's world 21 of unregulated and inadequately controlled CBD oil. 22       On Thanksgiving eve, just six months ago, we</p>	<p style="text-align: right;">Page 461</p> <p>1 responsibility and exercise your authority to 2 meaningfully assist patients, their families and 3 health professionals with a few simple yet important 4 questions.</p> <p>5       What is in a bottle containing CBD that is 6 purchased in a retail store or online? What does a 7 label say about what's in that bottle? And what can 8 it do to the patient, both good and bad? These are -- 9 well, there are families out there that will benefit 10 from FDA-approved prescription CBD medications just 11 like we have.</p> <p>12       Patients and their healthcare professionals 13 should have as much information and assurances as 14 possible in order to make informed decisions about a 15 substance that might be beneficial. They deserve to 16 have a clear vision for navigating their individual 17 health journey. Today they're flying blind. They 18 don't know what they're taking or what they're giving 19 to their little girl or boy.</p> <p>20       FDA, please require that these drugs are 21 subject to robust clinical trials and good 22 manufacturing processes to demonstrate safety,</p>

Page 462

1 efficacy and purity. Every patient deserves a chance  
 2 to receive the same blessings that our family has  
 3 received over the last six months. Thank you for your  
 4 time.  
 5 (Applause.)  
 6 MS. CRISTINZIO: Thank you. Next up, we move  
 7 to the "Public Safety" category. We start with number  
 8 107, Heather Despres.  
 9 PUBLIC SAFETY  
 10 MS. DESPRES: I'd like to thank you for  
 11 giving me the opportunity to speak here today. My  
 12 name is Heather Despres, and I am the director of  
 13 patient-focused certification at Americans for Safe  
 14 Access. It is a nonprofit organization whose mission  
 15 is to ensure safe and legal access to cannabis for  
 16 therapeutic and research.  
 17 The patient-focused certification program is  
 18 an independent compliance program whose goal is to  
 19 ensure that cannabis businesses are operating in  
 20 compliance with state regulations as well as other  
 21 regulations.  
 22 Today I'd like to present to you information

Page 463

1 about manufacturing and product safety as it relates  
 2 to validated analytical testing, product standards and  
 3 safety concerns. We will be presenting comments based  
 4 on everything that we present here today in much more  
 5 significant detail.  
 6 One of the questions presented centered  
 7 around current standards needed to address safety  
 8 concerns related to manufacturing of cannabis and  
 9 cannabis-derived products. And we would like to  
 10 address this by identifying industry standards that  
 11 already exist.  
 12 The American Herbal Products Association and  
 13 the American Herbal Pharmacopeia have issued best  
 14 practices for cannabis business, including  
 15 cultivation, manufacturing, distribution and  
 16 laboratory operations. From these standards, the  
 17 patient-focused certification program was created in  
 18 order to ensure compliance.  
 19 In addition to these standards, we would  
 20 recommend that personnel working in the cannabis  
 21 industry and regulators inspecting these businesses  
 22 have the education and training needed to safely

Page 464

1 perform the job that they are hired to do and that to  
 2 ensure that there are adequate numbers of inspectors  
 3 available to support the industry.  
 4 Validated analytical testing is a key factor  
 5 in ensuring safe products. Mandatory testing is  
 6 required in almost every state that has a cannabis  
 7 program and yet this testing is not consistent from  
 8 state to state.  
 9 This is a table of a subset of over 70  
 10 different pesticides that are required to be tested  
 11 for in various different states. And as you can see,  
 12 only six are the same throughout. Also all of the  
 13 limits are different. So for operators working in  
 14 various states, there's not consistency.  
 15 With consistent testing and limits, the  
 16 safety profile of cannabis products can get better.  
 17 Some of the major safety concerns for cannabis and  
 18 cannabis-derived products are the use of pesticides  
 19 and solvents in cultivation and manufacturing.  
 20 The majority of recalls that have been issued  
 21 have been for the use of non-permitted pesticides or  
 22 for exceeding the limits of allowable pesticides.

Page 465

1 Four different states have applied for a special local  
 2 needs registration, none of which have been approved  
 3 by the EPA. The type of solvents approved for use  
 4 also varies by state.  
 5 For example, some states will permit the use  
 6 of hydrocarbons such as butane, while others will only  
 7 permit the use of carbon dioxide. Additionally, the  
 8 equipment used in cannabis extraction is often  
 9 operated at high pressures and requires specific  
 10 training for safe operation.  
 11 We would encourage that operators be required  
 12 to obtain this special training prior to being able to  
 13 use the equipment.  
 14 While pesticides and solvents are major  
 15 concerns, the potency of THC-rich products is also a  
 16 concern. People have varied reactions to this, to the  
 17 THC present in cannabis and cannabis-derived products  
 18 as many factors may play into how this person reacts,  
 19 including their weight and rate of metabolism, the  
 20 amount and type consumed, the method of consumption  
 21 and their personal experience with cannabis.  
 22 Some states require that products containing

<p style="text-align: right;">Page 466</p> <p>1 THC be tested for homogeneity and we would encourage  2 this type of testing for all products, not just THC-  3 rich products.</p> <p>4 Proper testing with representative sampling  5 will ensure that products are labeled accurately,  6 allowing the consumer to know exactly what  7 cannabinoids and how much are in the products that  8 they are consuming.</p> <p>9 There are many challenges facing the cannabis  10 industry. However there are solutions available. We  11 have worked with state regulators to develop and  12 implement these standards and we look forward to  13 working with you together to help implement these  14 standards as well. Thank you.</p> <p>15 PANEL MEMBER: Just one quick question. You  16 mentioned recalls. Any data that you have on the  17 recalls that have occurred in states or the processes  18 surrounding it would be greatly appreciated, if you  19 could submit that.</p> <p>20 MS. DESPRES: We do plan on submitting that.</p> <p>21 PANEL MEMBER: Fantastic. Thank you.</p> <p>22 MS. DESPRES: Thank you.</p>	<p style="text-align: right;">Page 468</p> <p>1 it. We have no idea what the THC levels are. And it  2 is vastly unregulated compared to our municipal water  3 that I don't drink.</p> <p>4 Our request for action is that the FDA should  5 proceed with extreme caution and treat any levels of  6 THC as unsafe, especially for vulnerable populations.  7 And to protect the public health and safety, we urge  8 the FDA to prohibit THC in CBD containing consumer  9 goods, that is any amount.</p> <p>10 I won't go over all of the concerns of the  11 harmful effects of CBD -- or THC, I mean. You've  12 heard that ad nauseam today. But suffice it to say  13 that we know that THC significantly impacts youth much  14 more than adults. And the question is how much THC is  15 too much.</p> <p>16 We have no idea of the THC amount percentage  17 by weight consumed that causes dependency or  18 addiction. We have no idea of the THC amount that  19 causes first-time episodic psychosis or other chronic  20 adverse health effects. We also know that THC  21 permanently changes brain structure in the developing  22 mind.</p>
<p style="text-align: right;">Page 467</p> <p>1 MS. CRISTINZIO: Thank you. Our next speaker  2 is John Redman.</p> <p>3 MR. REDMAN: Good afternoon, and thank you  4 for allowing me to speak today. I'm John Redman. I'm  5 the CEO of Community Alliances for Drug Free Youth.</p> <p>6 We're a non-for-profit organization based out  7 of California that focuses -- that was created during  8 the parent movement of the late '70s/early '80s and  9 focusing on youth drug prevention. We focus and  10 support sound drug policy not only at the local, but  11 state, national and international levels. CADFY holds  12 consultative status at the United Nations and we work  13 on global drug policy at that level.</p> <p>14 We're not here to really discuss or argue the  15 merits of the medicinal use of CBD. What we are  16 concerned about however is the amount of THC that will  17 be allowed as an adulterant within CBD products that  18 negatively impact our youth.</p> <p>19 If you take a look at this picture, I took  20 that only weeks ago in my hometown. That is water  21 that's being sold to businesses and homes that says it  22 has CBD products in it and I have no idea what's in</p>	<p style="text-align: right;">Page 469</p> <p>1 One thing to look at is how much THC is too  2 much. If we take a look at some of the states, or if  3 we just take a look at Oregon, Oregon has stated that  4 5 mg of THC will produce psychoactivity. So that  5 means no more than 5 mg of THC in a serving. But when  6 we take a look at the hemp bill, we have 0.3 percent  7 by dry weight.</p> <p>8 Well, what does that mean? If you take a  9 look at a joint that contains 63 mg, 17 mg of THC is  10 ingested into the body. An edible that contains 50 mg  11 packaging, a serving is 5 mg of THC.</p> <p>12 If you take a look at a 30-count bottle that  13 can have 360 mg in a single 4 g CBD gummy bears, those  14 can have -- a single gummy bear can have 12 mg of THC  15 for a CBD product. For 30 mL bottles that contain CBD  16 oil, that could contain 82 percent mg in a single  17 serving of 2.73 percent. All you do have to take two  18 servings and you're over Oregon's limit.</p> <p>19 Some available products, I looked on the  20 website. Here's one product on the left that has 2.8  21 mg. If you multiple that times the 0.3 percent you  22 get at the bottom what they say is 84 mg of THC in</p>

<p style="text-align: right;">Page 470</p> <p>1 that CBD product. Another one, that 2.89 percent of  2 THC, you have 86 mg.  3       When we take a look, it's been said that all  4 we have to do is just put an age limit on it. It  5 didn't work for alcohol, folks. It didn't work for  6 tobacco. We know that putting age restrictions on  7 products doesn't work and we also know that the most  8 abused drugs in our youth, number one, alcohol, number  9 two, tobacco. It's not going to be any different for  10 marijuana products.  11       The three things that come together to  12 increase youth use is attitude, advertising and  13 availability. I've heard all of those talked about  14 today. All three of those will create a perfect  15 storm.  16       All one has to do is look at the permissive  17 drug policies of certain states that have legalized  18 marijuana and look at the higher youth use rates in  19 those states than those that don't have it. And yes,  20 we have the data on that.  21       Our request for action is the FDA should  22 proceed with extreme caution and treat any levels of</p>	<p style="text-align: right;">Page 472</p> <p>1 And it works quite well. It measures the retina using  2 a visual field technology in a virtual goggle,  3 smartphone and Bluetooth response.  4       However, it is my previous roles in previous  5 careers for which I am offering my testimony today.  6 Prior to doing research, I spent 20 years as a  7 clinician specializing in vision loss and blindness.  8 Under that capacity, I did see many multi-handicapped  9 children, much like some of the children you have  10 heard described today. They are complex and the  11 parents are very challenged in identifying treatments  12 and care for their children.  13       I'm also a parent. I stopped seeing patients  14 because, at the age of 36, after I had my family, I  15 was diagnosed with idiopathic familial dilated  16 cardiomyopathy. It's familial because even though the  17 clinicians had determined I was beyond the potential  18 of risk of having the disease, I had lost a 17-year-  19 old sister to cardiac health and a 19-year-old sister  20 to cardiac death.  21       When I was diagnosed, I couldn't walk up a  22 flight of stairs. I was worked up for a heart</p>
<p style="text-align: right;">Page 471</p> <p>1 THC as unsafe, especially for vulnerable populations.  2 To protect the public health and safety, we urge the  3 FDA to prohibit THC in CBD-containing consumer goods,  4 any level.  5       Please treat this as a drug and not as a  6 commodity. Please look at this as a public health  7 issue and not as a profit issue. We urge the FDA to  8 look at this and strictly regulate it. Our youth  9 deserve it. Our nation demands it. Thank you.  10       (Applause.)  11       MS. CRISTINZIO: Thank you. Our next speaker  12 is Denise Valenti.  13       DR. VALENTI: Good afternoon. I know it's  14 been a long day. But I've found it pretty exciting  15 because I've learned quite a bit from many of the  16 previous testimonies, and I hope you have also.  17       I'm Dr. Denise Valenti. I'm an optometrist.  18 I'm a CEO and president of IMMAD. IMMAD is Impairment  19 Measurement Marijuana and Driving. Our current  20 funding source comes from NIH, NIDA in the form of an  21 SBIR. We have our first prototype of a technology  22 that is intended for roadside use by law enforcement.</p>	<p style="text-align: right;">Page 473</p> <p>1 transplant. But that's not the worst.  2       Two years later, the next generation. The  3 oldest child in our family was diagnosed. He was 15  4 years old. He died three months later. So it was  5 with horror we realized that the disease that we  6 thought was only affecting one generation was  7 autosomal dominant. It meant my two-year-old had a 50  8 percent chance of potentially not surviving to the age  9 of 21.  10       So I know the desperation and the feelings of  11 some of these parents that would do anything and go to  12 any lengths to solve and improve the health of their  13 children. And I would never suggest that these  14 severely impaired children that are having some of  15 their quality of life significantly improved by CBD go  16 off the CBD.  17       But we do need to do more research because  18 there are side effects that are treatable. One of  19 them is that there is increased pressure in the eye  20 with CBD. While we often hear about marijuana being  21 able to lower the pressure in the eye, that's only  22 with THC, only with THC. We never hear about the CBD</p>

<p style="text-align: right;">Page 474</p> <p>1 causing an increase in the IOP.</p> <p>2 The very research papers that were put</p> <p>3 forward by proponents to advocate for glaucoma as one</p> <p>4 of the treatment -- diseases to treat with CBD</p> <p>5 actually had research in them demonstrating that CBD</p> <p>6 elevates the pressure of the eye.</p> <p>7 Glaucoma is painless. Glaucoma is a disease</p> <p>8 that it creeps up on you and steals your vision and</p> <p>9 you don't know it before it's too late. Why is CBD</p> <p>10 potentially doing this? Well, there are cannabinoid</p> <p>11 receptors in multiple parts of the eye, every layer.</p> <p>12 It's in the retina. That's why we're able to identify</p> <p>13 vision loss and develop technology. But it's also in</p> <p>14 the anterior chamber.</p> <p>15 In neurologic systems, and particularly in</p> <p>16 the eye, THC and CBD tend to have opposite effects.</p> <p>17 And the THC acts on the ciliary body as does the CBD.</p> <p>18 But they can do it in opposite ways. The one human</p> <p>19 study that I talked about earlier found a dose-</p> <p>20 dependent response. And these doses, relative to what</p> <p>21 we hear about are being used to treat many diseases,</p> <p>22 aren't that high.</p>	<p style="text-align: right;">Page 476</p> <p>1 (Applause.)</p> <p>2 MS. CRISTINZIO: Any questions?</p> <p>3 PANEL MEMBER: Absolutely please submit your</p> <p>4 data. Thanks.</p> <p>5 MS. CRISTINZIO: Thank you. Our next speaker</p> <p>6 is Shawn Hauser.</p> <p>7 MS. HAUSER: Hi. Good afternoon. I'm Shawn</p> <p>8 Houser. I'm an attorney with the Vicente Sederberg</p> <p>9 LLP and here today on behalf of the Cannabis Trade</p> <p>10 Federation.</p> <p>11 The Cannabis Trade Federation is a national</p> <p>12 coalition of cannabis businesses representing all</p> <p>13 aspects of what has primarily been a state-based</p> <p>14 marketplace. Our companies include large multistate</p> <p>15 operators who have been subject to stringent</p> <p>16 regulations under these state systems for the better</p> <p>17 part of the past decade.</p> <p>18 We're eager to share today with the FDA data</p> <p>19 arising from our many years of operation and our views</p> <p>20 on federal regulation.</p> <p>21 We believe the appropriate regulation of</p> <p>22 products containing lawful cannabinoids already exist</p>
<p style="text-align: right;">Page 475</p> <p>1 These are some of the doses that are</p> <p>2 suggested for many diseases. As you can see, they are</p> <p>3 beyond the dose of risk, the 40 mg that was found in</p> <p>4 this study.</p> <p>5 However, there are additional studies. There</p> <p>6 is a rabbit study that I don't cite here. On the</p> <p>7 other hand, a colleague of mine, when I wanted</p> <p>8 somebody to look into this, used some of his funding</p> <p>9 to investigate it further and he definitely found CBD</p> <p>10 causes an elevation in IOP in his mouse model.</p> <p>11 We need to investigate this further. Again,</p> <p>12 I'm not suggesting that anybody go off a lifesaving</p> <p>13 drug. But if there is an elevation of IOP, it can be</p> <p>14 treated. But we don't really know exactly what's</p> <p>15 happening in humans.</p> <p>16 I'm concerned that there is going to be a new</p> <p>17 generation of needless vision loss because we did not</p> <p>18 look closely at CBD. Thanks.</p> <p>19 MS. CRISTINZIO: Thank you.</p> <p>20 DR. VALENTI: Oh, there's a good ending. My</p> <p>21 son was negative. And we developed a mouse model for</p> <p>22 my own disease and we developed treatments for me.</p>	<p style="text-align: right;">Page 477</p> <p>1 under the framework of DSHEA and that the data arising</p> <p>2 out of these state-regulated regimes supports such</p> <p>3 regulation. The evidence of CBD safety is clear, as</p> <p>4 acknowledged today and by agencies such as the World</p> <p>5 Health Organization and DEA and their findings that</p> <p>6 CBD is safe, well-tolerated and non-addictive.</p> <p>7 State-controlled cannabis regulatory regimes</p> <p>8 provide years of evidence demonstrating that</p> <p>9 consistent quality products containing cannabinoids</p> <p>10 can be safely and transparently sold in a manner like</p> <p>11 dietary supplements.</p> <p>12 Our operators are familiar with the</p> <p>13 complexities of issues faced by consumers, regulators</p> <p>14 and businesses when compliance means navigating a</p> <p>15 patchwork of state regulations and differing legal</p> <p>16 interpretations.</p> <p>17 However, whether right or wrong, the current</p> <p>18 situation has created a perceived regulatory vacuum</p> <p>19 and it opens the door to bad actors and allows for</p> <p>20 substandard products, often available to the most</p> <p>21 vulnerable of our population.</p> <p>22 We produce products containing lawful</p>



<p style="text-align: right;">Page 478</p> <p>1 cannabinoids and desire to market these products. But                  2 the lack of a federal pathway for regulation,                  3 particularly the refusal to accept NDI notifications                  4 for CBD and other regulatory impossibilities, remains                  5 a barrier to proper regulation. Our industry is ready                  6 to meet FDA requirements and, in many cases, already                  7 complies with the elements of FDA regulations.                  8 In virtually every regulated state market,                  9 most businesses are required to apply for and obtain a                  10 state and local license for each facility they                  11 operate. These facilities are subject to rigorous and                  12 regular inspections by various agencies. These state                  13 regulatory frameworks increasingly require the                  14 implementation of CGMP systems for the manufacturing                  15 of cannabis products.                  16 For example, cannabis businesses in Florida                  17 must employ CGMPs, pass a food safety GMP inspection                  18 by a nationally accredited certifying body. If they                  19 don't pass, they can't process until they demonstrate                  20 corrective action. Similarly, New York requires CBD                  21 supplement manufacturers to adhere to FDA standards                  22 for the production of CBD products, including CGMP and</p>	<p style="text-align: right;">Page 480</p> <p>1 statements and symbols indicating the presence of                  2 cannabinoids and instructions that the products be                  3 kept away from children. As demonstrated by the                  4 chart, these requirements are effective.                  5 In California and Colorado, product                  6 manufacturers have achieved an average 90 percent                  7 passage rate for mandatory testing for label accuracy                  8 in the presence of microbial, pesticide and heavy                  9 metal contaminants. This data demonstrates that                  10 cannabis manufacturers can and do comply with DSHEA-                  11 like standards to protect consumer safety.                  12 Many states also follow the FDA's approach                  13 with recall and adverse event reporting, requiring a                  14 review and investigation of consumer complaint that                  15 extends to all relevant batches and records.                  16 Based on investigative findings arising out                  17 of adverse event reporting, manufacturers and                  18 regulatory authorities issue public notifications and                  19 recall the affected products where appropriate.                  20 In sum, cannabis products can be safely                  21 regulated under the existing DSHEA framework and,                  22 where products are intended for non-medicinal</p>
<p style="text-align: right;">Page 479</p> <p>1 packaging and labeling.                  2 Truth in labeling is at the core of our state                  3 cannabis regulatory regimes. In addition to                  4 comprehensive labeling regulations in most states,                  5 many states like Indiana, Utah and Texas require that                  6 hemp -- CBD product labels include scannable bar codes                  7 linked to information regarding the manufacture of the                  8 product such as batch IDs, ingredients and a link to                  9 certificates of analyses.                  10 Use of independent third-party testing labs                  11 to verify label content for each production batch is                  12 standard. Using accredited and independent testing                  13 laboratories to confirm the accuracy of labeled                  14 information including potency and to ensure compliance                  15 with state requirements helps ensure consumer                  16 confidence in the product being sold by standardizing                  17 the analysis procedure and eliminating the risk of                  18 bias.                  19 Warning labels for vulnerable subgroups,                  20 particularly children, is a virtually universal                  21 requirement in our state-regulated cannabis regimes,                  22 with labels generally requiring both written</p>	<p style="text-align: right;">Page 481</p> <p>1 purposes, it's appropriate to regulate them as such.                  2 The years of data from these state regulatory regimes                  3 are a very important source of data for the agency to                  4 consider in determining the appropriate regulatory                  5 pathway here.                  6 We stand ready as the Cannabis Trade                  7 Federation to advance to the next level with FDA an                  8 effective regulation of cannabinoid products to ensure                  9 consumer safety.                  10 MS. CRISTINZIO: Thank you.                  11 PANEL MEMBER: Hi. As we've asked in other                  12 instances, if your organization has a report that                  13 details some of those findings at the state, could you                  14 make sure that they get into the docket?                  15 MS. HAUSER: Absolutely.                  16 PANEL MEMBER: Thanks.                  17 MS. CRISTINZIO: Great. Our next speaker is                  18 speaker number 111, Dana McMurchy.                  19 RETAILERS/DISTRIBUTORS                  20 MR. MCMURCHY: Yes. Thank you for inviting                  21 me. I'm here in Washington by your invitation. My                  22 challenge is will you listen. The authority that I'm</p>

<p style="text-align: right;">Page 482</p> <p>1 given to speak comes from the constitution of the  2 United States of America which grants me and every  3 person I this room the right to life, liberty and the  4 pursuit of happiness.  5       Why did I start that way? I believe that a  6 balanced endocannabinoid system is fundamental for  7 human life. That's why I ended up supporting Yes on  8 788 in Oklahoma. We also demand liberty to decide  9 what laws and regulations we're willing to live under  10 without interference from anyone, including law  11 enforcement because they don't create law. We do.  12       Oklahoma has a population of under 4 million  13 people. In the vote that we gave -- that we did, we  14 surpassed all election turnouts for any kind of vote  15 and there were 507,000 voters that approved medical  16 cannabis.  17       So I represent those voters. Those are  18 people in chronic pain, in despair over their opioid  19 dependence, patients with MS, lupus, Alzheimer's,  20 Parkinson's, cancer or the veterans with PTSD.  21       We're joining 32 other states that have  22 already approved cannabis either recreational or for -</p>	<p style="text-align: right;">Page 484</p> <p>1 all know this really well. But I'm shocked and  2 constantly impressed that people do not know about  3 this.  4       We funded it from the department of health  5 and human services. It was assigned in the United  6 States and it was assigned in 2003. Okay. What do  7 they claim? They claim that cannabinoids are  8 antioxidants and neuro-protectants.  9       So that now makes sense as to why it can have  10 application in a wide variety of oxidative diseases  11 such as ischemic, age-related -- I don't know anybody  12 who's getting younger -- inflammatory and autoimmune  13 diseases.  14       They have particular application as neuro-  15 protectants. And I will specify that in this case  16 they took the THC out. They made some changes. But  17 they're claiming on behalf of the American people that  18 this has potential in 2003. 2003.  19       I had to do educational seminars. I had to  20 debate physicians who said what's the urgency, what's  21 the emergency. The opioid crisis that we face, the  22 number of deaths in the U.S. exceeds what we lost in</p>
<p style="text-align: right;">Page 483</p> <p>1 - sorry, medically or for reasonable adult use. I am  2 the voice of the people without the money to buy or  3 influence the practices of medical provider.  4       You might have noticed that I was a  5 pharmaceutical and medical device rep. So I have a  6 lot of experience in that area.  7       And then, not to gain -- I'm the voice of  8 people who do not have the money to gain privileged  9 access to the FDA and the demands of people for access  10 to cannabis and our parents and grandparents who are  11 the number one use of medical cannabis.  12       And if you look, American College of  13 Pediatrics, Journal of Prevention Medicine and  14 national survey on drug use shows that in youth, most  15 of that use has gone down with a slight use there.  16       So why did I get so involved in this? Ten  17 years ago, if you told me I'd be promoting medical  18 cannabis, I'd have said nonsense, there's no medical  19 proof. They just want to get high.  20       And then, I found this patent in addition to  21 much other research. We funded this information.  22 This is Patent Number 6630507 and I assume that you</p>	<p style="text-align: right;">Page 485</p> <p>1 World War II. Okay. Twenty-two veterans committed  2 suicide. Twenty-two today. Twenty-two tomorrow. And  3 cannabis prohibition has been a big part of the  4 problem.  5       So proceedings of the National Academy of  6 Sciences, 1995 -- that's a long time ago. CBD and THC  7 is antioxidants and neuro-protectants. The  8 endocannabinoid system is our master balancing and  9 homeostasis system and it was discovered in the 1990s.  10 How come our doctors don't know about this? Only 13  11 percent of physicians are trained in the  12 endocannabinoid system in medicine right now.  13       We demand a new model, not the pay-for-play  14 science funded by corporate money. We have paid the  15 price of corporate greed and I carry some weight on  16 that. The opioid crisis. That's how I got to retire  17 at age 50. It pays really, really well.  18       Sixty percent of our U.S. biomedical research  19 is funded by the for-profit pharmaceutical industry.  20 And of course this is the best slide of all. March  21 1973, cannabidiol and other cannabis compounds could  22 reduce hippocampal seizures. It took 45 years using</p>

<p style="text-align: right;">Page 486</p> <p>1 the model we currently have to reach patients. I'm 2 thrilled that Epidiolex got approved. But I beg you 3 not to wait 45 years for the next one. 4 And you asked about full spectrum hemp oil. 5 It's not CBD. It's cannabidiol, terpenes, flavonoids, 6 fatty acids, vitamins and minerals. Okay. And I 7 think it's important that we regulate cannabis as 8 generally regarded as safe and the regulations should 9 match other products out there. And I just think this 10 is helpful. 11 MS. CRISTINZIO: Please wrap up. 12 MS. MCMURCHY: Yes. Thank you. I'm the home 13 grower who makes my food -- sorry, my food my first 14 and best medicine. I trust -- oh, sorry. Okay. 15 And we the people in the United States have 16 claimed back our rights to this whole plant medicine 17 from generally ill-guided federal policy, not 18 necessarily just the FDA. I'm not saying you guys did 19 that. But we require and respectfully require the FDA 20 to respect our common voices and self-governance. 21 MS. CRISTINZIO: Thank you. 22 (Applause.)</p>	<p style="text-align: right;">Page 488</p> <p>1 has no impurities and no traces of solvent. 2 Further we're using cottonized industrial 3 hemp fibers to make up the absorbent body of our 4 tampon. To achieve cottonization, the fiber is soaked 5 in purified water and then treated with high voltage 6 electric process, separating and softening individual 7 fibers. 8 The advantages of using cottonized hemp are 9 that the porous structure of the fibers allows for 10 improved absorption and moisture retention, thus 11 reducing the size of the tampon and the likelihood of 12 vaginal abrasions which often occur from the insertion 13 and removal of a dry tampon. We take great care to 14 ensure our tampons are produced safely by introducing 15 clean room manufacturing and gamma ray sterilization. 16 Vaginal applications of CBD are quite novel. 17 And here is what we know so far. Unlike other forms 18 of CBD, vaginally applied CBD works by binding to 19 cannabinoid receptors in the vaginal epithelium, 20 working locally and mechanically. Oops, sorry. 21 The endocannabinoid system is being 22 discovered in many organs, including the vaginal</p>
<p style="text-align: right;">Page 487</p> <p>1 MS. CRISTINZIO: We are now on speaker 112, 2 Valentina Milanova. 3 MS. MILANOVA: Good afternoon. Thank you for 4 the opportunity to be here today. We are Valentina 5 Milanova and Dr. Harry Baxter from Daye. We are a UK- 6 based female health company. And we are delighted to 7 present our research on CBD-coated feminine hygiene 8 tampons as well as the quality standards we're 9 implementing in our supply chain and manufacturing. 10 Let's start with the supply chain. The CBD 11 we use is extracted through a proprietary process 12 capable of separating all cannabinoids from one 13 another. Importantly the process fully removes -- oh, 14 I think there's an issue with the clicker. Oh, there 15 it is. 16 Importantly the process fully removes any and 17 all traces of THC, THCA, making the end extract 18 suitable for medical and consumer uses. The 19 advantages of the method are that the synergetic 20 effects of CBD, CBN and CBG are retained while THC is 21 fully removed to ensure that the tampons do not cause 22 a high. Importantly the extract prepared in this way</p>	<p style="text-align: right;">Page 489</p> <p>1 canal, where it plays an important physiological role, 2 as we have heard today. A few promising studies in 3 rats, rabbits and human volunteers so far have shown 4 the lubricating and skin conditioning properties of 5 topical CBD. 6 These are advantageous for vaginal use again 7 as the dry surface of tampons is known to cause 8 abrasions in the vaginal canal which are associated 9 with a heightened risk of toxic shock syndrome. 10 Moving on to how we -- sorry. Is there are a -- 11 DR. BAXTER: Where are we pointing the 12 clicker? 13 MS. MILANOVA: It's not working. The next 14 slide should be about manufacturing standards. Should 15 we click? Yes, down please. Further down. Down. 16 Down. Down. Here it's perfect. One up. Thank you. 17 All right. How we ensure quality in our 18 supply chain. So first we have three years agreements 19 for the supply of CBD and cottonized hemp which 20 ensures that we get a consistent quality of raw 21 materials and can build long-term relationships with 22 our partners.</p>

<p style="text-align: right;">Page 490</p> <p>1 Second, each and every batch of CBD that we  2 receive is tested in two independent labs for  3 concentration, toxic shock syndrome, staph,  4 Escherichia coli, candida, total anaerobes, total  5 yeast, arsenic, nickel, lead and mercury.  6 Third, we have strict conformity agreements  7 with our suppliers, ensuring that they are  8 incentivized to continuously provide the best quality  9 product or face liability.  10 Moving forward to manufacturing standards, if  11 I can have the next slide please, we use FDA-approved,  12 medical grade machine parts in all of our proprietary  13 CBD tampon coating machines which are housed in ISO 8,  14 Grade D certified clean rooms. We also sterilize the  15 CBD-coated packaged tampons -- perfect. We sterilize  16 the CBD-coated packaged tampons using gamma rays,  17 ensuring no harmful bacteria or contamination are left  18 on the tampon surface when it reaches the consumers.  19 Next slide, please. Shelf-life testing and  20 stability are really important questions when it comes  21 to CBD. We've conducted accelerated shelf-life  22 testing on our raw materials as well as the finished</p>	<p style="text-align: right;">Page 492</p> <p>1 claims with regards to our products. It's important  2 to note here as well that we've received clearance  3 from the European Medicines Agency to market our  4 products in the EU.  5 Dosing is another issue in CBD products, as  6 we heard today, that deserves further research. How  7 we chose the dose that we use today was based on  8 extensive peer-reviewed literature reviews as well as  9 volunteer trials with self-reported efficacy outcomes.  10 That's the next slide. Thank you. Next slide.  11 MS. CRISTINZIO: Please wrap up.  12 MS. MILANOVA: So from the studies that we've  13 seen so far, CBD was tolerated really well in all  14 volunteers with no signs of toxicity or serious side  15 effects. The reported minor side effects that we had  16 included tiredness and diarrhea. Finally --  17 DR. BAXTER: And finally, we are prioritizing  18 high quality research to ensure our products are safe  19 and effective. We've demonstrated that CBD suppresses  20 E. coli, Staph aureus and E. coli growth at  21 therapeutic levels in vitro and we have completed  22 preclinical trials including CBD showing that it does</p>
<p style="text-align: right;">Page 491</p> <p>1 products to ensure that our CBD tampons have a 12-  2 month shelf-life.  3 To ensure product stability in natural  4 consumer environments, we wrap our tampons in medical  5 paper with a lacquer finish and then place them in  6 heat-sealable, airtight plastic pouches.  7 When it comes to labeling -- next slide,  8 please, thank you -- we have clear indications on our  9 packaging and in informational pamphlets on the risk  10 of toxic shock syndrome as well as the risk of CBD  11 allergies.  12 We don't recommend that first-time tampon  13 users employ the CBD tampon and we limit sales to over  14 18-year-olds. We can do that through our e-commerce  15 business model -- as the data on CBD's impact on the  16 development of the vaginal tract is still limited.  17 We're currently thinking about marketing our product  18 simply as CBD tampons, with the view of expanding to  19 soothing, lubricating and finally cramp-fighting as we  20 obtain regulatory approvals and more peer-reviewed  21 clinical data.  22 At present, we will not be making any medical</p>	<p style="text-align: right;">Page 493</p> <p>1 not irritate vaginal epithelium and is pH-balancing.  2 Finally, we have undertaken extensive  3 volunteer trials with CBD-coated tampons which were  4 well-tolerated and so far have shown no adverse  5 events. In our oncoming research pipeline, we are  6 currently undertaking further preclinical trials with  7 animal models to interrogate other potential rare  8 adverse events.  9 We are currently undertaking a double-blind,  10 multicenter RCT at an EMA-certified facility with 80  11 patients using CBD tampons for menstrual symptoms.  12 And finally, we are investigating the effect of CBD on  13 the vaginal microbiome using qualitative PCR analysis.  14 In conclusion, we look forward to working  15 with the FDA on ensuring a stable regulatory framework  16 for CBD, especially in women's health, is put in place  17 in the future. We will be submitting all our written  18 testimony and quoted research for submission.  19 MS. MILANOVA: Thank you. I'm sure you must  20 have questions.  21 PANEL MEMBER: Do you have data -- do you  22 have data on absorption through the vaginal mucosa?</p>

<p style="text-align: right;">Page 494</p> <p>1 MS. MILANOVA: So what we have data about is</p> <p>2 CBD binding to endocannabinoid receptors in the</p> <p>3 vaginal epithelium. And we're currently conducting</p> <p>4 blood plasma tests to see the absorption of CBD</p> <p>5 through the vaginal mucosa.</p> <p>6 What we know is that in rat models, CBD is</p> <p>7 well-absorbed through the skin. But what we've seen</p> <p>8 in the vaginal canal from in vitro studies with</p> <p>9 vaginal epithelium cells is that it tends to bind to</p> <p>10 the endocannabinoid receptors.</p> <p>11 DR. BAXTER: And we're currently undertaking</p> <p>12 it in a rabbit model to assess vaginal absorption.</p> <p>13 PANEL MEMBER: And were you saying that the</p> <p>14 CBD coating was leading to a lower risk of TSS than</p> <p>15 with standard tampons? I couldn't tell if that's what</p> <p>16 you were saying or not.</p> <p>17 MS. MILANOVA: So the research on toxic shock</p> <p>18 syndrome shows that the main reason for it is the dry</p> <p>19 surface of the tampon causing minor incisions on the</p> <p>20 vaginal entrance and the vaginal walls from the</p> <p>21 friction from the insertion and the removal of the</p> <p>22 tampon. And through these incisions, bacteria can</p>	<p style="text-align: right;">Page 496</p> <p>1 before we close is Craig Brand, from Folium</p> <p>2 Biosciences, for five minutes.</p> <p>3 MR. BRAND: Dale told me I could speak until</p> <p>4 all of you fell asleep. But five minutes shouldn't</p> <p>5 say that. Anyway, I literally asked -- my name is</p> <p>6 Craig Brand. I'm general counsel for Folium</p> <p>7 Biosciences in Colorado Springs, Colorado.</p> <p>8 I asked to be the first speaker. That way,</p> <p>9 when I sat down, I was literally the best speaker. So</p> <p>10 I got moved all the way to the back where everything I</p> <p>11 wanted to talk about is pretty much gone now.</p> <p>12 So I would like to start off first by</p> <p>13 thanking the FDA for this day, thanking the</p> <p>14 stakeholders for this day, thanking all who are</p> <p>15 listening on Wi-Fi for being present with us, thanking</p> <p>16 all that are in the room with us. Thank you for</p> <p>17 sharing your birthdays. Thank you for sharing beer</p> <p>18 30. Thank you for all the time that everybody has</p> <p>19 given to these issues.</p> <p>20 Now, given the fact that almost everything I</p> <p>21 did want to say has already been said or I should just</p> <p>22 button my lips, let me repeat what I did hear. I did</p>
<p style="text-align: right;">Page 495</p> <p>1 enter the bloodstream and toxic shock syndrome</p> <p>2 happens.</p> <p>3 Now, there's two ways in which we believe</p> <p>4 we're reducing the risk of toxic shock syndrome. The</p> <p>5 first one is that by being infused with CBD on the</p> <p>6 outer layer, on the protective sleeve of our tampon,</p> <p>7 it's effectively lubricated, so significantly reducing</p> <p>8 the risk of those ulcerations happening from friction</p> <p>9 from insertion and removal.</p> <p>10 And then second because we sterilize the</p> <p>11 tampons using gamma rays which is the standard in</p> <p>12 surgical tools. That's where we borrowed that from.</p> <p>13 We ensure that there's no bacteria that could enter</p> <p>14 through any ulcerations or abrasions.</p> <p>15 MS. CRISTINZIO: Great. Thank you so much.</p> <p>16 DR. BAXTER: Thank you.</p> <p>17 MS. MILANOVA: Thank you.</p> <p>18 MS. CRISTINZIO: Sorry for the technical</p> <p>19 difficulties with your slides.</p> <p>20 MS. MILANOVA: No worries. Thanks for</p> <p>21 helping.</p> <p>22 MS. CRISTINZIO: Our last presenter today</p>	<p style="text-align: right;">Page 497</p> <p>1 hear that what we're here today to discuss is about a</p> <p>2 product that is a pharmaceutical product or a dietary</p> <p>3 supplement or a food ingredient or even a dispensary</p> <p>4 product. Yes, it is.</p> <p>5 I did hear that we're talking about issues</p> <p>6 of adulteration, of diversion, of mislabeling, of</p> <p>7 improper product manufacturing. Yes, we did. I did</p> <p>8 hear us talk about safety, conformity, standards and</p> <p>9 protocols. Yeah, we did that too.</p> <p>10 I heard people mentioning about the farming</p> <p>11 business, the genetic business, the harvesting, the</p> <p>12 extraction, the production, the fulfillment and even</p> <p>13 pharmaceutical interest. Yeah. We did that as well.</p> <p>14 I heard people talk about competition, global</p> <p>15 intervention. There's even, if you look just across</p> <p>16 the pond, a new category for CBD called novel foods</p> <p>17 that maybe the FDA needs to direct some attention to.</p> <p>18 But yes, we did.</p> <p>19 So we have an industry. We have an American-</p> <p>20 made industry. Now, let's do everything we can that</p> <p>21 we keep this American-made industry, that we don't let</p> <p>22 this American-made industry go bye-bye to the world as</p>

<p style="text-align: right;">Page 498</p> <p>1 we know it.</p> <p>2 Let's look to work in harmony, bring all of</p> <p>3 what I just discussed, whether it's a pharmaceutical</p> <p>4 product, a dietary supplement, a feed ingredient or</p> <p>5 dispensary product, let's figure out a way to make it</p> <p>6 work and let's come up with solutions.</p> <p>7 So Folium Biosciences is located in part in</p> <p>8 Colorado Springs, Colorado. There are -- I'm going to</p> <p>9 give a shout out to all of the other Colorado</p> <p>10 companies that came up here today and talked before me</p> <p>11 because, one, they deserve the shout out and, two, I</p> <p>12 love my state.</p> <p>13 But all of us here are here for a single</p> <p>14 purpose. There were people that came up and I heard a</p> <p>15 lot of badmouthing about CBD. I heard badmouthing</p> <p>16 about THC. Guys, it's an industry. It's a business.</p> <p>17 We're all here to make it better. We're not here</p> <p>18 because we want to do things wrong. We're in this</p> <p>19 room. We're listening over the Wi-Fi. We're</p> <p>20 listening over TV, whatever it is, because we're</p> <p>21 trying to get it right. With you or without you,</p> <p>22 we're moving forward and we're doing a really, really</p>	<p style="text-align: right;">Page 500</p> <p>1 But let's not kid ourselves. It goes on in</p> <p>2 every single business. For those who know me also</p> <p>3 know that I was healthcare attorney of the year. I'm</p> <p>4 a senior partner in one of the largest healthcare law</p> <p>5 firms in the country. I also was CEO of a very large</p> <p>6 pharmaceutical chain.</p> <p>7 So there's a lot about the history of this</p> <p>8 building, of what is done here that I have firsthand</p> <p>9 knowledge about. So what happened, all you have to do</p> <p>10 is look just a few years back.</p> <p>11 Look to the illegal drug diversion issue and</p> <p>12 look how the states got smart and created all the</p> <p>13 solutions to counter that, to prevent that and to move</p> <p>14 forward going forward in the future. And all of what</p> <p>15 we saw here today, from the labeling issues, from the</p> <p>16 people making improper products --</p> <p>17 MS. CRISTINZIO: Please wrap up.</p> <p>18 MR. BRAND: -- to people improperly</p> <p>19 fulfilling, all of that has been answered. All we</p> <p>20 have to do is look to the states and look to the laws</p> <p>21 that they've written. Thank you very much.</p> <p>22 (Applause.)</p>
<p style="text-align: right;">Page 499</p> <p>1 good job.</p> <p>2 So I ask you how many of you sitting on the</p> <p>3 panel have even ever tried CBD. You don't have to say</p> <p>4 anything. I ask you the following. How many of you</p> <p>5 sitting on the panel have even come out to one of</p> <p>6 Colorado's best or any other state's best and even</p> <p>7 seen how the industry actually works? It should be</p> <p>8 first base or home plate.</p> <p>9 And I invite you, and I'm sure my Colorado</p> <p>10 brethren would probably have no objection as well to</p> <p>11 come out and see us. See what it is we do.</p> <p>12 Folium Biosciences is one of the largest</p> <p>13 seed-to-sale facilities in the entire world, with</p> <p>14 facilities going around the world, with our product</p> <p>15 going around the world. So it's first base for you.</p> <p>16 It's the way that you get your answers to your</p> <p>17 questions.</p> <p>18 So I know that my time is almost up. But let</p> <p>19 me say the following. All that we talked about today,</p> <p>20 from the labeling issues, from the diversion issues,</p> <p>21 from the adulteration issues, does it go on? Yes, it</p> <p>22 does.</p>	<p style="text-align: right;">Page 501</p> <p>1 CLOSING REMARKS</p> <p>2 MS. CRISTINZIO: Thank you. That concludes</p> <p>3 the end of our public comment and formal presentation.</p> <p>4 I want to remind everyone that the docket is still</p> <p>5 open. It remains open until July 2nd. Please submit</p> <p>6 comments to the docket. Thank you to everyone who</p> <p>7 joined us in person today and on webcast. And this</p> <p>8 concludes our public hearing. Thank you very much.</p> <p>9</p> <p>10 (Whereupon, the foregoing was concluded.)</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>

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 3 foregoing proceeding was taken, do hereby certify that  
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 9 of the parties to the action in which this was taken;  
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 11 any counsel or attorney  
 12 hereto, nor financially e  
 13 outcome of this action.

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 17 STATE OF MARYLAND  
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 9 which this was taken; and, further, that I am not a  
 10 relative or employee of any counsel or attorney  
 11 employed by the parties hereto, nor financially or  
 12 otherwise interested in the outcome of this action.  
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15 BENJAMIN GRAHAM  
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<b>&amp;</b>	<b>1.4</b> 120:11	<b>13</b> 61:11 159:15	<b>1990s</b> 175:13
<b>&amp;</b> 6:17 7:13 9:21 14:17 16:5 18:3 18:17 81:5,8 101:21 102:1,7,17 156:1 447:9	<b>10</b> 51:10,21 52:5 58:22 84:16 96:20 132:12 203:6 211:16,18 238:1 274:3 277:11 283:4 292:5 302:16 314:13 318:12 320:4 347:18 359:12,20 375:17,19 397:10 430:13	190:4 252:2 485:10 <b>13,000</b> 426:6 <b>130</b> 348:2 <b>132</b> 126:7 <b>135</b> 18:14 <b>14</b> 61:13 238:2 333:2 427:16	221:22 485:9 <b>1993</b> 395:21 <b>1994</b> 273:8 <b>1995</b> 485:6 <b>1998</b> 160:12 <b>1:30</b> 281:22 <b>1st</b> 169:9
<b>0</b>	<b>10,000</b> 78:19 395:15	<b>145</b> 18:15 <b>147</b> 18:16 <b>149</b> 84:14 <b>15</b> 1:11 50:13 63:16 235:18 288:4 328:3 335:4 359:9,11 372:21 473:3	<b>2</b>
<b>0.001</b> 314:13 <b>0.02</b> 314:21 <b>0.03.</b> 345:19 <b>0.1</b> 296:2 313:22 314:6 <b>0.10.</b> 314:14 <b>0.17</b> 299:16 <b>0.2</b> 240:3,4 296:2 <b>0.3</b> 28:21 69:1 84:8 85:16,22 190:10,21 191:20 211:7 240:5,8 275:10 296:1,5,10 313:20 341:6 345:19,19 368:6 424:20 469:6,21 <b>0.3.</b> 314:4 <b>0.4</b> 292:6 <b>0.5</b> 299:16	<b>100</b> 141:3 207:7 213:3 232:7 239:5 270:20 342:13 359:10 425:12 <b>101</b> 429:13 <b>102</b> 435:2 <b>103</b> 442:15 <b>104</b> 447:6 <b>105</b> 451:5 <b>107</b> 462:8 <b>10903</b> 1:18 <b>10:45</b> 172:20 <b>11</b> 59:2 246:1 <b>11.5</b> 454:20 <b>110</b> 159:22 <b>111</b> 163:2 348:16 481:18 <b>112</b> 487:1 <b>113</b> 24:20 <b>117</b> 159:17,22 348:16 <b>12</b> 61:10 191:5 299:22 311:12,12 341:8 448:17 469:14 491:1 <b>12,000</b> 108:22 153:14 161:21 <b>120</b> 301:15 425:22 <b>125</b> 394:17	<b>15.4</b> 300:21 <b>150</b> 126:1 <b>156</b> 18:18 <b>16</b> 66:18 91:22 250:7 318:9 319:2 <b>16,000</b> 196:8 <b>17</b> 66:20 469:9 472:18 <b>17004</b> 502:14 <b>17025</b> 134:1 135:7 372:5 443:10,11 <b>176</b> 18:20 <b>18</b> 43:15 70:17 84:17 209:8 256:5 256:12 258:20 491:14 <b>1896</b> 156:6 <b>19</b> 70:18 92:11 274:22 375:19 472:19 <b>1970</b> 28:10 <b>1973</b> 358:16 485:21 <b>1978</b> 132:19 <b>1983</b> 342:15 <b>1990</b> 273:9	<b>2</b> 27:6 108:21 262:12 344:10 <b>2,000</b> 107:9 206:15 289:13 <b>2,281</b> 78:17 <b>2,978</b> 453:10 <b>2.7</b> 51:11 <b>2.73</b> 469:17 <b>2.8</b> 361:6 469:20 <b>2.89</b> 470:1 <b>20</b> 18:4 63:2 72:11 160:4 174:6 182:4 201:5 223:11 227:7 238:5 239:22 245:22 270:21 299:20 319:6 339:15 342:19 359:19 458:5 472:6 <b>20,000</b> 289:18 <b>200</b> 51:8 116:10 359:10,19 <b>200,000</b> 52:7 125:12 289:12 <b>2003</b> 79:3 484:6 484:18,18 <b>2008</b> 442:4 <b>2009</b> 77:22 357:17 <b>201</b> 86:5 273:3 <b>2010</b> 294:3 367:7 <b>2012</b> 42:18 78:8 <b>2013</b> 141:20 334:10 <b>2014</b> 204:22 367:14 414:6
<b>1</b>	<b>1</b> 28:12 29:2 63:3 86:5 93:21 94:7 119:17 148:18 210:14 226:19 272:11 280:22 283:17 296:9,11 302:16 320:8 333:14 340:17 358:20 359:9 361:6 402:11 <b>1,000</b> 161:20 279:6 <b>1,100</b> 238:13 <b>1,500</b> 189:21 290:11 395:17		



<b>2015</b> 291:7 335:2 335:6 360:7 373:18 387:14 402:8 421:4 423:3	<b>24/7</b> 194:15 195:2 198:8 <b>25</b> 57:17 87:14 189:15 211:18 317:8 359:18 430:1,18 433:22 450:4 458:5	<b>32</b> 104:14 482:21 <b>32,000</b> 403:11 <b>321</b> 435:11 <b>33</b> 107:3 159:14 408:22 430:12 <b>33,000</b> 153:14 <b>33223</b> 312:3 <b>334,000</b> 43:12 <b>34</b> 111:5 238:7 249:17 <b>3406507</b> 1:20 <b>35</b> 111:8 259:15 311:18 <b>36</b> 115:18 472:14 <b>360</b> 469:13 <b>37</b> 18:8 119:1 <b>37.5</b> 277:13 <b>373</b> 19:5 <b>38</b> 250:7 447:16 <b>39</b> 125:8 450:7 <b>3:30</b> 372:22 <b>3a4</b> 179:1 180:12	<b>45</b> 41:6 137:15 190:22 193:21 485:22 486:3 <b>456</b> 19:6 <b>46</b> 142:17 430:14 <b>461</b> 19:7 <b>47</b> 144:22 <b>48</b> 147:8 <b>481</b> 19:8
<b>2016</b> 284:3 <b>2016-2017</b> 453:16 <b>2017</b> 312:19 335:7 368:9 392:13 402:13 422:7 427:11 <b>2018</b> 28:18 29:5 33:22 48:14 54:18 67:21 81:13 82:8 82:16 97:10 109:18 111:15 116:11 147:14 312:19 329:10 414:9 453:13 <b>2019</b> 1:14 27:6 49:3 110:10 116:12 161:1 312:19 <b>20993</b> 1:19 <b>21</b> 55:8,11,18,21 56:8 75:22 159:17 163:2 226:20 256:4,12 348:15 473:9 <b>217025</b> 443:6 <b>21st</b> 145:14 <b>22</b> 77:19 108:18 268:17 <b>22000</b> 372:5 <b>227</b> 18:21 <b>23</b> 43:17 188:9 190:20 <b>235</b> 18:22 <b>24</b> 83:8 173:21 223:17 248:10 306:5 311:8 318:19 349:3 375:17 <b>24.2</b> 300:21	<b>259</b> 19:3 <b>26</b> 18:6 91:6 248:14 251:11 <b>27</b> 61:18 92:15 94:1 <b>27.6</b> 375:11 <b>272</b> 261:22 <b>28</b> 95:14 <b>287</b> 19:4 <b>29</b> 98:10 <b>2c9</b> 179:15 180:1 <b>2nd</b> 53:3 66:9 104:8 110:16 124:18 501:5	<b>3</b>	<b>5</b>
	<b>3</b> 53:13 72:4 260:6 295:22 <b>3,000</b> 175:6 289:13 <b>3,500</b> 132:20 <b>3.4</b> 400:22 <b>30</b> 23:7 51:21 101:20 169:8 206:14 223:1 238:4 251:5 284:6 311:18,18 453:11 453:16,18 454:3 454:16,21,22 469:12,15 496:18 <b>30,000</b> 233:18 289:18 <b>300</b> 116:11 <b>300,000</b> 223:3 <b>301</b> 105:6,9 106:11 273:6 <b>31</b> 1:14,17 335:8	<b>4</b>	<b>5</b> 173:16 201:5 207:9,10 210:13 301:16,17,19 319:3 469:4,5,11 <b>5.2</b> 318:11 <b>50</b> 46:9 132:21 160:12 199:17 208:13 232:20 278:11 293:3 318:17 359:18 469:10 473:7 485:17 <b>500</b> 26:20 120:13 290:10 430:20 <b>500,000</b> 320:4 <b>501</b> 19:9 53:13 <b>507</b> 79:3 <b>507,000</b> 482:15 <b>51</b> 221:7 <b>53</b> 18:10 161:10 <b>54</b> 166:9 <b>55</b> 166:11 280:20 340:13 <b>57.9</b> 201:17 <b>58</b> 18:11 43:14 181:17 <b>59</b> 187:13 <b>5th</b> 92:8
		<b>6</b>	<b>6,000</b> 426:7 <b>6.4</b> 211:12 <b>6.5</b> 450:11

<p><b>60</b> 48:2 107:15 192:10 229:2 232:20 261:13 293:3 300:22 359:9 <b>60,000</b> 82:22 233:18 260:4 <b>600</b> 344:9,9 397:6 397:12 427:16 <b>601</b> 162:1 <b>607</b> 359:16 <b>60s</b> 388:13 <b>61</b> 200:13 <b>62</b> 204:9 <b>63</b> 209:22 469:9 <b>64</b> 216:10 248:15 349:2 <b>65</b> 76:4 <b>65.5</b> 275:12 <b>66</b> 18:12 227:15 261:16 430:14 <b>6630507</b> 483:22 <b>67</b> 235:10 <b>68</b> 240:15 <b>69</b> 335:9</p>	<p><b>76</b> 287:17,19 <b>77</b> 293:20 450:4 <b>78</b> 298:11 <b>788</b> 482:8 <b>79</b> 209:3 303:7</p>	<p style="text-align: center;"><b>a</b></p> <p><b>a.m.</b> 1:15 <b>a2la</b> 8:12 132:18 132:19 135:2 379:2 <b>a2la's</b> 379:4 <b>aaron</b> 14:2 353:8 353:10 <b>ab</b> 253:2 <b>abbreviated</b> 410:6 <b>abdicate</b> 117:20 <b>abdominal</b> 275:16 <b>abernathy</b> 2:2 21:7,7 <b>abhors</b> 37:22 <b>ability</b> 142:11 148:4 149:14 231:14 292:21 326:19 351:6 418:18 502:7 503:7 <b>able</b> 63:10 91:13 97:13 126:20 148:9 152:9 163:5 184:2 218:8 223:11 231:16 239:12 240:17 252:16 254:14 255:11,18 256:20 264:21 265:2 274:5 290:14 291:12 294:21 295:12 306:8 314:9 316:12 337:14 343:9,10 344:6 345:15 346:4,19 347:1,3 347:7 351:13 387:5 390:13 410:14 414:14 430:10 460:12 465:12 473:21 474:12</p>	<p><b>abnormal</b> 301:3 <b>abrasions</b> 488:12 489:8 495:14 <b>abroad</b> 268:21 <b>abrupt</b> 404:9 <b>absence</b> 28:15 37:19 106:10 108:7 265:17 341:13 445:19 <b>absent</b> 35:14 99:15 109:17 <b>absenteeism</b> 375:12 <b>absolutely</b> 53:2 68:6 124:19 125:4 169:20 170:1 231:10 251:21 277:22 281:15 309:19 310:12 337:2 358:11 360:1 404:21 413:1 476:3 481:15 <b>absorbed</b> 185:2 494:7 <b>absorbent</b> 488:3 <b>absorption</b> 75:9 185:22 366:14 371:8 488:10 493:22 494:4,12 <b>abstain</b> 223:11 <b>abstracts</b> 78:21 <b>abuse</b> 28:14 57:8 68:1 220:16 242:9 269:2 271:12,13 271:15 295:5 374:14 410:19 <b>abused</b> 470:8 <b>abuses</b> 192:4 <b>academia</b> 4:14 10:6 18:8 37:16 176:15,19 187:12 220:12 440:13</p>
<b>7</b>	<p style="text-align: center;"><b>8</b></p> <p><b>8</b> 397:9 490:13 <b>80</b> 27:13 261:14 311:1 431:1 493:10 <b>800</b> 26:22 270:20 <b>80s</b> 467:8 <b>81</b> 317:2 <b>82</b> 469:16 <b>825</b> 96:6 <b>82nd</b> 57:16 <b>83</b> 18:13 247:4 328:21 <b>84</b> 332:20 469:22 <b>85</b> 142:22 338:4 <b>85a</b> 342:4 <b>86</b> 262:1 347:12 470:2 <b>87</b> 353:8 <b>88</b> 356:19 <b>88.7</b> 276:1 <b>89</b> 361:11 <b>8:00</b> 1:15</p>		
<p><b>7</b> 108:18 450:11 <b>7.5</b> 277:6 <b>70</b> 43:11 51:10 248:10 252:19 260:10 309:13 340:18 397:11 464:9 <b>700</b> 93:8 120:11 233:19 239:8 <b>70s</b> 388:13 467:8 <b>71</b> 259:4 <b>72</b> 263:21 298:3,5 <b>73</b> 268:11 <b>75</b> 261:2,13 262:4 273:10 315:10 <b>75.3</b> 275:20 <b>750</b> 83:1</p>	<p style="text-align: center;"><b>9</b></p> <p><b>9</b> 27:15 292:2,6,12 <b>90</b> 229:20 309:13 366:5 426:6 480:6 <b>9001</b> 291:7 363:14 372:5 <b>91</b> 373:6 <b>92</b> 378:16 <b>93</b> 384:1 <b>95</b> 386:7 395:5 <b>98.2</b> 449:19 <b>99</b> 148:17</p>		

<b>academic</b> 18:20 37:8 236:20 422:11 <b>academically</b> 192:21 <b>academics</b> 292:15 432:7 <b>academies</b> 183:14 <b>academy</b> 224:18 485:5 <b>accelerate</b> 225:22 <b>accelerated</b> 112:21 223:20 490:21 <b>accept</b> 167:18 247:8 356:6 393:17 460:22 478:3 <b>acceptable</b> 28:16 85:7 332:4 <b>acceptance</b> 99:7 225:2 364:21 <b>accepted</b> 167:14 446:3 <b>accepting</b> 82:10 <b>access</b> 16:13 33:18 34:17 47:2 55:1,3 55:6,7 75:14 111:16 112:14 118:5 123:7 132:7 133:21 152:14 175:8 194:15 195:2 196:3 197:17 217:1,11 222:3 225:12 267:6,11 287:10 326:6 349:17 359:15,17 389:22 403:5 404:4,20 405:7 406:13 411:21 462:14,15 483:9,9 <b>accessed</b> 23:7	<b>accessibility</b> 266:20 <b>accessible</b> 382:13 <b>accessing</b> 143:1 <b>accidental</b> 144:5 <b>accommodate</b> 411:14 <b>accompanied</b> 370:18 <b>accompanies</b> 389:13 <b>accomplished</b> 133:8 134:1 <b>account</b> 36:15 123:14 337:19 437:13 <b>accountability</b> 365:2 376:5 377:5 408:15 <b>accountable</b> 47:22 149:17 <b>accounted</b> 123:20 <b>accounting</b> 95:7 <b>accreditation</b> 16:3 132:17,20 134:1,2 134:18,20 135:7 442:17,18 443:11 443:15,16 444:1,4 444:5,9 445:1,2,4 445:5,7,22 446:13 <b>accreditations</b> 372:6 <b>accredited</b> 132:21 134:15 135:6 443:5 445:14 446:17 478:18 479:12 <b>accumulates</b> 45:22 <b>accumulating</b> 80:9 <b>accuracy</b> 121:18 251:19 315:2 331:8,20 391:9	479:13 480:7 <b>accurate</b> 74:4 134:10 239:6 303:20 319:14 345:20 349:17 351:14 383:17 391:13,14 396:11 446:14 502:6 503:5 <b>accurately</b> 188:19 222:15 306:9 360:17 380:12 466:5 <b>acetaminophen</b> 202:11 203:1 <b>aches</b> 127:9 <b>achieve</b> 118:8 201:20 488:4 <b>achieved</b> 53:19 57:15 119:17 299:16 480:6 <b>achieves</b> 318:3 <b>achieving</b> 370:16 <b>acid</b> 45:21 <b>acids</b> 45:21 234:12 486:6 <b>acknowledge</b> 112:5 160:2 451:15 <b>acknowledged</b> 113:13 114:14 477:4 <b>acknowledgement</b> 293:1 435:7 <b>acne</b> 276:22 <b>acquired</b> 191:14 207:10 259:18 <b>acre</b> 83:1,2 233:18 233:19 288:18,19 289:13 <b>acres</b> 161:21 289:12,12 <b>act</b> 28:10,18 31:21 65:18 93:21 105:6	108:3 111:21 112:20 113:7,16 114:11,16 117:3 117:22 121:1,13 144:10 189:1 241:20,21 273:8,9 296:6 313:19 344:21 410:22 411:1,19,20 438:2 438:3 440:17 <b>acting</b> 4:7 20:11 25:22 146:14 220:19 443:14 <b>action</b> 42:12 85:1 85:4 89:7 120:4 139:14 160:6,8 186:20 392:5 396:20 468:4 470:21 478:20 502:9,13 503:8,12 <b>actions</b> 77:4 112:18 120:7 170:10 <b>active</b> 27:14 81:18 81:21,22 98:5 100:2 105:14 126:1 173:10 177:6,7 178:22 179:4,21 188:20 207:16 253:5 311:3,10 381:11 396:12 406:21 419:21 426:21 <b>actively</b> 132:21 235:1 428:1 <b>activities</b> 121:9 235:18 401:3 420:5 423:6 442:20 443:1,18 444:3 <b>activity</b> 108:21 209:13 324:12 372:13 383:7 397:16 428:4,10
---	--	---	---

<p><b>actors</b> 477:19</p> <p><b>acts</b> 270:10,11 474:17</p> <p><b>actual</b> 186:15 189:9 190:13 191:15 199:15 228:16,18 229:6 263:16 315:8 344:14</p> <p><b>acute</b> 41:10 213:21</p> <p><b>acutely</b> 212:14</p> <p><b>ad</b> 376:17 452:20 468:12</p> <p><b>adams</b> 7:4 14:14 91:7,12,17,20,20 92:14 373:7,9,10 378:7,11,13,15</p> <p><b>adb</b> 207:9,11</p> <p><b>add</b> 303:4 328:15</p> <p><b>added</b> 27:18,19 31:7 32:13 105:9 105:14 106:1,22 180:8 324:4 363:1 422:10 433:13 442:5 454:14</p> <p><b>addiction</b> 57:9 173:16 243:6 271:15 374:15,22 468:18</p> <p><b>addictions</b> 67:10</p> <p><b>addictive</b> 104:22 173:17 222:22 243:10 477:6</p> <p><b>adding</b> 31:21 111:22 304:6</p> <p><b>addition</b> 22:17 23:8 78:22 79:11 84:13 131:11,16 151:10 186:11 211:4,21 217:5 266:20 272:17 330:6 367:15 428:12 456:8</p>	<p>463:19 479:3 483:20</p> <p><b>additional</b> 25:19 46:7 61:3 66:8 75:13 88:9 90:11 129:4 155:11 168:14 213:3 257:14 320:12 327:16 360:16 381:22 441:8,10 442:9 475:5</p> <p><b>additionally</b> 53:21 99:4 106:4 465:7</p> <p><b>additive</b> 31:1 81:20 167:6</p> <p><b>additives</b> 52:19 64:11 99:21 120:9 124:8,9 144:8 416:22</p> <p><b>address</b> 35:2 53:10 109:13 115:13 117:3,21 119:5 120:4 131:7 150:19 182:7 285:8 302:11 338:2 378:19 385:17 399:20 463:7,10</p> <p><b>addressed</b> 149:12 256:11 272:6 288:20 385:21 439:1 455:13</p> <p><b>addresses</b> 213:9</p> <p><b>addressing</b> 71:16 428:4</p> <p><b>adequate</b> 78:10 134:6 157:9 181:13 379:15,20 439:1 464:2</p> <p><b>adequately</b> 147:2</p> <p><b>adhere</b> 195:10 196:21 478:21</p> <p><b>adhered</b> 415:18</p>	<p><b>adherence</b> 121:16 439:16</p> <p><b>adhering</b> 370:8</p> <p><b>adjectives</b> 215:4</p> <p><b>adjunct</b> 192:13</p> <p><b>adjust</b> 459:15</p> <p><b>administer</b> 203:3</p> <p><b>administered</b> 211:19 212:19 213:4,11 215:1 270:16,17 271:5 299:5</p> <p><b>administering</b> 212:14 285:15</p> <p><b>administration</b> 1:1,16 2:4,9,13,17 2:21 3:5,9,13,17 3:21 4:5,11 40:20 41:13 177:11 184:1,6,22 185:20 186:5,12,21 201:19 202:22 211:21 212:1 213:8 215:7 258:4 258:13 358:16 361:16 388:21 396:1 426:18 451:19 454:3</p> <p><b>administration's</b> 20:4</p> <p><b>administrations</b> 84:18</p> <p><b>administrative</b> 22:20 446:5</p> <p><b>administrators</b> 430:21</p> <p><b>admissions</b> 223:3</p> <p><b>admit</b> 208:20</p> <p><b>admitted</b> 92:4</p> <p><b>adolescent</b> 402:8</p> <p><b>adolescents</b> 225:4</p> <p><b>adopt</b> 437:6</p> <p><b>adopted</b> 314:10 426:8</p>	<p><b>adoption</b> 119:18 380:9 442:21</p> <p><b>adult</b> 51:11 108:18 146:5 174:13 247:19 248:8,8,15 340:18 359:8 361:8,8 430:13,14 451:14 454:2 483:1</p> <p><b>adulterant</b> 467:17</p> <p><b>adulterants</b> 99:14 133:14 192:8 195:15,19 216:21</p> <p><b>adulterated</b> 99:19 191:2,11,21 194:2</p> <p><b>adulteration</b> 199:12 208:14 400:5 497:6 499:21</p> <p><b>adults</b> 116:15,16 139:19 215:18 225:4 247:19 248:2 272:14,16 277:13 401:2 452:19 468:14</p> <p><b>advance</b> 24:11 25:13 108:13 240:16,19 342:11 425:19 481:7</p> <p><b>advanced</b> 37:20 84:12 311:16</p> <p><b>advancing</b> 167:16 381:19</p> <p><b>advantage</b> 82:20 82:21</p> <p><b>advantageous</b> 489:6</p> <p><b>advantages</b> 315:21 437:1 487:19 488:8</p> <p><b>adverse</b> 51:13 67:6,15,20 69:19 84:17 125:1 139:9 141:14 158:2</p>
--	--	---	--

179:7 193:15 194:12,17 195:3 196:16,17 197:21 198:7 199:15,20 199:22 200:8 209:17 218:7 220:3 269:12,15 285:18 300:2,4,6 300:10,10,13 301:1,4,4,6,13,16 301:18 302:1,7,8 302:9 318:20 326:2 358:19 380:15 388:16 431:3 438:18 442:2 468:20 480:13,17 493:4,8 <b>advertise</b> 375:9 <b>advertised</b> 345:21 <b>advertises</b> 376:16 <b>advertising</b> 82:12 221:2 247:8 255:7 375:14 425:8 470:12 <b>advice</b> 251:8 <b>advise</b> 422:17 <b>advising</b> 119:7 422:16 <b>advisor</b> 3:7 21:11 422:11 <b>advisory</b> 95:19 379:8 <b>advocacy</b> 47:21 142:20 236:1 253:1 401:4 432:11 <b>advocate</b> 138:9 140:2 242:4,11 369:5 381:12 393:15 474:3 <b>advocates</b> 88:2 124:7 130:15 <b>advocating</b> 256:3	<b>ae</b> 301:8 <b>aea</b> 262:12 <b>aes</b> 300:9,15 301:9 <b>afco</b> 166:16,17 167:2,7,13,17,19 168:9,13,19 169:4 169:14 <b>afco's</b> 168:8 <b>afco.org</b> 169:11 169:12 <b>afco.org.</b> 169:15 <b>afdo</b> 156:5,5,6 157:14,18,20 159:14 161:2 <b>affairs</b> 2:6,8,12 20:9 21:22 22:3,4 192:16 298:16,20 321:16 353:11,14 366:8 420:5 <b>affect</b> 142:11 405:16 451:20 <b>affiliated</b> 192:21 <b>affiliation</b> 25:5 <b>affirmation</b> 273:11 <b>affirmative</b> 280:8 <b>affirmed</b> 356:6 <b>affordable</b> 403:16 <b>aflatoxin</b> 100:3 <b>afraid</b> 208:11,18 208:19 403:8,9 <b>afternoon</b> 103:2 252:21 268:12 282:7 293:21 311:2,3 328:22 332:21 338:5 353:9 356:20 361:12 366:6 378:18 391:1 395:6 400:11 406:19 413:12 419:7,12,13 425:14 429:14 435:3 457:2 467:3	471:13 476:7 487:3 <b>afternoon's</b> 413:22 <b>ag</b> 262:12 <b>age</b> 55:18,21 56:2 57:17 69:12 91:22 165:15 248:16,18 256:1,5,9,13 258:5,12,19 388:12 409:18 470:4,6 472:14 473:8 484:11 485:17 <b>aged</b> 149:7 <b>agencies</b> 83:19 88:11 89:3,9 166:18,19 182:22 204:5 312:20 363:2,8 365:18 369:5 397:4 412:4 440:13 477:4 478:12 <b>agency</b> 26:2 35:21 50:1 63:12 65:16 84:5 87:12 96:1 98:16 100:18 101:10 113:15 118:9 136:1 155:15 200:20 244:15 258:22 304:6 320:12 346:6 347:5 353:19,21 354:22 356:3,5 396:10 397:4,15,17,19,22 399:9,10,16 411:2 414:20 419:19 438:3 440:11 442:6 481:3 492:3 <b>agency's</b> 38:11 84:10 85:1 113:5 329:12 460:17	<b>agenda</b> 20:10,17 24:19,22 27:1 36:18 37:2 91:6 95:13 98:10 101:20 104:12,15 111:7 122:7 125:8 342:2 <b>agent</b> 298:2 <b>agents</b> 124:8 146:17 203:18 <b>ages</b> 67:5 375:17 375:19 <b>aggregate</b> 34:2 <b>aggressive</b> 38:3 174:14 442:6 <b>aggressively</b> 382:15 436:14 <b>agnostic</b> 313:12 <b>ago</b> 62:5 63:6 122:12 179:13 182:5 209:2 246:9 283:13 288:7 392:3 426:1 449:8 459:4,22 467:20 483:17 485:6 <b>agonists</b> 94:16 <b>agony</b> 58:14 <b>agree</b> 44:14 76:10 286:5 321:17 324:6 405:7 419:2 419:3 433:11 <b>agreed</b> 111:20 305:21 <b>agreement</b> 47:13 294:8 <b>agreements</b> 489:18 490:6 <b>agrees</b> 136:7 243:22 <b>agribusiness</b> 43:4 44:6,10 <b>agricultural</b> 28:18 50:10 52:10 82:16 145:12 147:16
--	--	---	--

