UNITED STATES FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds

Part 15 Public Hearing

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White Oak Campus, Building 31
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Silver Spring, MD 20993

JOB No.: 3406507

REPORTER: KeVon Congo

A P P E A R A N C E S

Amy Abernathy, MD, PhD
Principal Deputy Commissioner
U.S. Food and Drug Administration

Nick Alexander
Director, Intergovernmental Affairs
Office of Policy, Legislation and International Affairs
U.S. Food and Drug Administration

Dayle Lewis Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration

Jarilyn Dupont
Director, Regulatory Policy
Office of Policy
U.S. Food and Drug Administration

Randall Gnatt
Regulatory Counsel
Center for Veterinary Medicine
U.S. Food and Drug Administration

A P P E A R A N C E S

Rebecca Goldberg
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration

Sharon Mayl
Senior Advisor for Policy
Office of Foods and Veterinary Medicine
U.S. Food and Drug Administration

Erik Mettler
Assistant Commissioner for Partnerships and Policy
Office of Regulatory Policy
U.S. Food and Drug Administration

Timothy Schell, PhD
Director, Office of Surveillance and Compliance
Center for Veterinary Medicine
U.S. Food and Drug Administration

Lowell Schiller
Principal Associate Commissioner for Policy
Office of Policy
U.S. Food and Drug Administration

A P P E A R A N C E S

Sherene Sepehri
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration

Ned Sharpless, MD
Acting Commissioner of Food and Drugs

Douglas Throckmorton, MD
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

ORAL COMMENTS WITHOUT SLIDE DECK

ACADEMIA

Peter Pitts
Center for Medicine in the Public Interest

Tory Spindle, PhD
Johns Hopkins University School of Medicine

AGRICULTURE (NON-GOVERNMENT)

Jason Amatucci
Virginia Industrial Hemp Coalition

A P P E A R A N C E S

Hunter Buffington
Hemp Feed Coalition

Jonathan Miller
U.S. Hemp Roundtable

Jonathan Vaught, PhD
Front Range Biosciences

CONSUMERS

Susan Cromer
LilyHemp

Pamela McColl
Smart Approaches to Marijuana Canada

Sally Schindel
Marijuana Victims Alliance

HEALTH PROFESSIONALS

Anne Hassel
Holyoke Visiting Nurse Association

Russell Kamer, MD
Partners in Safety

A P P E A R A N C E S

Ashley Morgan, DVM
American Veterinary Medical Association

MANUFACTURERS
Philip Blair, MD
Elixinol LLC
Charles Jolly
Baker Donelson
James Shults
WMI Consulting - Wildflower Brands
David Spangler
Consumer Healthcare Products Association
Stuart Titus, PhD
Medical Marijuana
Julian Wright
Science & Recreation

OTHER
William Bookout
National Animal Supplement Council

A P P E A R A N C E S

Betsy Booren, PhD
Grocery Manufacturers Association
Aubrey Adams* (for James Childs, MD)
Childs Dermatology Clinic
Robert Discordia, PhD
Corbus Pharmaceuticals
Kristina Garcia
Women Grow
Gabriel Giancaspro, PhD
US Pharmacopeia
Karen Howard
Organic & Natural Health Association
Rod Kight
Kight Law Office PC
Andrew Kline
National Cannabis Industry Association
Michael McGuffin
American Herbal Products Association
Megan Olsen
Council for Responsible Nutrition

A P P E A R A N C E S

David Rodman
The Rodman Law Group LLC
Zoe Sigman
Project CBD
Andy Snyder
Manward Press
Monica Weldon
Bridge the Gap - SYNGAP Education and Research Foundation
Anna Williams
A2LA

PATIENTS
Keith Fargo, PhD
Alzheimer's Association
Keith Chapman, MD
American Epilepsy Society
Kari Rosbeck
Tuberous Sclerosis Alliance

A P P E A R A N C E S

PUBLIC SAFETY
Patrick Bird
PMB BioTek Consulting

RETAILERS/DISTRIBUTORS
Crystal Guess
NuLeaf Naturals, LLC
David Heldreth
True Terpenes
Peter Matz
Food Marketing Institute

STATE/GOVERNMENT OFFICIALS/ENTITIES
Pam Miles
Virginia Department of Agriculture
Brenda Morris
Florida Department of Agriculture and Consumer Services
Joseph Reardon
North Carolina Department of Agriculture & Consumer Services

APPEARANCES

Erin Bubb
Pennsylvania Department of Agriculture

FORMAL PRESENTATIONS WITH SLIDE DECK
ACADEMIA
Barry Gidal, PharmD
University of Wisconsin-Madison
Igor Grant, MD
Center for Medicinal Cannabis Research, University of California, San Diego
Bill Gurley, PhD
University of Arkansas for Medical Sciences
Rick Kingston, PharmD
University of Minnesota; SafetyCall International PLLC
Igor Koturbash, MD, PhD
Center for Dietary Supplements Research, University of Arkansas
Michelle Peace, PhD
Virginia Commonwealth University

APPEARANCES

Ryan Vandrey, PhD
Johns Hopkins University
Larry Walker, PhD
University of Mississippi, National Center for Natural Products Research
Elise Wertz, PhD
Johns Hopkins Medicine; The College on Problems of Drug Dependence

AGRICULTURE (NON-GOVERNMENT)
Cameron Cane
Deutsche Process

CONSUMERS
Jaclyn Bowen
International Association for Cannabis Testing
David Evans
Cannabis Industry Victims Educating Litigators
Lisa Gill
Consumer Reports

APPEARANCES

Yael Ossowski
Consumer Choice Center

HEALTH PROFESSIONALS
Ann Allworth, PhD
Cannabis Education Solutions
Jerry Bryant
Vyripharm Biopharmaceuticals
Najla Guthrie
KGK Science
Sue Sisley, MD
Scottsdale Research Institute
Lucille Vega, MD
Vega Direct Medical Family Practice

MANUFACTURERS
Justin Blehar
Genco Pura Oil Company, LLC
Richard Brumfield
Full Spectrum Omega, Inc.

APPEARANCES

Rola Mazloum* (for Guy Chamberland, PhD)
Tetra Bio-Pharma Inc.
Josh Epstein
Socati
Bill Grubb* (for Scott Warner)
Noramco
Deb Kimless, MD
Pure Green
Douglas MacKay, ND
CV Sciences
Ray Mannion
Zynerba Pharmaceuticals, Inc.
Rosemary Mazanet, MD, PhD
Columbia Care Inc.
Alice Mead
Greenwich Biosciences
Marwan Moheyeldien
Maryland Packaging LTD
Stephen Mueller
Mile High Labs

APPEARANCES

Aaron Secrist
NOW Health Group, Inc.
James Sharkey, PhD
Therabis, LLC
Priyanka Sharma, PhD
Kazmira LLC
Pulak Sharma
Kazmira LLC
Thuy Vu
Hammer Enterprises

OTHER
Aubree Adams
Moms Strong
Susan Audino, PhD
S.A. Audino & Associates, LLC
James Beck, PhD
Parkinson's Foundation
Scott Coates
AOAC Research Institute, AOAC INTERNATIONAL

APPEARANCES

Daniel Fabricant, PhD
Natural Products Association
Jacqueline French, MD
Epilepsy Foundation
Jeffrey Gitto
Vanguard Legal PLLC
Garrett Graff
Hoban Law Group
Shawn Hauser
Vicente Sederberg LLC
Youn Lee, PhD
RTI International
Brian Malkin
Arent Fox LLP
Steve Mister
Council for Responsible Nutrition
Robert Morgan
ASTM International
Sheri Orlowitz
Artemis Holdings / MPP

APPEARANCES

Matt Sica
ANSI National Accreditation Board
David Steinberg
Steinberg & Associates, Inc.

PATIENTS
James Werline, PharmD
H-E-B

PUBLIC SAFETY
Heather Despres
Americans for Safe Access
John Redman
Community Alliances for Drug Free Youth
Denise Valenti, OD
IMMAD, LLC

RETAILERS/DISTRIBUTORS
Howard Baxter, PhD
Daye

APPEARANCES

Craig Brand
Folium Biosciences
Dana McMurchy
Harvard CBD Health Center, Oklahomans for Health
Valentina Milanova
Daye

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OPENING REMARKS

MS. CRISTINZIO: -- to the Food and Drug Administration's scientific data and information about products containing cannabis or cannabis-derived compounds public hearing.

I am Dayle Cristinzio, director of stakeholder engagement within the Office External Affairs, and I will be moderating today's hearing.

For today's agenda, we will hear from Dr. Ned Sharpless, FDA's acting commissioner, who is right here next to me. And then, we will proceed with the oral comment, without slides, portion of the hearing.

Afterwards, we will proceed with a group of state presentations and then finish with about six hours of formal presentations with slides. There are printed copies of the detailed agenda at the back of the room and at the registration desk with more information about the flow of the day.

Before we begin, I would like to ask our distinguished panel members seated at this table next to me to introduce themselves, except for Dr.

Sharpless. Please state your name, your position and office and center.

MR. SCHILLER: Good morning. My name is Lowell Schiller. I'm the principal associate commissioner for policy here at FDA. I also co-chair FDA's internal CBD working group

DR. ABERNATHY: Good morning. Amy Abernathy, principal deputy commissioner, and I also co-chair the CBD working group.

MS. MAYL: Good morning. My name is Sharon Mayl, and I am the senior advisor for policy in FDA's Office of Food Policy and Response in the commissioner's office and I co-chair the marijuana working group at FDA.

DR. THROCKMORTON: And I'm Doug Throckmorton. I'm the deputy director for regulatory programs in the Center for Drug Evaluation and Research at the FDA, and I am the other co-chair for the marijuana working group.

MR. METTLER: Good morning. Erik Mettler. I am the assistant commissioner for partnerships and policy in the Office of Regulatory Affairs.

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MR. ALEXANDER: Good morning. I'm Nick Alexander. I'm the director of intergovernmental affairs in the Office of Policy, Legislation and International Affairs in the Office of the Commissioner.

MS. GOLDBERG: Good morning. I'm Rebecca Goldberg. I'm an attorney in the FDA's Office of the Chief Counsel.

MS. SEPEHRI: Good morning. Sherene Sepehri, associate chief counsel in the Office of the Chief Counsel.

DR. SCHELL: And I'm Tim Schell. I'm the director of the Office of Surveillance and Compliance for the Center for Veterinary Medicine.

MS. CRISTINZIO: And now, I have a few general announcements to go over before we begin. In addition to the hundreds of people we are expecting to attend today's session in person, today's hearing is also being webcast and transcribed.

Public hearings are public administrative proceedings and are subject to FDA policy and procedures for electronic media coverage.

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Representatives of the electronic media are permitted, subject to certain limitations to videotape, film or otherwise record FDA public procedures, including the presentations of the speakers today.

The hearing will also be transcribed and copies of the transcript can be ordered through the docket or accessed on our website approximately 30 days after the hearing. In addition, the webcast of the hearing will be recorded and a copy of that recording should be available on our website by the end of next week.

No participant can interrupt the presentation of any other participant and only FDA panel members will be allowed to question the presenters. The press contact for today's meeting is Mr. Michael Felberbaum. If you are media and haven't checked in with him yet, please do so as soon as possible. I believe he is at the back of the room waving his hand at us.

I would like to remind everyone that members of the public and the press are not permitted in the panel area, which is the area beyond the speaker's podium towards the front of this room. Please do not

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approach panelists during the hearing. Also, please silence your cellphones -- mine is silenced -- and other electronic devices at this time and be respectful of the speakers and move outside of the room if you need to have a side conversation during today's session.

Lunch and refreshments are available for purchase just outside the Great Room throughout the day. If you are planning to purchase lunch, please consider filling out a lunch form and paying in advance during the morning break in order to help us get lunches distributed to this large number of people as quickly as possible.

Restrooms are located just outside the Great Room to the right. Just ask any of the staff outside and they will help direct you to them.

For our speakers, please be mindful of all your fellow presenters' time and do not go over your allotted amount. We have an ambitious agenda today, with over 113 speakers, and must stay within the time limitations in order to end on time.

Please also pay attention to the agenda which

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will be projected throughout the day and make your way to the podium before your time slot so that we do not lose valuable time between presentations. In order to help the transcribers identify who is speaking, please be sure to clearly state your name and affiliation at the beginning of your remarks.

Also, there is a colored light system on the podium microphone that will guide you through your allotted time. It will change from green to yellow when you have one minute remaining. And when the light changes to red, your time is up.

If you have not concluded your remarks by the time the light turns red, I apologize in advance, but I will interrupt you and ask you to stop, very nicely.

And I will be emphasizing this throughout the day. Your comments and presentations today will be included in the public docket. But if you run out of time and don’t get to complete your remarks, please submit additional information to the public docket for consideration.

And with that, I'd now like to introduce our distinguished acting commissioner, Dr. Ned Sharpless,

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for opening remarks.
Dr. Sharpless has been with the agency for a few months now, but is certainly not new to public health or the FDA. He has a long and distinguished career in public service, most recently serving as director of the National Cancer Institute at NIH.
He is also a world-renowned oncologist who was the director of the UNC Lineberger Comprehensive Cancer Center and served on the faculty of UNC School of Medicine as well as Harvard Medical School. Please join me in welcoming Dr. Sharpless to the podium.
(Applause.)
OPENING REMARKS
DR. SHARPLESS: Thank you, Dayle. Good morning, everyone. Thank you for joining the FDA today for this public hearing titled "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds."
I'm pleased to see that there's so much interest in this topic. We have over 500 people registered to attend in person. We expect more than 800 people registered to join us remotely and over a

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hundred speakers on today's very packed agenda and lots of interest from the media.
We encourage all stakeholders, presenters, attendees and those unable to participate in today's meeting to submit comments to our docket, which is open and will be open until July 2, 2019. Docket comments will help inform the FDA as we consider the important policy options related to the regulation of products containing cannabis or cannabis-derived compounds.
It's important to note that the FDA's role in the regulation of products containing cannabis is not new. Cannabis contains more than 80 biologically active chemical compounds, including the best known compounds, .-9-tetrahydrocannabinoil, or THC, and cannabidiol, or CBD.
If one of these compounds or the plant itself is added to a food or cosmetic, marketed as a drug or otherwise added to an FDA-regulated product in interstate commerce, then it falls within FDA's jurisdiction. As I said, this is nothing new for the FDA.

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At the same time though, some relevant laws have changed. First, some states have changed their laws to allow for medical use of marijuana or CBD and others have begun allowing for recreational marijuana use or decriminalized recreational marijuana possession.
Moreover, certain federal laws have changed as well. Part of the cannabis sativa plant have been controlled under the federal Controlled Substances Act, or the CSA, since 1970 under the drug class marijuana.
Marijuana is included in Schedule 1 of the CSA, the most restrictive schedule, due to its potential for abuse, largely attributable to the psychoactive effects of THC and the absence of a currently acceptable medical use in the United States.
Last year, the federal scheduling of cannabis changed. The Agricultural Improvement Act of 2018, otherwise known as the farm bill, removed hemp, meaning cannabis or derivatives of cannabis with a very low THC content. And that's below 0.3 percent by dry weight -- from -- so hemp was removed from the CSA

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definition of marijuana. As a result, while marijuana remains a Schedule 1 drug, hemp is no longer a controlled substance under federal law.
As these laws have changed, FDA's authorities have therefore become more relevant. The 2018 farm bill explicitly preserved the FDA's authority to regulate products containing cannabis or cannabis-derived compounds.
In doing so, Congress recognized FDA's important public health role with respect to all of these products that it regulates, including when those products are or contain cannabis ingredients.
FDA treats substances derived from cannabis just like we do any other substance and they are subject to the same authorities as any other substance. Under FDA's authorities, the relevant legal requirements vary depending on which type of product we're talking about.
For example, if a product is being marketed as a drug, meaning that it's intended to have a therapeutic effect such as treating a disease or affecting the body's structure or function, then it's

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regulated as a drug and it generally cannot be sold without FDA approval.

FDA has approved several products that contain compounds found in cannabis as drugs. These include Epidiolex, which contain CBD for the treatment of certain kinds of pediatric seizures, and Marinol and Syndros, which contain dronabinol, a synthetic version of THC, that's used for the treatment of anorexia, for example, in patients with AIDS.

These drugs have important therapeutic value and it is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis.

Food, including dietary supplements, is regulated differently, but with the same overarching goals throughout the FDA of protecting consumers and the public health. We know that American consumers depend on FDA to help make sure that the food they eat and that they serve to their families is safe. We do this through a number of requirements.

For example, while we don't generally require foods to be approved by FDA before coming to market,

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we do require that a new food additive be approved as safe by FDA before being put in the food supply, unless that substance is generally recognized as being safe, or GRAS.

This requirement applies to cannabis-derived ingredients just as it does to any other substance. Americans deserve to know that substances being added to their food are safe, regardless of the source.

I will note that several cannabis-derived substances have already come to market through the GRAS pathway. In December, FDA announced that we completed our evaluation of GRAS noticed for three hemp seed ingredients and had no objection to their being marketed in human foods for certain uses without approval, provided they comply with all other requirements.

As I mentioned earlier however, some compounds found in cannabis, specifically CBD and THC, have been studied and even approved as drugs. It's important to note that the federal Food, Drug and Cosmetics Act prohibits adding drugs to human or animal food in interstate commerce. That includes

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both substances that have been approved as drugs as well as compounds for which substantial clinical investigation have been instituted. Similarly the law excludes these products from the statutory definition of a dietary supplement.

Based on the information available to the FDA, we have concluded that these provisions apply to CBD and THC. And while there is an exception when the substance was marketed as a food or dietary supplement before it was studied as a drug, we have concluded that that is not the case for CBD or THC.

What that means is that under current law, CBD and THC cannot lawfully be added to food or marketed as a dietary supplement

Although the new law says that FDA could issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance. So if we were thinking about doing that for a substances like CBD, well, that would be new terrain for the FDA.

There are important reasons to generally prohibit putting drugs in the food supply. When FDA

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approves a drug, we carefully evaluate the risks and benefits of a specific formulation, dosage form and strength for a particular population. Often we conclude that to be safely used, it requires a prescription or other medical supervision to help protect against potential dangerous misuse. THC and CBD are no exception.

There are real risks associated with both substances and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products like pet food and cosmetics, which are subject to a separate regulatory framework.

And given the new interest in marketing cannabis products across a range of areas that the FDA regulates, we will need to carefully evaluate how all these pieces fit together in terms of how consumers might access cannabis products.

Nowhere is this truer than with CBD. While we've seen an explosion of interest in products containing CBD, there is still much that we don't know. Prior to the 2018 farm bill, population-based

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research mostly included cannabis-focused observations in aggregate. There still -- rather than specific to CBD.

When hemp was removed as a controlled substance, this lack of research and therefore lack of evidence to support CBD's broader use in FDA-regulated products, including in food and dietary supplements, has resulted in unique complexities for its regulation, including many unanswered questions related to its safety.

For example, how much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person may be taking? What if she's pregnant?

What if children access CBD products like gummy edibles? What happens when someone chronically uses CBD for prolonged periods? These and many other questions represent important and significant gaps in our knowledge.

To help us evaluate these questions as well

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as potential pathways for CBD products, FDA has formed an internal working group to address these data gaps specifically, and you will be hearing more from this group in the months to come.

FDA is aware that some companies appear to be marketing products containing cannabis and cannabis-derived compounds in ways that violate the law. FDA has issued warning letters to companies selling unapproved CBD products.

Our biggest concern is the marketing of products that put the health and safety of consumers at risk, such as those claiming to prevent, diagnose, mitigate, treat or cure serious diseases such as cancer in the absent of requisite approvals.

Selling unapproved drug products with unsubstantiated therapeutic claims is a violation of the law and puts patients at risk. Patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases if they're confused.

That being said, the agency does not have a policy of enforcement discretion with respect to any

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CBD products. There are lots of questions we will need to answer to ensure that FDA is taking an appropriate well-informed and science-based approach to the regulation of cannabis and cannabis derivatives, including CBD.

We hope that this meeting and the comments submitted in our public docket will help us as we try to approach this in a science-based way. This hearing is an important step in our continued evaluation of cannabis and cannabis-derived compounds in FDA-regulated products.

Now, that was a lot to go through quickly. So I will be tweeting the text of this speech as well as a link to where you can submit comments for the docket from the FDA commissioner account later today.

I thank you all for taking the time to join us today and your contributions toward this important topic. And as mentioned, we have a very fully agenda. So I'll leave it at that. Thank you this morning.

(Applause.)

MS. CRISTINZIO: Thank you, Dr. Sharpless. Now we are going to begin the open public comment

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period, or oral comment period of our program this morning. Those people on the agenda will have two minutes each to present.

Hopefully when you checked in outside, you were told that you were given a number. We'll have a numeric order for speakers. And they're organized by segment, how you identified yourself. Some of you identified yourself as academic first, and that is the first category that is up.

First, I have Peter Pitts, from the Center for Medicine in the Public Interest, as our first speaker. And if you all know your numbers, please make your way to the line behind him so that we can move quickly in between. Peter, you may begin.

ORAL COMMENTS WITHOUT SLIDE DECK

ACADEMIA

MR. PITTS: Thank you. Good morning. My name is Peter Pitts. I'm the president of the Center for Medicine in the Public Interest. The absence to date of advanced regulatory thinking relative to CBD has resulted in a maelstrom of false claims and shoddy quality standards. Nature abhors a vacuum.

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What's the relevant messages for the nascent, but swiftly growing CBD industry? First, that aggressive and misleading marketing campaigns need to be put on hold now that the FDA has stepped up to the plate. Next, as with all FDA-regulated products, manufacturing quality and labeling integrity are joined at the hip.

Many in the CBD community think this issue is one of regulatory creep on the part of the FDA. But waving away as "Big Brotherism" the important public health role of the FDA doesn't make the agency's position or authority any less real or relevant.

It's time for the proponents of CBD, including many highly vocal patients, physicians, pharmacists, manufacturers and distributors to become part of the solution.

Some key issues include, one, no current standard in quality of production. We mustn't repeat the tragic flaws of limiting FDA's hand via outdated DSHEA legislation. Quality must always trump corporate convenience. Two, no dosing standard. When patients are prescribed any FDA-approved medication,

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they are given a dosing schedule by the doctor telling them how much to take, how to take it and how often.

When people are told to use CBD by physicians, pharmacists, friends or Internet experts, they are not given any peer-reviewed guidelines about how they should take it or in what amounts, something that should never happen.

Three, potential for help and harm through chronic use. What does serious research tell us? Hardly anything. And the plural of anecdote isn't data. We mustn't repeat the mistakes that led to the opioid epidemic.

Four, legalization changes public opinion. If you can't measure it, then it doesn't count. Quantifying CBD's therapeutic and manufacturing bona fides for pain treatment isn't the end of the debate. It is only the beginning.

Now you must develop ways to measure its effectiveness and develop ways to capture the real-world evidence that must drive evolving best practice and reimbursement policies. Thank you.

MS. CRISTINZIO: Thank you. Next up is Tory

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Spindle from Johns Hopkins University School of Medicine.

DR. SPINDLE: Hi, everyone. My name is Tory Spindle, and I'm a cannabis researcher at Johns Hopkins University. I'm not speaking on behalf of Johns Hopkins today, and these are my own views.

Although I now specialize in cannabis research, I did my PhD work conducting research to inform product regulations for electronic cigarettes. From this research, I learned there's a lot of moving parts with e-cigarettes that will make it very difficult to regulate nicotine dosage and delivery.

But I've grown to realize from my cannabis research that regulating dosage for cannabis products will be exponentially more difficult. If you remember one thing from my talk today, remember that for cannabis, a dose is not necessarily a dose. Importantly, the same dose of cannabis can have very different effects on a person depending on the route of administration.

We recently published a paper in JAMA Network Open showing that the same dose of cannabis can

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produce stronger drug effects and greater impairment if it's inhaled with a cannabis vaporizer compared to with a smoked method.

When cannabis is inhaled, users can feel the drug effects within minutes. However, when cannabis is orally ingested, it can take up to 45 minutes for a person to feel a drug effect and often peak effects don’t occur until hours after ingestion. This delayed onset of effects makes it difficult for someone to titrate their dosage, which can lead to acute overdose.

Beyond these products, there are many other routes of administration that are becoming popular, including transdermal or topical cannabis products, sublingual sprays, lozenges and cannabis suppositories. But given the regulatory barriers to conducting cannabis research, we have very little scientific evidence available to inform regulation of these emerging products.

Just like the research currently being done to inform regulations for tobacco products, we desperately need to conduct cannabis regulatory

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science to inform appropriate product standards for the various forms of cannabis that are available today or that might become available tomorrow. Researchers need a streamlined, regulatory pathway that can facilitate research on the spectrum of commercially available products.

Clinical research studies have barely scratched the surface when considering the vast array of cannabis products available to consumers. The risk of retail cannabis products harming public health must be mitigated by swift and evidence-based regulatory action. Thank you all for allowing me to speak today.

MS. CRISTINZIO: Thank you. The next speaker is from the agriculture category. Jason Amatucci.

AGRICULTURE (NON-GOVERNMENT)

MR. AMATUCCI: Good morning. My name is Jason Amatucci. I founded the Virginia Industrial Hemp Coalition in 2012 and since that time I've been assisting with the crafting of legislation and policy for the Virginia and United States hemp industry. I want to thank the FDA for holding this public hearing on the subject of cannabis-derived products.

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I'd like to begin this morning by making a connection between safe, non-intoxicating hemp products being produced currently throughout America and the relationship to famers and agribusiness in those states.

Today, as many of you know, the American farmer is facing some of the toughest times in recent history. In my home state of Virginia, agriculture is the largest private industry by far. Nothing else comes a close second.

It has an economic impact of $70 billion annually and provides more than 334,000 jobs for our state. In neighboring Kentucky last year, hemp processors reported $58 million in gross product sales and they paid Kentucky farmers $18 million for harvested hemp materials. Hemp processors also spent $23 million in capital improvements in the state, while creating many new jobs in the process.

I truly believe the United States hemp industry is poised to take off. But to do so, we cannot have legal uncertainty which can hinder the growth in confidence in our industry.

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Currently farmers who grow crops on land where hemp also does well, such as corn, soybeans and tobacco, are being hit with multiple downward pressures. The recent popularity of hemp products have shown great economic promise in providing some hope for farmers and agribusiness in places where there currently is little hope to be found.

It is our request that the FDA strongly considers the new economic opportunities that farmers and agribusiness have when forming regulations. We recommend that you regulate hemp products as food and dietary supplements and give them all GRAS designation.

We wholeheartedly agree with the FDA that food and dietary supplement safety for the public is of the utmost importance. And the hemp industry has shown that it will work, as it has already started to, to self-regulate, to provide safe products and consumer products.

What we need from the FDA right now is clear communication as quickly as possible so that all stakeholders can get on the same page so that the

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American hemp industry can thrive to boost the economy, create jobs and give Americans safe and effective products for a better quality of life. Thank you for your time.

MS. CRISTINZIO: Thank you. Next, we have Hunter Buffington, from Hemp Feed Coalition.

MS. BUFFINGTON: Good morning. I'm Hunter Buffington, program director for the Hemp Feed Coalition, a group of farmers, processors, feed experts, researchers, animal nutritionists from across the United States and Canada.

Our goal is the legal approval of hemp as an animal feed ingredient, focusing on hempseeds and their byproducts. However, there is an opportunity to utilize flour grown commonly for CBD as forage and silage and significant interest in the nutritional value of post-extracted cannabinoid pulp material for the animal feed market as well.

Preliminary data shows that this is a valuable material with high levels of protein and omega fatty acids, including linoleic acid. This material is currently considered waste and accumulates

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in warehouses instead of providing a much needed secondary revenue stream for farmers and a high protein feed source for animal, poultry and fish producers.

Hemp is one of the oldest crops known to mankind and American farmers must be given the opportunity to have an additional cash crop to replace dwindling commodity prices.

Currently China produces 50 percent of the world's cannabis supply, a threat to cannabis interests around the world and particularly the U.S. market, as reported by Forbes. Not only is this a threat to small farmers and livestock producers, this introduces low quality and potentially harmful products into the U.S. market and to American consumers.

We need to ensure that the economic benefits of the emerging hemp industry start on the family farm with American-grown and processed feeds. Healthier feeds create healthier animals and in turn leads to healthier Americans.

We ask that the FDA and its commissioner do

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not utilize a lack of data and research, considering we've only had access to cannabis for the last three years, as a reason to implement a ban or incorrectly label it a drug.

Instead, we recommend the following steps: include data and research from qualified international sources and open research opportunities to private companies instead of a small group of universities. Identify a pathway for the production of hemp-derived foods and reconsider designation of a dietary supplement for products that contain CBD and other useful phytocompounds.

Your agreement to this shows a commitment to help farmers and animal producers to keep American agriculture competitive. Thank you.

MS. CRISTINZIO: Thank you. The next speaker, number five, is Jonathan Miller, U.S. Hemp Roundtable.

MR. MILLER: Good morning. The U.S. Hemp Roundtable is the hemp industry's leading business advocacy organization committed to fostering regulatory discussions and building an accountable

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industry. We're comprised of members from more than 60 firms from across the country who are involved in each link of the hemp supply and sales chain, as well as grassroots leaders such as the Hemp Industries Association.

Over the past several weeks, we have worked with members of Congress on the drafting of legislation that, if necessary, could provide a more efficient pathway for CBD while FDA considers rulemaking to allow the use of CBD in food and dietary supplements.

We believe Congress clearly intended on having hemp-derived products available to consumers as foods and dietary supplements when it passed the 2018 farm bill. There is an urgent need for an efficient regulatory framework for CBD as we continue to see a great deal of confusion among consumers and state and local regulators surrounding the lawfulness of hemp-derived products.

The roundtable appreciates the FDA's willingness to work with stakeholders. But we strongly believe that the FDA has all the tools

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necessary to make a change expeditiously. Multiple reviews, including the World Health Organization's June 2019 critical review of cannabidiol and ones from the FDA itself have found that CBD is safe, with a growing body of scientific research which demonstrates CBD's potential benefits.

Although hemp-derived CBD is safe, our members are not just relying on the current scientific literature; but rather, we are also investing millions of dollars to conduct our own safety studies. Moreover, the U.S. Hemp Authority's certification program is our industry's initiative to provide high standards, best practices and self-regulation, giving confidence to consumers and law enforcement that hemp products are safe and legal.

This effort, led by the roundtable, HIA top tier testing laboratories and quality assessors, provides comprehensive guidance for growers and processors of hemp to help ensure the safety and quality of hemp-derived products, including CBD.

We welcome the opportunity to discuss this important initiative with the FDA and use what we've

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learned to help the agency establish measures of quality, safety and transparency for the entire industry. Thank you.

MS. CRISTINZIO: Thank you. Panelists, do you have any questions? Okay. Our next speaker is Jon Vaught, from Front Range Biosciences.

DR. VAUGHT: My name is Jon Vaught. I have a PhD in organic chemistry from the University of Colorado at Boulder and I'm CEO and founder of Front Range Biosciences. We're an agricultural company that supports farmers of high value crops such as hemp and coffee.

Before Front Range, I spent 15 years developing technology platforms in human diagnostics that generated validated clinical data supporting the FDA drug approval process. I have a deep understanding of FDA regulations for taking drugs to market and the scientific rigor required to ensure safety and efficiency for consumers.

I strongly support the FDA's mission of ensuring public safety when it comes to bringing new products to market and am thankful for the role it

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plays, despite frequent criticism from the public. I can imagine it's not an easy job to do.

There are two key points: first, that cannabis-derived ingredients have an incredible safety profile compared to many over-the-counter products and FDA-approved drugs on the market. Besides it's measured therapeutic ratio, cannabis is 400 times safer than caffeine and 200 times safer and aspirin.

In published Epidiolex studies, doses as high as 10 mg/kg, or 70 milligrams a day for a normal adult, were well tolerated, with only 2.7 percent of the trial participants discontinuing treatment due to severe adverse events such as mild liver toxicity and sleepiness.

Given the last decade of state-regulated legal programs which have not created a public health crisis, in recent clinical data from the Epidiolex trials, there is more than enough evidence showing cannabis is generally at safe limits where it's marketed and regulated at the state level as a supplement or a wellness product, typically 10 to 30 mg per dose.

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Second, the economic impact of cannabis products is massive and it's important that regulations don't create a monopoly for any one segment of the industry. The current market in the U.S. hit over $10 billion last year, generating a billion dollars in tax revenue for state governments and representing over 200,000 jobs in the United States. That's more jobs than coal or textile manufacturing.

It has huge potential impact for agricultural regions in the U.S., providing opportunities that can raise the economic status of many farming communities that have been beaten down economically.

It's important we focus on a regulatory framework for cannabinoid-based products that ensures public safety, but provides the opportunity for not just one, but multiple segments of the industry to thrive, pharmaceuticals, dietary supplements, food additives, cosmetics and even animal feed.

MS. CRISTINZIO: Thank you.

PANEL MEMBER: Quick question. Are you willing to submit your data to the public docket so

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that it can be reviewed?