164:14 228:8,14 231:7 313:19,20 322:12,14 352:5 408:6,11 411:20 412:9 <b>agriculturally</b> 411:19 <b>agriculture</b> 4:20 9:16,18,21 10:3 11:11 18:9,21 42:14,15 43:8 47:15 161:15 166:12 227:14,16 368:3 <b>ah</b> 169:9 <b>ahead</b> 185:4 199:9 282:12 288:2 293:15 321:18 382:3 413:9 <b>ahold</b> 423:13 <b>ahpa</b> 111:12,13,15 111:20 112:2,17 113:10 <b>ahpa's</b> 112:15 <b>aid</b> 195:5 320:12 <b>aids</b> 30:9 <b>ailments</b> 261:11 262:5 341:12 <b>airborne</b> 57:16 <b>airplanes</b> 426:15 <b>airtight</b> 491:6 <b>akin</b> 416:15 <b>alabama</b> 180:3 336:12 <b>alarmed</b> 117:6 <b>alarming</b> 335:13 <b>alcohol</b> 56:1 123:19 151:16 409:10,12,17 412:13,16 431:9 470:5,8 <b>alerts</b> 77:3 439:8 <b>alex</b> 242:22	<b>alexander</b> 2:5 22:1,2 <b>alice</b> 13:16 338:4 338:5 <b>aligned</b> 239:3 <b>alike</b> 54:6 100:21 163:12 340:5 417:12 <b>alive</b> 245:6 <b>allen</b> 66:18 <b>allergen</b> 425:4 <b>allergies</b> 491:11 <b>alley</b> 431:19 <b>alleys</b> 431:11 <b>alliance</b> 5:15 8:20 56:16,18 142:20 143:9 144:13 <b>alliances</b> 16:15 467:5 <b>allocated</b> 98:16 168:14 <b>allotted</b> 24:19 25:9 <b>allow</b> 28:3 48:10 55:7 105:2 111:16 112:14 196:3 255:6,9,12 256:19 257:15,16 273:12 285:11 294:21 297:15 304:3 305:5 323:8 324:14 325:12 327:14 341:7 354:13 363:12 382:11 398:1 408:21 411:6 432:17,17,18,19 434:17,17 440:19 <b>allowable</b> 211:6 464:22 <b>allowances</b> 151:4 <b>alloway</b> 180:19 <b>allowed</b> 23:14 89:18 91:8 115:11	151:15 159:10 169:3 242:1 256:22 323:15 377:1,6,8,15,17 396:16 411:8 467:17 <b>allowing</b> 28:4 42:12 60:19 72:17 73:19 79:16 104:17 120:8 160:1 161:4 182:1 273:18 274:16 298:6 322:6 326:18 346:15 371:13 400:12 411:20 413:12 433:16 435:17 466:6 467:4 <b>allows</b> 82:21 167:18 267:11 285:16 290:17 374:18 375:1 433:13 437:3 447:1 477:19 488:9 <b>alluded</b> 177:2 <b>allworth</b> 12:6 259:4,6,7 263:19 <b>alter</b> 154:2 178:11 <b>alternately</b> 113:3 <b>alternative</b> 261:13 375:13 386:3 <b>alternatively</b> 408:14 <b>alternatives</b> 101:17 <b>alzheimer's</b> 8:16 135:16,18 136:3,5 136:6,9,16,21,22 137:8,11 482:19 <b>amatucci</b> 4:21 42:14,16,17 <b>amazon.com</b> 237:6	<b>ambiguity</b> 130:13 153:17 244:3 <b>ambitious</b> 24:19 <b>amend</b> 273:16 <b>amendment</b> 413:4 <b>america</b> 43:3 175:20 377:19 396:5 482:2 <b>america's</b> 237:19 <b>american</b> 6:3 7:19 8:18 30:17 43:6 45:1 46:6,15,19 47:14 63:16,19 72:18 78:9 82:18 83:5 111:8,11 125:13 126:17,20 132:16 137:19 138:4 166:15 195:18 216:22 297:18 348:4 355:1 434:3 463:12,13 483:12 484:17 497:19,21 497:22 <b>americans</b> 16:13 31:7 45:2 46:21 108:18 118:5 125:20 127:18 145:18 154:13 247:19 248:9,15 349:3 401:1 462:13 <b>ames</b> 271:7 <b>amino</b> 234:12 <b>amount</b> 24:19 69:8 78:10 117:1 164:6 199:2 211:8 213:15,15 214:8 224:1,12 238:8 239:12 275:9 289:1 317:19 343:8 455:1 465:20 467:16 468:9,16,18
--	---	---	---

<p><b>amounts</b> 39:6 157:5 174:10 175:15 224:13 308:12 341:5 455:10 <b>ample</b> 209:13 439:18 <b>amy</b> 2:2 21:7 61:11 <b>anab</b> 442:17 443:5 <b>anaerobes</b> 490:4 <b>analgesia</b> 224:12 <b>analgesic</b> 269:8 <b>analogs</b> 306:22 <b>analyses</b> 330:1 372:17 382:21 434:13 479:9 <b>analysis</b> 63:2 189:17 195:4 196:18 204:12 205:6 207:2,8 237:11 238:16,19 293:5 325:18 364:3 370:20 372:13 392:2,6 393:6 428:6,16 479:17 493:13 <b>analytes</b> 146:17 237:16,22 <b>analytical</b> 99:6 109:16 133:9 134:14 135:6 145:4,5,8,22 220:5 236:13 237:13 303:17 304:15 306:1,11 311:20,21 312:5 370:21 379:1 391:5,16 394:18 463:2 464:4 <b>analytics</b> 408:18 <b>analyze</b> 175:22 439:18</p>	<p><b>analyzed</b> 189:22 380:12 <b>anatomy</b> 259:15 <b>ancillary</b> 107:11 235:5 <b>anderson</b> 264:22 <b>andi</b> 336:15 <b>andrew</b> 7:16 107:3,5 <b>andy</b> 8:6 56:20 57:10,13 58:9 125:8,9 <b>andy's</b> 57:3,3,4,10 <b>anecdotal</b> 54:8 80:3,8 127:21 361:2 381:17 459:12 <b>anecdotally</b> 80:5 <b>anecdote</b> 39:10 <b>anemia</b> 142:3 <b>anesthesiologist</b> 317:9 <b>animal</b> 6:21 31:22 45:10,13,18 46:3 47:14 52:19 64:10 83:11 84:12 135:20 154:10 166:22 167:14,18 168:6,19 169:1,3 169:5 170:7,15,20 171:20 172:1 193:2 197:12 219:20 263:8 399:1,1 493:7 <b>animals</b> 46:20 54:6 64:5,10,21 66:2 84:9,22 86:16 169:19 170:4,22 171:3,11 171:13 357:12 <b>ann</b> 12:6 259:4,7 <b>anna</b> 8:11 132:14 132:15</p>	<p><b>anne</b> 5:18 59:2,4 62:11 <b>announced</b> 31:11 284:2 358:3 368:10 <b>announcement</b> 176:7 <b>announcements</b> 22:16 <b>annual</b> 289:19 <b>annually</b> 43:12 <b>anorexia</b> 30:9 <b>ansi</b> 16:3 442:18 <b>answer</b> 36:2 61:3 95:9 131:10 137:12 141:12 221:14 262:5,17 339:8,14 380:18 419:6 458:21 <b>answered</b> 460:4 500:19 <b>answering</b> 429:10 <b>answers</b> 200:3 306:6 402:4 414:17,18 499:16 <b>anterior</b> 474:14 <b>anti</b> 143:13 178:15 179:17,18 269:8,8 280:21 <b>antibiotic</b> 221:10 <b>antibiotics</b> 202:10 <b>anticipate</b> 101:6 <b>anticoagulation</b> 180:6 <b>antioxidant</b> 123:1 126:8 <b>antioxidants</b> 484:8 485:7 <b>antipsychotic</b> 269:8 <b>antonio</b> 294:15 457:6 459:6 <b>anxiety</b> 71:11 80:18 96:14</p>	<p>174:17 223:14 248:21 249:4 250:2 271:17 274:8 275:20,21 276:12 277:1 318:6 345:3 375:4 387:8,21 <b>anxiolytic</b> 80:18 269:7 <b>anxious</b> 243:14 <b>anybody</b> 55:14 97:9 241:14 475:12 484:11 <b>anyway</b> 496:5 <b>aoac</b> 14:21,21 145:7,21 391:2,3 391:18 394:16 <b>aoc</b> 371:12 <b>aosc</b> 379:10 <b>apap</b> 203:6 <b>api</b> 319:15 <b>aplastic</b> 142:2 <b>apologize</b> 25:13 335:1 <b>app</b> 321:7,7 <b>apparent</b> 144:3 <b>appeal</b> 452:18 <b>appear</b> 35:5 64:19 79:1 207:5 224:15 340:17,19 436:21 <b>appeared</b> 57:7 <b>appears</b> 78:16 <b>appetite</b> 251:12 <b>applaud</b> 88:7 109:8 137:1 176:4 383:21 <b>applauds</b> 322:8 <b>applause</b> 26:12 36:20 58:16 209:20 220:10 227:12 232:10 240:13 245:15 251:3 252:10 257:21 263:18</p>
---	--	--	--

273:20 281:18 326:11 341:22 378:5 419:9 451:3 462:5 471:10 476:1 486:22 500:22 <b>apples</b> 334:5,5 <b>applicability</b> 352:1 <b>applicable</b> 113:2 113:12 354:15 363:5 414:14 415:10 <b>application</b> 97:19 126:13 143:11 264:7,16 278:12 484:10,14 <b>applications</b> 284:6 284:9 294:9 311:20 353:6 419:1 488:16 <b>applied</b> 1:2 240:9 258:18 297:6 301:22 350:10 415:18 417:10 465:1 488:18 <b>applies</b> 31:5 34:12 106:1 <b>apply</b> 32:7 64:20 76:10 106:2 118:3 297:6 306:15 312:12 322:21 478:9 <b>applying</b> 159:19 368:15,20 394:19 417:2 <b>appreciably</b> 304:7 <b>appreciate</b> 56:11 69:6 74:8 77:17 83:13 102:18 140:6 153:11 178:5 197:6 216:5 232:9 320:20	<b>appreciated</b> 110:22 466:18 <b>appreciates</b> 48:20 <b>approach</b> 24:1 36:3,8 72:20 73:8 77:13 84:10 91:10 143:10 160:10 163:9,18 217:21 265:9 305:21 306:2 312:7 318:3 353:16 371:18 389:20 407:11,13 407:22 409:9,10 443:17 452:8 480:12 <b>approached</b> 421:6 <b>approaches</b> 5:13 265:12 456:9 <b>approaching</b> 148:8 157:4 <b>appropriate</b> 36:3 42:1 100:17 116:22 131:12 134:8 155:3,7 160:10 185:7 256:6 306:10 322:5 323:1 325:2 325:19 326:7 351:19 352:19 381:13 415:5 424:9,16 440:4 443:12 476:21 480:19 481:1,4 <b>appropriately</b> 155:5 307:8 323:12 325:8 436:2 <b>appropriateness</b> 328:10 <b>approval</b> 30:2 31:15 45:12 50:16 61:17 76:13 77:9 101:17 105:4,16 106:12 141:15	143:7 168:7 339:7 339:8 341:19 405:21 406:15,15 410:6 <b>approvals</b> 35:14 140:18 148:9 151:1 491:20 <b>approve</b> 221:10 221:11 392:5 <b>approved</b> 30:3,22 31:1,19 32:1 35:18 38:22 51:6 64:2 81:18 84:1 94:9 101:10 102:9 105:14 106:3,6,8 106:9 130:1,22 139:3 140:11 142:9 144:9 167:4 174:20,21 178:4 221:6,7,9 222:7 241:15 260:19 285:3 322:3 325:6 329:8 330:2 333:20 338:15,18 341:14,20 344:17 360:21 369:9 370:5 371:1,3,5 385:17,22 387:5 402:15 406:3 422:8 428:12 448:15 453:14 457:8 460:2 461:10 465:2,3 482:15,22 486:2 490:11 <b>approves</b> 33:1 185:12 <b>approving</b> 273:5 <b>approximately</b> 23:7 400:22 417:16 <b>apps</b> 284:10 <b>april</b> 433:12	<b>area</b> 23:21,21 99:22 100:7 137:1 185:14 200:6 247:5 251:15 252:15 264:7 266:1 289:4 290:8 292:3,13 368:6 483:6 <b>areas</b> 33:15 99:4 172:10 197:16 253:7 264:7 269:6 291:10 339:4 390:4 <b>argue</b> 467:14 <b>arguments</b> 328:16 345:8 <b>arising</b> 476:19 477:1 480:16 <b>arizona</b> 282:16 <b>arkansas</b> 10:13,19 188:5 200:17 239:4 <b>arm</b> 359:17 <b>armed</b> 306:3 <b>army</b> 57:14 67:2 96:5 <b>aroma</b> 151:9 328:6 <b>arose</b> 432:22 <b>arrangements</b> 293:12 445:3 <b>array</b> 42:8 76:20 76:21 138:13 270:11,13 324:7 337:19 <b>arrested</b> 82:9 <b>arrives</b> 383:20 <b>arsenic</b> 490:5 <b>artemis</b> 15:21 <b>arthritis</b> 186:7 209:5 276:12 <b>article</b> 324:9 360:11 435:18 436:4,8
--	--	---	--



<b>articles</b> 99:6 <b>articulate</b> 64:11 <b>articulating</b> 215:12 <b>artificial</b> 124:7 <b>artisanal</b> 261:22 <b>asdm</b> 379:10 <b>ashley</b> 6:2 63:16 63:19 <b>aside</b> 111:12 432:20 <b>asked</b> 57:7,9 98:6 118:12 248:19 249:6,14,21 250:18 251:10 269:11 386:8 417:14 448:21 449:1 481:11 486:4 496:5,8 <b>asking</b> 117:19,20 117:21 128:22 148:6 150:1 247:19 251:22 279:1 284:15 345:12,12 387:15 397:17 442:21 460:22 <b>asks</b> 269:20 <b>asleep</b> 496:4 <b>aspect</b> 201:15 202:3 332:5 357:10 410:20 <b>aspects</b> 146:21 187:5 259:14 387:4,14 427:17 443:2 476:13 <b>aspergillus</b> 393:22 <b>aspirin</b> 51:8 <b>assault</b> 376:22 <b>assays</b> 138:19 271:7 302:20,21 <b>assemble</b> 432:12 <b>assembling</b> 432:6	<b>assess</b> 279:4 494:12 <b>assessed</b> 299:3,9 300:18 444:22 <b>assessing</b> 455:2 <b>assessment</b> 61:12 134:3 175:14,18 199:11 314:2 442:19,22 443:11 443:18,21 444:15 444:20,22 446:1,7 <b>assessments</b> 175:22 200:21 389:16 443:17 444:12 <b>assessor</b> 379:3 <b>assessors</b> 49:17 134:12 <b>assigned</b> 484:5,6 <b>assist</b> 123:12 266:19 430:10 461:2 <b>assistance</b> 404:8 <b>assistant</b> 3:11 21:21 115:21 161:13 <b>assisting</b> 42:19 <b>assists</b> 410:8 <b>associate</b> 3:3,19 4:3 21:4 22:10 61:19 204:16 <b>associated</b> 33:8 68:3 93:3 143:7 158:2 174:3 271:15,20 379:19 453:7 489:8 <b>associates</b> 14:17 16:5 447:9 <b>association</b> 5:19 6:3,13 7:3,13,17 7:19 8:16 11:17 15:3 48:5 59:3 63:17,20 76:1,4 87:17 101:21	102:2,2 107:4,7 111:9,12 116:1 132:17 135:16 136:6,22 153:13 156:4 159:6 166:15 235:14 395:13,13 419:16 419:22 420:2 421:19 435:5 463:12 <b>associations</b> 241:17,17 <b>assume</b> 86:22 152:20 215:16 248:6 483:22 <b>assuming</b> 60:17 256:10 <b>assurance</b> 64:5 77:16 116:20 133:5,22 134:6,21 331:7 <b>assurances</b> 155:3 336:9 461:13 <b>assure</b> 123:5 138:16 303:12 305:14 316:7 438:3 <b>assures</b> 65:13 314:19 322:22 <b>assuring</b> 435:15 <b>asthmatic</b> 269:9 <b>astm</b> 15:19 425:15 425:22 426:5,7,10 426:18 427:1,10 428:3,21 429:3 <b>astounding</b> 349:10,21 <b>ataxia</b> 193:19 <b>athens</b> 311:6 <b>atlantic</b> 342:11 345:7,9 <b>atmosphere</b> 159:10	<b>attacks</b> 375:2 458:5 <b>attained</b> 371:22 <b>attempt</b> 142:4 175:8 333:6 <b>attempted</b> 373:22 <b>attempting</b> 119:20 <b>attempts</b> 57:19 <b>attend</b> 22:18 26:21 81:9 <b>attendees</b> 27:4 <b>attention</b> 24:22 60:16 185:17 192:5 201:7 202:4 203:5 204:7 303:3 497:17 <b>attest</b> 54:8 <b>attestation</b> 443:22 444:5 <b>attestations</b> 381:20 <b>attitude</b> 470:12 <b>attorney</b> 22:7 70:21 104:18 406:21 413:15 419:14,17,18 476:8 500:3 502:11 503:10 <b>attorneys</b> 420:10 <b>attraction</b> 75:3 <b>attributable</b> 28:14 330:15 <b>attributed</b> 207:12 <b>attributes</b> 133:6 351:8 <b>aubree</b> 14:14 373:7,10 <b>aubrey</b> 7:4 91:20 373:6 <b>audino</b> 14:16,17 378:17,18,22 <b>audio</b> 503:3 <b>auditable</b> 305:15
---	--	---	--

<b>audited</b> 231:16,17 232:2,6 343:2 348:16	42:2,3,6,9 48:13 74:5 78:18 81:17 87:9 94:8 97:22 100:20 123:3 129:3 133:17 137:4 152:22 156:21 158:9 188:12 216:6 230:15 257:19 285:2 325:20 330:2 336:19 355:1 358:21 359:1 361:7 364:1 369:17 374:6 387:12 401:8 403:22 405:12 406:5 448:18 451:18 452:11 456:15 464:3 466:10 469:19 477:20	<b>b</b>	<b>balance</b> 262:14 263:6
<b>auditing</b> 428:16	<b>avenue</b> 1:18	<b>b</b> 16:9 121:15 127:2	<b>balanced</b> 369:5 482:6
<b>august</b> 141:19 164:6 169:9	<b>average</b> 126:17,20 238:1,7,12 318:11 318:16 340:18 454:16 480:6	<b>baby</b> 96:4 249:4 376:3	<b>balancing</b> 485:8 493:1
<b>aureus</b> 492:20	<b>averaged</b> 302:16	<b>back</b> 20:17 23:18 92:10 114:21 120:3 127:22 175:11 178:8 179:3 180:11 247:13 275:14 279:15 281:12 284:3 289:5 292:1 312:15 334:10 335:2 372:22 374:2 408:2 421:4 422:7 431:11,19 486:16 496:10 500:10	<b>baltimore</b> 70:21
<b>australia</b> 94:1 213:5	<b>avma</b> 65:7	<b>background</b> 216:14 367:15 379:13 391:18 399:11	<b>ban</b> 47:3 258:16
<b>authoritative</b> 439:14	<b>avoid</b> 93:13 144:5 285:18	<b>background's</b> 419:18	<b>bank</b> 147:21
<b>authorities</b> 29:4 29:15,16 424:17 424:18 480:18	<b>avoiding</b> 151:5	<b>backup</b> 220:6	<b>banking</b> 82:17 95:21 148:6 423:17
<b>authority</b> 29:6 38:12 62:6 77:8 112:19 113:13,16 116:5 118:8,10 154:3 159:13,18 162:22 329:11 343:3 345:9 354:12 355:12 371:15 461:1 481:22	<b>await</b> 380:9	<b>bacteria</b> 330:10 490:17 494:22 495:13	<b>banks</b> 108:9 148:8 175:9
<b>authority's</b> 49:11	<b>awaiting</b> 60:8 108:1	<b>background's</b> 419:18	<b>banning</b> 124:7
<b>authorized</b> 105:15 285:1 381:1	<b>awaits</b> 168:9	<b>bad</b> 207:1 208:9 208:12 221:14 255:12,21 257:13 270:10 414:7 449:22 461:8 477:19	<b>bapp</b> 195:20
<b>autism</b> 261:3 277:12	<b>awarded</b> 79:3	<b>badmouthing</b> 498:15,15	<b>bar</b> 304:14 419:22 420:1 422:8 428:22 479:6
<b>autoimmune</b> 92:22 484:12	<b>aware</b> 35:5 140:10 140:12 157:22 176:11 186:2 218:20 291:3 316:1 364:17 397:16 442:1,10	<b>bacteriological</b> 146:17	<b>barrels</b> 59:19
<b>automatically</b> 117:16	<b>awed</b> 54:10	<b>bacteriological</b> 146:17	<b>barrier</b> 316:11 478:5
<b>autonomic</b> 386:1		<b>bad</b> 207:1 208:9 208:12 221:14 255:12,21 257:13 270:10 414:7 449:22 461:8 477:19	<b>barriers</b> 41:16 139:20 182:18,18
<b>autonomy</b> 445:15		<b>badmouthing</b> 498:15,15	<b>barring</b> 355:5
<b>autosomal</b> 473:7		<b>bag</b> 176:12	<b>barry</b> 10:7 176:16 176:20
<b>availability</b> 94:22 128:16 137:6 153:21 162:8,10 182:13 218:17 226:8 405:4 416:21 470:13		<b>bailiwick</b> 219:5	<b>base</b> 54:16 116:18 177:1 253:6 290:13 423:5 499:8,15
<b>available</b> 23:10 24:7 32:6 41:18		<b>baker</b> 6:9 70:19 70:22	<b>based</b> 32:6 33:22 36:3,8 42:11 52:15 61:17 72:20 74:3 75:6 78:5,7 78:15 81:16 84:10 88:3,22 95:20 98:17 100:4,14 102:6 112:13

115:22 118:17 128:7,17 131:4 134:7 143:10 144:8 157:3 183:10,16,22 184:10 201:4 222:14 226:12 238:1 239:2 240:8 271:6 323:2 324:21 333:1 357:13 360:20 379:22 380:11 381:18 382:4,19 383:16 384:18 385:9 389:20 407:16 411:16 413:15 416:12,13 425:18 445:7 453:15 463:3 467:6 476:13 480:16 487:6 492:7 <b>baseline</b> 119:12 146:9,16 350:8 <b>bases</b> 113:7 208:7 <b>basic</b> 219:17 <b>basically</b> 121:6 241:14 248:8 344:5,22 423:21 <b>basis</b> 169:2 248:14 269:18 342:17 368:7 444:14 <b>batch</b> 153:10 319:12,13 372:9 479:8,11 490:1 <b>batches</b> 283:20 314:21 315:5 480:15 <b>baxter</b> 16:20 487:5 489:11 492:17 494:11 495:16 <b>bcbc</b> 408:2	<b>bear</b> 184:16 341:8 469:14 <b>bears</b> 341:9 469:13 <b>beat</b> 249:17 <b>beaten</b> 52:13 <b>beautiful</b> 431:11 <b>beauty</b> 72:15 74:13,18 <b>beck</b> 14:18 384:1 384:3,7,9 385:1 390:6,11 <b>becoming</b> 41:13 <b>beds</b> 374:6 <b>beer</b> 151:8 450:10 496:17 <b>beg</b> 176:4 486:2 <b>began</b> 121:4 160:12 178:5 208:8 <b>beginning</b> 25:6 39:17 318:15 319:22 359:7 411:22 437:9 <b>begins</b> 73:12 <b>begs</b> 305:16 <b>begun</b> 28:4 304:9 <b>behalf</b> 40:5 76:3 83:12 98:15 119:3 125:11,13 137:18 138:4 144:12 153:12 220:13 252:22 298:21 317:10 329:3 345:10 400:22 419:15,15 425:15 476:9 484:17 <b>behavior</b> 261:20 271:11 451:14 <b>behold</b> 265:1 <b>bejesus</b> 402:21 <b>belief</b> 78:14,16 139:9	<b>believe</b> 23:17 43:19 48:12,22 63:20 72:1 73:4 79:7,18,20 80:13 80:17,19 84:11,20 85:9 101:1 103:1 104:2,11 109:14 115:9 117:11 122:18 126:14 143:18 149:12 150:18 158:5 163:3,9,12 176:9 194:7 196:1 217:11 219:22 253:22 259:10 274:2 275:3 276:16 277:16 298:1 306:21 313:15,21 314:8 315:14 320:17 326:15,15 333:22 334:16 347:22 352:10 355:20 356:5,8 362:11 379:4,21 380:1,3 402:19 441:5,19 456:19 457:16 476:21 482:5 495:3 <b>believed</b> 59:16 208:16 <b>believer</b> 59:5 <b>believers</b> 173:22 <b>believes</b> 65:7 136:22 <b>benchmarking</b> 195:5 <b>bene</b> 313:4 <b>beneficial</b> 54:5 224:17,22 261:7 408:5,11 461:15 <b>benefit</b> 68:8 79:2 80:5 163:12 184:12 221:4,17	224:3,14,20 265:7 292:22 295:11 310:8 352:11 358:22 370:2 387:17 461:9 <b>benefits</b> 33:2 46:17 49:6 71:17 73:16 79:19 86:5 123:3 126:21 127:12 192:1 225:17 256:16 257:4 268:3 276:4 276:11 293:9 294:5 379:19 380:14 381:18 382:7 383:11 410:16 445:22 <b>benjamin</b> 503:2 503:15 <b>benzodiazepines</b> 67:11 <b>berenson</b> 242:22 <b>best</b> 27:14 39:20 49:13 73:8 125:19 194:20 195:10 196:22 267:6 353:17,21 396:21 404:2,15 446:15 448:11 460:14 463:13 485:20 486:14 490:8 496:9 499:6,6 502:6 503:6 <b>bestseller's</b> 237:6 <b>bestselling</b> 237:19 <b>bet</b> 243:7 <b>betsy</b> 7:2 87:14,15 <b>better</b> 45:3 71:10 71:20 80:1,7,20 90:17 97:16 162:9 162:18 165:8 214:3,16 245:22 412:3 458:8 459:13 464:16
---	--	--	--

<p>476:16 498:17  <b>beverage</b> 34:13  88:6,14 227:22  290:4 306:22  342:15  <b>beverages</b> 154:8  304:19  <b>beyond</b> 23:21  41:12 71:3 72:6  77:3,5 110:7  178:15 179:17  182:9 442:10  443:19 472:17  475:3  <b>bias</b> 479:18  <b>bibs</b> 376:3  <b>bifurcating</b>  433:17  <b>big</b> 38:10 164:14  200:4 222:21  286:13 289:19  290:22 334:5  485:3  <b>bigger</b> 396:8  <b>biggest</b> 35:10  142:15 279:5  316:13,17 349:13  351:14  <b>bilirubin</b> 202:2  <b>bill</b> 10:12 13:6  28:19 29:6 33:22  48:15 54:19 81:13  82:8,17 111:15  147:15 150:21  154:2 160:21  161:1 185:11  187:13 188:3  226:10 295:22  311:1 313:19  329:10 341:6  414:6,9 423:20  469:6  <b>bill's</b> 111:19</p>	<p><b>billion</b> 43:11 52:5  52:6 108:21  119:21 238:7,13  344:10  <b>billionaire</b> 288:3  <b>billionaire's</b>  174:16  <b>billionaires</b> 176:1  <b>billions</b> 54:17  <b>bind</b> 494:9  <b>binding</b> 488:18  494:2  <b>bio</b> 13:3 298:16,20  299:1 302:13  <b>bioaccumulator</b>  146:13  <b>bioassay</b> 398:19  <b>bioassays</b> 398:15  <b>bioavailability</b>  319:6  <b>biochemical</b> 271:4  <b>biochemistry</b>  419:18  <b>biodistribution</b>  264:17  <b>biological</b> 60:1  324:12 379:11  394:13  <b>biologically</b> 27:13  <b>biologist</b> 259:13  <b>biology</b> 274:18  <b>biomass</b> 288:22  362:17 424:20  <b>biomedical</b> 175:7  356:22 485:18  <b>biopharmaceuti...</b>  264:2  <b>biopharmaceuti...</b>  12:9  <b>biosciences</b> 5:7  13:17 17:3 50:6  50:10 457:3 496:2  496:7 498:7  499:12</p>	<p><b>biotechnology</b>  362:2  <b>biotek</b> 9:4 145:3  <b>biotransformation</b>  177:4  <b>bipartisan</b> 284:14  <b>biphasic</b> 202:13  <b>bird</b> 9:3 144:22  145:2,3  <b>birth</b> 242:5  <b>birthday</b> 457:20  <b>birthdays</b> 496:17  <b>bit</b> 62:12 113:20  114:1 122:2  128:15 132:11,13  142:6 148:8,20  150:1,15 172:18  179:12 211:3  212:13 226:18  228:6 237:4  241:12 290:4  294:12 326:20  332:22 356:21  358:20 391:18  399:6 407:20  422:22 447:21  451:10 455:22  471:15  <b>bits</b> 417:8  <b>bitter</b> 328:12  <b>black</b> 54:16  253:21 254:2  272:18 346:19  <b>blair</b> 6:6 66:20,22  66:22 68:15,21  69:9,13,15,22  70:8,14  <b>blanket</b> 258:16  <b>blehar</b> 12:18  287:18,19,21,22  <b>blessings</b> 462:2  <b>blind</b> 299:8  461:17 493:9</p>	<p><b>blindness</b> 472:7  <b>blistering</b> 119:10  <b>block</b> 267:11  <b>blogs</b> 237:7  <b>blood</b> 142:5 212:6  213:8,11 276:9,9  281:10,15 339:20  340:2 388:9 494:4  <b>bloodstream</b>  143:16 495:1  <b>blue</b> 205:21 385:8  387:16  <b>bluetooth</b> 472:3  <b>blunt</b> 234:20  <b>board</b> 16:3 53:15  95:16,19 317:8  379:5 429:17  442:18  <b>boast</b> 175:10  <b>bob</b> 425:15  <b>bodies</b> 134:18  380:6 381:10  429:5 443:15  444:20,22 445:1,2  445:4,5,15  <b>body</b> 49:5 71:7,9  78:13 132:20  135:7 149:6  258:10 259:14  261:8 262:6,7,13  262:13,21 263:6  340:17,20 442:19  443:16 445:14  469:10 474:17  478:18 488:3  <b>body's</b> 29:22  <b>bog</b> 304:6  <b>bogus</b> 62:4  <b>boil</b> 149:21  <b>bold</b> 429:22  <b>boldly</b> 438:3  <b>bona</b> 39:15  <b>bones</b> 401:5</p>
---	--	--	--

<b>bongs</b> 375:14	<b>bovine</b> 86:12	<b>brian</b> 15:14 413:7	<b>brotherism</b> 38:10
<b>bonn</b> 211:11	<b>bowen</b> 11:16	419:10,13	<b>brought</b> 54:11,12
<b>bonni</b> 261:19	235:10,12,13	<b>brick</b> 207:22	57:22 58:5 78:6
<b>bonus</b> 376:17	<b>box</b> 272:18 320:14	208:6	292:2,14 338:19
<b>book</b> 242:22 243:4	438:9	<b>bridge</b> 8:9 129:21	357:15 389:21
275:13	<b>boy</b> 96:4 461:19	294:16 295:9,12	<b>brown</b> 274:20
<b>bookout</b> 6:20 83:8	<b>bpm</b> 300:22	296:15 297:13	450:9
83:10,11 85:15,18	<b>bradykinesia</b>	<b>brief</b> 120:7 176:7	<b>brownies</b> 257:11
85:21 86:4,10,13	385:15	459:1	<b>brumfield</b> 12:20
86:15,21 87:3,5,8	<b>brain</b> 56:20 80:8	<b>briefly</b> 91:15	293:20,21 294:1
<b>boomers</b> 249:4	93:14,16 94:16	110:19 434:6	298:9
<b>boon</b> 82:15	126:10 139:17	<b>brighter</b> 363:2	<b>bryant</b> 12:8
<b>booren</b> 7:2 87:14	221:19 260:11	<b>brilliant</b> 375:7	263:21,22 264:1
87:15,15 89:20	382:11 458:22	<b>bring</b> 76:15 77:6	268:8
90:14	468:21	145:13 161:16	<b>bubb</b> 10:2 166:11
<b>boost</b> 45:1 446:13	<b>brains</b> 377:1	166:6 168:11	166:14 169:20
<b>border</b> 425:7	<b>brand</b> 17:2 238:16	279:14 289:20	170:5 171:1,4,21
<b>borrowed</b> 495:12	279:20 280:3	345:16 391:21	172:11,14
<b>botanical</b> 78:5,14	322:1 343:20	460:7 498:2	<b>buckle</b> 275:19
79:11,15 99:6	357:8 452:17	<b>bringing</b> 50:21	<b>budding</b> 371:16
188:8,21 195:15	496:1,3,6 500:18	100:6 236:2 288:1	<b>budtender</b> 59:7
195:18,19 216:16	<b>branded</b> 89:22	352:8 386:13	62:11
216:21,22 218:13	<b>branding</b> 255:6,16	427:19 441:21	<b>buffington</b> 5:2
218:13 285:9	257:1	<b>brings</b> 340:9	45:6,7,8
297:8 323:5 324:2	<b>brands</b> 6:11 72:14	341:2,20 383:11	<b>build</b> 88:4 267:20
327:9,10	97:3 237:11 238:1	<b>broad</b> 84:3 89:15	307:1 489:21
<b>botanically</b>	238:20 255:9,17	111:16 263:12	<b>builders</b> 391:21
315:22	342:14 357:2,13	269:5 279:9 289:6	<b>building</b> 1:17
<b>botanicals</b> 195:16	452:13	292:18 303:10,21	47:22 500:8
316:2 396:14	<b>break</b> 24:11	305:19 306:18	<b>builds</b> 160:18
<b>bother</b> 227:7	172:17,18 173:4	307:16 308:1,8	<b>built</b> 339:16
<b>bottle</b> 70:4 120:2	268:10 274:14	309:2,3 324:16	348:10 379:1
279:7 459:17	281:20 366:5	358:17 417:18	<b>bulk</b> 297:5 302:19
461:5,7 469:12	372:22 377:15	418:11,11 424:11	303:1
<b>bottles</b> 450:10	450:5	430:9 432:15	<b>bullshit</b> 245:12
469:15	<b>breakthrough</b>	437:6,8	<b>bunch</b> 238:19
<b>bottom</b> 109:9	287:3	<b>broadened</b> 180:4	<b>burchman</b> 58:21
283:13 304:10,12	<b>breast</b> 259:15	<b>broader</b> 34:6	<b>bureau</b> 189:18
387:9 453:19	<b>brenda</b> 9:17	143:7 326:18	<b>bureaucracy</b>
469:22	158:13 159:3,4	337:19 353:5	446:4
<b>bought</b> 459:17	<b>brenda's</b> 158:13	<b>broadly</b> 76:19	<b>burgeoning</b>
<b>boulder</b> 50:9	<b>brethren</b> 499:10	129:2 219:18	170:12
<b>boutique</b> 53:11	<b>brfss</b> 453:16	<b>broke</b> 248:16	<b>burn</b> 229:10
419:19			289:17

<b>burns</b> 276:21 <b>business</b> 47:20 53:12 96:15 107:11 319:21 336:18 342:15 445:14 446:13 463:14 491:15 497:11,11 498:16 500:2 <b>businesses</b> 98:2 104:19 108:5 290:9,15 291:9 357:10 462:19 463:21 467:21 476:12 477:14 478:9,16 <b>businesswoman</b> 429:18 <b>butane</b> 465:6 <b>butchering</b> 111:6 <b>button</b> 295:18 496:22 <b>buy</b> 147:18,19 226:21 236:10 247:12,21 249:15 350:5 459:6 483:2 <b>buying</b> 73:14 175:4 207:19 237:8 249:20 290:10 337:5 431:22 <b>bye</b> 497:22,22 <b>byproduct</b> 210:8 232:22 <b>byproducts</b> 45:14 232:12	126:9,18,19 128:11 415:14 <b>cadfy</b> 467:11 <b>caffeine</b> 51:8 328:13 400:1 <b>cake</b> 168:17 170:19 <b>calcium</b> 415:13 <b>calculate</b> 394:5 <b>calibrate</b> 453:15 <b>california</b> 10:11 122:13 123:22 146:6 182:4,6 187:8 242:14 261:19 274:19 292:5 294:3,5,6 294:14 297:20 336:22 432:21 467:7 480:5 <b>call</b> 175:12 198:8 204:1 206:20 234:6 304:7 392:12,20 <b>called</b> 62:13 93:2 180:12 202:13 203:4 221:6 227:14 230:6 236:18 242:13 374:9,10 401:13 402:7 448:4 497:16 <b>calling</b> 109:7 <b>calm</b> 215:14 <b>caloric</b> 224:8 <b>cameron</b> 11:12 227:14,18 <b>camilla</b> 457:18,20 457:21,22 458:16 459:5,17 460:1,10 <b>camilla's</b> 458:6,13 459:9 <b>campaign</b> 97:16 176:3 376:5	<b>campaigns</b> 38:3 <b>campus</b> 1:17 <b>canada</b> 5:13 45:11 90:9 94:1 109:4 173:10 174:9,12 175:13 228:3 253:13 255:14 257:7 268:21 274:5 297:20 410:10 <b>canada's</b> 196:13 <b>canadian</b> 175:16 287:6 <b>canal</b> 489:1,8 494:8 <b>cancellation</b> 104:13 <b>cancer</b> 26:6,9 35:14 62:4 67:8 96:14 174:15 259:16 260:11 261:4 264:8,22 287:2 398:15,19 482:20 <b>candida</b> 490:4 <b>candispharma</b> 59:1 <b>candy</b> 34:13 <b>cane</b> 11:12 227:14 227:17,18 232:14 233:10,15 234:7 <b>canine</b> 96:12 358:6 <b>canines</b> 276:12 <b>cannabidiol</b> 27:16 49:3 80:14 101:2 101:6 115:9,10 128:16,17 143:5 184:5 201:2,16,16 201:17 202:14,18 202:21 203:15,15 212:14,16 222:2 226:10 368:12 395:22 398:13	485:21 486:5 <b>cannabinoid</b> 45:17 52:15 71:10 78:12,13 79:9,22 93:14,18,20 119:8 124:4 143:12,16 165:20 191:3 206:17 209:9 212:6 220:1 221:19 222:14 243:17 329:7,14 329:18 330:22 332:15 335:5 364:3 372:11 410:5 418:3 428:16 474:10 481:8 488:19 <b>cannabinoids</b> 78:11 79:2,8 84:5 136:5 144:2,6 150:20 152:11 174:1 177:20 182:11 190:3,11 191:12,22 195:17 210:19,19,22 211:5 214:9 216:20 222:1 226:20 244:16 279:11,13 308:6 311:14,19 324:8 327:8 329:21 331:11 350:18 362:18 392:14,18 392:18,21 393:22 394:2 410:15 417:19 418:6,11 443:3 466:7 476:22 477:9 478:1 480:2 484:7 487:12 <b>cannabis</b> 1:9,9 7:17 10:10 11:17 11:19 12:7 20:5,5 26:17,18 27:9,9
<b>c</b>			
<b>c</b> 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 53:13 79:11 86:5 121:16			

27:12,13 28:8,17 28:20,20 29:7,7 29:12,13 30:4,13 31:5,9,18 33:15 33:18 34:1 35:6,6 36:4,4,10,10 40:4 40:7,13,14,17,18 40:22 41:2,4,5,14 41:15,17,22 42:2 42:9,10,22 46:10 46:10 47:2 51:4,7 51:19 52:1 55:4 57:18 62:8 63:21 63:22 64:2,12,12 64:17 66:2 71:1 76:15 81:11,11,15 83:14 84:3 88:16 88:16 93:10,11,12 94:22 95:5,18,21 96:3,10,13 98:7 98:18,18 104:18 107:3,7,11 109:11 109:11,15 121:5,7 121:8 122:11,13 122:19 123:8,13 123:21 124:8 132:18 133:11,11 135:17 136:8,15 136:20 137:6,6 138:9,10,21 139:7 139:13,21 140:4 143:11,19,20 144:8 145:8,10,11 146:1,5,10,13 151:9,19 158:2 171:19 173:15 182:3,7,15,16 193:3,6,9,14 194:5,6,6,19 196:4 198:10 201:16 203:16 212:2,15 214:14 215:19,19 216:17 216:20 217:5,22	220:20,22 221:14 222:21 223:2 224:6,10,13 228:2 235:14 240:20 253:10,14,18 254:20,21 255:15 257:8,10 259:12 259:21 260:2,3,5 260:18 261:22 262:3,4,16 263:11 263:15 264:10,11 264:14 265:3,5,10 265:19 267:15 268:20 282:19 283:2,8,16 284:7 285:1,15 286:9 287:1 295:7 296:8 297:16 299:4,6,10 300:3,3,12,14,17 301:7,14,21 302:12,12,15,15 317:11 319:9 320:2 322:8 324:17,19,20 325:2 329:21 330:1,9,13,17 333:1,3,18 336:19 338:9,16,18 341:14,15,18 357:15,19 361:17 363:22 366:2 367:6,18,21,21,22 371:21,21 378:21 379:9,12,21,21 380:21 381:8,18 381:18 382:9,17 386:4,8,16 387:1 387:4,10,15 388:1 388:2,4,6,11 389:13 390:7,17 391:5 392:6,13,14 392:16 393:6,7,9 393:10,16,19,21 394:20 398:13	406:21,22 407:12 408:1,20 409:13 409:19 411:10 412:15 418:3,10 420:1,3,7,11,11 420:12,17,19,22 421:1,12 422:5,9 422:12,20 423:14 425:5,21 427:10 427:12,14,18 430:2,2,3,13,17 430:19 431:1,6,10 433:17 434:5 442:18 443:1 451:14,17,19,22 452:5,7,11 453:2 453:11,16,18 454:3,7,12 455:5 456:5 457:12,13 462:15,19 463:8,9 463:14,20 464:6 464:16,17,18 465:8,17,17,21 466:9 476:9,11,12 477:7 478:15,16 479:3,21 480:10 480:20 481:6 482:16,22 483:10 483:11,18 485:3 485:21 486:7 <b>canopy</b> 230:22 <b>capabilities</b> 228:9 <b>capable</b> 203:1 487:12 <b>capacity</b> 231:19 472:8 <b>capital</b> 43:17 <b>capitalize</b> 131:22 304:18 <b>capsule</b> 114:8 270:16 <b>capsules</b> 299:6 <b>capture</b> 39:19 296:17 298:4	451:22 <b>captured</b> 295:4 <b>carbon</b> 465:7 <b>card</b> 57:4,5 147:20 <b>cardiac</b> 300:18 301:3 302:7,9 376:15 472:19,20 <b>cardiomyopathy</b> 472:16 <b>cardiovascular</b> 193:20 <b>care</b> 13:15 59:16 62:15 88:6,15 138:5 194:20 199:18 261:13 277:21 332:22 333:1 334:10 472:12 488:13 <b>career</b> 26:5 367:2 <b>careers</b> 472:5 <b>careful</b> 344:16 <b>carefully</b> 33:1,16 219:21 339:19 <b>caregiver</b> 130:7 <b>caregivers</b> 131:18 <b>carneal</b> 359:7 <b>carolina</b> 9:21 161:14,18,21 162:2,3,19,20 208:4 228:20,21 229:8 233:6,9,13 <b>carrier</b> 308:21 <b>carries</b> 438:8 <b>carry</b> 444:2 485:15 <b>cars</b> 247:3 <b>cartridges</b> 124:9 <b>carve</b> 163:17 <b>carving</b> 258:17,17 <b>cas</b> 448:3 <b>casa</b> 345:10 <b>case</b> 32:11 81:19 122:18 183:22
--	--	---	---

191:8 201:19	340:2,6 375:17	81:19 82:6,7,18	178:22 179:14
207:21 229:8	387:18 403:6	82:21 83:4,4 84:4	180:4,7 181:4,11
258:14 404:2	487:21 489:7	84:6 94:22 102:7	182:10 188:11,13
417:19 444:20	<b>caused</b> 67:20	102:19 103:3,7	188:16 189:8,11
455:11 484:15	174:8 243:3 245:5	104:20 105:1,3,4	189:14,15,15
<b>cases</b> 62:21 193:20	449:22	105:18,19 106:6,7	190:2,6,7,13,16
205:7 206:14	<b>causes</b> 210:15	106:20 107:10,12	190:17,19 191:9
208:16 221:17	258:4 339:18	107:22 108:11,19	191:13,16,17,21
417:20 478:6	468:17,19 475:10	109:6 110:1	191:22 192:2
<b>cash</b> 46:7	<b>causing</b> 380:15	111:18,22,22	193:11,15,18,21
<b>cass</b> 393:4	474:1 494:19	112:4,7,9,15,21	194:2,9,21,21
<b>cass's</b> 393:5	<b>caustic</b> 59:19	113:8,14,19 114:9	196:1,5,12 202:4
<b>casual</b> 173:20	<b>caution</b> 431:13	114:14 116:3,6,8	203:6 204:3,3,12
<b>casualties</b> 434:3	468:5 470:22	116:8,10,14,15,16	205:7 206:20,22
<b>catastrophic</b>	<b>cautionary</b> 437:15	116:20 117:1,2,10	207:7,8,14,17
388:13	<b>cautious</b> 380:8	117:18 118:9	208:2,5,10,14,17
<b>catch</b> 183:5	<b>cautiously</b> 380:4	119:12,17,19	209:2,3 210:7,11
381:19	<b>cb1</b> 94:16 262:11	120:8,12,18 121:1	210:17 211:5,11
<b>categories</b> 64:15	270:4	121:14,16 122:3	212:18 213:1,4,7
68:22 113:12	<b>cb2</b> 262:11 270:4	122:10,12,19,22	213:9,10 214:1,9
193:2 453:20	<b>cb3</b> 262:12	123:12,13,22	214:19 215:1,8
<b>categorized</b> 93:17	<b>cbc</b> 150:20 275:9	124:3,5,7,11,22	217:1,7,13 218:6
<b>category</b> 37:9	<b>cbd</b> 8:5 17:5 21:6	125:18,21 126:6,8	228:2,4,22 230:5
42:14 53:6 58:20	21:9 27:16 28:3	126:15,16,21,22	233:7,14,18,19
66:17,18 83:7	30:5 31:18 32:8	127:3,8,14 128:3	234:10 236:15
99:9 120:19,20	32:11,13,19 33:7	128:9 130:10,14	237:8,19 238:5
135:11 144:21	33:19,21 34:3,11	131:4,4,9,17	239:1,7,12,14
147:8 153:7	34:12,13,14,17,19	137:6 139:4,5	243:12 246:3,18
187:13 201:2	35:1,9 36:1,5	140:10 142:14	247:20 248:2,6,9
220:12 235:9	37:20 38:2,8,13	148:17 149:8	249:9 250:12,19
236:15 238:9	39:3 45:15 47:11	150:18,22 151:5	251:6,18 252:3,16
249:1 253:10	48:9,10,16 49:4,7	153:22 154:9,14	253:11 254:13,22
259:3 264:19	49:20 54:4,5,7,9	154:22 156:13,16	255:1,7 256:13
287:15 323:16	54:11,14 62:9,13	156:19,21 157:3,4	257:15,18 269:1,3
350:21 359:4	62:16,17,21 63:2	157:9,11,13,15	269:5,17 270:4,9
373:5,6 439:5	65:3 67:1,5,7,19	158:3 159:7,11,16	270:14,15 271:2,3
456:22 462:7	67:22 68:2,4,6,18	160:1,3,4 161:1	271:6,7,9,14,16
497:16	70:2 71:2,4,6,9,15	162:5 163:18,22	271:19 272:6,15
<b>cats</b> 64:18 83:14	71:17 72:2 73:2,6	164:18 165:20	272:18 273:2,3,18
84:18 86:15	73:10,19 74:1,4	168:21 170:8,22	273:22 274:4
<b>cause</b> 57:9 175:20	74:13 75:9 76:11	171:3,7,12 174:3	275:2,9 276:1,14
177:20 201:18,22	76:18 77:7,9,13	174:20 175:3,4	277:9 279:6
202:14,15,16	78:5,7,10,15 79:5	176:5 177:3,8,10	280:13 281:4
203:1,16 268:1	79:8,12,15,19	177:19 178:9,14	288:7 289:1



292:15,15,16,22	438:5,19 439:5,14	<b>cdphe's</b> 368:13,18	471:18 500:5
293:10,16 299:17	439:21 440:1,3,20	369:2,7	<b>ceos</b> 430:20
301:10,15,16,17	441:6,13,19,21	<b>cease</b> 60:14	<b>certain</b> 23:2 28:7
301:19 303:14	448:1,3,4,7,9,19	<b>ceiling</b> 437:7	30:6 31:14 109:8
304:17 305:7,11	448:20 449:1,2,13	<b>celebrate</b> 457:20	121:16 228:17,17
305:16 306:5,12	449:15,16 450:1	<b>cell</b> 135:20 259:13	347:2,3 470:17
306:17 307:4	450:17,19,21	265:2 271:9	<b>certainly</b> 26:3
308:3 309:7,12	451:1 452:19	<b>cellphones</b> 24:2	80:2,9 84:19
312:1,3,13,17	453:4,7 455:8,9	<b>cells</b> 174:6 203:8	183:19 198:2
313:10,15 315:9	455:10 456:1,3	259:15 263:5	203:12 204:6
315:17,21 316:2,4	457:8 459:5,6,13	265:4 270:6 494:9	205:4 216:8
316:8 317:13,16	459:21 460:2	<b>celsius</b> 315:10	217:18 231:18
318:1 319:3,7	461:5,10 467:15	450:4,7	305:16 314:3
320:6,17,20 322:1	467:17,22 468:8	<b>celtic</b> 66:19	396:7 455:3
324:4,10,14 327:4	468:11 469:13,15	<b>center</b> 1:2 2:20	<b>certainty</b> 82:14
327:5,15,18,20	469:15 470:1	3:16 4:10,16	417:12
328:12 329:8,11	471:3 473:15,16	10:10,18 11:5	<b>certificate</b> 57:3
330:2,6 334:16,19	473:20,22 474:4,5	12:3 17:5 21:2,17	370:19 502:1
335:8,15 336:8,14	474:9,16,17 475:9	22:14 26:9 37:10	503:1
337:2,5 338:11	475:18 477:3,6	37:18 59:14	<b>certificates</b> 132:21
339:12,17,18,22	478:4,20,22 479:6	167:11 173:19	237:10 238:16,19
340:5,10,17,20,21	485:6 486:5 487:7	182:2,4 183:8	479:9
341:5 343:7,10,21	487:10,20 488:16	188:7 189:13	<b>certification</b> 49:11
345:14,16,20	488:18,18 489:5	192:14 195:13	235:19 289:21
347:16,17 348:8	489:19 490:1,13	197:13 198:8	462:13,17 463:17
348:22 349:3	490:15,16,21	200:5,18,19	<b>certifications</b>
350:10,12,14,16	491:1,10,13,18	201:12 216:14,16	290:18 305:13
351:10,20,22	492:5,13,19,22	217:3 253:1	363:15
353:15 354:1,3,13	493:3,11,12,16	257:20 264:3,4,5	<b>certified</b> 289:1
355:6,11 356:7,11	494:2,4,6,14	264:22 265:22	303:16 317:9
357:1,16 360:6	495:5 497:16	266:5 379:6	342:18,21 343:1,4
362:3 363:5	498:15 499:3	<b>centered</b> 463:6	343:4,5 490:14
364:10,22 365:5	<b>cbd's</b> 34:6 39:15	<b>centers</b> 182:7	493:10
369:21 378:20	49:6 123:2 126:12	386:6	<b>certifiers</b> 133:3
382:4,12,17	131:22 491:15	<b>central</b> 270:5	<b>certify</b> 305:8
390:10,13 394:2	<b>cbds</b> 103:11	381:1	502:3 503:2
397:5,5 401:18,22	<b>cbg</b> 150:20 210:22	<b>centuries</b> 71:5	<b>certifying</b> 478:18
402:13 403:3,14	275:9 487:20	381:16	<b>cetera</b> 279:8 308:7
403:18 404:8,9,20	<b>cbn</b> 150:20 210:22	<b>century</b> 145:14	386:1 409:19
410:22 417:18	235:6 487:20	<b>ceo</b> 50:9 53:11	<b>cfr</b> 159:17 163:2
418:1 422:20	<b>cdc</b> 312:20	95:16 102:1	348:15
424:10 431:17	<b>cdle</b> 422:21	117:11 129:21	<b>cfsan</b> 216:15
433:1,2,6,6 435:9	<b>cdphe</b> 369:4 370:5	142:19 268:13	269:22 400:2
436:15,21 437:10	371:4	294:1 342:8 467:5	

<b>cgmp</b> 214:13 311:3 313:15 330:20 363:14 478:14,22	271:8 338:17 342:1 374:20 429:22 431:10	<b>check</b> 95:20 104:14 209:6 444:7	480:3
<b>cgmps</b> 310:18,19 313:5 372:7 425:5 478:17	<b>changed</b> 28:2,2,7 28:18 29:4 175:9 175:10 373:12	<b>checked</b> 23:16 37:4 446:11	<b>children's</b> 377:9 426:17
<b>chain</b> 48:3 89:2 156:19 237:10 267:5,11 323:4 333:10 370:17 372:3 408:18 487:9,10 489:18 500:6	<b>changes</b> 25:11 39:13 54:11 202:2 271:16 427:6 468:21 484:16	<b>checkpoint</b> 231:17	<b>childs</b> 7:4,5 91:6 91:13,17,21,21 92:8
<b>chains</b> 305:10 322:20	<b>changing</b> 293:17 322:10 386:9 430:11,12	<b>chemical</b> 27:14 106:8 135:17 218:14 230:12 366:17 379:11 394:14 448:3	<b>china</b> 46:9 109:4
<b>chair</b> 21:5,8,13,18 145:6 420:2,3 421:4 422:10	<b>channels</b> 82:12 362:10 364:22 436:20 441:2	<b>chemicals</b> 60:2 131:14 336:4	<b>chips</b> 147:19,19
<b>challenge</b> 63:11 97:3 131:6 309:16 316:13,17 388:21 481:22	<b>chaos</b> 265:17 406:6	<b>chemist</b> 379:2 448:12	<b>chiropractors</b> 62:18
<b>challenged</b> 62:7 472:11	<b>chapman</b> 8:17 137:15,16,17,22 138:2,2 140:8,12 140:16 141:6,9,17	<b>chemistry</b> 50:8 236:13 237:14 324:21 447:10 450:1	<b>chocolates</b> 257:12 392:15
<b>challenges</b> 130:8 133:15 155:7 182:12 295:16 316:9 371:9 412:4 466:9	<b>characteristics</b> 69:11 455:6	<b>chemo</b> 67:8	<b>choice</b> 12:3 88:4 253:1,5 257:19 304:16 305:2 445:6
<b>challenging</b> 396:22	<b>characterization</b> 195:16 439:1	<b>chest</b> 260:10	<b>choices</b> 386:5
<b>chamber</b> 474:14	<b>characterize</b> 170:2 316:4 351:6	<b>chief</b> 3:3,4 4:3,4 22:8,10,10 77:21 150:14,14 357:7 384:9 400:14	<b>choir</b> 337:9
<b>chamberlain</b> 298:22	<b>characterized</b> 312:4 360:7,14 385:13	<b>child</b> 130:2,5,7 337:3 359:20 457:9 458:3 473:3	<b>choke</b> 231:10 232:2
<b>chamberland</b> 13:2 298:11	<b>characters</b> 129:12 129:13	<b>child's</b> 130:8	<b>chooses</b> 240:1 347:5
<b>chance</b> 127:19 207:19 396:4 402:11 458:7 462:1 473:8	<b>charged</b> 126:14 399:16 429:21	<b>childhood</b> 217:2	<b>choosing</b> 141:4
<b>change</b> 25:9 49:1 118:16 179:3 234:5 251:12	<b>charging</b> 382:22	<b>children</b> 34:17 62:22 121:16 128:3,6 130:2,17 131:1 132:4 139:17 157:1 165:1 174:13 242:5,10 244:19 245:3 269:6 325:4 330:9 360:22 380:8 400:3 401:2 401:10,10 449:9 449:12 459:12 472:9,9,12 473:13 473:14 479:20	<b>chose</b> 239:20 492:7
	<b>charles</b> 6:8 70:18 70:20		<b>chosen</b> 112:11
	<b>chart</b> 149:6 239:10 385:7 480:4		<b>chromatography</b> 189:22
	<b>charting</b> 77:1		<b>chronic</b> 39:9 214:1 261:12,15 261:16 299:10 318:10 375:11 468:19 482:18
	<b>cheaper</b> 96:17		<b>chronically</b> 34:18
			<b>chronicling</b> 358:15
			<b>cigarette</b> 341:10
			<b>cigarettes</b> 40:9,11 123:19 204:13

205:1,5 <b>ciliary</b> 474:17 <b>cinnamati</b> 180:20 <b>circular</b> 227:6 <b>circulatory</b> 263:2 <b>circumstance</b> 133:18 346:12 <b>circumstances</b> 71:12 195:1 403:21 436:6 <b>circumvent</b> 356:6 <b>cite</b> 418:22 475:6 <b>cited</b> 84:22 <b>citing</b> 369:19 <b>citizen</b> 73:18 75:11 <b>civil</b> 105:20 <b>claim</b> 74:15 96:18 186:6 188:11 189:3,4,10,21 190:8,16,18 191:7 191:8 192:6 239:9 239:20 240:1 268:18 351:15 436:9 449:11 484:7,7 <b>claimed</b> 190:20 320:10 486:16 <b>claimer</b> 343:21 <b>claiming</b> 35:12 484:17 <b>claims</b> 35:16 37:21 64:19,22 65:9 76:22 80:2 85:2 106:10 108:7 121:14,15 160:7,8 165:2 187:4 189:14,20 190:12 190:14 191:5,16 191:18 225:11 229:11 239:17 256:21 268:18 269:1,4 273:1,13 273:15 337:14	370:2 377:4 382:4 409:18 492:1 <b>clarification</b> 292:11 <b>clarify</b> 108:3 114:22 197:6 215:16 410:21 <b>clarity</b> 65:13 82:13,14 148:6,15 148:21 150:1 154:20 155:11 255:1 <b>class</b> 28:10 152:5 429:8 <b>classic</b> 71:12 385:19 <b>classical</b> 203:6 <b>classifications</b> 414:13 <b>classified</b> 302:1 <b>classify</b> 139:22 <b>classifying</b> 138:15 <b>clause</b> 273:3 <b>clauses</b> 407:20 <b>clean</b> 235:13,15 235:17,22 244:18 270:9 488:15 490:14 <b>cleaning</b> 428:5 <b>clear</b> 44:20 53:21 74:6 75:18 83:21 88:21 90:3 97:11 98:1 100:17 101:16 108:8 117:19 125:16 129:7,8 139:7 160:6,7 163:16 244:2 254:9 256:10 265:13 269:2 270:1 271:22 272:5 303:20 305:2 321:17 323:14,19 323:22 324:3	328:16 338:13 343:21 380:1 382:6 408:7 419:4 424:14 437:4 439:9 457:16 461:16 477:3 491:8 <b>clearance</b> 492:2 <b>clearing</b> 129:13 <b>clearly</b> 25:5 48:12 64:11,18 83:20 84:6 85:9 159:12 173:16 191:22 201:8 204:1 214:8 225:17 262:3 370:1 383:7 388:22 395:18 417:8 428:21 452:18 <b>click</b> 489:15 <b>clicker</b> 240:18 487:14 489:12 <b>clicking</b> 341:3 <b>client</b> 419:16 423:5 <b>clients</b> 54:12 70:10 71:1 231:12 268:17 343:8,11 418:20 420:19 421:1,12 422:17 <b>clinic</b> 7:5 <b>clinical</b> 32:2 42:7 50:15 51:17 73:4 75:5 93:22 94:17 96:11 106:13 123:7 126:1 136:12,19 143:3 143:11,22 178:3,4 178:6,19 179:8 180:13,18 192:12 193:17 194:11 196:3,9 197:20 198:1 201:5,6 218:18 219:10,11	219:15 226:1 268:17 270:15 271:14 284:8 286:22 299:1,3 311:19 316:5 317:18 318:4,4 319:1 326:19 334:11 339:13 354:21 358:5 360:20,21 381:13 460:6 461:21 491:21 <b>clinically</b> 318:13 <b>clinicaltrials.gov.</b> 128:19 <b>clinician</b> 472:7 <b>clinicians</b> 472:17 <b>clinics</b> 209:13 <b>clobazam</b> 143:14 178:20,22 179:2 180:11,11,14 360:3,5,6 406:4 <b>clogging</b> 205:11 <b>close</b> 43:10 174:8 250:15 315:8 383:9 430:18 496:1 <b>closed</b> 362:20 <b>closely</b> 87:12 94:17 130:20 146:3 195:12 322:17 475:18 <b>closer</b> 94:7,8 138:1 298:18 357:3 <b>closing</b> 19:9 123:18 152:13 153:10 307:4 315:12 326:4 341:11 399:8 501:1 <b>clothing</b> 375:14 <b>cloud</b> 205:15
---	---	--	--

<p><b>cmax</b> 299:15,19 299:20,21 300:1 301:5</p> <p><b>cmcr</b> 183:8,20</p> <p><b>co2</b> 372:18,18</p> <p><b>coa</b> 346:4</p> <p><b>coal</b> 52:8</p> <p><b>coalition</b> 4:22 5:3 42:18 45:6,9 53:16 107:12,15 376:6 476:12</p> <p><b>coated</b> 487:7 490:15,16 493:3</p> <p><b>coates</b> 14:20 390:22 391:1,2 395:3</p> <p><b>coating</b> 490:13 494:14</p> <p><b>cocaine</b> 271:12</p> <p><b>code</b> 159:21 397:16</p> <p><b>codes</b> 479:6</p> <p><b>codified</b> 313:5</p> <p><b>codify</b> 121:21</p> <p><b>coexist</b> 320:18 323:8 326:15</p> <p><b>coexists</b> 263:5</p> <p><b>coffee</b> 50:12</p> <p><b>coffeemakers</b> 247:15</p> <p><b>cofounder</b> 53:12 96:1</p> <p><b>cognition</b> 302:3 385:22</p> <p><b>cognitive</b> 67:12 86:6 211:17 212:22 213:6</p> <p><b>cold</b> 290:2 450:6</p> <p><b>cole</b> 121:6,12</p> <p><b>coli</b> 372:15 490:4 492:20,20</p> <p><b>coliform</b> 372:15</p> <p><b>collaborate</b> 73:21 198:12 322:17</p>	<p><b>collaborated</b> 195:13</p> <p><b>collaborating</b> 157:18 161:2</p> <p><b>collaboration</b> 198:3 264:21 364:8 426:2</p> <p><b>collaborative</b> 427:3</p> <p><b>collaborators</b> 451:15</p> <p><b>colleague</b> 211:10 475:7</p> <p><b>colleagues</b> 180:19 192:18 219:3 361:13</p> <p><b>collect</b> 90:11</p> <p><b>collected</b> 68:12 266:21 269:12 410:9 453:10,13</p> <p><b>collecting</b> 75:11 90:6 158:6 197:20 412:14</p> <p><b>collection</b> 74:15 158:1 410:8</p> <p><b>collects</b> 197:11</p> <p><b>college</b> 11:8 57:14 188:5 220:14 334:20 483:12</p> <p><b>colonel</b> 67:2</p> <p><b>colonic</b> 389:7</p> <p><b>colorado</b> 50:9 67:2 121:4 137:18 138:3 141:20 142:8 146:6 242:15 347:20 357:14,18,18 362:3 365:7 366:9 366:12 367:6 368:1,2,9 370:22 370:22 371:17 373:10 375:5,18 375:20 376:2,4,9 377:1,6,7,12</p>	<p>378:3 386:12 415:22 459:6 480:5 496:7,7 498:8,8,9 499:9</p> <p><b>colorado's</b> 499:6</p> <p><b>colored</b> 25:7 385:9</p> <p><b>columbia</b> 13:15 332:22,22 334:10 409:1</p> <p><b>column</b> 190:5,6,7 190:8,10 250:3,5</p> <p><b>combative</b> 243:15</p> <p><b>combatting</b> 269:9</p> <p><b>combination</b> 194:21 458:8</p> <p><b>combine</b> 350:20</p> <p><b>combined</b> 224:13 434:3</p> <p><b>come</b> 31:10 35:4 64:5 127:9 131:5 149:19 167:19 171:6 210:20 213:17 214:7 223:2 232:12 234:4 241:9 242:18 243:15,16 244:8 246:4 275:4 291:14 296:16 297:22 325:5 375:16 395:17 400:17 421:13 435:18 470:11 485:10 498:6 499:5,11</p> <p><b>comes</b> 43:10 50:21 131:8 148:10,12 148:13 149:4 174:8 232:6,13 254:1 256:4 266:11 304:17 391:9 397:3 424:19 438:1 441:15,15 471:20 482:1 490:20</p>	<p>491:7</p> <p><b>comet</b> 271:7</p> <p><b>comfort</b> 236:5 238:21 439:13</p> <p><b>coming</b> 30:22 71:17 235:17 236:20 238:14,19 256:8 276:18 278:22,22 289:11 307:5 343:8 384:12 420:21 422:2 424:4 447:12</p> <p><b>command</b> 239:13</p> <p><b>commend</b> 140:4 352:8 383:8</p> <p><b>comment</b> 20:13 36:22 37:1 65:21 83:13 85:13 89:5 115:6 120:6 152:20 153:11 164:5,9 173:5 193:8 197:16 226:7,9 313:8,18 433:16 440:19 447:13 448:16 501:3</p> <p><b>commentary</b> 414:1 416:20</p> <p><b>commented</b> 415:20</p> <p><b>comments</b> 4:13 18:7,17 25:16 27:5,7 36:6,14 37:15 58:19 66:9 68:9 69:5 79:17 80:10 81:1,10 83:16 89:14 91:14 98:16 107:14 111:14 114:22 115:4,14 116:3 117:7,11 118:19 118:20 122:7 123:18 124:13</p>
---	---	---	---

144:11,15 147:12 153:10 156:1 158:7,7,21 161:16 164:3 169:9 192:17,18 204:14 216:4 252:5 274:12 309:22 325:11 326:10 328:5 338:1 357:11 372:21 412:22 425:17 429:10 447:4 463:3 501:6 <b>commerce</b> 27:20 31:22 53:12 71:18 82:11 133:5 159:12 407:18,19 407:20 411:12 424:2,22 491:14 <b>commercial</b> 76:18 107:10 137:5 153:21 293:12 314:22 315:5 435:14,21 436:17 <b>commercially</b> 42:5 188:11 316:12 330:2,22 <b>commissioner</b> 2:3 3:11,19 4:7 20:11 21:5,8,21 22:5 25:22 36:15 46:22 61:19 97:10 117:8 161:13 433:11 <b>commissioner's</b> 21:13 <b>commitment</b> 47:13 137:2 329:6 348:14 428:22 <b>committed</b> 47:21 73:1 100:6 245:6 348:1 366:15 485:1 <b>committee</b> 67:21 123:11 314:3	406:20 407:5 408:11 420:2,7,8 422:8,9,13 427:11 427:12 429:3 <b>committee's</b> 123:14 <b>committing</b> 369:3 <b>commodity</b> 46:8 82:5 269:14 322:12,14 369:10 471:6 <b>common</b> 70:9 88:11 126:18 139:9 215:13 238:11 277:15 300:6,10,14 312:10 330:9 340:2 349:7 371:19 486:20 <b>commonly</b> 45:15 143:13 261:11 306:19 448:4 <b>commonsense</b> 129:14 <b>commonwealth</b> 10:21 204:18 <b>communicate</b> 130:5 <b>communication</b> 44:21 <b>communities</b> 52:12 <b>community</b> 16:15 38:8 66:12 82:16 100:12 122:13 131:11 143:2 144:13 228:8,14 231:7 375:5 384:13 385:3 386:2 387:20 388:20 389:10,19 401:19 402:2 403:10 440:13 467:5	<b>companies</b> 35:5,8 47:8 64:16 84:21 85:2 87:19 89:22 95:21 96:2 108:11 112:8 116:2 119:8 148:16 149:15 153:18 154:19 193:6 194:20 195:1,9,10 196:21 197:14 199:1,9 200:9 206:7 255:9 256:19 265:6 267:22 273:12 279:6 290:1 291:13 305:7 322:7 323:19 324:1,14 326:5,22 339:5 342:13 347:2 353:22 354:10,17 355:13 355:16,21 356:14 366:11 395:15 405:16 411:15 416:22 423:21 441:7,16,20,22 476:14 498:10 <b>company</b> 12:19 50:10 73:1 95:20 147:13 199:19 227:20 230:15 255:21 264:9 287:22 288:4 294:3 303:10 317:11 319:8 328:18 333:1 347:16 348:7 355:5 362:3 436:8 440:5 442:3 448:20 460:6,16 487:6 <b>company's</b> 355:2 <b>comparable</b> 183:18 212:4	<b>comparative</b> 307:2 <b>compare</b> 131:19 189:14 197:16 299:19 <b>compared</b> 41:2 51:5 83:1 102:12 103:13 206:13 212:3 287:2 315:21 453:7 454:21 455:15 468:2 <b>comparing</b> 455:7 <b>comparison</b> 186:15 <b>comparisons</b> 434:13 <b>compel</b> 414:1 <b>compelling</b> 127:21 <b>compendia</b> 99:2 <b>competence</b> 133:22 134:4,22 443:7,13,16 444:1 444:2,7,11,22 445:9,10 <b>competent</b> 133:8 444:13 446:12 <b>competition</b> 253:20 497:14 <b>competitive</b> 47:15 82:20 445:6 <b>competitors</b> 96:17 <b>compilations</b> 434:13 <b>complaint</b> 241:6 480:14 <b>complaints</b> 125:1 277:19 278:5,10 278:10 <b>complete</b> 25:18 83:16 140:1 145:9 168:15 169:6 303:4 319:22 326:19 363:12
--	--	---	---