DR. VAUGHT: Absolutely. I'll do it by July 2nd.

PANEL MEMBER: Thank you.

MS. CRISTINZIO: Thank you. Our next speakers in the consumer category, Susan Cromer from LilyHemp.

CONSUMERS

MS. CROMER: Thank you for taking the time to address this very important issue. I am Susan Cromer, founder and CEO of LilyHemp, a boutique and gourmet retail, wholesale and e-commerce business, cofounder of Women in Hemp, a 501(c)(3) dedicated to the education and support of women in the industry and I am a board member of the Virginia Industrial Hemp Coalition.

As a retailer, it is paramount to me to offer safe, effective, top quality products. This can easily be achieved by following the guidelines currently in place for supplements and for ingredients in foods. Additionally, require clear, truthful labeling, the implementation of good manufacturing

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practices and determination of shelf stability.
These are all systems the FDA already has in place to keep us safe. You got this. Just use them for CBD. Science has proven with the discovery of the endocannabinoid system that CBD is beneficial to humans and animals alike. The World Health Organization has deemed CBD safe. Much credible research and a multitude of anecdotal evidence attest that CBD has many positive effects.
Personally I have been privileged, awed and at times brought to ears by the positive changes CBD has brought to my customers' lives. My clients and thousands, if not hundreds of thousands of others, have felt the difference CBD can make.
Overregulation will simply drive consumers to the black market, costing our economy and tax base a projected revenue stream of many billions of dollars. The ending of prohibition of hemp with the 2018 farm bill was monumental for our country. I ask you not to repeat history by once again demonizing any part of this wondrous plant. We the people deserve and I daresay demand no less than safe and unfettered

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access. Thank you.
PANEL MEMBER: Could I ask, as a retailer, what steps are you taking relating to youth access to cannabis products?
MS. CROMER: As to what?
PANEL MEMBER: Youth access.
MS. CROMER: Youth access? We do not allow anyone under 21.
PANEL MEMBER: Within the store premises?
MS. CROMER: Correct. Well, I don't -- yeah, I mean, we don't sell to anyone under 21 personally. And I guess if parents decide they want to have them using, that's up to them. But, I mean, I can't control that obviously, nor can anybody.
PANEL MEMBER: Okay. Thank you.
MS. CROMER: With anyone, any subject -- I mean, any product.
PANEL MEMBER: And how was the age 21 selected?
MS. CROMER: Pardon me?
PANEL MEMBER: How did you select the age 21?
MS. CROMER: Just because of thinking of like

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alcohol or something like that, just seemed like the age that people usually use for substances.
PANEL MEMBER: Thank you.
MS. CROMER: That is just a safety guideline. There is no -- I know there is no set thing. But I know that other states that have -- I'm from Virginia. We really don't have any guideline for that.
But I know that other states have used 21. So we just did it as kind of a safety net. No particular -- just think that's a good idea. You guys can tell us. We'd appreciate that.
PANEL MEMBER: Thank you.
MS. CROMER: Thank you.
MS. CRISTINZIO: Thank you. Our next speaker is Sally Schindel, from the Marijuana Victims Alliance, speaker number eight.
MS. SCHINDEL: Sally Schindel, Marijuana Victims Alliance. My son was the consumer. My son's suicide note: "Marijuana killed my soul, plus ruined my brain." In the end, Andy understood the dangers of marijuana. And I have to ask do you understand.
What we need is our federal government

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enforcing federal laws. We need limits on THC potency. We need product safety warning labels. I have with me Andy's death certificate, Andy's medical marijuana card, Andy's dispensary frequent purchaser card.
And I took all of this to the dispensary and I asked the manager to save the next kid to appeared to abuse the drug. She told me marijuana does not cause addiction or death. I asked that she share Andy's warning with others. She refused, saying Andy must have used other drugs. He did not. His toxicology confirmed that.
Andy had been a kid with dreams. Join the army. Go to college. Get married. Have kids. He worked hard. He achieved some of that. He served with the 82nd Airborne. He earned two degrees. But by age 25, he was in a downward spiral of severe cannabis use disorder, serious mental illness, locked up in psych units, multiple suicide attempts, court-ordered mental healthcare.
I want you to understand the devastation marijuana brought to our family. And sadly, ours is

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not an isolated story. I can tell you of other tragedies directly linked to marijuana, a list of stories that goes on and on and keeps getting longer. Many families I work with find it too painful to be public about the harms this drug brought into their lives.

And even now, it still hurts me. But I am mad. So I speak for those other families. And I am sad. So I speak for my Andy, that his message and warning will be heard.

We need FDA to be more involved and take a leading role in marijuana research and policy formation. Being proactive, we can save other families the agony from a loss that so many of us have had. Thank you.

(Applause.)

MS. SCHINDEL: Thank you.

HEALTH PROFESSIONALS

MS. CRISTINZIO: Thank you for your comments. Our next category is health professionals. Our speaker number nine, Corey Burchman, is up next. All right. We will move on to speaker number 10, Nasser

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Hassan, CanDiscPharma, Incorporated. Nasser? Moving on to speaker number 11, Anne Hassel, Holyoke Visiting Nurse Association.

MS. HASSEL: My name is Anne Hassel. I am a physical therapist who was once a strong believer in medical marijuana and also an employee in the industry. I worked as a budtender in a Massachusetts medical marijuana dispensary for a year-and-a-half and learned this has nothing to do with public health, just profit.

I witnessed unethical and dangerous practices harmful to patients' physical and mental health. I saw and trimmed moldy marijuana plants at the cultivation center. I saw and sold moldy marijuana to dispensaries -- to patients at the dispensary who truly believed we were taking good care of them, looking out for their health. I was wrong.

Management policy was to mask moldy marijuana by dunking it into barrels of caustic hydrogen peroxide, an industry standard, all for the purpose of making a sale and a profit. This industry also has a lack of concern for its employees who work in

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environments exposed to biological toxins and harmful chemicals.

The marijuana industry is self-policing and self-reporting. The state is woefully incapable of effectively regulating marijuana to ensure patient and worker health and safety. Health hazards were reported to the state by a group of concerned workers. After two years, we are still awaiting a response, no response despite the fact I have documents to support my toxic exposure and heavy metal poisoning.

My state issued a waiver for testing of heavy metals and pesticides in marijuana products. I was fortunate to wake up to the harms of why marijuana is a medicine, cease consuming it, quit an industry more focused on profit over people and seek medical attention for my exposure.

The trusting patient population is assuming that medical marijuana is safe, as I did. What the states are allowing the medical marijuana industry to do is dangerous, wrong and a great threat to public health. The FDA needs to step in. You must create rigorous controls over the purity of marijuana

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products and especially levels of high potency THC in these products to protect the public. I am willing to provide additional information, answer any health-related questions. Thank you.

PANEL MEMBER: May I ask which state was the facility that you worked at located in?

MS. HASSEL: Massachusetts.

PANEL MEMBER: Thank you.

MS. CRISTINZIO: Thank you. The next speaker is speaker number 12, Lily Jin, from DataRevive. Lily? Moving on to number 13, Amy Jones, from the Toxicology and Risk Assessment Consulting. Any Jones? All right. We're on to speaker number 14, Russell Kamer, Partners in Safety.

DR. KAMER: Good morning. My name is Russell Kamer, from Partners in Safety. Despite the lack of FDA approval, this plant-based substance was legalized for medicinal use by 27 states.

The FDA associate commissioner, Dr. Stuart Nightingale, wrote, "Unfortunately, the lack of scientific evidence about the drug and the views of responsible orthodox spokespersons were viewed as of

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no consequence by state legislators and the public. Consumer groups were notably silent on this major public health issue." Of course, I am talking about Laetrile, the bogus cancer cure that swept the nation 40 years ago.

Once again, the FDA's authority to protect the public is being challenged. This time, it is in the form of cannabis-derived products, both THC and CBD.

THC products are sold as medical marijuana in the manner described by Anne, the budtender, this morning. And that is just a small bit of what happened at that so-called dispensary. CBD is sold in even less regulated way, if that's even possible.

As a practicing primary care physician, I can vouch for the extent of the CBD craze. Every day -- every day, I see a patient who has taken CBD. Some patients get it from drugstores or chiropractors while others purchase it online, at gas stations or even at flea markets. They think they are getting a THC-free, safe product. In two cases, they are providing CBD to their children.

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Most of these products have no independent lab analysis. Ones that do, for a 20 mg CBD tablet, there was 1 mg of THC. A person taking two or three of these tablets would be getting a significant exposure to THC.

As Dr. Nightingale said 40 years ago, experience tells us a successor to Laetrile is almost surely on the horizon, if not in our midst. It is hoped that those of us in medicine and science, in and out of government, would be able to meet the next challenge of quackery.

While the role of a drug regulatory agency may be limited, submission of scientific data should be encouraged. Thank you.

MS. CRISTINZIO: Thank you. The next speaker is number 15, Ashley Morgan, from the American Veterinary Medical Association.

DR. MORGAN: Thank you. Good morning. I am Dr. Ashley Morgan, with the American Veterinary Medical Association. We believe there is therapeutic potential in the development of cannabis-derived and cannabis-related compounds, and we would like to see

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that potential realized.

There are FDA-approved cannabis products for human use that veterinarians may use in an extra-label fashion. However, we ultimately desire products for use in animals that come with the assurance veterinarians need that they are of good and consistent quality and that they are efficacious and safe for use in our patients.

Currently products intended for use in animals may be animal drugs, food or feed or food or feed additives. The FDA should clearly articulate where the various cannabis-derived and cannabis-related products fall and what may or may not be included in the promotional and labeling materials for these categories.

There are many companies in the marketplace today selling unapproved cannabis-derived products for dogs, cats and horses, some of which make what clearly appear to be therapeutic claims. And while we know that DSHEA doesn't apply to products intended for use in animals, other manufacturers say that they are making no therapeutic claims or are simply selling

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supplements or nutraceuticals for veterinary use.

As justification, they ask rhetorically what is the difference between CBD and a glucosamine supplement intended to support joint health. Given known gaps in quality, limited information about these products' efficacy in veterinary patients and emerging concerns about their safety, AVMA believes FDA must seriously consider the need for efficacy and safety data when therapeutic claims are made or implied for these products.

To facilitate the development of such products for veterinary use, it is imperative that FDA provide a pathway that assures regulatory clarity and predictability and the economic viability of the industry.

Further the agency must make its enforcement policies known and then consistently and intentionally act on these priorities. Otherwise we will continue to face the Wild West and invariably greater numbers of therapeutic failures and toxicoses in our patients. Thank you for the opportunity to comment.

PANEL MEMBER: I have a -- I have --

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PANEL MEMBER: Do you have views on the use of cannabis products in feed-producing animals and the impact on human food?

DR. MORGAN: We definitely have concerns about that and would like to see the data and ensure that those products are safe, particularly, like you mentioned, as they're going to go into the food supply. We are going to be submitting additional comments by the July 2nd date.

PANEL MEMBER: Okay. Thank you.

PANEL MEMBER: Sorry. One more question, please. Is the veterinary community currently prescribing or using these products?

DR. MORGAN: No. Well, not legally.

PANEL MEMBER: Okay.

MS. CRISTINZIO: All right. Well, we are moving onto our next category of speakers in the manufacturer category. Number 16 is Robert Allen. Robert, from Celtic Wind Crops? Now we're moving on to number 17, Phillip Blair, from Elixinol.

MANUFACTURERS

DR. BLAIR: Hello. I am Dr. Philip Blair,

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MD, and I represent Elixinol, a hemp CBD manufacturer out of Colorado. I'm also a retired U.S. Army colonel and a veteran of the Gulf War.

I've been helping patients with hemp-derived CBD for over five years in all ages. None have experienced any significant adverse effects. On the contrary, CBD has protected many of my patients from the complications of cancer chemo and radiation therapies.

Patients with addictions to opioids and benzodiazepines and THC had no increase in physical or cognitive sedation, but instead rapidly reduced or discontinued these drugs, including Suboxone.

With respect to laboratory indicators, on patient has reported any adverse result. Yet many showed striking improvements in MRIs, retinal scans, PSAs and liver function tests, unlike Epidiolex.

Despite the concern for drug interactions, full spectrum CBD derived from hemp in my use has not caused any significant adverse effects or injuries. I also want to note that the 2018 WHO expert committee on drug dependence said, in humans, CBD exhibits no

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effects indicative of any substance abuse. And to date, there is no evidence of any recreational CBD use or any public health-related problems associated with use of CBD.

So in summary, high quality, full spectrum, hemp-derived CBD has an absolutely safe for all of my patients over the last five years while providing immeasurable levels of benefit. I'll be submitting my written comments with scientific data to support my testimony forthwith.

PANEL MEMBER: Please also include the mechanism through which you collected the data and the protocols or anything else you used. That would be great.

DR. BLAIR: Yes, ma'am.

PANEL MEMBER: Thank you.

PANEL MEMBER: Also, you used the term full spectrum CBD derived from hemp. And I'm wondering if you could elaborate on the term full spectrum and what you meant by that.

DR. BLAIR: So a legal hemp plant that fits all the categories that have been designated: less

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than 0.3 percent THC and deriving the substances from that as a full distillate and derivative. And in fact, there are very, very low levels of THC from the Elixinol products specifically.

PANEL MEMBER: In your submitted comments, we'd also appreciate it if you could provide information on how you determine dosing and what amount if safe or unsafe for a particular patient.

DR. BLAIR: Yes, sir.

PANEL MEMBER: Thank you.

PANEL MEMBER: And the characteristics of the patients, including age, would be really helpful.

DR. BLAIR: Yes, ma'am.

PANEL MEMBER: And --

DR. BLAIR: Thank you very much for your time.

PANEL MEMBER: Oh, sorry. I was just curious too. You mentioned that you hadn't seen any significant adverse effects. I'm curious if there are lesser, more mild side effects that you sometimes observe in your patients.

DR. BLAIR: There are sometimes mild side

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effects from perhaps too heavy a dosing. The variability of a patient's response to CBD is considerable so that a standard serving that would be on a bottle is too much for some, but far too little for others.

PANEL MEMBER: So what sorts of side effects do you see of the milder sort?

DR. BLAIR: You may see a mild, temporary headache. You might see -- the most common side effect that I've experienced for my clients has been fatigue.

PANEL MEMBER: Thanks.

MS. CRISTINZIO: Thank you.

DR. BLAIR: Again, thank you -- again, thank you very much.

MS. CRISTINZIO: We are now on speaker number 18, David Holmes, from Plant Life Group. David? Okay. Moving on to speaker number 19, Charles Jolly, from Baker Donelson.

MR. JOLLY: Good morning. My name is Charles Jolly. I'm an attorney with the Baltimore office of Baker Donelson. My firm represents a number of

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clients interested in various ways in the cannabis-derived compound CBD and dietary supplements.

It's beyond debate that hemp and its constituents, including CBD, have been part of the human dietary for centuries.

Given the legal status of CBD in this country, there's a surprisingly strong body of information that supports the notion that the digestion of CBD enables the body, utilizing the cannabinoid receptor system, to better cope with inflammation, anxiety, sleeplessness and possibly other circumstances. This is a classic definition of a dietary supplement -- a dietary ingredient impacting on human structure function.

If CBD is a dietary supplement can play even a small role in addressing these public health issues, the benefits would be huge. Because CBD is coming, whether as a matter of intrastate commerce or otherwise, with or without FDA, I would submit that the question is simple. Is the public health better served with FDA strongly regulating it or staying out? And I would submit they should strongly regulate.

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We believe the NDI system with a master file is the proper device for regulating CBD as a dietary supplement. The NDI submission would permit limitations on THC, 3 percent or less, mold, heavy metals, pesticide residues and other issues. Enforcement of the NDI must be extended beyond FDA in order to make it effective. Thank you very much for the opportunity to participate in this important discussion.

MS. CRISTINZIO: Thank you. Our next speaker is speaker number 20, James Shults, from WMI Consulting.

MR. SHULTS: Hello. My name is James Shults. I'm here representing Wildflower Brands today. We make infused beauty and wellness products.

Before I begin, I'd like to thank you all for allowing me to speak at this historic point in American history. It's through efforts like today's hearing that we can begin to take an honest and evidence-based approach to truly understanding the productive potential of this plant. So, thank you.

Fundamentally Wildflower is a health and

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wellness company committed to providing premium holistic products. While we recognize that CBD has demonstrable medical use when highly refined and used in a controlled clinical setting, we also believe there is sufficient evidence to safely regulate plant extracts containing CBD in a dietary supplement or cosmetic.

Wildflower understands that the best approach to establishing public safety and trust in our products is through the FDA regulating CBD for use in a dietary supplement or cosmetic.

As this industry begins to take shape globally, the public needs to trust that the products they are buying are safe, are made with the ingredients that are promised and don’t contain any misleading information about its benefits or uses.

To begin this process, I'll be submitting a citizen petition requesting -- or excuse me, requesting a regulation allowing the use of CBD in a dietary supplement or cosmetic and I encourage fellow stakeholders to collaborate and do the same.

At Wildflower, we have personally seen the

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public interest in CBD increase exponentially and it's only through -- and it's only getting started. Through evidence-based regulation and guidance, the FDA can ensure safe and accurate CBD products are available to the public and that the industry can grow with clear expectations of what good manufacturing looks like.

Thank you for your time. I truly appreciate the opportunity to speak here today and look forward to being part of this conversation as we develop this exciting new industry.

PANEL MEMBER: Could I ask what you view as the functional purpose of CBD in a beauty product?

MR. SHULTS: Personally I don't have a collection of the evidence to give you a hard claim on that.

We've had a lot of interactions with customers that it's simply more effective as a beauty product when we include that ingredient. I'm not -- yeah, I'm just not a hundred percent on the scientific reasoning.

PANEL MEMBER: And when you say effective,

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what do you mean by that?

MR. SHULTS: It delivers a more -- a higher sense, you know, of personal attraction, you know, increasing -- it's more desirable to the product, not through clinical definitions but, you know, through a consumer-based opinion.

PANEL MEMBER: Can I follow up on that about that? Do you have any information about the absorption of CBD from your products?

MR. SHULTS: Personally, no. I am -- so as part of my citizen petition, I'm collecting evidence and presenting it, you know, to the FDA, exactly. Getting additional information about the routes of access, specifically topical or ingested and things like that. We make, you know, both.

So yeah, no, that is at root of what we're trying to figure out and present to you to provide a clear grounds for why this is -- you know, why you can safely regulate this as those products. Okay. Thank you very much.

MS. CRISTINZIO: Thank you. We are now on speaker number 21, David Spangler, from the consumer

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Healthcare Products Association.

MR. SPANGLER: I'm David Spangler, speaking on behalf of the Consumer Healthcare Products Association. We represent over 65 manufacturers of OTC medicines or dietary supplements.

Four points. Point one, FDA speaks frequently about three priorities for both OTC medicines and supplements: public safety, product quality and informed consumers. We share these priorities and agree they apply to hemp-derived and CBD products.

Second point, we support the status quo for medicines. The existing new drug approval process provides a pathway for sponsors to develop data to bring cannabis-derived products to market once shown safe and effective.

Point three, we all see the intense consumer and commercial interest in CBD and hemp-derived products more broadly. But with little regulatory oversight, the marketplace offers a vast array of products of varying degrees of quality, an array of unapproved drug claims and even fraudulent products.

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While FDA is charting a course forward, enforcement needs to increase. For instance, more consumer alerts and follow-ups beyond morning letters on enforcement actions would be important steps.

Finally, point number four, beyond enforcement, dietary supplements need a path to bring CBD-containing products to market. One way to do that is for FDA to exercise its authority to exempt forms of CBD from the prior IND, prior new drug approval exception in the law's dietary supplement definition. Please do that this year.

Supplement makers would still need to file NDI notifications for CBD under this approach. Those NDIs would still need to meet the same legal standard of sufficient information to provide reasonable assurance the ingredient does not pose a significant or unreasonable risk. We appreciate this opportunity.

MS. CRISTINZIO: Thank you. Moving on to speaker number 22, Stuart Titus.

DR. TITUS: Good morning. My name is Stuart Titus. I'm the chief executive officer of Medical Marijuana, Inc., which was founded in March of 2009.

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In spite of our name, we are not engaged in the production, manufacture or sale of either recreational or medical marijuana.

Instead, we're focused on nutraceutical sales of botanical, hemp-based products containing CBD through our four operating divisions. We brought the first nutraceutical hemp-based CBD products to U.S. markets in 2012.

In our view, most American diets do not contain an adequate amount of CBD and other non-psychoactive cannabinoids, leaving most of us cannabinoid-deficient and lacking support for a key system in our body, our endogenous cannabinoid system.

Our belief was that fully botanical hemp-based CBD nutraceutical supplements would support health and wellness. The belief appears well-founded within the medical literature. There are 2,281 studies available PubMed with the term endocannabinoid in the title and there are another 10,000 other studies that mention the endocannabinoid system in their abstracts.

In addition, the National Institutes of

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Health appear supportive of our viewpoint, having mentioned the benefit of non-psychoactive cannabinoids in its 507 patent awarded in 2003. It also should be noted that on the NIH dietary supplement label database, a CBD product is already listed as a dietary supplement.

Accordingly we believe that non-psychoactive hemp products containing CBD and other cannabinoids as they support our endogenous cannabinoid system are an essential nutritional supplement for optimal health, just as is vitamin C. In addition, botanical hemp products containing CBD are safe and extremely well tolerated.

Given these facts, there is widespread public and legislative support for botanical CBD. Thank you for allowing this opportunity before you today. We will submit more in our written comments.

PANEL MEMBER: Question. What do you believe are the health benefits of hemp and CBD?

DR. TITUS: Well, we believe they do support this large self-regulatory system, the endogenous cannabinoid system and that helps move people to

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overall better levels of health and wellness. Certainly we don't make any medical claims.

But I think the anecdotal evidence is overwhelming, the public support. People are just seeing tremendous benefit. Anecdotally we see people less stressed.

We see people sleeping better. We see less brain fog, many other great anecdotal evidence that we're slowly accumulating. We'll certainly look forward in our written comments to showing more of this data to you.

PANEL MEMBER: A follow-up question. If I understood you, you're saying you believe that cannabidiol is non-psychoactive?

DR. TITUS: We have seen in the literature, particularly a U.S. government patent mentioning that it is non-psychoactive. We believe it does reduce anxiety. Thus, it may have anxiolytic effects. But we do believe, unlike THC, it is non-intoxicating. So that may be a better distinction.

PANEL MEMBER: If you had evidence to support what you just said, it'd be useful to see that when

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you submitted your comments.

DR. TITUS: Very good. We'll do that. Thank you.

MS. CRISTINZIO: Thank you. Moving onto our next speaker, Julian Wright, from Science & Recreation.

MR. WRIGHT: Good morning. My name is Julian Wright. I am the founder of Science & Recreation. It's an honor to attend today's proceedings and present the FDA with oral comments regarding products containing cannabis or cannabis-derived compounds.

Hemp was made legal at the federal level by signing into law the 2018 farm bill, with the FDA retaining control over regulation of products containing cannabis.

It is my understanding, based upon publicly available information, that a substance that has been approved by the FDA as an active ingredient in a prescription drug -- in this case, CBD -- is precluded from being a food additive. But in order for a substance to be an active ingredient in a prescription drug, the active ingredient must be a controlled

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substance.
But being that industrial hemp and its derivatives are no longer controlled substances, they should enjoy the same range of use as any other legal commodity.
Confusion regarding the status of CBD has negatively impacted responsible and legal uses of CBD post 2018 farm bill, resulting in detrimental effects. Grandmothers are being arrested at Disneyworld and by the TSA. National couriers are not accepting lawful shipments, thereby stifling commerce. Distribution and advertising channels are limited due to lack of clarity.
Hemp stakeholders need certainty and clarity. Hemp represents potentially the largest boon to the agricultural community since tobacco. The 2018 farm bill was passed, banking on that promise. Yet without a vibrant CBD market, American farmers will lag behind the rest of the hemp-producing world.
Our competitive advantage is in producing hemp which is high in CBD. This advantage allows farmers to realize crops that can return $60,000 per

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acre when compared to hemp sold for fiber at $750 per acre. This difference is stunning and should be paramount as the FDA considers crafting regulations regarding CBD. A strong CBD market means a stronger American economy. Thank you.
MS. CRISTINZIO: Thank you. We are moving onto our next category, which was titled "Other." Sorry for that. Number 24 is William Bookout.
OTHER
MR. BOOKOUT: Thank you. My name is Will Bookout. I'm the president of the National Animal Supplement council. On behalf of the members of NASC, we appreciate the opportunity to comment regarding cannabis-containing products for dogs, cats and horses. I'll be highlighting key points in the verbal comments. However, a more complete response will be submitted in writing.
We have three primary points. First, the regulatory agencies, as well as the industry need clearly defined and viable pathways for marketing of these products. FDA needs to provide clear guidance and definitions delineating compounds that would be

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considered approved drugs as opposed to compounds extracted from or derived from the whole plant or parts of the Cannabis sativa L plant containing broad spectrum constituents, including CBD, terpenes, trace THC and other cannabinoids. We would ask the agency to clearly define the meaning of CBD concentrates and isolates. We fully support THC levels of less than 0.3 percent.
Risk to animals. Consistent with the agency's risk-based approach, NASC provides visibility to regulators from our database which we believe is the most advanced in the world for animal supplements.
In addition to product labels, specific data regarding hemp-derived products are. There are 149 products currently in the marketplace. They've been in the market for over 10 years. There have been nine adverse events reports, none serious and over 18 million administrations in dogs, cats and horses.
While more research is certainly needed, we believe the data at this time suggests these compounds provided by responsible companies do not pose undue risk to animals and the species cited. We support the

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agency's position of taking regulatory action against companies for egregious violation in terms of claims and irresponsibly marketed products. In fact, we are disappointed that more action has not been taken against irresponsible participants.
Finally, solutions taking two to three years are simply not realistic or acceptable. NASC has initiated the formation of a taskforce of industry experts that we believe will provide a clearly defined comprehensive pathway that's both viable and responsible for all stakeholders. We'll be reaching out to FDA CVM for further discussion and we thank you for the opportunity to comment.
PANEL MEMBER: I have a question for you.
MR. BOOKOUT: Yes, sir.
PANEL MEMBER: On the 0.3 percent you mentioned --
MR. BOOKOUT: Yes.
PANEL MEMBER: -- do you have data that supports that use?
MR. BOOKOUT: Yes. Our threshold is less than 0.3 percent. We do have data, and we'll be

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submitting that to the docket.
PANEL MEMBER: Okay. Thank you. And what do you see as the intended use of this?
MR. BOOKOUT: We're consistent with intended use with 201(g)(1)(C), non-nutritional benefits, occasional discomfort, cognitive function, immune support, similar structure and function examples.
PANEL MEMBER: Thank you.
PANEL MEMBER: Just one other question.
MR. BOOKOUT: Yes, sir.
PANEL MEMBER: Do you have any data also on either swine or bovine as well?
MR. BOOKOUT: We don't.
PANEL MEMBER: Okay.
MR. BOOKOUT: Our focus is dogs, cats and horses only, not production animals.
PANEL MEMBER: All right. Thank you.
PANEL MEMBER: One last question. The safety database that you -- it'd be really useful to have a little more information about it.
MR. BOOKOUT: Yeah.
PANEL MEMBER: I assume it's spontaneous, as

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opposed to a required reporting and things like that, for instance.
MR. BOOKOUT: It is required reporting.
PANEL MEMBER: It is required?
MR. BOOKOUT: Yes.
PANEL MEMBER: So that kind of information would be really helpful to us.
MR. BOOKOUT: It's a condition of membership, and we've made the information available to CVM. In fact, we've conducted training sessions with the Division of Surveillance at CVM and we work very closely with the agency. Thank you.
MS. CRISTINZIO: Thank you. We are now on speaker number 25, Betsy Booren.
DR. BOOREN: Good morning. I'm Betsy Booren. I'm senior vice president for science and technology for the Grocery Manufacturers Association. GMA represents the world's leading consumer packaged goods companies.
The CPG industry plays a unique role as the single largest U.S. manufacturing sector, delivering products vital to the wellbeing of people's lives

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every single day.
GMA advocates for rational, uniform regulatory frameworks that are informed by risk-based science, promote choice and build consumer trust across the sectors we represent, which is personal care, to household, to food and beverage.
We applaud this effort by FDA for holding this public meeting as the first step of stakeholder engagement. We support the opportunity for additional stakeholder discussions as both stakeholders and FDA and other federal agencies share the common goal of providing consumers safe, trustworthy and reliable products.
As consumers' interest for food and beverage and personal care and household products containing cannabis and cannabis derivatives, the necessity for nationally uniform regulatory frameworks that protect public health is of a critical importance.
The potential patchwork of laws at the state and local level promotes confusion among consumers. We need clear, simple, consistent, national regulations informed by risk-based science that will

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enhance the consumer trust in these products and reduce frictions within the supply chain. FDA and other relevant agencies must provide this leadership.
We support a transparent regulatory process for stakeholder engagement, including comment and rulemaking, development of risk management strategies, development of any research action plans.
This will ensure that all stakeholders have an opportunity to provide insights to agencies during the development of this regulatory framework. Only with this type of transparency will effective and durable, long-lasting regulations be developed. Thank you.
PANEL MEMBER: Thanks for your comments. I was wondering if, given your broad representation of food and consumer products, if there are thoughts on how to deal with risks of cumulative exposure across many products if these substances are now allowed outside the drug context.
DR. BOOREN: Sure, and thank you for your question. I think that is one of interest whereas the branded national companies that we represent start

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diving into this space, that they would need to take into that.

We don't have any clear evidence at this time. But as we indicated, I think that that's part of the discussions we should have in the stakeholder process to make sure we're collecting the right data to protect public health.

PANEL MEMBER: And one other question, which is as other markets, significantly Canada, open up and many of your members sell products in that country, are you thinking about ways to collect additional data and information as those products might be sold legally in other jurisdictions?

DR. BOOREN: I think there's some opportunities for that. I think GMA is uniquely positioned to gather a lot of consumer information in our current framework of better understanding what consumers want, need and what they expect of these products. I think that's something that we would look at.

The market and the indications of what consumers want from these innovation processes or

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products is really indicative of the market to grow. Our inherent issue is making sure we have the strong legitimate regulatory framework which you all provide. Thank you.

MS. CRISTINZIO: Thank you. We are moving down our agenda to speaker number 26, James Childs.

MS. ADAMS: I have a question. He was not allowed to be here. He couldn't make it. But I have -- (off mic) -- thoughts to the docket.

MS. CRISTINZIO: Approach, so we can hear you.

MS. ADAMS: I'm sorry. I'm sorry. I just have a question. Dr. Childs was not able to be here. He did upload his comments to the docket. May be just briefly tell his story?

MS. CRISTINZIO: Sure.

MS. ADAMS: Okay. Dr. Childs --

MS. CRISTINZIO: Two minutes, please. And please state your name.

MS. ADAMS: Oh, my name is Aubrey Adams. And Dr. Childs has a son -- had a son named David Childs. He started smoking marijuana at the age of 16. The

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Internet taught him that marijuana was medicine. This past Thanksgiving, the day after, he found his son cutting his hand. He took him to the hospital. He was admitted into a psych unit and only testing positive for THC and diagnosed with psychosis.

He was discharged. His family put him in an outpatient program. On the fourth day of that program, it was December the 5th, David Childs came home. He went to the woods behind his house. He smoked marijuana. Then he came back into the house and he shot himself in the head. David was 19.

MS. CRISTINZIO: Thank you for telling that story. Any questions from the panel?

MS. ADAMS: Thank you.

MS. CRISTINZIO: Speaker number 27, Robert Discordia.

DR. DISCORDIA: Thank you. My name is Dr. Robert Discordia. I'm vice president of pharmaceutical development and manufacturing at Corbus Pharmaceuticals, where we are developing medicines that target the endocannabinoid system to treat rare, life-threatening autoimmune and genetic disorders.

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Under IND from FDA, treatment with our novel oral investigational drug called Lenabasum has been associated with improvement in efficacy outcomes in multiple Phase II studies in diseases such as scleroderma, dermatomyositis and cystic fibrosis. It has been granted both orphan and fast track designations. Two Phase III pivotal multinational studies are underway and over 700 patients have been dosed, some for longer than three years.

Lenabasum is not medical cannabis nor is it a cannabis-derived substance and it does not involve cannabis-derived compounds in its synthesis. It is a rationally designed NCE specifically designed to avoid interaction with cannabinoid receptors in the brain and purposefully focuses on immune system outside the brain.

And yet, because Lenabasum is categorized as a cannabinoid, we face obstacles that other drug developers targeting the same indications with non-cannabinoid experimental drugs do not because we fall under the Controlled Substances Act as a Schedule 1 whose restrictions have delayed our clinical trials

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only in the U.S., Canada and Australia, but not 27 other countries in which our trials are conducted.

We're here in the interest of public health as a drug developer that experiences unnecessary delays in this field. It is no exaggeration to state that had we not been obliged to comply with Schedule 1, we would be one year closer to completing our studies and potentially closer to making available our orphan drug to patients who have no approved medicines to treat their devastating conditions.