<p>370:13 440:6  <b>completed</b> 31:12  168:16 183:9  283:1 285:14  323:17 492:21  <b>completely</b> 396:9  397:3  <b>completes</b> 168:20  <b>completing</b> 94:7  <b>complex</b> 105:5  139:16 140:5  142:21 221:15  472:10  <b>complexities</b> 34:8  477:13  <b>compliance</b> 3:15  22:13 95:21 113:1  113:11 123:9  155:1 165:6 228:8  228:11,22 229:2,7  231:11,12,17  235:19 238:22  348:14,17,20  363:15,20 364:9  365:11 428:16  443:10 445:8  446:3 462:18,20  463:18 477:14  479:14  <b>compliant</b> 228:10  231:13 232:7  326:1 330:20  333:16 342:22,22  343:3,3,4,6 344:7  369:13  <b>complicate</b> 452:8  <b>complicated</b> 149:5  177:3,4,8 179:20  405:19 409:8  423:19 458:22  <b>complications</b>  67:8  <b>complies</b> 344:13  346:1 478:7</p>	<p><b>comply</b> 31:15 94:6  412:9 415:16  438:4,15 440:22  480:10  <b>component</b> 269:21  308:4 348:13  <b>components</b>  135:17 194:7  196:12 205:14  262:10 263:9  267:3 306:12,13  323:20 348:18  427:17  <b>composite</b> 260:22  <b>composition</b> 99:13  163:14 222:6  324:18 438:22  <b>compound</b> 71:2  119:16 127:12  230:11 233:3  246:3 270:10  389:7  <b>compounded</b>  389:4  <b>compounds</b> 1:9  20:6 26:18 27:10  27:14,15,17 29:8  30:4 31:18 32:2  35:7 36:10 63:22  81:11 83:22 84:1  84:20 93:12 94:15  98:19 106:5  109:11 133:11  138:16,17 139:8  139:13,16,21  140:1 141:22  151:12 165:21  169:2 194:3  222:12 225:13  230:1,5,8 234:10  234:11,21 235:3,3  306:17 308:6  350:17 351:3  361:18 366:2</p>	<p>371:22 418:3,10  450:6 485:21  <b>comprehensive</b>  26:8 49:18 85:10  120:5 167:3  196:17 265:9,12  267:21 329:9  338:7 339:17  434:18 479:4  <b>comprised</b> 48:1  <b>compromise</b>  411:14  <b>compromised</b>  144:1 399:2  <b>computers</b> 250:16  <b>concentrate</b>  114:13 229:16,17  229:20 240:11  294:12 308:17  392:14  <b>concentrated</b>  248:17 367:19  <b>concentrates</b> 84:6  371:7  <b>concentrating</b>  152:21  <b>concentration</b>  152:22 181:11  212:7,16 229:19  230:3 301:11  338:14 341:1  361:5 403:4 453:5  490:3  <b>concentrations</b>  272:1 401:22  <b>concern</b> 35:10  59:22 67:18 99:15  168:8 175:21  202:6,12,19  205:11 209:16  236:3 270:22  336:15 346:14  392:3 465:16</p>	<p><b>concerned</b> 60:7  246:12 252:3  279:3 290:5  334:21 353:13  360:1 388:3  389:10 447:15  449:5 467:16  475:16  <b>concerning</b>  425:18  <b>concerns</b> 65:7  66:4 102:18 103:3  109:12,14 117:9  127:1 138:8 139:4  139:15,18 142:15  193:10 223:9  252:1 270:3  340:13 367:20  386:19 391:9  463:3,8 464:17  465:15 468:10  <b>concertation</b>  212:17  <b>conciierge</b> 274:21  <b>concise</b> 98:1  <b>conclude</b> 33:4  176:3 272:22  <b>concluded</b> 25:12  32:7,10 320:5  501:10  <b>concludes</b> 102:7  501:2,8  <b>conclusion</b> 155:13  493:14  <b>conclusions</b> 104:3  136:4 360:19  <b>concrete</b> 426:16  <b>concurrent</b> 452:5  452:7  <b>concussion</b> 277:10  <b>concussions</b> 276:7  <b>condition</b> 87:8  149:8 401:13  459:20</p>
---	--	--	--

<b>conditional</b> 196:20 218:9	<b>confirmation</b> 196:22	<b>connecticut</b> 95:20	185:16 194:8
<b>conditioning</b> 113:10 489:4	<b>confirmed</b> 57:12 183:13	<b>connection</b> 43:2	196:14 217:9
<b>conditions</b> 94:10 96:14 139:1 184:4 221:6 260:20 261:1,2,8 262:8 263:9 281:2 319:12 332:5 356:4 400:6,6 415:9	<b>confiscating</b> 205:9 <b>conflict</b> 358:20 <b>conflicting</b> 371:11 <b>conflicts</b> 247:6 432:13 445:19 <b>conform</b> 133:6 <b>conformance</b> 444:19	<b>connotation</b> 270:11 <b>consecutive</b> 301:17 <b>consensus</b> 109:22 279:10 292:22 391:20 392:6 425:18 426:3 427:1 428:4 429:1 429:6	270:14 272:13 300:9 344:2 370:4 395:22 408:5 423:8 437:18 455:1 458:6,22
<b>conduct</b> 41:22 49:10 134:12 219:17 372:9,9 418:19	<b>conformity</b> 442:22 443:10,18 443:21 444:7,15 444:20,21 446:1 490:6 497:8	<b>consequence</b> 62:1 355:14 <b>consequences</b> 139:13 176:22 449:22	<b>considering</b> 42:8 47:1 160:5 249:11 279:11 320:20 418:1 422:19 437:1 456:7 459:10
<b>conducted</b> 87:10 94:2 135:19 159:14 169:21 189:12 211:10,22 299:1 339:13 418:17 490:21	<b>confound</b> 286:2 <b>confounding</b> 123:19 <b>confronted</b> 156:12 <b>confused</b> 35:20 150:5 205:8	<b>consequential</b> 183:2 <b>conservatively</b> 260:4 <b>consider</b> 24:10 27:7 65:8 98:7 110:14 169:17 184:19 213:1 214:12 272:3 306:21 331:20 383:16 388:18 433:11 437:4 442:21 443:8 447:2 481:4	<b>considers</b> 44:9 48:9 83:3 435:9 <b>consistency</b> 138:16 159:8 168:6 303:13 351:2 371:20 372:8 404:22 405:1 408:15 464:14
<b>conducting</b> 40:8 41:17 193:2 195:6 198:12 268:16 381:21 440:18 494:3	<b>confusing</b> 130:10 210:10 398:5 <b>confusion</b> 48:17 82:6 88:20 108:5 112:8 129:7 154:4 329:18 395:18 410:21 433:1 437:4	<b>considerable</b> 70:3 <b>consideration</b> 25:20 118:20 212:9 259:22 281:6 320:22 332:8 409:4 437:3 447:5 <b>considerations</b> 118:3 184:17 332:2 339:10 <b>considered</b> 45:22 84:1 115:9 118:3 151:13,18 160:22	<b>consistent</b> 64:7 84:9 86:4 88:21 94:12 136:19 163:9 166:4 221:8 265:14 267:6 350:2,9 351:4 381:14 393:16 407:13 464:7,15 477:9 489:20
<b>conference</b> 331:14 <b>confidence</b> 43:22 49:14 305:3 350:3 417:11 431:20,21 443:22 446:9 479:16	<b>congo</b> 1:21 502:2 502:15 <b>congress</b> 29:9 48:7 48:12 111:16 151:21 155:16 284:9 297:7 436:3		<b>consistently</b> 65:17 179:6 362:5 381:14 <b>consroe</b> 359:11 <b>constantly</b> 281:11 448:19 484:2
<b>confident</b> 132:4 148:8 251:17 317:13 407:7	<b>congressional</b> 112:14 <b>congruent</b> 146:8 <b>conjunction</b> 230:21 <b>conmen</b> 290:8		<b>constituent</b> 99:12 105:19 106:20,22 211:6 <b>constituents</b> 71:4 84:4 100:2 165:22 221:16 225:8 324:8 327:8 409:5
<b>confidential</b> 303:5 <b>confidentially</b> 324:15 <b>confines</b> 408:13 <b>confirm</b> 126:5 345:18 346:4 446:3 479:13			

<b>constitution</b> 482:1	257:2,19 278:16	362:13 363:7	111:18 112:3,9
<b>constraints</b>	304:11 305:2	364:17 365:3,13	113:8,15 133:10
325:12	312:22 315:2,17	366:1 383:6 411:4	138:21 143:20
<b>construct</b> 101:13	321:22 338:11,15	415:6,17 417:12	153:19 154:22
<b>construction</b>	344:20,21 346:6	426:1 438:11	189:8,11,15
428:20	347:8 349:6,16	446:8,9 453:3	190:11,22 193:11
<b>constructive</b>	350:3 353:2 361:6	455:17 456:6	193:15 196:4
291:22	362:21 363:9	477:13 490:18	204:3 212:15
<b>consultative</b>	364:15 365:20	<b>consumes</b> 34:13	273:1 324:7 329:8
467:12	396:6 409:18	34:14	329:18 351:21
<b>consulting</b> 6:11	426:4 437:19	<b>consuming</b> 60:14	355:11 362:18
9:4 61:12 72:12	466:6 468:8 471:3	123:6 131:19	371:21 437:10
145:3 379:10	479:15 480:11,14	132:3 173:14	438:6,19 461:5
447:10	481:9 487:18	182:15 280:2	465:22 468:8
<b>consumables</b>	491:4	466:8	471:3 476:22
394:1	<b>consumer.org.</b>	<b>consumption</b>	477:9,22
<b>consume</b> 34:11	252:8	146:18 174:11	<b>contains</b> 27:13
139:19 145:18	<b>consumers</b> 5:9	278:9 306:7	105:18 106:4
184:14 257:10	11:15 18:10,22	369:11 416:10	207:19 319:4
303:16	30:16,17 33:17	465:20	320:15 438:7
<b>consumed</b> 109:18	35:11,18 42:9	<b>contact</b> 23:15	469:9,10
342:16 465:20	46:16 48:13,17	132:16 287:12	<b>contaminant</b>
468:17	49:14 50:19 53:8	<b>contacted</b> 101:11	133:13 364:1
<b>consumer</b> 6:13	54:15 76:9 88:12	<b>contain</b> 29:12 30:4	<b>contaminants</b>
9:18,22 11:21	88:14,20 90:18,22	30:5,7 47:11	99:15 100:2,4
12:3 33:11 44:19	97:5,13,16,22	73:15 78:10	109:17 146:15
53:6 56:18 62:2	99:17 102:5 109:9	112:15 117:1	213:20 316:1
75:6,22 76:3,17	110:9 116:19,21	194:2 206:8	330:9,15 336:1
77:3 87:18 88:4	133:5 147:2 148:2	222:16 330:3	362:6 364:5
89:1,16 90:16	149:2 163:11,20	350:17 459:19	394:14,14 417:5
107:22 116:13,18	175:4 192:2	469:15,16	449:19,20 480:9
120:18 125:1	195:11 208:9,14	<b>contained</b> 120:6	<b>contaminated</b>
131:21 149:21	235:9,11 237:8	190:16 191:17,19	99:18
153:19 154:12,16	238:21 242:11	191:21 207:15	<b>contamination</b>
161:14,15 163:10	246:17,22 248:5,8	209:8 211:12	102:21 237:22
173:6 194:11	254:5,12 255:3,10	<b>container</b> 120:14	242:12 302:13
207:17 208:16	255:17 256:15,20	188:20 189:21	330:12,16 352:7
227:9 235:20	257:16 267:18	<b>containing</b> 1:9	490:17
236:1,2,9 237:7,9	268:2 291:9	20:5 26:17 27:9	<b>contemplating</b>
237:13 238:8	303:14 304:2,6	27:12 29:7 33:21	165:14
245:20 246:1,7	306:3,15 307:2,7	35:6 73:6 77:7	<b>content</b> 28:21
247:1,5,7,10,11	322:6 325:14	78:5 79:8,12	100:1 138:14,20
247:17 253:1,1,4	326:6 342:16	81:11,15 83:14	188:10,11,20
253:9 254:17	350:3 352:11	84:3 88:15 98:18	189:4,9,14 190:2



190:9,13,19,21 191:16 214:11 228:19 229:14 239:1 273:14 306:9 309:13 335:5 351:20 443:3 479:11 <b>contents</b> 189:2 364:17 <b>context</b> 89:19 118:1 201:21 407:22 408:6 <b>continue</b> 30:11 48:16 65:18 134:16 146:19 153:20 157:12 167:17 185:6 203:12 330:19 331:9 335:19 355:18 363:2 382:15 409:1 418:22 <b>continued</b> 36:9 401:12,15 458:12 <b>continues</b> 125:18 223:18 414:3 460:13 <b>continuing</b> 100:13 187:12 282:9 365:21 <b>continuously</b> 490:8 <b>contract</b> 268:14 349:18,20 352:2 <b>contractor</b> 216:18 218:22 <b>contradictory</b> 135:22 356:13 <b>contraindications</b> 124:2 <b>contrary</b> 67:7 431:5 <b>contrast</b> 197:16	<b>contravention</b> 146:12 <b>contributes</b> 426:22 <b>contributing</b> 198:5 <b>contributions</b> 36:17 446:17 <b>control</b> 55:14 81:14 117:4 144:1 147:1 166:16 197:13 213:20 214:12 236:19 294:20 296:21 297:2 314:6,18 320:1 331:20 333:6 342:21 345:15 346:20 351:1,5 362:16 363:17 365:11 366:16 367:21 370:9,13 379:5 382:21 383:18 386:3 401:9 402:11 428:7 431:12 446:16 <b>controlled</b> 28:9,9 29:3 34:4 73:4 81:22 82:3 93:21 136:12 210:22 212:1 219:12 222:5 241:20 296:6 299:8 322:13,15 332:5 351:8 401:21 459:21 477:7 <b>controlling</b> 314:15 <b>controls</b> 60:22 297:4 316:16 331:4,18 332:12 349:14 363:16 <b>controversial</b> 411:5	<b>controversy</b> 150:20 <b>convene</b> 392:5 <b>convenience</b> 38:21 156:15 453:15 <b>conventional</b> 112:1 188:18 260:9 263:10 272:19 323:9,17 328:8,10 415:9 <b>conventions</b> 415:2 <b>conversation</b> 24:5 74:10 175:9,11 291:12 365:10,16 <b>conversations</b> 131:5 460:19 <b>conversion</b> 213:10 <b>convey</b> 153:16 <b>convinced</b> 209:3 <b>convincing</b> 208:21 221:3 <b>convo</b> 291:6 <b>convulsions</b> 402:16 <b>coo</b> 342:9 <b>cookies</b> 96:21 <b>cooperation</b> 134:20 <b>coordinated</b> 219:7 <b>coordinating</b> 124:21 <b>cope</b> 71:10 <b>copies</b> 20:17 23:6 226:2 242:22 243:4 <b>copy</b> 23:9 <b>corbus</b> 7:7 92:19 <b>cord</b> 203:2 <b>core</b> 122:20 407:14 479:2 <b>corey</b> 58:21 <b>corn</b> 44:2 147:16 <b>corner</b> 289:3	<b>corporate</b> 38:21 127:17 298:21 485:14,15 <b>correct</b> 55:10 114:5 134:6 183:6 197:8 280:4 308:12 391:22 <b>corrective</b> 478:20 <b>correctly</b> 335:9 <b>correlate</b> 267:14 <b>correlates</b> 212:7 <b>correspond</b> 325:9 <b>corresponded</b> 359:19 <b>corresponding</b> 322:18 <b>cosmetic</b> 27:18 73:7,11,20 105:6 114:11,16 117:22 186:1 241:21 290:3 420:4 421:5 436:21 <b>cosmetics</b> 31:21 33:12 52:19 143:17 156:13 159:11 160:3 228:1 352:16 415:3 416:11 447:11 450:12,13 450:19 <b>cost</b> 140:22 254:19 434:2 <b>costing</b> 54:16 290:21 <b>costs</b> 446:5,16 <b>cottonization</b> 488:4 <b>cottonized</b> 488:2,8 489:19 <b>cough</b> 207:16 <b>coumadin</b> 278:3 <b>council</b> 6:21 7:21 15:17 83:12 115:18,21 195:18
--	--	---	---

<p>216:22 432:6,13 435:4 <b>counsel</b> 2:19 3:3,4 4:3,4 22:8,10,11 115:21 240:20 430:7 496:6 502:8 502:11 503:7,10 <b>count</b> 39:14 153:22 372:15 469:12 <b>counter</b> 51:5 96:22 207:16 245:21 320:16 500:13 <b>countless</b> 381:17 <b>countries</b> 94:2 166:19 311:10 427:17 <b>country</b> 48:2 54:19 71:7 90:10 153:15 160:22 242:4 253:17 267:19 369:10,14 377:11,13 500:5 <b>country's</b> 458:17 <b>couple</b> 182:8 200:3 210:2 252:14 288:5,16 307:12,16 452:16 <b>couriers</b> 82:10 <b>course</b> 62:3 77:1 110:8 113:1 184:20 186:18 202:6,19 212:5 278:12 284:20 379:16 406:1 409:9,20 418:2,13 449:21 485:20 <b>court</b> 57:19 244:21 <b>courts</b> 98:5 <b>cousin</b> 149:20 <b>coverage</b> 22:22</p>	<p><b>covered</b> 140:22 224:19 312:14 313:4 349:9 <b>covering</b> 245:21 389:17 <b>coveted</b> 373:5 <b>cow</b> 430:8,9 <b>cpg</b> 87:20 231:8 343:19 <b>crack</b> 374:9 <b>crafting</b> 42:19 83:3 <b>craig</b> 17:2 496:1,6 <b>cramp</b> 491:19 <b>craves</b> 440:12 <b>craving</b> 223:15 <b>craze</b> 62:16 <b>crazy</b> 374:7 459:8 <b>cream</b> 276:14,17 <b>creams</b> 154:9 <b>create</b> 32:16 45:2 46:20 52:3 60:21 113:14 116:5 130:13 138:19 151:4 152:14 205:15 206:10 228:10 332:17 363:2 365:1 378:20 405:1 414:8 422:4,8 432:4 446:8 470:14 482:11 <b>created</b> 51:16 105:5 130:14 230:16 243:8 383:10 427:19 434:1,2,5 463:17 467:7 477:18 500:12 <b>creates</b> 136:17 440:10 <b>creating</b> 43:18 152:11 159:9 163:18 230:20</p>	<p>309:17 357:16 365:22 371:22 442:5 <b>creation</b> 122:3 <b>credibility</b> 443:17 <b>credible</b> 54:7 200:21 336:20 <b>credit</b> 147:19 <b>creep</b> 38:9 <b>creeps</b> 474:8 <b>crime</b> 205:5,10 <b>criminal</b> 205:2,6 241:20 244:19 377:2,13 439:9 <b>criminals</b> 241:18 241:22 <b>crisis</b> 51:17 260:14 374:11 447:12,14 449:5 484:21 485:16 <b>cristinzi</b> 2:10 18:4 20:3,7 22:15 36:21 39:22 42:13 45:5 47:16 50:4 52:20 53:5 56:14 58:19 61:9 63:15 66:16 70:13,16 72:10 75:21 77:18 81:4 83:6 87:13 91:5,10,16,18 92:12,15 95:13 98:9 101:19 104:11 107:2 110:5,7 111:4 115:17 118:22 122:6 125:7 129:16 132:10 135:9 137:14,20 138:1 142:16 144:20 147:7 150:3,6,9 153:6 155:18 159:2 161:9 166:8 172:15 173:1</p>	<p>176:6 181:16,19 187:10,12,17 192:9 200:12 204:8 209:21 211:2 216:9 220:11 226:5 227:11,13 235:8 240:14,17 245:16 252:18 259:2 263:20 268:7,9 274:13 281:17,19 282:3,6 287:14,19 293:19 298:8,10 298:17 303:6 310:22 317:1,4 321:12 328:20 332:19 338:3 342:1 347:9,11 353:7 356:18 357:3,6 361:10 366:4 372:20 373:3 378:6,9,12 378:14,16 383:22 384:5,20 390:21 395:1,4 400:9 406:17 412:17,21 413:2,6,9 419:8 419:10 425:11 429:12 434:6,9 435:1 442:14 446:19 447:3 451:4,9 455:19 456:21 462:6 467:1 471:11 475:19 476:2,5 481:10,17 486:11 486:21 487:1 492:11 495:15,18 495:22 500:17 501:2 <b>criteria</b> 99:7 134:2 347:3 368:8 <b>critical</b> 30:11 33:9 49:3 88:18 108:13</p>
--	---	---	--

<p>163:10 174:2 259:16 266:20 269:21 297:15 332:12 351:7 394:21 428:6 450:15 <b>critically</b> 143:2 155:8 262:6 378:19 <b>criticism</b> 51:1 <b>crn</b> 115:22 116:2 117:6,8,10,11,19 117:21 118:18 435:5 440:17 <b>cro</b> 273:21 <b>cromer</b> 5:10 53:6 53:9,10 55:5,7,10 55:16,20,22 56:4 56:13 <b>crop</b> 46:7 147:16 162:4 164:15 229:11 302:18 <b>crops</b> 44:1 46:5 50:11 66:19 82:22 229:10 289:17 <b>cross</b> 296:9,11,15 330:16 <b>crossed</b> 171:12 398:7 399:4 <b>crossing</b> 411:20 <b>crossroads</b> 125:15 <b>crucial</b> 97:11 408:19 <b>crystal</b> 9:7 147:9 147:11 <b>crystalline</b> 315:9 327:15 <b>crystallization</b> 230:4 232:19 <b>crystallized</b> 234:15 <b>csa</b> 28:10,13,22 119:19 121:7 210:13</p>	<p><b>cto</b> 347:14 <b>cultivar</b> 325:15 <b>cultivars</b> 115:2 185:12 323:1 412:2 <b>cultivated</b> 368:5 <b>cultivation</b> 59:14 330:17 368:4 370:14 393:18 427:21 463:15 464:19 <b>cultivator</b> 427:10 <b>culture</b> 135:20 <b>cumulative</b> 89:17 <b>cure</b> 35:13 62:4 105:10 130:12 <b>cures</b> 260:8 <b>curiosity</b> 249:15 321:2 <b>curious</b> 69:17,19 128:14 441:4 <b>current</b> 32:12 38:17 49:8 52:4 90:17 95:16 108:17,20,21 116:7,15 118:8 120:18 138:9,12 140:18 154:21 162:4 217:1 287:5 320:19 323:7 327:10 329:17 353:13,16,20 354:9,12 362:17 363:5,11 368:15 368:20 371:12 383:12 384:19 385:18,21 387:5 412:8 420:12 432:14 454:6 463:7 471:19 477:17 <b>currently</b> 28:16 41:20 43:3 44:1,7 45:22 46:9 53:20</p>	<p>64:9 66:12 84:15 97:5 103:20 108:10 112:10 120:12 136:19 138:22 156:20 159:6 169:2 170:5 183:20 188:16 195:8 196:8 210:12 229:11 230:19 274:1 285:3 286:17 294:7 297:5 318:22 364:5 393:20 394:8 396:12 397:13 402:19 408:22 417:15 419:20 435:9 451:18,21 486:1 491:17 493:6,9 494:3,11 <b>curve</b> 183:3 185:5 199:9 <b>curves</b> 184:7 <b>custody</b> 237:10 333:10 <b>custom</b> 366:12 <b>customer</b> 120:13 <b>customers</b> 54:12 74:18 153:18 154:18 266:13 347:17 363:6 444:10 <b>customized</b> 348:10 <b>cutting</b> 92:3 <b>cv</b> 13:11 321:16 321:21 323:13 324:12 325:10 <b>cvm</b> 85:12 87:9,11 167:21 168:14,19 <b>cvm's</b> 168:8 <b>cycle</b> 319:18 444:12</p>	<p><b>cyp2b10</b> 202:6 <b>cyp2b6</b> 202:7 <b>cyp2e1</b> 202:9 <b>cystic</b> 93:5 <b>cytochrome</b> 177:6 179:1,15 180:12 202:9 271:21 360:2 <b>cytotoxicity</b> 265:4</p> <p style="text-align: center;"><b>d</b></p> <p><b>d</b> 20:1 490:14 <b>d37</b> 427:11,16 429:3 <b>dabs</b> 374:7,8,9 <b>dad</b> 457:14 <b>daily</b> 270:21 299:4 301:17 341:1 342:16 397:5 <b>dale</b> 496:3 <b>damage</b> 174:5,5,8 174:18 242:3,10 244:1 360:4 <b>damaging</b> 244:14 244:19 <b>damn</b> 187:21 <b>dana</b> 17:4 481:18 <b>dangerous</b> 33:6 59:11 60:20 109:17 206:17 207:20 209:9 242:21 336:14 376:22 <b>dangers</b> 56:20 192:3 243:10 <b>daniel</b> 15:2 395:5 <b>daresay</b> 54:22 <b>dark</b> 127:19 149:3 450:9 <b>dartmouth</b> 274:20 <b>data</b> 1:8 20:4 26:16 35:2 39:11 45:19 47:1,6 50:15 51:17 52:22 63:13 65:9 66:5</p>
--	---	---	---

68:9,12 76:14 80:11 84:13,20 85:19,22 86:11 90:6,11 103:17,20 104:7 110:20 128:2 134:14 136:20 152:21 153:4 165:11 180:2 181:2 185:21 186:3,22 187:5 190:4 195:4 196:3,7,17,17 197:7,17 198:5,22 201:5 203:10 211:18 214:3 216:5 218:8 219:6 220:17 222:22 236:6 261:21 295:4,4 296:18 301:14 303:4 317:18,21 318:4 318:13 320:3,12 321:2 324:16 327:22 352:22 359:14 360:16 361:2,3 399:9 408:18 410:8,9 439:19 440:7,16 451:13 453:10,13 456:4,15 466:16 470:20 476:4,18 477:1 480:9 481:2 481:3 491:15,21 493:21,22 494:1 <b>database</b> 79:5 84:11 86:19 267:10 339:17 <b>datarevive</b> 61:10 <b>datasets</b> 187:3 <b>date</b> 1:14 37:20 66:9 68:2 101:2,5 112:21 135:21 136:14 298:22 414:19 428:3	451:1 <b>dates</b> 133:16 <b>daughter</b> 128:8,11 457:8,18 <b>daunting</b> 119:20 <b>dave</b> 119:2 <b>david</b> 6:12 8:2 9:9 11:18 16:4 70:17 70:17 75:22 76:2 91:21 92:8,11 119:1 150:10,13 240:15 447:5,8 <b>davis</b> 174:9 175:12 <b>day</b> 20:19 24:9 25:1,16 34:12 51:10 62:16,17 88:1 92:2,7 104:2 120:11 129:9 145:18 153:18 154:15 169:8 176:16 245:14 268:1 270:20 272:11 277:7,11 277:12 278:11 301:7,9,19 335:1 340:18 345:5 359:12,18,19,20 377:16 379:17 383:20 397:6 453:11,16,18 458:5,11,11 471:14 496:13,14 <b>daye</b> 16:21 17:7 487:5 <b>dayle</b> 2:10 18:4 20:7 26:14 <b>days</b> 23:8 209:5,7 212:11 273:10 301:18 302:1,4 374:4 402:16 454:3,16,20,21,21 <b>dc</b> 115:22 253:6	<b>de</b> 98:7 260:2 263:16 <b>dea</b> 95:6 98:6 185:12 225:20 226:19 227:2 284:2,6,8,10,15 286:14 296:16 297:15 311:5 316:15,20 333:14 414:21 418:22 477:5 <b>dead</b> 245:3 <b>deadline</b> 204:15 <b>deadly</b> 374:20 401:16 <b>deal</b> 48:17 89:17 228:1 243:2 289:19 343:13 418:15 <b>dealers</b> 377:15 <b>dealing</b> 242:17 244:16 290:7 291:15 351:10 387:22 420:22 431:19 <b>deals</b> 421:22 447:10 <b>dearth</b> 293:4 358:8 <b>death</b> 57:3,9 375:17 376:15 401:13 404:11 472:20 <b>deaths</b> 207:12 245:4 484:22 <b>deb</b> 13:8 317:2 <b>debatable</b> 244:2 <b>debate</b> 39:16 71:3 117:12 364:20 484:20 <b>debilitating</b> 458:3 <b>deborah</b> 317:8 <b>decade</b> 51:15 193:14 476:17	<b>decades</b> 127:19 145:11 381:16 417:2 432:5 <b>deceitful</b> 176:3 <b>deceive</b> 173:15 <b>deceives</b> 173:13 <b>deceiving</b> 384:11 <b>december</b> 31:11 92:8 316:22 453:13 <b>decent</b> 454:22 <b>deception</b> 382:18 <b>deceptive</b> 373:16 <b>decide</b> 55:12 344:6 391:22 482:8 <b>decided</b> 343:20 393:4 <b>decision</b> 122:20 456:12 <b>decisions</b> 102:3 126:16 289:17,18 380:20 461:14 <b>decisively</b> 440:17 <b>deck</b> 4:13 10:5 18:7,17,19 37:15 156:1 176:16,18 <b>declaration</b> 443:19 <b>decrease</b> 261:14 262:2 <b>decreases</b> 223:15 260:13 <b>decriminalize</b> 430:2 <b>decriminalized</b> 28:5 <b>dedicated</b> 53:13 95:18 <b>dedication</b> 379:4 <b>deemed</b> 54:7 152:3 396:21 <b>deep</b> 50:16 205:10 385:8
--	---	--	---

<p><b>deeper</b> 246:19 365:2 387:13</p> <p><b>defects</b> 242:6</p> <p><b>defense</b> 342:22</p> <p><b>deficiency</b> 243:17</p> <p><b>deficient</b> 78:12</p> <p><b>deficits</b> 223:7</p> <p><b>define</b> 84:6 100:9 285:21</p> <p><b>defined</b> 83:20 85:9 119:14 144:9 211:7 219:11 303:22 307:19 331:2 365:6</p> <p><b>defining</b> 327:6,17</p> <p><b>definite</b> 261:16</p> <p><b>definitely</b> 66:4 115:13 141:21 278:15 475:9</p> <p><b>definition</b> 29:1 32:4 71:12 77:10 102:6 167:7,19 279:9 305:20</p> <p><b>definitional</b> 437:2 440:18</p> <p><b>definitions</b> 75:5 83:22 149:1 167:2 169:13,15 295:22 308:2 372:2 424:10</p> <p><b>definitive</b> 413:19 419:4 448:5</p> <p><b>degradants</b> 350:18</p> <p><b>degradation</b> 450:13</p> <p><b>degrade</b> 262:15</p> <p><b>degree</b> 274:18 276:21 358:2 360:15 361:5 451:19 454:1</p> <p><b>degrees</b> 57:16 76:21 315:9 450:4 450:4,7,7</p>	<p><b>delata</b> 292:2</p> <p><b>delaware</b> 311:6</p> <p><b>delay</b> 284:11</p> <p><b>delayed</b> 41:8 93:22 186:20 389:4,6</p> <p><b>delays</b> 94:5 268:2 458:13</p> <p><b>delete</b> 230:1,12</p> <p><b>deleterious</b> 431:8</p> <p><b>deliberately</b> 114:13</p> <p><b>deliberations</b> 320:13</p> <p><b>delighted</b> 248:1 487:6</p> <p><b>delineating</b> 83:22</p> <p><b>deliver</b> 265:7 341:9 366:17 389:1</p> <p><b>delivered</b> 389:9</p> <p><b>delivering</b> 87:21</p> <p><b>delivers</b> 75:2 321:22</p> <p><b>delivery</b> 40:12 313:12 437:14</p> <p><b>delta</b> 292:6,12</p> <p><b>delusional</b> 374:21</p> <p><b>delusions</b> 390:18</p> <p><b>demand</b> 54:22 97:20 108:1 116:14 147:3 153:19 154:9 192:4 209:11 243:6,9 436:14 440:21 482:8 485:13</p> <p><b>demanding</b> 291:9 439:16</p> <p><b>demands</b> 471:9 483:9</p> <p><b>dementia</b> 135:19 136:10,16,21</p>	<p><b>demise</b> 377:9</p> <p><b>democracies</b> 266:2</p> <p><b>demographic</b> 455:6</p> <p><b>demonizing</b> 54:20</p> <p><b>demonstrable</b> 73:3</p> <p><b>demonstrate</b> 134:15 305:12 315:8 317:21 330:1 351:22 356:3 428:22 461:22 478:19</p> <p><b>demonstrated</b> 102:16 103:15 152:5 191:15 381:6 445:18 460:16 480:3 492:19</p> <p><b>demonstrates</b> 49:5 123:21 283:6 318:13 480:9</p> <p><b>demonstrating</b> 263:15 445:8 474:5 477:8</p> <p><b>denise</b> 16:16 471:12,17</p> <p><b>denver</b> 173:18 357:13 367:3,10 413:15</p> <p><b>deny</b> 436:7</p> <p><b>denying</b> 173:15</p> <p><b>department</b> 9:16 9:18,21 10:3 121:5 161:14 166:12 198:11 204:17 244:13 344:13,15 365:7 367:3 368:3,9 374:12 415:22 429:19 484:4</p> <p><b>departments</b> 236:5 411:3 412:9</p>	<p><b>depend</b> 30:18 114:18</p> <p><b>dependence</b> 11:9 67:22 220:14,17 314:3 482:19</p> <p><b>dependency</b> 318:6 468:17</p> <p><b>dependent</b> 277:16 474:20</p> <p><b>dependently</b> 224:10</p> <p><b>depending</b> 29:17 40:19 327:21 390:16</p> <p><b>depends</b> 134:4 308:19 309:10 315:3</p> <p><b>depicting</b> 384:17</p> <p><b>depicts</b> 191:4</p> <p><b>deployment</b> 365:7</p> <p><b>deployments</b> 288:6</p> <p><b>deposit</b> 147:20</p> <p><b>depression</b> 374:22 375:4</p> <p><b>deputy</b> 2:3 4:9 21:8,16</p> <p><b>derivative</b> 69:2 114:19 130:11</p> <p><b>derivatives</b> 28:20 36:5 82:3 88:16 94:22 103:8,11 137:7 143:12 153:20 367:21</p> <p><b>derived</b> 1:9 20:5 26:18 27:9 29:8 29:13 31:5,9 35:7 36:10 42:22 47:9 48:13,19 49:7,20 51:4 62:8 63:21 64:12,17 67:4,19 68:6,18 71:2 76:10,15,18 81:11 84:2,14 93:11,12</p>
--	---	---	---

95:5 98:18 103:9 107:22 109:11 111:17 112:3,15 116:10,14 119:19 133:11 139:7,21 143:20 145:20 146:18 155:8 168:10 170:6,14 170:18 210:12,14 210:18 218:17 273:2,18 302:12 315:22 322:8 323:8,11,18 324:19 338:9,16 338:16,18 353:14 354:1,3,13 355:6 355:11 356:8,10 361:18 362:4,20 363:3 364:18 366:2 371:21 380:21 407:12 409:14,19 417:20 420:7 440:20 457:13 463:9 464:18 465:17 <b>deriving</b> 69:1 <b>dermatology</b> 7:5 <b>dermatomyositis</b> 93:5 <b>describe</b> 212:13 215:9 318:2 448:10,12 459:1 <b>described</b> 62:11 311:22 312:1,6 316:5 353:17 374:8 444:4 472:10 <b>descriptions</b> 130:11 206:9 <b>deserve</b> 31:7 54:21 118:5 315:17 461:15 471:9 498:11	<b>deserves</b> 462:1 492:6 <b>designated</b> 68:22 <b>designation</b> 44:13 47:10 <b>designations</b> 93:7 <b>designed</b> 93:13,13 140:3 266:18 348:10 <b>designer</b> 205:22 <b>designing</b> 268:16 <b>desirable</b> 75:4 <b>desire</b> 64:4 154:17 371:19 478:1 <b>desired</b> 306:11,15 <b>desk</b> 20:18 384:21 <b>desmethylcloba...</b> 179:5 <b>despair</b> 482:18 <b>desperate</b> 97:8 <b>desperately</b> 41:22 <b>desperation</b> 459:4 459:7 473:10 <b>despite</b> 51:1 60:9 61:16 67:18 116:7 284:9 401:7 <b>despres</b> 16:12 462:8,10,12 466:20,22 <b>destruction</b> 203:7 377:20 <b>detail</b> 114:22 312:15 313:9 392:17 456:16 463:5 <b>detailed</b> 20:17 111:13 123:14 185:11 325:11 <b>details</b> 197:3 238:3 481:13 <b>detect</b> 363:7 <b>detectable</b> 214:9 <b>detected</b> 190:7 191:10 302:14	<b>detection</b> 145:5 190:1 196:18 198:13 238:18 315:1 <b>detects</b> 238:20 <b>determination</b> 54:1 136:6 436:15 <b>determinations</b> 407:17 <b>determine</b> 69:7 444:19 460:19 <b>determined</b> 136:3 244:21 258:21 265:4 280:15 444:11 445:10,13 460:16 472:17 <b>determining</b> 481:4 <b>detrimental</b> 82:8 <b>deutsche</b> 11:13 227:18 <b>devastating</b> 94:10 <b>devastation</b> 57:21 <b>develop</b> 30:12 39:18,19 74:10 76:14 94:11 100:19 101:18 117:17 130:21 133:19 145:4 195:22 201:6 231:1 264:21 295:8 296:9 323:21 324:1 362:8 364:9 386:22 393:4,7,9 405:17 425:19 466:11 474:13 <b>developed</b> 89:12 134:3 267:10 294:4 302:17,19 374:14 380:22 426:6,12 427:2 428:3 437:8 475:21,22	<b>developer</b> 94:4 296:21 <b>developers</b> 93:19 <b>developing</b> 50:14 92:20 100:7 101:9 139:17 145:19 223:21 265:9 322:11 383:15,18 392:11 425:9 468:21 <b>development</b> 63:21 65:11 89:6 89:7,10 92:19 94:13,17 95:2 98:22 99:5 143:11 178:3,4,19 179:18 180:13 196:15 218:13 235:19 266:11 268:18 271:3 282:21 283:9 294:17 295:9 297:8,17 331:1,5,6 334:9 338:9 357:1 362:12 363:9 381:12,14 394:18 426:3,20 427:6,13 429:6 435:15 458:13 460:13 491:16 <b>developmental</b> 174:5 242:6 <b>device</b> 72:2 483:5 <b>devices</b> 24:3 265:20 426:21 <b>devoid</b> 229:1 <b>devon</b> 329:2 <b>devoted</b> 96:1 98:21 366:20 <b>dextromethorphan</b> 207:15 336:6 <b>diabetic</b> 276:8,19 <b>diagnose</b> 35:12 105:10
--	---	---	---

<b>diagnosed</b> 92:5 402:6 447:17 472:15,21 473:3	364:22 365:14 395:14 396:1,13 396:17 398:21,22 399:19 404:1	288:13 289:8 292:16 293:13 294:22 299:18 307:16,21,22	<b>diluted</b> 308:21 <b>diminished</b> 435:17 <b>ding</b> 291:5 <b>dioxide</b> 465:7
<b>diagnoses</b> 458:19	406:5 407:16	310:10 323:10,12	<b>direct</b> 12:15 24:16
<b>diagnosis</b> 136:2	410:19 416:3	324:2,9 325:3	108:22 401:4
<b>diagnostic</b> 264:6 264:16	417:1 433:14	326:13 339:4	419:22 497:17
<b>diagnostics</b> 50:14	435:6,10,18	374:5 388:20	<b>directed</b> 272:12
<b>dialog</b> 365:21	436:15 438:6,7,12	405:20 415:18	<b>direction</b> 187:7
<b>dialogue</b> 100:13	438:20 439:6	416:4 417:16,17	502:5
<b>dialysis</b> 278:3	440:9,20,22 441:4	418:6 420:14	<b>directions</b> 183:21
<b>diarrhea</b> 492:16	441:16 442:3,10	421:19,20,20	<b>directly</b> 58:2
<b>dichotomies</b> 432:16	450:20 477:11	422:1 426:6	96:22 137:10
<b>dichotomy</b> 432:21	497:2 498:4	448:21 455:3	207:3 208:15
<b>dictated</b> 176:2	<b>diets</b> 78:9	458:19,20 464:10	<b>director</b> 2:6,11,15
<b>died</b> 245:7 431:18 473:4	<b>differ</b> 189:2 337:22 455:22	464:11,13 465:1	3:15 4:9 20:7
<b>diego</b> 10:11	<b>difference</b> 54:14 65:3 83:2 120:15	470:9	21:16 22:2,13
<b>diet</b> 259:17	126:19 213:10	<b>differential</b> 120:17 202:14,17	26:6,8 45:8
<b>dietary</b> 10:18 30:14 32:5,9,14 33:10 34:7 44:12 44:15 47:10 48:10 48:14 52:18 71:2 71:5,13,13,15 72:2 73:6,11,20 76:5 77:6,10 79:4 79:5 98:13 99:1 101:15 102:8 111:22 116:1,9 117:15 120:9,21 128:17 144:2 154:8 159:19 162:6 188:8,21,22 189:1,5 200:18,22 205:21 268:19 269:13,17 272:19 273:1,4,7 296:3 323:9 324:4 327:11 337:12,18 350:11,12 352:15 353:12 354:14 355:6 356:1,11	236:12 272:11 288:9 292:3 293:16 300:21 433:6	<b>differentiate</b> 97:2 255:11 322:19	122:10 135:15 158:20 182:2 200:6,17 235:13 298:16,20 356:22 366:7 391:2 462:12
	<b>differences</b> 186:11 186:13 255:17 292:14 299:14 329:19 437:16 455:18	<b>differentiates</b> 324:13	<b>dirty</b> 270:9
	<b>different</b> 40:19 101:16 103:8 115:1,2 120:19 131:19 146:8 149:5,6 172:5,6 177:22 184:22 186:12,19 212:5 215:13,13 221:7 224:19 227:21 230:10 235:18 237:7 238:2 244:9 244:10 253:2 258:3,5,11,12,13 266:14 267:1,2,3 283:2 285:9 288:5	<b>differentiation</b> 266:17 338:14	111:21 <b>disappeared</b> 260:11
		<b>differently</b> 30:15 126:17 147:6 267:4 416:15	<b>disappointed</b> 85:4
		<b>differing</b> 477:15	<b>disappointing</b> 287:7
		<b>difficult</b> 40:12,15 41:9 157:11 179:12 208:22 215:11 351:1 390:1 396:22 423:12 448:13	<b>discern</b> 433:5
		<b>difficulties</b> 152:12 172:16 389:2 495:19	<b>discharged</b> 92:6 288:6 374:1
		<b>digestion</b> 71:9	<b>disciplines</b> 421:21 422:1
		<b>digestive</b> 263:1	<b>disclose</b> 214:8 238:1
		<b>digital</b> 253:8 452:13 503:3	<b>disclosed</b> 237:11 449:4
		<b>dilated</b> 472:15	<b>discomfort</b> 86:6
			<b>disconcerting</b> 191:1

<b>disconnect</b> 238:15	385:12,13 386:14	<b>distance</b> 408:21	<b>dmfs</b> 311:8
<b>disconnected</b> 261:3	386:17 387:11,22	<b>distillate</b> 69:2 292:19	<b>dna</b> 174:5,8
<b>discontinued</b> 67:13	388:5,10,12 389:5	<b>distillation</b> 152:9	<b>docket</b> 23:7 25:17 25:19 27:5,6 36:7
<b>discontinuing</b> 51:12	389:17 390:3	<b>distinct</b> 321:21	36:15 52:22 86:1
<b>discordia</b> 7:6	401:6 457:10	<b>distinction</b> 80:20 112:6 192:20	91:9,14 110:16
92:16,17,18 95:3	458:14 472:18	258:5	111:14 122:7
95:12	473:5 474:7	<b>distinguish</b> 195:9	124:18 125:3
<b>discount</b> 452:22	475:22	<b>distinguished</b> 20:21 25:22 26:4	153:2 161:6
<b>discover</b> 285:17	<b>diseases</b> 35:13,19	361:13	165:11 197:4
<b>discovered</b> 221:21	93:4 324:2 390:3	<b>distress</b> 224:8	204:14 216:6
294:19 295:11	457:17 474:4,21	<b>distributed</b> 24:12 330:22 362:10	310:2 325:21
388:17 485:9	475:2 484:10,13	<b>distribution</b> 82:11 157:10 166:21	412:22 447:4
488:22	<b>disguise</b> 373:17 377:3	329:19 463:15	456:15 481:14
<b>discovery</b> 54:4	<b>disincentivizes</b> 95:2 327:16	<b>distributors</b> 9:6 16:19 18:16 19:8	501:4,6
143:10	<b>disincentivizing</b> 326:17,18	38:15 147:8,10	<b>docs</b> 260:7
<b>discrepancies</b> 189:4,9	<b>disneyworld</b> 82:9	481:19	<b>doctor</b> 39:1 457:11
<b>discretion</b> 35:22	<b>disorder</b> 57:18 130:3 223:3 337:4	<b>district</b> 408:22	<b>doctor's</b> 251:8
113:6,11 353:18	<b>disorders</b> 92:22 130:4 222:10	<b>disturbing</b> 335:8	<b>doctorate</b> 356:21
380:2 436:3	264:8 300:7,8	<b>dive</b> 246:19	<b>doctors</b> 259:10 260:5 430:19
<b>discriminable</b> 212:21 215:2	302:2 386:1	<b>diverse</b> 123:8 262:4 270:13	458:21 460:19
<b>discuss</b> 49:21	<b>disparate</b> 130:7	318:5 321:19	485:10
176:22 362:19	<b>dispensaries</b> 59:15 193:6	<b>diversion</b> 497:6 499:20 500:11	<b>document</b> 158:1
467:14 497:1	222:13 381:9	<b>diving</b> 90:1 387:13	<b>documentation</b> 195:4 369:17
<b>discussed</b> 292:22	431:11	<b>division</b> 87:11 98:14 235:15	<b>documented</b> 123:22 143:14
393:7 498:3	<b>dispensary</b> 57:4,6 59:8,15 62:13	321:22 322:2	157:8 193:13
<b>discussion</b> 72:9	141:2 249:17	367:5 371:1 391:3	196:10 225:4
85:12 103:22	390:15 459:7	398:20	332:1
115:16 221:1	497:3 498:5	<b>divisions</b> 78:6 321:21	<b>documenting</b> 197:22 242:13
295:3,3,18,21	<b>displayed</b> 381:4	<b>dixie</b> 357:1,13	<b>documents</b> 60:9 392:17
350:15 399:14	<b>disrupt</b> 173:21	<b>dizziness</b> 301:2 388:9	<b>dod</b> 296:14
<b>discussions</b> 47:22	<b>disrupted</b> 262:8 263:13	<b>dmf</b> 311:14,15 312:6 314:14	<b>dogs</b> 64:18 83:14 84:18 86:15
88:10 90:5	<b>disruptions</b> 263:8	315:7 316:5	<b>doing</b> 29:9 32:19 140:15 162:18
<b>disease</b> 29:21	<b>disseminate</b> 100:11 415:5,17		182:20 186:14
102:10 105:11	<b>dissolved</b> 270:16		188:8 210:15
130:15 132:7			227:17 231:15
136:9 243:5 269:3			
272:21 337:14			
339:4,9 359:12			
374:14 384:14,18			



236:17 241:1,19 244:11 289:8 293:12 319:2 334:11,18 344:6 360:18 383:4 394:9,16,17,19 417:2 421:20 423:14 424:9 456:11 472:6 474:10 498:22 <b>doj</b> 121:6 <b>doj's</b> 121:11 <b>dollar</b> 119:21 291:1 <b>dollars</b> 49:10 52:6 54:17 162:4 290:21 291:20 348:3,5 435:16 <b>domestic</b> 110:19 287:8,9 <b>domestically</b> 228:4 <b>dominant</b> 473:7 <b>donelson</b> 6:9 70:19,22 <b>donors</b> 247:11 <b>don't</b> 25:18 30:21 33:21 41:8 55:10 55:11 56:7 73:15 74:14 80:2 86:13 90:3 95:3 97:9 108:5,10 115:2 128:7 137:9 148:13 149:9 150:21 158:12,14 178:12 179:2 181:10,13 183:15 186:8,22 187:9 208:10 212:19 213:22 215:7 224:11 225:8 232:3,4,5 234:15 242:2 243:20 244:4 251:13	254:15 255:18,22 256:13 280:18 284:18 297:2,11 304:12 308:15 313:21 346:14 349:14,17 350:1,3 350:4 376:4 382:20 391:10,13 391:14 395:9 403:20 404:4 412:21 417:6 432:17,19 448:8 455:10,11,16 461:18 470:19 474:9 475:6,14 478:19 482:11 484:11 491:12 497:21 499:3 <b>door</b> 354:19 355:10 375:13 428:19 477:19 <b>doors</b> 149:22 <b>dopamine</b> 385:14 <b>dormant</b> 407:20 <b>dosable</b> 334:7,12 <b>dosage</b> 33:2 40:12 40:14 41:10 105:15 118:2 130:11 359:9 397:11 409:17 410:16 425:3 437:7,14,15 <b>dosages</b> 118:13,16 120:17 320:4 358:17 359:17 <b>dose</b> 40:17,17,18 40:22 51:22 115:8 120:8,11 141:5 201:20,21,22 202:15,16 211:19 213:4,7,14 222:19 224:10 277:6,16 278:9 279:8 280:15 281:1,7	285:18 300:5,7,8 300:19 301:7 302:4,8 334:19 339:7 359:18,20 361:7 455:2 460:1 474:19 475:3 492:7 <b>dosed</b> 93:9 <b>doses</b> 51:9 124:5 181:5 184:11,13 202:13,21 211:16 213:4 217:16 270:19 271:5,8,9 299:4 302:9 410:5 433:18 474:20 475:1 <b>dosing</b> 38:21 39:1 69:7 70:1 131:12 149:4 177:9,10 212:4 264:16 272:9,10 277:3,18 278:7,8 293:5 300:22 301:21 302:1 319:14 338:14 389:2 492:5 <b>dossier</b> 272:5 <b>double</b> 299:7 493:9 <b>doug</b> 21:15 <b>douglas</b> 4:8 13:10 321:13,14 <b>dovetail</b> 192:17 <b>downregulation</b> 202:15 <b>downside</b> 127:14 <b>downward</b> 44:3 57:17 <b>dozen</b> 284:14 333:20 391:8 <b>dozens</b> 106:4 208:4 265:17 428:13	<b>dr</b> 20:10,22 21:7 21:15 22:12 25:22 26:2,11,14 36:21 40:3 50:7 53:2 61:15,19 63:6,18 63:19 66:4,14,22 66:22 68:15,21 69:9,13,15,22 70:8,14 77:20 79:20 80:15 81:2 87:15 89:20 90:14 91:13,17,21 92:17 92:17 95:3,12 98:11 101:4,8 117:8 135:14 137:9,16,17,22 138:2,2 140:8,12 140:16 141:6,9,17 162:13 174:9 175:12 176:20 181:18,21 186:2 186:14 187:6,11 187:14,19 192:11 192:18 193:10 197:8 198:6,19 199:4,8 200:2,14 204:10 210:1 211:4 214:22 215:11,18 216:1,8 216:11 217:3 218:2 220:13 226:11,14,16,19 242:8 259:6,7 261:12,18 263:19 274:16,17 279:22 280:3,6,8,10,17 281:5 282:5,14 298:22 317:3,6,8 321:5,14 332:21 337:21 356:20,20 357:5,7 361:12,19 378:18,22 384:3,7 385:1 390:6,11 395:6 396:9
---	--	---	---

398:18 399:22 400:11,12 405:18 451:6,11 455:20 456:18 457:2 471:13,17 475:20 487:5 489:11 492:17 494:11 495:16 <b>draft</b> 136:2 <b>drafting</b> 48:7 <b>dragged</b> 459:3 <b>dramatic</b> 181:5 260:13 <b>dramatically</b> 180:7 <b>dravet</b> 140:18 338:21 341:13 <b>dravet's</b> 174:21 <b>draw</b> 136:4 <b>dreams</b> 57:13 241:9 <b>dressings</b> 151:7 <b>dried</b> 302:15 392:15,22 <b>drink</b> 162:6 249:9 257:12 291:18 468:3 <b>drinks</b> 151:16 152:7 432:18,19 <b>drip</b> 276:1 <b>drive</b> 39:20 54:15 107:20 108:15 109:5,21 292:5 346:17 365:2,9 431:14 459:6 <b>driven</b> 425:18 <b>driver</b> 233:16 <b>drivers</b> 376:11 <b>drives</b> 399:14 <b>driving</b> 116:13 174:22 184:17 243:18 340:8 375:21 428:13 454:11 471:19	<b>dronabinol</b> 30:7 186:16 <b>drop</b> 279:8 <b>dropped</b> 275:12 318:17 <b>drops</b> 249:10 <b>drowsiness</b> 320:9 <b>drug</b> 1:1,16 2:4,9 2:13,17,21 3:5,9 3:13,17,21 4:5,10 4:11 11:9 16:15 20:3 21:17 27:18 28:10 29:2,20 30:1 31:20 32:10 33:1 35:15 41:1,5 41:7 47:4 50:16 57:8 58:5 61:21 63:12 67:18,22 76:13,22 77:9 81:19,22 89:19 93:2,18 94:4,9 95:2 101:17 102:6 102:11,13 105:4,6 105:9,14,16,22 106:3,6,8,9,10,12 106:13,14 107:14 114:11,15 117:21 124:2,4,15 131:9 136:9,10,14 141:16 142:2 143:5,12,15,15,18 144:16 151:1 156:5,6 157:3 159:6 174:7 175:18 177:12,21 177:22 178:6,11 178:20 179:14,19 180:6,7,16 181:6 181:10,15 202:4 202:20 203:17 204:2 205:18 208:8 209:14 211:17 212:2,5,7 212:20,21 213:13	213:14 214:19,19 215:2,2,3,10 216:19 217:17 218:14 220:14,16 241:21 242:9 265:5 269:4 271:18,20 282:20 283:9,12 284:21 284:21 286:3,18 286:18 287:5,6 292:6 294:17 295:5 296:4,20 297:3,8 300:9,16 306:7 311:11 312:2 313:11 314:3 315:16 320:18 322:3 323:22 325:4 327:1 331:16 334:9 339:9,11,18 339:22,22 344:3 353:5 359:22 360:21 361:15 375:18 377:14 388:2,3 389:22 396:1 401:19,20 401:20 403:21 404:14,17 405:6 405:11 410:22 411:1 419:17 420:3,6 421:5,21 426:18 429:21 433:17,22 435:15 435:17,19 436:8,9 436:22 449:10 458:6 460:20 467:5,9,10,13 470:17 471:5 475:13 483:14 500:11 <b>drugs</b> 4:7 30:4,10 30:12 31:19,21 32:1,22 34:15 50:17 51:6 57:11	64:10 67:13 84:1 93:20 94:13,18 131:2 138:10,16 140:1,4 144:9 168:22 175:22 178:10,14,15 180:22 183:18 184:3 205:1,19,22 206:1,3,8 207:20 209:14 214:13 218:13 245:21 271:12,13 290:18 313:6 315:3 323:9 324:1,2 325:6 329:8 340:3 374:18,18 377:17 377:18 398:8 405:22 406:3 447:11 450:19 461:20 470:8 <b>drugstore</b> 126:18 <b>drugstores</b> 62:18 <b>dry</b> 28:22 240:8 278:12 368:7 394:5 469:7 488:13 489:7 494:18 <b>dryers</b> 247:3 <b>dshea</b> 38:20 64:20 435:13 439:7,17 477:1 480:10,21 <b>dsm</b> 173:16 <b>dual</b> 409:9 434:5 <b>duality</b> 407:15 <b>due</b> 28:13 51:12 82:12 96:9 119:12 130:5 143:16 151:17 162:8 271:12 326:22 436:19 439:17 458:14 <b>dunking</b> 59:19 <b>dupont</b> 2:14
--	---	--	---

<b>durable</b> 89:12	427:5	484:19	209:17 211:17
<b>duration</b> 301:11	<b>easy</b> 51:2 152:14	<b>effect</b> 29:21 41:7	212:5,8,20 213:21
<b>dustin</b> 261:18	219:1 231:19	70:10 95:4 118:17	214:1 215:2,4
<b>duty</b> 371:19	278:16	129:3 174:1	217:17 222:19
<b>dvm</b> 6:2	<b>eat</b> 30:18 249:9	178:14 179:13	224:16 251:10
<b>dwelling</b> 184:8	<b>eating</b> 224:6	212:3,21 214:19	256:16 257:3
<b>dwindling</b> 46:8	<b>echo</b> 193:9	214:19 215:2,3,10	261:7 271:22
<b>dying</b> 328:2	<b>echoing</b> 408:19	255:4 258:9 271:2	277:15 306:19
<b>dynamic</b> 307:9	<b>ecodrop</b> 275:8	271:3 278:6	318:20 320:7
<b>dysfunction</b> 386:1	276:1,2,11 277:13	300:15,20 301:16	328:15 340:3,6,16
<b>e</b>	<b>economic</b> 43:11	301:18 306:19	340:19 358:16
<b>e</b> 2:1,1 3:1,1 4:1,1	44:5,9 46:17 52:1	318:20 328:7	359:13 361:3
5:1,1 6:1,1 7:1,1	52:12 65:14	330:8 358:15	376:8,13 380:15
8:1,1 9:1,1 10:1,1	108:16,21 233:16	389:4 407:6	386:19 388:3,4,16
11:1,1 12:1,1 13:1	<b>economically</b>	449:12 493:12	388:16,19 389:12
13:1 14:1,1 15:1,1	52:13	<b>effective</b> 45:3	405:6 431:4,8
16:1,1,9 17:1,1	<b>economy</b> 45:2	53:18 72:7 74:18	452:2,6 455:2
18:1 19:1 20:1,1	54:16 83:5	74:22 76:16 89:11	468:11,20 473:18
40:11 53:12 126:9	<b>ecs</b> 262:11,16	112:21 126:9	474:16 487:20
205:5,5,13 206:8	263:4,8	132:8 143:1	492:15,15
206:12,13 207:3	<b>edge</b> 209:12	232:20 236:5	<b>efficacious</b> 64:7
372:15 491:14	<b>edible</b> 185:21	248:4 250:4,6,13	<b>efficacy</b> 65:6,8
492:20,20	279:8,20 280:10	261:10 262:3	93:3 125:17 126:6
<b>eager</b> 429:3	454:5 469:10	263:10 265:13	131:8 136:4,13
476:18	<b>edibles</b> 34:18	266:12 277:3	140:4 143:4 168:2
<b>eagerly</b> 108:1	222:13 256:7	317:16 320:6	183:17 186:12
<b>earlier</b> 31:17	276:15,22 373:13	354:22 389:9	222:8 265:3
96:19 162:14	<b>edict</b> 432:22	403:18 480:4	282:18 283:8
210:17 360:8	<b>educate</b> 139:8	481:8 492:19	286:2,11 299:10
386:12 424:12	149:10 297:7	<b>effectively</b> 60:5	317:22 320:17
474:19	<b>educated</b> 149:2	97:14 160:3	329:15 333:22
<b>early</b> 96:2 104:13	<b>educating</b> 11:19	229:22 230:12	358:2,5 370:1
141:21 160:14	170:16 240:21	355:13 495:7	379:16,18 460:17
183:8 184:10	<b>education</b> 8:9 12:7	<b>effectiveness</b>	462:1 492:9
333:7 388:13	53:14 129:22	39:19 295:19	<b>efficiency</b> 50:19
433:12 440:3	149:13,22 189:1	<b>effects</b> 28:15	232:21 446:14
467:8	240:21 273:8,9	40:19 41:1,5,7,9	<b>efficient</b> 48:9,15
<b>earned</b> 57:16	278:21 364:20	54:9 67:6,20 68:1	<b>efficiently</b> 322:19
<b>ears</b> 54:11	393:11 396:6	69:19,20 70:1,6	427:2
<b>earth</b> 151:11	418:21 455:14	80:18 82:8 139:5	<b>effort</b> 49:16 88:7
<b>ease</b> 452:13 458:6	463:22	139:9,16,18 142:2	383:21 427:3
<b>easier</b> 151:2	<b>educational</b> 97:15	144:3 179:7	<b>efforts</b> 72:18
<b>easily</b> 53:19 124:3	98:2 122:11	193:16,17,20	109:8 124:22,22
131:18 382:13	130:19 401:3	195:4 200:9	146:1 170:17

<p>195:17 369:5 381:5 425:19 428:8,21 <b>egregious</b> 85:2 <b>eight</b> 56:16 109:1 121:9 127:19 160:5 318:15 339:4 402:9 <b>eighth</b> 373:14 <b>either</b> 78:2 86:12 104:2 159:22 189:20 191:7 270:16 284:10 316:10 349:18 354:9 370:20 482:22 <b>elaborate</b> 68:19 214:20 226:17 <b>elbow</b> 186:7 <b>elderly</b> 214:5 272:3 <b>elect</b> 159:5 <b>election</b> 482:14 <b>electric</b> 488:6 <b>electronic</b> 22:22 23:1 24:3 40:9 187:4 204:13 205:1 <b>element</b> 115:15 <b>elemental</b> 100:4 <b>elements</b> 478:7 <b>elevated</b> 201:7 202:1 238:18 300:22 <b>elevates</b> 474:6 <b>elevation</b> 203:2 475:10,13 <b>eleven</b> 248:21 <b>eligibility</b> 273:4 <b>eligible</b> 337:4 <b>eliminate</b> 334:2 <b>eliminating</b> 446:4 479:17</p>	<p><b>elise</b> 11:7 220:12 <b>elixinol</b> 6:7 66:20 67:1 69:4 <b>ema</b> 493:10 <b>email</b> 169:14 226:3 <b>emails</b> 208:13 <b>embarrassed</b> 208:11,20 <b>embolden</b> 287:11 <b>embrace</b> 285:11 <b>embraces</b> 322:3 <b>embracing</b> 267:9 <b>embryonic</b> 271:2 <b>emergency</b> 207:12 208:5 484:21 <b>emerges</b> 223:17 437:13 <b>emerging</b> 41:19 46:18 65:6 130:16 154:17 163:11 182:9 368:22 371:9 382:14 429:8 <b>emphasis</b> 358:1,1 <b>emphasize</b> 177:17 178:2,16 261:6 326:4 <b>emphasizing</b> 25:15 <b>empire</b> 111:7 <b>empirical</b> 220:17 259:22 260:18 262:18 361:2,2 <b>employ</b> 348:2 446:7 478:17 491:13 <b>employed</b> 357:21 502:8,11 503:8,11 <b>employee</b> 59:6 502:10 503:10 <b>employees</b> 59:22 247:13</p>	<p><b>empower</b> 305:2 307:7 <b>empowering</b> 380:19 <b>empty</b> 177:12 <b>enable</b> 362:12 365:12 426:1 <b>enables</b> 71:9 285:17 363:6 <b>enabling</b> 364:21 365:16 <b>enact</b> 120:22 160:22 <b>enacted</b> 221:5 352:11 <b>enactment</b> 111:19 <b>enantiomer</b> 179:21 <b>encounter</b> 316:10 <b>encourage</b> 27:3 73:20 98:2 104:6 107:17 110:15 120:3 138:18 139:22 175:12 197:18 214:6,10 354:17 358:21 414:19 419:5 465:11 466:1 <b>encouraged</b> 63:14 353:21 414:7 <b>encourages</b> 322:16 338:8 341:18 355:13 364:20 443:5 <b>encouraging</b> 304:15 <b>endanger</b> 163:20 <b>ended</b> 482:7 <b>endless</b> 127:12 <b>endocannabinoid</b> 54:5 78:18,20 92:21 94:14 259:11 262:5,20 263:13 482:6</p>	<p>485:8,12 488:21 494:2,10 <b>endocannabinoids</b> 262:12 <b>endocrine</b> 263:2 <b>endogenous</b> 78:13 79:9,21 <b>endostatins</b> 202:8 <b>endothelial</b> 203:8 <b>endpoint</b> 398:16 <b>ends</b> 146:8 234:5 <b>enforce</b> 121:7 244:10 273:7 330:19 354:9 412:10 439:4 <b>enforceable</b> 303:18 <b>enforced</b> 119:15 378:4 433:4 <b>enforcement</b> 35:22 49:14 65:16 72:6 77:2,4,6 102:18 113:6,11 121:1,2,10,13 160:6 189:18 192:7 205:7 235:20 353:17 367:10 371:1 411:3 471:22 482:11 <b>enforcing</b> 57:1 353:20 429:21 442:6 <b>engage</b> 200:9 214:6 <b>engaged</b> 78:1 304:3 <b>engagement</b> 2:11 20:8 88:9 89:5 365:16 <b>engaging</b> 199:10 <b>engineer</b> 235:17 <b>engineering</b> 96:5 348:9</p>
--	---	--	---

<p><b>enhance</b> 89:1 319:6</p> <p><b>enhanced</b> 446:9</p> <p><b>enhancement</b> 189:6,7</p> <p><b>enjoy</b> 82:4 127:7</p> <p><b>enrolled</b> 196:8</p> <p><b>ensure</b> 36:2 46:17 49:19 50:18 60:5 66:5 74:4 89:8 99:7,12 109:16 117:15 121:17 147:2 155:2 163:7 163:13 167:22 269:12 285:21 305:2,9 322:17 325:13 330:21 331:7,18 332:3,13 343:14 354:22 355:4,22 356:9 359:6 369:11,15 371:19 372:7 381:3 426:3 429:1 462:15,19 463:18 464:2 466:5 479:14,15 481:8 487:21 488:14 489:17 491:1,3 492:18 495:13</p> <p><b>ensures</b> 52:15 319:22 338:11 489:20</p> <p><b>ensuring</b> 50:21 112:16 145:17 329:9 393:16 426:14 428:10 464:5 490:7,17 493:15</p> <p><b>enter</b> 151:22 164:1 173:18 175:7 321:8 354:19 356:15 423:22 424:1 495:1,13</p>	<p><b>entering</b> 313:8 389:6</p> <p><b>enterprises</b> 14:11 366:8,10,15,19 369:1 370:7 372:4</p> <p><b>enters</b> 143:16</p> <p><b>entire</b> 50:2 120:14 152:5 168:15 256:8 267:5 282:20 285:4 309:12 319:15 329:3 341:10 418:10 458:4 499:13</p> <p><b>entirely</b> 119:14 120:19 247:10</p> <p><b>entities</b> 9:14 18:18 155:21 156:2 443:14</p> <p><b>entitled</b> 188:10</p> <p><b>entity</b> 218:14</p> <p><b>entourage</b> 306:19</p> <p><b>entrance</b> 494:20</p> <p><b>entrepreneurs</b> 107:13</p> <p><b>entry</b> 316:11</p> <p><b>environment</b> 108:4 130:13 322:10 357:18 365:8 367:4 368:10 396:20,21 426:5</p> <p><b>environmental</b> 146:14 366:22 367:8 379:6</p> <p><b>environments</b> 60:1 491:4</p> <p><b>envisioned</b> 185:10</p> <p><b>enzyme</b> 177:18,21 178:10 179:14 180:12</p> <p><b>enzymes</b> 177:6 178:1 201:7 202:1 203:2 262:14,15</p>	<p>271:21</p> <p><b>epa</b> 465:3</p> <p><b>epidemic</b> 39:12</p> <p><b>epidiolex</b> 30:5 51:9,17 67:17 102:11 120:10 139:3 140:11,16 141:16 143:4 174:20 178:3,19 180:14 181:4,5 201:6,8 210:13 270:21 272:9,12 334:17 337:5 338:17 339:1,21 359:15 401:22 402:14,14 403:11 405:11 411:1 433:19 460:1 486:2</p> <p><b>epilepsy</b> 8:18 15:5 137:18 138:4,6 139:2 140:20 143:1,7 178:21 217:2 221:12 261:11,20,21 262:1 269:6 325:4 338:21 400:10,14 400:16,17,20 401:1,5,8,13,19 402:7,7,15 403:20 404:6,19 405:20 458:20 459:12</p> <p><b>epilepticus</b> 401:15</p> <p><b>epileptologists</b> 386:15 458:18</p> <p><b>episodic</b> 468:19</p> <p><b>epithelium</b> 488:19 493:1 494:3,9</p> <p><b>epstein</b> 13:4 303:7 303:8,9 307:11,14 307:22 308:12,19 309:5,9,19,21 310:12,14,16,21</p>	<p><b>equal</b> 355:8 426:13 455:9</p> <p><b>equine</b> 96:12</p> <p><b>equipment</b> 127:6 134:6 227:19 348:5,11 445:12 465:8,13</p> <p><b>equipped</b> 441:18</p> <p><b>equivalent</b> 102:13 122:18</p> <p><b>er</b> 173:19 279:1 374:2</p> <p><b>eradicate</b> 253:21</p> <p><b>eras</b> 408:2</p> <p><b>erik</b> 3:10 21:20</p> <p><b>erin</b> 10:2 166:11 166:12 172:15</p> <p><b>eroding</b> 304:10</p> <p><b>errors</b> 446:16</p> <p><b>ers</b> 242:20</p> <p><b>escalation</b> 225:3</p> <p><b>escherichia</b> 490:4</p> <p><b>esoteric</b> 407:8 408:2</p> <p><b>especially</b> 61:1 102:22 113:3 130:20 132:3 141:20 153:21 170:9 188:21 189:5 200:9 201:3 217:17 254:5 292:1 396:19 453:3 456:1 468:6 471:1 493:16</p> <p><b>essence</b> 107:22 397:22</p> <p><b>essential</b> 79:10 99:16 108:12 404:22</p> <p><b>essentially</b> 136:8 230:11 233:3 422:14</p> <p><b>establish</b> 50:1 120:10 151:21</p>
--	--	---	--