We respectfully urge FDA to develop a transparent, consistent, fair and practical framework to support the investigation and development of drugs targeting the endocannabinoid system.

Specifically for compounds that are not potent brain-penetrating CB1 agonists, to have a clinical development pathway mirroring as closely as possible that of other investigational drugs without the need for onerous regulatory hurdles. I thank you for the opportunity.

PANEL MEMBER: One question. How does the availability of CBD or other cannabis derivatives in

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the marketplace potentially incentivize or disincentivizes your drug development?

DR. DISCORDIA: I don't think it actually has an effect since we're not phytocannabinoids. We're not derived from cannabis. I think that because of the regulations though, mostly DEA, we have to -- we have to follow strict guidelines in accounting for every milligram of the material. I'm sorry if I -- did I answer your question or --

PANEL MEMBER: You got it. Thanks. That's all.

DR. DISCORDIA: Thank you very much.

MS. CRISTINZIO: Next on the agenda, we are on speaker number 28, Kristina Garcia.

MS. GARCIA: Good morning. I'm Kristina Garcia, former CEO and current board member of Women Grow, an international women's networking organization dedicated to the cannabis industry.

I also serve on the advisory board of Green Check, a Connecticut company based on meeting the banking and compliance needs of cannabis companies and the financial institutions that serve them. I'm a

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cofounder of magnolia Partners, an agency devoted to providing strong foundations to early stage companies both in and outside of the cannabis landscape. I'm a new mother to a four-month-old baby boy and my husband is an army vet and an operating engineering in Local 825.

Through my role in the industry, I've had the privilege to hear many personal stories from patients whose lives have been transformed and even saved due to cannabis and hemp products.

I was also privy to clinical studies of equine, canine and feline patients using full spectrum both cannabis and hemp oils with positive results for conditions from anxiety to skin cancer.

I also hear from business owners who make quality products which undergo vigorous testing, yet are frustrated with their cheaper competitors who cannot claim the same exhaustive research.

While walking in a grocery store earlier this week, I came upon a shelf of no less than 10 products ranging from cookies to tinctures to gummies and the shelf was directly across from the pharmacy counter.

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As an expert in the industry, I have the knowledge to differentiate between those products and it's still a challenge. And I know that some of those brands are quality and some of those are not.

The consumers that are currently seeking out or stumbling upon these products in the marketplace do not have my expert knowledge or that of a trusted medical professional behind them. They're desperate for help and they don't have anybody to turn to.

In May of 2018, then commissioner Gottlieb said that it was crucial that we provide clear expectations so that the industry can meet them. It's just as important for consumers to be able to effectively use updated labels.

And we're launching a major educational campaign for consumers to help them better understand the new information that they'll be seeing in the marketplace. That was regarding the food labels and that same information and application can work here.

So I ask that you demand that suppliers have their products tested by reputable labs and that those test results be readily available to consumers prior

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to purchase. Implement clear and concise labeling rules and encourage businesses to provide educational information for medical professionals.

And I ask that you move with purpose, as the marketplace is already active and the federal courts have also, as recently as yesterday, asked the DEA to seriously consider the de-scheduling of cannabis in an expeditious manner. Thank you.

MS. CRISTINZIO: Great. We are now on number 29 on the agenda, Gabriel Giancaspro.

DR. GIANCASPRO: Good morning. My name is Gabriel Giancaspro. I'm the vice president for dietary supplements and herbal medicines at the science division at USP.

On behalf of USP, I would like to thank the agency for allocated time for us to offer comments on the value of robust science-based, quality standards for products containing cannabis and cannabis-derived compounds.

USP is an independent scientific nonprofit public health organization devoted to improving health through the development of standards for medicines,

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foods and dietary supplements. The organization publishes two legally recognized official compendia of the United States.

Additionally, one of USP's areas of expertise and focus is the development of the standards for articles of botanical origin, including analytical procedures and acceptance criteria to help ensure their identity, purity and strength.

Regardless of product category, the purpose of a public standard is to help regulators protect public health and by providing scientifically validated tests to ensure identity, constituent composition and strength of a product. The standards also help monitor product quality so adulterants and contaminants are absent or below the level of concern.

Public standards are essential to help prevent harm to patients and consumers. The facility -- they facilitate the production of non-contaminated, non-adulterated trials and help limit exposure to toxic substances, pathogenic microorganisms and harmful additives.

A robust standard in this area should

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therefore include specifications for the content of active constituents and limits for contaminants such as pesticide residue, microbial load, aflatoxin level, elemental contaminants based on reliable scientific information.

USP is committed to bringing our public health mission and expertise in this developing area through publications and information sharing. We've made significant progress to define suitable quality specifications for this plant material and we plan to publish our work in a scientific paper to disseminate this knowledge to the community.

We look forward to continuing the dialogue for exploration of the science-based standards that help prevent harm and protect public help once the regulatory status and path forward for these products are clear, USP stands ready, as appropriate, to work with the agency and other interested parties to develop reliable quality standards and make them available for use by manufacturers and regulators alike. Thank you.

PANEL MEMBER: Could you remind -- do you

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have -- I believe you've put out some materials on marijuana standards to date separate from cannabidiol. Is that right?

DR. GIANCASPRO: Yes.

PANEL MEMBER: And do you have a date when you anticipate that the cannabidiol might be released, the product might?

DR. GIANCASPRO: Our net process for developing quality standards requires the sponsor for the manufacturer that is approved by the agency. We contacted the manufacturer to supply the information. Unfortunately the manufacturer was not willing to supply the information for us to construct the public monitoring at this time.

Should the path forward for dietary supplements is clear or other path forward different from drug approval, we may have alternatives to develop quality standards. Thank you.

MS. CRISTINZIO: Thank you. Our next speaker is number 30 on the agenda, Karen Howard, from the Organic & Natural Health Association.

MS. HOWARD: Good morning. My name is Karen

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Howard. I'm the CEO of the Organic & Natural Health Association. We're a trade association whose decisions are rooted primarily in transparency and traceability and the quality of products provided to consumers and their interests.

Based on the FDA definition of a drug, Organic & Natural concludes that CBD is not precluded from use as a dietary supplement.

Hemp extract is not approved or investigated for the intended use of treating a disease. Hemp extract does not resemble the drug Epidiolex to which it is being compared to. For us, the issue is whether hemp extracts are equivalent to the drug, and it is not.

Hemp extracts will be proven safe, are safe and can be demonstrated as such, whether by an NDI or through GRAS. That said, Organic & Natural does have concerns related to enforcement and we appreciate the viral nature of how CBD has hit the marketplace.

With that, there are always going to be problems related to things like contamination and toxins, especially as it relates to the presence of

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any THC or heavy metals, which I believe you will hear more about this afternoon. Those would be our concerns. We remain in support of CBD safety.

PANEL MEMBER: A question. You're referring to hemp extract. Could you explain what exactly you mean by that?

MS. HOWARD: Well, we do mean CBD. But we also know that there are different derivatives that can be derived from the hemp plant.

I think our real issue is that hemp extract, hemp CBDs and all of the derivatives from the hemp plant are simply not related to the product that it's being compared to, which is the pharmaceutical.

PANEL MEMBER: You stated that the hemp extract has been demonstrated that it would be safe under the NDI and GRAS standard. And I'm wondering if you're putting in any data and information into the record on that regard.

MS. HOWARD: We have members of our organization that are currently working on safety data related to it. Our position is that there has been discussion in the industry as to whether this would

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require an NDI or whether it would require GRAS. We believe that at the end of the day, either will support those conclusions in recognition that some people will choose to go the NDI route while others will partake in the GRAS process.

PANEL MEMBER: Yeah. I would just encourage any safety data that you have be put into the record by July 2nd, if you have it.

MS. HOWARD: Thank you.

PANEL MEMBER: Thank you.

MS. CRISTINZIO: Thank you. I believe the next number on the agenda, Loren Israelsen, was an early cancellation this morning. I just thought I'd check before I move on. Okay. Number 32, Rod Kight, from Kight Law Office, is the next on the agenda.

MR. KIGHT: Good morning. My name is Rod Kight. Thank you for allowing me this opportunity to speak. I'm an attorney who represents cannabis businesses.

Numerous studies have found that CBD is safe. According to the World Health Organization, it is nontoxic, non-addictive and non-intoxicating. People

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who use CBD should have helpful guidance and reasonable regulations that will allow them to produce, sell and safely use CBD products.

The FDA's approval of a CBD seizure drug last year has created a complex legal scenario under section 301(ll) of the Food, Drug and Cosmetic Act.

Fortunately there are at least two paths forward. The first path is hemp extract. Section 301(ll) prohibits a drug being added to food only if the substance is intended to diagnose, cure, mitigate, treat or prevent disease through its use in food, as shown objectively by marketing and labeling representations and is the exact same moiety as the active ingredient in an approved drug and is added to the food in the same dosage range as authorized by the new drug approval.

Hemp extract as a food is an exception to this rule, notwithstanding that it contains CBD. This is because CBD is a constituent inherent in hemp which has been marketed and used at least since the Civil War.

The prohibition on marketing a drug in food

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applies only to a substance that is added to food and does not apply to a substance that is in food, even when the substance is identical to an approved drug. Additionally, hemp extract contains dozens of compounds and is not the same moiety as the FDA-approved CBD drug.

The second path is for CBD itself. The mere chemical identify of an approved drug does not -- or with an approved drug does not render a substance a drug in the absence of marketing claims.

Section 301(ll) excepts from its prohibition a drug that was marketed in food before any approval of the drug or before substantial clinical investigations involving the drug were instituted.

Marketed in food simply means that the substance has been present in food that has been marketed, regardless of whether or not it has been separately promoted.

Once a substance has been marketed in food as an inherent natural constituent, as with CBD, it remains within the marketed in food exemption, even if that constituent is later isolated and added to food.

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Thank you.

MS. CRISTINZIO: Thank you. We are on number 33, Andrew Kline, the National Cannabis Industry Association.

MR. KLINE: Good morning. My name is Andrew Kline, and I'm the lead -- the lead of public policy of the National Cannabis Industry Association, otherwise known as NCIA.

Today NCIA represents nearly 2,000 members, including CBD-related commercial manufacturers as well as cannabis and ancillary business leaders. Recently we formed a coalition of well over a hundred CBD entrepreneurs, scientists, medical professionals and food and drug lawyers to provide comments to FDA. Yesterday that coalition submitted more than 60 formal written pages on FDA's website.

We encourage interested parties to review our written submission, which can also be found on our website at thecannabisindustry.org.

I'd like to quickly drive home five important points today. The first is that time is of the essence. Hemp-derived CBD is in very high consumer

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demand and the industry is eagerly awaiting FDA's regulatory framework for these products. We strongly recommend that FDA act quickly to clarify the regulatory environment because there is significant confusion in the market. Businesses don't know who is legally permissible -- what is legally permissible, and some are making health claims in the absence of clear regulatory guidance.

Most significantly, banks and payment processors don't currently understand the regulatory landscape and as a result many CBD companies are at risk of losing essential financial services. Because of this, it is critical for FDA to advance regulations in an expedited fashion.

The second point I'd like to drive home is the significance of the economic impact of this nascent industry. Current research indicates that at present, about 7 percent of all adult Americans, or 22 million people, use CBD as a supplement.

The current market size is estimated at upwards of $2 billion. This current economic activity supports nearly 12,000 direct full-time jobs. A five-

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year projection shows a multiple of eight. We need to get this right. But we need to get this done as quickly as possible before we lose market share to Canada, China and other international players.

The third point I'd like to drive home is that CBD products are safe. There is no higher calling in government service than public safety and we applaud FDA's efforts to make certain that consumers are safe. The bottom line is this. An overwhelming preponderance of evidence indicates that cannabis and cannabis-derived compounds present minimal safety concerns.

Sorry. My pages are stuck. To address any potential safety concerns, we believe FDA should mandate that all cannabis products are tested in a licensed analytical laboratory to ensure that dangerous levels of potential contaminants are absent from products that are consumed. In July of 2018, we issued a report on lab testing. That report can be found on our website.

A fourth point I'd like to drive home is that we need consensus industry standards to get this

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right. While we know that CBD is safe, we also know that universal standards have worked in other industries to help protect the public from health and safety risks.

MS. CRISTINZIO: Sir, are you almost done?

MR. KLINE: Yes.

MS. CRISTINZIO: You're beyond your time.

MR. KLINE: Finally, of course, it's important that consumers be informed of any potential risks. In February of 2019, NCIA released a report on packaging and labeling. You can also find that on our website. Thank you.

PANEL MEMBER: One just quick remark. Anything that you would like us to consider, we would encourage you to put those reports and studies into the docket before July 2nd. Thank you.

MR. KLINE: We will. Thank you.

PANEL MEMBER: Just one other quick question. You mentioned the domestic industry and you briefly mentioned international. Any data that you have from the international industry would be greatly appreciated as well.

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MR. KLINE: I can get that for you.

PANEL MEMBER: Perfect. Thank you.

MR. KLINE: Thank you.

MS. CRISTINZIO: Thank you. We are now on speaker number 34, Ken Maciora. I'm sorry. I'm butchering your name, if you're here -- from the Empire Relations Group. Next on the agenda is speaker number 35, Michael McGuffin, the American Herbal Products Association.

MR. MCGUFFIN: Good morning. My name is Michael McGuffin and I am president of the American Herbal Products Association, or AHPA. Aside from my statement here, AHPA will submit detailed written comments to the docket.

AHPA understands that the 2018 farm bill reflected the intent of Congress to allow broad access to hemp and products derived from hemp, including those containing CBD.

Even prior to the farm bill's enactment, FDA stated its position with which AHPA has neither agreed nor disagreed that provisions of the FD&C Act prohibit marketing CBD dietary supplements and adding CBD to

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conventional foods.

AHPA notes that these provisions should not preclude use of hemp-derived ingredients containing naturally occurring quantities of CBD and urges FDA to -- excuse me -- publicly acknowledge this important distinction.

FDA's position on CBD has resulted in significant marketplace confusion, many companies now selling foods and supplements containing CBD have the mistaken impression that FDA does not currently regulate them. Others have chosen to stay out of the market.

Based on FDA's position to fully implement the congressional intent to allow access to products that contain hemp-derived CBD and to further AHPA's and FDA's shared goal of ensuring safe and well-manufactured supplements and foods, AHPA requests that FDA promptly take one of the two following actions.

FDA should use its authority under the FD&C Act to issue a regulation possibly as an interim final rule with an accelerated effective date permitting CBD as a lawful ingredient in supplements and foods. Of

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course this regulation would still require compliance with all other applicable federal regulations.

Alternately, and especially if FDA cannot issue this requested regulation promptly, FDA should issue guidance to state the agency's intent to exercise formal enforcement discretion with respect to the provisions of the FD&C Act on which FDA bases its position that CBD-containing supplements and foods are unlawful.

AHPA would support conditioning this exercise of enforcement discretion also on full compliance with all other regulations applicable to these categories.

FDA has previously acknowledged its authority to create a lawful pathway for marketing CBD-containing supplements and foods, and the agency should act promptly to use this authority. Thank you.

PANEL MEMBER: Yes. I was wondering, you mentioned products with naturally occurring levels, right, of CBD.

Is that -- if you could say a bit more about that, is that like in the proportion that you would usually see within the plant or sort of explain a

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little bit more what you mean about it --
MR. MCGUFFIN: Sure.
PANEL MEMBER: -- and also what sorts of levels you tend to see.
MR. MCGUFFIN: Correct. That is what I mean. I mean the proportion in a plant. So, for example, if a product came to the marketplace that was simply the plant packaged in a tablet or a capsule, then the naturally occurring presence of CBD should not be interpreted by FDA as the restriction under the provisions of the Food, Drug and Cosmetic Act.
I think also simple products, tinctures, extracts that do not deliberately concentrate up the level of CBD, those also should be acknowledged as not affected by those provisions of the Food, Drug and Cosmetic Act.
PANEL MEMBER: So what sorts of levels do you tend to see in those products and does it depend if it's a derivative from only part of the plant? Is that still within what you're talking about?
MR. MCGUFFIN: I'd have to get back to you, and we will submit comments to clarify that detail.

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But -- and there is also a range. There are different cultivars that have different levels. I don't know the numbers right now. But we'll make sure that we provide that information in our comments. Thank you.
PANEL MEMBER: One other thing that would be useful, when you submit that comment, is you had two proposed solutions.
I'm not sure if you're -- if there's a dose of cannabidiol that you believe should be considered safe or were there some higher level of cannabidiol that shouldn't be allowed under one or the other of those proposals.
MR. MCGUFFIN: We will definitely address that issue in our comments. Thank you for that question. I think it's a very important element of this whole discussion. Thank you.
MS. CRISTINZIO: Great. We are now on speaker number 36, Megan Olsen, from the Council for Responsible Nutrition.
MS. OLSEN: Thank you. I'm Megan Olsen. I'm the assistant general counsel for the Council for Responsible Nutrition. CRN, based in Washington, DC,

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is the leading trade association representing dietary supplement and functional food companies. CRN is here today to present comments about CBD use in supplements and foods, specifically to urge FDA to use its rulemaking authority as quickly as possible to create a legal pathway for CBD use in supplements and food.
Despite FDA's current position on the legality of CBD, the CBD food and supplement marketplace is exploding. For dietary supplements alone, hemp-derived CBD sales were over $200 million in 2018 and are expected to grow to over $300 million by the end of 2019.
Driving these sales is an intense consumer demand in hemp-derived CBD. Research suggests that a third of U.S. adults are current CBD users and nearly half of all U.S. adults have used CBD at some point. Lack of FDA oversight for these products leaves this growing consumer base vulnerable.
Without FDA oversight, consumers lack assurance that products labeled as CBD are safe. Consumers cannot trust that the products are manufactured in an appropriate manner or actually

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contain the amount of CBD listed on the label or any CBD at all. Therefore FDA does not have the luxury of time. They must act quickly to address a market that is out of control. Three to five years at a minimum for rulemaking is too long.
In fact, CRN was alarmed by the suggested timeframe and comments by FDA leadership, including former FDA commissioner, Dr. Gottlieb. CRN understands and respects FDA's concerns about safety of CBD products. But as CRN will expand on in further comments by CRN CEO Steve Mister, we do not believe that the safety debate has to impede rulemaking at that stage.
There is already a regulatory framework in place that is proven to ensure the safety of dietary supplements in food, one that will automatically be implemented should FDA develop a regulation permitting CBD use in food and supplements.
To be clear, FDA is not asking -- or CRN is not asking FDA to abdicate a safety review. Rather, CRN is asking FDA to address safety as the Food, Drug and Cosmetic Act intended. In the fact-specific

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context of how a product will be marketed, intended to be used, its form, dosage and other unique considerations that apply once a product is considered a supplement or food.

Americans deserve access to safe quality supplements and food, as well as protection from supplements and food that pose risk. FDA under current law has the authority to achieve both goals for CBD and we strongly urge the agency to use this authority as quickly as possible.

PANEL MEMBER: I'm going to ask you the same question I think that I asked the previous speaker, which is if you have information about safe dosages of these products or use in supplements, that would be very useful, including information about whether those dosages or recommended serving sizes would change based upon the intended effect.

MS. OLSEN: Yes, and CRN is intending to submit written comments. And we will take that into consideration with our written comments.

PANEL MEMBER: Okay. Thank you.

MS. CRISTINZIO: Thank you. We are now on

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speaker number 37, David Rodman.

MR. RODMAN: Good morning. My name is Dave Rodman, and I am here on behalf of The Rodman Law Group. I'd like to thank FDA for hosting this hearing and for having the foresight to address these important issues in a proactive manner.

My firm has been representing and advising companies in the cannabinoid space for the past five years and we have seen the industry as a whole grow at a blistering pace.

Even with this unprecedented expansion as a baseline, the CBD sector stands out due to its exponential growth. Yet this proliferation has occurred almost entirely outside any well-defined or widely enforced regulatory regime.

To my knowledge, no compound has ever been removed from Schedule 1. But CBD achieved mass adoption practically overnight, even before hemp-derived CBD was removed from the CSA. Now FDA is faced with the daunting task of attempting to regulate an unprecedented billion-dollar industry that shows no signs of slowing its growth.

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Ladies and gentlemen, the genie is out of the bottle here and it is probably impossible to force it back inside. Accordingly, I encourage FDA to take prompt action to address this unique regulatory situation. A more comprehensive exposition of my suggestions are contained in my written comment.

But in brief, my suggested actions include, one, allowing low dose CBD products to be sold as dietary supplements and/or food additives. The prescribing guidelines for Epidiolex establish the dose range between 700 mg and 1.4 g per day.

Most of the CBD products currently in the customer marketplace have less than 500 mg in their entire container and are generally intended to last about a month. This is a difference of several orders of magnitude.

The significant differential in dosages suggests the current consumer CBD products should be placed in an entirely different category than pharmaceutical products. The logical category for this is that of dietary supplements.

Two, enact a policy stating FDA will not

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prioritize enforcement of the FD&C Act against CBD operations that follow established enforcement priorities.

Soon after states like Colorado began to legalize cannabis, the Department of Justice issued the Cole memo, which basically stated that the DOJ would not enforce the CSA in states where cannabis has been legalized, provided that the state legal cannabis activities did not violate eight established enforcement priorities.

FDA could take a page from DOJ's playbook and issue guidance similar to the Cole memo with respect to the FD&C Act. Suggested enforcement priorities could include, A, strictly limiting claims about CBD to structure or function claims only; B, not marketing CBD to children; and, C, adherence to certain packaging, labeling and testing standards to ensure quality and accuracy of ingredients.

I should note that much of the industry has already voluntarily participated in rigorous testing programs and it would not be hard to codify such testing. And much of the industry would support it

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immediately.

I know I'm a little bit over time. My last suggestion would be to expedite the creation of a CBD OTC monograph. And I'm not going to read all of that because I'm about a minute late. Thank you.

MS. CRISTINZIO: Please submit the rest of your comments to the docket. Next on the agenda is Zoe Sigman.

MS. SIGMAN: Good morning. My name is Zoe Sigman, and I'm the program director at Project CBD, an educational nonprofit focused on cannabis science and medicine. Ten years ago, we introduced CBD to the medical cannabis community in California. It spread like wildfire and has become the hugely popular phenomenon that it is today.

There are occasions when public health priorities and pharmaceutical priorities are not equivalent. That is, we believe that this is the case with CBD and cannabis. We urge the FDA to maintain public health at the core of your decision-making process.

CBD is a nontoxic, non-intoxicating, non-

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habit-forming neuroprotective antioxidant. What's not to like? Given CBD's intrinsic safety and many potential benefits, it should be legally available without a prescription.

Sensible regulations can assure product safety without going through expensive, time-consuming clinical trials. The goal should be public access to diverse cannabis product options that are subject to rigorous manufacturing and compliance oversight.

Towards this end, we propose the formation of a committee for traditional herbal medicinal products to assist in implementing regulations for CBD, cannabis and other medicinal plants. Project CBD will provide a detailed account of the committee's responsibilities in a written submission to the FDA. For those interested, I have a list of the resources that informed that idea here today.

A few closing comments. Regarding pregnancy, when confounding variables like alcohol and cigarettes are accounted for, there is no science that demonstrates harm to the fetus from cannabis, as Project CBD documented in a report for California

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health officials.

Contraindications and drug interactions are easily manageable. Project CBD has published an extensive report on cannabinoid drug interactions, noting few problems, except with high doses of CBD isolates.

Project CBD advocates banning artificial thinning agents and flavor additives from cannabis oil vape cartridges unless these additives are proven safe when heated and inhaled. None have been. Let's regulate CBD to promote public health. Let's make the most of this historic opportunity. Thank you.

PANEL MEMBER: Thank you for your comments. You did again mention a few -- a study on pregnancy and a report on drug interactions.

MS. SIGMAN: Yes.

PANEL MEMBER: And I'm hoping that you will submit those to the docket before July 2nd.

MS. SIGMAN: Absolutely.

PANEL MEMBER: I do have a question for you. It sounds like your group is sort of coordinating a lot of efforts on CBD. Have you made any efforts to

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monitor any adverse events or consumer complaints related to these products? And, if so, are there reports that you could submit to the docket?

MS. SIGMAN: Absolutely, yeah. We have a research survey that over a thousand people have filled out. So we will. Thank you.

MS. CRISTINZIO: great. Thank you. We are now on agenda number 39, Andy Snyder.

MR. SNYDER: Good morning. My name is Andy Snyder. I'm the founder and publisher of Manward Press, and I'm not just here today on behalf of our 200,000 readers and their families. I'm here on behalf of my family, friends and every American listening and watching today online.

Our nation is at a crossroads, one that should be clear to everyone in this room today. While the evidence supporting both the safety and efficacy of CBD continues to pile up, response at the federal level has been slow at best and nonexistent at worse.

Today most Americans are under the impression that the research on CBD is insufficient. But that's merely a projection of the mainstream perception. The

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truth is there are more than 150 active clinical trials registered with the U.S. National Library of Medicine as I speak to you right now.

In fact, multiple published studies in the U.S. National Library of Medicine confirm the safety profile and efficacy of CBD.

One recent review of 132 studies found that not only is CBD safe, it's a powerful antioxidant that is more effective than vitamin C or E at protecting the human brain.

Make no mistake. This is just scratching the surface of CBD's potential for mainstream, widespread application in human health optimization.

I believe that if the folks charged with liberating CBD from its shackles make the right decisions, CBD is just a few years away from being perceived by the average American no differently than vitamin C or any other common drugstore vitamin. The main difference will be that, unlike vitamin C, the average American will be able to experience significant tangible benefits from CBD.

For many, CBD has already become the go-to

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natural solution for a variety of concerns, like one of my readers, Frank B. Frank wrote in to tell me about his experience with CBD.

Here's just a short example of what he wrote me: I'm an old guy that still works pretty hard. My friends are all older farmers, loggers and equipment operators that are still working because we enjoy it. We are using CBD oils and rubs to get through the aches and pains that come from that kind of work. This stuff makes it so we can going without the pain.

Ladies and gentlemen, we're talking about a safe, natural compound with seemingly endless benefits for users, one with very little, if any, risk of significant downside. For my money, CBD may be one of God's greatest gifts to mankind in the pursuit of health.

It's outrageous that corporate greed and red tape have forced most Americans to spend the last eight decades in the dark. Today is our chance to learn from past mistakes, open our eyes to the compelling scientific and anecdotal evidence and harness the power of nature to put our health back

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into our hands. Thank you.

PANEL MEMBER: Are you familiar with data regarding the safety of CBD use in children?

MR. SNYDER: Not personally, no.

PANEL MEMBER: Are you supportive of that?

MR. SNYDER: In children? I'm a publisher. So I don't have the research on that. Based on what I've heard, no, I wouldn't give my son or my daughter CBD.

PANEL MEMBER: Would you give your son or daughter vitamin C?

MR. SNYDER: I would.

PANEL MEMBER: Okay.

PANEL MEMBER: I'm curious just to ask you to speculate a little bit about the impact of expanding the availability of cannabidiol in the foods and dietary supplements based on study of cannabidiol formally and in the kinds of trials that you mentioned on clinicaltrials.gov. Do you think that would help that or in any way hinder it by potentially removing, you know, some incentives for that?

MR. SNYDER: You're asking if getting rid of

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the regulations on food supplements would help?

PANEL MEMBER: If it was more broadly available in that way. Would that -- what effect would that have on sort of additional scientific research?

MR. SNYDER: I think what we need to do is clear up the confusion. Anything -- any regulations we make need to be simple, clear. Our readers -- I hear it every day. They think there's opportunity out there. They just don't know what to do.

As we've heard today, there's a lot of shady characters in the market. There's some really good characters out there. And clearing that up with smart, commonsense regulation is what's needed. Thank you.

MS. CRISTINZIO: Thank you. We are now on speaker number 40, Ian Spotts. Ian? Okay. We are moving onto speaker 41, Monica Weldon

PANEL MEMBER: WSWA, whatever that is.

MS. WELDON: Hi. Thank you. Thank you. I'm Monica Weldon, and I'm president and CEO of bridge the Gap, SYNGAP Education Research Foundation. Imagine

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being told there is no FDA-approved product for your child. Picture watching your children suffer from a rare genetic disorder that physicians barely understand, marked by seizures, mood disorders, the inability for your child to communicate due to their being nonverbal. Put yourself in the shoes of a parent or a caregiver who is disparate for their child -- to treat their child's challenges, even just to find out what's wrong.

Now insert CBD. With all its confusing descriptions, derivative products, vague dosage recommendations, the cure-all marketing and then you create a legal environment of ambiguity around it and now you've just created the Wild West of CBD.

Like many pediatric rare disease advocates, we are particularly sensitive to new emerging therapies that are going to help our children.

Patients and their families look to us for guidance and trusted educational materials on potential treatments, especially as we work closely with researchers to develop targeted therapies for SYNGAP1. We have no approved targeted therapy for our

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children. So therefore we are focused on short-term repurposing of drugs and natural medications to mitigate SYNGAP1 symptoms.

CBD-based pharmaceuticals and OTC CBD products come up in conversations all the time. Our greatest challenge as an organization is how to address them. At this stage, we need further scientific research when it comes to safety, efficacy, product integrity, drug interactions, further CBD research will answer many of our questions.

In addition to our patient community, they have expressed appropriate dosing, potential interactions with other pharmaceuticals, where to purchase products free of harsh chemicals and pesticides.

In addition, we support regulations on standards of labeling of CBD products so that patients and caregivers can easily understand what they are consuming and compare labels for different products. We need regulatory shielding from predators and opportunists in the consumer product space looking to capitalize off CBD's popularity by peddling

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substandard and fake products.

We need to know exactly what we are consuming, especially if we are feeding it to our children. We need to feel confident that the products we are using are held to the highest safety standards. SYNGAP1 patients, along with other rare pediatric disease patients, need to have access to safe and effective therapies to improve their quality of life. Thank you.

MS. CRISTINZIO: Thank you. I just want to note we're running a little bit behind. We're about 10 minutes behind schedule. So I'm going to try and stick to the lights a little bit more vigorously. We are on number 42, Anna Williams.

MS. WILLIAMS: My name is Anna Williams, and I'm the main point of contact at the American Association for Laboratory Accreditation, otherwise known as A2LA, for their cannabis and hemp programs.

Established in 1978, A2LA is a nonprofit, third party accreditation body with over 3,500 actively accredited certificates representing all 50 states. We offer training and services to public and

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private testing laboratories, proficiency testing providers, reference material producers and product certifiers.

In the U.S., both government regulators and consumers seek assurance that products and commerce conform to specific quality attributes and/or regulatory requirements. This is generally accomplished via testing of the product by a competent analytical laboratory.

The same is true for products containing cannabis and cannabis-derived compounds and both the neat, plant and process materials should be testing for unacceptable levels of contaminant and adulterants.

The challenges at present are there few multi-laboratory validated test dates or realistically nationally available proficiency testing programs. This circumstance places the requirement on the lab to develop, validate and run their own internal methods without these necessary tools that laboratories in other industries have access to.

Assurance of laboratory competence is most

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often accomplished through ISO 17025 accreditation process. Accreditation uses criteria and procedures specifically developed for the assessment of technical competence of the laboratory and depends on multiple factors including qualifications and training of staff, correct equipment, adequate quality assurance procedures, properly statistical-based sampling practices, appropriate and valid testing procedures and methods, traceability of measurements to national standards, accurate recording and reporting procedures and suitable testing facilities.

Expert technical assessors conduct a thorough evaluation of a laboratory's management process, affecting the production of analytical test data and through being accredited laboratories demonstrate that these quality requirements have been and continue to be met.

Accreditation bodies themselves are also periodically evaluated and are part of international laboratory accreditation cooperation. It is through this process that assurance is provided to regulators and the public of technical competence of this testing

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laboratory.

In summary, it is the position of A2LA that any outcome of the FDA's request for information inform any future regulations to include language that requires proficient -- or excuse me, participating analytical testing laboratories to be accredited to ISO 17025 by a signatory accreditation body. Thank you.

MS. CRISTINZIO: Thank you. We are on number 43, Tiffany Wilson. Tiffany? So we are going to go on to the patient category. We have number 44, Keith Fargo.

PATIENTS

DR. FARGO: Hi. Good morning. My name is Keith Fargo. I'm the director of scientific programs and outreach for the Alzheimer's Association.

Although the chemical components of cannabis have been studied in relationship to Alzheimer's and dementia, most of this research has been conducted in in animal models and cell culture and not in people.

Furthermore, research findings to date have been inconclusive and contradictory. Accordingly, the

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Agency for Healthcare Research and Quality, in its recent draft report on the diagnosis and treatment of Alzheimer's, determined that there is insufficient evidence to draw conclusions about the efficacy or safety of cannabinoids for treatment of Alzheimer's, a determination with which the Alzheimer's Association agrees.

At this time, cannabis is essentially an untested drug for use in Alzheimer's disease and dementia. And like any untested drug, it cannot be responsibly recommended for human use.