155:12 163:22 214:11 255:19 305:22 325:16 332:12 393:10 397:2,22 450:17 <b>established</b> 121:2 121:9 132:19 182:4 270:2 329:6 329:16,22 330:18 331:5 332:9 369:9 396:14 425:22 441:1 445:6 <b>establishes</b> 173:16 338:13 <b>establishing</b> 73:9 146:15 194:10 266:19 291:8 327:6 393:12 <b>estate</b> 421:22 <b>estimate</b> 198:16 <b>estimated</b> 108:20 260:4 349:2 <b>estimates</b> 430:18 442:8 <b>et</b> 279:8 308:7 386:1 409:19 <b>ethanol</b> 202:11 <b>ethical</b> 366:16 <b>ethics</b> 421:11,13 <b>eu</b> 492:4 <b>euphoria</b> 300:8 <b>euphoric</b> 294:4 300:14 330:8 <b>europe</b> 207:13 333:2,21 <b>european</b> 253:17 492:3 <b>evaluate</b> 33:1,16 34:22 138:20 142:1 225:11 266:5 270:2 282:18 306:16 350:19 414:3 439:11,19 443:15	<b>evaluated</b> 134:19 168:2 205:20 269:22 325:1 335:4 369:22 380:13 445:2 446:11 <b>evaluation</b> 4:10 21:17 31:12 36:9 134:13 168:10 169:17 212:9 213:22 331:1 446:22 <b>evaluations</b> 169:21 <b>evans</b> 11:18 240:15,16,19 <b>eve</b> 459:22 <b>event</b> 194:12 196:17,17 218:7 220:3 326:2 442:2 480:13,17 <b>events</b> 51:13 84:17 125:1 141:14 158:2 194:17 197:21 198:7 199:15,20,22 269:12,16 285:19 300:2,4,6,10,11 300:13 301:1,4,4 301:6,13 302:1,7 302:9,10 358:19 438:18 493:5,8 <b>eventually</b> 285:11 345:8 <b>evergreen</b> 366:9 <b>everybody</b> 149:5 250:15 404:3 408:19 451:16 496:18 <b>evidence</b> 34:6 39:20 41:18 42:11 51:18 54:8 61:21 68:2 72:20 73:5 74:3,15 75:11	80:3,8,21 90:3 109:10 125:17 127:21 136:4,13 136:17 137:3 143:10 205:6 258:3,10 260:1,18 263:15 381:19 389:19 431:6 436:14 454:9 477:3,8 <b>evident</b> 202:1 302:3 <b>evolve</b> 285:21 <b>evolving</b> 39:20 <b>exacerbate</b> 203:18 <b>exact</b> 105:13 254:15 271:11 346:4 417:3 <b>exactly</b> 75:12 103:5 132:2 186:3 191:8 215:12 238:14 239:5,17 240:2 254:18 255:3,19 396:11 466:6 475:14 <b>exaggeration</b> 94:5 <b>examine</b> 146:3 436:12 455:5 <b>examined</b> 224:21 <b>examining</b> 436:19 <b>example</b> 29:19 30:9,21 34:11 114:6 127:4 202:15 221:9 267:10 284:13 290:19 305:22 339:12 341:7 365:13 380:11 403:1 432:21 452:16 454:19 455:7 465:5 478:16 <b>examples</b> 86:7 260:10 283:11	323:10 385:20 <b>exceeded</b> 190:9,17 190:21 191:20 240:5 332:4 <b>exceeding</b> 464:22 <b>exceeds</b> 484:22 <b>excellence</b> 216:16 386:6 <b>excellent</b> 141:17 <b>exception</b> 32:8 33:7 77:10 105:17 <b>exceptions</b> 32:16 163:18 258:16 <b>excepts</b> 106:11 <b>excessive</b> 283:7 286:9 <b>excessively</b> 283:20 <b>excited</b> 276:7 <b>exciting</b> 74:11 471:14 <b>excludes</b> 32:4 <b>exclusion</b> 435:12 436:11 <b>exclusionary</b> 435:11 <b>exclusive</b> 453:21 <b>exclusively</b> 272:12 413:16 <b>excuse</b> 73:18 112:5 135:5 150:14 197:2 215:15 327:10 368:17 416:3 433:3 <b>execution</b> 166:20 <b>executive</b> 77:21 158:20 235:13 <b>exempt</b> 77:8 411:13,19 <b>exemption</b> 106:21 <b>exemptions</b> 185:10 <b>exercise</b> 77:8 113:6,10 189:6
--	---	--	--

266:3 354:12 393:1 461:1 <b>exercising</b> 355:12 <b>exhaustive</b> 96:18 <b>exhibits</b> 67:22 <b>exist</b> 159:7 182:16 255:10 313:5 317:21 361:1 409:15 441:7 463:11 476:22 <b>existence</b> 311:13 <b>existing</b> 76:13 214:13 218:2,3 331:5,10 332:10 349:4 350:14 360:5 414:5,12,22 415:1 416:7,18 441:9,16 442:10 480:21 <b>exists</b> 331:11 <b>expand</b> 117:10 <b>expanded</b> 217:1 <b>expanding</b> 128:15 184:3 382:5 491:18 <b>expansion</b> 119:11 <b>expect</b> 26:21 90:18 141:22 147:3 193:18 303:14,19,21 304:3 346:12 394:9 417:6 452:10 <b>expectations</b> 74:6 97:12 269:19 307:3 381:4 <b>expected</b> 116:11 168:18 251:5 260:12 300:15 371:9 441:1 <b>expecting</b> 22:17 <b>expedite</b> 122:3 <b>expedited</b> 108:14	<b>expeditious</b> 98:8 <b>expeditiously</b> 49:1 <b>expensive</b> 123:6 206:13 252:4 <b>experience</b> 63:7 126:20 127:3 143:1 196:4 197:4 197:20 198:1 199:12 200:4 223:21 236:9 304:18 325:11 326:8 367:16 412:8 445:10 465:21 483:6 <b>experienced</b> 67:6 70:10 251:12 260:15 300:4,13 301:8 <b>experiences</b> 94:4 194:11 196:9 198:18 376:17 412:6 <b>experiencing</b> 260:15 <b>experiment</b> 174:16 <b>experimental</b> 93:20 <b>expert</b> 67:21 97:1 97:7 134:12 151:19 314:2 379:8 <b>expertise</b> 99:4 100:7 204:19 348:9 379:1 426:22 <b>experts</b> 39:4 45:10 85:9 197:11 200:21 324:6 392:5 432:6 433:22 444:13 <b>explain</b> 103:5 113:22 284:11 328:6 447:14	<b>explaining</b> 361:21 <b>explanation</b> 284:16 <b>explicitly</b> 29:6 329:10 452:21 <b>exploded</b> 441:14 <b>exploding</b> 116:9 348:22 <b>exploration</b> 100:14 <b>explore</b> 355:19 <b>explored</b> 184:16 <b>explosion</b> 33:20 <b>exponential</b> 119:13 <b>exponentially</b> 40:15 74:1 307:5 <b>export</b> 425:7 <b>exposed</b> 60:1 143:21 375:20 <b>exposition</b> 120:5 <b>exposure</b> 60:10,16 63:5 89:17 99:19 144:5 177:10 178:11 181:11 269:13,20,21 306:11 332:7 337:19 397:5 399:13,15 <b>exposures</b> 193:14 193:16,21 194:1 197:7,7 455:2 <b>express</b> 338:6 <b>expressed</b> 131:12 <b>expression</b> 202:14 270:6 <b>extend</b> 164:5,9 219:19 <b>extended</b> 72:6 217:11 359:15,17 <b>extends</b> 480:15 <b>extension</b> 169:9 299:9 370:3	<b>extensive</b> 124:4 267:12 492:8 493:2 <b>extensively</b> 179:22 413:18 <b>extent</b> 62:16 170:21 171:2 336:16 <b>external</b> 2:12 20:8 <b>extra</b> 64:3 <b>extract</b> 102:9,11 103:5,10,15 105:8 105:17 106:4 201:17 203:16 217:1,13 229:17 303:11 305:16 308:8 309:9 316:14 324:7,13 327:6,7,18 335:15 372:18,18 398:13 417:18,18 424:10 424:13 487:17,22 <b>extracted</b> 45:17 84:2 210:20 308:15 313:10 336:8 487:11 <b>extracting</b> 314:17 362:17 <b>extraction</b> 165:19 289:1 327:21 335:17 347:15 348:11 367:18 370:10,15 465:8 497:12 <b>extractions</b> 371:2 <b>extractors</b> 312:12 <b>extracts</b> 73:6 102:13,15 114:13 207:7 273:2 304:5 327:6 328:7 335:8 340:6 362:4 371:6 <b>extraneous</b> 286:1 <b>extrapolated</b> 414:15
---	---	--	---

<b>extreme</b> 174:17 468:5 470:22	194:14 217:22 255:9 263:16	<b>families</b> 30:19 58:4,8,14 125:12	46:6,13 47:14 50:11 82:18,22
<b>extremely</b> 79:12 250:4,13,17 251:17 271:5 339:16 405:8	278:4 284:18 304:2 318:20 320:7 326:14 336:13 340:13	130:18 136:18 141:1 142:7 217:15 338:19 460:8,18 461:2,9	127:6 156:14 162:3 229:9 233:12 288:18,18 288:19 289:16
<b>exuberance</b> 286:9	360:6,14 361:7	<b>family</b> 12:15	348:4 410:14
<b>eye</b> 473:19,21 474:6,11,16	382:20 389:4 430:21 434:16	46:18 57:22 92:6 125:13 209:2	411:8,21 412:1,1
<b>eyes</b> 127:20 460:4	496:20	276:3 374:11 403:17 457:8	<b>farming</b> 52:12 233:12,13 288:17 497:10
<b>f</b>	<b>factor</b> 397:10 437:17 464:4	458:4 462:2 472:14 473:3	<b>farms</b> 288:14,17 292:2
<b>fabricant</b> 15:2 395:5,6 399:22 409:2	<b>factors</b> 134:5 185:15 399:20 409:4 465:18	<b>fans</b> 334:5	<b>fasciitis</b> 276:19
<b>face</b> 65:19 93:18 148:5,5 150:22 202:17 484:21 490:9	<b>facts</b> 79:14 382:16 438:9	<b>fantastic</b> 276:10 336:21 466:21	<b>fashion</b> 64:4 108:14 185:8
<b>faced</b> 119:20 383:2 477:13	<b>faculty</b> 26:9 200:16	<b>far</b> 43:9 70:4 178:16 183:8,16 190:17 191:7	<b>fast</b> 93:6 430:12
<b>facilitate</b> 42:5 65:11 99:18 393:5	<b>fahrenheit</b> 450:5,7	217:14 221:7 228:15 232:20	<b>fatal</b> 35:19
<b>facilities</b> 134:11 231:18 232:3,6 289:7,9 290:2 311:5 316:19,20 342:20 347:19 349:11 441:10 442:9,11 478:11 499:13,14	<b>fail</b> 437:12	276:7,22 293:9 296:13 322:9	<b>father</b> 457:9
<b>facility</b> 61:6 99:17 229:15 326:1 345:6 438:14 441:9 478:10 493:10	<b>failed</b> 402:9	382:3 402:21 416:20 422:21 431:5 433:4 488:17 489:3 492:13 493:4	<b>fathom</b> 430:11
<b>facings</b> 43:7 153:17 182:12 466:9	<b>failures</b> 65:20	<b>fargo</b> 8:15 135:12 135:14,15 137:9	<b>fatigue</b> 70:11 251:13,13 301:3
<b>fact</b> 60:9 69:3 85:3 87:10 117:6,22 126:4 143:3 152:2 154:12 179:7 180:6 181:2,12 182:9,22 187:6 191:1 193:21	<b>fainting</b> 301:2	82:16 111:15,19 147:14 150:21 154:2 160:21 226:10 292:4 295:22 313:19 329:10 341:6 363:12 408:17 414:6,9 423:20	<b>fats</b> 234:11
	<b>fair</b> 94:12 239:12 345:13 369:6	<b>farm</b> 28:19 29:5 33:22 46:18 48:15 54:18 81:13 82:8	<b>fatty</b> 45:21 486:6
	<b>fairly</b> 140:19 217:16	82:16 111:15,19 147:14 150:21 154:2 160:21 226:10 292:4 295:22 313:19 329:10 341:6 363:12 408:17 414:6,9 423:20	<b>favor</b> 218:15
	<b>fake</b> 132:1	<b>farmer</b> 43:7	<b>favorite</b> 151:8
	<b>fall</b> 64:13 93:20 264:19 377:19 388:11	<b>farmers</b> 43:15 44:1,6,9 45:9 46:2	<b>fd&amp;c</b> 111:21 112:19 113:7 121:1,13 144:10 410:22 433:13
	<b>falls</b> 27:20 201:2 296:5 432:1		<b>fda</b> 21:5,14,17 22:21 23:3,13 26:4,15 27:7,19 27:22 29:13 30:2 30:3,16,18,22 31:2,11 32:7,15 32:17,20,22 33:15 34:6 35:1,5,7 36:2 36:10,15 38:4,5,9 38:11,22 42:21 44:8,14,20 46:22 48:9,22 49:4,22 50:16,17 51:6 54:2 58:11 60:21
	<b>false</b> 37:21 149:15 238:21 377:4		
	<b>famers</b> 43:4		
	<b>familial</b> 410:18 472:15,16		
	<b>familiar</b> 128:2 172:11 179:19 326:14 379:4 441:18 477:12		



61:17,19 64:2,11	282:20 283:1	425:16 426:21	138:12 145:9
65:7,12 71:19,21	284:19,20 285:2,4	429:4 430:4,5,8	146:2,12,22 156:7
72:6 73:10 74:4	285:7 290:5	430:21 431:12	160:11,17 165:7
75:12 76:6 77:1,8	291:11 295:3,10	432:7,22 433:7,7	166:18 182:22
81:10,13,18 83:3	296:2,14,16 297:7	433:8,15,19 435:9	195:8 218:21
83:21 85:12 88:7	297:10,15,22	436:3,11,18 437:3	228:16 229:11
88:10 89:2 93:1	298:1 303:4 304:3	437:19 438:2,10	231:17,20 241:19
94:11 102:6 106:5	304:3,8,18 305:6	438:14 439:4,10	241:22 265:8,11
107:14 108:3,13	305:22 306:4,10	439:13,17 440:6	265:17 268:1
109:14 111:19	306:21 307:6	440:10,17 442:21	284:3 292:6
112:4,10,18,19	311:5 312:6	443:8 450:16	294:15 312:22
113:3,4,7,13	316:19 317:22	457:7,7,16 460:2	329:20 354:16
114:10 116:4,17	320:18,20 322:2,4	460:5,16,22	356:9 363:1,18
116:19 117:2,7,8	322:8,11,17 323:6	461:10,20 468:4,8	364:8,9 369:20
117:17,19,20,21	323:7,13,14,16,17	470:21 471:3,7	377:15 378:3
118:7 119:4,19	324:3,12,16 325:1	476:18 478:6,7,21	407:18 409:22
120:3,22 121:11	325:5 326:5 329:4	481:7 483:9	411:3 412:11
122:19 123:15	329:6,7,16,22	486:18,19 490:11	413:21 414:8,20
130:1 138:11,16	330:2,19 331:2,9	493:15 496:13	421:14,14 429:4
138:18 139:3,22	331:11 332:9	497:17	429:20 432:20
140:2,4 142:9	337:9 338:15,19	<b>fda's</b> 20:11 21:6	476:20 478:2
143:7 144:7,8	339:6,7,8 340:14	21:11 22:7 27:11	486:17
145:12,16,20	341:19,20 342:18	27:20 29:4,6,9,16	<b>federally</b> 229:21
146:3,19,21 147:4	343:22 344:1,14	38:19 48:20 50:20	286:18
148:7 150:1 151:4	344:16,19,22	62:6 105:4 107:16	<b>federation</b> 476:10
151:14,17,21	345:5,8,11 346:17	108:1 109:8 112:7	476:11 481:7
152:14 154:3	347:5 350:7,13,19	112:13,16 116:7	<b>feed</b> 5:3 45:6,8,9
155:11,16 157:14	352:8 353:16	117:9 135:3 137:2	45:13,18 46:3
157:18 160:12,13	354:8 355:4,10,18	154:2 155:2	52:19 64:10,11
161:3,16 163:21	356:9 359:3	159:13 162:14	66:2 166:16,22,22
166:3 167:9,17,18	360:20 369:22	163:2,16 164:8	167:4,14,18 168:6
174:15,20 175:10	380:5 381:1,15	167:11 244:15	168:19 169:1,3,5
176:4 178:3	383:10,12,19	314:1 329:11	169:17 170:7,15
185:13 188:19,22	391:20 397:1	330:4 355:2 412:7	170:20,22 171:3
194:9 195:22	405:21 406:14	435:7 480:12	171:20 172:1
197:18 206:2	407:11,14 408:9	<b>fear</b> 291:11	392:7 498:4
214:6,10 219:5,16	408:16 410:17	<b>feasible</b> 404:5	<b>feedback</b> 164:8
222:7 225:20	411:8,10 412:3	<b>features</b> 452:20	<b>feeding</b> 132:3
227:3 236:16	414:2,12 415:4,16	<b>february</b> 110:10	<b>feeds</b> 46:19,20
239:19 241:16	416:16 419:5,19	237:2 373:18	<b>feel</b> 41:4,7 132:4
246:13 252:21	420:10,10,10,18	<b>federal</b> 28:7,9,17	148:7 215:5,5,12
266:8,19 268:5	420:19 421:2,8,9	29:3 31:20 56:22	231:15 286:8
269:2,11,20,22	422:5,19 423:1	57:1 81:12 88:11	310:8 314:10
270:1 279:14	424:3,6 425:2,3,8	98:5 113:2 125:18	334:6 341:13

374:7 394:21 457:6 <b>feeling</b> 215:3 301:3 321:9,10 <b>feelings</b> 246:7 473:10 <b>feet</b> 161:22 <b>feinstein</b> 185:11 <b>felberbaum</b> 23:15 <b>feline</b> 96:12 <b>fell</b> 496:4 <b>fellow</b> 24:18 73:20 276:2 <b>felt</b> 54:14 142:7 250:10 <b>female</b> 487:6 <b>feminine</b> 487:7 <b>fentanyl</b> 287:2 <b>fertilizer</b> 330:15 <b>fetal</b> 340:13,15 <b>fetus</b> 123:21 174:4 <b>fewer</b> 315:22 <b>ff</b> 273:3 <b>fi</b> 496:15 498:19 <b>fiber</b> 83:1 172:1 233:19 323:1,4 325:15 488:4 <b>fibers</b> 488:3,7,9 <b>fibrosis</b> 93:5 <b>fides</b> 39:16 <b>field</b> 94:5 195:3 203:13 229:14 316:21 345:13 472:2 <b>fielding</b> 154:19 194:16 <b>fifth</b> 190:8 <b>fighter</b> 457:22 <b>fighting</b> 433:22 491:19 <b>figure</b> 75:17 243:19 246:2 255:19,20 280:20 498:5	<b>figures</b> 212:12 <b>file</b> 72:1 77:12 173:10 312:2,6 324:15 <b>files</b> 355:19 <b>filled</b> 125:6 <b>filling</b> 24:10 <b>film</b> 23:2 <b>final</b> 112:20 153:7 285:7 286:22 351:7 <b>finally</b> 77:5 85:6 110:8 220:7 239:16 243:20 284:4 286:12,16 315:12 331:16 332:5 338:13 365:9 452:10 455:21 491:19 492:16,17 493:2 493:12 <b>financial</b> 95:22 108:12 <b>financially</b> 502:12 503:11 <b>find</b> 58:4 110:11 130:9 141:12 209:14 295:12 296:15 345:22 347:1,7 374:13 439:13 <b>finding</b> 191:1 206:19 239:1 <b>findings</b> 135:21 183:12 204:11 217:13 237:20 359:21 477:5 480:16 481:13 <b>fine</b> 424:2 <b>finish</b> 20:15 491:5 <b>finished</b> 158:9,10 158:11 302:22 348:18 351:9 362:9,12 364:2	369:15 370:16 372:11,19 417:1 490:22 <b>finishing</b> 220:11 <b>fired</b> 175:15 <b>firm</b> 70:22 119:7 379:11 381:7 413:15 419:16 420:12 447:10 <b>firms</b> 48:2 419:19 420:14,21 435:15 500:5 <b>first</b> 28:2 37:8,9 37:10,11 38:2 51:3 78:7 83:18 88:8 105:8 107:21 146:3 153:10,16 155:21 166:12 177:16 182:6 183:21 190:4 193:8 201:15 204:10 217:11 234:8 237:21 243:18 248:2,7 250:18 257:9 275:2,10,11 277:4 278:6 283:15 287:17 297:12 301:18 305:6 306:8 307:15 319:9 320:1 324:18 335:3 338:8,18 364:16 367:7,11,12 368:14,19 373:6 393:20 394:11 414:1 422:11 423:5,22 433:14 435:19 437:2,21 453:1 459:9 460:1 468:19 471:21 486:13 489:18 491:12 495:5 496:8,12 499:8,15	<b>firsthand</b> 500:8 <b>fish</b> 46:3 365:5 <b>fit</b> 33:17 239:9 263:4 <b>fits</b> 68:21 350:14 416:17 437:6 <b>fitted</b> 437:9 <b>five</b> 47:17 67:5 68:7 107:20 108:22 117:4 119:8 141:19 166:13 250:21 288:18 291:1 297:14,14 300:20 314:21 355:15 367:16 447:17 460:12 496:2,4 <b>fix</b> 262:4 <b>fixes</b> 263:12 <b>fixing</b> 297:19 <b>flags</b> 149:18 <b>flame</b> 190:1 <b>flavonoids</b> 486:5 <b>flavor</b> 124:8 205:17 <b>flavored</b> 151:7 <b>flaws</b> 38:19 <b>flea</b> 62:20 <b>flexibility</b> 437:12 <b>flexible</b> 305:3 <b>flight</b> 472:22 <b>flooded</b> 246:10 <b>florida</b> 9:18 333:15 478:16 <b>flour</b> 45:15 <b>flourish</b> 377:2 <b>flout</b> 355:14 <b>flow</b> 20:19 <b>flower</b> 257:9 282:19,20 284:19 285:4,5,15,17,19 286:4,8,10,11,16 287:1 334:6 411:18 432:17,18
---	---	---	--

<b>flowering</b> 285:22	354:18 355:16	271:18 272:19,19	<b>forbes</b> 46:12
<b>flowing</b> 327:15	372:6 480:12	273:5 290:3,4	<b>forbid</b> 291:17
<b>fluoro</b> 207:9,11	<b>followed</b> 299:8	305:13 306:14,22	<b>force</b> 120:2 234:20
<b>flying</b> 461:17	362:20 439:2	313:11 323:1,4,19	<b>forced</b> 127:18
<b>fmi</b> 155:6	<b>following</b> 47:5	323:20 324:4	229:10 287:6
<b>focus</b> 52:14 86:15	53:19 112:18	325:6,15 327:3,15	<b>foregoing</b> 172:21
99:5 138:5 173:21	173:11 227:2,3	328:8,10,16,17	282:1 373:1
184:4,5 205:22	300:18 301:17	337:11,17 342:10	501:10 502:3
218:5,6 253:7,10	310:19 314:17	342:13,15,22	503:4
264:8 350:15	344:8 434:4 499:4	361:15 363:20	<b>foreign</b> 285:5
357:9 379:14,18	499:19	365:1 367:11,20	<b>foreigners</b> 297:15
383:19 387:19	<b>food</b> 1:1,2,16 2:4,9	368:12,16,18,21	<b>foremost</b> 153:16
394:1 467:9	2:13,17,21 3:5,9	369:8 371:3,5	234:9 338:8 345:9
<b>focused</b> 34:1	3:13,17,21 4:5,7	391:19 392:7	<b>forensic</b> 204:17,19
60:15 78:4 122:11	4:11 9:12 20:3	394:20 396:1	335:21
131:1 183:9	21:12 27:18 30:14	398:6,10,21 416:3	<b>foresaw</b> 436:6
220:16 236:2	30:18 31:1,2,8,20	416:22 417:7	<b>foresight</b> 119:5
264:6 303:10	31:22 32:9,13,22	419:17 420:3,6	<b>forever</b> 374:21
309:6 348:7 363:4	33:12 34:7 44:11	421:5,21 426:18	460:5
408:14 412:7	44:15 48:10 52:18	428:20 433:2,3,3	<b>forget</b> 251:13
462:13,17 463:17	64:10,10 66:3,7	435:6,17 436:4,21	412:21
<b>focuses</b> 93:15	81:20 88:6,14	440:20,22 478:17	<b>forgive</b> 377:16
160:15 205:19	89:16 97:18 105:6	486:13,13 497:3	<b>form</b> 24:10 33:2
467:7	105:9,11,15,17,22	<b>foodborne</b> 367:2	62:8 118:2 203:15
<b>focusing</b> 45:13	106:1,2,12,15,16	367:12	249:6 320:6
150:18 393:21	106:19,21,22	<b>foods</b> 3:8 30:22	330:10 388:1
467:9	107:14 114:11,15	31:14 33:10 47:10	403:13 426:12
<b>fog</b> 80:8	116:2,6,8 117:16	48:14 53:21 99:1	450:6 471:20
<b>folium</b> 17:3 496:1	117:18,21 118:4,6	112:1,9,17,22	<b>formal</b> 10:5 18:17
496:6 498:7	118:7 120:9 129:1	113:8,15 116:4	18:19 20:16
499:12	143:17 145:11,14	128:16 151:3	107:15 113:6
<b>folks</b> 126:14	146:2,22 147:5	152:7 154:7	156:1 176:15,18
169:11 243:8	151:16 152:1,15	159:11 164:21,21	214:6 338:1
245:6 275:19	153:8,12 156:4,6	269:3 272:15	386:21 444:1
276:17 399:4	156:7,13 157:5,8	304:19 313:5	501:3
470:5	157:13 159:6,21	315:16 323:9,17	<b>formally</b> 128:18
<b>follow</b> 75:7 77:3	160:3,15,16 162:6	342:9 352:15	<b>formation</b> 58:13
80:12 95:7 121:2	167:6,15 169:1,3	370:5 415:3	85:8 123:10
141:11 152:19	169:18 170:22	416:11 433:14	<b>formed</b> 35:1
197:2 234:1 251:9	171:3,11,13	435:10 450:19	107:12 427:11
257:19 309:15	177:12 223:15	497:16	<b>former</b> 95:16
313:5 314:5	227:21 235:16,20	<b>forage</b> 45:15	117:8 373:10
316:12 319:1	238:9 241:15,21	171:22	429:18,20 432:7
339:6 352:13	257:12 269:14		

<b>forming</b> 44:10 123:1	466:12 474:3 490:10 493:14	297:10 299:1 318:18 352:14	<b>freely</b> 380:2
<b>forms</b> 42:2 77:8 208:8 317:18	498:22 500:14,14	402:16 414:1 417:16,16 465:1	<b>french</b> 15:4 400:10,11,13 405:18
338:21 371:7 373:17 389:3	<b>foster</b> 401:1	<b>fourth</b> 92:7 109:21 190:7	<b>frenzy</b> 382:4
403:19 405:14,16 405:20 425:4	<b>fostering</b> 47:21	414:17	<b>frequencies</b> 198:18
437:14 488:17	<b>fought</b> 458:7	<b>fox</b> 15:15 419:11 419:20	<b>frequency</b> 199:3,4 199:22 454:15
<b>formulary</b> 331:15	<b>found</b> 30:4 31:18 44:7 49:4 92:2	<b>framework</b> 33:13 48:16 52:15 89:10	<b>frequent</b> 51:1 57:4 215:19
<b>formulate</b> 351:3	104:20 107:18 109:20 126:7	90:17 91:3 94:12 108:2 117:14	<b>frequently</b> 76:7 157:9 202:10 454:20
<b>formulated</b> 334:3 334:12 337:22	140:9 151:12 153:1 154:13	145:19 154:21 162:7 163:6,12	<b>fresh</b> 280:2,9
<b>formulation</b> 33:2 143:5 319:5	171:8,8 174:7 175:14 186:13	165:9,19 194:8 196:11,14 304:14	<b>freshleaf</b> 276:15 279:20
334:19	187:2 194:5 206:16 207:8,9	307:1 322:6 325:2 331:10 332:14	<b>friction</b> 494:21 495:8
<b>forth</b> 149:11 185:1 186:21 241:7	209:6 211:11 212:6,18 213:8	338:8 341:18 372:1 438:12	<b>frictions</b> 89:2
269:2 368:8	237:20 238:3 248:4 260:8	445:14 477:1 480:21 493:15	<b>friday</b> 1:14
<b>forthcoming</b> 414:4	278:15 296:16 306:12,17 386:7	<b>frameworks</b> 88:3 88:17 478:13	<b>friend</b> 211:10 239:4
<b>forthwith</b> 68:10	349:14 440:3 471:14 474:19	<b>frank</b> 127:2,2 328:16	<b>friendly</b> 424:1
<b>fortunate</b> 60:13	475:3,9 483:20	<b>frankly</b> 206:18 308:3 313:1	<b>friends</b> 39:4 125:13 127:6 276:2
<b>fortunately</b> 105:7	<b>foundation</b> 8:10 14:19 15:5 129:22	316:13	<b>frightening</b> 382:8
<b>fortune</b> 342:13 430:20	163:3 384:2,10,13 385:2 386:11	<b>fraud</b> 192:3	<b>front</b> 5:7 23:22 50:6,9,13 354:19
<b>forty</b> 335:10	400:10,15,20 404:19 449:7	<b>fraudulent</b> 76:22 188:15	<b>fronts</b> 377:3
<b>forum</b> 393:5	<b>foundations</b> 96:2	<b>free</b> 16:15 62:20 131:14 239:17,18	<b>fruit</b> 151:4
<b>forward</b> 74:9 77:1 80:10 100:13,16	<b>founded</b> 42:17 77:22 78:16	239:20,21 240:1 286:5,6 305:17	<b>frustrate</b> 304:5
101:15,16 105:8 152:14 155:12,16	<b>founder</b> 50:9 53:11 81:8 125:10	306:1 310:4 327:15 362:3,5	<b>frustrated</b> 96:17
155:17 157:18 161:2,17 166:7	294:1 347:14 447:9	366:17,17,18,19 375:16 424:15	<b>frustrating</b> 423:17
184:19 195:22 204:4 217:20	<b>founders</b> 361:20	467:5	<b>frustration</b> 423:11 459:3
219:8 268:4 282:12 291:20	<b>four</b> 39:13 76:6 77:5 78:6 96:4	<b>freedom</b> 253:4 287:11	<b>frye</b> 261:12
293:6,16 295:17 321:1 325:10	191:8,9 248:8 249:19 250:9		<b>fsma</b> 146:22 343:4 363:20 372:7
326:9 337:8 356:10 365:21	279:12 283:1		<b>fsvp</b> 147:1
387:1 429:3,10 433:21 456:11			<b>ftc</b> 269:2
			<b>fubinaca</b> 206:17

<b>fuchsia</b> 342:9 343:19	263:15 482:6	<b>gain</b> 317:22 483:7 483:8	<b>generally</b> 30:1,21 31:3 32:21 51:19
<b>fuel</b> 426:15	<b>fundamentally</b> 72:22	<b>gained</b> 275:15	120:14 133:7
<b>fulfill</b> 146:19	<b>funded</b> 204:21	<b>galvanizing</b> 307:7	145:10 151:13
<b>fulfilling</b> 500:19	451:13 483:21	<b>gambling</b> 382:2	167:7 205:8
<b>fulfillment</b> 497:12	484:4 485:14,19	412:13,16	206:12 217:14
<b>full</b> 12:21 67:19	<b>funding</b> 393:17	<b>gamma</b> 488:15	400:4 422:5
68:5,17,19 69:2	397:17 451:15	490:16 495:11	479:22 486:8,17
96:12 108:22	471:20 475:8	<b>gap</b> 8:9 129:22	<b>generated</b> 50:15
113:11 148:13,17	<b>funds</b> 147:21	272:5 295:13	230:5 439:21
148:22 149:1	<b>fungi</b> 330:10	<b>gaps</b> 34:20 35:2	<b>generating</b> 52:5
155:1 228:21	<b>fungicides</b> 331:22	65:5 177:1 270:1	<b>generation</b> 473:2
229:16 234:2,6,7	<b>further</b> 65:16	386:18 455:13	473:6 475:17
242:12 275:8	85:12 112:15	<b>garcia</b> 7:8 95:14	<b>generations</b>
276:13 277:8,14	117:10 131:7,9	95:15,16	248:18
279:9 292:16	137:11 152:8	<b>garrett</b> 15:8 413:8	<b>generic</b> 351:17
294:1,7 303:22	157:7,10 184:16	413:10,14	352:3 449:1,4
305:19 306:18	203:8,18 204:1,2	<b>gas</b> 62:19 189:22	<b>generics</b> 449:11
307:17 308:5,8,10	204:6 217:19	<b>gastaut</b> 140:19	<b>genetic</b> 92:22
310:5,9 324:7	338:8 361:1	338:21 447:19	130:3 497:11
366:13 370:16	363:16 371:6	449:7	<b>genie</b> 120:1
372:2 377:2	386:21 389:7	<b>gastric</b> 389:6	<b>genotype</b> 267:13
417:17 418:8,9,12	475:9,11 488:2	<b>gastroparesis</b>	<b>gentleman</b> 210:16
424:11 428:3	489:15 492:6	389:6	233:17
486:4	493:6 502:10	<b>gateway</b> 374:17	<b>gentlemen</b> 120:1
<b>fully</b> 36:18 78:14	503:9	<b>gather</b> 90:16	127:11 200:14
84:7 112:13	<b>furtherance</b>	195:22 218:8	293:22
319:16 322:3	329:12	220:8 386:11	<b>georgia</b> 311:6
487:13,16,21	<b>furthermore</b>	<b>gathering</b> 219:6	<b>geriatric</b> 138:7
<b>fun</b> 248:22 250:10	135:21 202:12	<b>geffrey</b> 360:7	<b>getting</b> 58:3 62:20
<b>function</b> 29:22	397:14 452:4	<b>gel</b> 328:3	63:4 74:2 75:13
67:17 71:14 86:6	<b>future</b> 135:4	<b>genco</b> 12:19	128:22 142:7
86:7 121:15 175:1	152:18 160:14	287:22	148:13,14 169:4
177:14 270:7	162:20 219:8	<b>gene</b> 202:14	183:3 238:21
273:14 281:14,15	272:7 355:14	<b>general</b> 22:16	249:18 285:22
300:18 339:20	363:2 375:8 376:4	115:21 169:14	336:14 396:3,5
392:1	377:10 383:19	197:12 198:20	399:4 402:11
<b>functional</b> 74:13	408:8 493:17	199:5 228:2,7,9	459:13 484:12
116:2 435:6	500:14	238:15 258:18	<b>gfsi</b> 363:20
<b>functioning</b> 223:5	<b>g</b>	300:8 361:4	<b>gi</b> 224:8 270:7
<b>fund</b> 214:14	<b>g</b> 20:1 86:5 120:11	438:16 440:1	<b>giancaspro</b> 7:10
412:15	302:16 469:13	443:7 496:6	98:10,11,12 101:4
<b>fundamental</b>	<b>gabriel</b> 7:10 98:10	<b>generalinquiries</b>	101:8
259:22 262:18	98:12	169:12	

<b>gidal</b> 10:7 176:17 176:20,20	<b>glimpse</b> 365:19	317:6 344:22	289:11,13,15,16
<b>gifts</b> 127:15	<b>global</b> 268:14	346:3 352:18	289:16 290:5
<b>gill</b> 11:20 245:17	305:12 467:13	358:7 375:21	291:13,16,19
245:18,18 251:4	497:14	379:16 390:15	292:1 295:2
252:13	<b>globally</b> 73:13	400:20 403:1	296:18 316:6
<b>girl</b> 457:22 458:11	233:20 334:19	407:9,10 433:21	321:18 334:2
459:11 461:19	427:7	447:1 454:17	335:1,2 343:14,15
<b>gitto</b> 15:6 406:18	<b>glorifying</b> 375:15	455:20 468:10	343:16,16,18,20
406:19,20 412:19	<b>glucosamine</b> 65:3	473:11,15 475:12	344:10,18,21
413:1,3	<b>gluten</b> 239:19,21	497:22 499:21	345:14,14,17,19
<b>give</b> 44:12 45:2	<b>glycerin</b> 205:16	<b>goal</b> 45:12 88:11	346:10,17,17,18
74:15 128:8,10	<b>glycol</b> 205:15	112:16 123:7	346:21 357:9
148:7 162:17,22	<b>gma</b> 87:17 88:2	253:18 318:3	358:7 361:21
181:19 224:6	90:15	326:5 386:13	364:14 372:21
225:14 241:4	<b>gmp</b> 196:14	423:22 462:18	379:13 392:19
242:18,19 259:21	222:18 285:21	<b>goals</b> 30:16 118:8	393:4 395:11
282:3 363:6	286:5 315:18	146:8	402:5 405:20
364:14 392:17	319:12 325:22	<b>god</b> 289:4 291:17	407:2,9 418:4
394:3 402:5 424:6	333:16 343:5	<b>god's</b> 127:15	420:16 422:18
430:9 432:21	348:15 349:15	<b>goes</b> 58:3 232:8	423:6 430:8
434:4 439:17	351:13 416:6	347:17 443:19	434:16 440:15
443:22 447:13	438:15 478:17	500:1	451:12 470:9
458:7 498:9	<b>gmps</b> 159:21	<b>goggle</b> 472:2	475:16 498:8
<b>given</b> 33:14 37:5	194:10 218:7	<b>going</b> 36:22 66:7,8	499:14,15 500:14
39:1,5 41:16 46:6	337:10 348:17	102:20 118:11	<b>goldberg</b> 3:2 22:6
51:15 65:4 71:6	349:12 416:10	122:4 123:6	22:7 175:4
79:14 89:15 123:2	<b>gnatt</b> 2:18	127:10 130:17	<b>goldilocks</b> 305:1
141:12 155:9	<b>go</b> 22:16 24:18	132:12 135:10	<b>goldstein</b> 261:19
160:10 198:9	36:12 57:14 66:7	150:10 158:7,13	<b>good</b> 21:3,7,10,20
242:21 252:11	104:4 126:22	163:8 166:10	22:1,6,9 26:14
271:1 319:3 359:2	135:10 141:2,6,10	167:16 172:17	37:17 42:16 45:7
407:22 441:3	149:16 178:15	185:5 209:18	47:19 53:22 56:10
482:1 496:19,20	179:6,17 183:15	213:16 219:8	59:16 61:15 63:18
<b>gives</b> 287:12	223:7 227:4,5	222:20 231:20	64:6 70:20 74:6
421:13 432:16	229:15 230:2	241:10 242:20	77:20 81:2,7
<b>giving</b> 49:13 345:3	236:8,9 242:1	243:17,18 244:5,9	87:15 95:15 98:11
422:22 425:17	244:18 254:7	244:9 245:10,11	101:22 104:16
459:10 461:18	259:7 265:16	253:19,20,21	107:5 111:10
462:11	275:20 282:12	254:7,9 255:11	119:2 122:9 125:9
<b>glass</b> 450:9	284:22 288:2	256:3,14,15 257:3	129:12 135:14
<b>glaucoma</b> 474:3,7	292:4 293:15	257:4 258:19	137:12,16,16
474:7	295:10 297:11,13	260:1 274:3	145:2 147:11
	297:18 308:22	281:19,21 282:11	150:13 153:9
	309:11 312:15	288:21,21,22	156:3 166:14

173:8 176:20 188:1 192:7,11 196:2 204:10 210:1 221:14 223:12 234:19 235:4 244:17 246:14 252:21 254:5 255:11 268:12 277:12 282:7 284:13 286:14 293:21 303:16 305:11 311:2 319:16 321:20 328:22 331:13 332:21 335:14 338:5 350:6 353:9 356:20 361:12 366:6 368:15,21 369:12 378:18 383:9 391:1 395:6 395:8 400:11 406:19 407:1 413:11 414:7 419:12,13 421:16 422:15 425:14 429:14 435:3 457:2 461:8,21 467:3 471:13 475:20 476:7 487:3 499:1 <b>goods</b> 87:18 253:9 255:7 338:15 362:9 468:9 471:3 <b>gotten</b> 243:11 284:11 327:1 336:8 <b>gottlieb</b> 97:10 117:8 162:13 <b>gottlieb's</b> 433:12 <b>gourmet</b> 53:11 <b>governance</b> 486:20	<b>governing</b> 306:14 332:11 369:13 <b>government</b> 4:20 9:14 11:11 18:9 18:18,21 42:15 56:22 63:10 80:16 109:7 133:4 155:20 156:2 160:19 165:8 166:18,19 175:16 175:17 227:16 241:22 242:16 244:12,15 265:8 265:11 268:1 283:7 294:8 312:20 345:10 346:6 369:4 386:21 440:13 <b>governments</b> 52:6 157:21 <b>grade</b> 152:3 373:14 404:3 490:12,14 <b>graff</b> 15:8 413:8 413:10,11,14 <b>graham</b> 503:2,15 <b>grains</b> 171:20 <b>grandchildren</b> 209:4 <b>grandmothers</b> 82:9 <b>grandparents</b> 483:10 <b>grant</b> 10:9 181:17 181:18,21,22 186:2,14 187:6,11 <b>granted</b> 93:6 319:9 <b>grants</b> 482:2 <b>graph</b> 179:11 <b>gras</b> 31:4,11,12 44:12 102:17 103:16 104:1,5 152:6 153:4 167:8	218:2 273:11 323:18 356:6 <b>grasp</b> 268:4 <b>grassroots</b> 48:4 <b>grateful</b> 259:8 460:5 <b>gray</b> 229:3 290:8 291:10 292:3 <b>great</b> 24:8,14 44:5 48:17 60:20 68:14 80:8 98:9 115:17 125:7 137:9 142:16 144:20 153:6 161:9 165:10,12 172:15 175:21 187:10 220:11 236:16 243:2 246:8 254:22 255:1 274:13 384:4,7 389:3 392:17 414:9 415:12,21 418:15 432:12 481:17 488:13 495:15 <b>greater</b> 41:1 65:19 190:20 212:3 319:2 335:3 339:5 456:15 <b>greatest</b> 127:15 131:6 383:6 <b>greatly</b> 110:21 466:18 <b>greed</b> 127:17 485:15 <b>green</b> 13:9 25:9 95:19 317:10,15 319:8 320:1 385:19 <b>green's</b> 317:14 <b>greenhouses</b> 162:1 <b>greenwich</b> 13:17 457:3	<b>grew</b> 333:9 458:12 <b>grocery</b> 7:3 87:17 96:19 153:14 <b>groom</b> 375:8 <b>gross</b> 43:14 259:15 <b>grossly</b> 242:16 <b>ground</b> 312:10 <b>grounded</b> 435:21 <b>grounds</b> 75:18 <b>group</b> 8:3 14:3 15:9 20:14 21:6,9 21:14,19 35:2,4 45:9 47:8 60:7 70:17 111:7 119:4 124:21 145:7 180:3 253:2,3 268:20 294:5 353:11,13 354:18 360:9 385:10 387:19 394:6 413:15 420:13 421:8 <b>groups</b> 62:2 145:21 410:18 420:22 452:15 453:5 <b>grow</b> 7:9 44:1 74:5 91:1 95:17 116:11 119:9 153:20 229:5 290:14 307:5 316:14 <b>grower</b> 369:12 486:13 <b>growers</b> 49:18 161:20 233:7 284:4,7 286:15 <b>growing</b> 38:2 49:5 116:18 154:11 161:1,19 170:12 252:15 297:21 302:18
--	--	--	---

<b>grown</b> 40:13 45:15 46:19 146:11 161:22 162:1 403:14 427:16	218:21 265:13 266:10 272:9 314:5,17 331:3,15 349:15 350:13,14 351:13 353:3 363:9 364:10 366:16 369:20 370:8 372:7 394:15 411:11 425:5	250:11,12 251:16 260:13 275:1 281:7 <b>halfway</b> 282:8 <b>hallucinating</b> 209:7 <b>hallucinations</b> 206:10 209:17 374:21 <b>hammer</b> 14:11 366:8,10,15,19 369:1 370:7 372:4 <b>hampshire</b> 1:18 <b>hand</b> 23:18 38:19 92:3 361:21 379:17,17 433:9,9 475:7	403:1 495:2 <b>happiness</b> 482:4 <b>happy</b> 217:15 399:17 434:20 <b>harbor</b> 397:2 <b>hard</b> 57:15 74:15 121:21 127:5 206:21 212:13 321:19 334:6 360:10 430:11 <b>harken</b> 178:8 <b>harm</b> 39:8 99:17 100:15 123:21 160:15 173:20 257:6,14 277:4 387:18 <b>harmed</b> 375:3 <b>harmful</b> 46:14 59:12 60:1 99:21 257:17 374:20 410:11 468:11 490:17 <b>harming</b> 42:10 373:15 <b>harmonization</b> 331:14 <b>harmony</b> 498:2 <b>harms</b> 58:5 60:13 <b>harness</b> 127:22 <b>harpc</b> 343:3 <b>harry</b> 487:5 <b>harsh</b> 131:14 <b>harvard</b> 17:5 26:10 173:22 <b>harvest</b> 229:7 <b>harvested</b> 43:16 <b>harvesting</b> 497:11 <b>hassan</b> 59:1 <b>hassel</b> 5:18 59:2,4 59:4 61:7 <b>hauser</b> 15:10 476:6,7 481:15 <b>hazard</b> 428:6
<b>growth</b> 43:22 119:13,22 163:19 230:22 233:8 305:4 307:8 492:20	<b>guiding</b> 222:9 307:8 328:1	<b>hand</b> 23:18 38:19 92:3 361:21 379:17,17 433:9,9 475:7	
<b>grubb</b> 13:6 311:1 311:2 316:3,13	<b>guiding</b> 222:9 307:8 328:1	<b>handicapped</b> 295:14 472:8	
<b>gruesome</b> 459:1	<b>gulf</b> 67:3	<b>handle</b> 150:12 289:10 418:6 448:13	
<b>guarantee</b> 312:22	<b>gummies</b> 96:21 164:22	<b>handling</b> 427:22	
<b>guaranteeing</b> 319:13	<b>gummy</b> 34:18 341:8,9 469:13,14	<b>hands</b> 128:1 148:3 296:22	
<b>guess</b> 9:7 55:12 147:9,11,12 150:4 150:8 199:14,18 326:16 341:3 400:19 405:15 447:7	<b>gurley</b> 10:12 187:13,14,19 188:3 192:18 193:10	<b>haney</b> 220:18 224:2	
<b>guests</b> 361:13	<b>guthrie</b> 12:10 268:10,12,13 274:2,11	<b>hang</b> 246:1	
<b>guidance</b> 49:18 74:3 83:21 105:1 108:8 113:5 121:12 130:19 163:16 166:2 239:19 323:14 324:13 331:12 337:9 363:19 371:14 381:8 386:21 413:20 414:2 419:4 421:1 423:7 424:3,6 427:14	<b>guy</b> 13:2 127:5 298:10,22	<b>hanging</b> 151:4	
<b>guide</b> 25:8 146:1 241:5 386:20 411:6	<b>guys</b> 56:10 187:19 214:17 244:3 249:14 287:21 291:3,3,14 292:2 292:20 308:22 321:18 346:10 409:8 410:3 486:18 498:16	<b>happen</b> 39:7 377:17 383:14 398:1 406:3	
<b>guided</b> 486:17	<b>gw</b> 338:6 339:3 340:5,5 358:18	<b>happened</b> 62:13 136:15 149:20 336:10 423:3,20 500:9	
<b>guideline</b> 56:4,7 315:6	<b>h</b>	<b>happening</b> 183:4 246:21,22 255:8 397:13 420:13,18 423:4 441:19 475:15 495:8	
<b>guidelines</b> 39:5 53:19 95:7 120:10	<b>h</b> 16:9 <b>habit</b> 123:1 <b>haccp</b> 147:1 343:3 <b>halal</b> 343:1 <b>haley's</b> 403:13 <b>half</b> 59:8 116:16 159:17 246:9	<b>happens</b> 34:18 160:16 234:16 238:18 292:9	



<b>hazards</b> 60:6	282:9 296:1 314:2	275:2 278:18	428:15 443:3
<b>head</b> 92:11 282:16	329:13 332:10,17	326:19 334:22	480:8
355:15 375:12	344:12,14 353:11	358:8 396:9	<b>heightened</b> 489:9
<b>headache</b> 70:9	353:13,19 354:18	397:21 402:3	<b>heinous</b> 260:14
139:2	358:6 361:8 365:7	406:4 408:19	<b>held</b> 132:5 148:3
<b>headaches</b> 261:16	366:21 367:4,4,8	410:1 447:20	329:14 438:11
275:18 301:2	368:10 370:1	448:2,2,14,21	<b>heldreth</b> 9:9
<b>headlines</b> 208:3	382:2 386:19	468:12 470:13	150:10,12,13
<b>headquarters</b>	393:17 397:19	472:10 489:2	153:3
347:19	399:16 400:21	492:6 497:10,14	<b>hello</b> 66:22 72:13
<b>health</b> 5:17 7:13	407:13,22 408:10	498:14,15	245:18 259:7
12:5 14:3 17:5,5	409:19 415:22	<b>hearing</b> 1:11 20:6	274:16 303:8
18:11 19:3 26:4	433:20 440:2	20:9,13 22:18	317:6 406:19
29:10 30:17 35:11	451:20 452:2	23:5,8,9 24:1	<b>help</b> 24:11,16 25:4
38:11 42:10 49:2	455:2 456:1,7,8,8	26:16 35:3 36:8	27:7 30:18 33:5
51:16 54:6 58:18	456:10 461:3,17	42:21 72:19 119:4	34:22 36:7 39:8
58:20 59:9,12,17	468:7,20 471:2,6	148:11 150:17	47:14 49:19 50:1
60:6,6,21 61:3	472:19 473:12	156:10 164:4	97:9,16 99:7,10
62:3 65:4 68:3	477:5 484:4 487:6	166:4 187:16	99:14,16,19
71:16,20 72:22	493:16	209:5 290:16	100:15,15 110:3
78:16 79:1,10,19	<b>healthcare</b> 6:13	329:5 361:17	128:19 129:1
80:1 88:18 90:7	57:20 76:1,3	379:17 381:21	130:17 139:9
94:3 98:21,21	136:1 181:14	383:8,19 405:14	151:20 197:6
99:11 100:7	192:22 461:12	457:12 501:8	208:10 214:16
101:21 102:1	500:3,4	<b>hearings</b> 22:20	249:2,4 252:17
104:21 108:7	<b>healthier</b> 46:19,20	<b>heart</b> 150:16	266:9 286:13
110:3 122:16,20	46:21	300:19 351:5	288:8 294:22
124:1,11 126:13	<b>healthy</b> 215:17,18	472:22	297:7,22 317:22
127:16,22 137:2	272:15 325:7	<b>heartrate</b> 271:16	355:20 387:4,6
138:5 145:17	359:8 364:19	<b>heat</b> 491:6	391:17 427:1
146:20 156:22	388:17 398:11	<b>heated</b> 124:10	432:10 446:15
157:16 160:7,7	399:5	<b>heather</b> 16:12	466:13
165:2 173:19	<b>hear</b> 20:10 91:10	462:8,12	<b>helped</b> 250:7,11
174:9,12 175:13	96:8,15 103:1	<b>heavily</b> 303:12	277:2 432:4
180:8 187:4 189:1	129:9 181:21	343:6,6 412:12	<b>helpful</b> 69:12 87:7
192:3 196:13,13	187:22 246:16	<b>heavy</b> 60:10,11	105:1 219:7
198:11 214:1	252:6 298:14,18	70:1 72:4 103:1	243:14 246:18
221:21 223:8	384:3 398:8,8	234:14 237:17	249:22 256:14
225:6,11 244:13	435:7 448:19	278:18 306:13	352:20 387:7
245:19 247:5	473:20,22 474:21	312:8 319:19	421:2 424:5 425:3
253:9 256:21	496:22 497:1,5,8	330:10,14 336:2	486:10
259:3,5,18 260:14	<b>heard</b> 58:10 128:8	345:18 352:6	<b>helping</b> 67:4
265:22 266:1	129:11 166:5	358:1 362:6 364:4	260:13 384:21
268:14 273:8,13	171:18 234:2	372:12 417:5	413:19 495:21

<b>helpline</b> 193:13 197:11	226:12 233:7,7,8 233:13,14 240:8	<b>hepatotoxicity</b> 203:19 360:9 397:7 398:13	423:14 429:6 453:7,8 454:1 455:8,9,15 456:1 465:9 474:22 483:19 487:22 488:5 492:18
<b>helps</b> 79:22 186:7 479:15	273:2,17 295:22 303:11 304:5	<b>herbal</b> 7:19 98:13 111:8,12 123:11 205:20 463:12,13	<b>higher</b> 75:2 109:6 115:10 152:22 200:10 213:4,7 251:5 271:9 299:20,22 301:10 363:17 365:12 371:14 390:9,10 410:5 418:21 456:2 470:18
<b>hemoc</b> 334:8	308:4 316:14	<b>herbicides</b> 331:21	<b>highest</b> 132:5 238:8 364:13 366:1,20 377:7
<b>hemorrhage</b> 203:8	321:22 322:19,21	<b>hereto</b> 502:12 503:11	<b>highlight</b> 209:1 210:2 212:10 379:19
<b>hemp</b> 4:22 5:3,5 28:19,22 29:2 31:13 34:4 42:18 42:20 43:2,13,16 43:16,19 44:2,4 44:11,16 45:1,6,8 45:12 46:5,18 47:9,17,19,20 48:3,4,13,18 49:7 49:11,14,19,20 50:11 53:13,15 54:18 67:1,4,19 68:6,18,21 71:3 76:10,18 78:5,7 78:14 79:8,11,19 81:12 82:2,14,15 82:19,21 83:1 84:14 96:10,13 102:9,10,13,15 103:5,9,10,11,11 103:14 105:8,17 105:19 106:4 107:22 111:17,17 112:3,15 116:10 116:14 119:18 132:18 145:10,20 146:10,18 147:5 147:15 151:3,6,7 151:8,15,22 152:15 153:1,19 153:19 155:8,8 160:20 161:1,19 165:22 168:10,17 168:17,18 169:1,4 170:6,12,14,17,18 170:18 171:19 210:8,12,18 211:6 211:7 214:1	323:1,2,4,6,15,18 323:20 324:7,13 324:20 325:12,14 325:15,16 326:5,7 327:5,6,7,18 334:16,16 347:15 348:4 351:20 352:6 353:14,14 354:1,3,13 355:6 355:10 356:7,10 357:1,16,19 362:4 362:14,17,20 363:3 364:18 366:11 367:17 368:2,4,11,12,13 368:19 369:3,7,9 369:16,20 370:6 371:4,18 392:6 393:8,9,10,13,19 394:2,20 395:22 412:1,2 413:17 414:15 415:1,11 415:19 416:1,10 416:15 417:4,10 417:17,18,20,21 418:13 424:13,13 427:18 428:18,19 433:1,7 440:19,19 469:6 479:6 486:4 488:3,8 489:19	<b>heroin</b> 174:7 374:16 <b>hey</b> 248:19 250:19 252:20 276:18 293:2 <b>hhe</b> 396:15 397:1 398:1 <b>hi</b> 40:3 129:20 135:14 157:20 173:8 235:12 287:21 298:12,15 321:14 384:3 399:18 451:6 476:7 481:11 <b>hia</b> 49:16 <b>high</b> 13:21 45:20 46:2 49:12 50:11 51:9 61:1 68:5 82:21 107:22 124:5 175:6 184:15 201:19 202:4,15 206:6,10 206:21 207:6 208:21 209:11 212:16 215:5 230:6 243:3 271:5 276:9 283:20 304:14 317:20 325:14 333:17 334:19 347:14,14 362:11 365:11 366:16 375:6,10 375:13 376:18,19 390:13,17 396:4 401:22 407:2	<b>history</b> 43:8 54:20 72:18 247:4 332:10 391:19 408:1,3 426:19 500:7
<b>hempseeds</b> 45:13	<b>hepatic</b> 270:22 272:10,17	<b>hepatocellular</b> 175:1 201:9,10	<b>hire</b> 383:3 <b>hired</b> 464:1 <b>histomorphologi...</b> 202:2 <b>historian</b> 173:9 <b>historic</b> 72:17 124:12
<b>hepato</b> 360:4	<b>hepatotoxic</b> 139:5 142:2		

<b>hit</b> 44:3 52:5 102:19 288:15 295:17 297:14 390:16 <b>hits</b> 238:11 <b>hiv</b> 224:4 <b>hmm</b> 280:8 <b>hoban</b> 15:9 413:15 <b>hold</b> 38:4 149:14 149:17 267:17 295:17 354:9 <b>holding</b> 42:21 88:7 457:19 <b>holdings</b> 15:21 <b>holds</b> 408:9 467:11 <b>holistic</b> 73:2 <b>holistically</b> 325:1 <b>hollister</b> 359:10 <b>holmes</b> 70:17 <b>holyoke</b> 5:19 59:2 <b>home</b> 43:8 92:9 107:20 108:15 109:5,21 243:18 373:12 374:3 389:14 486:12 499:8 <b>homeland</b> 342:22 <b>homeostasis</b> 485:9 <b>homes</b> 375:22 377:18 467:21 <b>hometown</b> 467:20 <b>homogeneity</b> 466:1 <b>honest</b> 72:19 199:6 <b>honor</b> 81:9 200:15 361:14 <b>honorably</b> 288:6 <b>honored</b> 429:15 <b>honors</b> 429:19 <b>hope</b> 36:6 44:6,7 143:6 152:13 178:16 197:3	285:7,11,20 338:19 365:17 377:21,21 403:13 471:16 <b>hoped</b> 63:9 <b>hopeful</b> 157:14 <b>hopefully</b> 37:4 173:4 228:10 251:9 <b>hoping</b> 124:17 293:15 <b>hopkins</b> 4:18 11:3 11:8 40:1,5,6 210:4 211:15 <b>hops</b> 151:10,12 <b>horizon</b> 63:8 <b>horrible</b> 260:15 405:3 448:9 <b>horribly</b> 406:11 <b>horror</b> 473:5 <b>horses</b> 64:18 83:15 84:18 86:16 171:10 <b>hospital</b> 92:3 <b>hospitalized</b> 374:1 374:4 <b>hosting</b> 119:4 160:12 361:17 <b>hot</b> 418:2 <b>hotel</b> 417:7 <b>hour</b> 306:5 318:19 <b>hours</b> 20:16 41:8 173:21 223:17 275:16 298:3,5 299:16 318:19 <b>house</b> 92:9,10 254:13 348:20 349:18 370:20 377:21 <b>housed</b> 490:13 <b>household</b> 88:6,15 152:7 252:17 <b>houser</b> 476:8	<b>houston</b> 264:3 373:11 <b>howard</b> 7:12 16:20 101:20,22 102:1 103:7,19 104:9 242:8 <b>hpp</b> 343:2 345:6,7 345:9 <b>huge</b> 52:10 71:17 156:12 <b>hugely</b> 122:14 <b>hugh</b> 174:9 175:12 <b>human</b> 31:14,21 50:14 64:3 66:3 71:5,14 126:10,13 136:11,14 146:18 154:10 174:6,10 193:1 197:7,9 202:10 259:14,17 259:18 271:14 357:9 360:12 369:11 371:3 390:1 397:11 474:18 482:7 484:5 489:3 <b>humans</b> 54:6 67:22 145:13 202:7 211:1 358:16 475:15 <b>humble</b> 327:4 <b>humectants</b> 205:14 <b>humidity</b> 315:10 <b>hundred</b> 27:1 74:20 107:12 162:4 221:22 289:11 300:3,12 418:3 453:21 <b>hundreds</b> 22:17 54:13 290:21 431:17 <b>hung</b> 376:3 <b>hunter</b> 5:2 45:6,7	<b>huntington</b> 359:12 <b>hurdles</b> 94:19 150:22 283:5 <b>hurry</b> 297:10 <b>hurt</b> 376:4 <b>hurts</b> 58:7 <b>husband</b> 96:4 375:1 457:9 <b>hydrocarbons</b> 465:6 <b>hydrogen</b> 59:19 <b>hydrogenate</b> 232:15 <b>hydrogenated</b> 230:21 235:3 <b>hydrogenating</b> 234:21 <b>hydrogenation</b> 230:10,17,18 233:2 234:5,17,18 234:20 <b>hygiene</b> 487:7 <b>hyperemesis</b> 173:15 <b>hypertensive</b> 280:21 <b>hypotension</b> 388:10 <b>hypoxic</b> 269:9
			<b>i</b>
			<b>ian</b> 129:17,17 <b>iceberg</b> 203:22 <b>ich</b> 314:5,17 315:5 <b>idea</b> 56:10 123:17 158:8 184:15 185:2 207:18 225:9 253:19 255:3 257:6 266:7 285:12 286:4,7 288:7 352:17 355:19 386:20 448:20 467:22 468:1,16,18

<b>ideal</b> 341:16 405:10	434:1 500:11	<b>impaired</b> 215:5 376:11 473:14	112:5 115:15 119:6 143:2 155:9
<b>ideally</b> 258:19,20	<b>illegally</b> 355:6,9 431:2,2	<b>impairment</b> 41:1 174:22 211:20	157:19 161:3 177:22 178:20
<b>ideas</b> 309:20	<b>illinois</b> 146:6 377:22 430:14	212:3,8,20 213:1 213:6 270:22	179:4,17 180:2,21 181:8 210:3 211:6
<b>ideation</b> 174:22	<b>illness</b> 57:18 243:2 243:5 367:2,13	272:10,17 471:18	211:22 212:8 213:16 220:22
<b>identical</b> 106:3 151:14	459:9	<b>imparted</b> 400:7	223:19 240:7 247:22 249:8,11
<b>identified</b> 37:7,8 141:15 143:18	<b>illnesses</b> 338:10 339:3	<b>impartial</b> 443:14	250:17 251:5,7,16 254:8,11,19 255:2
236:19 321:8 439:12	<b>imagine</b> 51:2 129:22 151:6	<b>impartiality</b> 444:7 444:16 445:9,18	256:2 257:2,5 261:20 262:6,18
<b>identify</b> 25:4 47:9 106:8 306:9 393:8	334:6 395:10,11 458:19	<b>impede</b> 117:12	268:5 288:21 302:10 303:21
444:10 474:12	<b>imitations</b> 449:21	<b>imperative</b> 65:12 297:3	306:8 313:16 314:16,18 331:20
<b>identifying</b> 352:18 369:20 387:20	<b>immad</b> 16:17 471:18,18	<b>implement</b> 47:3 98:1 112:13	332:2 334:17 339:9 353:4 356:9
463:10 472:11	<b>immeasurable</b> 68:8	290:12 466:12,13	365:17 378:19 388:18 392:1
<b>identity</b> 99:8,12 163:13 168:1	<b>immediate</b> 407:6	<b>implementation</b> 53:22 369:2 446:2	397:21 399:3 404:13 405:5,8
273:17 315:18 324:11 325:17	<b>immediately</b> 122:1 214:11	478:14	408:10 435:20 448:16 457:6
331:19 354:2 356:1 368:6	<b>immune</b> 86:6 93:15 263:3 270:6	<b>implemented</b> 117:17 146:4	461:3 481:3 486:7 489:1 490:20
369:16 438:8,21 438:22	<b>immunocompro...</b> 380:8	362:15 409:3 416:1	492:1
<b>idiopathic</b> 472:15	<b>immunosuppres...</b> 180:22	<b>implementing</b> 123:12 194:11	<b>importantly</b> 40:18 178:13 417:22
<b>ids</b> 479:8	<b>impact</b> 43:11 52:1 52:10 66:3 108:16	367:11 487:9	487:13,16,22 409:16
<b>ignore</b> 293:10	128:15 205:2 226:10,16 266:5	<b>implications</b> 180:9 425:7	<b>impose</b> 409:16
<b>ignored</b> 244:7	288:11 290:15 293:17 302:3	425:7	<b>impossibilities</b> 478:4
<b>igor</b> 10:9,17 181:17,22 200:13	332:6 428:8,14 467:18 491:15	<b>implicitly</b> 312:7 438:10	<b>impossible</b> 120:2 333:8 356:14
200:16	<b>impacted</b> 82:7	<b>implied</b> 65:9	398:5
<b>ii</b> 93:4 283:1 299:2 299:7 301:14	<b>impacting</b> 71:13	<b>import</b> 287:6 297:16,20 425:7	<b>impressed</b> 276:8 484:2
485:1	<b>impacts</b> 156:22 157:16 173:14	439:8	<b>impression</b> 112:10 125:20
<b>iii</b> 93:7 143:3 284:19,21 286:17	178:10 219:18 468:13	<b>importance</b> 44:16 88:18 143:9	<b>improper</b> 330:13 497:7 500:16
286:19 360:21	<b>impair</b> 211:17	<b>important</b> 27:8,11 29:10 30:10 31:20	
<b>ilac</b> 445:5 447:2		32:21 34:20 36:9 36:17 38:10 49:22	
<b>illegal</b> 227:1 244:4 344:5 345:2,2		52:2,14 53:10 72:8 77:4 97:13	
354:11 421:15 423:9 431:14		107:20 110:9	
432:20 433:1			

<b>improperly</b> 500:18	194:10 196:14,20 239:8 256:22	<b>inclusion</b> 143:17 144:7 273:2	295:6 319:13,20 330:4 437:2
<b>improve</b> 132:8 352:11 473:12	262:11,22 269:19 273:16 308:11	<b>income</b> 289:19	443:12 446:11,22
<b>improved</b> 182:21 327:2 473:15 488:10	330:9 357:11 385:15 443:2 445:22 450:14 476:14 479:6	<b>incoming</b> 220:20 348:18	451:8 462:18 479:10,12 490:2
<b>improvement</b> 28:18 93:3 261:17 313:19	<b>included</b> 25:17 28:12 34:1 64:14 316:5 435:13 455:10 492:16	<b>incomplete</b> 160:17	<b>indeterminate</b> 190:15 191:6
<b>improvements</b> 43:17 67:16	<b>includes</b> 31:22 174:3 182:22 193:2 195:17 251:1 372:14 432:7 443:12	<b>inconclusive</b> 135:22	<b>index</b> 180:5
<b>improves</b> 224:7	<b>including</b> 23:3 27:14 29:11 30:14 34:7,9 36:5 38:14 41:14 45:21 49:2 49:20 67:13 69:12 71:4 84:4 89:5 99:6 107:10 111:17 117:7 118:15 134:5 143:14 145:10 153:13 154:7 156:22 157:16 165:21 174:4,7 181:1 182:12 183:7 184:21 193:4 194:16 195:3,16 196:5,16 225:4 293:5 306:4 318:6 368:12 369:21 376:14 379:10,12 397:10 414:21 430:13 463:14 465:19 478:22 479:14 482:10 488:22 492:22	<b>inconsistencies</b> 265:11	<b>indiana</b> 479:5
<b>improving</b> 98:21		<b>inconsistency</b> 349:19	<b>indicate</b> 272:9 397:9 453:22
<b>impurities</b> 138:15 312:9 314:6 315:1 331:21 488:1		<b>incorporate</b> 146:21	<b>indicated</b> 90:4 454:8
<b>impurity</b> 459:18		<b>incorporated</b> 59:1 294:2	<b>indicates</b> 108:17 109:10 190:9,10
<b>inability</b> 130:5 223:6		<b>incorrectly</b> 47:3 335:10	<b>indicating</b> 480:1
<b>inadequately</b> 459:21		<b>increase</b> 67:11 74:1 77:2 181:5 205:4 223:14 224:8 225:2 405:4 470:12 474:1	<b>indication</b> 382:7 397:7
<b>inappropriate</b> 213:2		<b>increased</b> 144:3 364:16 374:22 458:5 473:19	<b>indications</b> 90:21 93:19 274:6,7,8 328:12 491:8
<b>incapable</b> 60:4		<b>increasing</b> 75:4 161:1 182:14 225:3 410:7 420:9 423:5	<b>indicative</b> 68:1 91:1
<b>incentive</b> 137:10		<b>increasingly</b> 452:14 478:13	<b>indicators</b> 67:14
<b>incentives</b> 128:21 137:7 339:5 410:7		<b>incredible</b> 51:4 259:8 321:10	<b>indicted</b> 454:15
<b>incentivizations</b> 410:2,3		<b>increasingly</b> 452:14 478:13	<b>individual</b> 147:14 153:1 163:17 243:15 246:17 311:18 437:5 451:20 456:8 461:16 488:6
<b>incentivize</b> 95:1 435:15		<b>incredibly</b> 397:20	<b>individually</b> 437:17
<b>incentivized</b> 490:8		<b>ind</b> 77:9 93:1 217:1,11 227:4 419:1 435:12 436:10	<b>individuals</b> 136:18 137:3 149:15 224:5 384:15 388:6 401:11 404:10 452:20
<b>incident</b> 200:7		<b>indefinite</b> 436:7	<b>inds</b> 225:22,22
<b>incidents</b> 193:22 220:5,6 431:3,16		<b>independence</b> 445:9,13	<b>induced</b> 202:20 243:1 339:18 376:9,10,15
<b>incisions</b> 494:19 494:22		<b>independent</b> 63:1 98:20 283:16	
<b>include</b> 30:5 38:17 47:6 68:11 74:19 100:1 120:7 121:14 135:4 144:15 167:10 174:22 183:21			