Only large, randomized, controlled clinical trials can provide reliable evidence of efficacy or safety of any drug for human use. And to date, this has simply not happened with cannabis in relationship to Alzheimer's and dementia.

This lack of evidence creates substantial risks for individuals and their families. Simply put, there is currently no robust consistent clinical trial data to support the use of cannabis for treatment of Alzheimer's or dementia.

The Alzheimer's Association believes that

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more research in this area is needed, and we applaud the FDA's commitment to protecting the health and safety of individuals until such evidence becomes available. Thank you.

PANEL MEMBER: How do you view the commercial availability of cannabis and CBD and other cannabis derivatives as affecting incentives for research in Alzheimer's?

DR. FARGO: That's a great question. I don’t know that it directly affects the incentive to do further research in Alzheimer's. I just don't know that I have a good answer to that question. All right. Thanks.

MS. CRISTINZIO: Thank you. We are now on speaker number 45, Kevin Chapman.

DR. CHAPMAN: Good morning. Good morning. My name is Dr. Kevin Chapman, and I'm a pediatric epilepsy specialist in Colorado speaking on behalf of the American --

MS. CRISTINZIO: Can you speak a little louder, please?

DR. CHAPMAN: Sorry.

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MS. CRISTINZIO: Or move closer to the mic.
DR. CHAPMAN: My name is Dr. Kevin Chapman, and I'm a pediatric specialist in Colorado speaking on behalf of the American Epilepsy Society, representing over 4,400 health professionals who focus on the care of patients with epilepsy from neonates to the geriatric population.
We have significant concerns about the current status quo for cannabis products and advocate for regulation of cannabis products as drugs under the purview of the FDA.
The current patchwork of state and federal regulations has led to an array of products with variable phytocannabinoid content and potential impurities such as pesticides. By classifying these compounds and drugs, the FDA can assure consistency and safety of these poorly regulated compounds.
We strongly encourage the FDA and United States Pharmacopeia to create standard assays to evaluate content and purity, as well as quality standards for cannabis-containing products that are currently unregulated yet may be marketed and sold for

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the treatment of various medical conditions such as epilepsy, pain or migraine headache.
Studies of Epidiolex, an FDA-approved prescription CBD product, have raised concerns about hepatotoxic effects of CBD and interactions with other medications if taken outside of medical supervision.
Clear warning labeling of cannabis-derived compounds is necessary to educate about potential adverse effects and help offset the common belief that these products are, quote, "more natural," end quote, and therefore safer than pharmaceutical products.
Many questions remain regarding the long-term consequences of cannabis compounds whose underlying mechanism of action remains unknown.
We have specific concerns about the unknown effects of these compounds on the complex pathways of the developing brain in children. We also have concerns about the potential long-term effects on adults who regularly consume these products.
We support reducing regulatory barriers to research of cannabis-derived compounds. We strongly encourage -- we strongly urge the FDA to classify

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these compounds as drugs under the complete jurisdiction of the FDA. We also advocate for ongoing, well-designed studies into the safety and efficacy of cannabis drugs. We commend the FDA for tackling this complex problem of public safety, and I appreciate your time.
PANEL MEMBER: Question for you.
DR. CHAPMAN: Yes, ma'am.
PANEL MEMBER: Have you found any -- are you aware of patients using unapproved CBD products as opposed to Epidiolex, which has been approved?
DR. CHAPMAN: Yes. I am aware of that. There are quite a few.
PANEL MEMBER: And do you know why they are doing that?
DR. CHAPMAN: At this point, Epidiolex is limited to a very small segment of our population. There's two current approvals, Dravet syndrome and Lennox-Gastaut syndrome, which is a fairly small but serious epilepsy syndrome.
And so, all of the patients that are outside of that are not covered. And the cost of the

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medication is about 430,000 per year, whereas families can go to a dispensary and pick up something, you know, on the order of $100 per month or so.
PANEL MEMBER: And how are they choosing dose?
DR. CHAPMAN: They're making it up as they go along.
PANEL MEMBER: (Off mic.)
DR. CHAPMAN: Sorry. Sorry. They're just sort of making it up as they go along.
PANEL MEMBER: I'll just follow up on that, given that answer. Do you find that most of these patients are being monitored in some way by their physicians for adverse events like liver toxicity and others that were identified in the approval of the Epidiolex drug?
DR. CHAPMAN: It's an excellent question. I mean, so this has really been kind of an issue for five years. Since this WEEDS program in August of 2013, especially in Colorado, we had an influx of patients. And early on, we definitely did not know what to expect from these compounds.

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We instituted, you know, trying to evaluate drug interactions, hepatotoxic effects, aplastic anemia, those types of things, with sort of standardized -- at least some attempt at standardization of blood testing and things like that.

It's a bit variable because, you know, some families were getting -- we felt as physicians within Colorado we could not make recommendations about non-FDA-approved products because, at the time, we were worried for other regulatory reasons whether it may affect our ability to do research and things such as that.

So we have really -- there's so much variability within the CBD products and I think that's one of the biggest concerns that we have.

MS. CRISTINZIO: Great. Thank you. Our next speaker is Kari Rosbeck, number 46.

MS. ROSBECK: My name is Kari Luther Rosbeck, and I'm president and CEO of the Tuberous Sclerosis Alliance, an advocacy organization for people with tuberous sclerosis complex, or TSC.

About 85 percent of those with TSC will

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experience epilepsy. So accessing effective seizure medications is critically important for our community. In fact, a recent Phase III clinical trial reported efficacy of Epidiolex, a purified and standardized formulation of cannabidiol, for treating drug-resistant seizures in TSC, which we hope will lead to an FDA approval for broader use in epilepsy associated with TSC.

The TS Alliance recognizes the importance of taking an evidence-based approach to discovery, development and clinical application of cannabis and derivatives. Multiple drug cannabinoid interactions with commonly used anti-seizure medications are well-documented, including clobazam, valproate and others.

Risks of unexpected drug-drug interactions may occur if cannabinoid enters the bloodstream due to its inclusion in food, cosmetics and other products. Therefore we believe labeling of identified drug interactions should be required on any cannabis-derived or cannabis-containing products since people may be exposed to these products in multiple ways.

Clinical trial results could also be

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compromised if investigators are unable to control and verify dietary intake of cannabinoids which might lead to increased variability and apparent placebo effects.

In summary, without a wide safety margin to avoid accidental exposure of people with TSC to levels of cannabinoids which are known to interact with their medications, we urge the FDA to prohibit the inclusion of cannabis-based additives in any FDA-regulated products other than drugs as defined and approved under the FD&C Act.

Please refer to our written public comments for more information. Thank you on behalf of the TS Alliance and the TSC community.

PANEL MEMBER: Sorry. Do your written comments include the information you mentioned about drug interactions?

MS. ROSBECK: Yes. Yes, they do.

PANEL MEMBER: Okay. Thank you.

MS. ROSBECK: Thank you.

MS. CRISTINZIO: Great. Okay. We are moving on to the next category of public safety. We have number 47, Patrick Bird.

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PUBLIC SAFETY

MR. BIRD: Good morning. My name is Patrick Bird. And I'm the owner of PMB BioTek Consulting, which works to develop analytical methods and rapid detection platforms for analytical testing laboratories. I'm also the co-chair of the microbiology working group for AOAC International's cannabis analytical science program.

The complete lack of a federal regulatory scheme for cannabis generally, including both hemp and marijuana, has left cannabis decades behind other food and agricultural testing. And now, the FDA that must bring a plant that has been used by humans for millennia into a 21st century paradigm for food safety.

The FDA is responsible for protecting the public health by ensuring the safety of products millions of Americans consume every day.

In developing a new regulatory framework for hemp-derived products, the FDA, in partnership with industry groups like AOAC and testing laboratories like Titan Analytical, should look to two primary

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sources to guide its efforts: state cannabis regulations and federal food safety regulations.

First, the FDA should closely examine the regulatory schemes implemented by states with mature medical and adult use cannabis markets; namely California, Illinois and Colorado.

Although these states' regulatory structures have different ends, their policy goals are congruent because the same baseline safety issues are present regardless of whether a cannabis plant, hemp or marijuana is grown in accordance with or in contravention of federal law.

The cannabis plant is a bioaccumulator, acting as a sponge for a wide range of environmental and microbiological contaminants. By establishing baseline regulations for pesticides, metals, bacteriological agents and other key target analytes in hemp-derived products for human consumption, the FDA can continue to fulfill its responsibility to protect public health.

Second, the FDA should incorporate aspects of federal food safety regulations like FSMA such as

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HACCP, FSVP and preventative control planning that will adequately ensure product safety. Consumers should expect, if not demand the same levels of safety, traceability and recall readiness that the FDA already requires of food manufacturers. Hemp products should be treated no differently. Thank you.

MS. CRISTINZIO: Thank you. We are on a new category, retailers and distributors. Number 48, Crystal Guess.

RETAILERS/DISTRIBUTORS

MS. GUESS: Good morning. My name is Crystal Guess, and the comments that I am making today are my own and do not represent the company or any individual. I would like to speak to the 2018 farm bill, being that it now regulates hemp as any other agricultural crop, just like corn, wheat, rye, barley, potatoes.

I can walk into a Safeway and I can buy potato chips and buy those potato chips with a credit card. I can then -- Safeway can they deposit those funds into a national bank. We are having some very -- we are having some issues with now in the industry

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where there are a lot of people that are trying to provide this medicine to consumers.

But they are being held and their hands are being tied because they have no ability to take payment, whether it's online or face-to-face. The banking -- so we just -- we're asking for more clarity from the FDA to give -- to make these people feel a little bit more confident in approaching the banks and being able to get those approvals.

When it comes to labeling, I think, you know, when we have -- we're hearing some stories of people, that -- you know, when it comes to labeling, they don't know what they're getting when it comes to full spectrum versus isolate. We're getting questions about what is this, what's the clarity on that.

There are companies out there that are saying we're full spectrum, and yet it's 99 percent CBD spiked with 1 percent terpenes and they're putting these out there.

And so, there needs to be a little bit more clarity, I think maybe some sort of seal on the label saying this is full spectrum and a table of

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definitions as to what full spectrum means, what is isolate so that consumers are educated and they're not left in the dark as to what is this, what is this.

When it comes to dosing, this is a very complicated topic because everybody is different and every body is different. There's no magical chart that we can point to that says, oh, a woman aged this to this that has this condition takes this much CBD. We don't have that.

We have to educate the public as to how to titrate themselves and so on and so forth. And a lot of these things can be addressed I believe through labeling, through obviously education.

And we need to also have the ability to hold companies and individuals that are making these false promises to the public, we need to have a place to go where we can hold these people accountable, so that we can raise the flags and so that we aren't having people come up and saying my -- you know, this happened to my son or my cousin and they didn't know.

So it really does boil down to consumer education, labeling as well as opening the doors to a

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little bit more clarity we are asking from the FDA in regards to --

MS. CRISTINZIO: Your time is up.

MS. GUESS: -- states that -- yeah, that are a little confused as to what they can and cannot do.

MS. CRISTINZIO: Sorry for the interruption. We're running behind.

MS. GUESS: That's okay.

MS. CRISTINZIO: Thank you. Next we have David Heldreth from -- I'm not even going to try and pronounce it.

MR. HELDRETH: I'll handle that for you. Good morning. My name is David Heldreth. I'm the chief -- excuse me, chief science officer for True Terpenes. With a little bit of time, let me get to the heart of the matter.

While the majority of this hearing is focusing on things related to CBD, I believe there are other issues that we can address with less controversy. CBG, CBC, CBN, these are cannabinoids which are legalized under the farm bill, but don't require the regulatory hurdles that CBD and THC face

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with the drug approvals.

Even easier would be things like terpenes and products like hemp leaf foods which will provide low hanging fruit for the FDA to create allowances while avoiding again CBD and other issues.

Imagine hemp leaf salads and terpene dressings, hemp and terpene-flavored sodas or your favorite beer with a skunky hemp note. Terpenes are responsible for the taste and aroma of cannabis, in addition to hops, lavender and almost every scented plant on Earth.

When these compounds are found in hops or lavender, they're considered generally regarded as safe by the FDA. However, these identical molecules, when sourced from the hemp plant, are not allowed to be used in food, drinks, supplements or even alcohol due to TTB and FDA regulations.

True Terpenes is considered the industry expert by those sourcing terpenes from non-cannabis plants and we would relish the opportunity to help the FDA and Congress establish the safety and manufacturing requirements for hemp terpenes to enter

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our food system.

In fact, True Terpenes has our own such system that we deemed True Grade that we would love to provide you information on. As I previously stated, terpenes as an entire class have been demonstrated safe in GRAS panels and are used in innumerable household foods, drinks and other products.

Further, there are manufacturing techniques such as steam distillation that are able to selectively pull terpenes while leaving behind things such as cannabinoids that are creating these difficulties.

In closing, True Terpenes and myself hope the FDA can see an easy way forward to create more access for safe, sane hemp food products. Please, I recommend you visit our website for more information, trueterpenes.com, and I would love to provide some of this information for you in the future.

PANEL MEMBER: Just a quick follow-up question about your comment about selectively I assume concentrating specific terpenes. Any data you have available on the safety of those higher concentration

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of individual terpenes found in hemp would be really useful to have submitted to the docket.

MR. HELDRETH: We would love to. And again, most of that data has also been shown safe in GRAS panels. But we would love to provide that for you.

MS. CRISTINZIO: Great. Thank you. Our final speaker in this category is Peter Matz, from the Food Marketing Institute.

MR. MATZ: Good morning. I'm pleased to be closing out the first batch of comments and I appreciate the opportunity to provide comment today on behalf of the Food Marketing Institute, the trade association for the supermarket industry, including roughly 33,000 grocery stores and 12,000 pharmacies across the country.

I am here first and foremost to convey the seriousness of the regulatory ambiguity facing our member companies and their customers each day as consumer demand for products containing hemp and hemp derivatives continue to grow, along with the commercial availability of such products, especially those which count CBD as an ingredient.

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While most of the stakeholders participating today understand the farm bill did not alter FDA's authority over the use of such ingredients in FDA-regulated products, there is mass confusion in the marketplace for the public, for suppliers and retailers and also for state regulators.

From ingestible products including foods, beverages and dietary supplements to topical items such as creams and lotions, the demand for CBD products for both human and animal use is already staggering and growing rapidly.

In fact, just last month, a Consumer Reports survey found that more than a quarter of Americans say that they've tried CBD, while one out of seven of those people said they use it every day.

Because of the consumer interest in this emerging market and the desire of our members to provide products which their customers are seeking, we're fielding more and more questions from companies that are understandably seeking clarity about the current regulatory framework for the sale and labeling of products containing CBD in particular.

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And while we want to be in full compliance with all of FDA's requirements, we also want to ensure our members have appropriate assurances that the products they're merchandising are both safe and being sold appropriately.

Having said that, FMI sees the regulatory challenges surrounding the legal and appropriate sale of hemp and hemp-derived products as a critically important policy issue. And given the prevalence of these products in the marketplace, we respectfully urge FDA to move swiftly to provide additional clarity and establish a pathway forward.

In conclusion, please know that our industry would welcome the opportunity to be a resource to the agency throughout this regulatory process and we look forward to working with FDA, USDA and Congress as things move forward. Thank you very much.

MS. CRISTINZIO: Thank you. Now we are moving onto our next panel of speakers that are representatives from state and government officials and entities. Our first speaker is Pam Miles, for two minutes.

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ORAL COMMENTS & FORMAL PRESENTATIONS WITH SLIDE DECK

STATE/GOVERNMENT OFFICIALS/ENTITIES

MS. MILES: Good morning. I'm Pam Miles, and I'm the past president of the Association of Food and Drug Officials, AFDO. AFDO has been working toward uniformity in food and drug laws since 1896. AFDO represents federal, state and local food and medical products regulators primarily in the United States. Thank you for the opportunity to present at this public hearing.

Across the United States, state and local regulators have been confronted with the huge onslaught of CBD in food products and cosmetics being sold in all types of venues, from farmers markets, convenience stores up to some of the largest retailers and we also have standalone CBD stores opening in many states.

Recently a national quick service restaurant chain served CBD-infused sandwiches as part of a promotion. Currently states are struggling with a lack of sound, scientific research available on CBD and long-term health impacts of ingestion, including

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those to children.

Nearly all peer-reviewed research has been based on the usage of CBD as a drug. Most manufacturers are approaching CBD as if it is as safe as food ingredients that have had substantial amounts of long-term research.

Further, new reports across the United States have documented that food products purporting a specific quantity of CBD frequently are not adequate. Further, with the widespread distribution and usage of CBD across the U.S., it's making it very difficult for state and local regulators to continue with our stance that CBD cannot be used in food products.

AFDO is hopeful that FDA will begin to provide significant leadership as it relates to CBD, including research related to its health impacts. Thank you again for the opportunity to participate today. AFDO looks forward to collaborating with FDA on this important regulatory issue. Thank you.

PANEL MEMBER: Hi. Also I think AFDO is in sort of a unique position with state governments. And I'm wondering if there's -- if you're aware or have

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submitted to the document any systematic collection of adverse events associated with cannabis products or CBD products specifically.

MS. MILES: We do not have that right now. I believe we did do a national survey with all of our states and we're collecting the information that we are going to be making comments, written comments.

PANEL MEMBER: Any idea of when that might be finished or available?

MS. MILES: It is finished.

PANEL MEMBER: Oh, it is finished?

MS. MILES: I'm not sure. And I don't know if Brenda has -- Brenda's going to speak next. I don't know how many states have replied.

PANEL MEMBER: Okay.

MS. MILES: And we've been reaching out. But we have quite a few replies. And we're actually putting together that information right now.

PANEL MEMBER: Okay.

MS. MILES: And our executive director will be sending written comments.

PANEL MEMBER: All right. Thanks, Pam.

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MS. MILES: Thank you.

MS. CRISTINZIO: Thank you. Next up is Brenda Morris.

MS. MORRIS: Thank you. I'm Brenda Morris, and I'm president-elect and representing the Association of Food and Drug Officials. Currently a patchwork of laws exist for CBD across the nation, with very little consistency or uniformity in regulations, which is creating a Wild West type atmosphere where nothing -- anything is allowed.

CBD products in foods and cosmetics are being shipped in interstate commerce and this is clearly within FDA's regulatory authority. As of last week in a survey that AFDO has conducted in which we had 33 responses, 13 of the states that responded have legal CBD sales.

Over half are using 21 CFR 117 as their primary regulatory authority with a portion of those also applying parts of the dietary supplement regulations. The remainder states are using the retail food code and a few relying on GMPs under either 110 or 117.

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For states that are not allowing CBD, most all acknowledge they have insufficient resources to effectively end the sales of CBD in food and cosmetics in their state. Of the 20 responding states where CBD sales is not legal, only eight states were considering any sort of enforcement action on those with clear health claims and even when there are clear health claims, many states are not taking any action.

Many of the states noted they are struggling with the appropriate approach given the lack of federal participation in this process.

FDA began hosting 50 state meetings in 1998 and two key statements that were made by FDA at those early meetings were the vision for the future is an integrated food safety that focuses on preventing harm before it happens and food safety reform at the federal level will be incomplete and insufficient unless it strengthens state and local roles and builds true partnerships across all levels of government.

With the legislation of hemp as part of the farm bill, most every state legislature in this country considered and many will enact some type of

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state hemp growing bill in 2019, increasing CBD production. AFDO looks forward to collaborating with FDA on this very important regulatory issue. Thank you so much for allowing us to speak.

PANEL MEMBER: And the results of that survey of the states you'll be putting on the docket?

MS. MORRIS: Yes, we will.

PANEL MEMBER: Thanks so much.

MS. CRISTINZIO: Great. Thank you. Next, we have Joseph Reardon, speaker number 53.

MR. REARDON: Thank you very much for the opportunity to be here today. Again, my name is Joe Reardon. I serve as the assistant commissioner for consumer protection at the North Carolina Department of Agriculture and Consumer Services. I want to thank FDA today for this opportunity to bring these comments forward.

North Carolina, like many other states, has a rapidly growing industrial hemp industry. As of this year, we have over 1,000 growers licensed in the state of North Carolina, 12,000 acres of product that is being grown and 4.9 million square feet that's being

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grown in greenhouses. We have 601 registered processors just in the state of North Carolina alone.

The farmers in North Carolina have invested over a hundred million dollars in this current crop. We know that CBD is being sold across the nation in dietary supplements in food and drink and there's no regulatory framework for that to be done.

Due to the availability of these products in the marketplace, we've done some survey work to better understand the availability of these products in the marketplace. We've also sent letters out to our industry in our state informing them of the information that Dr. Gottlieb provided last year and earlier this year of FDA's position on these products.

We have done some market survey to understand the prevalence of these products in the marketplace to give us a more informed position here.

And in doing so and better understanding the prevalence of these products in North Carolina and the future production of those products, North Carolina will be seeking and will now ask our state legislature to give us the authority to have a regulation in place

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for the production of these products.

We will use the FDA's 21 CFR 111 as the foundation of writing those regulations. We believe with the support of our industry there and the input of our industry, we will be able to put a regulatory framework in place for the production of those products to ensure the suitability of those products going into the marketplace.

We believe a uniform and consistent approach is critical to consumer safety and long-term viability of this emerging industry. Consumers and industry alike benefit from a regulatory framework we believe to ensure the identity, the purity, the strength and the composition of those products.

The one thing I do want to say though, to be clear, without the FDA's guidance and leadership, individual states may carve out their own regulatory exceptions for CBD, creating a patchwork approach which will hinder the nationwide growth of this industry and endanger consumers.

We urge FDA to resolve the statutory issues and properly establish a legal pathway for CBD

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products to enter the marketplace. I want to thank you for the opportunity today to provide these comments.

We are hearing from some states that they would like to extend the written comment period from July to August. We think with the amount of people here today and the interest in this, you want to get all the feedback you can. So it may be in the FDA's interest to extend that written comment period. Thank you very much.

PANEL MEMBER: I have a question about your market survey.

MR. REARDON: Yes.

PANEL MEMBER: I know it's a big agricultural crop, particularly in your state. But when you did the market survey, do you have a sense of the synthetic market as well? There's a lot of synthetic CBD products out there as well.

MR. REARDON: We didn't look at that in our survey. We looked at the prevalence of it being sold in foods, what types of foods. Are they the traditional gummies that are being marketed to

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children? We wanted to understand the prevalence of health claims on those products as well, understand the prevalence of smokables, which is wide in the market today.

So we really wanted to understand what was in the marketplace, what the compliance level was on that and what information they need from the federal government or others to better understand what the legal framework is.

PANEL MEMBER: Yeah. That would be great to see that data if you could submit that to the docket. That would be great.

My other question is when you're contemplating a regulatory scheme at the state level, are you thinking about restrictions on retail, age limitations or labeling or other types of restrictions?

MR. REARDON: We're not. We're simply looking for a regulatory framework on the extraction, production and reconstitution of CBD or cannabinoid-related compounds, including terpenes and other constituents that may be in the hemp plant.

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We are really, like other states, looking for that guidance, and the industry in our state is as well from FDA to show that we have a uniform and consistent platform. What we're hearing from our industry, and you've heard it today, is they want a legal pathway to bring these products to market. So we look forward to partnering with you. Thank you.

MS. CRISTINZIO: Thank you. Our next speaker is William Tilburg, number 54. William? William's not here? All right. I'm going to welcome to the podium Erin Bubb, number 55, from the Pennsylvania Department of Agriculture. Erin is our first speaker to present for five minutes with slides.

MS. BUBB: Good morning, and thank you. I'm here today to represent the Association of American Feed Control Officials, known as AFCO.

AFCO is a voluntary membership organization of the states and federal government agencies, as well as government agencies from other countries, responsible for the execution of laws and regulations pertaining to the production, labeling, distribution and sale of animal feed and feed ingredients.

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Many states' laws or regulations reference the official terms and definitions of the AFCO official publication. This is the most comprehensive list of approved feed ingredients. There are three ways for an ingredient to make its way into the publication: through a food additive petition, a definition request to AFCO or a generally recognized as safe, also known as GRAS, voluntary notification to FDA.

All three routes include a safety and utility review done by FDA's Center for Veterinary Medicine. All three routes result in the ingredient being published in the AFCO official publication and accepted by the states as ingredients in animal feed and pet food products.

Let's see. I'm not advancing. But I'm going to continue. Okay. AFCO and FDA have a longstanding MOU that allows FDA to accept animal feed ingredients that have come through the AFCO ingredient definition process.

During this process, CVM reviews the ingredient submission packet to ensure the new

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ingredient has a standard of identity and has been evaluated for safety and efficacy for its intended use.

This route has served regulatory officials, the regulated industry and the public well by providing consistency to the animal feed ingredient approval process.

AFCO's and CVM's primary concern is the safety of the ingredient. AFCO awaits the industry's scientific evaluation of the safety of hemp-derived products in order to bring these ingredients legally into the market.

The AFCO process does take time. If additional resources could be allocated to CVM to more quickly complete their technical review, the entire process could be completed sooner.

Hemp seed oil, hemp seed meal or seed cake and whole hemp seeds are products expected to be reviewed by AFCO and CVM for use in animal feed when industry completes the safety studies. Materials and products that are CBD or phytocannabinoid-infused need to be treated as drugs and kept separate from other

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hemp products used in animal feed or pet food as there is currently no nutritional basis for these compounds to be allowed in animal feed or pet food.

AFCO is ready to participate in getting hemp products into the animal feed market as nutritional sources. We are waiting on the industry to complete the safety studies.

Lastly, I also respectfully request a 30-day extension for written comments to August 1st. Ah, there's my last slide. If there are any questions, folks are welcome to visit the afco.org website, generalinquiries@afco.org and those that are interested in ingredient definitions and providing a submission through AFCO can use the general email of definitions@afco.org. Thank you.

PANEL MEMBER: A quick question. When you do your evaluation of feed ingredients, do you consider residues that might be left in the tissues of food-producing animals?

MS. BUBB: That is absolutely one of the evaluations that would be conducted. And that is the information that is needed in a submission,

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absolutely.
PANEL MEMBER: Can you characterize for me what you see on the state level in the use of these products in animals?
MS. BUBB: Currently states are not recognizing the legality of hemp-derived products in animal feed. What we are seeing personally, in Pennsylvania, we are seeing CBD-infused products, pet treats especially. And we are issuing regulatory actions on such products in the marketplace. We are issuing stop sale orders, withdrawal from marketplace.
We do have a burgeoning, growing hemp industry in Pennsylvania. We want to see it succeed. They're very, very interested in hemp-derived products for the use in animal feed.
And we are educating them and supporting them in their efforts for study and research so that hemp-derived products such as hemp seed oil, hemp seed cake, meal could be used for nutritional purposes in animal feed. Okay.
PANEL MEMBER: To what extent are you seeing the use of CBD in the feed of food-producing animals?

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MS. BUBB: Could you repeat that?
PANEL MEMBER: To what extent are you seeing CBD in the feed of food-producing animals?
MS. BUBB: We have not seen anything like that yet. We do look for that type of product in the marketplace through inspections. We have not come upon that yet. The CBD-infused products are mainly being found -- wholly being found in pet treats and more of the treat/supplement world, maybe even for horses.
But right now, food production animals, they have not really crossed that line to put CBD into those food-producing animals at this time, although there's talk about it. There's interest. They would like to do it.
PANEL MEMBER: Okay, and one other question sort of on that regard. Are you seeing -- because we have heard and seen news stories about this, sort of the stalks of cannabis and hemp plants being used for animal feed like other grains are being used.
MS. BUBB: Okay. Have not seen anything like stalks, leaves or anything like that as forage or as a

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fiber ingredient yet in animal feed. I do know that again there's been some limited research. I know Penn State and University of Pennsylvania have been involved in some limited studies. They've talked about them on some different podcasts and some different outlets. There's been, you know, not a lot of information released yet.
PANEL MEMBER: Right. But not sort of widespread usage of those parts of the plants that might be used for other areas?
MS. BUBB: No. I am not familiar with that at all, no.
PANEL MEMBER: Okay. Thank you.
MS. BUBB: Okay.
MS. CRISTINZIO: Great. Thank you, Erin. And sorry for the technical difficulties. We have now a break on the schedule and we are still going to take the break, even though we are running a little bit behind because I know everyone could use a little stretch. We will begin again at 10:45. Thank you.
(Whereupon, the foregoing went off the record.)

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MS. CRISTINZIO: Please sit down. We're about to begin. We have someone joining us via phone for a two-minute presentation. Thank you, everyone. Hopefully you had a nice break. We have one person who has joined us via phone for an oral comment. She is a consumer. Her name is Pamela McColl and she is on the line. Pamela, you are up for two minutes.
MS. MCCOLL: Hi. Thank you. Good morning, everyone. I am a social historian and I've been active on the marijuana file in Canada for over seven years and I have the following to say.
The public is up against a narrative that is at war with science. The marijuana lobby deceives by saying consuming has no lasting negative impacts. They deceive by denying cannabis hyperemesis syndrome and addiction. The DSM-5 establishes clearly marijuana is highly addictive.
Every week, patients on MJ enter the Denver Health Center ER and must be restrained so as not to harm themselves or others. In casual users, THC can disrupt working memory and focus for 24 hours, says Harvard researchers. The true believers of

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cannabinoids, there can be placebo effect.
But it is critical that all be informed with the risk associated with CBD and THC. This includes pregnant women and the risks to the fetus, including developmental damage and DNA damage.
In 20 years of research on human cells, I have never found any other drug, including heroin, which comes close to the DNA damage caused by marijuana, Dr. Hugh Davis, at Health Canada. Even minuscule amounts of THC are not safe for human consumption.
Health Canada warns men not to use MJ if they wish to have children. MJ products put young adult males at risk of the most aggressive type of testicular cancer. The FDA must respond to the malevolent billionaire's marijuana experiment that has medical professionals and states in extreme anxiety over the damage industry profiteering has inflicted on the public.
For Epidiolex, the only FDA-approved CBD product approved for Dravet's and LGS, package warnings include suicidal ideation, driving impairment

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and hepatocellular injury, requiring liver function testing before starting. Are there such warnings for CBD products being sold at Walgreen's today? Are consumers buying Whoopi Goldberg and Maya's CBD THC rubs informed of these risks?
With 3,000 marijuana studies and high potency product research enter biomedical literature, reclassification is but an attempt to access the U.S. banks. We changed the conversation. Now we've changed the laws, boast the lobbyists. The FDA must take back this conversation and protect the public.
I would encourage you to call Dr. Hugh Davis from Health Canada, who in the late 1990s did a risk assessment of THC and found that even minuscule amounts were not safe. He was fired. That science was shredded. And the Canadian government lied to the United States government in saying that they had no risk assessment on this drug.
The subversion of truth and science and what's gone on in North America should cause everyone great concern and reason to pause and do risk assessments on these drugs and analyze the influence

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of the billionaires and the industry that have influenced public sentiment and dictated a very deceitful campaign. So with that, I conclude. I applaud the FDA for looking into this and I beg them to not reclassify THC or CBD. Thank you very much.
MS. CRISTINZIO: Thank you, Pamela. All right. I want to make just one brief announcement. I think we have a number of people waiting for seats in overflow. And I believe that we have enough space to pull them into the room.
I just want to make people aware, if you have a bag on a seat or you're saving a seat, that we would like everyone have a seat in the room. Thank you.
All right. Our next speaker represents academia. We're moving onto the formal presentations with slide deck part of the day. And we have Barry Gidal.
FORMAL PRESENTATIONS WITH SLIDE DECK
ACADEMIA
DR. GIDAL: Good morning. Barry Gidal, University of Wisconsin School of Pharmacy. My theme today is to discuss potential unintended consequences

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that may arise from our gaps in our knowledge base.
Now, as has been alluded to by other speakers this morning, CBD is a complicated molecule. It has a complicated biotransformation pathway, as you can see from my slide, being metabolized by a variety of cytochrome p450 enzymes to at least one active metabolite, at least active in a seizure model.
CBD also has a complicated pharmacokinetic profile. We've talked about dosing and the variability of dosing this morning. CBD exposure can vary by route of administration, whether or not this drug is taken with food or on an empty stomach and may vary by other patient-specific variables such as liver function.
Now, one of the things that I want to talk about some knowns and unknowns. And I first need to emphasize that we've known for a while, looking at the scientific and the metabolic literature, the enzyme literature for a while, that CBD as well as some other cannabinoids such as THC have the potential to cause drug interactions, specifically enzyme inhibition of a variety of different important drug-metabolizing

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enzymes.
But I want to emphasize it really wasn't until the Epidiolex clinical development, the FDA-approved preclinical and clinical development program that we began to really appreciate and understand the clinical ramifications of these potential drug interactions.
Now, we know again, if you harken back to my previous slide, because of the metabolism of CBD, there may be impacts of other enzyme-inducing drugs that may alter the exposure of this drug. We simply don't know enough yet.
And there's more importantly perhaps the effect of CBD on other drugs that may be used that maybe go beyond the anti-seizure drugs that have been studied so far and that's what I hope to emphasize today.
Now, let me talk about some knowns that came out of the Epidiolex clinical development program. We know that an important drug, clobazam, which is used in epilepsy, part of its metabolism can be inhibited by CBD. Clobazam is active. It's metabolized by

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cytochrome P450 3A4.
Interestingly enough, clobazam levels don't really change. I'll get back to why I think that's important in a few moments. But the active metabolite, the N-desmethylclobazame levels, have been shown quite consistently to go up. And this may in fact be responsible for some of the adverse effects that we see such as sedation in the clinical trial program.
Now, let me talk about some other things that maybe are less well recognized. This graph may be a little bit difficult to read. This is some work from a few years ago of looking at the effect of not just CBD but also THC and other drug-metabolizing enzyme systems such as cytochrome P450 2C9.
Now why am I telling you? Why is this important? Let's go beyond the anti-seizure development program or anti-seizure co-medication. I think many in this room are familiar with the drug warfarin. Warfarin also has a complicated pharmacokinetic profile. The more active enantiomer of warfarin, the s-warfarin, is extensively

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metabolized by P450 2C9.
Why is this important? Data that came out of the University of Alabama group recently showed again, as we broadened our use of CBD, in a patient receiving warfarin, which is a very narrow therapeutic index drug, in fact the anticoagulation potential of this drug as measured by INR went up dramatically when CBD was added. Now, this could have serious health implications.
Now, one of the other things, I want to get back to what I mentioned about clobazam. Clobazam is metabolized by an enzyme called cytochrome P450 3A4. We know from the clinical development program of Epidiolex that there was no interaction with clobazam.
We also know from published literature that there is no inhibition of metabolism of a probe drug for at least one isoform of P450 for midazolam. However, a report that just came out in the clinical literature from Rita Alloway and colleagues at University of Cincinnati looking at tacrolimus, which is an important and potentially toxic immunosuppressive drugs. It's used in a variety of

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regimens, including transplantation.
In fact, if you look at this data, a patient had been stabilized on tacrolimus, was part of also this CBD, the Epidiolex program. And within the label doses of Epidiolex, had a dramatic increase in the plasma levels of tacrolimus, necessitating drug reduction.
So again, why is this important? There's a lot of things we know. There's a lot of things we don't know. There is the potential for multiple drug interactions from CBD. The exposure-concentration relationship is still unclear. And in fact, some patients may be at risk if we don't have adequate oversight and involvement of healthcare practitioners when using this drug. Thank you.
MS. CRISTINZIO: Thank you. Our next speaker is number 58, Igor Grant.
DR. GRANT: Thank you very much.
MS. CRISTINZIO: Give us one second to pull up your presentation.
DR. GRANT: Sorry about that. I didn't hear what was just said. Okay. My name is Igor Grant.

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Thank you very much for allowing me to speak. I'm professor of psychiatry and director of the Center for Medicinal Cannabis Research at the University of California. That center was established about 20 years ago by the legislature of the state of California as perhaps the first of the national centers to actually address medicinal cannabis per se.

There are a couple of points I would like to make today beyond the fact that there is emerging science suggesting that THC, CBD and potentially other cannabinoids may have medicinal value.

We have some challenges facing us, including research that is limited by the availability of the increasing number of products that patients are consuming in states where cannabis or medicinal cannabis laws exist.

We also have some viscosity, shall I say, or I use the term barriers. It's not really barriers. Nobody's trying to prevent research obviously. But there is a kind of slowness in the process of doing research that perhaps could be improved. And that includes the fact that many federal agencies need to

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opine and regulate this research.

This is consequential because, in our view, we are rapidly getting behind the curve in terms of what is happening in the real world and what patients are utilizing. And we need to take steps to catch up and to provide the public with correct scientific information, including positives and negatives.

Now, as far as the CMCR center, we early on completed a number of studies, mostly focused on neuropathic pain and these used the NIDA's THC-based products. These all showed in the short term, in limited studies, positive results and these findings have been also confirmed many times by other investigators and by the National Academies report. I don’t have to go through that again.

Just by way of summary as far as THC-based products and neuropathic pain, the efficacy seems to be comparable to other used drugs and the toxicities certainly are no worse.

Currently the CMCR is moving in new directions and these include, first of all, in the case of THC-based products, to look at modes of

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administration, in particular because these do influence how patients are able to tolerate these drugs. The other is expanding to the range of conditions and the third is to focus much more on cannabidiol, which is a focus of this meeting.

We know that the route of administration matters. People have seen these curves before. I won't dwell on them.

One thing that was very interesting in some of our early studies with the THC-based products from NIDA is that actually rather small doses of THC seem to produce benefit in neuropathic pain.

And these were doses that were much, much less than people would typically consume if they wanted to get a high. So this idea of the therapeutic window needs to be explored further, and that may bear also on safety considerations such as for driving.

So I'd like to spend the last minute on just suggesting some paths forward to consider. One of course is that we obviously need more studies and including, as I've mentioned, routes of administration, different kinds of products people are

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using, products to put on their skin and so forth. We have no idea if these products are absorbed or are affected by those routes.

I said before we need to get ahead of the curve of what's going on in the public. Otherwise, the public will continue to use these products without appropriate information. But we need to get the information out in a more nimble fashion.

So what does that nimbleness suggest? Perhaps permit research exemptions such as envisioned in the Schatz-Feinstein bill, not requiring detailed pharmacology for all new cultivars if DEA approves manufacturing and if the FDA still requires all these toxicology studies, we'll be in a problematic area. And I've listed some of the other factors that I think should be considered. Thank you very much for your attention.

PANEL MEMBER: I have a question. I saw that you had -- you talked about how routes of administration matter and you talked about inhaled versus edible. And I wondered if there was any data on sort of absorption through the skin as would be

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received through a cosmetic.
DR. GRANT: I am not aware of it. Maybe there are data out there. But that's exactly the point I was trying to make, that we need to look at these modes of administration.
People claim that, you know, putting some kind of salve on your elbow helps with arthritis. Maybe it does. Maybe it doesn't. But we just don't know. An that's the kind of study that needs to be done.
PANEL MEMBER: And in addition to differences in efficacy with different routes of administration, have you found any differences in safety?
DR. GRANT: No, because we are now doing an actual comparison of an oral product, which is dronabinol, to a NIDA THC product. So we'll know more about that.
What we know from the literature of course is, because of the different pharmacokinetics, the onset of action is much delayed through oral administration and so forth. But in terms of long-term tolerability, I don't know that we have data on

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that.
PANEL MEMBER: Has your program found value in looking at real-world datasets to support some of your questions? So electronic health records, claims data, any other aspects?
DR. GRANT: We are in fact moving in that direction and particularly wanting to work with institutions within California itself to do that. But as of yet, we have not don't that.
MS. CRISTINZIO: Great. Thank you so much.
DR. GRANT: Thank you.
MS. CRISTINZIO: continuing in the academia category, we have number 59, Bill Gurley.
DR. GURLEY: Thank you very much for the opportunity to speak this morning at this public hearing.
MS. CRISTINZIO: Can you move the microphone up a little?
DR. GURLEY: Yeah, that's a -- us tall guys have a tough time with this. That's about it. Sorry. I'm taking up all my time playing around with the damn microphone. All right. So can you hear me now? All

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right. Very good.
All right. Again, thank you for the opportunity to speak. My name is Bill Gurley. I'm a professor of pharmaceutical sciences at the University of Arkansas for Medical Sciences College of Pharmacy and I'm also a principal scientist at the National Center for Natural Products Research. I've also been doing research in botanical dietary supplements for the past 23 years.
My talk this morning is entitled "Content v. Label Claim: A Survey of CBD Content in Commercially Available Products from the State of Mississippi." And in short, this study provides a snapshot of CBD product quality or lack thereof and is likely representative of the fraudulent nature of many, if not most CBD products currently sold in the U.S. market. I'll skip that slide.
Now, for conventional medications regulated by the FDA, product labels must accurately reflect the content of active ingredients within a container. For dietary supplements however, especially botanical dietary supplements regulated by the FDA under the

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dietary supplement Health and Education Act, it's not uncommon for a product's contents to differ markedly from its label claim.
Content versus label claim discrepancies are especially prevalent for dietary supplements marketed for weight loss, exercise performance enhancement and sexual performance enhancement. And so, the question is are CBD-containing products also subject to significant discrepancies between actual content and label claim.
All right. So a survey of CBD-containing products was conducted by investigators in the National Center for Natural Product Research to compare CBD as well as THC content to label claims for CBD. And there's 25 various CBD-containing products that were purchased from retailer vendors in the state of Mississippi and submitted for analysis by law enforcement officials from the Mississippi Bureau of Narcotics.
Product label claims ranged from either no label claim to as much as 1,500 mg per container. And products were analyzed by gas chromatography with

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flame ionization detection as well as mass spectrometry for both CBD and THC content as well as the presence of synthetic cannabinoids.

Now the data from the first 13 products represented in this table and the second column is the product label for CBD. Column three is the quantity of CBD detected within the product. The fourth column is the percent label claim. The fifth column indicates those products whose THC content exceeded 0.3 percent and the last column indicates products containing synthetic cannabinoids.

Now, in most instances, product label claims misrepresented the actual CBD content within the product. Percent label claims ranged from indeterminate values -- in other words, there was no claim for CBD -- to products that contained very little CBD to others that far exceeded the label claim.

In one instance, the CBD content was almost 23 times greater than the quantity claimed on the label. In three instances, THC content exceeded 0.3 percent, with one product containing 45 percent THC.

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An even more disconcerting finding was the fact that one product was adulterated with synthetic cannabinoid.

The second table depicts results from the next 12 products. Once again, percent label claims ranged from indeterminate values to values that were either far below label claim or, thankfully, in one case, exactly matched the label claim. In four instances -- in four instances, little to no CBD was detected. Yet three of these products, all of which were vaping oils, were adulterated with synthetic cannabinoids.

So in summary, a small sampling of CBD products acquired from retailers in the state of Mississippi demonstrated marked variability in actual CBD content versus product label claims. Several products had no CBD while others contained significantly more than label claims.

One product contained only THC while others exceeded the 0.3 percent limit on THC. Several vaping products contained CBD but were adulterated with synthetic cannabinoids. So clearly many CBD products have little or no relation to any potential benefits of CBD itself and pose a range of risks to consumers from both fraud to serious health dangers.

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The public demand and potential abuses in this unique market sector warrant special attention to regulation of such products in terms of label claim restrictions, good manufacturing practice enforcement and monitoring for potential adulterants. Thank you.

MS. CRISTINZIO: Thank you. Our next speaker is number 60, Rick Kingston.

DR. KINGSTON: Good morning. My name is Rick Kingston, and I'm a clinical professor of pharmacy at the University of Minnesota, an adjunct professor at the University of Mississippi in the National Center for Natural Product Research and lastly I'm president, regulatory and scientific affairs at SafetyCall International. My comments today will dovetail comments made by my colleagues, Dr. Gurley, Koturbash and Walker at the University of Mississippi.

At SafetyCall, we have the distinction of being the only academically affiliated, multidisciplinary healthcare practice providing third party post-market surveillance for both human and animal product categories. That includes conducting post-market surveillance for medical cannabis programs in multiple states, including Minnesota, where we are the sole provider of safety surveillance for all medical cannabis companies and the dispensaries in the state.

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First, I wanted to comment on the pet side of the cannabis safety issue and echo some of the concerns raised by Dr. Gurley regarding issues of product integrity for many CBD-containing products in the marketplace.

Our pet poison helpline has documented cannabis exposures in pets for over a decade and more recently for CBD-containing products where adverse effects reported after pet exposures to such products is oftentimes resulted in clinical effects that are uncharacteristic for what we would expect for CBD such as significant ataxia, lethargy, vomiting and, in some cases, significant cardiovascular effects.

In fact, for CBD exposures, up to 45 percent of the incidents require veterinarian intervention.

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This suggested to us many of these exposures may be secondary to adulterated CBD products that contain other potentially toxic compounds.

As for information regarding properly manufactured cannabis products such as those found in medical cannabis products in the medical cannabis program in Minnesota, I believe components of that program could be considered as part of a framework for an FDA-regulated program for CBD.

This would include establishing GMPs, sharing of consumer clinical experiences and implementing robust mandatory adverse event reporting -- monitoring and reporting such as required in Minnesota.

In fact, in the Minnesota program, there are requirements for 24/7 access to medical professionals for fielding any safety issues, including reports of adverse events.

Regarding post-market surveillance for other cannabis products, we are already providing standard of care pharmacovigilance to best practice companies that manufacture both CBD, THC and CBD combination THC products.

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In these circumstances, these companies have us provide 24/7 access to medical professionals to field any safety issue, including reports of adverse effects and documentation of such data for analysis and benchmarking to aid in safety profiling and conducting surveillance for safety signals.

Quite simply, in a market where such products are not currently regulated at a federal level, these companies seek to distinguish themselves from companies that do not adhere to best practices to protect their consumers.

We also have worked very closely and collaborated with the National Center for Natural Product Research at the University of Mississippi regarding investigations into botanical adulterants where proper characterization of botanicals including cannabinoids. This includes our mutual efforts to support the American Botanical Council and their botanical adulterants prevention program, known as BAPP.

So in summary, the question is what would be a path forward for FDA to gather or develop solid

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safety information for CBD. We believe tapping into the programs mentioned here would be a good start and also allow access to safety data and clinical experience with cannabis-containing products, including CBD-only products.

We would specifically recommend initiating data-sharing with the Minnesota program, where there are currently more than 16,000 patients enrolled in their program where clinical experiences are being prospectively documented.

As for a potential regulatory framework for CBD, we think a model with components similar to Health Canada's natural health product regulatory framework might be considered, which would include GMP development, product registration and a post-market surveillance process including submission of adverse event data along with comprehensive adverse event data analysis for signal detection and investigation into any potential safety issues.

This could also include a conditional registration process for companies that adhere to a variety of best practices for safety confirmation and

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product stewardship. Thank you very much.

PANEL MEMBER: Excuse me. Just a follow-up question. I hope that you submit some of the details about the Minnesota experience to the docket. This is a rich source of information and I think we'd really appreciate that help. Just I wanted to clarify, these are data on both pet exposures and human exposures?

DR. KINGSTON: That's correct. We have two sides of our practice. One is our human toxicology staff and then we have a whole veterinary team of experts. And so, our pet poison helpline collects information from the general public as an animal poison control center.

But we also do it for companies that actually market products. So we have information from both areas to compare and contrast. And maybe in comment to your question about access to the Minnesota data, I would strongly encourage FDA to reach out to Minnesota where we could share information with the patients that we're collecting that clinical experience because the spontaneous reporting of adverse events which we're documenting is then integrated within their

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system of clinical experience. So I think it's a very rich program and we'd certainly like to see some collaboration there.

PANEL MEMBER: Thank you. So you're contributing data to that other system now too?

DR. KINGSTON: Yes. We're the sole supplier of all the spontaneous reported adverse events from our 24/7 call center.

That information is then given to the state of Minnesota and the medical cannabis program within the Minnesota department of health. And so, we collaborate on conducting safety surveillance and signal detection.

PANEL MEMBER: Thank you.

PANEL MEMBER: So I just have one more question for you. Sorry. Do you have any estimate on the relative size of the market related to the frequencies that you're seeing these experiences?

DR. KINGSTON: The size of the market? You're talking about in general?

PANEL MEMBER: Yeah, and you mentioned that -- you mentioned that you have the data for specific

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companies. So I would suspect that you would know relative to their marketing amount how much -- what the frequency is for reporting.

DR. KINGSTON: I'd say the frequency for reporting in the general market is pretty small, to be honest with you.

PANEL MEMBER: Okay.

DR. KINGSTON: I think that there's a small number of companies that are ahead of the curve and are actually engaging organizations like ours to do third party assessment and investigations into potential adulteration and monitor the experience of their products.

PANEL MEMBER: But I guess my question is more on the actual adverse events related to a particular product.

Would it be -- you know, you mentioned 50 percent of these need veterinary care and I guess I'm thinking if I'm a company and I have a product and you're taking all my adverse events for it, then I know how much I'm marketing and you know how many adverse events I have. So I know what that frequency

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is.

DR. KINGSTON: Right. Okay. So there's a couple of answers to that. One is if you look at it big picture and having the experience from the public poison center perspective, as previously being a director in that area, it's probably got one of the lowest incident rates that I've seen for a marketed product. It's rare that we get significant adverse effects, especially for these companies that engage us. So I think they have a higher quality product.

PANEL MEMBER: Okay. Thanks.

MS. CRISTINZIO: Thank you. Our next speaker is number 61, Igor Koturbash.

DR. KOTURBASH: Ladies and gentlemen, it's both a pleasure and honor being here today. My name is Igor Koturbash. I'm a faculty at the University of Arkansas for Medical Sciences and I'm also co-director of the Center for Dietary Supplements Research.

The mission of our center is actually to provide industry, regulatory agency and public with credible information, assessments and experts opinions about the safety of dietary supplements and various

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phytochemicals.

As cannabidiol falls into the category of phytochemicals, it is of our interest and especially because there is, as you know, about -- based on clinical data, about 5 to 20 percent of patients who receive Epidiolex during the clinical trial develop elevated liver enzymes. And if you pay attention to the warning label on Epidiolex, it clearly states the potential for hepatocellular liver injury -- for hepatocellular injury.

Therefore, we performed a series of studies within the last few years at our center and I would love really to share some of the highlights of our studies.

First of all, aspect number one, that cannabidiol, or we use cannabidiol rich cannabis extract that had 57.9 percent of cannabidiol in it. It cannot really cause liver injury. If for single administration case, you really need relatively high dose to achieve it.

In the context of repeated dose, then you have to use very low dose actually to cause liver

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injury evident as elevated liver enzymes, spiking levels of bilirubin and histomorphological changes.

Aspect number two I would like to point your attention to is a very high potential for CBD drug interaction, as has been mentioned today by various speakers. Of particular concern of course is CYP2B10 in mouse, which is CYP2B6 in humans, responsible for metabolism of the majority of endostatins as well as CYP2E1 which is a major cytochrome for metabolism of mostly frequently used make human antibiotics like ethanol and acetaminophen.

Furthermore our concern is in regards to the so-called biphasic response when various doses of cannabidiol can cause differential gene expression. For example, high dose will cause downregulation but low dose will cause upregulation, right? So that's why you may face really very differential responses on cannabidiol.

And the third concern of course is the potentiation of drug-induced liver injury. In the study, when we used the nontoxic doses of cannabidiol and mice received up to that one single administration

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of acetaminophen which was capable only to cause transient elevation in liver enzymes, when you cord administer them, we observed significant liver injury.

It was a so-called sinusoidal obstruction syndrome like if you would pay attention to the slide and we did 10 mg/kg CBD + APAP. It is a classical picture of the toxic destruction of sinusoidal and endothelial cells with further hemorrhage into the liver tissue.

We published some of our data. There are several more manuscripts at various stages under review to preparation and we certainly continue working in this field.

The three major points once again that cannabidiol, at least in the form of the cannabidiol-rich cannabis extract, can cause liver injury. It has a very significant potential for drug interaction and can further exacerbate other agents inducing hepatotoxicity.

So in my understanding, we just really are only scratching the top of the surface and it's like we're really just observing the tip of the iceberg.

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Our call is that clearly further research is needed to further understand the safety and drug interaction potential for CBD and CBD-containing products.

And we are looking forward to working with the regulatory agencies, with the industry and certainly with public to further understand this. Thank you for your attention.

MS. CRISTINZIO: Thank you. Next we have speaker number 62, Michelle Peace.

DR. PEACE: All right. Good morning. First, thank you for the opportunity to present our findings on the analysis of CBD products intended to be used in electronic cigarettes. I will also be submitting comments to the docket regarding laboratory testing standards before the deadline.

My name is Michelle Peace. I'm associate professor in the department of forensic science at Virginia Commonwealth University. My subject matter expertise is forensic toxicology and I do have a relevant scientific story for you.

I have been funded by the National Institute of Justice since 2014 to study the manipulation and

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use of electronic cigarettes to vape drugs other than nicotine and the impact on the criminal justice system.

We have certainly seen an increase in the submission of e-cigarettes and e-liquids into crime labs for analysis as evidence in criminal justice cases. With regards to CBD products, law enforcement is generally very confused about what they need to do about these products in terms of confiscating them and submitting them to crime labs. And there is deep concern about clogging the system that is already has tremendous workload.

To set the stage here, what is an e-liquid. The predominant components are the humectants that create the cloud, propylene glycol and vegetable glycerin mixed in some kind of ratio. We know that there are thousands of flavor profiles and that the most predominant drug is nicotine.

However, my lab focuses on drugs other than nicotine. We have evaluated herbal substances like blue lotus and kratom and dietary supplements. But our main focus is on designer drugs, legal novel

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psychoactive substances and drugs scheduled by the FDA.

What most people say about vaping drugs other than nicotine is that people know what they're vaping or they know they're vaping something that will make them high. We have been monitoring this website and similar websites for years. Companies do not list what drugs the e-liquids contain. But the descriptions in the user reviews will say this will get you high or this will create hallucinations for you or it will make you mellow.

The e-liquids are usually generally very expensive compared to nicotine e-liquids. In some cases, like you see here, they range from $30-ish to $2,000. You can also see the shoddy product packaging. In this particular instance, we found a dangerous synthetic cannabinoid, MDMB-FUBINACA and frankly nobody was surprised.

Shortly after publishing this finding, I received a call from a young man who was vaping CBD products and he had a really hard high that scared him. He wanted to know if CBD is supposed to do that

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or if he just had a bad reaction. We told him to send it to us for analysis and also purchased a number of the same e-liquid products directly from the manufacturer.

You can see here that the products appear professionally produced and the website is high quality and they proclaim 100 percent CBD extracts. Upon analysis, we found CBD in all of the products. We also found 5-fluoro ADB in the young man's sample and in what we acquired from the manufacturer. 5-fluoro ADB has sent thousands of people to the emergency rooms and been attributed to overdose deaths in the United States and Europe.

Several CBD samples we purchased from the manufacturer also contained dextromethorphan, the active ingredient in over-the-counter cough syrups. A consumer wanting to purchase CBD because they want to relieve pain or manage seizures has no idea of the chance of buying something that also contains dangerous drugs.

This is the case whether someone purchases from the Internet or walks into a brick-and-mortar

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store. We have seen a rash of reports nationwide of people being poisoned from taking CBD products that they purchased. In these particular headlines from North Carolina, dozens of soldiers went to the emergency room after taking CBD products purchased in brick-and-mortar stores outside of their military bases.

We began monitoring drug forms specifically regarding consumers who had bad reactions after taking CBD products. They don't know where to turn for help. They are embarrassed or afraid to report having had a bad reaction.

We have received more than 50 emails from consumers after we reported the adulteration of CBD products purchased directly from the manufacturer. In all cases, the consumer purchased what they believed was CBD.

Mostly people are afraid of the short-term and potential long-term symptom. They are afraid of losing their jobs and/or embarrassed to admit they took something that made them high. Convincing them to send me the sample is difficult. But many have.

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To highlight this problem, just two weeks ago, we received two CBD samples from the family of a 79-year-old woman who was convinced to take CBD by her grandchildren to relieve pain from rheumatoid arthritis. After not hearing from her for a few days, they did a wellness check. They found her hallucinating and still trembling days after taking it. Seventeen of the 18 samples we received contained a dangerous synthetic cannabinoid.

This unregulated industry with no -- with high public demand and no requirements in oversight for quality that is skirting the edge of legality has ample room for nefarious activity. Clinics will not find these kinds of drugs when they just do drug testing.

So we have significant concern with those who are reporting hallucinations or adverse effects are probably just going to say it was just THC when it was likely something else. Thank you for your time.

(Applause.)

MS. CRISTINZIO: Thank you. Our next speaker is number 63, Ryan Vandrey.

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DR. VANDREY: Okay. Good morning. So I want to just try to highlight a couple of things that I think are important and I want to note that although I work for Johns Hopkins, I'm here representing myself and not the university.

So from a regulatory perspective as a researcher, we know that CBD is the predominant byproduct of hemp and that's what most people have been talking about today.

From a research standpoint, it's confusing from a regulatory perspective because CBD is both currently unscheduled if it's derived from hemp. It's Schedule 5 under the CSA at Epidiolex. And it's Schedule 1 if it's synthetically derived. So that causes problems for us doing research.

Also, as mentioned by the gentleman from true Terpenes earlier today, it's not just CBD that can be derived from hemp. There are a number of other cannabinoids and non-cannabinoids that can be extracted. And those products can come to market. There are some on the market already. Minor cannabinoids like CBG, CBN, we have no controlled

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research on what these do pharmacologically in humans.

MS. CRISTINZIO: Can you move your microphone up a bit?

DR. VANDREY: Yes. Sorry. So in addition to CBD and some of these other minor cannabinoids, THC is an important constituent that is allowable in hemp products. Hemp is defined as 0.3 percent THC. But that's a percentage and not a total amount in a product.

A study conducted by my friend and colleague, Marcel Bonn-Miller, found that CBD oils sold on the Internet contained up to 6.4 mg of THC per milliliter of liquid.

And to kind of put that in perspective, laboratory studies that we've done at Hopkins have shown that oral doses of 10 mg of THC can produce mild to moderate drug effects and can impair cognitive performance. So the data there show 10 in a 25 mg dose orally administered and showing significant impairment on a working memory task.

In addition, route of administration is important. And so, we've conducted a number of

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controlled administration studies and showed that vaporization of cannabis produces a stronger drug effect and a greater impairment compared with smoking it. Smoking and oral dosing produce comparable peak drug effects. But the time course is very different.

We found that the blood cannabinoid concentration correlates poorly with subjective drug effects and impairment and that's important as a consideration for evaluation of these products. And I want to also highlight -- and things got wonky with the transition from Mac to PC again these days.

But even though these figures are a little bit hard to see, I'll describe an ongoing study that we have where we're acutely administering cannabidiol as a pure substance as well as cannabis containing a high concentration of cannabidiol and a low concertation of THC.

What we found is that when CBD by itself is orally administered, we don't see much in the way of subjective drug effects or impairment. When it's vaporized, we see a discriminable drug effect. It's not THC-like and does not produce cognitive

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impairment. But to consider CBD non-psychoactive I think is inappropriate.

Additional research -- this is with 100 mg dose of CBD. Higher doses administered at the University of Wollongong in Australia by Nadia Solowij have shown some mild cognitive impairment with a higher dose of CBD.

We found no THC in blood after administration of pure CBD, which kind of addresses the potential for conversion there. What we do see is difference in CBD in blood when THC is co-administered.

I also want to point out that when we did urine drug testing, two of our six participants had positive drug tests with a dose of about 4 mg of THC in this product. So the amount -- again, the amount of THC in the product is going to be important as these retail products come out.

So points that I want to make outside of the laboratory studies we've done is that standards for quality control testing and contaminants is urgently needed and while we know a lot about acute effects, we don't know much in terms of systematic evaluation of

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long-term health effects of chronic use of hemp or CBD products.

We need to have better data on special populations such as pregnancy, psychiatric populations, elderly and other at-risk populations. And I encourage the FDA to engage in a formal pharmacovigilance program as these products come to market. Labeling should clearly disclose the amount of THC, CBD and any other detectable cannabinoids.

And so, what I would encourage the FDA to do is to establish regulations immediately for content, for quality control and for labeling and to consider the use of existing CGMP regulations for drugs and supplements but also to urgently fund cannabis regulatory science and provide a pathway for researchers to better do what we need to do to help inform you guys. Thank you.

PANEL MEMBER: I have a question. You said that CBD has a drug effect, a psychoactive drug effect but not like THC. Can you elaborate on what you mean by that?

DR. VANDREY: Sure. So when we've

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administered pure CBD in the laboratory, people report discriminable drug effects. They on a drug effect scale report feeling a drug effect. But when we look at adjectives that are THC-like effects, do you get the munchies, do you feel impaired, do you feel high, and they say no to that. So the things that we typically see with THC administration we don't see with CBD.

PANEL MEMBER: So what do they describe as the drug effect?

DR. VANDREY: They've had a difficult time articulating exactly what they feel and it's been different from different people. The most common is relaxing, calm, somewhat sedating.

PANEL MEMBER: Excuse me. One other thing. I just -- just to clarify, I assume those studies were done in healthy volunteers.

DR. VANDREY: These were healthy adults who were non-cannabis -- non-frequent-cannabis users at the time. So they were all -- had tested negative for THC.

PANEL MEMBER: But had used it in the past?

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DR. VANDREY: They had used it in the past, but not in the prior month.

PANEL MEMBER: Okay, and second, like many other comments that have been made, we'd really appreciate any data that you could submit to the docket or make available, you know, in that way to us. Thanks.

DR. VANDREY: Certainly.

MS. CRISTINZIO: Thank you. Our next speaker, number 64, is Larry Walker.

DR. WALKER: Thank you very much for the opportunity. I represent the University of Mississippi. And just some -- it's a little off-center, but just a quick pointers on some background, we've had a program for several years with CFSAN for botanical ingredients research, a center of excellence there, not cannabis-related.

We also have been the contractor for many, many years for the NIDA drug supply program for cannabis and cannabinoids. We're a partner in the botanical adulterants prevention program of the American Botanical Council and have now ongoing a

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current expanded access IND for CBD extract in refractory childhood epilepsy at the University of Mississippi Medical Center with Dr. Ingram as the PI.

It's been touched on already here that in addition to the risk with cannabis smoking and presumably THC-related that there are also a number of potential CBD safety issues, product quality issues particularly, but maybe others as well that need to be considered.

In our program in Mississippi, which is just a small extended access IND, but I believe the first that was done in the, quote, "restricted" THC states on a CBD extract and the findings were, you know, so far generally it's well tolerated and the patients and the families seem to be happy.

But we have had, even with fairly low doses, significant side effects and especially in the drug interaction realm. So these are certainly things that need to be further studied and monitored.

A possible path forward it seems to us is prudent to have a multitrack approach with these products that are cannabis-related. In fact, we

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already have in some respects some of these programs existing. Dr. Sharpless mentioned the GRAS program already existing.

Our thinking would be that in the supplement world, some type of program with a special focus, limits on CBD and special focus on the NDI notifications, GMPs, adverse event surveillance, that we need to be able to gather this data and maybe some type of conditional registration for manufacturers that might participate in a quality stewardship -- safety and quality stewardship program.

There's also also ready the track for the development of botanical drugs under the botanical drug route or single chemical entity. And we're very much proponents and very much in favor of this.

But one of the key issues is how do we relax the restrictions on the availability of plant-derived material for clinical research. This has been a major issue for us in Mississippi and all other state programs that I'm aware of, how do we work under the federal guidelines with those types of materials. How do we source those? Even though we are the contractor

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for NIDA for this, it's not been easy for us.

And then, I think just it's been touched on by my colleagues, but about these state medical marijuana programs, although this is obviously out of the FDA bailiwick, so to speak, but I really think gathering data from those programs in some type of coordinated national way would really be very helpful for us in the future going forward.

And so, I would just mention these in summary. We need a lot more clinical research. We need a lot more clinical research on well-defined products, whether they're under controlled substances or not. This necessitates some relaxation of the restrictions for producing these materials for legitimate clinical researchers.

It would be outstanding I think if the FDA could conduct some basic studies in this realm. It's a national need. It impacts so broadly that I think it's very unique. We need to extend some of the animal work that's been presented here to look at NOELs, you know, very carefully.

We need I believe a national testing program

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for cannabinoid quality and standardization. You can see what the product picture looks like. A national adverse event reporting program for whatever products are out there and rapid response program for products where there are serious incidents. We need analytical backup on many of these things where serious incidents have occurred. And then, finally, if possible, to gather research outcomes in these state medical programs. Thank you very much.

(Applause.)

MS. CRISTINZIO: Great. Finishing out our academia category, we have Elise Weerts.

DR. WEERTS: I'm actually here on behalf of the college on the problems of drug dependence. And this is one of the longest standing scientific organizations focused on the problems of drug abuse and dependence and empirical data for its treatment.

I'm presenting also for Margaret Haney, who is the acting president this year, and I am the incoming president. Both of us study cannabis in laboratory studies.

So medical cannabis -- important in the

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discussion, is it marketing or science. This slide shows you the proliferation of advertising that's out there and convincing people that there's some medical benefit. It's very polarizing.

At the same time, the states have enacted laws that have so-called approved medical conditions. Up to 51 so far have been approved in the different states. And they're not even consistent in which things are being approved. So, for example, like New York could approve an antibiotic for the treatment of an infection and then Kansas could approve it for epilepsy.

We need science to inform policy. Is cannabis good or bad? The answer is actually it's a little of both. So it's pharmacologically complex. It has multiple constituents. And it can have medical benefit in some cases and then also have problematic use.

The cannabinoid receptor in the brain is widely spread. We're just starting to learn about what it does for your health. It was only discovered in the 1990s. The plant itself has over a hundred

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unique cannabinoids. Unfortunately research has been limited primarily to two of them, THC and cannabidiol. And that's because of access.

We're in a vacuum right now. We really do need randomized placebo controlled trials of testing products that have known composition. Right now, they are marketed and they're not tested under FDA-approved strategies for safety and efficacy. The public opinion is guiding how we're treating a number of disorders.