<b>inducing</b> 178:10 203:18	241:17 242:5 243:8 244:19	<b>influenced</b> 35:18 176:2	175:5 369:5 380:20 383:15	
<b>industrial</b> 4:22 42:17 53:15 82:2 161:19 227:19 362:4,14 366:11 367:17 368:2,4,11 368:12,13,18 369:2,7,16 370:6 371:4,18 395:22 428:18 488:2	254:20 256:8 266:9 291:2,6 294:18 297:4,6,18 307:9,19 322:3,8 322:16 323:14 344:8,10,11 346:9 348:1,12 351:16 352:2,12 357:15 361:13 363:3 364:8 365:6,19 366:21 367:11,17 367:17 368:22 369:6 370:7 371:4 371:10 373:16 375:8 376:16 377:8,9 378:1 379:9 410:17 412:2 420:13,22 426:1,7 427:10,19 428:2 429:1 432:8 434:2 435:6 437:19 441:4 463:10,21 464:3 466:10 478:5 485:19 497:19,20 497:21,22 498:16 499:7	<b>influx</b> 141:20 <b>inform</b> 27:7 40:9 41:18,21 42:1 135:4 214:17 221:13 427:1 456:9 <b>information</b> 1:8 20:4,19 25:19 26:17 32:6 61:3 65:5 69:7 71:8 73:16 75:8,13 77:15 81:17 86:20 87:6,9 90:12,16 97:17,19 98:3 100:5,8 101:11,13 103:17 115:4 118:13,15 135:3 144:12,15 152:4 152:16,18 158:6 158:18 162:13 165:7 169:22 172:7 183:7 185:7 185:8 194:4 196:1 197:5,12,15,19 198:9 200:21 226:3 228:15 256:18 266:21 267:4,7,12,19 279:15 287:12 296:19 298:4 306:4 313:9 362:1 390:14 405:5 415:5,17 454:14 456:16 461:13 462:22 479:7,14 483:21	461:14 <b>informing</b> 162:12 <b>infrastructure</b> 348:6 363:17 364:15 426:16 <b>infused</b> 72:15 156:19 168:21 170:8 171:7 257:15 258:6 303:14 367:12,19 367:22 432:18,19 495:5 <b>ingest</b> 257:16 340:21 <b>ingested</b> 41:6 75:14 306:5 469:10 <b>ingestible</b> 154:7 <b>ingesting</b> 382:6 <b>ingestion</b> 41:8 156:22 366:14 371:8 <b>ingram</b> 217:3 <b>ingredient</b> 45:13 71:13 74:19 77:16 81:18,21,22 105:14 112:22 153:22 167:5,12 167:19,22 168:1,6 168:9 169:13 172:1 207:16 268:19 269:17 303:11 311:4,11 315:3 324:19,20 324:21 325:20 350:9,11 353:1 356:1,3 365:1,9 368:13,16,18,21 369:21 436:13,16 440:8,9 441:15 497:3 498:4	
<b>industries</b> 48:4 110:3 133:21 227:22 307:1 323:3 412:12 413:17 415:13 427:18	364:8 365:6,19 366:21 367:11,17 367:17 368:22 369:6 370:7 371:4 371:10 373:16 375:8 376:16 377:8,9 378:1 379:9 410:17 412:2 420:13,22 426:1,7 427:10,19 428:2 429:1 432:8 434:2 435:6 437:19 441:4 463:10,21 464:3 466:10 478:5 485:19 497:19,20 497:21,22 498:16 499:7	<b>industry</b> 7:17 11:19 38:2 42:20 43:9,20,22 44:16 45:1 46:18 48:1 50:3 52:4,17 53:14 59:7,20,21 60:3,14,19 65:15 73:12 74:5,11 83:19 85:8 87:20 95:18 96:7 97:1 97:12 103:22 107:3,7 108:1,17 109:22 110:19,21 119:9,21 121:19 121:22 145:21 147:22 151:18 153:13 155:13 161:19 162:12 163:4,5,11,11,20 166:2,5 168:5,20 169:6 170:13 174:18 176:1 200:20 204:5 209:10 228:12 230:13 231:13 232:8 240:20 241:1,4,9,11,13	<b>industry's</b> 47:20 49:12 168:9 <b>ineffective</b> 383:4 <b>inevitable</b> 307:8 <b>infantile</b> 447:18 <b>infection</b> 221:11 <b>infections</b> 330:14 <b>inflammation</b> 71:11 <b>inflammatory</b> 269:8 484:12 <b>inflicted</b> 174:18 <b>influence</b> 175:22 184:2 483:3	<b>informed</b> 36:3 76:9 88:3,22 110:9 123:17 162:17 174:2

<b>ingredients</b> 29:12 31:6,13 51:4 53:20 73:15 112:3 121:18 154:3 157:5 166:22 167:4,14,18 168:11 169:17 188:20 216:16 273:4 306:14,15 323:7,8,10,15,18 323:21 325:17 348:8 354:3,3,5 354:14 355:11 356:8,11,12 362:8 365:5 372:10 380:13,15 396:12 417:1 431:17 438:20 459:18 479:8 <b>inhalation</b> 299:5,5 302:6 366:14 371:8 388:22 <b>inhaled</b> 41:2,4 124:10 185:20 300:3 313:14 <b>inherent</b> 91:2 105:19 106:20 <b>inherently</b> 412:3 <b>inhibited</b> 178:21 <b>inhibition</b> 177:21 180:16 271:20 360:2 <b>initial</b> 394:1 423:3 436:15 <b>initiated</b> 85:8 <b>initiating</b> 196:6 <b>initiative</b> 49:12,22 305:13 367:7 <b>injuries</b> 67:20 401:12 <b>injury</b> 175:1 201:9 201:10,18 202:1 202:20 203:3,16 339:18 404:10,17	<b>innate</b> 259:16 <b>innovation</b> 90:22 253:4 266:6 304:16 407:14 <b>innovators</b> 295:13 <b>innumerable</b> 152:6 <b>input</b> 163:4 <b>inquirer</b> 336:12 <b>inr</b> 180:7 <b>insert</b> 130:10 <b>insertion</b> 488:12 494:21 495:9 <b>inside</b> 120:3 236:14 276:10 <b>insight</b> 317:22 <b>insights</b> 89:9 <b>insist</b> 439:18 <b>insomnia</b> 318:6 <b>inspected</b> 441:11 <b>inspecting</b> 463:21 <b>inspection</b> 331:12 346:6 438:15 478:17 <b>inspections</b> 171:6 367:4,9 478:12 <b>inspectors</b> 464:2 <b>inspects</b> 369:10 <b>inspired</b> 237:5 <b>instability</b> 450:22 <b>instance</b> 77:2 87:2 190:19 206:16 <b>instances</b> 190:12 190:21 191:9,9 313:4 354:2 481:12 <b>institute</b> 9:12 12:13 14:21 26:6 153:8,12 204:21 242:9 282:11,17 295:5 391:3 420:6 451:8 <b>instituted</b> 32:3 106:14 142:1	<b>institutes</b> 78:22 <b>institutions</b> 95:22 187:8 264:5 418:21 <b>instructed</b> 339:19 <b>instructions</b> 480:2 <b>instructor</b> 379:3 <b>insufficient</b> 125:21 136:3 160:2,17 <b>insurance</b> 229:10 229:12 410:16 <b>intake</b> 144:2 223:16 224:8 301:18 <b>integrate</b> 264:9 266:9 <b>integrated</b> 160:15 197:22 264:11 318:3 333:4,5 366:8,11 370:12 <b>integration</b> 319:21 <b>integrity</b> 38:6 131:9 193:11 341:19 366:17 381:3 408:22 <b>intellectual</b> 264:20 <b>intelligence</b> 259:16 <b>intend</b> 223:7 345:13 <b>intended</b> 29:20 48:12 64:9,20 65:4 86:3,4 102:10 105:10 117:22 118:1,17 120:14 168:2 204:12 272:7 313:11 315:15 324:19,22 325:3,3 340:4 436:9 471:22 480:22	<b>intending</b> 118:18 <b>intense</b> 76:17 116:13 <b>intensity</b> 275:21 <b>intent</b> 111:16 112:14 113:5 <b>intentionally</b> 65:17 383:3 <b>interact</b> 34:15 144:6 398:9 <b>interaction</b> 93:14 180:14 202:5 203:17 204:2 217:18 271:19 278:5 404:18 420:20 <b>interactions</b> 67:18 74:17 124:2,4,15 131:9,13 139:5 142:2 143:12,15 143:19 144:16 177:21 178:7 181:11 225:20 271:20 277:20 278:4 340:1 359:22 382:10 405:6 459:15 <b>intercellular</b> 270:3,11 <b>interchangeable</b> 307:20 <b>interdependencies</b> 383:17 <b>interest</b> 4:16 26:20 27:2 33:14 33:20 37:11,19 45:16 74:1 76:18 88:14 89:21 94:3 154:16 164:7,9 171:14 201:3 246:8 247:7 301:15 345:16 420:9 432:14 435:21 445:19
---	--	---	--

453:9 497:13 <b>interested</b> 71:1 100:18 107:17 123:16 169:13 170:14 252:16 334:11 502:12 503:12 <b>interesting</b> 184:9 239:3,18 326:12 336:7 359:11 <b>interestingly</b> 179:2 <b>interests</b> 46:11 102:5 365:19 435:14 <b>interface</b> 267:10 <b>interference</b> 482:10 <b>interferes</b> 271:11 <b>intergovernmental</b> 2:6 22:2 <b>interim</b> 112:20 398:2 414:2 <b>intermediary</b> 424:19 <b>intermediate</b> 372:10 <b>internal</b> 21:6 35:2 133:19 282:15 <b>international</b> 2:7 10:15 11:17 14:21 15:13,19 22:4 47:6 95:17 109:4 110:20,21 134:19 192:17 235:14 322:21 331:2,14 335:22 347:20 379:9 391:4,19 423:6 425:16,22 426:7 427:8 442:19,22 443:6 451:7 467:11 <b>international's</b> 145:7	<b>internationally</b> 253:12 293:11 443:14 <b>internet</b> 39:4 92:1 207:22 211:12 237:6 243:11 346:5 <b>interplay</b> 421:13 423:1,15 <b>interpretations</b> 477:16 <b>interpreted</b> 114:10 341:7 <b>interrogate</b> 493:7 <b>interrogatory</b> 241:7 <b>interrupt</b> 23:12 25:14 <b>interruption</b> 150:6 <b>interstate</b> 27:20 31:22 159:12 424:1,22 <b>intervention</b> 193:22 374:12 440:2 497:15 <b>intoxicating</b> 43:2 80:19 104:22 122:22 323:5 <b>intracranial</b> 271:9 <b>intranasal</b> 270:18 <b>intrastate</b> 71:18 411:17 <b>intricate</b> 383:16 <b>intrinsic</b> 123:2 <b>introduce</b> 20:22 25:21 288:2 327:3 <b>introduced</b> 122:12 380:4 <b>introduces</b> 46:14 <b>introducing</b> 488:14 <b>introduction</b> 454:12	<b>invariably</b> 65:19 <b>invention</b> 294:18 <b>inverse</b> 410:17 <b>invested</b> 162:3 348:1 460:6 <b>investigate</b> 436:2 436:5 475:9,11 <b>investigated</b> 102:9 <b>investigating</b> 493:12 <b>investigation</b> 32:3 94:13 196:18 226:9 367:13 480:14 <b>investigational</b> 93:2 94:18 <b>investigations</b> 106:14 195:15 199:11 367:9,10 <b>investigative</b> 245:19 480:16 <b>investigator</b> 367:3 367:8 <b>investigators</b> 144:1 183:14 189:12 283:11 <b>investing</b> 49:9 303:11 <b>investment</b> 247:16 304:16 305:4 327:1 <b>investments</b> 246:20 <b>invitation</b> 481:21 <b>invite</b> 499:9 <b>inviting</b> 481:20 <b>involve</b> 93:11 <b>involved</b> 48:2 58:11 172:4 283:7 334:10 393:18 413:18 420:4,17 421:4 483:16 <b>involvement</b> 181:14 391:20	<b>involves</b> 456:5 <b>involving</b> 106:14 <b>ionization</b> 190:1 <b>iop</b> 474:1 475:10 475:13 <b>ip</b> 264:20 355:21 419:17,19 421:22 <b>irb</b> 227:5 333:20 453:14 <b>ironically</b> 440:5 <b>irony</b> 441:12 <b>irrational</b> 373:18 <b>irrelevant</b> 228:18 <b>irrespective</b> 436:5 <b>irresponsible</b> 85:5 242:16 353:21 <b>irresponsibly</b> 85:3 <b>irritability</b> 223:14 <b>irritate</b> 493:1 <b>irvine</b> 274:18,19 <b>ischemia</b> 269:10 <b>ischemic</b> 484:11 <b>ish</b> 206:14 <b>iso</b> 134:1 135:7 291:7 363:13 372:5 379:3 490:13 <b>isoform</b> 180:17 <b>isolate</b> 148:14 149:2 230:5,16 234:10 277:9 289:5 303:22 305:19 308:1,3 351:2 372:19 410:15 417:18 <b>isolated</b> 58:1 106:22 292:15 324:4 327:4,5,14 418:13 <b>isolates</b> 84:7 124:6 418:12 <b>isolation</b> 232:18 232:19 234:8
---	---	---	---



<b>israel</b> 293:11 <b>israelsen</b> 104:12 <b>issue</b> 32:16 38:8 53:10 62:3 91:2 102:12 103:10 112:20 113:4,5 115:14 121:12 141:18 155:9 157:19 161:3 193:9 195:3 218:19 242:17 244:20,22 253:12 263:11 268:6 273:4 284:18 292:18 302:11 334:21 340:9 388:5 389:5 396:8 398:5,5 405:18 437:2 450:1 457:12 471:7,7 480:18 487:14 492:5 500:11 <b>issued</b> 32:17 35:8 60:11 109:19 121:5 463:13 464:20 <b>issues</b> 38:17 71:16 72:5 119:6 146:9 147:22 150:19 151:5 163:21 193:10 194:16 196:19 217:7,7 218:16 236:19 254:1 263:12 264:16 278:15 281:4 291:4,15 343:12 349:7,13 351:15,15 387:8 387:21 399:4,19 418:4 421:13 423:17,18 428:19 440:18 477:13 496:19 497:5 499:20,20,21	500:15 <b>issuing</b> 170:9,11 433:15 <b>it'd</b> 80:22 86:19 310:1,9 <b>it'll</b> 298:4 <b>items</b> 154:8 304:20 455:16 <b>iteration</b> 319:7 <b>iupac</b> 448:4	<b>john</b> 16:14 467:2 467:4 <b>johns</b> 4:18 11:3,8 40:1,4,6 210:4 <b>join</b> 26:11,22 36:16 57:13 440:14 <b>joined</b> 38:7 173:5 361:20 501:7 <b>joining</b> 26:15 173:2 282:8 482:21 <b>joint</b> 65:4 248:21 249:5 250:8 358:6 454:5 469:9 <b>jolly</b> 6:8 70:18,20 70:21 <b>jon</b> 50:6,7 <b>jonathan</b> 5:4,6 47:17 <b>jones</b> 61:11,12 <b>joseph</b> 9:20 161:10 <b>josh</b> 13:4 303:7,8 <b>journal</b> 483:13 <b>journalist</b> 245:20 <b>journals</b> 312:20 <b>journey</b> 461:17 <b>joy</b> 400:2 <b>julian</b> 6:16 81:5,7 <b>july</b> 27:6 53:2 66:9 104:8 109:18 110:16 124:18 164:6 368:9 501:5 <b>june</b> 49:3 422:7 448:15 <b>jurisdiction</b> 27:21 140:2 <b>jurisdictions</b> 90:13 253:15 <b>justice</b> 121:5 204:22 205:2,6 429:18	<b>justification</b> 65:2 <b>justify</b> 258:12 436:7 <b>justin</b> 12:18 287:19,22 <b>juvenile</b> 402:7
<b>k</b>			
	<b>jaelyn</b> 11:16 235:9 235:12 <b>jacqueline</b> 15:4 400:10 <b>jama</b> 40:21 335:3 335:13 <b>james</b> 6:10 7:4 14:4,18 16:8 72:11,13 91:6 356:19,20 384:1,9 456:22 457:3 <b>january</b> 237:2 247:18 <b>jaqueline</b> 400:13 <b>jarilyn</b> 2:14 <b>jason</b> 4:21 42:14 42:17 <b>jeffrey</b> 15:6 406:18,20 <b>jerry</b> 12:8 263:21 263:22 <b>jersey</b> 244:13 <b>jet</b> 426:15 <b>jin</b> 61:10 <b>job</b> 1:20 51:2 236:5 321:18 437:20,21 464:1 499:1 <b>jobs</b> 43:12,18 45:2 52:7,8 108:22 208:20 <b>joe</b> 161:12	<b>kamer</b> 5:20 61:14 61:15,16 <b>kandypens</b> 452:17 <b>kansas</b> 221:11 <b>karen</b> 7:12 101:20 101:22 <b>kari</b> 8:19 142:17 142:18 <b>kazmira</b> 14:7,9 361:21 362:2 363:4 <b>keep</b> 47:14 54:3 245:12 378:8 497:21 <b>keeping</b> 355:2 <b>keeps</b> 58:3 <b>keith</b> 8:15,17 135:11,15 <b>ken</b> 111:5 <b>kentucky</b> 43:13,15 <b>kept</b> 168:22 412:3 480:3 <b>kevin</b> 137:15,17 138:2 <b>kevon</b> 1:21 502:2 502:15 <b>key</b> 38:17 51:3 78:12 83:15 146:17 160:13 218:16 237:20 239:1 348:13 386:11 387:3 389:14 427:10,19 464:4 <b>kg</b> 51:10 203:6 270:21 272:11 340:17 358:20	

359:10,12,18,19 359:20 361:6 397:10,11 <b>kgk</b> 12:11 268:13 268:16,19 <b>kid</b> 57:7,13 227:8 500:1 <b>kidding</b> 275:5 276:21 <b>kidney</b> 281:14 <b>kids</b> 57:14 375:9 375:13 376:4,19 <b>kight</b> 7:14,15 104:14,15,16,17 <b>kill</b> 376:20 <b>killed</b> 56:19 376:8 376:10,13 <b>kills</b> 374:17 <b>kilograms</b> 347:16 <b>kimless</b> 13:8 317:2 317:3,6,8 321:5 <b>kind</b> 56:9 87:6 127:9 141:18 182:20 186:7,9 205:16 211:14 213:9 228:18 231:5 239:13 247:8,9 255:8 308:16 310:8 344:3 345:16 346:15 349:8 353:4 368:14,19 394:3 421:1,7 424:5,16,19 482:14 <b>kinds</b> 30:6 128:18 184:22 209:14 247:20 425:1 <b>king's</b> 334:20 <b>kingston</b> 10:14 192:10,11,12 197:8 198:6,19 199:4,8 200:2	<b>kline</b> 7:16 107:3,5 107:6 110:6,8,17 111:1,3 <b>knew</b> 339:12 374:7 <b>know</b> 30:17 31:7 33:22 37:12 43:6 56:5,6,8 64:19 75:3,3,5,12,15,18 97:3 103:8 108:5 110:1,1 115:2 122:2 128:21 129:10 132:2 137:10,11 140:14 141:3,21 142:1,6 148:10,12,13 149:19,20 155:13 158:12,14 162:5 164:14 172:1,2,6 172:19 178:8,12 178:20 180:13,15 181:9,10 184:6 186:6,9,16,18,22 199:1,17,21,21,22 201:4 205:16 206:4,5,22 208:10 210:7 213:21,22 216:6 217:13 219:21 225:8,15 227:8 228:10,13 228:15,17 229:4 230:1,4,15,16,22 231:2,2,4,5,6,14 231:16,17,18,20 231:21,22 232:6 232:18,20,20 233:15,17 234:13 234:14,16,16 235:1,2,4 239:11 239:12 247:1 249:6,14 251:20 252:8,13,15 254:5 254:15,18,20 255:7 256:1,2,20	257:2 259:20,20 260:3 267:19 277:21 279:1,7 281:9,13 283:4,9 284:1,20,22 285:2 286:2,14 287:4,8 291:18,21 292:5 293:1,8 306:20 307:18,19 308:14 312:21 313:1,12 314:7,13 316:4 327:13 328:2 335:2,6 336:11,13 336:17 337:8 339:17,22 340:10 344:8 345:4 346:10 347:22 348:21 349:7 351:11 352:5,17 353:1,4 373:15 374:19 380:15,16 380:18 383:8 385:12 391:13,14 401:20 402:2 403:11,20 405:10 406:2,7,9 410:22 418:15 421:6,9 422:1 431:1 434:1 448:8,14 453:4 455:10,12,16,17 458:13 459:14 461:18 466:6 468:13,20 470:6,7 471:13 473:10 474:9 475:14 484:1,2,11 485:10 488:17 494:6 498:1 499:18 500:2,3 <b>knowing</b> 269:20 442:12 446:10 <b>knowledge</b> 34:21 97:1,7 100:12 119:16 177:1	262:19 272:5 386:18 417:3 432:3 434:11 441:3 455:12 500:9 502:7 503:6 <b>known</b> 27:14 28:19 46:5 65:5 65:17 107:8 132:18 144:6 166:16 167:8 177:17 195:19 222:6 260:21 302:20 306:19 360:4,5 377:7 382:7 387:11 409:18 410:11,12 426:10 452:6 457:10 489:7 <b>knowns</b> 177:16 178:18 <b>knows</b> 289:4 442:4 449:15 459:16 <b>kosher</b> 343:1 <b>koturbash</b> 10:17 192:18 200:13,14 200:16 <b>kratom</b> 205:21 <b>kristina</b> 7:8 95:14 95:15
<b>I</b>			
<b>I</b> 84:3 <b>lab</b> 63:2 109:19 133:18 205:19 236:14 237:14,14 278:15 294:9,15 319:13 330:1,4 340:13 346:5 398:18 443:16 444:9 <b>label</b> 47:4 64:3 79:4 117:1 148:21 181:4 188:11 189:3,4,10,14,20			

189:21 190:6,8,12 190:14,17,21 191:5,7,8,16,18 192:6 201:8 231:8 235:13,15,17,22 238:6 239:3 299:9 315:2 331:7,19 351:15 366:12 370:2 381:4,7 391:9,13 403:12 438:8,15 448:17 450:22 451:2 461:7 479:11 480:7 <b>labeled</b> 116:20 222:15 320:14 335:5,9,9,10,11 335:11 400:4 466:5 479:13 <b>labeling</b> 38:6 53:22 64:14 98:1 105:12 110:11 121:17 131:17 139:7 143:18 148:10,12 149:13 149:22 154:21 165:16 166:21 214:8,12 236:3 254:10 255:1 265:14 267:20 273:1,9,16 279:5 303:19 304:15,21 326:1 337:12 364:19 369:18,20 399:19 400:6 409:18 414:13 415:2 425:9 428:5 479:1,2,4 491:7 499:20 500:15 <b>labels</b> 57:2 84:13 97:14,18 131:19 188:19 236:4 330:4 344:18 479:6,19,22	<b>labor</b> 421:22 <b>laboratories</b> 49:17 133:1,20 134:15 135:6 145:6,21 283:18 319:20 363:22 364:7 379:11 382:18,20 383:3 443:6,8 444:6,21 479:13 <b>laboratory</b> 67:14 109:16 132:17 133:9,16,22 134:4 134:20 135:1 204:14 211:15 213:19 215:1 220:21 224:3,9 266:2 287:1 306:2 346:3 370:21,21 391:14 392:9 424:16 427:21 428:14 443:13 444:2 445:7,16,20 463:16 <b>laboratory's</b> 134:13 <b>labs</b> 13:21 97:21 205:6,10 251:19 289:2,2,21 347:14 347:15 349:18,20 349:20 351:17 352:3 381:3,9 442:18 479:10 490:2 <b>lack</b> 34:5,5 47:1 59:22 61:16,20 82:12 116:17,19 136:17 145:9 156:21 160:10 188:14 304:8 328:11 361:3 371:14 389:10 478:2 <b>lacking</b> 78:12	<b>lacks</b> 338:12 <b>lacquer</b> 491:5 <b>ladies</b> 120:1 127:11 200:14 293:21 <b>lady</b> 231:21 <b>laetrile</b> 62:4 63:7 <b>lag</b> 82:18 <b>land</b> 44:1 368:5 450:18 <b>landscape</b> 96:3 108:11 329:17 430:16 432:10 <b>lane</b> 379:14 438:5 <b>lanes</b> 323:12 <b>laney</b> 402:6 403:4 <b>laney's</b> 402:6 <b>laneys</b> 403:4 <b>language</b> 135:4 279:11 <b>large</b> 24:12 79:21 136:12 288:12,19 309:10 336:16,22 344:8 433:7 454:1 476:14 500:5 <b>largely</b> 28:14 266:7 333:3,12 432:1 <b>larger</b> 289:7 411:21 <b>largescale</b> 227:19 228:3 347:15 348:10 <b>largest</b> 43:9 82:15 87:21 156:15 342:10,12 345:6 366:10 384:13 385:3 395:13 434:1 499:12 500:4 <b>larry</b> 11:4 216:10 <b>lasted</b> 318:18 <b>lasting</b> 89:12 173:14	<b>lastly</b> 169:8 192:15 257:6 287:4 293:7 415:20 418:14 <b>late</b> 122:5 175:13 287:2 388:13 467:8 474:9 <b>launching</b> 97:15 <b>lavender</b> 151:10 151:13 <b>law</b> 7:15 8:3 15:9 29:3 32:3,12,15 35:7,17 49:14 81:13 104:15 118:8 119:3 146:12 189:17 205:7 241:5 265:22 354:18 355:5,14,17 356:13 377:15 378:4 400:7 413:15,15 420:3,4 420:6,11,14,18,21 421:5,6,14,22 422:9,12,12,18 450:18 471:22 482:10,11 500:4 <b>law's</b> 77:10 <b>lawful</b> 82:10 112:22 113:14 273:12 437:22 476:22 477:22 <b>lawfully</b> 32:13 322:7 <b>lawfulness</b> 48:18 <b>lawmaking</b> 421:3 <b>lawnmowers</b> 247:4 <b>laws</b> 28:1,3,7 29:4 57:1 88:19 156:6 159:7 166:20 167:1 175:10 182:16 221:6 256:10 258:17,17
--	--	---	--

266:8 354:16 369:13 393:12 414:12 415:21 421:14,15 422:15 429:21 430:11 434:12,13,18 482:9 500:20 <b>lawsuits</b> 241:8 <b>lawyer</b> 241:3 429:19 <b>lawyers</b> 107:14 240:22 407:1,1 422:16 430:19 432:8 <b>layer</b> 474:11 495:6 <b>layers</b> 283:7 <b>lazy</b> 335:17 <b>lead</b> 41:10 107:6,6 143:6 144:2 238:8 265:8 291:7 367:2 370:7 379:2 385:14 389:1 390:17 404:10 490:5 <b>leader</b> 391:4 <b>leaders</b> 48:4 107:11 <b>leadership</b> 89:3 117:7 157:15 163:16 422:4,15 <b>leading</b> 47:20 58:12 87:18 116:1 267:22 339:4 400:21 435:5 458:17 494:14 <b>leads</b> 46:20 351:15 356:15 <b>leaf</b> 151:3,6 280:2 <b>learn</b> 127:20 221:20 266:14 412:4 <b>learned</b> 40:10 50:1 59:9 267:8 275:5 317:15	333:7 358:18 360:8 471:15 <b>leave</b> 36:19 234:11 <b>leaves</b> 116:17 171:22 286:2 <b>leaving</b> 78:11 152:10 <b>led</b> 39:11 49:16 138:13 259:19 386:10 388:11 449:5 451:11 <b>lee</b> 15:12 451:5,6,6 451:11 455:20 456:18 <b>left</b> 145:11 149:3 169:18 230:6 245:1 254:3 265:19 361:21 454:4 469:20 490:17 <b>legal</b> 15:7 29:17 43:21 45:12 49:15 51:16 68:21 71:6 77:14 81:12 82:4 82:7 105:5 116:6 121:8 130:13 155:7 159:15 160:5 163:22 165:9 166:6 205:22 240:21 241:4 253:14 254:22 261:1 286:18 296:6 307:4 324:6 353:12 354:14 368:1 407:5 421:16,21 423:16 424:8,9 433:2 448:15 449:10 453:12 462:15 477:15 <b>legalities</b> 292:1 <b>legality</b> 116:8 170:6 209:12	329:19 <b>legalization</b> 39:13 225:2 367:6 373:14 386:10 393:15 <b>legalize</b> 121:5 253:17 <b>legalized</b> 61:17 121:8 150:21 257:9 265:18 470:17 <b>legalizing</b> 376:21 <b>legally</b> 66:14 90:13 99:2 108:6 108:6 123:3 168:11 396:2 453:11 <b>legend</b> 342:20 <b>legislation</b> 2:7 22:3 38:20 42:19 48:8 160:20 257:8 411:7 446:2 <b>legislative</b> 79:15 396:20 420:5 430:7 <b>legislators</b> 62:1 430:20 <b>legislature</b> 160:21 162:21 182:5 <b>legitimate</b> 91:3 219:15 336:17 372:1 431:7 440:9 <b>lenabasum</b> 93:2 93:10,17 <b>lends</b> 361:5 <b>lengths</b> 473:12 <b>lennox</b> 140:19 338:21 447:19 449:7 <b>lenses</b> 457:13,15 <b>lesser</b> 69:20 <b>lethargy</b> 193:19 <b>letter</b> 346:11 395:19	<b>letters</b> 35:8 77:3 162:11 284:12,15 291:14 439:7 <b>level</b> 51:20 81:12 88:20 99:15 100:3 114:14 115:10 125:19 160:17 165:6,14 170:3 195:8 238:18 243:14 316:21 317:21 327:8 345:13 349:19 363:18 364:13 387:7 392:19 397:12,22 399:13 399:15 408:17 409:22 410:16 411:2 413:21 424:20 437:15 467:13 471:4 481:7 <b>levels</b> 45:20 61:1 68:8 69:3 80:1 84:7 109:17 113:18 114:4,17 115:2 133:13 144:5 147:3 160:19 179:2,5 181:6 202:2 239:14 283:20 288:13 301:16 302:16 309:7 327:18,20 330:7 332:4 337:11,17 338:14 340:19 341:1 360:13 363:7 377:7 396:14 397:8 400:2 413:21 437:15 439:12 444:16 467:11 468:1,5 470:22 492:21
---	--	--	--

<b>leverage</b> 331:9	<b>lily</b> 61:10,11	<b>liquor</b> 230:7 233:1	226:17 228:6
<b>leveraged</b> 332:15	<b>lilyhemp</b> 5:11	234:22	237:4 241:11
<b>levodopa</b> 385:18	53:7,11	<b>lisa</b> 11:20 245:17	281:20 290:4
<b>lewis</b> 2:10	<b>limit</b> 99:19 191:20	245:18 252:8	294:12 298:17
<b>lgill</b> 252:8	240:9 314:14,20	<b>list</b> 58:2 123:16	326:20 332:22
<b>lgs</b> 174:21 341:13	341:6 360:15	167:4 206:7	353:18 356:21
449:9	446:5,16 469:18	225:14 237:6	358:11 371:10
<b>liability</b> 490:9	470:4 491:13	276:5,13 310:7,10	380:17 384:10
<b>liberating</b> 126:15	<b>limitation</b> 287:5	351:7 371:1	391:18 402:5
<b>liberty</b> 482:3,8	<b>limitations</b> 23:2	<b>listed</b> 79:5 117:1	405:18 407:8
<b>library</b> 126:2,5	24:21 72:4 165:16	185:15 238:6,12	422:22 430:9
<b>license</b> 226:20	<b>limited</b> 63:13 65:5	239:2 300:11	447:21 451:10
284:4 286:15	82:12 140:17	312:2 330:3	457:21 458:11
297:5 319:10	172:2,4 182:13	<b>listen</b> 481:22	459:11 461:19
333:14 346:15	183:12 222:2	<b>listened</b> 231:21	<b>live</b> 260:12 385:5
347:2 478:10	288:22 387:12	<b>listening</b> 125:14	401:11 482:9
<b>licensed</b> 109:16	491:16	279:16 377:22	<b>liver</b> 51:13 67:17
161:20 283:17	<b>limiting</b> 38:19	402:20 496:15	141:14 175:1
292:10 317:11	121:14	498:19,20	177:13 201:7,9,18
319:20 325:16	<b>limits</b> 51:19 57:1	<b>listing</b> 238:19	201:22 202:1,20
333:2 367:13	100:2 218:6	<b>literally</b> 263:5	203:2,3,9,16
<b>licenses</b> 320:2	258:12 327:5	308:15 403:6	271:1 272:20
<b>licensing</b> 322:22	331:4 341:1 394:7	496:5,9	281:4,6,14 339:13
<b>lied</b> 175:16	452:1 464:13,15	<b>literature</b> 49:9	339:18,19 360:5
<b>lies</b> 371:19	464:22	78:17 80:15 175:7	404:17
<b>life</b> 45:3 70:17	<b>line</b> 37:13 109:9	177:18,19 180:15	<b>lives</b> 54:12 58:6
92:22 132:8	171:12 173:7	180:19 186:18	87:22 96:9 243:7
293:17 294:2	282:3 291:18	223:1 224:19	338:17 379:22
319:18 332:8	304:13 387:9	270:20 325:19	401:14 403:7
334:9 338:10,20	452:20 454:15	492:8	429:22 430:3
401:6 458:8	<b>lineberger</b> 26:8	<b>litigators</b> 11:19	<b>livestock</b> 46:13
460:14 473:15	<b>lines</b> 265:2 296:7	240:21	<b>living</b> 377:14
482:3,7 490:19,21	296:11 319:22	<b>little</b> 41:17 44:7	384:14 385:4
491:2	403:2 411:20	70:4 76:19 86:20	460:14
<b>lifesaving</b> 401:20	<b>link</b> 36:14 48:3	114:1 122:2	<b>llc</b> 6:7 8:3 9:8
403:22 404:21	479:8	127:13 128:15	12:19 14:5,7,9,17
475:12	<b>linked</b> 58:2 479:7	132:11,13 137:20	15:11 16:17
<b>lifestyle</b> 253:3,8	<b>linoleic</b> 45:21	148:8,20 150:1,5	<b>llp</b> 15:15 476:9
325:8	<b>lipids</b> 234:12	150:15 159:8	<b>lo</b> 265:1
<b>light</b> 25:7,11,13	<b>lips</b> 496:22	172:18,19 179:12	<b>load</b> 100:3 224:11
<b>lighter</b> 385:9	<b>liquid</b> 205:13	187:18 190:17	<b>lobby</b> 173:13
<b>lights</b> 132:13	207:3 211:13	191:9 192:1	<b>lobbyist</b> 288:3
<b>likelihood</b> 488:11	<b>liquids</b> 205:5	212:12 216:13	<b>lobbyists</b> 175:10
	206:8,12,13	221:15 222:11	245:11

<p><b>local</b> 48:18 88:20 96:5 156:7,11 157:12 160:18 236:11 253:15 265:12 413:21 414:12 465:1 467:10 478:10 <b>locally</b> 488:20 <b>located</b> 24:14 61:6 264:2,4 270:5 274:5 297:20 329:2 366:9 498:7 <b>location</b> 1:16 <b>locations</b> 229:6 <b>locked</b> 57:18 295:5 <b>loggers</b> 127:6 <b>logical</b> 120:20 <b>logistics</b> 292:9 293:13 <b>london</b> 334:20 <b>long</b> 26:4 89:12 117:5 139:12,18 156:22 157:6 163:10 186:21 208:19 214:1 225:21 242:1,1 247:4 304:18 346:21 377:15 391:19 406:22 408:1 426:19 441:1 471:14 485:6 489:21 <b>longer</b> 29:2 58:3 82:3 93:9 286:7 <b>longest</b> 220:15 <b>longstanding</b> 167:17 <b>look</b> 74:9 80:9 90:19 100:13 130:18 145:22 155:15 164:19 166:7 171:5 181:2 183:22 186:4</p>	<p>200:3 215:3 219:20 223:13 224:20 225:15 237:16 239:19 245:14 250:3 252:7 253:8 261:10 262:10,19 265:3 268:4 274:5 278:1 295:10 299:12,21 300:2 301:6,13 311:17 321:1 326:8 333:21 350:5 352:6,21 365:21 397:17 398:7 404:15 415:13 423:2 429:10 453:2,6 454:4 456:11 457:11 466:12 467:19 469:1,2,3,6,9,12 470:3,16,18 471:6 471:8 475:8,18 483:12 493:14 497:15 498:2 500:10,11,12,20 500:20 <b>looked</b> 164:20 243:1 343:10 397:5 469:19 <b>looking</b> 59:17 131:21 165:19 166:1 176:4 177:17 179:13 180:20 187:3 204:4 224:3 245:2 251:14 254:8 274:4,7,9 283:1 287:1 288:8,10 312:8 335:22 395:16 398:19 402:4 420:10 421:2 424:2</p>	<p><b>looks</b> 74:7 157:18 161:2 220:2 279:14 325:10 448:8 <b>looms</b> 433:7 <b>loren</b> 104:12 <b>lose</b> 25:3 109:3 224:6 286:10 382:16 403:5,7 <b>losing</b> 108:12 208:20 403:10 <b>loss</b> 58:14 189:6 385:14 472:7 474:13 475:17 <b>lost</b> 472:18 484:22 <b>lot</b> 36:12 40:10 74:17 90:16 124:22 129:11 148:1 149:11 164:17 172:6 181:9,9 213:21 219:10,11 222:22 224:19 228:1,15 236:16 239:17 242:7 245:10,11 248:16 249:11 252:15 253:8,13 254:1 255:15 256:2,3 275:20 276:22 277:12 285:18 286:10 288:14 290:16 302:15 305:18 312:10,16 334:18 346:3 348:21 349:22 350:16 359:5 360:9 387:11 396:5 398:6,8,8 399:10 399:10,11,15 403:16 421:12 423:5,7,11 424:7 483:6 498:15 500:7</p>	<p><b>lotion</b> 34:13 <b>lotions</b> 154:9 <b>lots</b> 27:2 36:1 302:15 <b>lotus</b> 205:21 <b>louder</b> 137:21 384:10 <b>love</b> 152:3,17 153:3,5 201:13 252:6 291:5 498:12 <b>loved</b> 338:20 377:1 <b>low</b> 28:21 46:14 69:3 120:8 151:3 201:22 202:16 212:16 217:16 239:14 270:14 271:8 277:7 340:19 358:20 388:9 390:9,12 403:3 455:8,9 456:1 <b>lowell</b> 3:18 21:4 <b>lower</b> 271:13 285:18 352:16,18 433:18 450:13 473:21 494:14 <b>lowering</b> 276:9 <b>lowest</b> 200:7 281:1 281:7 <b>loyalty</b> 255:19 <b>lozenges</b> 41:15 <b>lps</b> 228:3 <b>lubricated</b> 495:7 <b>lubricating</b> 489:4 491:19 <b>lucid</b> 230:12 <b>lucille</b> 12:14 274:14,17 <b>luck</b> 321:20 <b>lunch</b> 24:7,9,10 268:10 274:14 281:22</p>
--	---	---	--

<b>lunches</b> 24:12	218:18 228:4	<b>managing</b> 264:1	346:13 353:2,12
<b>lupus</b> 482:19	278:4 358:4	413:14 428:6	366:13
<b>luther</b> 142:18	464:17 465:14	<b>mandate</b> 109:15	<b>manufacturers</b>
<b>luxembourg</b>	<b>majority</b> 150:17	329:12	6:5 7:3 12:17
253:16	202:8 228:2 248:3	<b>mandated</b> 383:2	18:12 19:4 38:15
<b>luxury</b> 117:2	250:1 251:11	<b>mandates</b> 283:22	64:21 66:21 76:4
<b>lying</b> 243:9	300:8,15 318:21	<b>mandatory</b>	87:17 100:20
<b>lymphatic</b> 263:2	358:13 441:20	194:12 269:15	107:10 147:5
<b>lymphoid</b> 265:2	464:20	439:8 464:5 480:7	157:4 218:9 231:9
<b>m</b>	<b>makers</b> 77:12	<b>manifest</b> 262:8	287:9,16,20 290:3
	382:17	<b>manipulation</b>	290:3,20 306:16
<b>ma'am</b> 68:15	<b>making</b> 43:1	204:22	310:19 346:16,16
69:13 140:8 258:1	59:21 64:22 91:2	<b>mankind</b> 46:6	346:18 349:17
<b>mac</b> 212:11	94:8 108:7 122:20	127:15	350:1,5,10 351:10
<b>machine</b> 490:12	141:6,10 147:12	<b>manner</b> 62:11	362:9,14,21
<b>machines</b> 247:3	149:15 157:11	98:8 116:22 119:6	363:13,19 364:1,7
490:13	158:7 289:18	290:7 291:22	365:22 382:22
<b>maciora</b> 111:5	291:18 305:8	316:15 477:10	383:1 406:14
<b>mackay</b> 13:10	316:18 353:2	<b>mannion</b> 13:12	415:12,14,19
321:13,14,14	365:20 374:7	328:21,22 329:1	427:3 449:2
326:21 327:20	388:7 456:12	<b>manufacture</b> 78:2	478:21 480:6,17
328:9	487:17 491:22	194:21 312:3	<b>manufactures</b>
<b>mad</b> 58:8	500:16	325:22 332:11	480:10
<b>madison</b> 10:8	<b>males</b> 174:14	333:17 342:13,14	<b>manufacturing</b>
<b>maelstrom</b> 37:21	359:8	343:11,15,18	38:6 39:15 52:9
<b>magical</b> 149:6	<b>malevolent</b> 174:16	344:17,19 345:14	53:22 74:6 87:21
<b>magnitude</b> 120:16	<b>malignant</b> 265:1	346:22 347:3	92:19 123:9
<b>magnolia</b> 96:1	<b>malkin</b> 15:14	348:15 353:22	151:22 152:8
<b>main</b> 126:19	413:7 419:10,12	381:2 451:1 479:7	185:13 192:7
132:16 205:22	419:13	<b>manufactured</b>	292:17 303:10,16
253:7 270:3	<b>man</b> 206:20	112:17 116:22	304:14,20 305:12
350:15 375:18	395:21	194:5 240:9,11	309:12 311:14
494:18	<b>man's</b> 207:9	314:22 318:1	319:17 329:1
<b>maine</b> 261:18	<b>manage</b> 207:18	319:11 333:10	331:6,13,18 332:1
<b>mainstream</b>	321:19	370:5,18 372:8	332:16 333:14,16
125:22 126:12	<b>manageable</b> 124:3	<b>manufacturer</b>	336:4 343:9
231:2	<b>management</b>	66:18 67:1 101:10	345:17 346:2
<b>maintain</b> 122:19	59:18 89:6 134:13	101:11,12 207:4	348:8,13 350:7
262:13	362:22 363:11,20	207:10,15 208:15	354:10 362:2,16
<b>maintains</b> 263:6	365:11 427:22	285:5 287:7	363:4 364:13
341:19	428:6 445:19	288:12 292:10	367:20 368:16,21
<b>maintenance</b>	<b>manager</b> 57:7	297:5 308:20	370:11,16 371:20
359:20 427:13	442:17	309:3 311:1,4	393:19 405:2
<b>major</b> 62:2 97:15		342:10,12 346:8	416:2,9,12 425:20
202:9 203:14			

460:7 461:22	371:2 373:12,13	423:22 431:14	162:16 163:8
463:1,8,15 464:19	373:15 374:3,9,13	436:1 437:11,22	164:1 165:6
478:14 487:9	374:16,17,20	440:11 441:15,21	170:10,11 171:6
488:15 489:14	375:2,3,7,11,12	445:6 446:9	193:12 231:3
490:10 497:7	375:15,19,20	451:18,22 452:15	236:8 237:2,12
<b>manuscripts</b>	376:1,2,3,5,8,9,9	454:13 478:1,8	246:21 312:17
203:11	376:11,14,14,15	492:3	354:7 355:16
<b>manward</b> 8:7	376:16,21 377:9	<b>marketable</b> 231:1	356:15,16 408:6
125:10	395:8 413:16	<b>marketed</b> 27:18	428:11 438:2
<b>map</b> 302:18	421:7 433:2,6	29:19 31:14 32:9	441:13 476:14
384:16	470:10,18 471:19	32:14 51:20 85:3	<b>markets</b> 62:20
<b>marcel</b> 211:11	473:20	105:20 106:12,15	78:8 90:9 146:5
<b>march</b> 77:22	<b>marinol</b> 30:6	106:17,19,21	156:14 253:21
485:20	<b>marked</b> 130:4	118:1 138:22	254:2 258:8
<b>margaret</b> 220:18	191:15 329:17	164:22 189:5	283:22 357:20
224:2	<b>markedly</b> 189:2	200:7 222:7 269:5	371:16 411:10,21
<b>margarine</b> 448:11	<b>market</b> 30:22	269:7 272:15,16	424:1 430:5
<b>margin</b> 144:4	31:10 45:18 46:12	323:12 355:9	452:21 453:3
269:20,20	46:15 50:18,22	374:10 377:6	<b>marla</b> 457:19
<b>margins</b> 269:13	51:6 52:4 54:16	433:14 438:6	<b>married</b> 57:14
340:22	76:15 77:7 82:18	440:22	<b>marwan</b> 13:18
<b>marijuana</b> 5:13	83:4 84:16 90:21	<b>marketer</b> 438:9	342:4,8
5:15 6:15 21:13	91:1 108:5,20	438:17	<b>maryland</b> 13:19
21:18 28:3,4,5,11	109:3 112:12	<b>marketing</b> 9:12	261:13 294:15
28:12 29:1,1	117:3 129:12	33:14 35:6,10	342:5,8,9,18,21
56:15,17,19,21	154:17 162:15	38:3 83:20 105:12	344:13 345:1
57:4,8,22 58:2,12	164:12,16,17	105:22 106:10	379:7 502:17
59:6,8,13,14,18	165:4 166:6	111:22 113:14	<b>mask</b> 59:18
60:3,5,12,13,18	168:12 169:5	121:15 130:12	<b>mass</b> 119:17 154:4
60:19,22 62:10	188:17 192:5	153:8,12 199:2,21	190:1 338:12
77:22 78:3 91:22	193:1,3 194:18	221:1 236:4	374:9
92:1,10 101:2	195:7 196:15	239:15 256:20	<b>massachusetts</b>
145:11 146:11	197:15 198:17,19	273:11 326:2	59:7 61:7 242:14
173:10,13,17	199:5 210:20,21	354:11 355:6	<b>massive</b> 52:2
174:9,16 175:6	214:8 229:4	375:7 381:5 382:2	<b>master</b> 72:1 312:2
219:4 241:1,4,11	239:13 246:10,10	414:22 423:18	355:19 485:8
241:13,14 242:5	254:22 284:22	452:13 491:17	<b>match</b> 486:9
242:11,12,21	307:4 322:7 325:5	<b>marketplace</b>	<b>matched</b> 191:8
243:1,3,6,7,8,10	338:12 346:19	64:16 76:20 84:15	<b>material</b> 45:17,20
244:2,16,22 245:5	348:22 349:8	95:1 97:6,18 98:5	45:22 95:8 100:10
245:8 260:6 294:5	354:1,19 360:12	102:19 112:8	133:2 218:18
322:19 341:10	395:17,18 396:17	114:7 116:9	286:1 296:8,21,22
367:9,10,12,13,16	403:3 406:1	120:13 154:5	297:2 303:1 312:5
368:2 370:22	407:15 409:6	155:10 162:9,11	323:2,6 327:22



348:19 369:14 389:1 394:3 428:20 451:2 <b>materialize</b> 440:12 <b>materials</b> 43:16 64:14 101:1 130:19 133:12 168:20 218:21 219:14 297:4 302:22 309:10 311:7 312:4 331:21 351:6,9 363:6 364:2 372:10 381:18 392:7,15,22 393:9 394:21 411:18 427:14 489:21 490:22 <b>matrices</b> 371:13 <b>matrix</b> 351:19 352:1,5 <b>matt</b> 16:2 442:15 <b>matter</b> 71:18 150:16 185:20 204:18 339:7 360:6 406:14 <b>matters</b> 184:7 <b>matthew</b> 442:16 <b>mature</b> 146:4 357:19 453:3 <b>matz</b> 9:11 153:7,9 <b>maximum</b> 450:3 <b>maya's</b> 175:4 <b>mayl</b> 3:6 21:10,11 <b>mayne</b> 413:6 <b>mazanet</b> 13:14 332:20,21 337:21 <b>mazloun</b> 13:2 298:12,12,15,15 298:19,19 <b>mccoll</b> 5:12 173:6 173:8	<b>mcg</b> 302:16 <b>mcguffin</b> 7:18 111:8,10,11 114:2 114:5,21 115:13 <b>mcmurphy</b> 17:4 481:18,20 486:12 <b>md</b> 1:19 2:2 4:6,8 5:20 6:6 7:4 8:17 10:9,17 12:12,14 13:8,14 15:4 18:6 67:1 264:22 <b>mdmb</b> 206:17 <b>mead</b> 13:16 338:4 338:5,5 <b>meal</b> 168:17 170:19 <b>mean</b> 55:11,13,17 75:1 103:6,7 114:1,5,6 141:18 214:20 239:17 240:2 308:14 312:7 313:15 326:21 327:11 399:22 406:2 418:13 424:15,21 437:20 468:11 469:8 <b>meaning</b> 28:20 29:20 84:6 264:16 271:10 <b>meaningful</b> 334:3 455:12 <b>meaningfully</b> 461:2 <b>means</b> 32:12 83:4 106:15 149:1 239:21 265:10,12 267:8 341:9 402:18 444:9 460:18 469:5 477:14 <b>meant</b> 68:20 239:20 255:20 473:7	<b>measure</b> 39:14,18 <b>measured</b> 51:7 180:7 321:4 449:18 453:19 <b>measurement</b> 446:14 471:19 <b>measurements</b> 134:9 345:20 <b>measures</b> 50:1 472:1 <b>measuring</b> 305:21 <b>mechanically</b> 488:20 <b>mechanism</b> 68:12 139:14 301:12 302:5 313:13 <b>mechanisms</b> 235:20 414:12 415:2 <b>media</b> 22:22 23:1 23:16 27:2 236:20 382:4 <b>medical</b> 6:3,15 10:13 12:15 26:10 28:3,16 33:5 57:3 59:6,8 60:15,18 60:19 62:10 63:17 63:20 73:3 77:21 78:3,17 80:2 93:10 97:8 98:3 107:13 122:13 139:1,6 146:5 156:7 174:17 188:5 193:3,6 194:6,6,15 195:2 198:10 200:17 217:3 219:3 220:8 220:22 221:3,6,16 224:20 244:22,22 256:15 258:15 259:15 260:6 264:3,4,5,10,14 265:2,5,18 266:5 267:15,17,20	268:3 274:19,20 275:5 277:3 294:5 317:11 319:9 320:2 333:1,3,18 336:18 357:15 379:21 381:9 386:8 400:14 409:1,2,18 410:17 415:8 421:7 426:20 431:7 482:15 483:3,5,11 483:17,18 487:18 490:12 491:4,22 <b>medically</b> 262:1 483:1 <b>medicated</b> 404:7 <b>medication</b> 38:22 141:1 179:18 250:20,21 251:7 277:22 280:21 334:17 338:18 341:14 390:2 403:22 404:21 436:22 460:3,8,11 <b>medications</b> 131:2 139:6 143:2,13 144:7 188:18 277:20 280:19 338:9,17 340:1 402:10 415:8 458:10 459:15 460:12 461:10 <b>medicinal</b> 10:10 61:18 123:11,13 182:3,7,11,15 264:9 344:3 467:15 480:22 <b>medicine</b> 2:20 3:8 3:16 4:16,18 11:8 22:14 26:10 37:11 37:19 40:2 60:14 63:9 92:1 122:12 126:3,5 148:2 167:11 241:15
---	---	---	---

245:19 259:12	55:15,18,21 56:3	309:15,20 310:1	199:17 202:5
260:3,5,9,18,20	56:12 61:5,8	310:13,15,17	210:16 218:2
261:7,10 262:3,17	65:22 66:1,10,11	315:20 316:9	237:9 253:22
263:10,14,16	66:15 68:11,16,17	321:1 326:12	307:16 308:7
264:10,11,15,19	69:5,10,11,14,17	327:17 328:5	310:3 315:20
266:12 267:16,16	70:6,12 74:12,22	337:16 352:13	385:3 409:2
267:18,18,18	75:7 79:18 80:12	379:5 390:5,7	466:16
282:15 285:3,9	80:21 85:14,16,19	399:18 405:9	<b>mentioning</b> 80:16
286:20 317:9	86:2,8,9,11,14,17	413:8 429:17	497:10
327:9,12 374:10	86:18,22 87:4,6	434:10,21 441:3	<b>merchandising</b>
377:4 379:6	89:14 90:8 94:21	442:8 456:14,20	155:4
400:16 483:13	95:10,16 100:22	466:15,21 476:3	<b>mercury</b> 490:5
485:12 486:14,16	101:5 103:4,14	481:11,16 493:21	<b>mere</b> 106:7
<b>medicines</b> 76:5,8	104:6,10 110:13	494:13	<b>merely</b> 125:22
76:13 92:20 94:9	110:18 111:2	<b>members</b> 20:21	<b>merits</b> 467:15
98:13,22 260:19	113:17 114:3,17	23:13,19 48:1,7	<b>mess</b> 291:19
337:7 338:15	115:5 118:11,21	49:8 83:12 90:10	<b>message</b> 58:9
341:20,21 458:14	124:13,17,20	103:19 107:9	439:9
492:3	128:2,5,10,13,14	154:17 155:3	<b>messages</b> 38:1
<b>medieval</b> 275:4	129:2,19 137:5	247:10 276:3	389:14
<b>mediums</b> 229:6	140:7,9,14 141:4	284:9 406:19	<b>met</b> 134:17 307:3
<b>meet</b> 63:10 77:14	141:8,11 144:14	427:16 428:21	332:13 354:16
97:12 227:4	144:18 152:19	445:3	427:10
245:10 347:3	153:18 157:20	<b>membership</b> 87:8	<b>meta</b> 293:5
368:6 369:19	158:8,11,15,19,22	166:17	<b>metabolic</b> 177:18
478:6	161:5,8 164:11,14	<b>memo</b> 121:6,12	<b>metabolism</b> 178:9
<b>meeting</b> 23:15	165:10 169:16	<b>memory</b> 173:21	178:21 180:16
27:5 36:6 88:8	170:2,21 171:2,16	211:20 223:7	202:8,9 271:1
95:20 184:5	172:8,13 185:18	<b>men</b> 174:12 224:1	465:19
243:13 249:8	186:11 187:2	224:16	<b>metabolite</b> 177:7
344:14 363:5	197:2 198:4,14,15	<b>menstrual</b> 493:11	179:5
386:12 389:15	198:21 199:7,14	<b>mental</b> 57:18,20	<b>metabolized</b> 177:5
443:9,19 449:7	200:11 214:18	59:12 243:2,5	178:22 180:1,12
<b>meetings</b> 160:12	215:9,15,22 216:3	<b>mentality</b> 408:14	<b>metabolizing</b>
160:14 344:12	226:6,12,15,17	<b>mention</b> 78:20	177:22 179:14
395:10	232:11 233:5,12	124:14 219:9	<b>metal</b> 60:10
<b>meets</b> 319:16	233:21,22 252:11	411:22	330:14 345:18
369:16 381:4	257:22 258:2,9	<b>mentioned</b> 31:17	480:9
<b>megan</b> 7:20	264:1 273:21	36:18 66:7 69:18	<b>metals</b> 60:12 72:5
115:18,20	274:10 279:18	79:2 85:17 110:19	103:1 146:16
<b>mellow</b> 206:11	280:1,5,7,9,11,12	110:20 113:18	234:14 237:17
<b>melting</b> 315:9	281:2 298:14	128:18 144:15	278:18 306:14
<b>member</b> 52:21	307:10,12,15	180:11 184:21	312:9 319:19
53:4,15 55:2,6,9	308:10,13 309:2,7	196:2 198:21,22	330:11 336:3

352:6 362:6 364:4 372:12 417:5 428:15 443:3 <b>meth</b> 374:16 <b>method</b> 41:3 315:15 319:15,16 327:21 351:18,20 351:21 352:1 354:20 392:10,11 394:15 465:20 487:19 <b>methodologies</b> 371:12 <b>methods</b> 133:19 134:9 145:4 311:21 312:5 316:7 348:20 349:18 351:12,18 352:3 364:10 379:2 381:12 391:11,12,15,22 392:2,6,8,20,21 393:2,3,8 394:18 416:7 428:14 445:12 <b>metrics</b> 362:20 <b>mettler</b> 3:10 21:20 21:20 <b>mg</b> 51:10,22 63:2 63:3 120:11,13 189:21 203:6 211:12,16,18 213:3,14 270:20 270:21 272:11 277:6,11,13 278:11 279:6 280:22 301:16,17 301:19 319:3,6 328:3 340:17,18 341:8 358:20 359:9,10,12,18,19 359:19 361:6 397:6,10 469:4,5 469:9,9,10,11,13	469:14,16,21,22 470:2 475:3 <b>mic</b> 91:9 138:1 141:8 298:18 <b>mice</b> 202:22 360:9 <b>michael</b> 7:18 23:15 111:8,11 <b>michelle</b> 10:20 204:9,16 246:14 <b>michigan</b> 317:12 319:8 320:2 <b>micro</b> 288:18 <b>microbes</b> 330:10 336:2 <b>microbial</b> 100:3 286:6 330:12 332:3,3 352:7 362:6 364:4 372:14 480:8 <b>microbials</b> 319:19 <b>microbiological</b> 146:15 443:4 <b>microbiology</b> 145:7 393:21 <b>microbiome</b> 493:13 <b>micronucleus</b> 271:7 <b>microorganisms</b> 99:20 <b>microphone</b> 25:8 187:17,22 211:2 357:4 447:8 451:9 <b>mid</b> 342:11 345:7 345:9 <b>midazolam</b> 180:17 <b>midst</b> 63:8 <b>migraine</b> 139:2 275:18 <b>migraines</b> 261:11 261:15 <b>milanova</b> 17:6 487:2,3,5 489:13 492:12 493:19	494:1,17 495:17 495:20 <b>mild</b> 51:13 69:20 69:22 70:8 211:16 213:6 300:9,16 301:9 318:9 <b>milder</b> 70:7 <b>mile</b> 13:21 347:14 347:14 <b>miles</b> 9:15 155:21 156:3,3 158:4,10 158:12,16,20 159:1 <b>milestones</b> 460:13 <b>military</b> 208:6 283:2 294:10 <b>millennia</b> 145:14 408:12 <b>millennials</b> 249:3 <b>miller</b> 5:4 47:17 47:19 211:11 <b>milligram</b> 95:8 279:7 281:7 <b>milligrams</b> 51:10 <b>milliliter</b> 211:12 <b>million</b> 43:14,15 43:17 84:18 108:19 116:10,11 161:22 162:4 238:11 239:22 240:4 248:15 260:6 314:13 344:9 347:18 349:2 385:5 400:22 430:18 482:12 <b>millions</b> 49:9 145:18 247:10 342:16 348:3,5 430:17 435:16 <b>mind</b> 245:13 281:12 468:22 <b>mindboggling</b> 432:15	<b>mindful</b> 24:17 <b>mine</b> 24:2 269:12 425:13,14 475:7 <b>mineral</b> 449:3 <b>minerals</b> 486:6 <b>minimal</b> 109:12 277:3 278:9 <b>minimize</b> 331:8 <b>minimum</b> 117:4 304:8 407:18 409:16 411:10 412:11 <b>minnesota</b> 10:15 192:13 193:4 194:7,13,14 196:7 197:4,17,18 198:10,11 <b>minor</b> 210:21 211:5 492:15 494:19 <b>minus</b> 238:5 <b>minuscule</b> 174:10 175:14 <b>minute</b> 25:10 122:5 173:3 184:18 245:1 282:4 288:1 295:17 300:20 372:22 378:7 <b>minutes</b> 37:3 41:5 41:6 91:18 132:12 155:22 166:13 173:7 245:2 298:7 300:22 318:15 496:2,4 <b>miracles</b> 260:17 <b>miraculous</b> 260:8 <b>mirroring</b> 94:17 <b>misinformation</b> 228:7 <b>misabeled</b> 312:17 349:9,11 <b>mislabeling</b> 497:6
---	--	--	---

<b>misleading</b> 38:3 73:16	443:21 444:15 446:1 475:10,21	<b>monitored</b> 141:13 217:19	135:14 137:16,16 145:2 147:11
<b>misrepresented</b> 190:13 312:17	485:13 486:1 491:15 494:12	<b>monitoring</b> 101:14 192:8	150:13 153:9 156:3 166:14
<b>mission</b> 50:20 100:7 200:19	<b>models</b> 135:20 322:21 398:20	194:12 206:6 208:8 303:2	173:8 176:20 177:3,10 187:15
282:17 353:19 355:2,3 393:16	399:1 493:7 494:6	<b>monograph</b> 122:4 450:18	188:10 192:11 204:10 210:1
397:19 422:13 462:14	<b>moderate</b> 211:17 300:16 318:10	<b>monographs</b> 365:14	234:2 396:8 417:7
<b>missioned</b> 394:3	<b>moderating</b> 20:9	<b>monopoly</b> 52:3 436:8	<b>morris</b> 9:17 159:3 159:4,4 161:7
<b>mississippi</b> 11:5 188:12 189:17,18	<b>modes</b> 183:22 186:5 454:3 455:3	<b>month</b> 96:4 120:15 141:3	<b>mortar</b> 207:22 208:6
191:15 192:14,19 195:14 216:13	455:4	290:11 347:17,18 403:15 491:2	<b>mother</b> 96:4 230:7 233:1 234:22
217:3,10 218:19 423:12	<b>moheyeldien</b> 13:18 342:4,7,8	<b>months</b> 26:3 35:4 227:7,7 248:10	<b>motility</b> 389:7 <b>motions</b> 241:6
<b>mistake</b> 126:11 448:22	347:10	260:12 291:19 320:4 349:3 414:4	<b>motives</b> 453:6 455:22
<b>mistaken</b> 112:10	<b>moiety</b> 105:13 106:5	447:17 458:1 459:3,22 460:15	<b>motor</b> 385:14 387:4,8,13
<b>mistakes</b> 39:11 127:20 257:7	<b>moisture</b> 332:6 372:13 488:10	462:3 473:4	<b>mou</b> 167:18 <b>mouse</b> 202:7
<b>mister</b> 15:16 117:11 435:2,3,4	<b>molasses</b> 448:10	<b>monumental</b> 54:19	360:2 397:9 398:14,14,15,17
441:12 442:12	<b>mold</b> 72:4 283:20 372:14 405:3	<b>mood</b> 130:4 300:14 386:1	398:19 475:10,21 <b>move</b> 24:4 37:14
<b>misuse</b> 33:6	<b>oldy</b> 59:13,14,18	63:16,18,19 66:4 66:14 425:12,13	58:22 79:22 98:4 104:14 138:1
<b>mitigate</b> 35:13 105:10 131:3	<b>molecular</b> 233:3	425:15	155:11,17 187:17 211:2 265:15
229:22	<b>molecule</b> 177:3	<b>morning</b> 21:3,7,10 21:20 22:1,6,9	282:12 287:15 290:14 291:20
<b>mitigated</b> 42:11	<b>molecules</b> 151:14	24:11 26:15 36:19 37:2,17 42:16	293:6,15 298:17 357:3 373:5 451:9
<b>mix</b> 390:11 407:1	<b>mom</b> 373:11 376:3	43:1 45:7 47:19 61:15 62:12 63:18	462:6 500:13
<b>mixed</b> 205:16	<b>moment</b> 408:21 410:14 421:10	70:20 77:3,20 81:7 87:15 95:15	<b>moved</b> 373:11 431:10 496:10
<b>mixture</b> 448:10	<b>moments</b> 179:4	98:11 101:22 104:13,16 107:5	<b>movement</b> 385:16 467:8
<b>mj</b> 173:18 174:12 174:13	<b>moms</b> 14:15 376:12	111:10 119:2 122:9 125:9	<b>moving</b> 40:10 59:1 61:11 66:17,19
<b>ml</b> 469:15	<b>monascus</b> 396:15		70:18 77:18 81:4 83:6 91:5 129:18
<b>mm</b> 280:8	<b>money</b> 127:14 355:22 403:16		
<b>mobility</b> 253:8	483:2,8 485:14		
<b>mode</b> 451:19	<b>monica</b> 8:8 129:18 129:21		
<b>model</b> 177:7 196:12 224:9	<b>monitor</b> 99:14 125:1 199:12		
241:5,6,6 304:22	339:19 452:2		
343:10 365:6	459:14		
398:14,14 442:22			

144:20 155:19 176:15 183:20 187:6 233:7 259:3 263:20 275:19 295:16 310:22 337:8 387:1 429:3 489:10 490:10 498:22 <b>mpp</b> 15:21 429:16 430:1 432:2 433:21 <b>mpp's</b> 430:7 <b>mra</b> 447:2 <b>mrjs</b> 67:16 <b>mucosa</b> 493:22 494:5 <b>mueller</b> 13:20 347:12,13,13 352:21 <b>multi</b> 133:16 454:1 455:4 472:8 <b>multibillion</b> 291:1 <b>multicenter</b> 319:1 493:10 <b>multidisciplinary</b> 192:22 <b>multinational</b> 93:7 <b>multiple</b> 44:3 49:1 52:17 57:19 93:4 109:1 126:4 134:4 143:12,21 181:10 193:4 221:16 230:17,20 261:4 269:5 294:9 299:4 300:7,19 301:21 301:22 302:9,20 308:2 340:20,21 344:12 411:15 454:2 469:21 474:11 <b>multistate</b> 476:14 <b>multitrack</b> 217:21	<b>multitude</b> 54:8 <b>munchies</b> 215:5 <b>municipal</b> 468:2 <b>murders</b> 376:10 <b>muscular</b> 263:3 <b>mustn't</b> 38:18 39:11 <b>mutagenic</b> 271:6 <b>mutual</b> 195:17 436:7 445:3 <b>mutually</b> 453:20 <b>mycotoxin</b> 302:13 <b>mycotoxins</b> 232:4 234:12 237:18 286:6 302:14,21 372:12 <b>myoclonic</b> 402:7 <b>myth</b> 341:4	181:22 188:3 192:11 200:15 204:16 227:17 263:22 274:17 278:19 279:21 280:3 293:22 317:8 321:14 328:22 342:7 347:13 353:9 361:19 362:7 366:6 373:10 378:22 406:20 413:14 419:13 425:15 448:4 451:6 457:2 462:12 496:5 <b>named</b> 91:21 <b>narco</b> 242:15 <b>narcotics</b> 189:19 <b>narrative</b> 173:12 320:15 <b>narrow</b> 180:5 305:6 <b>nasc</b> 83:12 84:10 85:7 <b>nascent</b> 38:1 108:17 <b>nasser</b> 58:22 59:1 <b>nation</b> 62:4 125:15 159:7 162:5 368:14,19 374:19 471:9 <b>nation's</b> 385:3 <b>national</b> 6:21 7:17 11:5 16:3 26:6 78:22 82:10 83:11 88:21 89:22 107:3 107:7 126:2,5 134:9 147:21 156:18 158:5 182:6 183:14 188:6 189:13 192:14 195:13 204:21 219:7,18	219:22 220:2 224:18 236:11 242:8 247:17 294:10 295:5 331:15 336:11 400:21 424:18 442:18 446:2 451:21 467:11 476:11 483:14 485:5 <b>nationally</b> 88:17 133:17 478:18 <b>nations</b> 467:12 <b>nationwide</b> 163:19 208:1 395:15 <b>natural</b> 7:13 11:6 15:3 101:21 102:1 102:7,17 106:20 127:1,12 131:2 139:10 188:7 189:13 192:15 195:13 196:13 286:11 323:7,11 395:12 491:3 <b>naturally</b> 112:4 113:18 114:9 323:8 357:15 <b>naturals</b> 9:8 <b>nature</b> 37:22 102:19 127:22 188:15 <b>nauseam</b> 468:12 <b>navigate</b> 283:5 <b>navigating</b> 461:16 477:14 <b>nce</b> 93:13 <b>nci</b> 398:18 <b>ncia</b> 107:8,9 110:10 <b>nd</b> 13:10 <b>ndi</b> 72:1,3,6 77:13 102:16 103:16 104:1,4 218:6
	<b>n</b>		
	<b>n</b> 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1,1 19:1,1 20:1 179:5 319:2 <b>nadia</b> 213:5 <b>najla</b> 12:10 268:10 268:13 <b>name</b> 21:1,3,10 25:5 37:18 40:3 42:16 50:7 59:4 61:15 70:20 72:13 77:20 78:1 81:7 83:10 91:19,20 92:17 98:11 101:22 104:16 107:5 111:6,10 119:2 122:9 125:9 132:15 135:14 137:17 138:2 142:18 145:2 147:11 150:13 161:12 173:6		

269:17,21,22 270:2 272:4 273:10,11 324:15 439:2,16 440:5 478:3 <b>ndin</b> 354:15,21 355:7,20 356:7 <b>ndis</b> 77:14 <b>nearing</b> 238:10 <b>nearly</b> 107:9 108:22 116:15 157:2 229:19 233:15,19 238:13 320:4 356:14 385:5 426:6 <b>neat</b> 133:12 <b>necessarily</b> 40:17 254:15 255:16 307:19 395:9 486:18 <b>necessary</b> 48:8 49:1 133:20 139:8 256:10 278:9 332:13 356:2 410:8 452:2 <b>necessitates</b> 219:13 <b>necessitating</b> 181:6 <b>necessity</b> 88:16 266:11 <b>ned</b> 4:6 18:6 20:10 25:22 <b>need</b> 24:5 33:16 36:2 38:3 41:22 42:4 44:20 46:17 48:15 56:22 57:1 57:2 58:11 64:6 65:8 77:6,12,14 82:14 83:19 88:21 90:1,18 94:19 109:1,2,22 129:6 129:8 131:7,20 132:2,4,7 149:14	149:16 165:7 168:21 177:16 182:22 183:5 184:20 185:4,7 186:4 199:18 201:19 205:8 214:3,16 217:8,19 218:8 219:10,11 219:18,19,22 220:5 221:13 222:5 225:1,5,11 225:15,16,22 226:7 232:1 254:22 256:15,18 256:19,20 257:15 259:20 260:2 266:9 268:2 278:15,20,20,21 279:1 287:10,10 291:20 294:11,19 295:12 296:19 297:1,6,22 298:17 306:4,6 312:21 336:19,20 350:2 352:6,21 360:16 360:16 377:10 378:20 380:3,8 383:14 387:9 388:3 389:15,18 389:19,22 391:15 404:20 406:13 411:16,18 414:4 414:10,15,19 415:21 416:4,14 422:3 425:4 430:4 441:10 446:6 455:13 473:17 475:11 <b>needed</b> 30:12 46:1 84:19 129:14 137:1 169:22 204:1 213:21 225:1 259:20 382:3 403:10	452:9 460:7 463:7 463:22 <b>needless</b> 475:17 <b>needs</b> 60:21 73:13 77:2 83:21 95:21 148:20 184:16 186:9 262:19 267:5 295:1 363:18 381:6,19 396:6 409:5 431:21 436:18 438:2 442:6 446:6 450:2,16 457:17 465:2 497:17 <b>nefarious</b> 209:13 <b>negative</b> 173:14 215:20 302:3 330:8 340:16 475:21 <b>negatively</b> 82:7 467:18 <b>negatives</b> 183:7 <b>negligence</b> 244:15 <b>negligent</b> 244:14 383:7 <b>neighborhoods</b> 377:14,19 <b>neighboring</b> 43:13 <b>neither</b> 111:20 458:21 502:8 503:7 <b>neonates</b> 138:6 <b>nervous</b> 263:2 270:5 300:7 302:2 <b>net</b> 56:9 101:8 <b>network</b> 40:21 288:12 <b>networking</b> 95:17 <b>networks</b> 289:2 291:7 <b>neuro</b> 484:8,14 485:7 <b>neurodegenerati...</b> 385:13 388:18	389:19 <b>neurologic</b> 301:1 301:4 302:7,8 474:15 <b>neurological</b> 264:8 <b>neurologists</b> 386:5 386:14 387:15,17 458:17 <b>neurology</b> 400:15 <b>neurons</b> 385:14 <b>neuropathic</b> 183:10,17 184:12 <b>neuropathy</b> 276:8 276:20 <b>neuroprotective</b> 123:1 269:7 <b>nevada</b> 229:1,3 <b>never</b> 32:17 39:7 174:7 246:4 263:10 272:16 317:18 398:22 406:15 473:13,22 <b>new</b> 1:18 26:3 27:13,21 30:12 31:1 32:15,16,20 33:14 43:18 44:9 50:21 74:11 76:13 77:9 96:4 97:17 105:16 130:16 145:19 147:7 157:7 167:22 183:20 185:12 221:9 227:13 242:22 244:13 254:21,21 256:8 267:9 268:19 269:17 279:10 290:18 295:11 307:9 323:21 324:1,1 333:13,13 338:19 347:21 350:11 356:1,11 368:10,16,18,21
---	--	--	--

368:22 369:6	104:22,22 122:22	417:13,14,22	132:14 135:9,11
373:5 397:3	122:22 142:8	430:5 453:20	137:15 142:17
416:13,13 420:1,6	151:19 210:19	492:2	144:22 147:8
421:6,7 427:6	213:1 215:19,19	<b>noted</b> 79:4 160:9	161:10 166:9,11
437:12 438:20	227:16 238:20	313:22	176:8 181:17
441:15 460:7,13	294:4 323:5	<b>notes</b> 112:2 321:5	182:14 183:9
475:16 478:20	329:22 330:2	321:8	187:13 192:10
485:13 497:16	340:5 350:20	<b>notice</b> 433:15	199:9 200:13
<b>newest</b> 428:18	363:7 387:8,13	440:19	201:15 202:3
<b>news</b> 171:18 282:7	409:13,20 411:9	<b>noticed</b> 31:12	204:9 207:2
336:11,14 383:9	464:21 467:6	483:4	209:22 210:18
<b>nice</b> 173:4	477:6 480:22	<b>notices</b> 323:18	211:22 216:10
<b>nicely</b> 25:14	<b>noncompliant</b>	<b>noticing</b> 277:9	217:6 222:9 224:3
<b>nick</b> 2:5 22:1	229:3,21	<b>notification</b> 167:8	227:15 235:10
<b>nickel</b> 490:5	<b>nonexistent</b>	272:4 273:10	239:1 240:15
<b>nicotine</b> 40:12	125:19	350:11 438:21	247:15 248:2,20
205:2,18,20 206:4	<b>nonprofit</b> 98:20	439:2,16 440:6,7	251:4 252:19
206:13 452:7	122:11 132:19	<b>notifications</b>	254:9 259:4 261:6
454:12,22	247:2 451:7	77:13 218:7	262:2 263:21
<b>nida</b> 184:11	462:14	268:19 269:18	268:11 274:3
186:16 216:19	<b>nonsense</b> 483:18	324:15 478:3	275:14 287:17,19
219:1 283:11,14	<b>nontoxic</b> 104:22	480:18	293:20 295:21
283:16 285:1	122:22 202:21	<b>noting</b> 124:5	297:10,14,14
451:13 471:20	<b>nonverbal</b> 130:6	<b>notion</b> 71:8	298:11 303:7
<b>nida's</b> 183:10	<b>noramco</b> 13:7	<b>notwithstanding</b>	311:1,15 317:2
<b>night</b> 373:20	311:3,17	105:18	328:2,21 332:20
<b>nightingale</b> 61:20	<b>noramco's</b> 313:7	<b>novel</b> 93:1 205:22	335:14 340:6,11
63:6	<b>normal</b> 51:10	488:16 497:16	342:3 343:16
<b>nightmare</b> 293:14	400:6	<b>november</b> 453:13	346:3 347:12
<b>nih</b> 26:6 79:4	<b>normalcy</b> 266:16	<b>nsaids</b> 318:11	353:8 356:19
296:14 440:13	<b>normalizing</b>	<b>nuleaf</b> 9:8	361:10 366:5
471:20	375:15	<b>number</b> 24:12	373:6 375:17
<b>nimble</b> 185:8	<b>north</b> 9:21 161:14	30:20 37:5 47:17	378:16 384:1,15
<b>nimbleness</b> 185:9	161:18,21 162:2,3	56:16 58:21,22	395:5 407:21
<b>nine</b> 58:21 84:16	162:19,20 175:20	59:2 61:10,11,13	422:21 425:12
274:2 335:9 458:1	208:4 228:20,21	63:16 66:18,20	429:13 435:2
<b>nobody's</b> 182:19	229:8 233:6,9,13	70:16,18,22 72:11	442:15 446:5
<b>noel</b> 269:19	<b>notably</b> 62:2	75:22 77:5,19	448:3 454:16,20
<b>noels</b> 219:21	<b>notary</b> 502:1,16	83:8 87:14 91:6	462:7 470:8,8
<b>non</b> 4:20 11:11	<b>note</b> 27:11 31:9,20	92:15 95:14 98:9	481:18 483:11,22
18:9,21 42:15	56:19 67:21	101:20 104:12,14	484:22
43:2 78:10 79:2,7	121:19 132:11	107:2 111:5,8	<b>numbers</b> 37:12
80:14,17,19 86:5	151:8 210:3 240:7	115:18 119:1	65:19 115:3 277:7
93:19 99:18,19	249:19 399:3	125:8 129:17	464:2

<p><b>numeric</b> 37:6  <b>numerical</b> 342:6  <b>numerous</b> 104:20  441:10  <b>nurse</b> 5:19 59:3  <b>nutraceutical</b> 78:4  78:7,15 271:18  <b>nutraceuticals</b>  65:1 227:22  <b>nutrient</b> 273:14  323:20  <b>nutrition</b> 1:2 7:21  15:17 115:19,22  290:3 325:7 435:4  440:12  <b>nutritional</b> 45:16  79:10 86:5 169:2  169:5 170:19  273:9 372:17  396:13  <b>nutritionists</b>  45:10  <b>nutritive</b> 328:6  <b>nuts</b> 241:4  <b>nutshell</b> 226:22  <b>nyu</b> 400:15</p>	<p><b>observing</b> 203:22  <b>obstacles</b> 93:18  <b>obstruction</b> 203:4  <b>obtain</b> 390:2  446:21 465:12  478:9 491:20  <b>obtained</b> 222:12  299:12,19,22  301:14 320:3  363:13  <b>obtaining</b> 363:19  <b>obvious</b> 378:1  <b>obviously</b> 55:14  149:13 182:19  184:20 219:4  228:13 230:13  256:5,17 258:21  299:17 326:13  401:19 404:2  405:13 418:15  420:9  <b>occasional</b> 86:6  <b>occasions</b> 122:16  <b>occur</b> 41:8 143:16  223:3 271:22  330:12 452:3  488:12  <b>occurred</b> 119:14  220:7 301:9  466:17  <b>occurring</b> 112:4  113:18 114:9  <b>od</b> 16:16  <b>odds</b> 397:18  <b>offer</b> 53:17 98:16  132:22 267:9  305:5  <b>offering</b> 366:13  444:6 472:5  <b>offers</b> 76:20  <b>office</b> 2:7,12,16  3:4,8,12,15,20 4:4  7:15 20:8 21:2,12  21:13,22 22:3,4,7</p>	<p>22:10,13 70:21  104:15 245:13  276:10  <b>officer</b> 77:21  150:14 357:8  384:9 400:14  429:16 502:2  <b>offices</b> 347:20  <b>official</b> 99:2 167:2  167:3,13 381:12  392:2,21 393:2  <b>officials</b> 9:14  18:18 124:1  155:20 156:2,5  159:6 166:16  168:4 189:18  268:5  <b>offset</b> 139:9  <b>offsite</b> 444:12  <b>oftentimes</b> 193:17  <b>oh</b> 69:17 91:20  149:7 158:11  240:19 275:3  298:9 311:12  378:11 412:19  448:7 455:20  475:20 486:14  487:13,14  <b>oil</b> 12:19 34:14  124:8 168:17  170:18 249:10  270:17 275:3,8  276:11 277:8,14  287:22 290:13  299:6,10,18 301:7  301:14 302:15  308:21 309:13  322:1 372:18  404:8 417:20  448:19,20 449:1,2  449:3,3,3,13  457:8 459:5,21  469:16 486:4</p>	<p><b>oils</b> 96:13 127:8  191:11 211:11  256:7 257:9  362:18 364:22  365:5 418:13  <b>ok</b> 451:6  <b>okay</b> 50:5 55:15  66:10,15 70:18  75:19 86:2,14  91:17 104:14  118:21 128:13  129:17 144:18,20  150:8 158:15,19  167:17 170:20  171:16,21 172:13  172:14 181:22  199:7 200:2,11  210:1 216:3  240:19 244:6  245:11 246:2  248:19 259:1  277:10 278:3  280:5,9 282:6,14  295:17 298:9,13  298:13,19,22  307:14 308:10  313:20 335:2,5  357:6 368:18  378:14 385:1  434:8 447:7  449:15 450:1  484:6 485:1 486:6  486:14  <b>oklahoma</b> 482:8  482:12  <b>oklahomans</b> 17:5  <b>old</b> 96:4 127:5  209:3 226:20  227:8 254:20  260:11 375:5  447:16,17,19  458:2 472:19,19  473:4,7</p>
<b>o</b>			
<p><b>o</b> 18:1 19:1 20:1  <b>oak</b> 1:17  <b>objection</b> 31:13  499:10  <b>objective</b> 389:15  393:5 435:22  <b>objectively</b> 105:12  <b>obligation</b> 415:16  <b>obligations</b> 446:5  <b>obliged</b> 94:6  <b>observation</b> 391:7  <b>observations</b> 34:1  <b>observe</b> 69:21  <b>observed</b> 203:3  300:5,20 301:16  301:19</p>			



<p><b>older</b> 127:6 452:20</p> <p><b>oldest</b> 46:5 395:13 473:3</p> <p><b>olds</b> 491:14</p> <p><b>olsen</b> 7:20 115:18 115:20,20 118:18</p> <p><b>omega</b> 12:21 45:21 294:2</p> <p><b>once</b> 54:20 59:5 62:6 76:15 100:15 106:19 118:3 191:5 203:14 229:15 230:2 234:16 248:10,12 296:9 309:11,11 345:22 395:7</p> <p><b>oncologist</b> 26:7</p> <p><b>oncoming</b> 493:5</p> <p><b>onerous</b> 94:19</p> <p><b>ones</b> 49:3 63:2 237:1 283:12 338:20 377:1 423:1</p> <p><b>ongoing</b> 140:3 212:13 216:22 274:1 439:12 444:12,14</p> <p><b>online</b> 62:19 125:14 148:5 222:12 225:16 246:11 249:20 251:21 278:16 279:2 362:10 397:3 461:6</p> <p><b>onset</b> 41:9 186:20</p> <p><b>onsite</b> 372:6 444:12</p> <p><b>onslaught</b> 156:13</p> <p><b>onus</b> 415:12</p> <p><b>oops</b> 488:20</p> <p><b>open</b> 27:6,6 36:22 40:22 47:7 90:9 127:20 278:12</p>	<p>299:9 326:10 426:12 501:5,5</p> <p><b>opened</b> 428:19 448:17</p> <p><b>opening</b> 18:5 20:2 26:1,13 149:22 156:16</p> <p><b>openness</b> 381:21</p> <p><b>opens</b> 355:10 477:19</p> <p><b>operate</b> 346:11,17 359:4 411:15 478:11</p> <p><b>operated</b> 465:9</p> <p><b>operates</b> 321:21</p> <p><b>operating</b> 78:6 96:5 244:6 268:20 349:12 362:3 411:10 462:19</p> <p><b>operation</b> 367:14 370:12 465:10 476:19</p> <p><b>operations</b> 121:2 366:7 370:6 463:16</p> <p><b>operators</b> 127:7 464:13 465:11 476:15 477:12</p> <p><b>opine</b> 183:1</p> <p><b>opinion</b> 39:13 75:6 222:9 231:6 327:4 407:5 410:4 441:5</p> <p><b>opinions</b> 200:21</p> <p><b>opioid</b> 39:12 241:9 251:1 260:13 261:14 318:6 482:18 484:21 485:16</p> <p><b>opioids</b> 67:10 224:11 271:13</p> <p><b>opportunists</b> 131:21</p>	<p><b>opportunities</b> 44:9 47:7 52:11 90:15</p> <p><b>opportunity</b> 45:14 46:7 49:21 52:16 65:21 72:8 74:9 77:17 79:16 83:13 85:13 88:9 89:9 94:20 104:17 124:12 129:9 151:20 153:11 155:14 156:9 157:17 161:12,16 164:2 187:15 188:3 204:11 216:12 259:9 268:6 273:19 317:7 326:8 329:4 352:12 373:9 378:19 384:8 413:13 418:5 425:17 429:9 431:12 439:10,18 462:11 487:4</p> <p><b>opposed</b> 84:1 87:1 140:11</p> <p><b>opposite</b> 271:12 474:16,18</p> <p><b>ops</b> 288:17</p> <p><b>optimal</b> 79:10 285:14</p> <p><b>optimistic</b> 284:2</p> <p><b>optimization</b> 126:13</p> <p><b>option</b> 255:18 317:16 341:15</p> <p><b>options</b> 27:8 123:8 223:12 287:10,10 394:13</p> <p><b>optometrist</b> 471:17</p> <p><b>oral</b> 4:13 18:7,17 20:13 37:1,15 81:10 93:2 156:1</p>	<p>173:5 186:15,20 211:16 212:4 224:10 270:19 278:9 299:10 301:7,14 313:14 358:16 366:14 389:3</p> <p><b>orally</b> 41:6 211:19 212:19 270:16 299:6</p> <p><b>orange</b> 387:17 454:15</p> <p><b>order</b> 24:11,21 25:3 37:6 72:7 81:20 141:3 168:11 228:9 229:22,22 230:22 233:2 342:6 370:4 382:11 390:2 412:15 414:11,17 461:14 463:18</p> <p><b>ordered</b> 23:6 57:20 417:7</p> <p><b>orderly</b> 383:11</p> <p><b>orders</b> 120:15 170:11</p> <p><b>oregon</b> 292:4 469:3,3</p> <p><b>oregon's</b> 469:18</p> <p><b>organic</b> 7:13 50:8 101:21 102:1,7,17 343:2</p> <p><b>organism</b> 302:18</p> <p><b>organisms</b> 443:4</p> <p><b>organization</b> 47:21 54:7 95:17 98:21 99:1 103:20 104:21 131:6 142:20 166:17 236:1 240:22 246:20 247:2 268:15 296:1 377:2 385:7 393:18 400:21</p>
--	---	---	--

462:14 467:6 477:5 481:12 <b>organization's</b> 49:2 314:2 <b>organizations</b> 199:10 220:16 244:1 377:13 379:9 427:19 445:16 <b>organized</b> 37:6 <b>organophosphates</b> 278:19 <b>organs</b> 382:11 488:22 <b>origin</b> 99:6 369:14 <b>original</b> 334:8 453:10 <b>orlowitz</b> 15:20 429:13,14,15 434:8,16,22 <b>orphan</b> 93:6 94:9 <b>orthodox</b> 61:22 <b>ossowski</b> 12:2 252:19,20 258:1,7 258:14 <b>otc</b> 76:5,7 122:4 131:4 436:22 <b>outbreak</b> 367:2,13 <b>outcome</b> 135:3 264:18 502:13 503:12 <b>outcomes</b> 93:3 220:8 223:22 225:18 492:9 <b>outdated</b> 38:19 <b>outer</b> 495:6 <b>outgrew</b> 447:18 <b>outlets</b> 172:6 <b>outlined</b> 326:13 350:7,13 <b>outlines</b> 369:18 <b>outpatient</b> 92:7 <b>outrageous</b> 127:17	<b>outreach</b> 135:16 <b>outside</b> 24:4,8,14 24:15 37:4 89:19 93:15 96:3 119:14 139:6 140:21 208:6 213:18 251:19 341:12 353:5 408:13 432:8 <b>outstanding</b> 219:16 <b>outweighed</b> 431:5 <b>ovarian</b> 259:16 <b>overall</b> 80:1 238:15 293:1,6 306:21 454:4 <b>overarching</b> 30:15 <b>overdose</b> 41:11 207:12 <b>overdosed</b> 245:7 <b>overflow</b> 176:9 <b>overlay</b> 420:19 <b>overnight</b> 119:18 <b>overregulation</b> 54:15 290:22 434:1 <b>overseas</b> 288:5 358:14 423:10 <b>oversight</b> 76:20 116:17,19 123:9 181:14 209:11 222:11 303:18 312:22 329:9,20 331:10,12 338:13 370:13 371:10 408:16 414:9 431:12 <b>overuse</b> 285:19 <b>overview</b> 18:3 420:16 422:22 <b>overwhelming</b> 80:4 109:10 318:22 320:10 321:3,10	<b>owner</b> 145:3 288:4 <b>owners</b> 96:15 <b>oxidative</b> 484:10 <b>oxley</b> 268:20 <b>oxycontin</b> 251:2 <b>oxygen</b> 332:7  <b>p</b> <b>p</b> 2:1,1 3:1,1 4:1,1 5:1,1 6:1,1 7:1,1 8:1,1 9:1,1 10:1,1 11:1,1 12:1,1 13:1 13:1 14:1,1 15:1,1 16:1,1 17:1,1 20:1 <b>p450</b> 177:6 179:1 179:15 180:1,12 180:17 271:21 <b>p450s</b> 360:3 <b>pace</b> 119:10 <b>package</b> 174:21 <b>packaged</b> 87:18 114:8 255:15 450:9 490:15,16 <b>packaging</b> 13:19 110:11 121:17 206:16 278:16 290:2 332:7 342:5 342:9,10,18 364:18 428:5 469:11 479:1 491:9 <b>packed</b> 27:1 <b>packet</b> 167:22 <b>pacts</b> 411:17 <b>page</b> 18:2 19:2 44:22 121:11 433:8 <b>pages</b> 107:16 109:13 <b>paid</b> 43:15 393:14 457:4 485:14 <b>pain</b> 39:16 127:10 139:2 183:10,17 184:12 207:18 209:4 224:9,11,12	248:21 249:5 250:8 261:12,15 274:8 275:12,12 277:22 287:3 299:11 317:9 318:7,8,10,11,14 318:16,18 320:10 320:16 387:21 482:18 <b>painful</b> 58:4 <b>painless</b> 474:7 <b>painquench</b> 276:14,17 <b>pains</b> 127:9 432:12 <b>pam</b> 9:15 155:21 156:3 158:22 <b>pamela</b> 5:12 173:6 173:7 176:6 <b>pamphlets</b> 491:9 <b>pancreatitis</b> 261:3 <b>panel</b> 20:21 23:13 23:21 52:21 53:4 55:2,6,9,15,18,21 56:3,12 61:5,8 65:22 66:1,10,11 66:15 68:11,16,17 69:5,10,11,14,17 70:6,12 74:12,22 75:7 79:18 80:12 80:21 85:14,16,19 86:2,8,9,11,14,17 86:18,22 87:4,6 89:14 90:8 92:13 94:21 95:10 100:22 101:5 103:4,14 104:6,10 110:13,18 111:2 113:17 114:3,17 115:5 118:11,21 124:13,17,20 128:2,5,10,13,14 129:2,19 137:5 140:7,9,14 141:4
--	--	---	---

141:8,11 144:14 144:18 152:19 155:19 157:20 158:8,11,15,19,22 161:5,8 164:11,14 165:10 169:16 170:2,21 171:2,16 172:8,13 185:18 186:11 187:2 197:2 198:4,14,15 198:21 199:7,14 200:11 214:18 215:9,15,22 216:3 226:6,12,15,17 232:11 233:5,12 233:21,22 252:11 257:22 258:2,9 273:21 274:10 279:18 280:1,5,7 280:9,11,12 281:2 298:14 307:10,12 307:15 308:10,13 309:2,7,15,20 310:1,13,15,17 315:20 316:9 321:1 326:12 327:17 328:5 337:16 352:13 385:11 390:5,7 395:2 399:11,18 405:9 407:2 410:1 413:8 417:14 418:1 434:10,21 441:3 442:8 456:14,20 466:15 466:21 476:3 481:11,16 493:21 494:13 499:3,5 <b>panelists</b> 24:1 50:4 293:22 <b>panels</b> 152:6 153:5 379:8 <b>panic</b> 375:2	<b>pantry</b> 236:13 <b>paper</b> 40:21 100:11 261:20 335:13 491:5 <b>papers</b> 242:9,13 336:12 474:2 <b>paradigm</b> 145:14 327:10 <b>paradigms</b> 285:8 285:9 325:8 <b>paragraph</b> 344:1 <b>parallel</b> 320:17 <b>parameters</b> 271:4 299:12,18 346:4 413:20 <b>paramount</b> 53:17 83:3 <b>paranoid</b> 373:19 <b>pardon</b> 55:20 <b>parent</b> 130:7 337:3 467:8 472:13 <b>parents</b> 55:12 245:4 449:9 472:11 473:11 483:10 <b>park</b> 261:12 <b>parkinson's</b> 14:19 384:2,10,13,14,18 385:2,12 386:11 386:14,17 387:10 387:22 388:5,10 388:12 389:5,17 390:3,8 482:20 <b>part</b> 1:11 28:8 38:9,16 54:20 71:4 74:10 75:11 90:4 114:19 134:19 156:19 160:20 176:16 178:21 181:3 194:8 245:22 247:7,16 278:1 309:10,21 395:8	422:5 428:2 452:12 476:17 485:3 498:7 <b>partake</b> 104:5 <b>participant</b> 23:12 23:13 <b>participants</b> 51:12 85:5 213:13 <b>participate</b> 27:4 72:8 157:17 169:4 218:10 <b>participated</b> 121:20 <b>participating</b> 135:5 154:1 <b>participation</b> 160:11 427:20 444:13 <b>particular</b> 33:3 56:10 69:8 154:22 184:1 199:16 202:6 206:16 208:3 267:13 279:12 351:11 352:4 382:10 394:2,12 484:14 <b>particularly</b> 46:11 66:6 80:16 130:16 164:15 187:7 217:8 225:19 249:8 253:13 256:14 330:8 380:7 438:1 441:6 474:15 478:3 479:20 <b>parties</b> 100:18 107:17 348:16 380:5 446:12 502:9,11 503:8,11 <b>partner</b> 216:20 500:4 <b>partnered</b> 266:4 358:4	<b>partnering</b> 166:7 268:4 <b>partners</b> 5:21 61:14,16 96:1 230:22 288:6 489:22 <b>partnership</b> 145:20 369:3 <b>partnerships</b> 3:11 21:21 160:19 247:9 427:18 <b>parts</b> 40:11 84:3 159:19 172:9 238:7,11,13 239:22 240:3,4 314:13 348:15 368:11 369:8 474:11 490:12 <b>party</b> 132:20 193:1 199:11 305:9 325:22 343:2 346:3 349:20 351:17 370:21 381:3 383:17 479:10 <b>pass</b> 230:3 278:6 478:17,19 <b>passage</b> 480:7 <b>passed</b> 48:14 82:17 283:21 430:14 <b>passing</b> 379:18 <b>pat</b> 320:18 <b>patches</b> 276:19 <b>patchwork</b> 88:19 138:12 159:7 163:18 290:19 477:15 <b>patent</b> 79:3 80:16 293:2 319:5 483:20,22 <b>patented</b> 235:3,4 <b>patents</b> 230:18
---	---	---	--

<p><b>path</b> 77:6 100:16 101:15,16 105:8 106:7 195:22 217:20 303:5 320:18 346:9 347:1,7 359:3 430:8,9 433:12,19 434:5 437:22 440:10</p> <p><b>pathogenic</b> 99:20</p> <p><b>paths</b> 105:7 184:19 407:15</p> <p><b>pathway</b> 31:11 42:4 47:9 48:9 65:13 76:14 85:10 94:17 113:14 116:6 155:12 163:22 166:6 177:4 214:15 225:7 228:11 231:5 304:4 322:6 323:19,22 328:18 339:6 356:10 364:21 365:22 378:20 433:18,18 457:12 478:2 481:5</p> <p><b>pathways</b> 35:1 83:20 139:16 297:17 326:13 407:5</p> <p><b>patient</b> 60:5,17 62:17 67:15 69:8 131:11 135:11 177:13 180:4 181:2 267:14 279:4 280:13 285:12,14 318:9 340:11 360:22 379:16 386:20 387:20 456:22 460:20 461:8 462:1,13,17 463:17</p>	<p><b>patient's</b> 70:2</p> <p><b>patients</b> 8:14 16:7 18:14 19:6 30:9 35:17,17 38:14,22 59:12,15 62:18 64:8 65:6,20 67:4 67:7,10 68:7 69:12,21 93:8 94:9 96:8,12 99:17 130:18 131:17 132:6,7 135:13 138:6 140:10,21 141:13 141:21 173:18 181:13 182:14 183:4 184:2 196:8 197:19 201:5 217:14 223:10 224:4 260:7,8 261:14,15,21,22 266:8 270:22 272:13 277:21 278:3 281:3 285:17,19 287:2 294:6,22 299:10 300:4,13 301:8 315:16 317:14,17 318:21 319:3 320:10 321:7 334:4,12 339:11 339:20 340:12 341:12,21 359:12 359:16 379:22 380:5,7,19 383:6 383:20 386:8 390:8 457:1 460:8 461:2,12 472:13 482:19 486:1 493:11</p> <p><b>patricia</b> 261:12</p> <p><b>patrick</b> 9:3 144:22 145:2</p> <p><b>patrol</b> 425:8</p>	<p><b>pause</b> 175:21</p> <p><b>pave</b> 430:8</p> <p><b>pay</b> 24:22 201:7 203:5 485:13</p> <p><b>paying</b> 24:10</p> <p><b>payment</b> 108:9 148:5</p> <p><b>pays</b> 403:15 485:17</p> <p><b>pc</b> 7:15 212:11</p> <p><b>pcqi</b> 342:18 372:6</p> <p><b>pcr</b> 493:13</p> <p><b>pd</b> 384:15 385:4,5 385:8,20 386:5,15 388:7,12 390:12 390:19</p> <p><b>peace</b> 10:20 204:9 204:10,16 246:14</p> <p><b>peak</b> 41:7 212:4</p> <p><b>peddling</b> 131:22</p> <p><b>pediatric</b> 30:6 130:15 132:6 137:17 138:3 272:13 374:14 403:19 458:17</p> <p><b>pediatrics</b> 483:13</p> <p><b>peer</b> 39:5 157:2 312:19 325:18 445:2 491:20 492:8</p> <p><b>peeve</b> 279:5</p> <p><b>penalties</b> 241:21</p> <p><b>pending</b> 319:5</p> <p><b>penetrating</b> 94:16</p> <p><b>penn</b> 172:2</p> <p><b>pennsylvania</b> 10:3 166:11 170:8,13 172:3 329:2</p> <p><b>people</b> 22:17 24:12 26:20,22 37:2 39:3 54:21 56:2 60:15 79:22 80:4,5,7 104:4,22 108:19 125:5</p>	<p>135:20 142:20 143:20 144:5 148:1,7,11 149:17 149:19 154:15 164:6 176:8,11 184:7,14,22 186:6 206:3,4 207:11 208:2,18 210:8 215:1,13 221:3 223:4 241:18 243:9 244:6 245:3 245:13 246:5,5 247:13,20 248:3 248:15,17 250:1,5 250:19 251:16 252:16 256:2,3 257:13,18 275:22 277:1,6,10 278:22 280:20 290:6,19 293:13,17 305:18 308:7 309:1 310:4 310:10 312:10,12 313:1 335:16,17 337:7 340:21 345:20 346:21,21 348:3 376:7,10,13 378:2,3 382:6 385:5,8,20 386:13 386:15 387:21 388:12 389:5 390:3,12,17,19 391:21 397:21 399:10,11,11 400:17 401:8 402:2 404:6,13,16 404:22 406:5,9,12 410:19 430:3,17 430:18,22 431:18 432:8,13 448:9 455:3,7 457:17,17 465:16 482:13,18 483:2,8,9 484:2 484:17 486:15 497:10,14 498:14</p>
---	---	--	---

500:16,18 <b>people's</b> 87:22 245:2 297:11 304:10 401:14 <b>perceived</b> 126:17 477:18 <b>percent</b> 28:21 46:9 51:11 69:1 72:4 74:20 84:8 85:16,22 108:18 142:22 148:17,18 190:8,10,14,22,22 191:5,20 193:21 199:18 201:5,17 207:7 211:7 223:1 223:11 229:2,3,20 232:7,20 238:4,5 239:5,9 240:6,8 248:10,14,21 249:1,16,17 250:3 250:7,8,9 251:5 251:11 252:2 261:13,14,16 262:1 275:10,12 275:15,20 276:1 296:1,1,2,2,5,10 300:4,13 309:14 313:20,22 314:7 314:14,21 315:10 318:17 320:8 335:4,8,10 341:6 368:7 376:1 386:7 402:11 424:20 449:19 450:21 453:21 469:6,16 469:17,21 470:1 473:8 480:6 485:11,18 <b>percentage</b> 211:8 254:16 468:16 <b>percentages</b> 453:22 455:15 <b>perception</b> 125:22	<b>percocet</b> 251:2 <b>perfect</b> 111:2 385:1 417:7,9 470:14 489:16 490:15 <b>perform</b> 354:20 358:5 382:20 464:1 <b>performance</b> 189:6,7 211:18 392:12 426:4,15 <b>performed</b> 201:11 265:21 302:21 354:5 364:2,5 446:15 <b>performing</b> 351:22 364:12 <b>period</b> 37:1,1 164:5,9 306:6 318:19 355:7 <b>periodically</b> 134:19 <b>periods</b> 34:19 <b>peripheral</b> 270:6 <b>permanently</b> 468:21 <b>permissible</b> 108:6 108:6 <b>permissive</b> 470:16 <b>permit</b> 72:3 185:10 273:3 436:4 465:5,7 <b>permitted</b> 23:1,20 269:3 464:21 <b>permitting</b> 112:21 117:17 <b>peroxide</b> 59:20 <b>person</b> 22:18 26:21 34:15 40:19 41:7 63:3 173:4 281:13 375:16 388:10 465:18 482:3 501:7	<b>personal</b> 75:3 88:5 88:15 96:8 243:14 465:21 <b>personalized</b> 264:19 <b>personally</b> 54:10 55:11 73:22 74:14 75:10 128:4 170:7 246:3 247:14 <b>personnel</b> 381:9 446:7 463:20 <b>perspective</b> 200:5 210:6,11 211:14 367:1 <b>perspectives</b> 400:18 <b>pertaining</b> 166:21 443:1 <b>pesticide</b> 72:5 100:3 237:17 238:11 330:17 362:6 366:17 368:8 372:13 394:13 480:8 <b>pesticides</b> 60:12 131:15 138:15 146:16 232:5 234:14 238:10,10 278:19 286:6 312:8 319:19 330:11 331:22 345:18 364:4 366:18 392:16 394:7 428:15 443:3 464:10,18 464:21,22 465:14 <b>pet</b> 33:12 167:15 169:1,3 170:8 171:8 193:8,13,16 197:7,11 279:5 290:2 357:8 <b>peter</b> 4:15 9:11 37:10,14,18 153:7	<b>petition</b> 73:18 75:11 167:6 <b>petroleum</b> 449:3 <b>pets</b> 193:14 252:12,14,17 <b>ph</b> 242:8 450:10 493:1 <b>pharma</b> 13:3 298:16,20 299:1 302:14 <b>pharmaceutical</b> 92:19 103:13 120:20 122:17 139:11 188:4 285:10 304:4 311:4,10,19 315:3 322:2 326:22 330:20 331:1,6 332:12 353:5 358:19 374:18 396:12 404:3 405:11,17 435:14 435:22 483:5 485:19 497:2,13 498:3 500:6 <b>pharmaceuticals</b> 7:7 13:13 52:18 92:20 131:4,13 228:1 329:2 338:6 <b>pharmacies</b> 153:14 <b>pharmacist</b> 457:14 <b>pharmacists</b> 38:15 39:4 <b>pharmacokinetic</b> 177:8 179:21 274:4 <b>pharmacokinetics</b> 186:19 <b>pharmacological</b> 300:15 <b>pharmacologica...</b> 211:1 221:15
---	---	--	--

<b>pharmacologist</b> 270:8	<b>phthalates</b> 238:12	<b>pipes</b> 375:14	228:16,18 229:2
<b>pharmacology</b> 185:12	<b>physical</b> 59:5,12 67:11 243:5	<b>pitched</b> 422:7	243:12 261:22
<b>pharmacopeia</b> 7:11 138:19 331:15 463:13	<b>physician</b> 62:15 278:7,17 279:6 282:15 338:13	<b>pitts</b> 4:15 37:10,17 37:18	267:13 286:1 294:19 302:19
<b>pharmacovigila...</b> 194:20 214:7 320:3	<b>physician's</b> 404:8	<b>pivotal</b> 93:7 369:1	303:1 308:4,15
<b>pharmacy</b> 96:22 176:21 188:5 192:12 457:11	<b>physicians</b> 38:14 39:4 130:3 141:14 142:7 278:21 279:1 339:19 380:5,20 484:20 485:11	<b>pizza</b> 376:18	312:9 324:8
<b>pharmd</b> 10:7,14 16:8	<b>physiological</b> 271:4,16,22 489:1	<b>pk</b> 299:4,12,17 319:2	327:21 333:15 335:17 336:19
<b>phase</b> 93:4,7 143:3 283:1 284:19,21 286:17 286:19 299:2,2,3 299:7,9,13 300:17 300:19 301:14,20 301:21 360:21	<b>phytocannabinoid</b> 138:14 168:21 294:2	<b>place</b> 53:20 54:3 117:15 149:16 162:22 163:6 236:21 242:20 251:18 269:11 327:2 349:15 379:22 397:7 409:22 415:2 416:11 424:4 436:12 438:17 442:2 450:10 491:5 493:16	339:2,15 368:12 369:8 389:1 392:7 392:15,22 394:2 394:21 410:11 411:18 416:13 418:10 424:14 486:16
<b>phd</b> 2:2 3:14 4:17 5:6 6:14 7:2,6,10 8:15 10:12,17,20 11:2,4,7 12:6 13:2 13:14 14:4,6,16 14:18 15:2,12 16:20 40:8 50:8	<b>phytochemicals</b> 201:1,3	<b>placebo</b> 144:3 174:1 222:5 299:8	411:18 416:13 418:10 424:14 486:16
<b>phenomenon</b> 122:15	<b>phytocompounds</b> 47:12	<b>placed</b> 120:19	<b>plantar</b> 276:19
<b>phenotype</b> 267:13	<b>pi</b> 217:3	<b>places</b> 44:6 133:18 289:1	<b>plants</b> 59:13 123:13 151:20 171:19 172:9 285:22 294:20 368:5 382:10
<b>philadelphia</b> 336:12	<b>pick</b> 141:2	<b>plain</b> 255:14	<b>plasma</b> 181:6 494:4
<b>philip</b> 6:6 66:22	<b>picked</b> 336:11 406:8	<b>plan</b> 100:10 274:11 346:1 375:7 386:22 408:4 466:20	<b>plastic</b> 417:8 491:6
<b>phillip</b> 66:20	<b>pictograph</b> 229:18	<b>planned</b> 397:16 459:5	<b>plasticizers</b> 237:17
<b>phone</b> 173:2,5 282:9	<b>picture</b> 130:2 200:4 203:7 220:2 263:4 283:13 320:14 467:19	<b>planning</b> 24:9 147:1 312:16	<b>plate</b> 38:5 372:15 499:8
<b>phones</b> 250:15	<b>pieces</b> 283:11	<b>plans</b> 89:7	<b>platform</b> 166:4 264:12 266:18,22 267:21 361:16
<b>photo</b> 457:19	<b>piece</b> 292:21	<b>plant</b> 27:17 28:8 54:21 61:17 68:21 70:17 72:21 73:5 84:2,3 100:10 103:9,12 113:22 114:6,8,19 133:12 145:13 146:10,13 151:11,15 165:22 218:17 221:22	<b>platforms</b> 50:14 145:5
<b>photographs</b> 245:13	<b>pile</b> 125:18		<b>play</b> 71:15 422:2 423:21 424:19 465:18 485:13
<b>phrases</b> 417:17 418:8	<b>pill</b> 385:19		<b>playbook</b> 121:11
	<b>pilot</b> 299:8 318:4		<b>played</b> 369:1
	<b>pioneers</b> 357:14		<b>players</b> 109:4
	<b>pipe</b> 375:16 454:5 454:19		<b>playing</b> 187:21 316:21 345:13
	<b>pipeline</b> 493:5		<b>plays</b> 51:1 87:20 379:15 489:1

<p><b>please</b> 21:1 23:17 23:22 24:1,9,17 24:22 25:4,18 26:10 37:12 66:12 68:11 77:11 91:18 91:19 122:6 137:21 144:11 152:15 155:13 173:1 226:17 249:18 259:21 347:6 357:4 373:3 400:19 412:18,21 434:6 446:19,20 447:1,3 451:9 455:19 461:20 471:5,6 476:3 486:11 489:15 490:11,19 491:8 492:11 500:17 501:5 <b>pleased</b> 26:19 153:9 429:15 <b>pleasure</b> 200:15 252:21 <b>pledge</b> 286:15 <b>plenty</b> 399:8 436:11 <b>pllc</b> 10:16 15:7 <b>plots</b> 288:19 <b>plural</b> 39:10 <b>plus</b> 56:19 229:20 238:5 256:12,12 322:1 412:14 <b>pmb</b> 9:4 145:3 <b>pms</b> 276:8 <b>podcasts</b> 172:5 <b>podium</b> 23:22 25:2,8 26:11 166:11 <b>point</b> 72:17 76:6 76:12,17 77:5 108:15 109:5,21 116:16 132:16 140:16 149:7</p>	<p>186:4 202:3 213:12 223:19 231:10 232:2 255:6 286:22 287:9 288:11 292:9 295:3,15,18 295:21 300:21 305:20 315:8,9 337:1 341:2,4 351:12 388:15 430:6 458:10 <b>pointed</b> 256:17 <b>pointers</b> 216:14 <b>pointing</b> 489:11 <b>points</b> 51:3 76:6 83:15,18 107:21 182:8 203:14 213:18 245:1 254:7 275:13 285:7 288:16 295:3 315:13 414:1 428:7 <b>poised</b> 43:20 <b>poison</b> 193:13 197:11,13 200:5 377:3 431:17 <b>poisoned</b> 208:2 <b>poisoning</b> 60:10 378:2 <b>polarizing</b> 221:4 <b>police</b> 347:4 <b>policies</b> 39:21 65:17 470:17 <b>policing</b> 60:3 <b>policy</b> 2:7,15,16 3:7,11,12,19,20 21:5,11,12,22 22:3,21 27:8 35:22 42:19 58:12 59:18 107:6 120:22 146:8 155:9 221:13 253:7,19 266:1 368:11,13,19</p>	<p>369:7,18 393:14 467:10,13 486:17 <b>pond</b> 497:16 <b>pooled</b> 261:21 <b>poorly</b> 138:17 212:7 <b>populace</b> 361:4 431:21 <b>popular</b> 41:13 122:14 237:7 398:17 <b>popularity</b> 44:4 131:22 <b>population</b> 33:3 33:22 60:17 138:7 140:17 320:9 360:22 361:9 388:17,18 399:5 440:1 451:20 452:1,2,15 456:8 477:21 482:12 <b>populations</b> 214:4 214:5,5 272:2,8 318:5 340:12 398:12 468:6 471:1 <b>porous</b> 488:9 <b>portal</b> 313:9 <b>portion</b> 20:13 159:18 <b>pose</b> 77:16 84:21 118:7 192:2 <b>position</b> 21:1 38:12 85:1 103:21 111:20 112:7,13 113:8 116:7 135:2 157:21 162:14,17 313:7 350:6 401:18 435:8 <b>positioned</b> 90:16 452:18 <b>positive</b> 54:9,11 92:5 96:13 183:12 213:14 224:4</p>	<p>288:9,10 290:15 306:7 318:7 <b>positives</b> 183:7 <b>possession</b> 28:6 <b>possibility</b> 401:15 <b>possible</b> 23:17 24:13 44:21 62:14 94:18 109:3 116:5 118:10 217:20 220:7 257:17 258:18 281:1 334:13 450:14 461:14 <b>possibly</b> 71:11 112:20 279:10 281:7 356:16 <b>post</b> 45:17 82:8 193:1,3 194:18 196:15 277:10 300:22 325:5 408:13 409:11 <b>posted</b> 344:1 <b>pot</b> 375:5 <b>potato</b> 147:19,19 <b>potatoes</b> 147:17 <b>potency</b> 57:2 61:1 175:6 237:18,21 243:3 285:16 319:18 369:21 371:13 372:11 377:7 394:13 417:4 438:22 465:15 479:14 <b>potent</b> 94:16 260:18 <b>potential</b> 28:14 33:6 35:1 39:8 49:6 52:10 63:21 64:1 72:21 88:19 109:14,17 110:9 123:3 126:12 130:20 131:12 138:14 139:8,18 176:22 177:20</p>
---	--	---	---

178:6 180:6 181:10 192:1,4,8 196:11,19 199:12 201:9 202:4 203:17 204:3 208:19 213:9 217:7 267:17 271:6,15,19 284:7 334:18 339:2 356:11 380:13 404:17 405:5 439:22 452:6 472:17 484:18 493:7 <b>potentially</b> 46:14 82:15 94:8 95:1 128:20 180:21 182:10 194:3 336:13 339:12 354:19 356:1 401:6 410:12 473:8 474:10 <b>potentiation</b> 202:20 <b>pouches</b> 491:6 <b>poultry</b> 46:3 <b>pounds</b> 289:13 <b>power</b> 127:22 408:9 <b>powerful</b> 126:8 260:15 339:22 <b>practical</b> 94:12 407:14 <b>practically</b> 119:18 <b>practice</b> 12:15 39:20 192:7,22 194:20 197:9 274:22,22 314:12 <b>practices</b> 49:13 54:1 59:11 134:8 195:10 196:22 303:16 319:17 350:7 363:21 368:16,21 446:15	463:14 483:3 <b>practicing</b> 62:15 260:5 <b>practitioners</b> 181:14 <b>prayers</b> 460:3 <b>pre</b> 325:5 <b>precious</b> 355:22 <b>precipitous</b> 409:11 <b>precisely</b> 380:12 <b>preclinical</b> 178:4 339:14 492:22 493:6 <b>preclude</b> 112:3 <b>precluded</b> 81:19 102:7 <b>predators</b> 131:20 <b>predatory</b> 375:7 377:8 <b>predictability</b> 65:14 <b>predictable</b> 322:5 437:22 440:10 <b>predicted</b> 360:7 <b>predominant</b> 205:14,18 210:7 <b>preemption</b> 356:10 <b>prefer</b> 277:17 278:7,17 <b>preference</b> 397:7 <b>preferred</b> 453:4 <b>pregnancy</b> 123:18 124:14 214:4 400:3 <b>pregnant</b> 34:16 174:4 225:5 272:3 340:12 376:2 415:9 <b>preliminary</b> 45:19 372:17 <b>premises</b> 55:9	<b>premium</b> 73:1 239:13 <b>preparation</b> 203:12 330:13 <b>prepared</b> 320:11 487:22 503:3 <b>preponderance</b> 109:10 <b>prescribed</b> 38:22 458:14 <b>prescribing</b> 66:13 120:10 281:10 <b>prescription</b> 33:5 81:19,21 123:4 139:4 245:21 285:2 286:19 324:14 407:16 410:15 436:22 448:18 460:2 461:10 <b>prescriptions</b> 251:1 285:10 410:2 <b>presence</b> 102:22 114:9 190:3 330:7 480:1,8 <b>present</b> 37:3 75:17 81:10 106:16 108:18 109:11 116:3 133:15 146:9 156:9 166:13 204:11 240:11 264:9 298:21 309:1 317:7,20 329:4 337:15 397:1 407:4 449:17 462:22 463:4 465:17 487:7 491:22 496:15 <b>presentation</b> 23:12 173:3 181:20 320:21 366:5 391:6	447:12 501:3 <b>presentations</b> 10:5 18:17,19 20:15,16 23:4 25:3,16 156:1 176:15,18 349:10 365:18 <b>presented</b> 219:20 317:17 418:16 463:6 <b>presenter</b> 495:22 <b>presenters</b> 23:14 24:18 27:3 349:1 <b>presenting</b> 75:12 220:18 342:4 451:13 463:3 <b>preservative</b> 366:18,19 <b>preserve</b> 404:20 405:13,14 <b>preserved</b> 29:6 329:10 <b>preserving</b> 405:16 <b>president</b> 37:18 83:11 87:16 92:18 98:12 111:11 129:21 142:19 156:4 159:5 192:15 220:19,20 264:1 268:13 321:15 329:1 353:10 471:18 <b>press</b> 8:7 23:14,20 125:11 <b>pressure</b> 276:9 281:10,15 388:9 473:19,21 474:6 <b>pressures</b> 44:4 276:10 465:9 <b>presumably</b> 217:6 <b>pretty</b> 127:5 199:5 275:13 335:13 349:10,21 377:2 396:4 429:22
---	--	--	--



471:14 496:11 <b>prevalence</b> 155:9 162:16,19 164:20 165:1,3 384:17 453:18 454:11 <b>prevalent</b> 189:5 452:5 <b>prevent</b> 35:12 99:17 100:15 105:11 182:19 454:6 500:13 <b>preventative</b> 147:1 <b>preventing</b> 160:15 <b>prevention</b> 195:19 216:21 467:9 483:13 <b>preventive</b> 342:21 <b>previous</b> 118:12 178:9 253:2,22 360:2,8 471:16 472:4,4 <b>previously</b> 113:13 152:4 200:5 329:8 <b>price</b> 485:15 <b>prices</b> 46:8 <b>primarily</b> 102:3 156:8 222:2 243:9 263:7 309:5 357:9 385:13 390:9 476:13 <b>primary</b> 62:15 83:18 145:22 159:18 168:8 277:21 353:19 359:21 <b>principal</b> 2:3 3:19 21:4,8 188:6 450:1 <b>principles</b> 312:11 328:1 407:14 <b>printed</b> 20:17 342:3	<b>prior</b> 33:22 77:9,9 97:22 111:19 216:2 452:4 454:10 465:12 472:6 <b>priorities</b> 65:18 76:7,10 121:3,10 121:13 122:17,17 387:20 <b>prioritize</b> 121:1 <b>prioritizing</b> 492:17 <b>privacy</b> 253:4 <b>private</b> 43:9 47:7 133:1 274:22,22 367:16 426:2 <b>privilege</b> 96:8 361:14 <b>privileged</b> 54:10 483:8 <b>privy</b> 96:11 <b>priyanka</b> 14:6 361:11,19 364:12 <b>proactive</b> 58:13 119:6 <b>probably</b> 120:2 200:6 209:18 243:11 254:10 256:3 272:18 279:10 280:20 340:19 391:7 405:19 499:10 <b>probe</b> 180:16 <b>problem</b> 140:5 209:1 231:3 243:16 291:1 294:16 340:7 384:7 390:11 413:11 456:2 485:4 <b>problematic</b> 185:14 221:17 <b>problems</b> 11:8 68:3 102:21 124:5	210:15 220:14,16 223:5,21 224:5 242:6 246:13 349:22 351:16 385:22 390:18,19 450:8 <b>procedure</b> 479:17 <b>procedures</b> 22:22 23:3 99:7 134:2,7 134:8,10 311:22 316:7 317:15 331:13 <b>proceed</b> 20:12,14 358:7 434:19 468:5 470:22 <b>proceeding</b> 502:3 503:4 <b>proceedings</b> 22:21 81:9 485:5 502:4 502:6 503:6 <b>process</b> 11:13 43:18 50:16 73:17 76:13 89:4 90:6 101:8 104:5 122:21 133:12 134:2,13,21 155:15 160:11 167:20,21 168:7 168:13,16 182:20 196:16,21 225:19 227:6,18,19 229:13,15,19 231:11 232:12,16 232:18,19 233:2 234:4,8,15,17 266:17 270:2 282:21 283:9 284:10 285:4 289:21,22 290:7 298:2 309:12 332:2 336:4 339:8 341:20 348:9 355:20 356:7 363:16 365:10	370:11,14 383:11 397:1 410:6 426:13 437:9 444:16 446:22 478:19 487:11,13 487:16 488:6 <b>processed</b> 46:19 280:7,10 284:8 286:7 <b>processes</b> 90:22 229:21 230:17,18 230:21 291:8 292:17 305:8 317:14 319:16 330:20 331:2,7 332:1,11 362:17 363:4 365:20 367:19 381:1,15 425:21 427:15 428:17 429:7 436:12,18 460:7 461:22 466:17 <b>processing</b> 228:9 229:15 231:8,18 232:3 289:9 297:21 308:17 317:11 319:15 330:16 424:19 427:22 <b>processor</b> 319:9 <b>processors</b> 43:14 43:16 45:9 49:19 108:10 162:2 <b>proclaim</b> 207:7 <b>procured</b> 237:12 <b>produce</b> 41:1 105:3 184:12 211:16 212:4,22 224:12 297:1 311:18 314:9 330:8 342:15 351:13 359:2 362:9 371:7 469:4 477:22
--	---	---	--

<b>produced</b> 43:3 207:6 311:21 315:17 358:12 374:10 441:7 488:14	235:21 236:3 238:9 239:5 240:11 246:8 247:12 248:11 252:1 255:13,20 255:21 265:14 266:14 267:12 268:18 278:17 279:2,12,21 280:3 280:7,10 294:4,17 294:18 295:7,14 296:10,10,12 297:1 302:12,22 304:7 305:17 306:15 309:3 311:11 315:2,11 316:18 319:22 324:20 325:3,6 327:9 328:3,18 330:4,6,21 331:1 331:5,7,16,18,19 332:7 333:9 334:1 334:7 336:5,8 343:15,17 345:22 346:2,19,20 349:16 350:2,5 351:2 352:6 362:8 362:11,21 363:7,9 363:12 364:13,20 365:10 369:22 370:19 379:15 381:2,4,7,13 382:2,4 383:1,5 402:17,19 403:5 404:3 405:1,7 408:6,12,14 414:13 415:3,19 416:3,8,12,16 421:9 423:13 425:20 426:3 427:6 428:10 429:2 437:5 438:6 438:10,22 439:2,3 439:8,20 441:2,8	446:16 447:1 451:22 452:20 453:11,18 454:1 454:17 455:5,8,9 459:7,11 460:9,20 463:1,2 469:15,20 470:1 479:6,8,16 480:5 490:9 491:3 491:17 497:2,2,4 497:7 498:4,5 499:14	<b>product's</b> 189:2 380:12,13 <b>production</b> 38:18 47:9 78:2 86:16 99:18 134:14 161:2 162:20 163:1,6 165:20 166:21 171:11 228:5 230:16 233:14,20 289:10 305:14 315:15 319:12,18 347:19 350:8 371:3 429:7 478:22 479:11 497:12 <b>productive</b> 72:21 266:3 <b>products</b> 1:8 6:13 7:19 11:6 15:3 20:5 26:17 27:9 27:12 29:7,11,12 30:3 32:4 33:11 33:15,18,20 34:7 34:17 35:1,6,9,11 35:15 36:1,11 38:5 40:14 41:12 41:14,19,21 42:6 42:9,10,22 43:3 44:4,11,18,19 45:3 46:15 47:11 48:13,19 49:15,20 50:22 51:5 52:2 52:15 53:18 55:4	60:12 61:1,2 62:8 62:10 63:1 64:2,4 64:9,13,17,20 65:6,10,12 66:2,6 66:13 69:4 72:15 73:2,10,13 74:4 75:9,19 76:1,3,11 76:15,19,21,22 77:7 78:5,7 79:8 79:12 81:10,14 83:14,21 84:14,15 85:3 87:22 88:13 88:15 89:1,16,18 90:10,12,19 91:1 96:10,16,20 97:2 97:6,21 98:18 100:16 102:4 105:3 108:2 109:6 109:15,18 111:9 111:12,17 112:14 113:18 114:12,18 116:17,20,21 117:10 118:14 120:8,12,18,20 123:11 125:2 130:11 131:5,14 131:17,19 132:1,4 133:5,10 138:9,10 138:13,21 139:10 139:11,19 140:10 142:9,14 143:17 143:20,21 144:9 145:17,20 146:18 147:5 151:3 152:7 152:15 153:19,21 154:4,7,10,18,22 155:4,8,10 156:8 156:13 157:8,13 158:2,3 159:11 162:8,10,14,16,19 162:20 163:1,7,7 163:14 164:1,18 165:2 166:6 167:15 168:11,18
---	---	--	---	---

168:21 169:1,5 170:4,6,8,10,14 170:18 171:7 174:13 175:3 182:14 183:11,17 183:22 184:10,22 185:1,2,6 188:7 188:12,16 189:8 189:12,15,22 190:4,9,10,16 191:5,10,14,17,21 191:22 192:6 193:11,15,16 194:2,5,6,19,22 195:7 196:4,5 197:15 199:13 204:3,12 205:7,9 206:21 207:3,5,8 208:2,5,10,15 210:20 211:7 212:9 213:17 214:2,7 217:22 219:12 220:3,4 222:6,16 226:8,13 228:22,22 229:4 231:1,22 236:10 237:8,19 238:4 239:7 240:9 242:12 243:7 245:12 246:10 247:14 254:5,6,14 255:12,12,15 256:4,13 257:14 257:16 258:6 265:10,19 267:4 268:3 269:1 272:7 272:19 273:3 276:14 294:14,22 297:12,16 302:13 303:15 305:8 306:9,12,17,20 308:22 311:9 313:20 318:1 321:22 322:8	325:14 326:7 329:7,10,11,14,18 330:3,13,17,22 332:12,16 333:22 334:4,12 335:4,14 336:18 337:2,20 337:22 338:11 341:5,15,18 343:9 347:7,18 348:19 349:9 350:4,16,21 350:22 351:3,7,9 351:21 352:3 353:2,15 354:1,4 354:6,11,13 355:1 355:8,11 356:16 357:1,16,17 358:2 358:13 359:2,5 360:17 362:5,12 363:3 364:3,6,11 364:18 365:12 366:2,13,19 367:12,19,22 369:15,19 370:4 370:10,16,18 371:7,21 372:8,11 372:19 373:16 377:6 378:21 379:22 380:9,21 380:22 382:5,12 382:17,21 390:9 390:10 394:20 395:12,17 396:13 396:16 397:14,18 398:11 400:1 407:7,12 409:14 409:20,21 414:15 415:1,11 416:2,10 416:13,19 417:1,4 417:10,20 420:7 420:15 422:20 423:18 425:1,2,21 427:14 429:8 432:15 433:2,3,3 437:7,10,16 438:1	438:4,13 440:21 444:8,17,18,21 446:10 450:14 451:18 452:3,9,12 453:2,7,8 454:6 454:12 456:6,10 457:13 463:9,12 464:5,16,18 465:15,17,22 466:2,3,5,7 467:17,22 469:19 470:7,10 476:22 477:9,20,22 478:1 478:15,22 480:2 480:19,20,22 481:8 486:9 491:1 492:1,4,5,18 500:16 <b>professional</b> 97:8 369:3 440:3 <b>professionally</b> 207:6 <b>professionals</b> 5:17 12:5 18:11 19:3 58:18,20 98:3 107:13 138:5 174:17 194:15 195:2 259:3,5 282:9 461:3,12 <b>professor</b> 182:2 188:4 192:12,13 204:17 400:15 422:11 <b>proficiency</b> 133:1 133:17 370:20 393:10 444:14 <b>proficient</b> 135:5 <b>profile</b> 51:5 126:6 177:9 179:21 303:9 418:9,12 464:16 <b>profiles</b> 205:17 372:12 394:15 418:13	<b>profiling</b> 195:5 <b>profit</b> 59:10,21 60:15 377:8 467:6 471:7 485:19 <b>profiteering</b> 174:18 <b>program</b> 37:1 45:8 49:12 92:7,8 122:10 141:19 145:8 178:4,19 179:9,18 180:13 181:4 187:2 194:7 194:8,9,14 195:19 196:7,9 198:2,10 214:7 216:15,19 216:21 217:10 218:2,5,11 219:22 220:3,4 282:7 294:21 295:10 297:8 301:22 303:2 318:2 342:21 359:16,17 368:2,15,20 369:3 369:9 391:4,5,16 398:19 400:16 421:8 423:4 429:20 462:17,18 463:17 464:7 <b>programs</b> 4:9 21:16 51:16 121:21 132:18 133:17 135:15 193:3 196:2 218:1 218:20 219:4,6 220:9 295:7 296:17 320:19 393:11 394:20 401:3 409:1 421:19 422:22 <b>progress</b> 100:9 <b>progressive</b> 368:15,20 371:17 <b>prohibit</b> 32:22 111:21 144:7
--	---	---	---

<p>468:8 471:3  <b>prohibited</b> 435:9  <b>prohibition</b> 54:18  105:22 106:11  409:11 485:3  <b>prohibitionist</b>  408:13  <b>prohibits</b> 31:21  105:9  <b>project</b> 8:5 122:10  123:13,22 124:3,7  235:14,15,17,22  <b>projected</b> 25:1  54:17 289:12  307:4  <b>projection</b> 109:1  125:22  <b>projects</b> 393:20  <b>proliferation</b>  119:13 221:2  329:17  <b>prolonged</b> 34:19  <b>promise</b> 44:5  82:17  <b>promised</b> 73:15  <b>promises</b> 149:16  <b>promising</b> 489:2  <b>promote</b> 88:4  124:11 253:18,19  253:20 305:3  353:18 381:11  445:5 460:9  <b>promoted</b> 106:18  <b>promotes</b> 88:20  <b>promoting</b> 257:1  366:21 381:17  483:17  <b>promotion</b> 156:20  <b>promotional</b>  64:14  <b>prompt</b> 120:4  <b>prompted</b> 340:14  <b>promptly</b> 112:18  113:4,16</p>	<p><b>pronounce</b> 150:11  <b>proof</b> 259:11  483:19  <b>propagation</b>  370:14  <b>proper</b> 72:2  195:16 283:18  349:14 455:14  466:4 478:5  <b>properly</b> 134:7  163:22 194:4  289:8 422:17  <b>properties</b> 269:9  274:4 328:11  489:4  <b>property</b> 264:20  375:22  <b>prophylaxis</b> 277:5  <b>proponents</b> 38:13  218:15 474:3  <b>proportion</b> 113:21  114:6 233:6 454:2  <b>proposals</b> 115:12  <b>propose</b> 123:10  337:17  <b>proposed</b> 115:7  <b>proprietary</b>  320:12 487:11  490:12  <b>propylene</b> 205:15  <b>prosecutor</b> 429:20  <b>prospectively</b>  196:10  <b>protect</b> 33:6 61:2  62:6 88:17 90:7  99:10 100:15  110:3 146:20  175:11 195:11  266:8 305:9 307:6  329:12,16 337:10  353:18 435:14  468:7 471:2  480:11</p>	<p><b>protectants</b> 484:8  484:15 485:7  <b>protected</b> 67:7  307:3 433:19  <b>protecting</b> 30:16  126:9 137:2  145:16 326:6  332:10 379:15  426:4 435:21  <b>protection</b> 118:6  161:14 344:21  355:21 456:7,10  <b>protective</b> 495:6  <b>protects</b> 322:6  <b>protein</b> 45:20 46:3  <b>protocol</b> 370:9  453:14  <b>protocols</b> 68:13  267:2 497:9  <b>prototype</b> 471:21  <b>prove</b> 256:21  295:15  <b>proved</b> 224:21  <b>proven</b> 54:4  102:15 117:15  124:9 401:21  403:18 409:14,21  <b>provide</b> 44:18  48:8 49:12 61:3  65:13 69:6 75:17  77:15 83:21 85:9  89:3,9 91:3 97:11  98:2 107:14 115:4  123:14 136:13  148:2 151:3 152:4  152:17 153:5,11  154:18 155:11  157:15 164:2  183:6 195:2  200:20 214:15  242:6 269:18  284:7 325:2,13  347:7 355:20  359:5 393:11</p>	<p>414:2 415:4  422:14 425:17  433:19,19 434:17  437:12 440:15  443:17 457:15  477:8 490:8  <b>provided</b> 31:15  84:21 102:4 121:8  134:21 162:13  239:19 354:14  363:18 439:7  <b>provider</b> 193:5  483:3  <b>providers</b> 133:2  <b>provides</b> 43:12  49:18 52:16 76:14  84:10 188:13  261:7 323:5,10,14  325:6 381:7  417:11 444:5,9,15  445:16  <b>providing</b> 44:5  46:1 52:11 62:21  68:7 73:1 88:12  96:2 99:11 168:6  169:13 192:22  194:19 326:6,9  357:11 358:1  361:16 437:21  445:20  <b>proving</b> 410:10  <b>provision</b> 327:2  355:13 435:11,11  435:13,20  <b>provisional</b>  346:15 347:2  <b>provisions</b> 32:7,17  111:21 112:2  113:7 114:11,15  <b>prudent</b> 217:21  <b>psas</b> 67:17  <b>psoriasis</b> 276:19  <b>psych</b> 57:19 92:4</p>
---	---	---	---

<b>psychiatric</b> 214:4	156:10 168:5	<b>publisher</b> 125:10	438:22 449:17,19
<b>psychiatry</b> 182:2	173:12 174:19	128:6	462:1
<b>psychoactive</b>	175:11 176:2	<b>publishes</b> 99:2	<b>purport</b> 382:18
28:15 78:11 79:2	183:6 185:5,6	<b>publishing</b> 206:19	<b>purported</b> 270:13
79:7 80:14,17	187:15 192:4	<b>pubmed</b> 78:18	<b>purporting</b> 157:8
206:1 213:1	197:12 200:4,20	325:20	<b>purpose</b> 59:20
214:19 390:14	204:6 209:11	<b>pueblo</b> 375:5,10	74:13 98:4 99:9
<b>psychoactivity</b>	222:8 265:8,22	375:19 376:4	344:3 403:15
469:4	266:8 278:14	<b>pulak</b> 14:8 361:20	453:1 498:14
<b>psychosis</b> 92:5	286:15 313:16	361:22	<b>purposefully</b>
334:19 376:14	314:19 329:4,13	<b>pull</b> 152:10 176:10	93:15
390:18 468:19	329:16 331:8	181:19 384:6	<b>purposes</b> 170:19
<b>psychotic</b> 271:17	332:10,17 353:5	<b>pulling</b> 308:5	226:15 233:8,14
376:10,16	353:19 355:1	<b>pulp</b> 45:17	481:1
<b>psychotropic</b>	361:17 365:7	<b>pumping</b> 458:10	<b>purpureus</b> 396:15
409:13,20 411:9	366:21,21 367:3,4	<b>pura</b> 12:19 287:22	<b>pursued</b> 365:13
<b>ptsd</b> 260:15 276:6	368:10 380:3	<b>purchase</b> 24:8,9	<b>pursuing</b> 322:2
277:5 283:3 318:6	382:2 393:17	62:19 98:1 131:14	372:5
482:20	397:19 399:16	207:17 226:22	<b>pursuit</b> 127:15
<b>public</b> 1:11 4:16	407:6,13,21	247:14	482:4
9:2 16:11 18:15	408:10 416:10	<b>purchased</b> 189:16	<b>purview</b> 138:11
19:7 20:6 22:20	426:2 455:13,14	207:2,14 208:3,5	316:19
22:20 23:3,20	456:7,10,15 457:7	208:15,16 246:6	<b>push</b> 229:4 286:13
25:17,19 26:3,5	462:7,9 468:7	247:14 461:6	<b>put</b> 31:2 35:11
26:16 29:10 30:17	471:2,6 480:18	<b>purchaser</b> 57:4	38:4 92:6 101:1
36:7,22 37:11,19	501:3,8 502:1,16	<b>purchases</b> 207:21	104:7 110:15
38:10 39:13 42:10	<b>publication</b> 167:3	<b>purchasing</b> 407:7	127:22 130:6
42:21 44:15 50:21	167:6,13 335:3,7	<b>pure</b> 13:9 212:15	136:18 163:5
51:1,16 52:16,22	393:7	213:9 215:1	171:12 174:13
58:5 59:9 60:20	<b>publications</b>	265:16 316:18	185:1 211:14
61:2 62:1,3,7 68:3	100:8	317:10,14,15	244:1 250:15
71:16,20 73:9,13	<b>publicly</b> 81:16	319:8 320:1 448:9	279:6 282:20
74:1,5 76:8 79:14	112:5 315:7	<b>purification</b> 230:2	285:3 286:16
80:4 88:8,18 90:7	358:21 359:1	230:4 232:16	298:3 338:1
94:3 98:21 99:10	<b>publish</b> 100:11	347:15 348:11	343:20 346:19
99:11,16 100:6,15	392:1	370:10,15	397:11 409:7
101:13 107:6	<b>published</b> 40:21	<b>purified</b> 143:4	422:21 434:14
109:7 110:3	51:9 124:3 126:4	324:3,9 488:5	447:22 470:4
122:16,20 123:7	167:13 180:15	<b>purify</b> 351:2	474:2 493:16
124:11 132:22	203:10 261:19	<b>purity</b> 60:22 99:8	<b>puts</b> 35:17 268:2,3
134:22 140:5	325:18 335:22	138:20 163:13	<b>putting</b> 32:22
144:11,21 145:1	346:5 384:19	222:18 315:18	103:17 148:18
145:17 146:20	385:10	331:19 364:3	158:18 161:6
149:10,16 154:5		409:17 410:5,16	186:6 236:12