There's also little regulatory oversight. Recent testing of compounds that are obtained online or from dispensaries of edibles and other things that are cannabinoid-based have shown that they're not accurately labeled and that less than a third actually contain even some of the products that they say they do.

What about the GMP and purity and how about dose? And how do we take it? This all effects whether it's going to do anything.

And then, the big question, is cannabis addictive? Yes. There's a lot of data in the

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scientific literature showing that 30 percent of regular users will come to have a cannabis use disorder and about 300,000 treatment admissions occur each year. And why do people seek treatment? They've having problems with functioning. They're having an inability to stop using. They're smoking more than they intend. They have memory deficits. They go through withdrawal and they have other health concerns.

Few patients that seek treatment actually are able to abstain, only about 20 percent. The treatment options are not that good.

So what does withdrawal look like? Well, typically you see increase in anxiety, irritability, craving and restlessness. They have decreases in food intake and sleep quality.

This withdrawal emerges after 24 hours when you stop and it continues for weeks. And a really important point is that women seem to be more vulnerable. They have an accelerated trajectory for developing problems and they also experience more withdrawal and have worse outcomes, even when they're

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using the same amount as men.

Now, to switch sides, Margaret Haney has done a number of laboratory studies looking at benefit. So she did some studies in HIV-positive patients and showed that these individuals who often have problems eating and lose weight, when you give cannabis, it actually improves those symptoms. So there's reduced GI distress and the increase of caloric intake.

She also did a laboratory pain model where smoked cannabis and oral THC dose dependently reduced pain sensitivity and then load opioids that don't produce any amount of analgesia or pain relief when combined with small amounts of cannabis actually do have a benefit.

However, again, women appear less sensitive to these effects than men. So it may not be beneficial for women.

There's also the National Academy of Sciences review that covered a lot of the different literature that's out there to look for medical benefit. Only three of the things that were examined actually proved to be beneficial.

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So more research is needed. We need to increase research because legalization and acceptance is increasing use. So there's an escalation that's well documented in adolescents and adults, including pregnant women, that's rising. We need to understand how this is affecting health.

There's also no regulatory pathway for all these constituents and we really don't know anything about them. The idea that they've been said to be safe is ridiculous. It hasn't been done. And then also we need to evaluate the health claims. But we can't do that if research can't access these compounds.

And then, I give you a list of things that we need to research and, you know, you can look at that online. But we need to understand the risks and benefits. There's clearly both. And then, there's some recommendations here for the regulatory outcomes, about streamlining the process, particularly for interactions between the DEA and the FDA because that's very long.

And INDs, we need to accelerate the INDs so

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we can actually study these things in clinical trials. If you would like copies of the slides or you want more information, well, that was my email that was up there that went away. Thank you. Questions?

MS. CRISTINZIO: Thank you.

PANEL MEMBER: I have a question for you, for just -- so you comment about the need to have a streamlined availability of products for investigation. Could you comment what you think the impact of the farm bill removing cannabidiol --

DR. WEERTS: For a researcher --

PANEL MEMBER: -- and other hemp-based products --

DR. WEERTS: For a researcher --

PANEL MEMBER: For research purposes, yeah.

DR. WEERTS: It has no impact.

PANEL MEMBER: Please elaborate just a little bit.

DR. WEERTS: So I have a DEA Schedule 1 license to study cannabinoids. My 21-year-old son can walk into a store and buy it and I cannot. That's really it in a nutshell. I cannot purchase, store or

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test that product. It is illegal for me to do so because I am following the regulations of the DEA and I'm following the regulations of the FDA, which anything that I test has to go through an IND and meet all those requirements and go through our IRB.

It's a very circular process and can take months and months. But it does bother me that my 20-year-old kid can now get it and, you know, take it and I can't even touch it, unless I was a consumer. Any other questions?

MS. CRISTINZIO: Thank you.

(Applause.)

MS. CRISTINZIO: We are now onto a new segment called agriculture. And we have Cameron Cane up next, number 66.

AGRICULTURE (NON-GOVERNMENT)

MR. CANE: How are we doing? My name is Cameron Cane. I'm with Deutsche Process. We are a largescale industrial scale sanitary process equipment company.

We work in a variety of different food, beverage-related industries as well as nutraceuticals,

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pharmaceuticals, cosmetics, a lot that deal with the general cannabis and CBD space. We work with majority of the largescale LPs out of Canada as well as some of the major producers here domestically for CBD production.

We're here to talk about a little bit today about some of the misinformation on just general compliance in the agricultural community as well as the general processing capabilities in order to hopefully, you know, create a more compliant product and a more simple pathway for compliance in the industry.

So, you know, that being said, obviously there's -- in the agricultural community, there has been a lot of information as far as, you know, the federal tolerance for THC and the actual plant itself. You know, in certain states, in certain varieties of the plant, it's kind of irrelevant of the actual content of the THC.

States like -- we're in North Carolina. And the state of North Carolina, we almost had full compliance last year for THC products or CBD products

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devoid of THC in there. In states like Nevada, same plant varieties, almost 40 percent compliance, a 60 percent noncompliant product. But Nevada has a gray market where, you know, they can push their products to. There was no real reason other than just grow mediums and the actual locations and the timing of harvest of that compliance that actually had that.

If that was the case in North Carolina, you would have had farmers who unfortunately would have been forced to burn their crops, submit insurance claims, which currently there are no federal crop insurance for that.

But what is unknown about the process, regardless of what the THC content is in the field, once you go through a processing facility, you process this stuff and you concentrate the full spectrum extract down to a concentrate, as you can see from the pictograph here.

Through the concentration process, nearly all, 90 percent plus of all the concentrate itself will be federally noncompliant. There are processes in order to mitigate that, in order to effectively

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delete THC from those compounds. You know, as you see on here, you go through a purification step once you pass through that concentration.

You know, purification is the crystallization of the CBD compounds, generated in an isolate product. You'll then be left with a high THC, what is called the mother liquor. In that product, you will have a variety of other compounds in there as well.

And you can take that through several different steps, whether that's hydrogenation or reduction of that THC compound to essentially effectively delete the lucid chemical that is obviously the stigma in the industry.

By taking these very simple steps, which are readily available -- you know, we are not the company that created, you know, isolate production or hydrogenation processes. There are multiple hydrogenation processes that have patents out there currently.

We are also creating multiple other hydrogenated processes in conjunction with one of our partners, Canopy Growth, in order to, you know,

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develop more products that are marketable for a, you know, mainstream use down -- you know, without the problem of THC in the marketplace.

You know, how do we regulate this and how do we make sure, you know, this is kind of the pathway? You know, in our opinion, again, what's being regulated right now is the agricultural community. It's not processing. It's not the white label CPG manufacturers.

The simple choke point here is absolutely from a compliance standpoint. Is our process in compliance? And speaking with our clients, they want to be a compliant, a regulated industry that has transparency and, you know, has the ability to make all of us feel very safe in what we're doing.

You know, being able to have an audited -- you know, a federal audited compliance checkpoint, you know, through our processing facilities is certainly the way to make it easy from a capacity standpoint from federal regulators and so we know what is going into -- you know, when I listened to the lady from VCU and you see these products, it's scary. You know,

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there's no need for that.

If we had an audited choke point being the processing facilities, you don't have to worry about THC. You don't have to worry about mycotoxins. You don't have to worry about pesticides because when it comes out of these audited facilities, you know it is 100 percent compliant and there is no question in the industry and there goes the stigma as well. I appreciate your time.

(Applause.)

PANEL MEMBER: I have one question for you. What other byproducts would come out of this process? Is there a waste stream that comes out?

MR. CANE: There is. And that's -- you would hydrogenate the waste stream or you'd take that through another purification process of you'd throw it away.

You know, there are -- the isolation process, the crystallization and isolation process is roughly, you know, 50 to 60 percent effective, you know, as far as an efficiency standpoint. And you take that byproduct, the waste stream from that, which is the

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mother liquor that has THC in it, and you take that through a hydrogenation process in order to essentially reform that molecular compound that was THC.

PANEL MEMBER: Quick question for you. In North Carolina, what do you think the proportion of hemp growers are moving then their hemp for CBD specifically versus other purposes for hemp growth in North Carolina?

MR. CANE: I'm not sure I understood the question.

PANEL MEMBER: Among farmers who are farming hemp in North Carolina, how many of them are farming hemp for CBD production versus for other purposes?

MR. CANE: Nearly all. There is -- you know, when you talk about an economic driver, another gentleman said it today, you know, you can make $30,000 to $60,000 an acre on CBD product. You can make $700 an acre on fiber. Nearly all of it is CBD production. That's globally.

PANEL MEMBER: Thanks.

PANEL MEMBER: Can I ask a question real

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quickly? I want to follow up on the waste stream. So we heard this morning about full spectrum phytocannabinoids and things like that. Do these -- they come out of this same process as the hydrogenation change what ends up in what you would call full spectrum or --

MR. CANE: So your full spectrum, you would take that through the isolation process, first and foremost.

And that would isolate the CBD compounds and leave out the rest of your other compounds, fats, waxes, lipids, amino acids, your THC, the mycotoxins, anything else that might -- you know, some of the pesticides, heavy metals, things like that. You know, they don't get crystallized during that process.

And, you know, once that happens, you know, you take that through the hydrogenation process. We have done testing on selective hydrogenation. They have been varied results, not very good. It is more of a blunt force trauma of hydrogenation where we're hydrogenating all of the compounds that are in that mother liquor stream.

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And you know, we're still very actively testing in real time. But there are, you know, THC compounds that are patented -- hydrogenated compounds that are patented out there with, you know, good results that do have ancillary revenue streams or you just take it down and reduce that down to CBN. Thank you.

MS. CRISTINZIO: Thank you. Our next speaking category is consumers. And we have Jaclyn Bowen, number 67.

CONSUMERS

MS. BOWEN: Hi. Thank you. I'm Jaclyn Bowen. I'm the executive director of Clean Label Project, the international association for cannabis testing is a division of Clean Label Project.

I'm a food safety and quality systems engineer. So before coming to Clean Label Project, for 15 years I worked on different activities related to standards development, certification, compliance and enforcement mechanisms within food and consumer product safety.

Specifically for us at Clean Label Project,

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what we do is we're a consumer advocacy organization focused on bringing truth and transparency to consumer product labeling. More specifically, what we concern ourselves with is what's not on the labels. Marketing departments can do an effective job at selling comfort and security. So for us, in data and science we trust.

So what we do is we go out to the marketplace and I simulate the consumer shopping experience. I go out. I actually buy the products from the -- be it websites or local, national retailers. The only difference is instead of taking them and putting them in my pantry, I take them to an analytical chemistry lab to see what's actually inside.

So why did we test the CBD category? Really because of a lot of the great work that FDA has already been doing over the past several years. You've already called it. There have been systemic quality control issues that have been identified. And we see this coming out in other media, academic studies that have been taking place.

So for us, we also wanted to validate that.

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The samples that we selected were the ones that were out in the marketplace between January and February of this year.

So a little bit more about the study. How did we test the study? We were inspired by the Amazon.com bestseller's list as well as an Internet search of different types of consumer blogs of popular CBD products that consumers were buying.

We used, like I mentioned before, consumer chain of custody rather than relying on certificates of analysis as disclosed by brands. We went out into the marketplace, procured the samples ourselves just like a consumer would and took it to an analytical chemistry lab. Had it validated by another lab as well.

What did we look at? Over 400 analytes -- heavy metals, pesticide residues, plasticizers, potency, THC as well as mycotoxins. And we tested America's bestselling CBD products.

So three key findings that we found. The first one is highly variable potency and contamination. We tested for over 400 analytes. The

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average of top 10 brands based on what they disclose on their website is about 14 different tests. What we found within our testing, and I'll show more details to this, is that you see over 30 percent of products are plus or minus 20 percent of the CBD value that's listed on the label.

We see on average 34 parts per billion of lead, which is the highest amount of any consumer product or food category that we've ever tested. The pesticides that we see, the total pesticides, nearing 41 parts per million. The most common pesticide hits listed here. Average phthalates, which I was really surprised about, nearly 1,100 parts per billion. I'm not exactly sure where that's coming from.

Overall what we see is a general disconnect between brand-reported certificates of analysis and what's actually showing up on retail store shelves. What happens is this elevated level of detection coming from certificates of analysis listing a bunch of non-detects results in unsuspecting brands and consumers getting a false sense of comfort, security and compliance.

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So, number two key finding, the CBD content varies widely based with the values listed on the label. What's I think so interesting here and aligned with my friend over in Arkansas is I think that's the same product we tested that was exactly 100 percent accurate with the other one.

We see products that had zero CBD. We had another one that I didn't include on here that had 700 percent of the claim. But it wouldn't fit on my chart.

And then, you know, another question is, you know, I see a fair amount of CBD washing. To be able to kind of command this market premium, it's almost something where it has very, very low levels of CBD, but it's still really marketing that.

Finally another question would be we see a lot of THC-free claims. So what exactly does it mean to be THC-free? It's interesting because, for me, I look at words like FDA-provided guidance on gluten-free. And that meant if you chose to make a claim of gluten-free, then that means that you have to be less than 20 parts per million.

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If someone chooses to make a THC-free claim, well then what exactly what does that mean? In terms of my sensitivity, we tested down to 0.2 parts per -- or sorry, 0.2 parts per million. So it was one where we did not see anything that exceeded this 0.3 percent.

But I think what's important to note is the 0.3 percent THC is based on dry weight in hemp and the limit is being applied to manufactured products. But there's no rule or regulation as to how much THC can be present in a concentrate or manufactured product. Thank you.

(Applause.)

MS. CRISTINZIO: Thank you. Our next speaker is David Evans, number 68.

MR. EVANS: And how do I advance the slides?

MS. CRISTINZIO: You should be able to do it with your clicker?

MR. EVANS: That's the advance? Oh, okay. I am the senior counsel to the Cannabis Industry Victims Educating Litigators. We are a legal education organization that trains lawyers in how to sue the

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marijuana industry. We've spent the last year doing research on that. This year we're rolling it out.

So if a lawyer wants to sue somebody in the marijuana industry, we give them a suit to nuts legal guide on how to do it, the law, the science, a model complaint, model responses to motions, model interrogatory questions and so forth.

Right now, we have about a thousand lawsuits against the opioid industry. And if our dreams come true, we'll have the same thing going against the marijuana industry in a year or two or maybe a little bit more.

Now, who are the marijuana industry? Basically it's anybody that's selling marijuana as a medicine or as a food that has been approved by the FDA. They have set themselves up in various associations and industry associations.

The reality is these people are criminals. They are doing this in violation of the federal Controlled Substances Act and also the criminal penalties within the Food, Drug and Cosmetic Act. They're criminals. And the federal government has

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allowed this to go on for a long, long time.
I have no sympathy for them. I don't respect them. I have seen the widespread damage that they are affecting on this country. We advocate for the victims of the marijuana industry, children with birth defects, developmental problems. We'll provide you all the science on it. We've got a lot of science.
Talk to Dr. Howard (ph) at the National Institute on Drug Abuse. She's written papers on the damage to unborn children.
We also advocate for marijuana consumers. Marijuana products are full of contamination. We have papers documenting all this, even in the so-called regulated states such as Massachusetts and California.
Colorado is now a narco-state. The state government there has been grossly irresponsible in dealing with this issue. And if somebody from one of those states wants to give you a tour, come to us and we'll give you our tour. We'll show you what's really going on there in the ERs and every place else.
Marijuana is very dangerous. I have given three copies of a book by Alex Berenson, a New York

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Times reporter, who has looked into marijuana-induced mental illness and violence. A great deal of violence is being caused by high-potency marijuana. Read his book. You've got three copies of it there.
Mental illness, physical disease and addiction to marijuana. Now, is there a demand for marijuana products? You bet your lives there is. These folks in the marijuana industry have created the demand, primarily by lying to people about the addictive qualities and the dangers of marijuana. We've probably all gotten things on the Internet about CBD, that it's the wondrous plant.
And by the way, this meeting has been very helpful to me on a personal level. I am an anxious, combative individual and I have come -- and I have come to realize that my problem is I have a cannabinoid deficiency. And I'm going to -- my wife is driving me home. That's the first thing I'm going to tell her, is sweetheart, I've figure out what's wrong with me finally. I don't have enough of this stuff.
Now, who agrees with me? All of these

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organizations have put in damage reports about marijuana. The science is clear. It's not debatable. There is no regulatory ambiguity. You guys have said don't sell this stuff. It's illegal.
Now I'm just going to ask you a question. These people have been operating for years, okay? And they have ignored you. What makes you think if you come out with something now that the situation is going to be any different? The only way it's going to be different is if you enforce it. And you have not been doing that.
And in all my years in government -- I used to work for the New Jersey Department of Health -- this is the most negligent, damaging thing I've ever seen a government agency do, the FDA's negligence in not dealing with marijuana and cannabinoids.
You've seen very good science here and I urge you clean it up. Redeem yourselves and go after this criminal industry that's damaging our children.
This is not a states' rights issue. The U.S. Supreme Court has determined that regulation of medical marijuana is a medical issue. I've got a

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minute left and I've got other points. But I want to just spend a few minutes looking at some people's children. Every one of these people is dead, except for one. And their parents all say that their deaths were caused by marijuana. This is the only one of these folks that's alive. They committed suicide, they overdosed or they died as a result of their marijuana use.
So you have a tremendous responsibility. You're going to meet with a lot of smooth talking lobbyists here, okay, who are going to spin a lot of bullshit to you about their products. Keep these people in mind. Their photographs are on my office. I look at them every day. Thank you.
(Applause.)
MS. CRISTINZIO: Thank you. Next, we have Lisa Gill.
MS. GILL: Hello. I'm Lisa Gill. I am a health and medicine investigative reporter for Consumer Reports. I have been as a journalist covering prescription and over-the-counter drugs now for the better part of 20 years. And I've spent about

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11 of those at Consumer Reports. Hang on here. Let's figure out -- okay.

CBD for me personally represented a compound that I had never really come across before, both in terms of how people used it, why people used it, how they purchased it, how it's regulated or not. Consumer Reports had very similar feelings about it and started to take a great interest in this product about a year-and-a-half ago when we started seeing the market flooded with products, the retail market and online.

At the same time, we became quite concerned by some of the safety problems uncovered by the FDA as well as good researchers like Michelle Peace and Ryan Vandrey and others.

At the same time, we also started to hear stories of individual consumers telling us though that CBD was actually very helpful to them. And so, we took a deeper dive into this topic and the organization made substantial investments in trying to understand what was happening in the marketplace and what was happening with consumers.

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Now, you may know Consumer Reports as an organization that -- nonprofit, that tests things like cars and washing machines and washers and dryers and even lawnmowers. But we have a long, 83-year history in the area of consumer health and safety.

And I have to say I have no conflicts of interest to report. Part of that is because Consumer Reports does not accept any kind of advertising or sponsorship or partnerships of any kind. We are supported entirely by consumer members, millions of them, and consumer donors.

We actually buy every product that we test and we sell it back to people like me, employees, who purchase those products. I've personally purchased a number of coffeemakers on my own.

So part of the substantial investment that Consumer Reports made in this space was a national representative survey just this past January of 4,355 adults, adult Americans, a telephone survey asking people all kinds of questions. Do you take CBD? Where'd you get it from? Why did you buy it? Did it work? And there were three really important takeaways

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that I'm very delighted to show you today.

First off, number one, many adults use CBD. The second, a majority of people told us that they found it effective though for the thing that they were trying to treat. And the third is that consumers may assume that CBD is safe.

All right. So the first thing here, many adult consumers, basically one out of every four adult Americans told us that they had tried CBD at least once in the last 24 months. About 70 percent of those told us that they had taken the product more than once.

One out of seven said that they take it on a regular basis. If you're wondering, 26 percent of adult Americans represents about 64 million people, which is a lot. We also broke it down by age. You can see it's concentrated mostly in the people under the age of 44. But all generations are represented.

Okay. We also asked, hey, why do you use this stuff? Number one reason, to reduce stress and anxiety. Also joint pain. Eleven percent told us they use it for fun or recreation. And I think that's

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where we get into a whole other category. Ten percent said they did it to help with their sleep. Not surprisingly, millennials said they use it to treat anxiety. Baby-boomers said that they use it to help with their joint pain.

Also we asked, you know, what form do you use it in. the top three that I think are really important, particularly for this meeting, they told us the top way they got it, they drink CBD or they eat it or, second way, they use drops or oil sprays or they vape it. I think that's important considering a lot of the vaping research that's been done. There's other ways as well.

Then we asked, you know, where do you guys buy this stuff, just out of curiosity. So I was very surprised to see that 40 percent get it from a dispensary. That beat out 34 percent that said they were getting it at a retail store. And please take note here. One out of every four said they were buying it online.

All right. Then we asked, well, is it helpful for the thing you're trying to treat. A

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majority here, for the people who said they were treating it for stress or anxiety, I'd like you to look at this column here. Sixty-three percent that it was extremely or very effective.

The column on the right shows when people said that it was slightly or not effective at all. That was 16 percent. You can see that it helped 38 percent with joint pain.

Twenty-four percent were satisfied with how they felt after using it for fun or recreation. And half of them said that it helped with their sleep. But taken in total, about half said that CBD was very or extremely effective for them.

And this is the slide I'd like you to -- everybody should put down the phones and close the computers because there are three stats on here that are extremely important.

And the first one is that when we asked people, hey, did you use your CBD to replace it with any medication that you were taking, one out of every five told us that they stopped taking a medication as a result. And of that, a third said that they stopped

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using their opioid prescriptions, and that includes things like Percocet and OxyContin, Vicodin --

(Applause.)

MS. GILL: The other number that was important and much higher than I expected, 30 percent said that they were taking their CBD along with medication, which is important. We did not ask them if they did this with their doctor's advice or not. That would hopefully be a follow-up survey.

All right. We also asked about side effects. The majority told us no. But the 26 percent who did said that they experienced a change in appetite or fatigue. And don't forget, fatigue might be something that they actually are looking for.

And in terms of the area of safety, most important, half of the people told us that they were extremely or very confident that there was a regulation in place that required their CBD to be tested for safety and accuracy by outside labs. But we know if you get it at a retail store in most states or online, that is absolutely not true.

It was also asking about safety, when we said

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what are your top concerns, that the product wasn't safe, only 13 percent told us that. They were actually much more concerned that CBD would be too expensive.

If you have any comments or questions, I would love to hear it. If you think we're wrong about anything or you'd like us to take a look at something, let me know. I'm at Lisa, or lgill@consumer.org. Thank you.

(Applause.)

PANEL MEMBER: Did you ask if they had given it to pets?

MS. GILL: You know, we did not. But we have done a couple -- or at least one story on pets. And we do know that it is a growing area and that a lot of people are very interested in how CBD might be able to help their household pets. Thank you.

MS. CRISTINZIO: Thank you. Next, we have speaker number 70, Yael Ossowski. Sorry.

MR. OSSOWSKI: Hey, you got it the second time. Thank you. Good afternoon, FDA. Pleasure to speak with you all. So I'm here on behalf of the

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Consumer Choice Center. We are a consumer advocacy group, ab it different than the previous speaker. We're the group that is actually supporting lifestyle freedom, innovation, privacy, science and consumer choice. We are active around the world, though our base is here in Washington, DC.

And the main policy areas that we focus on are digital, mobility, we look a lot at lifestyle and consumer goods and health and science. And it's in that last category that we focus on cannabis and specifically CBD.

We've worked on this issue internationally. We've done a lot, particularly in Canada where cannabis is now legal recreationally, and also in many local jurisdictions throughout the United States and also now in Luxembourg, which is to be the next European country that will legalize recreationally.

So our goal is to promote smart cannabis policy. The idea that you're going to promote competition, that you're going to promote safety and you're going to eradicate black markets.

I believe the previous speaker mentioned a

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lot of issues before. I think that really comes because of the black markets because there is no regulation and it's left only where there is no regulation, there are no rules and there's no way for consumers especially to have good products or to know what the products are.

So I'm going to go through some of our points here, things that are very important for us, looking at smart regulation. Number one is going to be clear labeling standards. I think that's probably one of the most important things.

It sounds as if there are many consumers in the house who've been to some CBD shops or stores. They've been able to see what some of the products are there. But we don't necessarily know the exact percentage.

And as a consumer, how are you supposed to know exactly what to take, how much to take, at what cost? This is the thing that's very important to know, is that as old as the cannabis industry or cannabis use has been, everyone is new to the new legal CBD market. Therefore we need to have great

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clarity and great labeling as to how much CBD is in this, how much THC is in this. That's very important for consumers. Otherwise they have no idea exactly what they're taking and the effect that will be on them.

The second point is to allow branding and advertising of CBD goods. I know this is already happening. So we're just kind of regulating after the fact. But we have to allow companies and brands to exist because that's the only way the consumers are going to be able to differentiate between good products and bad products. We allow that with every other product.

Unfortunately in Canada, there they've plain-packaged a lot of their cannabis products. So there is no branding necessarily. You can't really tell the differences between brands. And because consumers don't have that option, they're not really able to establish loyalty. They can't figure out exactly which product is meant for them and they can't figure out if it's a bad company and a product that they don't want to use.

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Next is age restriction. I know that this is important for a lot of people here. I know that there are probably going to be a lot of people advocating for 21. When it comes to the smokable products, obviously an 18 age restriction we think is very appropriate.

But because of the oils and the edibles and this entire new industry that's coming about, that's something to where the age restrictions might not be as necessary and assuming that we have clear laws and standards, should be addressed in the right way.

But to have a total 18-plus or 21-plus even age restriction on all CBD products, we don't really think that's going to be helpful, particularly to the medical consumers who are going to need that.

Next is the benefits and the side effects. Obviously as many researchers have pointed out, there is a need for more research, for more information. But we don't need to allow the companies that are marketing. As consumers, we need to be able to know what are the health claims. Can they prove them? And they should be allowed to testify that and to include

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that in their promoting and in their branding.

As a consumer, it's very important to know that what the side effects are going to be, what the benefits are going to be. We think that's very important and something that should be upheld.

And lastly, harm reduction. So the idea is -- and the mistakes that were made in Canada when it came to cannabis legislation is they actually legalized the flower and the oils first.

So if you wanted to consume cannabis, you could only smoke it. You couldn't have any brownies or chocolates or food or drink. And that's been very bad for many people who would like to take these products and not have that additional harm.

So we need to allow CBD to be infused in many of these products and allow consumers to ingest them in the least harmful way possible. And I have some testimonials of people who do use CBD that is available and you can follow us, Consumer Choice center. Thank you very much.

(Applause.)

PANEL MEMBER: I have a question.

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MR. OSSOWSKI: Yes, ma'am.
PANEL MEMBER: I have a question for you. What evidence do you have about the different routes of administration that causes you to have a distinction of age restrictions between different types of infused products?
MR. OSSOWSKI: That's been done in some states, in some markets. Again, this is --
PANEL MEMBER: But in terms of its effect on the body, why would it -- do you have evidence that shows that some routes are different than others that would justify having different age limits for different routes of administration?
MR. OSSOWSKI: In that case, we're mostly talking about medical uses and because if you have the blanket ban, then you have exceptions, then we're just carving out laws that's carving out laws. It has to be as general as possible so it can be applied.
Ideally if there's going to be any age restriction, we talk about 18. Ideally there wouldn't be perhaps. That's to be determined by obviously your agency. So thank you very much. Any other questions?

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Okay. Thank you.
MS. CRISTINZIO: Thank you. Now we are moving onto the health professionals category. Speaker number 71, Ann Allworth?
HEALTH PROFESSIONALS
DR. ALLWORTH: I've got to get this down. There we go. Hello, everyone. I'm Dr. Ann Allworth and I'm very grateful to have this incredible opportunity to share the reasons why I, like thousands of other scientists and doctors, believe that the endocannabinoid system is scientific proof that cannabis is medicine.
I'm a cell biologist who studied, researched and taught various aspects of the human body for over 35 years. Cells, medical school gross anatomy, breast and ovarian cancer, innate intelligence, the critical role diet has to human wellbeing. And over these years, I've acquired much wisdom about human health, which has led me here today.
We need to know -- we know the needed cannabis research cannot be done. So please give strong consideration to the fundamental empirical

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evidence that I'm going to share with you today relative to the need for de-scheduling cannabis.
What do we know about cannabis as medicine? Conservatively, it's estimated that more than 60,000 doctors are practicing cannabis medicine and there are more than 3 million registered medical marijuana patients. The stories these docs tell are variations of miraculous cures in patients who found no relief from conventional medicine.
Some examples. A young teen whose 70 chest tumors disappeared. A two-year-old with brain cancer not expected to live three months is now six-and-a-half. Dramatic decreases in opioid use, helping to resolve this heinous health crisis. Veterans who experienced horrible PTSD experiencing powerful relief.
These stories are not miracles. They're empirical evidence that cannabis is potent medicine. It works when approved medicines do not. And it works for a wider range of conditions than any medicine known.
Here is a composite of the -- of all the

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qualifying conditions that are in the legal states. There are more than 75 of them. And these conditions are as disconnected as autism is to pancreatitis as cancer is to multiple sclerosis.
There's no time to read all of these. These slides are here to emphasize their number and range of beneficial effects this medicine provides for conditions in every single system of the body.
Some of you might ask, well, just how effective is this medicine. Let's look at three of the commonly treated ailments: migraines, epilepsy and chronic pain. Dr. Patricia Frye, of Takoma Park Alternative Care in Maryland, saw a 60 to 75 percent decrease in opioid use in 80 percent of her patients with chronic pain. And in patients with migraines and chronic headaches, 66 percent showed definite improvement.
Dr. Dustin Sulak in Maine, Russell Saneto in Washington and Bonni Goldstein in California published a very important paper in Epilepsy Behavior using pooled data on epilepsy patients treated with artisanal whole-plant cannabis. In 272 patients with

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medically refractory epilepsy, 86 percent had some decrease in the number of their seizures.

Clearly cannabis is effective medicine. But how is it that cannabis can fix 75 very diverse ailments? The answer is the endocannabinoid system, a critically important body system, a system that regulates every system in our body, and when it's disrupted, can manifest as the very conditions we just saw.

So let's take a quick look at the components of the system, the ECS. Receptors include CB1, CB2, CB3. We have endocannabinoids AEA and 2-AG which we make in our body that our body uses to maintain balance. We have the enzymes that synthesize them, the enzymes that degrade them.

So what does the ECS have to do with cannabis as medicine? The simple answer is everything. And though empirical, it is important fundamental knowledge that needs to be recognized. Just look at the relationship of the endocannabinoid system to other body systems.

Our systems include the reproductive, the

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urinary, the digestive, the respiratory, the endocrine, the circulatory, the nervous, lymphatic immune, skeletal, muscular.

So where does the ECS fit into this picture? It literally coexists with cells in all systems of the body. It is everywhere. It maintains balance in every system and between systems. Research, primarily animal studies, shows that disruptions of ECS components are seen in many conditions.

Conventional medicine is never effective because it's not treating the real issue. Cannabis resolves a broad spectrum of issues because it fixes the disrupted endocannabinoid system. And it is the only medicine that can do this. All of this is fundamental evidence demonstrating that cannabis is in fact actual medicine which should be de-scheduled. Thank you.

(Applause.)

DR. ALLWORTH: Any questions?

MS. CRISTINZIO: Thank you. Now we're moving onto speaker number 72, Jerry Bryant.

MR. BRYANT: Thank you. My name is Jerry

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Bryant. I'm president of -- and managing member of Vyripharm Biopharmaceutical. We're located in Houston, Texas in the medical center and we -- we're located in the Texas Medical Center and we work with several institutions within the medical center.

Vyripharm is focused on diagnostic and therapeutic application in the area -- in the areas of neurological disorders and cancer. The focus was to present the company where we can integrate medicinal cannabis with traditional medicine. So medical cannabis integrated with traditional medicine was sort of the platform.

We had to ask several questions. The question that we had to ask is, is medical cannabis a medicine. Did it have uniformity in the sector? Diagnostic application, meaning the dosing issues as well as the biodistribution. Also the treatment outcome, how can be quantitate? Do we have -- can it fall into the category of personalized medicine and IP, intellectual property?

We were able to develop a collaboration with the University of Texas MD Anderson Cancer Center.

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And lo and behold, we studied some of the malignant lymphoid cell lines. We were able to use medical cannabis to treat and look at the efficacy of the -- and cytotoxicity of those cells. And we determined that medical cannabis is a drug.

The work that's been done by companies such as Vyripharm can only deliver its true benefit to the public if the federal government takes the lead in developing a uniform and comprehensive approach towards cannabis products. Uniformity means the federal government must resolve inconsistencies in state and local approaches. Comprehensive means guidelines, effective testing, QC/QA and clear and consistent product labeling.

Let me move to the next slide here. There we go. As you can see from this slide, we have pure chaos. In the absence of federal regulation, dozens of states have legalized medical and recreational cannabis products that have been left to their own devices.

According to the study performed by the Center for Public Health Law Research at Temple

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University in the area of health policy, states are serving as laboratory democracies.

But the exercise is only productive if research, which we have done, and partnered in Texas Medical Center, step up to rigidly evaluate the impact on state innovation.

We largely have no idea about how well these laws protect patients and the public. The FDA really need to integrate and help this industry with guidelines on standardization. Uniformity is a necessity when it comes to the development of safe and effective medicine. It is only through uniform standards that regulators, sellers and customers can learn about what actually makes one product different from the other.

And so, you get some normalcy and differentiation in this whole process. And that's one thing that Vyripharm has really designed platform to maybe assist the FDA in establishing.

Accessibility is critical. In addition of uniform standards, information collected must be under a universal, recognizable, usable platform and the

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status quo, which we have now, different states use different testing protocols.

Tests have different components, track products differently and do not share information with each other. However, the entire supply chain needs to have access to the best and most consistent information.

What we have learned at Vyripharm means embracing what new technology has to offer. For example, we have developed an interface and database using block chain technology that allows access to extensive product information down to the strain source, genotype, phenotype and particular plant that you can correlate with a patient.

If we actually think that medical cannabis is a medicine, well, let's treat it as medicine. We do hold tremendous medical potential. Then we must treat this medicine as medicine. Consumers of medicine in our country know and they can rely on the information of medical labeling because we have to build a uniform and comprehensive platform.

Companies like Vyripharm are leading this

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cause right now. But every day the federal government delays in taking the need puts more consumers at risk and puts the true benefits of these medical products out of the grasp. We look forward to partnering with FDA and other regulatory officials in this important issue. Thank you for the opportunity to speak.

MS. CRISTINZIO: Thank you.

MR. BRYANT: Thank you.

MS. CRISTINZIO: We have two more speakers before we break for lunch. Next up is Najla Guthrie, speaker number 73.

MS. GUTHRIE: Thank you. Good afternoon. I'm Najla Guthrie, CEO and president of KGK Science, a global health and wellness contract research organization.

KGK Science has been designing and conducting clinical trials for over 22 years to support clients with product development claims, claim substantiation and new dietary ingredient notifications. KGK Science is a subsidiary of Oxley Cannabis Group, operating in Canada and abroad.

The volume -- sorry. The volume of

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unsubstantiated claims being made on CBD products is a clear abuse of the rules set forth by FDA and FTC. CBD foods are not permitted to make disease or therapeutic drug claims.

CBD has been marketed for multiple broad areas besides rare epilepsy in children. It has been marketed for its neuroprotective, anxiolytic, antipsychotic, analgesic, anti-inflammatory and anti-asthmatic properties, as well as combatting hypoxic ischemia.

FDA has asked what systems are in place to ensure adverse events are collected to mine toxicology signals and about margins of exposure. Dietary supplements are the only food commodity which there is a mandatory reporting requirement for serious adverse events.

CBD is a new dietary ingredient. NDI notifications must provide the basis for reasonable expectations of safety, which should include the NOEL. FDA asks about margin of exposure. Knowing the margin of exposure is a critical component of the NDI evaluated by the NDI review team at FDA CFSAN.

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There are clear gaps in safety. But FDA has an established NDI process to receive and evaluate those concerns. There are two main intercellular targets for CBD, namely CB1 and CB2 receptors. They are located in the central nervous system and some expression in peripheral tissues on cells with immune function and in the GI tract.

However, a pharmacologist might ask -- or might say that CBD is a dirty rather than a clean compound, not because of where it acts or any bad connotation. It acts on a wide array of intercellular targets. Therefore it is not surprising that there is a diverse array of purported uses.

CBD is considered to have low toxicity. In clinical trials and research studies, CBD is administered orally as either a capsule or dissolved in an oil solution. It can also be administered through sublingual or intranasal routes.

A wide range of oral doses have been reported in the literature, from 100 up to 800 mg per day. It is used in Epidiolex at up to 20 mg/kg daily with some concern in patients with hepatic impairment. This is

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not surprising, given its liver metabolism.

Studies on CBD show no effect on embryonic development. CBD has no effect on a wide range of physiological and biochemical parameters unless administered at extremely high doses.

CBD has no mutagenic potential, based upon Ames, comet and micronucleus assays. In rats, CBD at low doses does not change the threshold for intracranial cell stimulation. At higher doses, CBD actually raises the threshold, meaning that it interferes in reward behavior. This is the exact opposite of what drugs of abuse due, like cocaine and opioids. Drugs of abuse lower the threshold.

In human clinical research, CBD was not associated with abuse potential or addiction. Unlike THC, CBD showed no physiological changes on heartrate, psychotic symptoms or anxiety.

In terms of food, nutraceutical and drug interaction, there is only potential for CBD to be associated with drug interactions through inhibition of some cytochrome P450 enzymes. However it is not yet clear whether these effects occur at physiological

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concentrations.

In terms of unique populations such as pregnant women and elderly, one should consider undertaking safety studies for NDI notification or other safety dossier. There is a clear knowledge gap in our understanding of CBD which should be addressed in the future if products are to be intended for these sensitive populations.

The Epidiolex dosing guidelines indicate that with severe hepatic impairment, dosing should vary between 1 and 4 mg/kg/day. A significant difference however is that Epidiolex is exclusively directed to pediatric patients, which are not considered smaller versions of adults.

CBD in foods is typically marketed to healthy adults and should never be marketed to those with hepatic impairment. In addition, there should probably be a voluntary black box warning on all CBD food products, conventional food or dietary supplement that they should not be used in the setting of liver disease.

And to conclude, the recommendations for

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labeling and claims for dietary supplements containing hemp-derived CBD extracts is to remove the inclusion clause in 201(ff) for CBD products to permit eligibility as dietary ingredients. Issue a regulation approving as a food substance under section 301(ll).

Enforce the regulations from the Dietary Supplement, Health and Education Act of 1994 and the 1990 Nutritional Labeling and Education Act. This would require an NDI notification within 75 days of marketing, would require GRAS affirmation and NDI status will allow lawful companies to make scientifically validated health claims regarding nutrient content, structure function and qualified claims.

And amend the labeling regulations to include separate identity statement and standardized hemp-derived CBD symbol. And thank you for allowing me the opportunity to speak today.

(Applause.)

PANEL MEMBER: Quick question. As a CRO in this space, how many CBD-related studies do you

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currently have ongoing?
MS. GUTHRIE: We've got I believe around nine of 10 studies now going on and a number of them are looking at the pharmacokinetic properties of CBD and THC being located in Canada where we're able to look at both of those, as well as other indications.
So we're looking at indications such as sleep, anxiety, pain are some of the indications we're looking at.
PANEL MEMBER: Thank you.
MS. GUTHRIE: And we plan to submit written comments as well.
MS. CRISTINZIO: Great. Thank you. We have one last speaker before we break for lunch, Lucille Vega.
DR. VEGA: Hello, and thank you for allowing me to speak today. My name is Dr. Lucille Vega. I have a degree in biology at University of Irvine -- University of California, Irvine. I went to medical school at Dartmouth Medical School, Brown University for residency and also I have been on concierge private practice, private practice for the last 19-

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and-a-half years.
When I first heard about CBD, I did not believe it worked. I thought it was snake oil. Oh, come on. This is from the medieval times. Are you kidding me? I would have learned this in medical school, right?
Well, since then, I have done a trial with EcoDrop oil. Since it's full spectrum, it has the CBD, CBG, CBC and that trace amount of THC, less than 0.3 percent. In my trial, the first question -- let's do this here. In my trial, the first question is pain: 65.5 percent dropped their pain scale by two points. Pretty significant in my book.
Number two, sleep question. Let's get back to that sleep question: 43.1 percent gained more than two hours of sleep. Here's the abdominal question. To save time, here's a quick review of the results. Also for my headaches and migraine question as well.
Moving along, buckle up, folks. We have a lot more to go. Anxiety, 75.3 percent had a reduction of their anxiety symptoms or the intensity of it. And then, my last question, would other people represent

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the CBD drip, or the EcoDrop now, 88.7 percent would recommend the EcoDrop to their fellow friends or family members.
Other witnessed benefits that I have seen, there's a list here. You've seen more today I'm sure. But PTSD, that one really surprised me. I was very excited to see that. As far as concussions and diabetic neuropathy, wow, I'm impressed. PMS, sure. And then, high blood pressure, wow, I'm lowering blood pressures right inside the office. That's fantastic.
Other benefits of the EcoDrop oil I saw, arthritis in canines and separation anxiety. There's a full list. Not enough room on this slide. Other CBD products I use is PainQuench cream and also FreshLeaf edibles.
Again, I did not believe this stuff would work. PainQuench cream, I was surprised that folks were coming to me and saying, hey, it works for my psoriasis patches. Plantar fasciitis, diabetic neuropathy. What? I did not understand. Wow.
Second degree burns, you kidding me? Wow. Acne. And then, as far as the edibles, a lot of

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people came to me and said the anxiety and the sleep, it really helped with that. Again, I'm always about minimal effective dosing. I remember in medical school, first do no harm.
Here we have PTSD trigger prophylaxis. People are using it at 7.5 mg per dose, two to three times a day. You may see these as low numbers. But with the full spectrum oil, it doesn't require as -- I'm noticing it doesn't require as much CBD isolate.
Okay. Post-concussion, people are using it 10 mg. We usually do it three times a day for a week and then twice a day. Autism, seeing a lot of good results in adults with 37.5 mg, all using this EcoDrop oil because it's full spectrum.
Most common side effects, it's too relaxing. Perhaps that's dose-dependent, which I believe it is. Next, my thoughts about safety, I prefer sublingual dosing.
Why? One, I didn't get many complaints in the medications interactions because they're my primary care patients. I know what they're writing. And do I write for pain medication? Absolutely. And

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I'm here to testify, to say, look, I want to be part of the solution.

Okay. We had Coumadin and dialysis patients. Again, no major interactions. In fact, there were no interaction complaints in that trial. Also I didn't have to worry about that first pass effect with the sublingual dosing. That's why as a physician I prefer sublingual dosing.

Oral consumption, the minimal dose necessary, I have no complaints at the -- I had no complaints at the 50 mg or less at one to two times a day. Topical application, of course not for open wounds. On dry skin.

Last thing, my thoughts about public safety issues. Definitely lab results need to be found online or easy in the packaging for consumer. I would prefer as a physician also product testing, which we've heard before today, heavy metals, organophosphates, pesticides, to name a few.

We need more research. We need more research. We need more education for physicians. Why? Because people are coming to me, coming to the

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ER asking us physicians what do I do. I need to know what's online. Or if you're putting out a product, what do you have in there. What am I concerned about, so I can start to assess this patient.

Labeling. My biggest pet peeve as a physician, seeing these CBD companies put out 1,000 mg in a bottle. I want to know what's the milligram per smallest dose unit, per drop, per edible, et cetera. Also, definition, broad spectrum, full spectrum, we should probably get a consensus on it, possibly a new language considering how many cannabinoids are in this particular product. There are one, two, three, four cannabinoids.

It looks like the FDA may have to bring me back for some more information on my study. And thank you all for listening and being here today and testifying. Thank you.

PANEL MEMBER: I have a quick question. I saw on your slides you said something about a FreshLeaf edible. And I wasn't -- is that a brand name of a product --

DR. VEGA: It is.

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PANEL MEMBER: -- or are you talking about actually consuming a fresh leaf?

DR. VEGA: it is a brand name of a product, correct.

PANEL MEMBER: Okay. Thank you.

DR. VEGA: Sorry about that.

PANEL MEMBER: So it's a processed product.

DR. VEGA: Mm-hmm. (Affirmative.)

PANEL MEMBER: Not a fresh -- okay.

DR. VEGA: A processed product, edible.

PANEL MEMBER: Thank you.

PANEL MEMBER: And when you're recommending a specific -- when you're recommending a patient use CBD for a specific use, you had several on your slide, how have you determined what dose to recommend for each use?

DR. VEGA: So I always start with sublingual because, to me, I don’t have to worry as much about the medications that they're taking.

I figure most people over 55 are probably one some type of anti-hypertensive, cholesterol medication and such. So I always start with 1 mg and let's see

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how you do, the lowest dose possible.

PANEL MEMBER: Are there any conditions for which you are screening patients before recommending use of CBD? So liver issues or things like that?

DR. VEGA: I actually take that into consideration with the liver. That's why I start with the very lowest dose, possibly maybe half a milligram and see how we do.

But on the other end, I know what I'm prescribing them for their blood pressure, their cholesterol and such. And so, that's constantly in the back of my mind.

Every person I see, I always want to know what's your kidney function, what's your liver function and what's your blood pressure. Absolutely. Thank you very much.

MS. CRISTINZIO: Thank you.

(Applause.)

MS. CRISTINZIO: We are now going to take a break. Unfortunately we went a little over and we're going to have to take some of that time out of the lunch. We will reconvene at 1:30. Thank you.

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(Whereupon, the foregoing went off the record.)
MS. CRISTINZIO: Sue, on the line, give us one more minute.
DR. SISLEY: Sure.
MS. CRISTINZIO: Okay. We are ready to begin our afternoon program. The good news is we're about halfway through our speakers. We have joining us on the phone, continuing our health professionals segment, Sue Sisley from Scottsdale Research Institute. And she's going to tell us verbally when to move the slides forward. Thank you. Go ahead, sue.
DR. SISLEY: Okay. Wonderful. I'm Sue Sisley. I'm an internal medicine physician from Arizona and I'm the head of Scottsdale Research Institute. You can see on the next slide our mission is to strive to evaluate the safety and efficacy of smoked and vaporized cannabis flower. So we're striving to put flower through the entire FDA drug development process.
On the next slide you'll see we just

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completed an FDA Phase II trial looking at four different varieties of cannabis for military veterans with PTSD. And on the next slide, you'll see why this study took us 10 years to get through, you know, to navigate all of the regulatory hurdles.
And this schematic really demonstrates the excessive layers of government red tape involved in trying to study efficacy of cannabis through the -- you know, the regular drug development process.
The next slide, you'll see these are some examples of pictures from investigators who used NIDA study drug in the past. The top ones were from a few years ago. The bottom picture is our most recent shipment from NIDA and on the next slide you'll see we were one of the first scientists to ever do secondary independent testing on the cannabis from NIDA.
And we sent this to Schedule 1 licensed laboratories in the U.S. to do proper testing. And we did three rounds of testing that all showed excessively high levels of mold in all the batches that would not have passed state testing in any of these regulated markets that mandates testing.

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Next slide you'll see, you know, we were somewhat optimistic to see that the DEA announced on the Federal register back in 2016 that they would finally license other growers for research.
And on the next slide, you'll see that even though the DEA received almost 30 applications from potential growers that wanted to provide cannabis for clinical trials, the DEA has not processed any of these applications. And despite members of Congress repeatedly urging the DEA to either process the apps or explain the delay, we've gotten no response to these letters.
And the next slide shows you a good example of one of the -- of one of over a dozen bipartisan letters that was sent to DEA asking for an explanation, and nothing.
So you'll see, next slide, shows you that the real issue for us is the fact that we don't have flower to use for FDA Phase III trials. So right now, you know, the FDA of course requires that whatever drug you use in Phase III, it's a drug that you would, you know, go to market with later.

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And NIDA cannabis is not authorized, you know, to be available for sale as a prescription FDA-approved medicine. So there's currently no way to put flower through the entire FDA process unless we use flower from a foreign manufacturer.
So next slide, you'll see here are just our final points for the FDA, things that we hope you can address. We'd like to see the paradigms with botanical medicine become different than the paradigms we use for standard pharmaceutical prescriptions. Like we hope that eventually you'll allow, embrace the idea of patient self-titration.
We're using that in the recent study we just completed. Patient self-titration was an optimal way of administering smoked cannabis flower because it allows for small variations in the potency of the flower and it enables patients to discover a much lower therapeutic dose and avoid a lot of the adverse events that we see when patients overuse flower.
So next slide, you'll see that we also hope that the way you define GMP will evolve to ensure that we're only getting the flowering tops of the plants,

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not the extraneous plant material, stems, sticks, leaves, that all, you know, confound the efficacy of the study drug.

The idea is just flower only and other things that we agree on that should be GMP, like free from pesticides, free from microbial and mycotoxins. But the idea is not so over-processed that it no longer resembles real world flower. We feel that in this excessive exuberance to make sure that the cannabis flower is so standardized, that we lose a lot of the efficacy of the natural flower.

So finally, the next slide shows you that our big push here today is to urge you to help us, you know, work with the DEA to urge them to make good on their pledge to the public and license other growers for research so that we can finally put flower through the Phase III trials because currently there is no federally legal drug supply for drug that can be used in Phase III and then sold later as a prescription medicine.

And the next slide shows you, this is my final point, that the next clinical trial at our

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laboratory will be looking at smoked cannabis flower compared to fentanyl for late-stage cancer patients with breakthrough pain.

But lastly because of the -- you know, of this limitation with the current drug supply, we are forced to import study drug from a Canadian manufacturer. And that's disappointing to us. We'd like to see our own domestic -- you know, a variety of domestic manufacturers. The point is that researchers need access to options. Scientists need options to embolden scientific freedom. And my last slide just gives you my contact information. Thank you very much.

MS. CRISTINZIO: Thank you, Sue. All right. I think we're about to move onto our next category of speakers. We have next manufacturers up. And the first one is number 76.

MR. BLEHAR: Is that me?

MS. CRISTINZIO: Number 76, Justin Blehar.

MANUFACTURERS

MR. BLEHAR: Hi, guys. How are you? I'm Justin Blehar, with Genco Pura Oil Company. And I

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think we'll be bringing up our slide in a minute. I'll just go ahead and introduce myself to start. I started -- I'm not a billionaire. I'm not a lobbyist. I am an owner of a company that I started. I am a 15-year veteran, served overseas a couple different deployments, honorably discharged. And my partners and I had no idea what CBD was a few years ago.

We started looking at what could help, what would make a positive difference. This is what we got into looking at vets and trying to have a positive impact. Since that time, we've become a single point manufacturer with a large network. We work at all different levels.

And we'll start with the farms. A lot of the other stuff has been touched on. But I want to hit a couple of these points. So one of the things that we do is working with the farms and the farming co-ops is these farmers, you have micro farmers, one acre, five acre plots and then you have these large farmers.

One of the things that wasn't addressed that is going to be important, there's going to be a surplus of biomass and there's going to be a limited

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amount of certified extraction places to make CBD. We also work with the networks of these labs. These labs could be anywhere of something like a small corner area over there that God knows what they're putting in there in the back of their room, sending out isolate, broad spec.

Then you have larger facilities that are doing it properly and there's different types of processing. These facilities are not -- there's not enough of them in the U.S. to handle the production that's going to be coming out. A hundred thousand acres to 200,000 acres is projected for this year, 2,000 to 3,000 pounds per acre. It's not going to work.

So you're going to have a surplus. Then you're going to have farmers that are going to have to make decisions on whether to burn their crops or not. And then making those decisions on $20,000 or $30,000 of annual income is a big deal.

So just something that I want to bring up. And having a certification process for the labs or some type of QA or QM process is something we've been

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working on and other companies are as well.
Cold packaging facilities, we work with pet food manufacturers, cosmetic manufacturers, nutrition and food and beverage. All of them are a little bit sketch and concerned about what's going on in the FDA and how to work with that and how to get people to process stuff in a quality manner and not be dealing in the gray area or the conmen and the Wild West.
You also have several small businesses trying to get started right now. They're buying $500 to $1,500 at a time every month. They're trying to do the right thing. They want to implement testing. They want to have stuff on the base oil. And they want to be able to move everything through and grow their businesses and have a positive impact.
A lot of what I'm hearing is not stuff that allows them to do that. They can't do through any of these new drugs' certifications. You've got the patchwork of states. Utah, for example, people are already having to register as manufacturers. Per SKU can start costing so many hundreds of dollars.
So I think overregulation would be a big

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problem. We're five years into a multibillion dollar industry right now and we're just talking about it with you guys and you guys weren't aware of some of the issues for the researchers to be testing stuff.
So it's not a ding on you. I love we're having this convo. But I think the industry should take the lead, utilizing networks, using ISO 9001 2015 standards and establishing those processes that the consumers and businesses are already demanding.
All right. So sticking with the gray areas, it shouldn't be a fear of the FDA. This should be a conversation that we should be able to have. Companies shouldn't be scared that they're going to get warning letters to come up here and tell you guys some of the issues they're dealing with and other stuff going on.
But they're scared because, God forbid, you know, I tell you I'm making a drink line in a few months and it's not ready and it's going to mess up our dollars. We need to move forward in a way that everyone is being safe and can do this, you know, in a constructive manner.

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So the legalities especially, and going back to the farms, you guys brought it up, delata-9 versus THCA. There is a difference and there's a gray area in regulation. If I want to go from a farm in Oregon and drive, you know, 10 truckloads down to California, is my delta-9 at 0.4? Am I now a federal drug trafficker?
All right. And then, is everyone done and what happens from that point in our logistics systems? So if I'm a manufacturer and we're licensed, there should be some variance in that and clarification on THCA versus delta-9 so we don't have to work in that area and worry about it.
It was already brought up the differences in CBD. Along with academics and research, isolated CBD is different from utilizing full spec CBD at scale with manufacturing processes. This can become an issue. So that's when you get into broad spectrum and distillate, something we can submit later on to you guys as well.
Next piece, ability for real research we discussed. Consensus and the benefit to CBD, everyone

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sees that overall and acknowledgement, you know, that hey, we do have a patent on this and we've been studying this stuff for over 50, 60 years at least right now. There is a dearth of research. There's meta-analysis, including stuff on dosing. We have enough to move forward overall.
All right. Lastly, as we're running short on time, one of the things is I just, you know, always like to stick this out there as far as the benefits of CBD. We can't ignore that. We see it across the world internationally along with in the UK and Israel. We're doing commercial trial arrangements with different people and working logistics. All of them a nightmare.
So I'm hoping we can go ahead and move that forward. But that small difference, what CBD can do can make a life-changing impact in people. I'm out of time. Any questions? All right. Thanks so much.
MS. CRISTINZIO: Thank you. Next we have speaker number 77, Richard Brumfield.
MR. BRUMFIELD: Good afternoon, ladies and gentlemen and panelists. My name is Richard

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Brumfield. I'm the CEO and founder of Full Spectrum Omega, Incorporated. We are a phytocannabinoid life science company out of California since 2010. We have developed a non-euphoric THC product which has shown benefits in the California medical marijuana group of patients that we are serving in California.

Full Spectrum currently has two signed agreement with the United States government to do research in their lab for multiple applications supporting national security and specifically military need.

Now, I want to concentrate a little bit on why we're here today. We're here today because we are trying to get our products from California to the federal lab in Maryland and San Antonio, Texas. And our problem is there is no bridge between research and drug development to have our product tested because the product in the industry is my own invention.

We discovered the plant that we need. And we are in control of those plants. And we work in a state-sponsored program which is able to allow us to use these products to help patients in different

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needs.

Now, my next slide, going through some discussion points, discussion point one is FDA recommends data and the data is captured by the National Institute of Drug Abuse and locked away where researchers like myself who are in independent states with cannabis programs, we cannot take our product that we didn't develop into research because there's no bridge between a state-sponsored development program to where it could go to the FDA and say, look, we discovered a new benefit.

So we need to be able to find a way to bridge that gap where innovators like myself are not handicapped to use a subpar or substandard product to try to prove a point.

The next slide is the challenges moving forward. Wait a minute. Hold on. Okay. I hit the wrong button. Discussion point we want to talk about is safety and effectiveness. I just went over that. I'm sorry.

Discussion point number two. There are now three definitions for hemp. The farm bill has 3

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percent -- 0.3 percent. The World Health Organization has got 0.2 percent. FDA has done 0.1 percent. Where is the standard between dietary supplements and a drug? There's no standard. You have no separation. Everything that falls under 0.3 percent and it says under the Controlled Substances Act that it's legal to ship across state lines.

But if your source material is cannabis, Schedule 1, how do you cross over once you develop a product that's 0.3 percent? Can that product now cross state lines if it starts with a Schedule 1 product?

As far as we understand, it cannot. I've been working two years with the FDA, NIH and DoD trying to find that bridge to cross over. And what we have found is that if the FDA and the DEA don't come together and work with these state programs to capture the data that we have, then we aren't even going to get the true information that we need.

Let's see here. Next slide. Any drug developer has to control his raw material. I cannot trust my raw material in the hands of someone else to

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produce a quality product every time I need it. If we don’t have control of our raw material, how can we not have a drug shortage later on? So it's imperative that the industry controls its raw materials. And the bulk manufacturer license that's currently being applied don't apply to industry standards. So we need the FDA to help educate Congress on what is a botanical drug development program and what is research.

I'm trying to hurry up. Number four, the FDA don’t want us to go around using other people's products without it first being tested. But if there's no bridge to go there, how can we get there?

Let me hit number five. Number five is the most critical one to me. FDA and DEA allow foreigners to import cannabis products to the United States for research and development. But there are no pathways for American industry to go. That is not right.

As Sue Sisley just said, she's fixing to import from Canada. I'm located in California. We are growing. We are processing and we're treating. Now we need the FDA to come in and help us regulate

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that because we believe the FDA should be the regulatory agent over this process. That's it.

This slide will be put up in 72 hours. So if anyone wants to capture the information, it'll be up in 72 hours. And we just want to thank you for allowing us to stand up here and talk to you for these few minutes. Thank you.

MS. CRISTINZIO: Thank you.

MR. BRUMFIELD: Oh, okay. No questions.

MS. CRISTINZIO: Our next speaker is Guy Chamberland, speaker number 78.

MS. MAZLOUM: Hi. I'm Rola Mazloum. I think that's okay. Is that okay?

PANEL MEMBER: No. We still can't hear you.

MS. MAZLOUM: Hi. I'm Rola Mazloum, regulatory affairs director at Tetra Bio-Pharma.

MS. CRISTINZIO: You need to move a little closer to the mic so we can hear you.

MS. MAZLOUM: Okay. I'm Rola Mazloum, a regulatory affairs director at Tetra Bio-Pharma. I am here to present you the corporate slides on behalf of Dr. Guy Chamberlain. Next. Okay. To date, Tetra

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Bio-Pharma has conducted four clinical trials, three of which were Phase I trials and one Phase II trial. Phase I clinical studies assessed safety, tolerability and PK of single and multiple daily doses of cannabis administered by smoke inhalation, vapor inhalation or orally as cannabis oil capsules.

Phase II trial was a randomized, double blind, placebo-controlled pilot study followed by an open label extension phase that assessed safety and efficacy of oral cannabis oil in patients with chronic pain.

When we look at the PK parameters obtained from Phase I trials, there's no -- there are no significant differences between smoke and vapor. We see that Cmax for both smoke and vapor is reached between 0.5 and 0.17 hours and this was also achieved for both THC and CBD. Obviously we see that PK parameters for oil are much more different.

When we compare the THC Cmax obtained from smoke, it is six to 20 times higher than the THC Cmax reported in Sativex. When we look at the THC Cmax obtained from vapor, it is around 12 times higher the

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THC Cmax reported for Sativex.

When we look at the adverse events reported with inhaled cannabis, with smoked cannabis, hundred percent of patients experienced adverse events. There was a dose-related trend that was observed.

The most common types of adverse events in single dose were nervous system disorders and multiple dose were euphoria and general disorders. Majority of AEs were mild and considered drug-related. There were some severe adverse events and most common adverse events are listed here.

With vaporized cannabis, again, hundred percent of patients experienced adverse events. Most common was euphoric mood, which is the cannabis expected pharmacological effect. Majority of AEs were drug-related and were mild to moderate in severity.

In Phase I trial with smoked cannabis, we have also assessed cardiac function following the multiple dose phase. There was a substantial heart rate effect that was observed at five minute time point. That difference ranged between 15.4 and 24.2 bpm and it remained elevated 60 minutes post dosing.

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Neurologic adverse events that were reported, we're talking about dizziness, fainting, headaches, fatigue, somnolence, feeling abnormal. Cardiac adverse events and neurologic adverse events were related to Cmax.

And now, if we look at the adverse events with oral cannabis oil, after seven day repeated dose, two out of seven patients experienced at least one AE. All AEs were mild. They occurred and resolved on day one and did not reoccur even with higher CBD concentration throughout the study duration, which suggests a mechanism of tolerance.

Now if we look at adverse events and safety data obtained from oral cannabis oil from our Phase II study, here the THC/CBD ratio of interest is 120, with 5 mg CBD. There are no observed adverse effect levels while at 5 mg CBD, following a daily consecutive intake for six days. The first time an adverse effect was observed was at day seven with 5 mg CBD.

Now again with our Phase I trial with smoked cannabis, for the multiple dosing phase, we have applied a program titration where after multiple

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dosing for seven days, no adverse events classified as nervous system disorders were reported, where also the negative impact on cognition was not evident after seven days of repeated dose, which also suggests the mechanism of tolerance.

So to summarize, with inhalation, we have much more neurologic and cardiac adverse events. With single dose, we have much more neurologic adverse events. And with multiple doses, cardiac adverse events are much more important.

Another safety issue that we have to address here with cannabis product and cannabis-derived products is the mycotoxin contamination. Tetra Bio-Pharma detected and quantified mycotoxins in three lots of dried cannabis and one lot of cannabis oil. Levels averaged between 1 and 10 mcg/g.

Several screening tools were developed and validated to map out the organism growing on a crop and bulk plant supplies. Tetra has developed also and validated assays to quantify multiple known mycotoxins. We also performed assays on all raw materials as well as finished product and all our

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supplies of bulk plant material are subject to our monitoring program.

Thank you for your attention. I just want to add that complete data will be submitted to the FDA through the confidential path.

MS. CRISTINZIO: Thank you. Next we have speaker number 79, Josh Epstein.

MR. EPSTEIN: Hello, and thank you. I'm Josh Epstein, from Socati. On screen is a short profile of our company. We're focused on manufacturing broad spectrum hemp extract as an ingredient by investing heavily in science and technology to assure quality and consistency.

Consumers rightfully expect CBD-infused products to be made like others they routinely consume, using certified good manufacturing practices and quality standards with validated analytical testing and with enforceable oversight.

They rightfully expect labeling that is standardized, accurate, relevant and clear. And they expect important terms such as THC, broad spectrum, full spectrum, isolate to be well defined and

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universally understood.

Consumers, and in fact producers, will also expect FDA to be engaged. Some will want FDA to allow only a pharmaceutical pathway for the regulation of hemp extracts. In our view, this will frustrate consumers and bog down the agency without adding appreciably to product safety. Others may call for the barest minimum of an FDA regulation. A lack of regulation has already begun to trigger a race to the bottom in our view, eroding people's trust and consumer safety.

We don't want a race to the bottom. We want a race to the top. The starting line is a regulatory framework that sets a high bar for manufacturing, analytical testing and labeling, encouraging investment in quality, choice and innovation.

When it comes to CBD, we recommend that the FDA capitalize on its long experience in regulating foods, beverages and supplements, specifically with respect to these three items, the manufacturing, testing and labeling.

The model, in our view, represents the

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goldilocks zone of regulation that's strong enough to ensure consumer safety, clear enough to empower choice and confidence and flexible enough to promote investment and growth.

Sorry about that. Allow me to offer some specifics. First, the FDA should narrow the wide variances in the standards for how CBD companies are now making products, certify their processes through third party validation and protect and ensure the transparency of their supply chains.

A good start would be requiring CBD producers to demonstrate quality manufacturing through global food safety initiative recognized certifications. This would assure that every stage of production is both validated and auditable.

Certainly the use of CBD extract begs the question how do we validate a product as THC-free, which a lot of other people have touched on today, or full spectrum or isolate or broad spectrum. And there is no standard definition of that right at this point in time and no agreed upon approach to measuring it.

The FDA should for example establish this

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threshold for THC-free and a standard analytical laboratory approach to validate it.

In short, consumers should be armed with the information they need, including FDA recommendation as to how much CBD can safely be ingested in a 24-hour period and they need answers on whether and how much consumption may trigger a positive drug test.

The first important step is being able to accurately identify the content of products. Accordingly, the FDA should also require appropriate analytical testing and exposure of both the desired and undesired components found in CBD products.

For the undesired components such as heavy metals, the regulations governing food ingredients may apply. For desired ingredients, consumers and product manufacturers will want to evaluate the synergies and various compounds found in CBD products, whether it's full spectrum or broad spectrum, the synergistic effects commonly known as the entourage effect. But to do so, again, we must know what's in the products.

Overall, we believe the FDA can consider a range of analogs from food, beverage and supplement

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industries to build a regulatory framework and do so with comparative speed. With that, consumers will be well protected and have their expectations well met.

In closing, a legal CBD market is projected to grow exponentially in the coming years. Behind wise and timely regulation, the FDA can both protect and empower consumers while galvanizing and appropriately guiding the inevitable growth of a dynamic new industry. Thank you.

PANEL MEMBER: I have a question.

MR. EPSTEIN: Yes?

PANEL MEMBER: Well, actually a couple of questions.

MR. EPSTEIN: Okay.

PANEL MEMBER: so the first one, you mentioned a couple of different terms, broad spectrum and full spectrum.

Are those -- and I know you said they're not, you know, necessarily defined in the industry. But are you using those terms interchangeable or are they the same or different?