279:2 289:4 354:4 470:6	363:17 364:14,16 364:20 365:11,12 366:1,16 367:20 370:9 371:20 372:8 379:5 382:21 383:13 387:11 405:11 423:14 425:20 426:4,11 427:22 429:2,6 458:8 473:15 477:9 487:8 489:17,20 490:8 492:18	264:14 273:21 275:10,11,14,15 275:16,18,22 279:18 305:17 307:10 309:15 310:15 352:14 390:5 405:15 424:8 434:11 436:1,11,16 450:15 456:14 466:15 468:14	107:20 108:3 109:3 116:5 117:3 118:10 168:15 234:1 343:12 352:11 437:3 440:17 453:9 455:21
<b>q</b>			
<b>qa</b> 265:13 289:22 <b>qc</b> 265:13 <b>qm</b> 289:22 <b>quackery</b> 63:11 <b>qualifications</b> 134:5 <b>qualified</b> 47:6 273:14 <b>qualify</b> 324:18 <b>qualifying</b> 261:1 <b>qualitative</b> 493:13 <b>qualities</b> 243:10 <b>quality</b> 37:22 38:6 38:18,20 45:3 46:14 49:17,20 50:2 53:18 64:7 65:5 68:5 76:9,21 96:16 97:4 98:17 99:14 100:9,19 101:9,18 102:4 118:5 121:18 132:8 133:6 134:6 134:16 136:1 138:20 188:14 200:10 207:7 209:12 213:20 214:12 217:7 218:10,11 220:1 223:16 235:16 236:19 290:7 297:1 303:12,17 304:16 305:12 315:18 320:1 325:14 329:7,15 330:21 331:6,7,18 331:19 332:13,16 333:6 334:20 336:9 348:14 350:8 351:5,8 353:10 362:11,15 362:19,21 363:11	<b>quantified</b> 302:14 <b>quantify</b> 302:20 <b>quantifying</b> 39:15 <b>quantitate</b> 264:18 <b>quantitation</b> 314:20 360:15 394:7 <b>quantities</b> 112:4 <b>quantity</b> 157:9 190:6,20 <b>quarter</b> 154:13 <b>question</b> 23:14 52:21 66:11 71:20 79:18 80:12 85:14 86:9,18 89:21 90:8 91:7,13 94:21 95:9 103:4 110:18 115:15 118:12 124:20 137:9,12 140:7 141:17 152:20 164:11 165:13 169:16 171:16 185:18 189:7 195:21 197:3,17 198:16 199:14 214:18 222:21 226:6 232:7,11 233:5,11,22 239:11,16 244:5 257:22 258:2	<b>questions</b> 33:9 34:9,20,22 36:1 50:5 61:4 92:13 131:10 139:12 148:14 154:19 169:10 187:4 226:4 227:10 241:7 247:20 252:5 258:22 263:19 264:13 293:18 298:9 307:13 326:10,16 328:9 332:18 339:9,14 352:12 380:19 390:19 395:1 399:17 410:1 413:3 414:18 417:15 419:6 420:21 424:5,7 425:10 429:11 438:21 461:4 463:6 476:2 490:20 493:20 499:17 <b>quick</b> 52:21 110:13,18 152:19 156:18 169:16 216:14 233:5 262:10 273:21 275:17 279:18 434:10 466:15 <b>quickly</b> 24:13 36:12 37:14 44:21	<b>quilt</b> 376:12 <b>quit</b> 60:14 374:8 <b>quite</b> 140:13 158:17 179:6 195:7 246:12 308:2 312:15 336:7 399:6 412:1 412:17,19 471:15 472:1 488:16 <b>quo</b> 76:12 138:9 267:1 <b>quote</b> 139:10,10 217:12 <b>quoted</b> 493:18
			<b>r</b>
			<b>r</b> 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 20:1 <b>rabbit</b> 475:6 494:12 <b>rabbits</b> 489:3 <b>race</b> 304:9,12,13 436:1,2,5 <b>radar</b> 375:9 <b>radiation</b> 67:8 <b>radical</b> 371:17 <b>raise</b> 52:12 149:18 428:22 <b>raised</b> 139:4 193:10 <b>raises</b> 271:10 <b>ramifications</b> 178:6 <b>ran</b> 373:21

<b>randall</b> 2:18	<b>raw</b> 296:21,22	286:8 292:21	490:20 492:13
<b>randomized</b>	297:2,4 302:21	421:22 449:14	498:22,22
136:12 222:5	323:2 331:21	<b>realistic</b> 85:7	<b>realm</b> 217:18
299:7 401:21	351:6 362:4,8	<b>realistically</b>	219:17
<b>range</b> 5:7 33:15	363:5 364:2	133:16	<b>reardon</b> 9:20
50:6,10,13 82:4	369:14 372:10,18	<b>reality</b> 241:18	161:10,11,13
105:15 115:1	389:1 411:18	360:10 430:16	164:13,19 165:18
120:11 146:14	451:1 489:20	<b>realize</b> 40:13	<b>reason</b> 47:3
184:3 192:2	490:22	82:22 243:16	175:21 229:5
206:14 260:20	<b>ray</b> 13:12 328:21	311:16 435:20	248:20 316:11
261:6 270:19	328:22 488:15	<b>realized</b> 64:1	333:4,19 357:21
271:3 306:22	<b>rays</b> 490:16	393:1 473:5	452:10 494:18
309:9 358:17	495:11	<b>realizing</b> 343:11	<b>reasonable</b> 77:15
359:18 397:11	<b>rct</b> 493:10	<b>really</b> 56:7 69:12	105:2 269:18
426:14 432:15	<b>reach</b> 197:18	86:19 87:7 91:1	483:1
437:10,14 439:7	460:13 486:1	129:12 141:18	<b>reasoning</b> 74:21
451:22 452:11	<b>reached</b> 299:15	142:13 149:21	<b>reasons</b> 32:21
<b>ranged</b> 189:20	<b>reaches</b> 490:18	153:1 165:5 166:1	142:10 259:9
190:14 191:6	<b>reaching</b> 85:11	171:12 178:2,5	328:15,19 401:17
300:21	158:16	179:3 182:18	449:11
<b>ranging</b> 96:21	<b>reaction</b> 207:1	197:5 201:13,18	<b>rebecca</b> 3:2 22:6
<b>rapid</b> 145:4 220:4	208:12	201:19 202:17	<b>recall</b> 147:4
388:22	<b>reactions</b> 208:9	203:20,22 206:21	344:22 439:8
<b>rapidly</b> 67:12	465:16	216:4 219:5,7	480:13,19
154:11 161:19	<b>reacts</b> 465:18	222:4 223:18	<b>recalls</b> 367:11
183:3 322:10	<b>read</b> 122:4 179:12	225:8 226:22	464:20 466:16,17
382:5	243:3 261:5	236:15 238:12	<b>receive</b> 201:6
<b>rare</b> 92:21 130:3	335:13 336:21	239:15 242:19	270:2 337:5
130:15 132:6	375:2	246:4 247:22	346:11 462:2
200:8 269:6	<b>readers</b> 125:12	249:7 254:1	490:2
457:10,17 493:7	127:2 129:8	255:16,18 256:13	<b>received</b> 186:1
<b>rash</b> 208:1	<b>readily</b> 97:22	266:8,18 276:6	202:22 206:20
<b>rat</b> 431:17 494:6	230:15	277:2 283:6 310:1	208:13 209:2,8
<b>rate</b> 300:20	<b>readiness</b> 147:4	314:8 316:7	284:6 343:17
375:12 465:19	<b>ready</b> 100:17	321:18,19 333:7,9	458:19 462:3
480:7	169:4 218:12	334:21 336:7	492:2
<b>rates</b> 200:7 470:18	282:6 291:19	337:6 347:22	<b>receiving</b> 180:4
<b>ratio</b> 51:7 205:16	373:4 389:22	348:2,7 349:5,15	<b>receptor</b> 71:10
301:15	444:9 478:5 481:6	349:21 350:6,8	221:19
<b>rational</b> 88:2	<b>real</b> 33:8 38:12	351:13,18 352:20	<b>receptors</b> 93:14
<b>rationally</b> 93:13	39:19 103:10	387:9 422:14	262:11 270:4
382:15	183:4 187:3 229:5	455:17,20 456:16	474:11 488:19
<b>rats</b> 271:7 340:14	233:22 235:2	467:14 475:14	494:2,10
489:3	263:11 284:18	484:1 485:17,17	

<b>reclassification</b> 175:8	<b>reconvene</b> 281:22	<b>refer</b> 144:11	<b>regards</b> 150:2
<b>reclassify</b> 176:5	<b>record</b> 23:3	<b>reference</b> 133:2	202:12 205:7
<b>recognition</b> 104:3	103:18 104:7	167:1 312:18	353:14 408:10
444:1 445:3	172:22 282:2	391:10,12,15	492:1
<b>recognizable</b>	373:2 395:20	392:8 393:3,9	<b>regime</b> 119:15
266:22	434:14 502:6	<b>referenced</b> 426:8	409:3 412:8
<b>recognize</b> 73:2	503:5	<b>references</b> 314:1	<b>regimens</b> 181:1
341:11	<b>recorded</b> 23:9	440:16	<b>regimes</b> 409:14
<b>recognized</b> 29:9	502:4	<b>referencing</b> 428:9	477:2,7 479:3,21
31:3 99:2 167:7	<b>recording</b> 23:10	<b>referred</b> 435:12	481:2
179:11 262:19	134:10 503:4	<b>referring</b> 103:4	<b>regions</b> 52:11
305:13 354:14	<b>recordkeeping</b>	<b>refined</b> 73:3 371:6	<b>register</b> 284:3
427:7 440:8	326:3	<b>refinement</b> 367:18	290:20
442:19 443:15	<b>records</b> 187:4	370:15	<b>registered</b> 26:21
<b>recognizes</b> 143:9	480:15	<b>reflect</b> 188:19	26:22 126:2 162:1
408:11	<b>recreation</b> 6:17	399:6,7 427:5	260:6 311:5,7
<b>recognizing</b> 170:6	81:6,8 248:22	<b>reflected</b> 111:16	316:19,20 325:16
368:11	250:10 431:8	342:2	342:19 368:5
<b>recommend</b> 44:11	<b>recreational</b> 28:4	<b>reform</b> 160:16	438:14
47:5 108:3 152:16	28:5 68:2 78:2	233:3	<b>registration</b> 20:18
196:6 276:2	265:18 433:20	<b>refractory</b> 217:2	196:15,21 218:9
280:15 304:17	453:12 482:22	262:1	322:22 368:4
376:2 434:4,5	<b>recreationally</b>	<b>refreshments</b> 24:7	370:6 416:4,5
463:20 491:12	253:14,17	<b>refusal</b> 478:3	465:2
<b>recommendation</b>	<b>recruited</b> 429:19	<b>refused</b> 57:10	<b>registrations</b>
306:4	<b>recycled</b> 450:10	<b>regard</b> 103:18	311:8 416:6
<b>recommendations</b>	<b>red</b> 25:11,13	171:17	<b>regret</b> 317:20
130:12 142:8	127:17 283:7	<b>regarded</b> 151:13	<b>regular</b> 223:2
225:18 272:22	396:15	486:8	248:14 283:9
394:4,5 430:10	<b>redeem</b> 244:18	<b>regarding</b> 81:10	478:12
434:4,19	<b>redman</b> 16:14	82:6 83:4,13	<b>regularly</b> 139:19
<b>recommended</b>	467:2,3,4	84:14 97:18	446:11
118:16 136:11	<b>reduce</b> 80:17 89:2	123:18 128:3	<b>regulate</b> 29:7
390:13	235:6 248:20	139:12 193:10	40:12 44:11,18
<b>recommending</b>	446:4 485:22	194:4,18 195:15	71:22 73:5 75:19
280:12,13 281:3	<b>reduced</b> 67:12	204:14 208:9	112:11 119:20
<b>recommends</b>	224:7,10 502:5	273:13 315:13	124:11 183:1
295:4	<b>reducing</b> 139:20	358:9 360:13	231:4 297:22
<b>reconcile</b> 414:5,10	446:6 488:11	479:7	325:2 329:11
414:11 415:21	495:4,7	<b>regardless</b> 31:8	347:5 351:1
<b>reconsider</b> 47:10	<b>reduction</b> 181:7	99:9 106:17	409:21 411:9
<b>reconstitution</b>	230:11 257:6	146:10 229:14	412:10 416:15
165:20	275:20 318:14	313:15 315:15	471:8 481:1 486:7
		349:4	



<p><b>regulated</b> 27:19 30:1,15 34:6 36:11 38:5 51:15 51:20 62:14 138:17 144:8 154:4 168:5 188:18,22 194:9 195:8 231:7,13 242:14 246:6 283:22 318:2 319:16 320:19 323:6,16 330:1 333:12 343:6 368:1 409:6 412:12 415:4 416:16 421:9 425:2 477:2 478:8 479:21 480:21</p> <p><b>regulates</b> 29:11 33:16 147:15 262:7 368:3 369:10</p> <p><b>regulating</b> 40:14 60:5 71:21 72:2 73:10 255:8 304:18 352:15 363:14 407:17 408:20 420:11 456:9</p> <p><b>regulation</b> 27:8,12 32:18 34:9 36:4 41:18 49:13 73:19 74:3 81:14 112:20 113:1,4 117:17 129:14 138:10 162:22 192:6 240:10 244:21 251:18 254:3,4,9 265:17 273:5 292:4 304:4,8,9 305:1 307:6 322:4 332:15 347:6 352:10 368:3 371:18 378:1</p>	<p>396:19 398:2 407:11 411:7 417:9 423:6 430:4 432:1 433:15,17 456:5 476:20,21 477:3 478:2,5 481:8</p> <p><b>regulations</b> 32:16 40:9 41:21 44:10 50:17 52:3 83:3 88:22 89:12 95:6 105:2 108:13 113:2,12 123:5,12 129:1,7 131:16 135:4 138:13 146:2,2,16,22 151:17 159:9,20 163:3 166:20 167:1 214:11,13 227:2,3 273:7,16 306:14 322:12,18 323:7 325:1 326:2 331:13 332:11 349:4 369:6 371:11 383:15 414:5 426:9 434:12 438:16 447:11 462:20,21 476:16 477:15 478:7 479:4 482:9 486:8</p> <p><b>regulators</b> 48:18 84:11 99:10 100:20 133:4 134:21 154:6 156:8,12 157:12 231:20 266:13 383:14 392:4 393:12 417:12 426:1 427:3 444:17 446:1,6,18 446:21 463:21 466:11 477:13</p>	<p><b>regulatory</b> 2:15 2:19 3:12 4:9 21:16,22 33:13 37:20 38:9 41:16 41:22 42:4,11 47:22 48:16 52:14 63:12 65:13 76:19 79:21 83:19 85:1 88:3,17 89:4,10 91:3 94:19 100:16 108:2,4,8,10 117:14 119:15 120:4 131:20 133:7 139:20 142:10 145:9,19 146:4,7 150:22 153:17 154:21 155:6,15 157:19 159:13,18 161:3 162:7 163:5,12,17 165:14,19 168:4 170:9 192:16 196:11,13 200:20 204:5 210:6,11 214:15 222:11 225:7,18 244:3 268:5 283:5 298:2 298:16,20 304:13 307:1 312:4 321:16 322:5,21 323:22 325:8 327:10 329:20 331:10,11 338:7 341:17 353:11 357:17 363:1,8 364:9 365:18 366:8 367:15 369:4 371:10 372:1 378:20 380:6 381:10 409:9 412:8 413:20 414:3,8 416:1,5,18 422:18 426:22 429:5</p>	<p>430:6 432:3,9,14 436:20 437:4 438:5,11 451:12 452:8 457:12 477:7,18 478:4,13 479:3 480:18 481:2,4 491:20 493:15</p> <p><b>reimbursement</b> 39:21 337:4</p> <p><b>reinvent</b> 414:16</p> <p><b>reiterating</b> 436:10</p> <p><b>rejecting</b> 418:18</p> <p><b>related</b> 27:8 34:10 61:4 63:22 64:13 68:3 102:18,21 103:12,21 107:10 125:2 150:18 157:16 165:21 198:17 199:15 216:17 217:6,22 227:22 235:18 273:22 300:5,9,16 301:5 312:11 314:6,15,18 399:19 422:20 445:15 463:8 484:11 502:8 503:7</p> <p><b>relates</b> 102:22 157:15 356:7 420:20 425:8 463:1</p> <p><b>relating</b> 55:3</p> <p><b>relation</b> 192:1</p> <p><b>relations</b> 111:7</p> <p><b>relationship</b> 43:4 135:18 136:15 181:12 262:20 408:4 420:1</p> <p><b>relationships</b> 489:21</p> <p><b>relative</b> 37:20 198:17 199:2</p>
--	---	--	---

260:2 315:10 316:2 355:19 454:11 474:20 502:10 503:10 <b>relatively</b> 201:19 340:19 359:8 361:8 455:15 <b>relax</b> 218:16 <b>relaxation</b> 219:13 <b>relaxing</b> 215:14 277:15 <b>released</b> 101:6 110:10 172:7 346:2 <b>relevance</b> 426:11 <b>relevant</b> 28:1 29:5 29:16 38:1,12 89:3 204:20 303:20 422:19 425:5 444:8 480:15 <b>reliable</b> 88:12 100:4,19 136:13 319:14 383:17 394:18 444:10 <b>relief</b> 224:12 260:8,16 318:18 381:22 <b>relieve</b> 207:18 209:4 <b>reliever</b> 320:16 <b>religious</b> 410:18 <b>relish</b> 151:20 <b>rely</b> 267:19 337:7 <b>relying</b> 49:8 159:21 237:10 446:17 <b>remain</b> 33:9 103:3 139:12 418:22 <b>remainder</b> 159:20 <b>remained</b> 300:22 <b>remaining</b> 25:10 361:22	<b>remains</b> 29:2 106:21 139:14 478:4 501:5 <b>remark</b> 110:13 <b>remarks</b> 18:5 19:9 20:2 25:6,12,18 26:1,13 400:12 501:1 <b>remember</b> 40:15 40:16 277:3 <b>remind</b> 23:19 100:22 501:4 <b>remotely</b> 26:22 <b>removal</b> 404:9 488:13 494:21 495:9 <b>remove</b> 273:2 308:17 <b>removed</b> 28:19,22 34:4 119:17,19 308:9,14 487:21 <b>removes</b> 487:13 487:16 <b>removing</b> 128:20 226:10 <b>render</b> 106:9 <b>renders</b> 319:5 <b>renowned</b> 26:7 <b>reoccur</b> 301:10 <b>rep</b> 483:5 <b>repeat</b> 38:18 39:11 54:20 171:1 322:13 496:22 <b>repeated</b> 201:21 301:7 302:4 <b>repeatedly</b> 284:10 <b>repeating</b> 373:19 <b>replace</b> 46:7 250:19 <b>replicate</b> 418:4 <b>replicated</b> 365:4 415:11 <b>replied</b> 158:14	<b>replies</b> 158:17 <b>report</b> 109:19,19 110:10 123:22 124:4,15 136:2 180:18 183:14 208:11 215:1,3 247:7 315:6 318:7 384:19 385:9 386:7 397:6 430:17 434:18 481:12 <b>reported</b> 43:14 46:12 60:7 67:15 143:3 193:16 198:7 208:14 238:16 270:19 299:21 300:1,2 301:1 302:2 314:9 318:21 320:8 359:13 431:3 454:2,6,10,20 455:8 492:9,15 <b>reporter</b> 1:21 243:1 245:19 <b>reporting</b> 60:4 87:1,3 134:10 194:12,13 197:21 199:3,5 209:17 220:3 269:15 326:3 361:3 394:4 438:17 480:13,17 <b>reports</b> 11:21 84:17 110:15 125:3 154:12 157:7 194:16 195:3 208:1 244:1 245:20 246:1,7 247:1,8,17 381:17 459:12 <b>represent</b> 34:20 67:1 76:4 88:5 89:22 147:13 166:15 216:12 275:22 360:17	395:12,14 412:1 482:17 <b>representation</b> 89:15 <b>representations</b> 105:13 <b>representative</b> 188:15 247:18 403:9 418:9,12 466:4 <b>representatives</b> 23:1 155:20 377:21 <b>represented</b> 190:5 246:3 248:18 <b>representing</b> 52:7 72:14 116:1 119:7 132:21 138:4 159:5 210:4 311:3 421:12 427:17 429:16 435:5 476:12 <b>represents</b> 70:22 82:15 87:18 104:18 107:9 156:7 176:14 248:15 304:22 418:9 <b>reproductive</b> 262:22 <b>repurposing</b> 131:2 <b>reputable</b> 97:21 380:10 <b>reputation</b> 383:4 <b>request</b> 44:8 135:3 167:7 169:8 324:16,17 347:1 369:17 414:2 427:9 468:4 470:21 <b>requested</b> 113:4 <b>requesting</b> 73:18 73:19 418:20
---	---	--	--

<b>requests</b> 112:17 <b>require</b> 30:21 31:1 53:21 104:1,1 113:1 150:22 193:22 273:10,11 277:8,9 306:10 340:14 461:20 465:22 478:13 479:5 486:19,19 <b>required</b> 50:18 87:1,3,4 143:19 194:13 251:18 323:14 337:10 350:12 372:2 410:2 411:12 419:1 464:6,10 465:11 478:9 <b>requirement</b> 31:5 133:18 269:15 439:17 440:2 442:5 479:21 <b>requirements</b> 29:17 30:20 31:16 133:7 134:16 151:22 155:2 194:15 209:11 227:5 326:3 331:17 337:13 364:19 369:19 383:2 392:12 415:15,16 416:6 436:20 439:5,5 441:1,18 442:1,7 443:7,9 444:17,19 445:8 446:4 478:6 479:15 480:4 <b>requires</b> 33:4 101:9 135:5 147:5 185:13 284:20 369:7 370:5 371:4 381:2 456:7 465:9 478:20 <b>requiring</b> 175:1 185:11 305:11	368:5 383:13 479:22 480:13 <b>requisite</b> 35:14 324:15 354:20 356:2 <b>research</b> 4:10 8:9 10:10,18 11:6 12:13 14:21 21:17 34:1,5 39:9 40:8,8 40:10,14 41:17,20 42:5,7 47:1,6,7 49:5 54:8 58:12 84:19 89:7 96:18 108:17 116:14 125:5,21 128:7 129:5,22 131:8,10 135:19,21 136:1 137:1,7,11 139:21 142:11 156:21 157:2,6,16 170:17 172:2 174:6 175:7 182:3,13,19,21 183:1 185:10 188:7,8 189:13 192:15 195:14 200:18 204:1 210:10,15 211:1 213:3 216:16 218:18 219:10,11 220:8 222:1 225:1 225:2,12,15 226:15 241:2 249:12 256:18 259:21 263:7 265:22 266:4 268:14 270:15 271:14 278:20,21 282:10,16 284:4 286:16 292:15,21 293:4 294:9,16 295:8 297:9,17 315:5 327:16 334:3 340:16 341:19 356:22	357:22 358:1,8 379:6 381:11,13 382:14 386:22,22 387:9,12 389:12 389:18 390:1 391:3 401:3 405:7 408:14 410:7 414:19 418:14,15 418:17,19 419:5 423:10,14 427:20 435:16,22 437:13 439:13,21 440:11 440:14 451:8 456:12 462:16 472:6 473:17 474:2,5 483:21 485:18 487:7 492:6,18 493:5,18 494:17 <b>researched</b> 259:13 433:5 <b>researcher</b> 40:4 210:7 226:11,14 <b>researchers</b> 42:3 45:10 130:21 173:22 214:16 219:15 246:14 256:17 287:9 291:4 295:6 <b>researching</b> 339:3 339:15 <b>resemble</b> 102:11 360:11 <b>resembles</b> 286:8 <b>residency</b> 274:21 <b>residual</b> 308:12 319:18 360:14 362:5 364:3 372:12 428:15 <b>residue</b> 100:3 <b>residues</b> 72:5 169:18 237:17 372:13 394:13	<b>resistant</b> 143:6 458:6 <b>resolve</b> 163:21 260:14 265:11 396:7 440:18 <b>resolved</b> 301:9 <b>resolves</b> 263:12 <b>resource</b> 155:14 323:11 446:6 <b>resources</b> 123:16 160:2 168:14 355:22 393:11 <b>respect</b> 29:10 35:22 67:14 113:6 121:12 242:2 304:20 326:22 407:17 413:19,22 414:6,22 416:9,21 417:13 418:8,14 436:19 486:20 <b>respected</b> 312:20 439:14 <b>respectful</b> 24:4 <b>respectfully</b> 94:11 155:10 169:8 354:8 355:4,18 443:8 486:19 <b>respective</b> 411:9 <b>respects</b> 117:9 218:1 414:20 415:15 <b>respiratory</b> 263:1 <b>respond</b> 174:15 322:9 <b>responded</b> 159:15 392:4 <b>responding</b> 160:4 <b>response</b> 21:12 60:8,9 70:2 83:16 125:18 202:13 220:4 284:11 344:20 345:3 392:3 427:9 455:11 472:3
---	---	--	--

474:20 <b>responses</b> 159:15 202:17 241:6 455:16 456:3 <b>responsibilities</b> 123:15 <b>responsibility</b> 146:19 245:9 461:1 <b>responsible</b> 7:21 15:17 61:22 82:7 84:21 85:11 115:19,22 145:16 151:9 166:20 179:7 202:7 322:3 322:16 326:5 346:8,16 353:12 354:10,17 356:14 393:12 435:4 442:17 <b>responsibly</b> 136:11 380:4 <b>rest</b> 82:19 122:6 234:11 385:15 396:4 447:4 <b>restaurant</b> 156:18 <b>restlessness</b> 223:15 <b>restrained</b> 173:19 <b>restricted</b> 217:12 <b>restriction</b> 114:10 256:1,5,13 258:20 <b>restrictions</b> 93:22 165:15,17 192:7 218:17 219:14 256:9 258:5 337:13 470:6 <b>restrictive</b> 28:13 431:13 <b>restrooms</b> 24:14 <b>result</b> 29:1 67:15 108:11 167:12 245:7 250:22 330:14 441:17	452:3 <b>resulted</b> 34:8 37:21 112:7 193:17 <b>resulting</b> 82:8 <b>results</b> 96:13 97:22 143:22 161:5 183:12 191:4 234:19 235:5 238:20 275:17 277:13 278:15 315:6 318:7 330:5 351:14 371:14 380:9 394:9 453:17 454:18 <b>resume</b> 342:6 <b>retail</b> 42:10 53:12 159:21 165:15 213:17 238:17 246:10 249:18 251:20 344:11 362:10 461:6 <b>retailer</b> 53:17 55:2 189:16 <b>retailers</b> 9:6 16:19 18:16 19:8 147:8 147:10 154:6 156:15 191:14 236:11 431:20 452:14 481:19 <b>retained</b> 487:20 <b>retaining</b> 81:14 <b>retention</b> 488:10 <b>retina</b> 472:1 474:12 <b>retinal</b> 67:16 <b>retire</b> 485:16 <b>retired</b> 67:2 <b>return</b> 82:22 <b>returned</b> 440:7 <b>revenue</b> 46:2 52:6 54:17 235:5	<b>revenues</b> 412:14 <b>review</b> 49:3 107:17 117:20 126:7 167:11 168:15 203:12 224:19 269:22 275:17 331:12 354:22 409:8 410:6 424:3 443:12 445:11,13 480:14 <b>reviewed</b> 39:5 53:1 157:2 168:19 312:19 325:18 491:20 492:8 <b>reviews</b> 49:2 167:21 206:9 394:7 439:14,22 492:8 <b>reward</b> 271:11 <b>rewards</b> 407:15 <b>rhetoric</b> 414:20 418:22 419:3 <b>rhetorically</b> 65:2 <b>rheumatoid</b> 209:4 <b>rice</b> 396:15 <b>rich</b> 197:5 198:2 201:16 203:16 323:20 340:6 398:13 465:15 466:3 <b>richard</b> 12:20 293:20,22 <b>rick</b> 10:14 192:10 192:11 <b>rid</b> 128:22 <b>ridiculous</b> 225:10 <b>right</b> 20:11 24:15 44:20 58:22 61:13 66:16 86:17 90:6 101:3 109:2 110:1 113:19 115:3 126:3,15 137:13 158:4,18,22	166:10 171:11 172:8 176:7,14 187:22 188:1,2 189:11 200:2 202:16 204:10 222:4,6 231:7 241:8 248:7 249:21 250:5 251:10 256:11 268:1 275:6 276:10 284:19 287:14 290:10,12 291:2,10 292:8 293:4,7,18 297:18 305:20 309:4 310:22 316:14 344:9 349:1 352:2 364:22 368:17 385:19 390:1 396:3,5 401:8 407:9 419:12 421:3 425:10 447:8 448:5 453:17 455:20 460:4,20,20,21 477:17 482:3 485:12 489:17 498:21 <b>rightfully</b> 303:14 303:19 <b>rights</b> 244:20 486:16 <b>rigidity</b> 385:16 <b>rigidly</b> 266:5 <b>rigor</b> 50:18 325:5 <b>rigorous</b> 60:22 121:20 123:9 315:4 329:15 365:10 380:18 478:11 <b>rigors</b> 381:15 <b>rise</b> 432:16 <b>rising</b> 225:5
--	---	--	--

<b>risk</b> 35:12,17 42:9 61:12 77:17 84:9 84:10,22 88:3,22 89:6 108:12 118:7 127:13 174:3,14 175:13,18,21 181:13 214:5 217:5 268:2 331:8 332:18 349:15 374:22 383:7 399:20 404:16 407:14 472:18 475:3 479:17 489:9 491:9,10 494:14 495:4,8	96:7 259:17 313:13 369:1 379:14 429:16 489:1 <b>roles</b> 160:18 472:4 <b>rolling</b> 241:2 <b>room</b> 20:18 23:18 23:22 24:5,8,15 125:16 176:10,13 179:19 208:5 209:13 276:13 289:5 308:2 385:11 482:3 488:15 496:16 498:19	<b>rubs</b> 127:8 175:5 <b>ruined</b> 56:19 430:3 <b>rule</b> 105:18 112:21 240:10 355:5 <b>rulemaking</b> 48:10 89:6 116:5 117:5 117:12 323:13 433:16 440:19 <b>rules</b> 98:2 254:4 269:2 393:12 438:4 <b>run</b> 25:17 133:19 318:5 <b>running</b> 132:11 150:7 172:18 293:7 319:1 398:20 <b>russell</b> 5:20 61:13 61:15 261:18 <b>ryan</b> 11:2 209:22 246:14 <b>rye</b> 147:16	104:20 109:6,9 110:1 112:16 115:10 116:20 118:5,13 124:9 126:8 127:12 132:7 151:14 152:6,15 153:4 155:4 157:4 167:8 174:10 175:15 225:10 231:15 248:6 252:2 266:11 291:21 317:16 320:6 323:5 325:14 343:16,18 347:7 349:6 350:2,5 354:22 356:3 358:2 359:5 361:8 362:13 397:2,6 437:18 439:12,15 462:13,15 464:5 465:10 477:6 486:8 492:18
<b>risks</b> 33:1,8 89:17 110:4,10 136:18 143:15 174:4 175:5 192:2 225:16 316:1 329:22 380:14 382:7 399:21 401:12 451:20	<b>rooms</b> 207:12 490:14 <b>root</b> 75:16 396:16 <b>rooted</b> 102:3 <b>rosbeck</b> 8:19 142:17,18,18 144:17,19 <b>rosemary</b> 13:14 332:20	<b>s</b> 2:1 3:1 4:1 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 179:22 <b>s.a.</b> 14:17 <b>sad</b> 58:9 337:6 <b>sadly</b> 57:22 <b>safe</b> 16:13 30:19 31:2,4,8 34:11 43:2 44:18 45:2 49:4,7,15 51:19 53:18 54:3,7,22 60:18 62:21 64:8 66:6 68:6 69:8 73:14 74:4 76:16 79:12 88:12 102:15,15 103:15	<b>safeguard</b> 332:6 <b>safely</b> 33:4 73:5 75:19 105:3 306:5 323:6 338:12 463:22 477:10 480:20 488:14 <b>safer</b> 51:8,8 139:11 <b>safety</b> 1:2 5:21 9:2 16:11 18:15 19:7 33:10 34:10 35:11 44:15 49:10,19 50:2,19,21 51:4 52:16 56:4,9 57:2 60:6 61:14,16 65:7,8 73:9 76:8 86:18 103:3,20 104:7 109:7,12,14 110:4 117:9,12,15 117:20,21 123:2,6 125:17 126:5
<b>rita</b> 180:19 <b>road</b> 375:22 <b>roadside</b> 471:22 <b>robert</b> 7:6 15:18 66:18,19 92:15,18 425:12 <b>robust</b> 98:17 99:22 136:19 194:12 322:4 331:10 332:14 341:18 361:1 370:9 461:21 <b>rod</b> 7:14 104:14 104:16 <b>rodman</b> 8:2,3 119:1,2,3,3 <b>rola</b> 13:2 298:12 298:15,19 <b>role</b> 27:11 29:10 38:11 50:22 58:12 63:12 71:16 87:20	<b>roughly</b> 153:14 232:19 359:9 <b>rounds</b> 283:19 <b>roundtable</b> 5:5 47:18,20 48:20 49:16 <b>route</b> 40:19 104:4 168:4 177:11 184:6 211:21 218:14 353:4 <b>routes</b> 41:13 75:13 167:10,12 184:21 185:3,19 186:12 258:3,11,13 270:18 388:21 <b>routinely</b> 303:15 318:18 398:22 <b>rti</b> 15:13 451:7 453:14		

128:3 131:8 132:5 136:5,14 137:3 138:17 140:3,5 144:4,21 145:1,15 145:17 146:2,9,22 147:2,4 151:21 152:22 160:15,16 163:10 167:10 168:2,9,10,20 169:7 184:17 186:13 193:5,9 194:16 195:3,5,6 196:1,3,19,22 198:12 200:22 204:2 217:7 218:11 222:8 235:16,21 246:13 247:5 251:15,19 251:22 253:20 269:19 270:1 272:4,5 277:17 278:14 282:18 295:19 299:3,9 301:13 302:11 304:7,11 305:2,13 312:22 313:17 314:19 317:22 320:17 324:17,21 327:7 328:1,4 329:7,15 330:21 331:8 332:13 337:10 339:10 340:22 352:22 354:4,20 356:2 358:6,9 359:6,15 359:16 361:1 362:21 363:20 364:15 365:9,10 365:20 366:1,21 367:11,20 369:11 369:22 371:20 372:7 379:16,19 386:19 389:12,15 391:19 397:10	408:20 425:20 426:17 429:2 436:1,11,12,14,16 436:19 437:2,5,6 437:8,19 439:11 439:19 440:7,11 440:16 460:17 461:22 462:7,9 463:1,3,7 464:16 464:17 468:7 471:2 477:3 478:17 480:11 481:9 497:8 <b>safetycall</b> 10:15 192:16,20 <b>safeway</b> 147:18,20 <b>salads</b> 151:6 <b>sale</b> 59:21 78:2 154:21 155:7 166:22 170:11 285:2 319:8 499:13 <b>sales</b> 43:14 48:3 78:4 116:10,13 159:16 160:3,5 415:1 491:13 <b>sally</b> 5:14 56:15 56:17 <b>salmonella</b> 372:16 <b>salve</b> 186:7 <b>sample</b> 207:9 208:22 351:19 352:1,5 449:18 453:15 454:2 <b>samples</b> 207:14 209:2,8 237:1,12 <b>sampling</b> 134:7 191:13 466:4 <b>san</b> 10:11 294:15 457:6 459:6 <b>sanctions</b> 439:9 <b>sandwiches</b> 156:19	<b>sane</b> 152:15 <b>saneto</b> 261:18 <b>sanitary</b> 227:19 <b>sanitation</b> 428:5 <b>sat</b> 344:15 496:9 <b>satisfaction</b> 460:17 <b>satisfied</b> 250:9 <b>satisfy</b> 324:17 <b>sativa</b> 28:8 84:3 <b>sativex</b> 299:21 300:1 <b>save</b> 57:7 58:13 275:17 <b>saved</b> 96:9 <b>saving</b> 176:12 <b>saw</b> 59:13,14 185:18 261:13 262:9 276:11 279:19 349:10 398:12,21,22 400:2 422:3 500:15 <b>saying</b> 57:10 80:13 148:16,22 149:19 173:14 175:17 276:18 375:16 405:13 406:7 419:1 421:15,15 451:16 486:18 494:13,16 <b>says</b> 32:15 149:7 173:21 296:5 313:19 314:12 327:2 343:21 376:4,17 467:21 <b>sbir</b> 471:21 <b>scale</b> 215:3 227:19 275:12 292:16 314:22 318:11,12 318:16 <b>scannable</b> 479:6 <b>scans</b> 67:16	<b>scared</b> 206:21 291:13,17 <b>scares</b> 402:21 <b>scary</b> 231:22 <b>scenario</b> 105:5 404:2 <b>scenarios</b> 321:15 <b>scented</b> 151:10 <b>schatz</b> 185:11 <b>schedule</b> 28:12,13 29:2 39:1 93:21 94:6 119:17 132:12 172:17 210:13,14 226:19 283:17 296:9,11 333:14 <b>scheduled</b> 206:1 263:16 <b>scheduling</b> 28:17 98:7 260:2 <b>schell</b> 3:14 22:12 22:12 <b>schematic</b> 283:6 <b>scheme</b> 145:10 165:14 322:22 416:5 431:13 432:9,14 <b>schemes</b> 146:4 414:3,8 416:1,18 430:6 432:4 <b>schiller</b> 3:18 21:3 21:4 <b>schindel</b> 5:14 56:15,17,17 58:17 <b>scholarships</b> 375:6 <b>school</b> 4:18 26:9 26:10 40:1 176:21 259:15 274:20,20 275:6 277:4 358:5 375:6,10,13 400:16 <b>schools</b> 375:21 422:12
---	---	---	---

<b>science</b> 6:17 12:11 30:12 36:3,8 42:1 54:4 63:9 81:5,8 87:16 88:4,22 98:14,17 100:14 122:11 123:20 145:8 150:14 173:13 175:15,19 182:10 204:17 214:15 221:1,13 236:6 241:5 242:7 242:7 244:2,17 253:4,9 268:13,16 268:19 294:3 303:12 335:21 357:7 380:11 382:3,19 383:16 391:5,16 393:6 397:3 398:8 399:6 399:7 407:2 451:12 485:14 <b>sciences</b> 10:13 13:11 188:4,5 200:17 224:18 321:16,21 323:13 324:12 325:10 356:22 485:6 <b>scientific</b> 1:8 20:4 26:16 41:18 49:5 49:8 50:18 61:21 63:13 68:9 74:20 98:20 100:4,11 127:21 129:4 131:8 135:15 156:21 168:10 177:18 183:6 192:16 204:20 220:15 223:1 259:11 287:11 317:18 321:15 324:6 339:17 381:2,8,19 384:9 425:18	<b>scientifically</b> 99:11 273:13 <b>scientist</b> 188:6 451:7 <b>scientists</b> 107:13 259:10 283:15 287:10 391:21 432:7 <b>scleroderma</b> 93:5 <b>sclerosis</b> 8:20 142:19,21 261:4 <b>scope</b> 323:15 427:12 444:4 <b>score</b> 318:11,16 <b>scores</b> 456:2 <b>scott</b> 13:6 14:20 390:22 391:2 <b>scottsdale</b> 12:13 282:10,16 <b>scratched</b> 42:8 <b>scratching</b> 126:11 203:21 338:22 <b>screen</b> 303:9 312:2 314:1 <b>screened</b> 397:14 <b>screening</b> 281:3 302:17 <b>screenshots</b> 452:17 <b>se</b> 182:7 <b>seal</b> 148:21 <b>sealable</b> 491:6 <b>search</b> 237:7 <b>seat</b> 176:12,12,13 373:3 <b>seated</b> 20:21 <b>seats</b> 176:8 <b>seattle</b> 449:8 <b>second</b> 43:10 52:1 76:12 106:7 108:15 146:21 181:19 190:5 191:4 216:3 248:3 249:10 252:20	255:6 276:21 317:4 324:19 342:11 348:13 363:11 364:21 383:1 384:5,22 393:22 404:12 409:9 413:4 414:4 453:4 457:20 490:1 495:10 <b>secondary</b> 46:2 194:2 283:15 <b>secondly</b> 415:12 <b>secretary</b> 354:12 <b>secretary's</b> 355:12 <b>secrist</b> 14:2 353:8 353:9,10 <b>section</b> 105:6,8 106:11 273:5 321:6,9 420:4 421:5,20 435:11 <b>sector</b> 87:21 119:12 192:5 264:15 <b>sectors</b> 88:5 426:7 <b>security</b> 236:6 238:21 294:10 342:22 428:17 <b>sedating</b> 215:14 <b>sedation</b> 67:12 179:8 <b>sederberg</b> 15:11 476:8 <b>see</b> 26:19 48:16 62:17 63:22 66:5 70:7,8,9 76:17 80:5,7,7,22 86:3 113:22 114:4,18 152:14 165:11 167:16 170:3,13 177:4 179:8 198:2 206:14,15 207:5 212:13,19,21 213:10 215:7,7 220:2 223:14	229:17 230:1 231:22 236:14,20 238:4,7,10,15 239:7,12,16 240:5 248:17 249:16 250:7 254:14 265:16 276:7 277:7 280:22 281:8,13 282:17 282:22 283:3,10 283:14 284:1,2,5 284:17 285:6,8,19 285:20 287:8 293:10 296:20 299:15,17 309:8 320:15 326:16 342:4 349:8,13,19 359:2 372:22 375:13 384:20 395:8 400:1,17 407:1 421:1 424:5 452:17 453:17,22 454:5,9,15,19 455:7,15 456:2 457:22 464:11 472:8 475:2 494:4 499:11,11 <b>seed</b> 31:13 168:17 168:17,17 170:18 170:18 322:22 323:18 325:16 412:2 417:20,21 418:13 424:14 499:13 <b>seeds</b> 168:18 <b>seeing</b> 80:5 97:17 170:7,8,21 171:2 171:17 198:18 246:9 277:12 279:6 310:18 321:2 327:19 399:21 420:13,18 421:18 423:4 472:13
--	--	---	--

<p><b>seek</b> 60:15 133:5 195:9 223:4,10 404:16</p> <p><b>seeking</b> 97:5 154:18,20 162:21 386:2 387:22</p> <p><b>seeks</b> 339:10</p> <p><b>seemingly</b> 127:12</p> <p><b>seen</b> 33:20 69:18 73:22 80:15 119:9 171:4,18,21 184:7 200:7 205:4 208:1 242:3 244:15,17 263:9 276:4,5 309:1 328:16 338:16 354:7 360:12 409:12 431:16 448:6,9 492:13 494:7 499:7</p> <p><b>sees</b> 155:6 293:1</p> <p><b>segment</b> 37:7 52:4 140:17 227:14 282:10</p> <p><b>segments</b> 52:17</p> <p><b>seizure</b> 105:4 143:1,13 177:7 178:15 179:17,18 337:3 402:9 404:10</p> <p><b>seizures</b> 30:6 130:4 143:6 207:18 262:2 401:1,2,9,11,16 402:1,4,12 439:8 447:18 458:1,3,4 458:12 460:11 485:22</p> <p><b>select</b> 55:21 444:10</p> <p><b>selected</b> 55:19 237:1 312:18 358:14</p>	<p><b>selective</b> 234:18</p> <p><b>selectively</b> 152:10 152:20</p> <p><b>self</b> 44:18 49:13 60:3,4 79:21 285:12,14 347:4 356:6 363:14 373:14 388:7 443:19 486:20 492:9</p> <p><b>sell</b> 55:11 90:10 105:3 244:4 247:13 335:18 345:2 377:3</p> <p><b>sellers</b> 266:13</p> <p><b>selling</b> 35:8,15 64:17,22 112:9 236:5 241:14 431:21</p> <p><b>seminars</b> 484:19</p> <p><b>senate</b> 396:3</p> <p><b>senator</b> 395:19,20</p> <p><b>send</b> 207:1 208:22 439:9</p> <p><b>sending</b> 158:21 289:5</p> <p><b>senior</b> 3:7 21:11 87:16 240:20 375:6 391:2 500:4</p> <p><b>seniors</b> 375:10 452:21</p> <p><b>sense</b> 75:3 164:16 238:21 314:7 318:22 320:11 321:3,10 373:19 399:15 484:9</p> <p><b>sensible</b> 123:5 415:4 417:11</p> <p><b>sensitive</b> 130:16 224:15 272:8</p> <p><b>sensitivity</b> 224:11 240:3</p> <p><b>sent</b> 162:11 207:11 283:17</p>	<p>284:15 374:3</p> <p><b>sentiment</b> 176:2</p> <p><b>separate</b> 33:13 101:2 168:22 273:17 322:12,14</p> <p><b>separately</b> 106:18 350:19</p> <p><b>separating</b> 487:12 488:6</p> <p><b>separation</b> 276:12 296:4</p> <p><b>sepehri</b> 4:2 22:9,9</p> <p><b>september</b> 402:13</p> <p><b>sequentially</b> 437:21</p> <p><b>series</b> 201:11</p> <p><b>serious</b> 35:13,19 39:9 57:18 84:17 140:20 180:8 192:3 220:5,6 269:15 338:10 341:12 401:6,12 404:17 431:3 492:14</p> <p><b>seriously</b> 65:8 98:7</p> <p><b>seriousness</b> 153:17</p> <p><b>serve</b> 30:19 95:19 95:22 161:13 366:1,7,12 379:8 391:4 392:1</p> <p><b>served</b> 26:9 57:15 71:21 156:19 168:4 288:5 395:21</p> <p><b>serves</b> 379:11 413:16</p> <p><b>service</b> 26:5 109:7 156:18 445:17</p> <p><b>services</b> 9:19,22 108:12 132:22 161:15 374:12 401:4 444:11,18</p>	<p>445:21 446:10 484:5</p> <p><b>serving</b> 26:5 70:3 118:16 266:2 294:6 341:1 469:5 469:11,17</p> <p><b>servings</b> 469:18</p> <p><b>sesame</b> 449:3</p> <p><b>session</b> 22:18 24:6</p> <p><b>sessions</b> 87:10</p> <p><b>set</b> 56:5 205:13 241:16 269:2 321:19 394:17 399:14 413:19 444:17</p> <p><b>sets</b> 304:14</p> <p><b>setting</b> 73:4 272:20 338:12 341:1 362:11 366:20 368:7 372:4</p> <p><b>seven</b> 154:14 173:10 248:13 301:7,8,19 302:1 302:4</p> <p><b>seventeen</b> 209:8</p> <p><b>seventy</b> 376:1</p> <p><b>severe</b> 51:13 57:17 272:10 300:10 339:3 375:4 403:19</p> <p><b>severely</b> 452:1 473:14</p> <p><b>severity</b> 300:16</p> <p><b>sexual</b> 189:7</p> <p><b>shackles</b> 126:15</p> <p><b>shadows</b> 382:14</p> <p><b>shady</b> 129:11</p> <p><b>shape</b> 73:12 427:1 432:10</p> <p><b>share</b> 57:9 76:9 88:11 109:3 197:19 201:13 259:9 260:1 267:4</p>
---	--	--	---



<p>325:11,13 326:8 429:9 455:21 460:10 476:18 <b>shared</b> 112:16 326:5 <b>sharing</b> 100:8 194:10 196:7 496:17,17 <b>sharkey</b> 14:4 356:19,20,21 357:5,7 <b>sharma</b> 14:6,8 361:11,12,19,20 364:12 <b>sharon</b> 3:6 21:10 400:1 <b>sharpless</b> 4:6 18:6 20:11 21:1 25:22 26:2,11,14 36:21 218:2 396:9 398:18 <b>shawn</b> 15:10 476:6,7 <b>sheet</b> 370:19 <b>shelf</b> 54:1 96:20 96:22 332:8 345:1 346:20 350:17 490:19,21 491:2 <b>shelves</b> 238:17 <b>sherene</b> 4:2 22:9 <b>sheri</b> 15:20 429:13 429:14 <b>shielding</b> 131:20 <b>shiny</b> 375:14 <b>ship</b> 296:7 <b>shipment</b> 283:14 <b>shipments</b> 82:11 <b>shipped</b> 159:12 <b>shipping</b> 349:16 <b>shock</b> 489:9 490:3 491:10 494:17 495:1,4 <b>shocked</b> 484:1</p>	<p><b>shoddy</b> 37:21 206:15 <b>shoes</b> 130:6 <b>shop</b> 375:12 <b>shopping</b> 236:9 <b>shops</b> 254:13 376:1,3 <b>short</b> 127:4 131:1 183:11 188:13 208:18 293:7 303:9 306:3 317:19 392:13 396:18 <b>shortage</b> 297:3 <b>shortly</b> 206:19 <b>shot</b> 92:11 <b>shout</b> 498:9,11 <b>show</b> 166:3 211:18 238:3 242:19 248:1 271:2 358:15 359:22 384:16,16 445:15 452:4 454:10 455:22 <b>showed</b> 67:16 180:3 183:11 212:1 224:5 261:16 271:16 283:19 449:18 <b>showing</b> 40:22 51:18 80:10 211:19 223:1 238:17 315:7 492:22 <b>shown</b> 44:5,17 76:15 105:12 153:4 179:6 211:16 213:6 222:14 294:4 314:22 330:5,6 334:17 358:19 360:2 385:18 489:3 493:4</p>	<p><b>shows</b> 45:19 47:13 109:1 119:21 221:2 250:5 258:11 263:8 284:13,17 286:12 286:21 335:16 340:16 385:7 387:16,17 454:16 483:14 494:18 <b>shredded</b> 175:16 376:18 <b>shults</b> 6:10 72:11 72:13,13 74:14 75:2,10 <b>sica</b> 16:2 442:15 442:16,16 446:21 <b>sick</b> 337:6 <b>side</b> 24:5 69:20,22 70:6,9 193:8 217:17 251:10 256:16 257:3 277:15 318:20 320:7 340:6,16,18 358:15,15 359:13 361:3,22 388:3,4 388:16,19 389:11 405:5 454:4 473:18 492:14,15 <b>sides</b> 197:9 224:2 <b>sigman</b> 8:4 122:8 122:9,10 124:16 124:19 125:4 <b>sign</b> 375:16 <b>signal</b> 196:18 198:13 <b>signaled</b> 438:10 <b>signals</b> 195:6 269:13 <b>signatories</b> 447:2 <b>signatory</b> 135:7 445:5 <b>signature</b> 502:14 <b>signed</b> 294:7</p>	<p><b>significance</b> 108:16 <b>significant</b> 34:20 45:16 63:4 67:6 67:20 69:19 77:16 100:9 108:4 112:8 120:17 126:21 127:14 138:8 157:15 189:9 193:19,20 200:8 203:3,17 209:16 211:19 217:17 272:11 275:13 299:14 318:14 322:9 348:2 359:13 362:15 463:5 <b>significantly</b> 90:9 108:9 191:18 324:9 335:4 458:12 468:13 473:15 495:7 <b>signing</b> 81:13 <b>signs</b> 119:22 492:14 <b>silage</b> 45:16 <b>silence</b> 24:2 <b>silenced</b> 24:2 <b>silent</b> 62:2 <b>silver</b> 1:19 <b>similar</b> 86:7 121:12 196:12 206:7 246:7 320:15 328:9,12 330:5 409:10,16 <b>similarly</b> 32:3 478:20 <b>simple</b> 71:20 88:21 114:12 129:8 228:11 230:14 231:10 262:17 345:15 461:3</p>
---	--	---	--

<b>simplest</b> 313:3	<b>size</b> 108:20 198:17	368:17 384:21	375:20
<b>simply</b> 54:15	198:19 348:22	400:19 417:13	<b>smoked</b> 41:3
64:22 74:18 85:7	437:6 488:11	448:1 485:20	92:10 224:10
103:12 106:15	<b>sizes</b> 118:16	489:14 490:11,19	282:19 285:15
114:7 136:15,18	<b>skeletal</b> 263:3	491:7 492:10,10	287:1 300:3,17
165:18 178:11	<b>sketch</b> 290:5	<b>slides</b> 20:13,16	301:20
195:7 355:10	<b>skf</b> 342:21	166:13 226:2	<b>smoking</b> 91:22
416:5 491:18	<b>skills</b> 445:11 502:7	240:16 261:6	212:3,4 217:5
<b>simulate</b> 236:9	503:6	279:19 282:12	223:6 341:10
<b>singing</b> 337:9	<b>skin</b> 96:14 185:1	298:21 317:3	<b>smooth</b> 245:10
<b>single</b> 87:21 88:1	185:22 278:13	384:4,6,12,16	<b>smprs</b> 392:12
201:18 202:22	489:4 494:7	495:19	<b>snake</b> 275:3
218:14 261:8	<b>skip</b> 188:17	<b>slight</b> 342:1	396:16
288:11 299:4	<b>skirting</b> 209:12	447:13 483:15	<b>snapshot</b> 188:13
300:7 302:8	<b>sku</b> 290:20	<b>slightly</b> 250:6	<b>snow</b> 373:21
316:17 342:19	<b>skunky</b> 151:8	<b>slip</b> 327:11	<b>snyder</b> 8:6 125:8,9
405:21 457:15	<b>sleep</b> 223:16 249:2	<b>slot</b> 25:2	125:10 128:4,6,12
469:13,14,16	250:11 274:8	<b>slow</b> 125:19 389:7	128:22 129:6
498:13 500:2	275:14,15,16	393:2	<b>soaked</b> 488:4
<b>sinusoidal</b> 203:4,7	277:1 382:17	<b>slowing</b> 119:22	<b>socati</b> 13:5 303:9
<b>sir</b> 69:9 85:15	385:22 387:8,21	<b>slowly</b> 80:9	<b>social</b> 173:9
86:10 110:5	<b>sleepiness</b> 51:14	382:14	374:12 410:18
412:17 446:19	340:7	<b>slowness</b> 182:20	451:7
<b>sisley</b> 12:12 282:5	<b>sleeping</b> 80:7	385:16	<b>society</b> 8:18 138:4
282:10,14,15	<b>sleeplessness</b>	<b>small</b> 46:13 47:8	383:12
297:19	71:11	62:12 71:16	<b>sociodemographic</b>
<b>sister</b> 472:19,19	<b>sleeve</b> 495:6	140:17,19 184:11	453:5
<b>sit</b> 173:1	<b>slide</b> 4:13 10:5	191:13 199:5,8	<b>sodas</b> 151:7
<b>sitting</b> 499:2,5	18:7,17,19 37:15	217:11 224:13	<b>soft</b> 328:3 448:11
<b>situation</b> 120:5	156:1 169:10	285:16 289:3	<b>softening</b> 488:6
244:8 333:11	176:16,18 177:5	290:9 293:16	<b>soil</b> 312:9 330:15
382:8 406:8,12	178:9 188:17	341:7 359:8	<b>sold</b> 30:1 59:14
441:13 477:18	203:5 221:1	<b>smaller</b> 272:13	62:10,13 83:1
<b>six</b> 20:15 213:13	250:14 265:15,16	<b>smallest</b> 279:8	90:12 120:8
260:12 299:20	276:13 280:14	<b>smart</b> 5:13 129:14	138:22 155:5
301:18 318:4,18	282:17,22 283:3	253:18 254:9	156:14 162:5
335:11 406:21	283:10,14 284:1,5	399:10,10 500:12	164:20 175:3
428:3 457:21	284:13,17 285:6	<b>smartphone</b> 321:7	188:16 211:11
458:10 459:22	285:20 286:12,21	472:3	286:19 335:15
460:14 462:3	287:11 288:1	<b>smell</b> 375:20	344:3,4,4 467:21
464:12	295:2,16 296:20	<b>smokable</b> 256:4	477:10 479:16
<b>sixty</b> 250:3 335:9	298:3 311:15	<b>smokables</b> 165:3	<b>soldiers</b> 208:4
485:18	314:12 315:20	<b>smoke</b> 257:11	<b>sole</b> 193:5 198:6
	323:10 352:14	299:5,14,15,20	380:2

<b>soliciting</b> 381:22	95:8 109:13 111:5	<b>sourced</b> 151:15	153:7 155:21
<b>solid</b> 195:22 315:9	137:22 141:9,9	369:8	161:10 166:8,12
380:10	144:14 150:6	<b>sources</b> 47:7 146:1	176:14 181:16
<b>solowij</b> 213:5	172:16 181:21	169:6 340:21	192:9 200:12
<b>soluble</b> 319:6	187:20 198:16	370:5 404:9	204:9 209:21
<b>solution</b> 38:16	211:4 240:4	<b>sourcing</b> 151:19	216:10 240:14
127:1 270:17	252:19 268:22	<b>soybeans</b> 44:2	252:19 253:2,22
278:2 352:10	280:6 295:20	<b>space</b> 90:1 119:8	259:4 263:21
398:3	305:5 311:12,15	131:21 176:9	268:11 274:14
<b>solutions</b> 12:7	342:2,11 344:9	228:2 247:17	293:20 298:10,11
85:6 115:7 366:9	357:5 366:18	273:22 310:20	303:7 317:2,2
466:10 498:6	370:22 378:9,13	327:15 333:18	328:20 332:20
500:13	384:20 412:17,19	357:22 358:9	338:4 345:10
<b>solve</b> 473:12	413:9 483:1	395:14 406:21,22	347:11 353:8
<b>solvent</b> 416:12	486:13,14 488:20	420:15 422:5,15	361:10 373:6
488:1	489:10 495:18	422:17 441:17,19	378:16 384:1,1
<b>solvents</b> 319:18	<b>sort</b> 70:7 113:22	442:1,3 443:2	390:21 395:4,7
331:21 360:14	124:21 129:4	<b>spangler</b> 6:12	406:17 425:12
362:5 364:4 371:1	141:10 142:3	75:22 76:2,2	429:13 435:1
371:3,5 372:12	148:21 157:21	<b>spark</b> 364:19	442:14,15 447:5
428:15 449:17	160:6 171:17,18	<b>speak</b> 42:12 58:8	451:5 456:21
464:19 465:3,14	172:8 185:22	58:9 72:17 74:9	467:1 471:11
<b>somebody</b> 241:3	264:11 326:12,17	104:18 126:3	476:5 481:17,18
242:17 335:18	333:10 336:14	137:20 147:14	487:1 496:8,9
475:8	399:1 420:17	158:13 161:4	<b>speaker's</b> 23:21
<b>somewhat</b> 215:14	422:4 423:2 424:3	182:1 187:15	<b>speakers</b> 23:4
284:2	448:10	188:3 219:5	24:4,17,20 27:1
<b>somnolence</b> 301:3	<b>sorts</b> 70:6 114:3	252:22 268:6	37:6 53:6 66:17
360:6	114:17 310:7	273:19 274:17	155:19 177:2
<b>son</b> 56:18 91:21	449:22	384:8 401:17	202:6 268:9 282:8
91:21 92:2 128:8	<b>sought</b> 398:3	413:13 462:11	287:16 402:20
128:10 149:20	<b>soul</b> 56:19	467:4 482:1 496:3	<b>speaking</b> 25:4
226:20 373:13,18	<b>sound</b> 156:21	<b>speaker</b> 37:12	40:5 76:2 137:18
373:21,21 374:4	467:10	42:13 47:17 50:5	138:3 231:12
374:14,18 447:16	<b>sounds</b> 124:21	56:14,16 58:21,22	235:9 408:1
475:21	254:12	59:2 61:9,10,13	409:20 419:14,14
<b>son's</b> 56:18	<b>source</b> 31:8 46:3	63:15 70:16,18	419:15
<b>soon</b> 23:17 121:4	197:5 218:22	72:10,11 75:22	<b>speaks</b> 76:6
373:14	267:13 296:8	77:19 81:5 87:14	400:22
<b>sooner</b> 168:16	323:2 408:9	91:6 92:15 95:14	<b>spearheading</b>
<b>soothing</b> 491:19	423:12,13,14	101:19 111:5,7	367:9
<b>sops</b> 311:22	451:15 471:20	115:18 118:12	<b>spec</b> 289:6 292:16
<b>sorry</b> 66:11 69:17	481:3	119:1 129:17,18	<b>special</b> 192:5
83:8 91:12,12		137:15 142:17	214:3 218:5,6

<p>465:1,12  <b>specialist</b> 137:18  138:3 317:10  <b>specialize</b> 40:7  367:8 386:14,15  <b>specialized</b> 446:7  <b>specializing</b>  367:18 472:7  <b>species</b> 84:22  <b>specific</b> 33:2 34:2  84:13 117:22  133:6 139:15  152:21 157:9  177:13 198:22  280:13,14 312:21  324:18 337:17  393:8 409:4  410:15 425:6  439:12,19 444:2  444:17,19 452:15  465:9  <b>specifically</b> 31:18  35:3 69:4 75:14  93:13 94:15 116:4  134:3 158:3  177:21 196:6  208:8 233:8  235:22 236:3  253:11 294:10  304:19 312:1,18  348:12 358:9  360:13 397:5  408:3,4 416:14  <b>specification</b>  348:20 370:19  <b>specifications</b>  100:1,10 348:18  363:10 444:8  449:16 450:17  <b>specifics</b> 305:6  <b>specified</b> 400:5  445:8  <b>specify</b> 484:15</p>	<p><b>spectrometry</b>  190:2  <b>spectrum</b> 12:21  42:5 67:19 68:5  68:18,19 84:4  96:12 148:14,17  148:22 149:1  229:16 234:2,6,7  263:12 275:8  277:8,14 279:9,9  292:18 294:1,7  303:11,21,22  305:19,19 306:18  306:18 307:16,17  308:1,5,8,8,10  309:2,3 310:5  366:13 417:17,18  418:9,11 424:11  486:4  <b>speculate</b> 128:15  <b>speech</b> 36:13  <b>speed</b> 307:2  <b>spell</b> 421:2  <b>spend</b> 127:18  184:18 245:2  355:21  <b>spent</b> 43:16 50:13  241:1 245:22  339:15 348:3,5  472:6  <b>spiked</b> 148:18  <b>spiking</b> 202:1  <b>spin</b> 245:11  <b>spindle</b> 4:17 40:1  40:3,4  <b>spiral</b> 57:17  <b>spirit</b> 443:20  <b>spite</b> 78:1  <b>split</b> 372:18  <b>spokespersons</b>  61:22  <b>sponge</b> 146:14  <b>sponsor</b> 101:9</p>	<p><b>sponsored</b> 294:21  295:9  <b>sponsors</b> 76:14  <b>sponsorship</b> 247:9  <b>spontaneous</b>  86:22 197:21  198:7  <b>spots</b> 129:17  <b>sprays</b> 41:15  249:10  <b>spread</b> 122:13  221:20  <b>spring</b> 1:19  386:12  <b>springs</b> 496:7  498:8  <b>square</b> 161:22  <b>squarely</b> 416:18  <b>stability</b> 54:1  315:4,6 332:7  428:10 450:14  490:20 491:3  <b>stabilized</b> 181:3  <b>stable</b> 315:11  448:17 450:2,3,11  450:11 493:15  <b>staff</b> 24:15 134:6  197:10 445:11  <b>stage</b> 96:2 117:13  131:7 205:13  287:2 305:14  331:4  <b>stages</b> 203:11  389:16  <b>staggering</b> 154:11  <b>stairs</b> 472:22  <b>stake</b> 432:9  <b>stakeholder</b> 2:11  20:8 88:8,10 89:5  90:5 389:14  426:21 427:20  <b>stakeholders</b> 27:3  44:22 48:21 73:21  82:14 85:11 88:10</p>	<p>89:8 154:1 352:9  358:22 364:9  365:2,19 386:11  426:13 427:11  428:13 429:5  456:13 496:14  <b>stalks</b> 171:19,22  <b>stance</b> 157:12  344:18  <b>stand</b> 298:6  343:21,22 346:10  481:6  <b>standalone</b> 156:16  <b>standard</b> 38:18,21  59:20 70:3 77:14  99:10,22 103:16  138:19 168:1  194:19 285:10  296:3,4 305:20  306:1 309:17  314:11 368:6  369:16 372:5  392:11 400:1  428:13 437:6,8  443:6,20 444:3  479:12 494:15  495:11  <b>standardization</b>  142:5 220:1  266:10 310:9  <b>standardize</b>  363:16  <b>standardized</b>  142:4 143:4  273:17 286:10  303:20 364:10  371:12  <b>standardizing</b>  408:15 479:16  <b>standards</b> 37:22  42:1 49:13 98:17  98:22 99:5,13,16  100:14,19 101:2,9  101:18 109:22</p>
--	--	--	---

110:2 121:17	288:2,14 290:21	198:9 218:19	<b>states</b> 1:1 28:2,16
131:17 132:5	305:11 308:1	219:3 220:8	42:20 43:5,19
134:10 138:21	325:15 343:9	228:21 242:15,15	45:11 52:8 56:6,8
204:15 213:19	355:15 365:16	265:12 266:6	60:19 61:18 99:3
235:19 254:10	385:1 391:6	283:21 294:21	121:4,7 132:22
256:11 266:13,21	392:11 407:21	295:9 296:7,11,17	138:19 146:4,7
291:8 297:6	435:7 451:16	318:1 319:9,19	150:4 156:8,11,17
303:17 305:7	462:7 482:5	320:2,19 329:20	156:20 157:7
329:16 330:21	487:10 496:12	342:20 344:13	158:6,14 159:15
331:16 332:13,17	<b>started</b> 44:17 74:2	345:1 353:14	159:20 160:1,4,5
333:17 337:11	91:22 246:8,9,16	356:13 357:18	160:8,9 161:6,18
348:15 362:11,16	288:3,4,8 290:10	363:3 369:9,14,19	163:17 164:4
363:5 364:14	343:11 345:7	371:11,11 376:8	166:1,18 167:1,14
365:12,20 366:2	367:1 373:13	383:2 407:17,18	170:5 174:17
366:16,20 372:2	392:13 394:8,12	408:16 409:3,4,22	175:17 182:15
379:3 383:13,18	402:13 421:18	411:3,6,8,13,16	193:4 201:8
389:11 393:8	458:1	411:20,21 412:8	207:13 217:12
394:17 405:2	<b>starting</b> 175:2	413:20 414:5,11	221:5,8 228:17,20
407:18 409:16	221:20 304:13	415:21 420:1	229:1 242:14,18
411:11 412:11	309:10 312:4	421:14,15 422:8	244:20 251:20
414:14 415:18	318:11 323:5	424:1,17 429:4	253:15 258:8
417:3,9 425:9,19	327:22 402:17	430:5,6,11 432:3	261:1 265:18
426:3,6,8,10,14	430:6	432:20 434:12,18	266:1 267:1
426:20 427:1,8,9	<b>starts</b> 296:11	462:20 464:6,8,8	290:19 294:8
427:13 428:1,4,10	348:8 450:5	465:4 466:11	295:6 297:16
428:12 429:1,6	<b>startup</b> 342:14	467:11 476:13,16	333:2,4,11,12,13
436:12 442:20	<b>state</b> 9:14 18:18	477:2,7,15 478:8	333:15,21 334:13
446:3 463:2,7,10	20:15 21:1 25:5	478:10,12 479:2	357:20 358:10,12
463:16,19 466:12	43:8,13,17 48:17	479:15,21 481:2	384:15,17 385:7,8
466:14 478:21	51:15,20 52:6	481:13 498:12	385:9 386:10
480:11 487:8	60:4,7,11 61:5	502:17	392:4 408:22
489:14 490:10	62:1 88:19 91:19	<b>state's</b> 409:5	409:12 410:9
497:8	94:5 113:5 121:8	411:12 499:6	411:6,15 412:3,5
<b>standing</b> 220:15	138:12 146:1	<b>stated</b> 103:14	412:5,10 414:7
369:13	154:6 155:20	111:20 121:6	415:21 426:9
<b>standpoint</b> 210:10	156:2,7,11 157:12	152:4 469:3	428:9 430:12,13
231:11,19 232:21	157:21 160:4,12	<b>statement</b> 111:13	432:1,16,17,17,18
<b>stands</b> 100:17	160:18,21 161:1	273:17 321:5	432:19 433:7,9,10
119:12	161:20 162:2,12	369:21 419:3	445:4 453:12
<b>staph</b> 490:3	162:21 164:15	430:1 433:12	464:11,14 465:1,5
492:20	165:14 166:2	438:8	465:22 466:17
<b>start</b> 46:18 89:22	170:3 172:3 182:5	<b>statements</b> 160:13	469:2 470:17,19
196:2 279:4	188:12 189:16	437:15 480:1	479:4,5 480:12
280:17,22 281:6	191:14 193:7		482:2,21 484:6

486:15 500:12,20 <b>stating</b> 120:22 344:2 370:1 <b>stations</b> 62:19 <b>statistical</b> 134:7 <b>statistically</b> 318:14 <b>stats</b> 250:16 <b>status</b> 52:12 71:6 76:12 82:6 100:16 138:9 267:1 273:12 401:15 467:12 <b>statute</b> 354:13 436:4 <b>statutes</b> 353:20 354:9 <b>statutory</b> 32:4,17 163:21 398:3 <b>stay</b> 24:20 112:11 379:13 396:16 411:12 <b>staying</b> 71:21 <b>steals</b> 474:8 <b>steam</b> 152:9 <b>steel</b> 426:15 <b>steinberg</b> 16:4,5 447:5,7,8,9 <b>stems</b> 286:1 <b>step</b> 36:9 60:21 88:8 230:2 266:5 306:8 370:14 429:7 <b>stephen</b> 13:20 347:12,13 <b>stepped</b> 38:4 383:9 <b>steps</b> 47:5 55:3 77:4 183:5 230:10 230:14 <b>sterilization</b> 488:15 <b>sterilize</b> 490:14,15 495:10	<b>steve</b> 15:16 117:11 435:2,3 <b>stewardship</b> 197:1 218:10,11 366:22 <b>stick</b> 132:13 293:9 <b>sticking</b> 291:10 <b>sticks</b> 286:1 448:12 <b>stifle</b> 419:5 <b>stifled</b> 414:20 <b>stifling</b> 82:11 <b>stigma</b> 230:13 232:8 <b>stimulation</b> 271:9 <b>stomach</b> 177:12 <b>stop</b> 25:14 170:11 223:6,18 402:1 431:19 <b>stopped</b> 250:21,22 402:15 472:13 <b>stopping</b> 401:16 <b>storage</b> 330:13 332:5 <b>store</b> 55:9 96:19 208:1 226:21,22 238:17 249:18 251:20 377:3 450:6 461:6 <b>storefronts</b> 395:15 <b>stores</b> 153:14 156:15,16 208:6 254:13 375:21 <b>stories</b> 58:3 96:8 148:11 171:18 246:17 260:7,17 <b>storm</b> 470:15 <b>story</b> 58:1 91:15 92:13 204:20 252:14 374:19 375:1 402:5,6 448:22 <b>strain</b> 267:12 <b>strategies</b> 89:6 222:8	<b>stream</b> 46:2 54:17 232:13,15,22 234:1,22 <b>streamline</b> 372:1 <b>streamlined</b> 42:4 226:8 <b>streamlining</b> 225:19 <b>streams</b> 235:5 398:6 <b>strength</b> 33:3 99:8 99:13 163:13 315:19 331:19 352:18 <b>strengthened</b> 445:1 <b>strengthens</b> 160:18 <b>strengths</b> 352:16 <b>stress</b> 248:20 250:2 443:10 <b>stressed</b> 80:6 <b>stretch</b> 172:20 <b>strict</b> 95:7 348:17 366:15 490:6 <b>strictest</b> 370:8 <b>strictly</b> 121:14 471:8 <b>striking</b> 67:16 <b>stringent</b> 332:16 362:16 476:15 <b>strive</b> 282:18 <b>striving</b> 282:20 <b>strong</b> 14:15 59:5 71:7 83:4 91:2 96:2 259:22 305:1 338:7 341:17 352:10 374:8 376:12 <b>stronger</b> 41:1 83:4 212:2 340:3 364:14 <b>strongly</b> 44:8 48:22 50:20 71:21	71:22 108:2 118:9 138:18 139:21,22 197:18 322:16 326:15 333:22 358:21 381:13 439:4 <b>structure</b> 29:22 71:14 86:7 121:15 273:14 448:5 468:21 488:9 <b>structured</b> 443:21 <b>structures</b> 146:7 <b>struggling</b> 156:20 160:9 424:10 <b>stuart</b> 6:14 61:19 77:19,20 <b>stuck</b> 109:13 <b>studied</b> 31:19 32:10 135:18 178:16 217:19 259:13 265:1 435:19 <b>studies</b> 42:7 49:10 51:9 78:18,20 93:4,8 94:8 96:11 104:20 110:15 126:4,7 139:3 140:3 168:20 169:7 172:4 175:6 183:9,12 184:10 184:20 185:14 201:11,14 211:15 212:1 213:19 215:16 219:17 220:21 224:3,4 236:21 263:8 270:15 271:2 272:4 273:22 274:3 299:3 325:19 328:4 339:14 340:5,14 351:22 352:22 354:5,20,21 356:2 358:14 359:1
--	--	--	--

360:17 397:9	438:15,20 461:21	325:10 355:7	<b>successfully</b> 365:4
440:3 451:11	476:15 478:11	466:20 493:17	368:1
452:4 475:5 489:2	<b>subjective</b> 212:7	<b>suboxone</b> 67:13	<b>successor</b> 63:7
492:12 494:8	212:20	<b>subpar</b> 295:14	<b>sudden</b> 401:13
<b>study</b> 124:14	<b>subjects</b> 390:1	356:15	<b>suddenly</b> 403:5
128:17 170:17	<b>sublingual</b> 41:15	<b>subpopulation</b>	<b>sue</b> 12:12 240:22
186:9 188:13	270:18 277:17	452:12	241:3 282:3,10,13
202:21 204:22	278:7,8 280:17	<b>subset</b> 464:9	282:14 287:14
211:10 212:13	317:13,16 318:1	<b>subsidiary</b> 268:20	297:19
220:20 226:1,20	318:16 319:4,7	<b>substance</b> 29:3,14	<b>suffer</b> 130:2
237:4,5 265:21	320:5	29:16 31:3,6 32:9	<b>suffered</b> 449:12
279:15 283:4,8,12	<b>submission</b> 63:13	32:18 34:5 61:17	<b>suffering</b> 338:20
285:13 286:3	72:3 107:18	68:1 81:17,21	341:12 415:8
287:6 299:8	123:15 167:22	82:1 93:11 105:10	458:7
301:11,15 335:22	169:14,22 196:16	106:1,2,3,9,16,19	<b>suffers</b> 375:3
336:22 358:5	205:5 337:16	212:15 273:5	458:4
359:8,12,19	493:18	322:13,15 461:15	<b>suffice</b> 468:12
389:22 398:12,16	<b>submit</b> 25:19 27:5	<b>substances</b> 28:9	<b>sufficient</b> 73:5
451:13 474:19	36:14 52:22 71:19	29:13 31:7,10	77:15 330:7
475:4,6	71:22 79:17	32:1,19 33:9 56:2	360:15 389:12
<b>studying</b> 293:3	111:13 114:22	69:1 82:3 89:18	<b>suggest</b> 185:9
<b>stuff</b> 127:10	115:6 118:19	93:21 99:20	430:4 433:8
229:16 243:21	122:6 124:18	205:20 206:1	473:13
244:4 248:20	125:3 165:11	219:12 241:20	<b>suggested</b> 117:6
249:15 276:16	197:3 216:5	296:6 314:6,15,18	120:7 121:13
288:15 290:7,13	229:10 274:11	382:6 433:13	194:1 403:2 475:2
290:16 291:4,16	292:19 310:2	459:19	<b>suggesting</b> 182:10
293:3,5 393:3	314:14 320:11	<b>substandard</b>	184:19 407:10
449:14	325:21 344:18	132:1 295:14	475:12
<b>stumbling</b> 97:6	354:21 395:20	383:4 477:20	<b>suggestion</b> 122:3
<b>stunning</b> 83:2	412:22 434:20	<b>substantial</b> 32:2	<b>suggestions</b> 120:6
<b>sturge</b> 457:10	447:4 456:18	106:13 136:17	<b>suggests</b> 84:20
<b>sub</b> 359:9	466:19 476:3	157:5 246:20	116:14 120:18
<b>subcommittee</b>	501:5	247:16 300:19	301:12 302:4
428:18	<b>submits</b> 440:5	<b>substantiate</b> 382:3	323:13 324:12
<b>subcommittees</b>	<b>submitted</b> 36:7	<b>substantiation</b>	455:17 456:4
427:21	69:5 81:1 83:17	268:18	<b>suicidal</b> 174:22
<b>subgroups</b> 479:19	107:15 153:2	<b>substantive</b> 326:9	374:2 375:4
<b>subject</b> 22:21 23:2	158:1 189:17	<b>subversion</b> 175:19	<b>suicide</b> 56:19
29:15 33:12 42:22	303:4 354:15	<b>succeed</b> 170:13	57:19 245:6
55:16 123:8 189:8	<b>submitting</b> 66:8	<b>successes</b> 412:5	373:22 374:22
204:18 303:1	68:8 73:17 86:1	<b>successful</b> 365:6	375:18 485:2
316:15 365:17	204:13 205:10	369:2 402:22	<b>suicides</b> 376:9
409:13 410:6	309:22 321:6	417:10 430:22	

<p><b>suit</b> 241:4 316:12  <b>suitability</b> 163:7  <b>suitable</b> 100:9  134:11 487:18  <b>sulak</b> 261:18  <b>sum</b> 480:20  <b>summarize</b> 302:6  <b>summarized</b>  315:12  <b>summary</b> 68:5  135:2 144:4  183:16 191:13  195:21 219:10  317:21 332:9  440:17 456:18  <b>summer</b> 373:11  394:10  <b>superimposed</b>  387:19  <b>supermarket</b>  153:13  <b>supervision</b> 33:5  139:6 347:4  <b>supplement</b> 6:21  32:5,9,14 44:15  47:11 51:21 65:4  71:13,15 72:3  73:6,11,20 77:10  77:12 79:4,6,10  83:12 102:8  108:19 116:2,8  118:4 159:19  171:9 189:1 218:4  272:19 273:8  306:22 313:11  325:7 357:8,10  359:4 365:1  395:14 396:2  404:1 406:5  410:20 415:14  416:3 428:20  433:14 435:6  436:21 438:7,7,9  439:6 441:4,17,22</p>	<p>442:3,11 478:21  497:3 498:4  <b>supplemental</b>  433:18  <b>supplements</b>  10:18 30:14 33:11  34:7 44:12 48:11  48:14 52:18 53:20  65:1 71:2 76:5,8  77:6 78:15 84:12  98:13 99:1 101:16  111:22 112:9,17  112:22 113:8,15  116:3,6,9 117:16  117:18 118:6,7,14  120:9,21 128:17  129:1 151:16  154:8 162:6 188:8  188:21,22 189:5  200:18,22 205:21  214:14 269:14  273:1 296:3  304:19 313:6  315:16 323:9  324:3,5 327:11  337:12,18 350:12  352:15 353:12  355:7 361:7  365:14 396:13,17  398:21,22 399:20  407:16 415:3  416:11 435:10,18  436:5 438:12,16  438:19 440:20,22  441:6,6,21 442:7  450:20 477:11  <b>supplier</b> 198:6  <b>suppliers</b> 97:20  154:5 490:7  <b>supplies</b> 302:19  303:1  <b>supply</b> 31:2 32:22  46:10 48:3 66:8  89:2 101:11,13</p>	<p>216:19 267:5  286:18 287:5  305:10 311:7,9  322:20 323:4  327:3 345:2  404:15 408:18  487:9,10 489:18  489:19  <b>support</b> 30:12  34:6 50:20 53:14  60:9 65:4 68:9  76:12 78:12,15  79:9,15,20 80:4  80:21 84:7,22  86:7 88:9 89:4  94:13 103:3 104:3  113:10 121:22  131:16 136:20  139:20 163:4  187:3 195:18  268:17 338:7  341:17 363:1,9,17  363:19 364:8  410:17,18 411:6  429:7 439:22  446:2 456:12  457:17 464:3  467:10  <b>supported</b> 247:10  328:4 457:3  <b>supporting</b> 50:15  125:17 170:16  253:3 294:10  394:19 482:7  <b>supportive</b> 79:1  128:5  <b>supports</b> 50:11  71:8 85:20 108:22  325:7 477:2  <b>supposed</b> 206:22  254:17  <b>suppositories</b>  41:16</p>	<p><b>suppresses</b> 492:19  <b>supreme</b> 244:21  <b>sure</b> 25:5 30:18  89:20 90:6 91:2  91:16 114:2 115:3  115:8 158:12  214:22 231:5  233:10 238:14  276:5,8 282:5  286:9 308:1 313:1  336:9 343:17  344:7 345:4 346:7  349:5 360:16  405:2 459:11  481:14 493:19  499:9  <b>surely</b> 63:8  <b>surface</b> 42:8  126:12 203:21  338:22 489:7  490:18 494:19  <b>surgery</b> 458:22  <b>surgical</b> 495:12  <b>surpassed</b> 482:14  <b>surplus</b> 288:22  289:15  <b>surprise</b> 391:10  <b>surprised</b> 206:18  238:13 249:16  276:6,17  <b>surprising</b> 270:12  271:1 387:3  <b>surprisingly</b> 71:7  249:3 386:4  <b>surrounding</b>  48:18 155:7  466:18  <b>surveillance</b> 3:15  22:13 87:11 193:1  193:3,5 194:18  195:6 196:16  198:12 218:7  452:1</p>
--	---	--	---



<p><b>survey</b> 125:5 154:13 158:5 159:14 161:5 162:9,15 164:12 164:16,20 188:11 189:11 247:18,19 251:9 387:14 453:12 455:16 483:14</p> <p><b>surveyed</b> 386:5 453:10</p> <p><b>surveys</b> 451:21 454:10</p> <p><b>survive</b> 377:10</p> <p><b>surviving</b> 473:8</p> <p><b>susan</b> 5:10 14:16 53:6,10 378:17,22 383:22</p> <p><b>susceptible</b> 382:18</p> <p><b>suspect</b> 199:1</p> <p><b>sustainable</b> 365:22</p> <p><b>sweet</b> 457:21</p> <p><b>sweetheart</b> 243:19</p> <p><b>swept</b> 62:4</p> <p><b>swift</b> 42:11</p> <p><b>swiftly</b> 38:2 155:11 438:2</p> <p><b>swimming</b> 438:5</p> <p><b>swine</b> 86:12</p> <p><b>switch</b> 224:2</p> <p><b>symbol</b> 273:18</p> <p><b>symbols</b> 480:1</p> <p><b>sympathy</b> 242:2</p> <p><b>symphony</b> 440:14</p> <p><b>symptom</b> 208:19</p> <p><b>symptoms</b> 131:3 224:7 271:17 275:21 318:5 385:15,18,21 386:3 387:8 388:5 388:7 389:17,20 493:11</p>	<p><b>synchronized</b> 322:18</p> <p><b>syndrome</b> 140:18 140:19,20 173:15 203:5 338:21,22 447:20 457:10 489:9 490:3 491:10 494:18 495:1,4</p> <p><b>syndros</b> 30:7</p> <p><b>synergetic</b> 487:19</p> <p><b>synergies</b> 306:16</p> <p><b>synergistic</b> 306:18 308:6</p> <p><b>syngap</b> 8:9 129:22</p> <p><b>syngap1</b> 130:22 131:3 132:6</p> <p><b>synthesis</b> 93:12</p> <p><b>synthesize</b> 262:14</p> <p><b>synthesized</b> 313:10</p> <p><b>synthesizing</b> 316:2,10</p> <p><b>synthetic</b> 30:7 164:17,17 190:3 190:11 191:2,11 191:22 206:17 209:9 314:17 315:21 431:16</p> <p><b>synthetically</b> 210:14 312:3,13</p> <p><b>syrups</b> 207:16</p> <p><b>system</b> 25:7 54:5 71:10 72:1 78:13 78:13,20 79:9,21 79:22 92:21 93:15 94:14 152:1,3 198:1,5 205:3,11 259:11 261:8 262:5,6,6,7,11,20 263:7,13 270:5 300:7 302:2 438:17 442:2 482:6 485:8,9,12</p>	<p>488:21</p> <p><b>systematic</b> 158:1 213:22 439:22</p> <p><b>systemic</b> 236:18</p> <p><b>systems</b> 54:2 179:15 235:16 262:21,22 263:5,7 269:11 292:9 340:20 362:22 363:11 409:21 437:14 474:15 476:16 478:14</p> <p><b>t</b></p> <p><b>t</b> 18:1,1 19:1,1</p> <p><b>table</b> 20:21 148:22 190:5 191:4 319:4 464:9</p> <p><b>tablet</b> 63:2 114:8 318:16 319:3,5,7 319:11,15</p> <p><b>tablets</b> 63:4</p> <p><b>tackling</b> 140:5</p> <p><b>tacrolimus</b> 180:20 181:3,6</p> <p><b>tailor</b> 452:14</p> <p><b>tailored</b> 348:12</p> <p><b>take</b> 39:2,2,6 41:6 43:20 58:11 72:19 73:12 90:1 112:18 118:19 120:3 121:11 148:4 168:13 172:17 175:11 183:5 209:3 222:19 227:6,8 230:9 232:15,21 233:1 234:8,17 235:6 236:13 246:8 247:20 248:13 249:18 252:7 254:18,18 257:13 262:10 281:5,19 281:21 291:7 295:7 337:18</p>	<p>339:11 343:22 344:18 359:3 372:21 373:3 376:18 389:14 399:17 401:14 403:2,11 404:3 407:11 418:5 423:2 430:5 437:13 467:19 469:2,3,6,8,12,17 470:3 488:13</p> <p><b>takeaway</b> 414:1</p> <p><b>takeaways</b> 247:22 387:3</p> <p><b>taken</b> 62:17 85:4 139:6 177:12 248:11 250:12 353:3,16 392:5 409:3 432:12 502:3,9 503:9</p> <p><b>takes</b> 149:8 265:8 403:13</p> <p><b>takoma</b> 261:12</p> <p><b>talk</b> 40:16 171:14 177:15 178:18 179:10 188:10 228:6 233:16 242:8 258:20 295:18 298:6 334:15 345:20 357:9 390:7 420:16 421:16 447:21 448:2 496:11 497:8,14</p> <p><b>talked</b> 172:4 177:9 185:19,20 310:4 310:17 348:21 349:1 352:14 389:11 424:11 470:13 474:19 498:10 499:19</p> <p><b>talking</b> 29:18 62:3 114:20 127:11 198:20 210:9</p>
--	---	---	--

245:10 258:15 280:1 291:2 301:2 312:11 336:1,2,3 361:22 398:10 399:5 449:8 497:5 <b>tall</b> 187:19 <b>tame</b> 383:12 <b>tampon</b> 488:4,11 488:13 490:13,18 491:12,13 494:19 494:22 495:6 <b>tampons</b> 487:8,21 488:14 489:7 490:15,16 491:1,4 491:18 493:3,11 494:15 495:11 <b>tandem</b> 408:16 411:7 <b>tangible</b> 126:21 <b>tape</b> 127:18 283:7 <b>tapping</b> 196:1 <b>target</b> 92:21 146:17 394:7 452:14 <b>targeted</b> 130:21 130:22 387:7 452:13 <b>targeting</b> 93:19 94:14 389:20 <b>targets</b> 270:4,12 <b>task</b> 119:20 211:20 <b>tasked</b> 322:11 <b>taskforce</b> 85:8 395:8 <b>taste</b> 151:9 328:6 328:12,14 <b>taught</b> 92:1 259:14 <b>tax</b> 52:6 54:16 378:1 412:14 <b>taxed</b> 412:15 <b>team</b> 197:10 269:22 329:3	348:9 <b>technical</b> 134:3,12 134:22 168:15 172:16 325:17 328:7,15 381:8 425:19 426:11,22 427:12 444:6,13 445:11 495:18 <b>techniques</b> 152:8 <b>technology</b> 50:14 87:16 267:9,11 303:12 427:6 471:21 472:2 474:13 <b>teen</b> 260:10 <b>telephone</b> 247:19 <b>tell</b> 39:9 56:11 58:1 91:15 127:2 243:19 255:16 260:7 282:11 291:14,18 332:22 340:5 374:19 375:1 494:15 <b>telling</b> 39:1 92:12 179:16 246:17 334:22 345:1 346:11 <b>tells</b> 63:7 335:19 <b>temperature</b> 450:3 <b>temple</b> 265:22 <b>temporary</b> 70:8 411:13 <b>ten</b> 122:12 249:1 483:16 <b>tend</b> 114:4,18 474:16 <b>tends</b> 494:9 <b>tens</b> 348:3,5 <b>tenth</b> 413:4 <b>term</b> 68:17,19 78:18 131:1 139:12,18 156:22 157:6 163:10	182:18 183:11 186:22 208:18,19 214:1 396:19 448:19,22 449:4 489:21 <b>terminology</b> 417:14,15 <b>terms</b> 33:17 85:2 167:2 183:3 186:21 192:6 205:9 213:22 240:2 246:5 251:15 258:9 271:18 272:2 303:21 307:16,20 310:7,10 349:11 396:6 420:18,20 422:17,19 424:4 443:9 <b>terpene</b> 151:6,7 372:11 428:16 <b>terpenes</b> 9:10 84:4 148:18 150:15 151:2,8,18,19,22 152:2,5,10,13,21 153:1 165:21 210:17 308:7 319:4 350:18 486:5 <b>terrain</b> 32:20 <b>territory</b> 396:10 397:4 <b>test</b> 97:22 133:16 134:14 227:1,4 236:15 237:5 247:12 306:7 312:5 315:5 316:6 334:4 349:17 351:6,12,14,17 360:11 379:12 381:12 428:13 433:5 444:21 <b>testament</b> 418:16	<b>tested</b> 97:21 109:15 215:20 222:7 237:18,22 238:9 239:5 240:3 251:19 294:17 297:12 315:18 319:12,17 340:11 345:18 348:19 369:15 370:20 464:10 466:1 490:2 <b>testicular</b> 174:15 <b>testify</b> 256:22 278:1 <b>testifying</b> 279:17 460:9 <b>testimonials</b> 257:18 <b>testimonies</b> 377:22 391:8 471:16 <b>testimony</b> 68:10 378:22 381:22 472:5 493:18 <b>testing</b> 11:17 49:17 60:11 92:4 96:16 109:19 121:17,20,22 133:1,1,8,12,17 134:8,11,22 135:6 142:5 145:5,12,21 175:2 204:14 209:15 213:13,20 219:22 222:5,12 234:18 235:2,15 238:3 265:13 267:2 278:17 283:16,18,19,21 283:22 290:12 291:4 303:18 304:15,21 306:11 311:20 315:4 319:13,20 330:4,6 330:20 331:4
--	---	--	--

332:2,3,3,8	47:15,16 50:3,4	204:7,8,11 209:19	456:11,20,21
351:21 352:3	52:20 53:4,5,9	209:21 214:17	462:3,6,10 466:14
362:22 363:22	55:1,15 56:3,12	216:9,11 220:9	466:21,22 467:1,3
364:2,5,7,10	56:13,14 58:15,17	226:4,5 227:11	471:9,11 475:19
370:9 371:12,14	58:19 61:4,8,9	235:6,8,12 240:12	476:5 481:10,20
372:2,9 375:19	63:14,15,18 65:21	240:14 245:14,16	486:12,21 487:3
379:2,5,15,16,20	66:10 68:16 69:10	252:9,17,18,21	489:16 491:8
380:10,11,18	69:15 70:13,14,14	257:20 258:22	492:10 493:19
381:3,9 382:19	72:7,10,16,21	259:1,2 263:17,20	495:15,16,17
383:5,13,18	74:8 75:19,21	263:22 268:6,7,8	496:16,17,18
391:14 392:9,19	77:18 79:15 81:2	268:12 273:18	500:21 501:2,6,8
393:10 394:15	81:4 83:5,6,10	274:10,13,16	<b>thankful</b> 50:22
414:13 416:20,21	85:12 86:2,8,17	279:15,17 280:5	<b>thankfully</b> 191:7
416:22,22 424:17	87:12,13 89:12,20	280:11 281:16,17	<b>thanking</b> 496:13
425:4 427:21	91:4,5 92:12,14	281:22 282:12	496:13,14,15
428:14 439:3	92:17 94:19 95:12	287:12,14 293:19	<b>thanks</b> 70:12
443:1,2,18 444:6	98:8,15 100:21	298:5,7,8 303:3,6	89:14 95:10
444:10,14,18	101:18,19 104:9	303:8 307:9	137:13 158:22
446:14 463:2	104:10,11,17	310:14,21 315:19	161:8 200:11
464:4,5,7,15	107:1,2 110:12,16	316:22 317:1,6	216:7 233:21
466:2,4 479:10,12	110:17 111:2,3,4	320:21 321:1,11	293:18 310:13
480:7 490:19,22	113:16 115:4,14	321:12 326:7	352:12 475:18
<b>tests</b> 67:17 99:12	115:16,20 118:21	328:20 329:3	476:4 481:16
213:14 238:2	118:22 119:4	332:18,19 337:14	495:20
247:2 267:3 319:2	122:5 124:12,13	338:2,3 341:21	<b>thanksgiving</b> 92:2
339:20 424:16	125:6,7 128:1	342:6,7 347:9,10	459:22
446:17 458:18	129:14,16,20,20	353:6,7 356:16,18	<b>that's</b> 422:18
494:4	132:9,10 135:7,9	361:9,10,12,15	<b>the</b> 27:15 28:15,21
<b>tetra</b> 13:3 298:16	137:4,14 142:16	364:12 365:15	30:8 31:18 32:8
298:20,22 302:13	144:12,18,19	366:3,4 372:19,20	32:11,13 33:6
302:19	147:6,7 150:9	373:4,7,9 378:4,6	57:1 61:1 62:8,10
<b>tetrahydrocanna...</b>	153:6 155:17,18	378:15,18 383:21	62:20 63:3,5
27:15	156:9 157:17,19	383:22 384:8	67:11 69:1,3 72:4
<b>texas</b> 264:3,4,22	159:1,2,4 161:3,9	390:4,20,21 391:1	80:19 84:5,7 92:5
266:4 294:15	161:11,15 164:1,9	394:21 395:2,3,6	103:1 150:22
373:11 457:6	166:7,8,14 169:15	400:8,9,11 405:8	173:20 174:3,10
479:5	172:13,15,20	406:16,17 413:1,2	175:4,14 176:5
<b>text</b> 36:13	173:3,8 176:5,6	413:5,12 419:6,8	177:20 179:14
<b>textbook</b> 422:12	176:13 181:15,16	425:9,10,11,14,14	182:10 183:10,16
<b>textile</b> 52:8	181:18 182:1	425:16 429:9,11	183:22 184:10,11
<b>thank</b> 26:14,15	185:16 187:10,11	429:12 434:8,9,21	186:16 189:14
36:16,19,21 37:17	187:14 188:2	434:22 435:1	190:2,9,21,22
39:21,22 42:12,13	192:8,9 197:1	441:2 442:13,14	191:19,20 194:21
42:21 45:4,5	198:4,14 200:12	447:3 451:2,4	194:21 209:18

211:5,7,12,16 212:17,22 213:8 213:11,14,16 214:9,20 215:4,7 215:21 217:6,12 222:2 224:10 228:16,19,22 229:1,14 230:1,6 230:11 231:3 232:4 233:1,4 234:12 235:2 237:18 239:17,18 240:1,8,10 255:2 271:16 274:5 275:9 294:4 299:17,19,20,21 300:1 301:15 303:21 305:17 306:1 308:9,11 310:4 327:5,18 329:8 330:7 335:12,14 341:4,5 341:8,9 345:19 350:20 360:13 362:3 363:7 368:7 377:20 382:12 390:9,10,12,17 394:2,4 397:14,17 409:2 411:10 412:1 424:15,20 425:8 449:20 450:14 453:4,8 455:8,9,10 456:1 459:19 465:15,17 466:1,2 467:16 468:1,6,8,11,13 468:14,16,18,20 469:1,4,5,9,11,14 469:22 470:2 471:1,3 473:22,22 474:16,17 484:16 485:6 487:17,20 498:16	<b>thca</b> 292:3,12 487:17 <b>thecannabisindu...</b> 107:19 <b>theme</b> 176:21 371:19 <b>theory</b> 411:14 <b>therabis</b> 14:5 357:8 <b>therapeutic</b> 29:21 30:10 35:16 39:15 51:7 63:20 64:19 64:22 65:9,20 180:5 184:15 264:7 269:4 285:18 380:14 462:16 492:21 <b>therapies</b> 35:19 67:9 130:17,21 132:8 385:17,22 387:5 401:7 <b>therapist</b> 59:5 <b>therapy</b> 130:22 <b>thereof</b> 188:14 370:3 <b>thing</b> 40:16 56:5 115:5 163:15 184:9 215:15 241:10 243:18 244:14 248:4,7 249:22 254:19 266:18 278:14 290:12 310:3 321:17 344:7 346:13,14 349:4 351:11 388:14,15 404:12 414:7 453:19 469:1 <b>things</b> 75:14 87:1 102:21 142:3,5,11 149:12 150:18 151:2 152:10 155:17 177:15 179:10 180:10	181:9,9 210:2 212:10 215:6 217:18 220:6 221:9 222:13 224:21 225:14 226:1 234:3,14 243:11 247:2 251:2 254:8,11 281:4 285:7 286:4 288:16,20 293:8 308:17,18 310:4 336:3,21 354:9 373:19 391:16 396:15 400:3 405:3 406:4 419:21 424:11 425:2 430:12 459:8 470:11 498:18 <b>think</b> 38:8 56:10 62:20 80:3 89:21 90:4,14,15,19 95:3,5 103:10 114:12 115:15 118:12 128:19 129:6,9 142:14 148:10,21 157:20 164:6 176:8 179:3 179:19 185:15 196:12 197:5 198:1 199:8 200:10 210:3 213:2 219:2,5,16 219:18 226:9 233:6 239:3,4 240:7 244:7 248:22 249:7,11 252:6 254:1,10 256:5,14 257:4 267:15 287:15 288:1 290:22 291:6 298:12 312:10 313:22 314:16 321:16	327:14 336:7,13 336:15 337:6,8 338:1 343:5 350:9 350:14,18,21 351:8 352:21 353:4 387:16 391:16 395:7,16 395:19 396:4,8,21 397:20 398:6,7,19 399:3,8,22 400:4 400:7 401:17 404:12 405:9 441:9,12 442:5,9 447:14 452:18 455:11 486:7,9 487:14 <b>thinking</b> 32:19 37:20 55:22 90:11 165:15 199:19 218:4 374:21 390:8 491:17 <b>thinner</b> 340:2 <b>thinning</b> 124:8 <b>third</b> 109:5 116:15 132:20 184:4 192:22 199:11 202:19 222:15 248:5 250:22 305:9 325:22 343:2 346:3 348:16 349:20 351:17 363:22 370:21 377:12 381:3 383:17 394:6 401:8 410:21 414:11 446:12 453:6 479:10 490:6 <b>thorough</b> 134:12 <b>thought</b> 104:13 275:3 387:15,18 413:3 421:16 422:4,15 425:3 447:22 459:5
---	---	--	---

473:6 <b>thoughts</b> 89:16 91:9 277:17 278:14 352:19 375:4 399:19 <b>thousand</b> 125:5 241:8 289:11 395:15 405:19 <b>thousands</b> 54:13 54:13 205:17 207:11 259:9 338:19 347:16 <b>threat</b> 46:10,13 60:20 <b>threatening</b> 92:22 338:10,20 401:6 <b>three</b> 31:12 39:8 47:2 63:3 76:7,17 83:18 85:6 93:9 117:4 167:4,10,12 190:6,21 191:10 203:14 224:21 237:20 242:22 243:4 247:22 249:7 250:3,16 260:12 261:10 277:6,11 279:12 283:19 295:22 299:1 302:14 304:20 315:20 323:18 326:13 335:10 355:15 362:19 375:10 393:20 394:11 395:18 407:9,10 407:17 411:5 441:14 449:8 458:19,20 470:11 470:14 473:4 489:18 <b>threefold</b> 453:1 <b>threshold</b> 85:21 271:8,10,13 306:1	<b>thresholds</b> 412:11 <b>threw</b> 432:22 <b>thrilled</b> 486:2 <b>thrive</b> 45:1 52:18 <b>throckmorton</b> 4:8 21:15,15 <b>throw</b> 232:16 <b>thuy</b> 14:10 366:5 366:6 <b>tied</b> 148:4 <b>tier</b> 49:17 <b>tiffany</b> 135:10,10 <b>tightly</b> 314:15 <b>tilburg</b> 166:9 <b>tim</b> 22:12 <b>time</b> 1:15 24:3,18 24:20,21 25:2,3,9 25:11,13,18 28:1 36:16 38:13 42:18 45:4 53:9 62:7 69:16 74:8 84:20 90:4 98:16 101:14 107:21 108:22 110:7 117:3 122:2 123:6 131:5 136:8 140:6 142:9 150:3 150:15 168:13 171:13 187:20,21 209:19 212:5 215:11,20 221:5 232:9 235:2 242:1 246:12,16 252:21 261:5 275:17 281:21 288:11 290:11 293:8,18 297:1 300:20 301:18 305:21 317:19 320:21 325:12 341:3 355:8,8,22 356:17 361:9 365:15 372:21 381:7 390:4 397:21 398:20 406:22	409:11 413:6 418:5,5 419:7 421:17 424:4,8,15 426:5 436:19 439:17 453:9,12 457:4 458:4 459:1 459:9 460:21 462:4 468:19 485:6 491:12 496:18 499:18 <b>timeframe</b> 117:7 <b>timeline</b> 409:7 <b>timely</b> 307:6 <b>times</b> 43:7 51:7,8 54:11 183:13 190:20 243:1 275:4 277:7,11 278:11 299:20,22 469:21 <b>timing</b> 229:6 <b>timothy</b> 3:14 <b>tincture</b> 308:21 <b>tinctures</b> 96:21 114:12 <b>tip</b> 203:22 <b>tiredness</b> 492:16 <b>tissue</b> 203:9 <b>tissues</b> 169:18 270:6 <b>titan</b> 145:22 <b>title</b> 78:19 <b>titled</b> 26:16 83:7 447:12 <b>titrate</b> 41:10 149:11 <b>titration</b> 285:12 285:14 301:22 389:8 <b>titus</b> 6:14 77:19,20 77:21 79:20 80:15 81:2 <b>tobacco</b> 41:21 44:3 82:16 409:17 412:13,16 416:15	451:12 452:5,7 454:7 470:6,9 <b>today</b> 23:4 24:19 25:16 26:16 36:15 36:17 40:6,16 42:2,12 43:6 64:17 72:14 74:9 79:16 107:9,21 116:3 122:15 123:17 125:11,14 125:16,20 127:19 129:11 147:12 153:11 154:2 157:18 161:12,16 164:2,7 165:4 166:5,15 175:3 176:22 178:17 182:9 192:17 200:15 202:5 210:9,17 228:6 233:17 248:1 259:19 260:1 273:19 274:17 276:5 278:18 279:16 286:13 294:13,13 305:18 308:7 309:1 310:11 311:17 312:11,14 313:4 314:10 315:7 317:7 324:16 326:20 334:15 336:16 337:15 348:22 349:2,10 349:22 350:15 354:7 357:9 358:8 358:18 360:8 361:15,17 362:19 363:13 364:1 365:18 379:14,18 382:8 384:8 400:12 402:20 413:13 416:20 417:4 418:2,16
--	---	--	--

419:14 420:17 424:12 430:3,8,12 430:14,19 440:6 451:12 457:5 459:2 461:17 462:11,22 463:4 467:4 468:12 470:14 472:5,10 476:9,18 477:4 485:2 487:4 489:2 492:6,7 495:22 497:1 498:10 499:19 500:15 501:7 <b>today's</b> 20:9,10 22:18,18 23:15 24:6 27:1,4 72:18 81:9 329:4 381:21 383:8 457:11 459:20 <b>told</b> 37:5 39:3 57:8 130:1 207:1 248:3,9,11,21 249:8 250:21 251:11,16 252:2 374:3,6 401:18 402:10 431:18 449:13 483:17 496:3 <b>tolerability</b> 186:22 299:3 389:16 <b>tolerance</b> 228:16 301:12 302:5 <b>tolerate</b> 184:2 <b>tolerated</b> 51:11 79:13 217:14 320:6 359:21 440:4 477:6 492:13 493:4 <b>tomorrow</b> 42:3 485:2 <b>tools</b> 48:22 133:20 302:17 436:13	439:7 495:12 <b>top</b> 49:16 53:18 203:21 238:1 249:7,9 252:1 283:12 304:13 452:17 <b>topic</b> 26:20 36:18 149:5 246:19 418:2 421:16 <b>topical</b> 34:12 41:14 75:14 154:8 278:11 313:14 447:11 489:5 <b>tops</b> 285:22 <b>tory</b> 4:17 39:22 40:3 <b>total</b> 211:8 238:10 250:12 256:12 315:1 359:16 372:14,15,15 394:4 453:21 490:4,4 <b>totally</b> 405:6 <b>touch</b> 227:9 <b>touched</b> 217:4 219:2 288:15 305:18 <b>tough</b> 187:20 321:18 <b>toughest</b> 43:7 <b>tour</b> 242:18,19 <b>town</b> 374:5,6 <b>toxic</b> 60:10 99:20 180:21 194:3 203:7 339:13 489:9 490:3 491:10 494:17 495:1,4 <b>toxicities</b> 183:18 <b>toxicity</b> 51:13 141:14 270:14 340:13,15 492:14 <b>toxicology</b> 57:12 61:12 185:14	197:9 204:19 269:12 325:19 398:6,10,21 399:12 <b>toxicoses</b> 65:20 <b>toxins</b> 60:1 102:22 380:14 459:19 <b>toys</b> 426:17 <b>trace</b> 84:4 275:9 331:16 341:5 449:20 <b>traceability</b> 102:4 134:9 147:4 363:12 370:17 372:3 408:20 <b>traces</b> 487:17 488:1 <b>track</b> 93:6 218:12 267:3 331:16 <b>tracking</b> 408:15 <b>tract</b> 270:7 491:16 <b>trade</b> 102:2 116:1 153:12 395:13 435:5 476:9,11 481:6 <b>traditional</b> 123:11 164:22 264:10,11 320:16,18 <b>traditionally</b> 441:22 <b>trafficker</b> 292:7 <b>tragedies</b> 58:2 <b>tragic</b> 38:19 <b>trained</b> 485:11 <b>training</b> 87:10 132:22 134:5 334:8 463:22 465:10,12 <b>trains</b> 240:22 <b>trajectory</b> 223:20 <b>transcribed</b> 22:19 23:5 <b>transcriber</b> 503:1	<b>transcribers</b> 25:4 <b>transcript</b> 23:6 503:3,5 <b>transdermal</b> 41:14 <b>transfers</b> 411:17 <b>transformed</b> 96:9 <b>transient</b> 203:2 320:9 <b>transition</b> 212:11 <b>transparency</b> 50:2 89:11 102:3 231:14 236:2 305:10 364:17 365:3 381:20 <b>transparent</b> 89:4 94:12 370:13 426:12 446:22 <b>transparently</b> 477:10 <b>transplant</b> 473:1 <b>transplantation</b> 181:1 <b>transport</b> 424:21 <b>transportation</b> 428:1,17 <b>trauma</b> 234:20 <b>travel</b> 457:4 <b>traveled</b> 457:5 <b>treat</b> 35:13,19 92:21 94:10 105:11 130:8 171:9 248:5 249:3 249:22 265:3 267:16,17 324:2 325:4 339:3,10 375:2 416:1 456:1 468:5 470:22 471:5 474:4,21 <b>treatable</b> 473:18 <b>treated</b> 147:6 168:22 261:11,21 318:10 438:20 475:14 488:5
---	--	--	--

<b>treating</b> 29:21 102:10 143:5 222:9 250:2 263:11 297:21 339:20 389:20	326:19 333:20 334:11,18 361:1 401:21 460:6 461:21 492:9,22 493:3,6	295:15 317:13 333:16,21 377:16 384:22 418:6	155:21 160:13 173:3,7 197:8 202:3 209:1,2 213:13 222:2 239:1 241:11 260:11 268:9 270:3 275:12,14 275:16 277:6 278:11 279:12 294:7 295:21 296:14 301:8 320:7 321:21 329:18 337:1 338:20 341:9 342:20 343:12,16 354:8 382:16 392:3,21 393:2,2 393:3 407:15 409:14 447:19 457:13,15 469:17 470:9 473:2,7 485:1,2,2 490:2 495:3 498:11
<b>treatment</b> 30:5,8 39:16 51:12 93:1 136:2,5,20 139:1 220:17 221:10 223:3,4,10,11 264:17 317:16 374:13 388:1,7 403:19 458:15 474:4	<b>tried</b> 154:14 248:9 458:6 499:3	<b>trying</b> 75:17 142:1 148:1 182:19 186:4 246:20 248:5 249:22 283:8 288:10 290:9,11 294:14 296:15 297:10 327:13 336:17 350:20 374:8 388:19 390:12 422:14 437:5 459:5 498:21	<b>type</b> 29:17 89:11 159:9 160:22 171:5 174:14 218:5,9 219:6 280:21 289:22 323:15 359:1 389:8 402:6,15 453:18 454:17 455:6 465:3,20 466:2
<b>treatments</b> 130:20 458:9 472:11 475:22	<b>trigger</b> 277:5 304:9 306:7	<b>ts</b> 143:9 144:12	<b>tsa</b> 82:10
<b>treats</b> 29:13 170:9 171:8	<b>trimmed</b> 59:13	<b>tsc</b> 142:21,22 143:6,8 144:5,13	<b>tss</b> 494:14
<b>trembling</b> 209:7	<b>tripartite</b> 407:11	<b>tst</b> 151:17	<b>tuberos</b> 8:20 142:19,21
<b>tremendous</b> 80:5 205:12 245:9 267:17 339:2 343:8	<b>truckloads</b> 292:5	<b>tubers</b> 8:20 142:19,21	<b>tumor</b> 398:15
<b>treatments</b> 130:20 458:9 472:11 475:22	<b>true</b> 9:10 133:10 150:14 151:18 152:2,3,13 160:19 173:22 210:16 241:10 251:21 265:7 268:3 296:19 313:21 358:10,10,11 383:13 405:22 406:9 502:6 503:5	<b>turn</b> 46:20 97:9 208:10	<b>tumors</b> 260:11
<b>treats</b> 29:13 170:9 171:8	<b>truer</b> 33:19	<b>turned</b> 377:12 459:4	<b>turn</b> 46:20 97:9 208:10
<b>trembling</b> 209:7	<b>trueterpenes.com</b> 152:17	<b>turnouts</b> 482:14	<b>turns</b> 25:13
<b>tremendous</b> 80:5 205:12 245:9 267:17 339:2 343:8	<b>truly</b> 43:19 59:16 72:20 74:8 361:14 380:20	<b>tv</b> 498:20	<b>turns</b> 25:13
<b>tremor</b> 385:15 387:5	<b>trump</b> 38:20	<b>tweeting</b> 36:13	<b>tv</b> 498:20
<b>trend</b> 300:5	<b>trust</b> 73:9,13 88:4 89:1 116:21 236:7 296:22 304:10 365:3,13 436:18 446:8 486:14	<b>twenty</b> 250:9 335:11 485:1,2,2	<b>twice</b> 277:12 458:11
<b>trial</b> 51:12 136:19 143:3,22 179:8 201:6 275:7,10,11 278:5 283:1 286:22 293:12 299:2,7 300:17 301:20 318:8,9 319:1 320:10 359:15 360:20,21	<b>trusted</b> 97:7 130:19 426:10	<b>two</b> 37:2 38:21 51:3 57:16 60:8 62:21 63:3 85:6 91:18 93:7 99:2 105:7 112:18 115:6 120:22 140:18 145:22	<b>types</b> 142:3 156:14 164:21 165:16 218:21 237:7 258:6 289:8 300:6 309:7 322:7 350:22 415:3,10 416:8,12,16 417:16 426:20 453:2 458:20
<b>trials</b> 51:18 93:22 94:2 99:19 123:7 126:2 128:18 136:13 222:5 226:1 268:17 270:15 284:8,19 286:17 299:1,2,13 316:6 318:5,8	<b>trusting</b> 60:17		<b>typewriting</b> 502:5
	<b>trustworthy</b> 88:12		
	<b>truth</b> 126:1 175:19 236:2 479:2		
	<b>truthful</b> 53:21		
	<b>try</b> 36:7 132:12 150:10 210:2		

<p><b>typical</b> 416:7  <b>typically</b> 51:21  184:14 215:7  223:14 272:15  441:14  <b>typo</b> 448:22</p> <hr/> <p style="text-align: center;"><b>u</b></p> <hr/> <p><b>u.s.</b> 1:16 2:4,9,13  2:17,21 3:5,9,13  3:17,21 4:5,11 5:5  46:11,15 47:17,19  49:11 52:5,11  67:2 78:7 80:16  87:21 94:1 116:15  116:16 126:2,5  133:4 157:11  175:8 188:16  244:20 283:18  289:10 311:8,14  331:15 333:1  362:15 383:21  384:18 386:6  395:20 408:3  423:8 428:9 432:9  432:9,14 484:22  485:18  <b>uk</b> 293:11 347:21  487:5  <b>ulcerations</b> 495:8  495:14  <b>ultimately</b> 64:4  309:11  <b>unable</b> 27:4 144:1  <b>unacceptable</b>  133:13  <b>unanswered</b> 34:9  414:18  <b>unapproved</b> 35:9  35:15 64:17 76:22  140:10 341:14  <b>unaware</b> 404:14  404:16  <b>unbelievable</b>  430:16 460:15</p>	<p><b>unborn</b> 242:10  <b>unc</b> 26:8,9  <b>uncertainty</b> 43:21  <b>uncharacteristic</b>  193:18  <b>uncharted</b> 396:10  <b>unclear</b> 181:12  <b>uncommon</b> 189:2  <b>uncontrolled</b>  400:17 401:11  402:4  <b>uncovered</b> 246:13  <b>undergo</b> 96:16  <b>undergone</b> 315:4  <b>underground</b>  346:18  <b>underlining</b> 385:6  <b>underlying</b> 139:13  <b>understand</b> 56:21  57:21 97:16  108:10 130:4  131:18 154:2  162:10,15 165:1,2  165:5,8 178:5  204:2,6 225:5,16  246:21 276:20  296:13 309:16  333:8 350:1,4  386:16 387:10  388:19 402:3  405:1 408:7,8  432:10 450:2  457:7  <b>understandably</b>  154:20  <b>understanding</b>  50:17 72:20 81:16  90:17 162:18  203:20 272:6  327:7 354:2 387:1  389:8 456:5  <b>understands</b> 73:8  111:15 117:9</p>	<p><b>understood</b> 56:20  80:13 233:10  304:1 411:2  <b>undertaken</b> 493:2  <b>undertaking</b>  272:4 333:20  493:6,9 494:11  <b>underway</b> 93:8  <b>underwent</b> 458:18  <b>undesired</b> 306:12  306:13  <b>undue</b> 84:21  <b>unduly</b> 431:13  <b>uneducated</b>  353:22  <b>unethical</b> 59:11  <b>unexpected</b>  143:15  <b>unexplained</b>  401:13  <b>unfettered</b> 54:22  <b>unfortunately</b>  61:20 101:12  222:1 229:9  255:14 281:20  312:16 401:7  <b>uniform</b> 88:2,17  163:9 166:3 265:9  266:12,21 267:20  425:9  <b>uniformity</b> 156:6  159:8 264:15  265:10 266:10  <b>unify</b> 414:5,10  <b>uninformed</b>  353:22  <b>unintended</b>  176:22 449:21  <b>unique</b> 34:8 87:20  118:2 120:4  157:21 192:5  219:19 222:1  272:2 324:11,11  339:11 367:1</p>	<p>401:18 408:9  <b>uniquely</b> 90:15  <b>unit</b> 92:4 279:8  <b>united</b> 1:1 28:16  42:20 43:19 45:11  52:7 99:3 138:18  156:8,11 157:7  175:17 207:13  253:15 294:8  297:16 333:21  334:13 357:20  358:10,12 384:15  384:17 385:7  386:10 409:12  426:9 445:4  467:12 482:2  484:5 486:15  <b>units</b> 57:19  <b>universal</b> 110:2  266:22 479:20  <b>universally</b> 304:1  <b>universities</b> 47:8  <b>university</b> 4:18  10:8,10,13,15,19  10:21 11:3,5 40:1  40:5 50:8 172:3  176:21 180:3,20  182:3 188:4  192:13,14,19  195:14 200:16  204:18 210:5  213:5 216:12  217:2 264:22  266:1 274:18,19  274:20 358:4  423:11  <b>unknown</b> 139:14  139:15 229:13  410:12 419:6  451:21 459:18  <b>unknowns</b> 177:16  340:9 382:9  <b>unlawful</b> 113:9</p>
--	---	---	---



<b>unnecessary</b> 94:4 332:17	139:22 144:7 155:11 163:21	180:4 182:18 185:6 201:16,22	<b>useful</b> 47:12 80:22 86:19 115:6
<b>unofficial</b> 353:17	244:17 286:13,14	205:1 214:1,13	118:15 153:2
<b>unparalleled</b> 432:5	354:11 468:7 471:2,7	221:18 223:2 225:3 231:2 245:8	310:1,9 387:2,16 434:15 456:16
<b>unprecedented</b> 119:11,21 431:10	<b>urgency</b> 385:6 484:20	248:2,19,22 249:3 249:4,6,10 250:19	<b>user</b> 206:9 451:14
<b>unproven</b> 459:10	<b>urgent</b> 48:15	254:21 255:22	<b>users</b> 41:4 116:15
<b>unrealized</b> 410:12	<b>urgently</b> 213:20 214:14	257:18 260:13 261:14 265:2	127:13 173:20 215:19 223:2
<b>unreasonable</b> 77:17	<b>urges</b> 112:4 440:17	267:1 276:14 280:13,14,16	375:8 377:10,10 427:4 453:11 454:7 456:6 491:13
<b>unregulated</b> 138:22 209:10 316:15 382:5,12 402:19 459:11,21 468:2	<b>urging</b> 284:10	281:4 284:19,21 285:4,10 294:22	<b>uses</b> 31:14 34:19 73:16 82:7 134:2 258:15 262:13 270:13 325:3,9 352:2,19 375:11 402:18 407:16 408:5 431:7 436:9 449:15 487:18
<b>unsafe</b> 69:8 349:16 356:16 431:14 468:6 471:1	<b>urinary</b> 263:1	295:14 305:16 315:16 323:20	<b>usp</b> 98:14,15,20 100:6,17 315:14 365:14 450:17
<b>unscheduled</b> 210:12	<b>urine</b> 213:13	324:20,22 326:18 330:17 345:14,17	402:18 407:16 408:5 431:7 436:9 449:15 487:18
<b>unsubstantiated</b> 35:16 269:1	<b>usable</b> 266:22	346:1 351:19,21 352:15 354:5	<b>usp's</b> 99:4
<b>unsuspecting</b> 238:20	<b>usage</b> 157:3,10 172:9 368:8 433:20	356:4 371:4 373:17 382:5	<b>usually</b> 56:2 113:22 206:12 277:11 455:8
<b>untargeted</b> 394:14	<b>usda</b> 155:16 322:11,17 342:20	390:2,8 392:9,20 397:6 398:18	<b>utah</b> 290:19 479:5
<b>untested</b> 136:9,10 459:10	391:20 408:16 411:7 412:10	399:5,9 400:5,6 414:12 415:7	<b>utility</b> 167:10 387:10
<b>unwillingness</b> 399:14	<b>use</b> 28:3,5,16 33:10 34:6 35:18 39:3,9 48:10 49:22 54:3 56:2 57:18 61:18 64:3 64:3,5,8,9,20 65:1 65:12 66:1 67:19 68:2,4 73:3,10,19 82:4 85:20 86:3,5 97:14 100:20 102:8,10 105:1,3 105:11 108:19 112:3,19 113:16 116:3,4,6 117:18 118:9,14 128:3 136:9,11,14,20 143:7 146:5 154:3 154:10,15 163:2 168:3,19 169:14 170:3,15,22 172:19 174:12	416:6 424:16 430:3,13,14 433:16,20 435:10 435:18 436:7,13 440:4 443:5 444:18 446:1 447:2 448:15 449:21 450:12,19 452:5,7,8,11 453:6,16 454:1,7 454:7,9,14 455:8 464:18,21 465:3,5 465:7,13 467:15 470:12,18 471:22 479:10 483:1,11 483:14,15,15 487:11 489:6 490:11 492:7	<b>utilize</b> 45:15 47:1 388:6
<b>updated</b> 97:14 364:18 427:5			<b>utilized</b> 369:8 427:7 445:12
<b>upheld</b> 257:5 355:5			<b>utilizing</b> 71:9 183:5 291:7 292:16
<b>upload</b> 91:14 313:8			<b>utmost</b> 44:16
<b>upregulation</b> 202:16			<b>v</b>
<b>ups</b> 77:3			<b>v</b> 188:10
<b>upwards</b> 108:21			<b>vacuum</b> 37:22 222:4 477:18
<b>ur</b> 383:22			
<b>urge</b> 94:11 116:4 118:9 122:19			

<p><b>vaginal</b> 488:12,16 488:19,22 489:6,8 491:16 493:1,13 493:22 494:3,5,8 494:9,12,20,20 <b>vaginally</b> 488:18 <b>vague</b> 130:11 <b>valenti</b> 16:16 471:12,13,17 475:20 <b>valentina</b> 17:6 487:2,4 <b>valid</b> 134:8 <b>validate</b> 133:19 236:22 305:17 306:2 <b>validated</b> 50:15 99:12 133:16 237:14 273:13 302:18,20 303:17 305:15 311:21 312:5 316:6 319:11 348:19 351:12,18,20 352:4 362:22 392:10 463:2 464:4 <b>validation</b> 305:9 354:21 394:15 <b>valproate</b> 143:14 360:3,4 406:3 <b>valuable</b> 25:3 45:20 365:15 <b>value</b> 30:10 45:17 50:11 98:17 182:11 187:2 238:5 328:6 <b>values</b> 190:15 191:6,6 239:2 355:3 <b>vandrey</b> 11:2 209:22 210:1 211:4 214:22 215:11,18 216:1,8</p>	<p>246:15 <b>vanguard</b> 15:7 406:18 <b>vape</b> 124:9 205:1 249:11 454:5 <b>vapes</b> 416:15 <b>vaping</b> 191:11,20 206:3,4,5,20 249:12 454:22 <b>vapor</b> 299:5,14,15 299:22 <b>vaporization</b> 212:2 <b>vaporized</b> 212:21 282:19 300:12 <b>vaporizer</b> 41:2 <b>variability</b> 70:2 142:14 144:3 177:10 191:15 315:22 350:22 404:14 <b>variable</b> 138:14 142:6 237:21 <b>variables</b> 123:19 177:13 334:2 <b>variance</b> 292:11 <b>variances</b> 305:7 371:13 <b>variation</b> 455:1 456:6 <b>variations</b> 260:7 285:16 <b>varied</b> 234:19 356:13 465:16 <b>varies</b> 239:2 309:17 452:12 465:4 <b>varieties</b> 228:17 229:2 283:2 <b>variety</b> 127:1 177:5,22 180:22 196:22 227:21 230:8 287:8 362:18 484:10</p>	<p><b>various</b> 42:2 64:12 71:1 139:1 189:15 200:22 202:5,13 203:11 241:16 259:14 306:17 322:7 371:7,13 389:16 404:8 418:8 442:20 464:11,14 478:12 <b>vary</b> 29:17 177:11 177:13 272:10 354:6 453:5 <b>varying</b> 76:21 <b>vast</b> 42:8 76:20 434:11 437:10 <b>vastly</b> 468:2 <b>vaught</b> 5:6 50:6,7 50:7 53:2 <b>vcu</b> 231:21 <b>vega</b> 12:14,15 274:15,16,17 279:22 280:3,6,8 280:10,17 281:5 <b>vegetable</b> 205:15 <b>vendors</b> 189:16 411:4 <b>venues</b> 156:14 <b>verbal</b> 83:15 <b>verbally</b> 282:11 <b>verified</b> 323:4 326:1 <b>verify</b> 144:2 479:11 <b>version</b> 30:8 342:3 408:2 <b>versions</b> 272:14 <b>versus</b> 148:14 185:21 189:4 191:16 233:8,14 292:2,12 407:15 453:4 455:9,9 <b>vertical</b> 319:21 <b>vertically</b> 333:3,5 366:11 370:12</p>	<p><b>vested</b> 365:19 <b>vet</b> 96:5 <b>veteran</b> 67:3 288:5 433:21 <b>veterans</b> 260:14 283:2 452:22 482:20 485:1 <b>veterinarian</b> 193:22 <b>veterinarians</b> 64:3 64:6 <b>veterinary</b> 2:20 3:8,16 6:3 22:14 63:17,19 65:1,6 65:12 66:12 167:11 197:10 199:18 358:4 <b>vets</b> 288:10 <b>viability</b> 65:14 163:10 <b>viable</b> 83:20 85:10 <b>vibrant</b> 82:18 <b>vice</b> 87:16 92:18 98:12 321:15 329:1 353:10 <b>vicente</b> 15:11 476:8 <b>vicodin</b> 251:2 <b>victims</b> 5:15 11:19 56:15,18 240:20 242:5 375:18 <b>videotape</b> 23:2 <b>view</b> 74:12 78:9 137:5 183:2 304:5 304:10,22 430:9 491:18 <b>viewed</b> 61:22 <b>viewpoint</b> 79:1 <b>viewpoints</b> 321:20 <b>views</b> 40:6 61:21 66:1 476:19 <b>vigorous</b> 96:16 <b>vigorously</b> 132:13</p>
---	---	--	---

<p><b>violate</b> 35:7 121:9 410:22 411:1</p> <p><b>violation</b> 35:16 85:2 241:19 342:19</p> <p><b>violence</b> 243:2,2</p> <p><b>violent</b> 373:20</p> <p><b>viral</b> 102:19</p> <p><b>virginia</b> 4:22 9:16 10:21 42:17,20 43:8 53:15 56:6 204:18</p> <p><b>virtual</b> 472:2</p> <p><b>virtually</b> 478:8 479:20</p> <p><b>viscosity</b> 182:17</p> <p><b>visibility</b> 84:10</p> <p><b>vision</b> 160:14 457:16 461:16 472:7 474:8,13 475:17</p> <p><b>visit</b> 152:16 169:11</p> <p><b>visiting</b> 5:19 59:2</p> <p><b>visual</b> 472:2</p> <p><b>vital</b> 87:22</p> <p><b>vitamin</b> 79:11 126:9,18,18,19 128:11 415:14</p> <p><b>vitamins</b> 486:6</p> <p><b>vitro</b> 492:21 494:8</p> <p><b>vocal</b> 38:14</p> <p><b>voice</b> 426:13 483:2 483:7</p> <p><b>voices</b> 486:20</p> <p><b>voltage</b> 488:5</p> <p><b>volume</b> 268:22,22</p> <p><b>voluntarily</b> 121:20 370:8</p> <p><b>voluntary</b> 166:17 167:8 272:18 400:21</p> <p><b>volunteer</b> 492:9 493:3</p>	<p><b>volunteered</b> 374:11</p> <p><b>volunteers</b> 215:17 489:3 492:14</p> <p><b>vomiting</b> 193:19</p> <p><b>vote</b> 482:13,14</p> <p><b>voters</b> 482:15,17</p> <p><b>vouch</b> 62:16</p> <p><b>vu</b> 14:10 366:5,6,6</p> <p><b>vulnerable</b> 116:18 223:20 340:11 360:22 468:6 471:1 477:21 479:19</p> <p><b>vyripharm</b> 12:9 264:2,6 265:7 266:18 267:8,22</p> <hr/> <p style="text-align: center;"><b>w</b></p> <hr/> <p><b>wait</b> 295:17 386:20 486:3</p> <p><b>waiting</b> 169:6 176:8</p> <p><b>waiver</b> 60:11</p> <p><b>wake</b> 60:13</p> <p><b>walgreen's</b> 175:3</p> <p><b>walk</b> 147:18 226:21 472:21</p> <p><b>walker</b> 11:4 192:19 216:10,11</p> <p><b>walking</b> 96:19</p> <p><b>walks</b> 207:22</p> <p><b>walls</b> 494:20</p> <p><b>want</b> 42:21 55:12 57:21 67:21 90:18 90:22 132:10 155:1,2 161:15 163:15 164:1,7 166:5 170:13 176:7,11 177:15 178:2 180:10 207:17 210:1,3 212:10 213:12,18 226:2 231:12 234:1 245:1</p>	<p>255:22 278:1 279:7 281:13 288:15 289:20 290:12,13,14 292:4 294:12 295:18 297:11 298:5 303:3 304:3 304:12,12 306:16 323:19 324:1 326:4 337:1 346:7 346:7,21 347:6 349:5 351:11 352:8 359:6 384:7 388:14 391:6 405:17 422:16 423:22 424:3 431:15 448:16 450:12,16 483:19 496:21 498:18 501:4</p> <p><b>wanted</b> 165:1,5 184:15 193:8 197:6 206:22 236:22 257:10 284:7 376:20 407:4 451:14 453:1,4,6 455:5 455:21 475:7 496:11</p> <p><b>wanting</b> 187:7 207:17</p> <p><b>wants</b> 241:3 242:18 298:4 374:19</p> <p><b>war</b> 67:3 105:21 173:13 377:17,18 433:22 434:2 485:1</p> <p><b>warehouses</b> 46:1</p> <p><b>warfarin</b> 179:20 179:20,22,22 180:5 340:1</p> <p><b>warner</b> 13:6</p>	<p><b>warning</b> 35:8 57:2 57:10 58:10 139:7 201:8 272:18 291:14 377:4 439:7 479:19</p> <p><b>warnings</b> 174:22 175:2 409:19 415:7,10</p> <p><b>warns</b> 174:12</p> <p><b>warrant</b> 192:5</p> <p><b>wars</b> 434:3</p> <p><b>washers</b> 247:3</p> <p><b>washing</b> 239:12 247:3</p> <p><b>washington</b> 115:22 253:6 261:19 481:21</p> <p><b>waste</b> 45:22 232:13,15,22 234:1 428:5</p> <p><b>watched</b> 460:3</p> <p><b>watching</b> 125:14 130:2</p> <p><b>water</b> 319:5 372:13 428:4,9 467:20 468:2 488:5</p> <p><b>waters</b> 383:10</p> <p><b>waving</b> 23:18 38:10 375:16</p> <p><b>waxes</b> 234:12</p> <p><b>way</b> 25:1 36:8 37:13 62:14 77:7 128:20 129:3 141:13 152:14 167:5 183:16 212:19 216:6 219:7 231:19 243:13 244:9 249:9,10 254:4 255:10 256:11 257:17 285:3,14 285:21 291:20 295:12 313:3</p>
--	--	--	---

339:4,8,16 348:2 349:6 356:6 375:8 388:22 389:9 396:7,8 411:1 415:5 417:10,11 417:11 433:1 442:12 448:7,11 482:5 487:22 496:8,10 498:5 499:16 <b>ways</b> 35:7 39:18 39:19 71:1 90:11 143:21 167:5 249:13 325:13 386:3 416:17 474:18 495:3 <b>we've</b> 33:20 47:2 49:22 74:17 87:9 87:10 100:8 129:11 158:16 162:9,11 175:9 177:9,17 211:15 211:22 213:19 214:22 216:15 238:9 241:1 242:7 243:11 253:12,13 274:2 278:18 284:11 288:11 289:22 293:2 311:13 314:14 326:19 338:16 339:14,16 342:14 344:12 348:3,4,10 348:16 349:19 354:7 357:16 358:8 379:17 391:7 395:16 401:18 406:3 422:21 424:11 432:12 448:14 481:11 490:21 492:2,12,19 494:7 <b>weaker</b> 340:3	<b>wean</b> 460:12 <b>weapon</b> 377:20 <b>weaponized</b> 376:22 <b>webcast</b> 22:19 23:8 501:7 <b>weber</b> 457:10 <b>website</b> 23:7,10 107:16,19 109:20 110:12 152:16 169:11 206:6 207:6 238:2 343:19 469:20 <b>websites</b> 206:7 236:11 <b>weed</b> 374:9 <b>weeds</b> 141:19 <b>week</b> 23:11 96:20 159:13 173:18 277:11 359:11 <b>weeks</b> 48:6 209:1 223:18 448:18 449:8 457:21 467:20 <b>weerts</b> 220:12,13 226:11,14,16,19 <b>weight</b> 28:22 189:6 224:6 240:8 340:17 368:7 394:5 465:19 468:17 469:7 485:15 <b>welcome</b> 18:3 49:21 155:14 166:10 169:11 347:6 430:4 <b>welcoming</b> 26:11 <b>weldon</b> 8:8 129:18 129:20,21 <b>wellbeing</b> 87:22 259:17 318:22 320:11 321:3,9,10 321:11 401:2	<b>wellness</b> 51:21 72:15 73:1 78:16 80:1 209:6 268:14 431:7 433:20 <b>went</b> 92:9 172:21 180:7 208:4 226:4 237:11 274:19 281:20 282:1 295:19 373:1 448:7 458:4 <b>werline</b> 16:8 456:22 457:2,3 <b>wertz</b> 11:7 <b>west</b> 65:19 130:14 159:9 290:8 383:12 <b>wheat</b> 147:16 <b>wheel</b> 414:16 <b>where'd</b> 247:21 <b>wherewithal</b> 417:3 <b>white</b> 1:17 231:8 366:12 <b>who've</b> 254:13 <b>wholeheartedly</b> 44:14 <b>wholesale</b> 53:12 <b>wholly</b> 171:8 <b>whoopi</b> 175:4 <b>wi</b> 496:15 498:19 <b>wide</b> 144:4 146:14 165:3 270:11,19 271:3 305:6 337:19 340:22 437:14 439:5 484:10 <b>widely</b> 119:15 221:20 239:2 354:6 405:12 417:17 <b>wider</b> 260:20 <b>widespread</b> 33:10 79:14 126:12 157:10 172:9	242:3 <b>wife</b> 243:17 447:16 457:19 458:16 459:4 <b>wild</b> 65:19 130:14 159:9 290:8 383:12 <b>wildfire</b> 122:14 <b>wildflower</b> 6:11 72:14,22 73:8,22 <b>william</b> 6:20 83:8 166:9,9 <b>william's</b> 166:9 <b>williams</b> 8:11 132:14,15,15 <b>willing</b> 52:22 61:2 101:12 482:9 <b>willingness</b> 48:21 <b>wilmington</b> 311:6 <b>wilson</b> 135:10 <b>wind</b> 66:19 <b>window</b> 184:16 <b>winning</b> 377:17 <b>wisconsin</b> 10:8 176:21 <b>wisdom</b> 259:18 <b>wise</b> 307:6 <b>wish</b> 174:13 378:3 411:15 <b>withdrawal</b> 170:11 223:8,13 223:17,22 <b>witness</b> 377:19 <b>witnessed</b> 59:11 276:4 <b>wmi</b> 6:11 72:11 <b>woefully</b> 60:4 <b>wollongong</b> 213:5 <b>woman</b> 149:7 209:3 <b>women</b> 7:9 53:13 53:14 95:16 174:4 223:19 224:15,17 225:5 272:3
--	---	--	--

340:12 376:2 <b>women's</b> 95:17 493:16 <b>wonder</b> 460:3 <b>wondered</b> 185:21 <b>wonderful</b> 282:14 <b>wondering</b> 68:18 89:15 103:16 113:17 157:22 248:14 399:18 <b>wondrous</b> 54:21 243:12 <b>wonky</b> 212:10 <b>woods</b> 92:9 <b>words</b> 190:15 239:19 326:18 441:8 <b>work</b> 40:8 44:17 48:21 58:4 59:22 87:11 97:19 100:11,17 127:9 130:20 162:9 179:12 187:7 210:4 218:20 219:20 227:21 228:2 236:16 244:13 247:22 264:4 265:6 276:17 286:14 288:12 289:2,14 290:2,6 292:12 294:20 296:17 322:9 352:9 358:11 360:2,10 394:9 426:2 429:4 432:3,11 433:8 457:5 467:12 470:5,5,7 498:2,6 <b>worked</b> 48:6 57:15 59:7 61:6 110:2 195:12 235:18 253:12 275:3 419:18,19 466:11 472:22	<b>worker</b> 60:6 <b>workers</b> 60:7 <b>working</b> 21:6,9,14 21:18 35:2 103:20 127:7 145:7 155:16 156:5 173:21 203:13 204:4 211:20 288:17 290:1 293:13 296:14 315:14 325:12 363:8,14 378:2 394:6 409:5 426:19 428:1,9 430:2 463:20 464:13 466:13 488:20 489:13 493:14 <b>workload</b> 205:12 412:7 <b>works</b> 127:5 145:4 260:19,19 276:18 472:1 488:18 499:7 <b>world</b> 26:7 39:20 46:11 49:2 54:6 82:19 84:12 104:21 171:9 183:4 187:3 218:5 253:5 286:8 293:11 296:1 311:9 314:2 377:12,14 386:7 403:5 405:10 426:9 430:22 442:20 459:20 477:4 485:1 497:22 499:13,14 499:15 <b>world's</b> 46:10 87:18 <b>worried</b> 142:10 <b>worries</b> 458:12 495:20	<b>worry</b> 232:3,4,5 278:6 280:18 292:13 <b>worse</b> 125:19 183:19 223:22 388:8 406:11 <b>worsen</b> 459:20 <b>worsening</b> 404:10 <b>worst</b> 473:1 <b>worth</b> 436:10 <b>worthy</b> 435:22 <b>wounds</b> 278:12 <b>wow</b> 276:8,9,20 276:21 <b>wrap</b> 412:18 446:19,20 455:19 456:4 486:11 491:4 492:11 500:17 <b>wright</b> 6:16 81:5,7 81:8 <b>write</b> 277:22 <b>writing</b> 83:17 163:3 277:21 396:19 <b>written</b> 68:9 79:17 80:10 107:16,18 111:13 118:19,20 120:6 123:15 144:11,14 158:7 158:21 164:5,9 169:9 242:9 274:11 325:11 326:9 357:10 398:2 479:22 493:17 500:21 <b>wrong</b> 59:17 60:20 130:9 243:20 252:6 295:18 433:8 448:7 477:17 498:18 <b>wrote</b> 61:20 127:2 127:4 422:11	<b>wsua</b> 129:19 <b>y</b> <b>yael</b> 12:2 252:19 <b>yanked</b> 406:10 <b>yeah</b> 55:10 74:20 75:16 86:21 104:6 125:4 150:4 165:10 187:19 198:21 226:15 310:12,16 326:21 326:21 352:13 378:12 413:8 434:21 446:21 497:9,13 <b>year</b> 28:17 43:13 52:5 59:8 77:11 94:7 105:5 109:1 141:1 161:20 162:13,14 209:3 220:19 223:4 226:20 227:8 228:22 237:3 241:1,2,11 246:9 247:4 260:11 288:5 289:12 314:22 317:8 335:21 355:15 374:15 403:11 447:16 459:4 472:18,19 473:7 491:14 500:3 <b>years</b> 47:3 50:13 60:8 62:5 63:6 67:5 68:7 84:16 85:6 93:9 117:4 119:9 122:12 126:16 141:19 173:11 174:6 179:13 182:5 188:9 201:12 206:7 216:15,19 235:18 236:17 244:6,12 245:22 259:15,18 268:17
--	---	--	---

275:1 283:4,13	<b>z</b>
288:7 291:1 293:3	<b>zealand</b> 347:21
296:14 307:5	<b>zero</b> 239:7 318:12
311:13 339:15	<b>zoe</b> 8:4 122:8,9
342:19 367:16	<b>zone</b> 305:1
392:3 393:3	<b>zynerba</b> 13:13
394:17 395:18	329:1,3
406:22 413:19	
414:4 418:21	
425:22 430:1	
431:1 435:16	
441:14 447:19	
472:6 473:2,4	
476:19 477:8	
481:2 483:17	
485:22 486:3	
489:18 500:10	
<b>yeast</b> 372:14	
396:15 490:5	
<b>yellow</b> 25:9 454:8	
<b>yesterday</b> 98:6	
107:15 358:3	
430:12	
<b>york</b> 221:10	
242:22 333:13,13	
420:1 421:7	
478:20	
<b>youn</b> 15:12 451:5	
451:6	
<b>young</b> 174:13	
206:20 207:9	
260:10 401:10	
<b>younger</b> 373:20	
373:21 452:19	
484:12	
<b>youth</b> 16:15 55:3	
55:6,7 377:11	
467:5,9,18 468:13	
470:8,12,18 471:8	
483:14	
<b>yucky</b> 448:11	