MR. EPSTEIN: No. They are different. So

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broad spectrum -- start with isolate, and I'm sure there are multiple definitions within this room, quite frankly. But isolate is CBD without any other component that came from the hemp plant.

Full spectrum is pulling through all of the synergistic compounds, other cannabinoids that other people have mentioned today, terpenes, et cetera, into an extract. That's full spectrum. Broad spectrum would be that, but with THC removed.

PANEL MEMBER: Okay. So full spectrum would include THC?

MR. EPSTEIN: The residual amounts, correct.

PANEL MEMBER: Got it. And is there any -- I mean, is anything removed or is this, you know, literally just extracted from the plant and you don't do anything else with it or do you do some kind of processing, concentrate some things, remove other things?

MR. EPSTEIN: Well then it depends on what the manufacturer is producing. So it could be in a tincture where it's diluted with a carrier oil. It could go into all of the other products that you guys

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have seen people present on today.

PANEL MEMBER: So the broad spectrum -- because you manufacturer a broad spectrum product, right?

MR. EPSTEIN: That's what we're primarily focused on, yes.

PANEL MEMBER: So what types of levels of CBD do you see in that?

MR. EPSTEIN: In the extract, it's a range. It depends on the starting materials in large part. But ultimately, anywhere -- once you do -- once you go through the entire manufacturing process, the CBD content in the oil will be anywhere from 70 to 90 percent.

PANEL MEMBER: Just a follow-up question to both of those. You can understand the challenge in creating a standard around something that varies like that.

MR. EPSTEIN: Absolutely.

PANEL MEMBER: If you have ideas for --

MR. EPSTEIN: That's part of what we'll be submitting in our comments, yes.

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PANEL MEMBER: -- it'd be really useful to have you submit those to the docket just so we -- and then, the other thing was just you had mentioned a few other things, THC-free and other people have talked about full spectrum phytocannabinoids or something like that.

If there's a list of these sorts of terms that you feel would benefit from some kind of a standardization, it'd be just useful if we had a full list of the different terms that people are using today.

MR. EPSTEIN: Yeah, absolutely.

PANEL MEMBER: Thanks.

MR. EPSTEIN: Thank you.

PANEL MEMBER: Just one last question.

MR. EPSTEIN: Yeah.

PANEL MEMBER: You also used -- you talked about CGMPs as well. Are you seeing that most manufacturers are actually following the CGMPs in this space?

MR. EPSTEIN: No. Thank you.

MS. CRISTINZIO: All right. Moving onto our

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next manufacturer, number 80, Bill Grubb.

MR. GRUBB: Good afternoon. I'm here this afternoon representing Noramco. We are a CGMP active pharmaceutical ingredient manufacturer. We're registered with the FDA and DEA at our facilities in Wilmington, Delaware and Athens, Georgia.

We supply around -- materials registered under around 24 U.S. DMFs and then other registrations around the world. We supply our products into 40 countries. And again, that's active pharmaceutical ingredient, not drug product.

For 12 of the -- oh, sorry. For 12 of the 40 years that we have been in existence, we've been manufacturing cannabinoids, again under a U.S. DMF. And that's up on my slide, the DMF number. Sorry. Didn't realize it hadn't advanced.

If you look at Noramco today, we actually produce 30 -- over 30, around 35 individual cannabinoids that are used in pharmaceutical, clinical or analytical testing applications. And again, those are produced using validated analytical methods and procedures described in our SOPs.

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More specifically to CBD, as described in our drug master file that's listed up on the screen there, 33223, we manufacture CBD synthetically using well-characterized regulatory starting materials. We also test our material with validated analytical methods as described in our DMF on file with the FDA.

So while our approach does implicitly mean that we're not looking out for pesticides or heavy metals from the soil or plant impurities, I still think that we have a lot of common ground with people that are talking here today related to the principles that should apply to extractors or people who are producing CBD synthetically.

Some of this has been covered today and so I won't go back through it in quite as much detail as I was planning. But unfortunately there's a lot of mislabeled or misrepresented CBD in the marketplace.

And so, I selected specifically a reference from 2017, 2018 and 2019, all from peer-reviewed journals or respected government agencies like the CDC to say, you know, that there is a need for specific federal oversight to guarantee consumer safety and to

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make sure that frankly people know what they're taking.

To me, the simplest way to get there -- and this has bene covered in some instances today -- is to follow codified CGMPs that exist for foods, supplements and for drugs.

And Noramco's position and what we're entering in is a comment and we'll upload our information in more detail to the portal is that whether the CBD is extracted or synthesized, whether it's intended as a drug, a food or a supplement and whether -- you know, we're agnostic to the delivery mechanism because that's not our role.

But if it's oral, topical or inhaled, we believe that CBD -- I mean, CGMP regardless of which one of those is very, very important for public safety.

Our next comment is that while the Agricultural Improvement Act, or the farm bill, says 0.3 percent might be okay for agricultural products, we don't believe that to be true.

We think that 0.1 percent, as noted in the

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references that are on the screen, the FDA's own assessment, the World Health organization's expert committee on drug dependence is certainly less than the 0.3.

And if you just follow ICH guidelines for control of related substances and impurities, 0.1 percent makes sense. And so, that, you know, is something that we really do believe in. And we're able to produce that as are others that have reported today. And so, we feel that it should be adopted as a standard.

In practice, as it says on the slide, you know, we're around 10 parts per million, or 0.001 percent. And we've submit in our DMF a limit of 0.10.

Tightly controlling related substances is very important and I think that whether you're extracting or synthetic, following ICH guidelines for the control of related substances is very important and assures public safety.

We ourselves down to a limit of quantitation of 0.02 percent, have five batches that we manufactured this year shown at commercial scale that

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have no detection of total impurities.

End product label accuracy, consumer or drugs, depends on a pharmaceutical ingredient that has undergone rigorous stability testing. And again, we test our research and commercial batches under an ICH stability guideline and we report those results in our DMF. I'm showing some publicly here today just to demonstrate the point that very close to the actual melting point of CBD, crystalline solid, 40 degrees Celsius at 75 percent relative humidity, you can have a stable product.

Finally and in closing, I've summarized our points here, as well as one I didn't make regarding working with the USP. But we do believe that regardless of the method of production, the intended use for drug, foods or supplements that patients and consumer deserve a CBD that's produced according to GMP and that's tested for identity, purity, quality and strength. Thank you.

PANEL MEMBER: You mentioned on slide three several advantages to synthetic CBD compared to botanically derived, less variability, fewer

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contaminants. Are you aware of any risks in synthesizing CBD relative to botanicals?

MR. GRUBB: No, I'm not. And I'm not because these are -- you know, it's well characterize CBD. It's described in a DMF. It's included in clinical trials. And we're going through validated test methods and procedures to assure that it really is CBD.

PANEL MEMBER: What challenges do you encounter in synthesizing it that might be either a barrier to entry or might be a reason why others might not be able to follow suit commercially?

MR. GRUBB: Frankly our biggest challenge right now is that if you grow and extract hemp in an unregulated manner, you're not subject to DEA controls, and we are.

That is our single biggest challenge is that we're making a very pure product that's under the purview of the FDA and registered facilities and even DEA-registered facilities because both of ours are. But it's not a very level playing field since last December. Thank you.

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MS. CRISTINZIO: Thank you. Our next speaker, speaker number 81, is Deb Kimless.

DR. KIMLESS: So how do we do the slides?

MS. CRISTINZIO: Just one second. We're almost there.

DR. KIMLESS: There we go. Hello, and thank you for this opportunity to present to you today. My name is Dr. Deborah Kimless, and I'm a 25-year, board-certified anesthesiologist and pain medicine specialist. I'm here on behalf of Pure Green, a licensed medical cannabis processing company in Michigan.

I was confident to try sublingual CBD with patients because of Pure Green's processes and procedures. And what I learned is that Pure Green sublingual CBD was safe and effective treatment option for my patients. And while I've presented our clinical data in many scientific forms, never in this short amount of time.

So I do regret that I can only present a high level summary to demonstrate that data does exist to help the FDA gain insight into safety and efficacy of

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sublingual CBD products manufactured under a state-regulated program. And I'll describe how an integrated approach achieves this goal.

So the clinical data. Six pilot clinical trials were run in diverse populations with symptoms including PTSD, opioid dependency, insomnia, anxiety and pain and all with positive results. I will report here on one of those trials, the pain trial.

So we had a 16-patient trial with mild to moderate chronic pain that was being treated with NSAIDs. The average starting pain scale score was 5.2 on a scale of zero to 10.

The data demonstrates clinically and statistically significant pain reduction most beginning within eight minutes of taking the sublingual tablet where the average pain scale score dropped by more than 50 percent.

Pain relief routinely lasted four to six hours, sometimes over a 24-hour period, without adverse effects. In fact, the one side effect that was reported by the majority of patients was an overwhelming sense of wellbeing. We're currently

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running a follow-up multicenter clinical trial with an n greater than 16 and we're also doing PK tests.

The tablet. Patients were given a 5 mg CBD sublingual table that also contains terpenes. The patent-pending formulation renders the tablet water soluble to enhance bioavailability. A 20 mg sublingual CBD iteration of this tablet has been on sale in Michigan because the company Pure Green was granted the first state medical cannabis processor license.

The tablet is manufactured under a validated GMP production conditions and each batch is tested by an independent testing lab guaranteeing every batch to have accurate and reliable dosing.

The entire tablet processing method and API processes method is fully regulated, meets good manufacturing practices and is tested throughout the production life cycle for potency, residual solvents, heavy metals, microbials and pesticides by the state licensed independent testing laboratories.

The vertical integration of the business lines ensures complete beginning to end product

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quality control. Pure Green was one of the first Michigan medical cannabis state licenses and because of this they've obtained pharmacovigilance data in nearly 500,000 dosages in just 10 months.

And it can be concluded that this sublingual form of CBD was well tolerated, safe and effective. And in fact, the only two side effects that were reported, one in less than 1 percent of the population, was transient drowsiness and then, from the pain trial, where patients claimed an overwhelming sense of wellbeing. And we're prepared to submit additional proprietary data to aid the agency in deliberations.

And here's a picture of a labeled box that contains a similar narrative to what you would see with a traditional over-the-counter pain reliever. We believe that with CBD safety and efficacy, a parallel pat can coexist, the traditional FDA drug path along with the current regulated state programs.

We appreciate the FDA considering this CBD presentation and thank you again for your time and consideration.

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PANEL MEMBER: Thank you, and look forward to seeing your data. Out of curiosity, what's overwhelming sense of wellbeing and how is it measured?

DR. KIMLESS: It was a statement in the notes section in their -- when they were submitting them on the app. We have a smartphone app that patients who are identified get to enter it in. And in the notes section, many say they had a feeling of wellbeing or overwhelming feeling of wellbeing or incredible sense of wellbeing. Thank you.

MS. CRISTINZIO: Thank you. Next up, we have Douglas MacKay.

DR. MACKAY: Hi. My name is Douglas MacKay. I'm scenarios vice president, scientific and regulatory affairs, for CV Sciences. I think there's one thing that we can all agree is very clear. You guys have a really tough job ahead of you. It's going to be really hard to manage this diverse set of viewpoints and good luck with that.

CV Sciences operates two distinct divisions. The consumer division delivers hemp products through

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its Plus CBD oil brand and we also have a pharmaceutical division that's pursuing an FDA-approved drug. Responsible industry fully embraces robust FDA regulation.

An appropriate and predictable regulatory framework protects consumers while allowing a pathway for companies to lawfully market various types of cannabis-derived products. Industry applauds FDA for the significant work done so far to respond to this rapidly changing environment.

USDA and FDA have been tasked with developing regulations that separate an agricultural commodity from a controlled substance. Let me repeat that. You have to separate an agricultural commodity from a controlled substance.

Responsible industry strongly encourages that FDA and USDA closely collaborate to ensure that the corresponding regulations are synchronized to efficiently differentiate the hemp and marijuana supply chains.

International hemp regulatory models apply a seed licensing and registration scheme that assures

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that only appropriate food, fiber hemp cultivars are used as a raw material source for the hemp-based industries.

A verified food fiber hemp supply chain provides a safe, non-intoxicating botanical starting material. Hemp can be safely regulated by FDA like other natural ingredients. Current FDA regulations allow naturally derived ingredients to coexist as conventional foods, dietary supplements and drugs. This slide provides examples of different ingredients derived from the same natural resource being appropriately marketed in different lanes.

CV Sciences suggests that FDA rulemaking is not required if FDA provides clear industry guidance to the type and scope of hemp ingredients allowed in each FDA-regulated category.

For conventional foods, FDA has completed three GRAS notices for hemp seed derived ingredients. The food pathway is clear for companies that want to use nutrient-rich components of hemp in food or to develop new ingredients.

The drug regulatory pathway is also clear for

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companies that want to develop new drugs or new botanical drugs to treat different diseases. For supplements, FDA has been clear that highly purified and isolated CBD can't be added to food or dietary supplements.

However, scientific and legal experts agree that a hemp extract containing a full array of cannabinoids and other plant constituents is a significantly different article than a highly purified CBD.

Each has a unique identity and a unique biological activity. CV Sciences suggests an FDA guidance that differentiates a hemp extract from a prescription CBD will allow companies to confidentially file the requisite NDI notifications.

Today, FDA has made a broad request for data on cannabis safety. To satisfy this request, one must first qualify the specific composition of the cannabis-derived ingredient and, second, the intended use of the ingredient. Cannabis or hemp product safety is based on the chemistry of the ingredient and the intended use.

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FDA regulations, when evaluated holistically, provide an appropriate framework to regulate cannabis for different intended uses. A product intended to treat children with epilepsy is a drug and it should come with the pre- and post-market rigor of FDA-approved drugs. However, a food product that provides nutrition or a supplement that supports a healthy lifestyle have regulatory paradigms that appropriately correspond with those uses.

CV Sciences looks forward to submitting detailed written comments to share our experience working with hemp. Time constraints will only allow me to share a few ways that we ensure we provide consumers with safe and high quality hemp products.

We start with a food fiber hemp cultivar from a licensed and registered hemp seed. We establish the identity of our ingredients through technical analysis. We have published in the peer-reviewed literature the appropriate toxicology studies on our ingredient. Those are available on PubMed and I will submit them to the docket.

We also manufacture in a third party GMP-

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verified facility and we are compliant with labeling and marketing regulations, as well as adverse event reporting and recordkeeping requirements.

In closing, I want to emphasize that responsible hemp companies and FDA have a shared goal of protecting consumers while providing access to appropriate hemp products. Thank you for this opportunity to share our experience and we look forward to providing more substantive written comments, and I'm open to questions.

(Applause.)

PANEL MEMBER: It's interesting that you sort of outlined three different pathways, which obviously we're familiar with. But -- and the fact that you believe -- seem to believe strongly that they coexist.

And I guess one of my questions is do you see any of them disincentivizing sort of the other, in other words, allowing a broader use disincentivizing the ability to complete clinical trials. We've heard a little bit about that today.

MR. MACKAY: Yeah. I mean -- yeah. So if -- with all due respect, the pharmaceutical companies

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have gone through the investment and gotten the drug improved. The provision that is in place that says we can't introduce that to the food supply.

So isolated CBD in my humble opinion, isolated CBD and THC are off limits. But we have hemp extracts. And defining a hemp extract, establishing the safety of the hemp extract, understanding the level of cannabinoids and other constituents in that product is what we do in botanical medicine under the current regulatory paradigm -- excuse me, botanical dietary supplements. That was a slip. I didn't mean to say medicine.

You know, it's all there is what I'm trying to say. But yes, I think if we allow isolated crystalline CBD to be free-flowing in the food space, it disincentivizes additional research.

PANEL MEMBER: And so how are you defining hemp extract and what levels of CBD and THC are you seeing in that?

MR. MACKAY: Well, the levels of CBD are depending on not only extraction method, the plant starting material, but also the data we have on

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safety. Those are all guiding principles.

I know you're dying for a number. Our product has about 15 mg per soft gel in it and that's what was supported by our safety studies.

PANEL MEMBER: In any of your comments, do you explain the taste, aroma, nutritive value or technical effect that these extracts would have in a conventional food?

MR. MACKAY: So I have similar questions about the appropriateness in conventional food because of the lack of those properties. There's some indications that CBD does have a bitter taste similar to caffeine.

So we might have a taste and there may be some technical effects that might be reasons to add it to food. But I haven't seen frank, clear arguments about how it could be or why it could be a food product. And my company hasn't gone down that pathway for those reasons.

MS. CRISTINZIO: Thank you. Our next speaker is number 83, Ray Mannion.

MR. MANNION: Good afternoon. My name is Ray

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Mannion, vice president of manufacturing with Zynerba Pharmaceuticals, located in Devon, Pennsylvania. On behalf of the entire Zynerba team, I'd like to thank FDA for the opportunity to present at today's public hearing.

There's an established FDA commitment to quality and safety of cannabinoid products. FDA has previously approved drugs containing CBD and THC, thereby ensuring comprehensive oversight of the products. The 2018 farm bill explicitly preserved FDA's authority to regulate CBD products in furtherance of the agency's mandate to protect the public health.

All cannabinoid products should be held to the same rigorous quality, safety and efficacy standards established by FDA to protect the public. The current landscape is marked by, one, proliferation of cannabinoid-containing products and, two, confusion about the legality of distribution and differences between federal and state regulatory oversight of cannabis and cannabinoids.

There are established risks with non-FDA-

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regulated cannabis. Lab analyses demonstrate that some non-FDA-approved, commercially available CBD products do not contain what is listed on their product labels. FDA's independent lab testing has shown similar results.

In addition, CBD product testing has shown the presence of THC at levels which may be sufficient to produce a negative euphoric effect, particularly among children. Common cannabis contaminants include microbes in the form of bacteria and fungi, heavy metals and pesticides.

Microbial contamination may occur during improper preparation and storage of cannabis products and can result in infections. Heavy metal contaminants may be attributable to soil fertilizer and/or cross-contamination during processing. Pesticide use in the cultivation of cannabis products is well established.

FDA should therefore continue to enforce pharmaceutical compliant CGMP processes and testing standards to ensure product quality and safety for all commercially distributed cannabinoid products.

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Pharmaceutical product development, evaluation and processes are well defined in FDA and international guidelines.

Testing limits and controls for each stage of product development are established. Existing pharmaceutical development, manufacturing and quality assurance processes ensure product quality, label accuracy and minimize the risk to public safety.

FDA should therefore continue to leverage the existing robust regulatory framework in the oversight of cannabinoids. There exists the FDA regulatory oversight guidance, review and inspection and within that, the good manufacturing procedures regulations, the International Conference on Harmonization Guidelines, U.S. Pharmacopeia and national formulary standards and finally drug product track and trace requirements.

Product quality manufacturing controls ensure product identity, purity, strength, quality and label accuracy. It's important to consider the control of raw materials, solvents, the impurities, herbicides, pesticides and fungicides.

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Documented manufacturing processes and end process testing are important considerations, as are microbial testing, as is microbial testing to ensure that acceptable levels are not exceeded. And then finally, controlled storage conditions on this aspect can safeguard against the impact of moisture like packaging and oxygen exposure. Product stability and shelf life testing is also a consideration.

In summary, FDA has a well-established history of protecting the public health. Existing regulations and processes governing the manufacture of pharmaceutical products establish critical controls to ensure necessary quality and safety standards are met.

This robust framework can and should be leveraged in the regulation of all cannabinoid products. Less stringent manufacturing and quality standards would create an unnecessary public health risk. Thank you. Any questions?

MS. CRISTINZIO: Thank you very much. We are now on speaker number 84, Rosemary Mazanet.

DR. MAZANET: Good afternoon. I'd like to tell you a little bit about Columbia Care. Columbia

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Care is U.S.-based medical cannabis company. We're in 14 states. We're also in Europe now. We're licensed for medical cannabis. We are largely vertically integrated in each of those states. And the reason why we have always been vertically integrated or made every attempt is to control quality.

We learned early on that it was really impossible to have a -- to understand what your product really had been through unless you grew it, manufactured it and had sort of chain of custody throughout the whole situation in most states.

We are in states that largely are regulated. We're in New York. In some states like New York, we have a DEA Schedule 1 license around our manufacturing plant. In some states like Florida, all of our manufacturing is GMP. So we try to be as compliant as we can with having very high standards for manufacture in the medical cannabis space.

And the reason for that is because we are undertaking more than a dozen IRB-approved trials in the United States and Europe to try to look at efficacy in these products. And we believe strongly

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that you have to have the same product. You have to eliminate variables if you're going to do any meaningful research. So we have very formulated products and those are what we test in patients, apples to apples. We're not big fans, as you might imagine, of flower because we feel that it's very hard to have a dosable product.

So I'm a HEMOC by original training. I actually have done drug development my whole life and I became involved with Columbia Care back in 2013 because they were interested in doing clinical trials with formulated dosable products in as many patients as possible in the United States. And that's what we're about.

But what I'm here today to talk about is hemp, hemp CBD because we believe that that's an important medication. Epidiolex has shown us that it has a lot of potential. We're actually doing trials globally with a high dose CBD formulation in psychosis out of King's College, London. But again, quality is really the issue here that we're concerned about.

I'm telling you something that you've heard

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all day. I apologize for that. But I'm going to say it again. Okay. We know, going back to 2015, the first publication in JAMA that said that greater than 15 percent of the products evaluated had significantly less cannabinoid content than labeled. Okay. You know, that was 2015.

So we have another publication in 2017 that's more disturbing. Only 31 percent of CBD extracts were labeled correctly. Sixty-nine were labeled -- or 69 percent were labeled incorrectly. Forty-three were under-labeled. Twenty-six were over-labeled. And some of those actually had THC in them. So this is pretty alarming if you actually read that JAMA paper. There was THC in a good number of those products that were sold as a CBD extract.

Now what that shows is just that people are lazy. People will do an extraction of whatever plant they have and they'll sell it. And until somebody tells them that they can't do that, they will continue to do it.

This past year, Forensic Science International had a study that was published looking

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at again not just contaminants. We're not talking about microbes here. We're not talking about heavy metals. We're talking about things that during the manufacturing process, chemicals that got into that product that shouldn't have been there.

And some of that was dextromethorphan, which really is quite interesting when you think about how that would have gotten into CBD extracted product. Again, there were no quality assurances to make sure that that happened.

You know, the national news has picked up on this, the Philadelphia Inquirer, some Alabama papers. But again, you know, I think the fact that potentially dangerous CBD is sort of getting into the news is something that should concern us all. Andi think to a large extent that's why we're here today.

You know, we're trying to make a legitimate business out of the medical products that might be available in the cannabis plant. And so, we need to be credible and we need to get away from some of the fantastic, if you will, things that we read.

There was a large study done in California

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recently. I want to point out here that there are two products that had absolutely no CBD in them at all. If I were a parent of a child that had a seizure disorder and I was not eligible for reimbursement to receive Epidiolex and I was buying CBD, this would make me sick. This is just really sad when we think that there are people that rely on these medicines.

So moving forward, again, I think, you know, singing again to the choir here, that the FDA guidance should protect safety. GMPs should be required. There should be standards for the levels in food and dietary supplements. There should be labeling requirements. And there should be restrictions on disease claims. And thank you for being able to present today.

PANEL MEMBER: Are you -- is your submission -- does it propose specific levels for food and dietary supplements? And if so, does it take into account exposure across a broader -- a wide array of products?

DR. MAZANET: We actually have many formulated products that may differ because of that.

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So I think when we put in some formal comments, I can address that, yes. Thank you.

MS. CRISTINZIO: Thank you. Next up, we have speaker 85, Alice Mead.

MS. MEAD: Good afternoon. I'm Alice Mead, from GW Pharmaceuticals. We're here to express our support for a strong and comprehensive regulatory framework that first and foremost further encourages development of cannabis-derived medications for serious and life-threatening illnesses.

Next, ensures that CBD consumer products can be safely used in a mass market setting that lacks physician oversight. And finally, establishes clear differentiation in dosing and concentration levels between FDA-approved medicines and consumer goods.

We've seen that cannabis-derived derived medications can change lives. Epidiolex is not only the first cannabis-derived medication approved by the FDA. It's brought new hope to thousands of families with loved ones suffering from two life-threatening forms of epilepsy, Dravet syndrome and Lennox-Gastaut syndrome. And we're just scratching the surface with

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Epidiolex.

There's tremendous potential in this plant to treat many more severe illnesses. GW is researching eight different disease areas. We're leading the way. But without greater incentives, few companies will follow us down the FDA pathway.

So why dose FDA approval matter? Because the FDA approval process is the only way to answer important questions about a drug, about the disease it seeks to treat and safety considerations that are unique to the patients who will take the drug.

For example, no one knew CBD is potentially toxic to the liver until we conducted clinical and preclinical studies. To answer such questions, we've spent the past 20 years researching this plant.

Along the way, we've built an extremely comprehensive scientific database on CBD. We know that CBD causes drug-induced liver injury. Therefore physicians are instructed carefully to monitor liver function with blood tests when treating patients with Epidiolex.

We also know that CBD has powerful drug-drug

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interactions with other medications like warfarin, a common blood thinner. This can cause these other drugs to have stronger or weaker effects than intended.

GW and non-GW studies alike tell us that CBD-rich extracts can cause a number of other side effects such as sleepiness, which can be a problem when driving.

That brings me to the issue of unknowns. There is still so much we do not know about CBD. It has not been tested in a number of vulnerable patient populations such as pregnant women and patients over 55. In fact, concerns about fetal toxicity in lab rats prompted FDA to require us to do more studies in fetal toxicity.

Our research shows that negative side effects from CBD begin to appear at 1 mg/kg of body weight, or about 70 mg per day for an average adult. These side effects appear at relatively low levels probably because CBD affects multiple systems in the body. And people will ingest CBD from multiple sources. And therefore there should be wide safety margins when

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setting concentration limits and daily serving levels.

That brings me to my last point, which I guess I should have been clicking all this time, shouldn't I? My last point is THC. It's a myth that CBD products will have only trace amounts of THC.

The 0.3 percent limit from the farm bill could be interpreted to allow, for example, a small gummy bear to have as much as 12 mg of THC. That means that two gummy bears could deliver more THC than smoking an entire marijuana cigarette.

In closing, we recognize that there are patients suffering from serious ailments outside of Dravet and LGS who feel as though in the absence of an approved cannabis medication, using unapproved cannabis products is their only option. But this is not ideal.

That's why we support a strong regulatory framework for cannabis products that encourages robust research, maintains the integrity of the FDA approval process for medicines and brings more FDA-approved medicines to patients. Thank you.

(Applause.)

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

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

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

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

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

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

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

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

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

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

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

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

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shelf in the state of Maryland if you're telling me that it's illegal to supply it or illegal to sell it. The response was you're giving us anxiety. Well, you know, I'm sure we are.

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

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

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

Once we find out that the product that we

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plan on using complies, then we will use it in manufacturing. Before our product is released, our lot number will go to a third party laboratory to be able to confirm the same exact parameters. That COA from the lab would be published on the Internet for inspection by any government agency and any consumer.

All we want to do is we want to make sure that we are a responsible manufacturer in the industry. But we have to have a path. We have to know where you guys are going to stand because if we receive a letter telling us that we can't operate under any circumstance, we expect you to do the same thing with every other manufacturer.

The last thing is my concern is if we don't have a provisional kind of license allowing manufacturers or responsible manufacturers like us to operate, all the FDA is going to do is going to drive those manufacturers underground and you're going to have a black market to be able to put this product in. You can't control the product on the shelf. And as long as people want it, people are going to manufacture it.

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So my request is to be able to find a path for a provisional license for certain companies that meet certain criteria to be able to manufacture and we will self-police ourselves under the supervision of the FDA or any agency that chooses to regulate us. But we want regulation and we welcome it. So please find a path for us to be able to provide safe products for the consumer.

MS. CRISTINZIO: Thank you.

MR. MOHEYELDIEN: That's it. Thank you.

MS. CRISTINZIO: Next, we have speaker number 86, Stephen Mueller.

MR. MUELLER: My name is Stephen Mueller. I'm the founder and CTO of Mile High Labs. Mile High Labs is a largescale hemp extraction and purification company that produces thousands of kilograms of CBD every month. Through our customers, that CBD goes into maybe 10 million products every month.

Our production facilities and headquarters are in Colorado. We also have international offices in the UK and New Zealand.

You know, we really believe in and are

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committed to and have invested in this industry in a really significant way. We employ more than 130 people. We've spent many tens of millions of dollars on hemp that has gone to American farmers. We've spent tens of millions of dollars on equipment and infrastructure.

So our company is really focused on manufacturing of CBD ingredients. And that starts with our process expertise and our engineering team. And we've designed and built largescale customized extraction and purification equipment that specifically is tailored to this industry.

The second key component of our manufacturing is our commitment to quality and compliance. We manufacture according to GMP standards, 21 CFR parts 111 and 117 and we've been audited by third parties for compliance to these GMPs. We have strict specifications on all incoming components and finished products and each material is tested using validated in-house methods for compliance and specification.

You know, this has been talked a lot about today. But the size of the CBD market is exploding

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right now. Many other presenters have talked about that today. But it's estimated that up to 64 million Americans have used CBD in the past 24 months. So regardless of the existing regulations, this thing is taking off and we really want to make sure that it's done in a way that's safe for the consumer.

You know, here are some of the common issues that we see in the market, and these have kind of been covered as well. Mislabeled products. Some of the presentations I saw today were pretty astounding in terms of just how mislabeled they are. Facilities that aren't operating under GMPs. This is one of the biggest issues that we see out there.

If you don't have the proper controls in place per the GMP guidelines, you're really at risk of shipping unsafe product to the consumer. And many manufacturers don't have access to accurate test methods, either in-house or through contract labs.

The level of inconsistency that we've see with some of the contract labs and third-party labs is really -- is pretty astounding.

So one of the problems today is that a lot of

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the manufacturers don't actually understand what they need to do to make a safe and consistent product for the consumer. Consumers also don't have confidence in the products themselves and don't understand which manufacturers they can look to, to buy a safe product.

And really, our position is that the good manufacturing practices already outlined by the FDA are really the baseline for production of a quality and consistent ingredient and we think that this should be applied to all CBD manufacturers.

So new dietary ingredient notification should also be required for all CBD dietary supplements. This is already outlined in FDA guidelines and we think that CBD fits into those existing guidelines.

The main focus of the discussion today seems to be around CBD. But a lot of the products on the shelf also contain many other compounds, so other cannabinoids, terpenes, degradants and we think that the FDA should evaluate all of these separately instead of trying to combine all of the non-THC products under one category. I think there's so much variability in the types of products out there that

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it's very difficult to regulate or to control consistency of the product. We can isolate and purify these compounds and formulate products with them that are more consistent.

So the heart of quality control is the ability to characterize and test raw materials and final products. Here's a list of some of the critical quality attributes that we think should be controlled for all of the materials and finished products that CBD manufacturers are dealing with.

You know, one thing in particular I want to point at here is using validated test methods, per the GMP guidelines, and really being able to produce accurate test results. This is one of the biggest issues that leads to some of the label claim issues and other problems in the industry.

The third-party labs are using generic test methods and the method really should be validated for each sample matrix. It's not appropriate to use a method that was validated for CBD content in hemp and also use that method for testing products containing CBD without performing studies to demonstrate the

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applicability of the method to the sample matrix.

Right now most of the industry uses contract labs who are testing products using generic methods that have not been validated for that particular sample matrix. You know, being an agricultural product of hemp, we also need to look at heavy metals and microbial contamination.

So I want to commend the FDA for bringing together all of the stakeholders to work together towards a solution. We believe strong regulation enacted quickly will benefit consumers and improve the industry. Thanks for the opportunity. Any questions?

PANEL MEMBER: Yeah. Just one follow-up question. So your slide four, you talked about regulating use in dietary supplements, foods and cosmetics at lower strengths.

I didn't know if you had an idea for how we would go about identifying that lower strength that would be appropriate for those uses and any thoughts you had with that would be really helpful.

MR. MUELLER: So I think you'd need to look at some of the safety data out there in the studies

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that have been done. You know, as an ingredient manufacturer, we're not making consumer products that have guidelines on how much can be taken. But you know, we think this is an important route for kind of the broader public outside of pharmaceutical drug applications. Thank you.

MS. CRISTINZIO: Thank you. Next we have speaker number 87, Aaron Secrist.

MR. SECRIST: Good afternoon. My name is Aaron Secrist. I'm the vice president of quality and regulatory affairs for NOW Health Group. As a responsible manufacturer of legal dietary supplements, NOW Health Group is very concerned about the current state of affairs with regards to hemp and hemp-derived products such as CBD.

The current approach taken by FDA, which seems to be best described as unofficial enforcement discretion, does little to promote and protect the public health, the primary mission of the agency.

By not enforcing the current statutes, the agency has encouraged irresponsible or, at best, uneducated and uninformed companies to manufacture and

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market CBD and other hemp-derived products without understanding in many instances the identity of the CBD ingredients or hemp-derived ingredients that they're putting in the products and without any safety studies performed on these ingredients that they use in the products that seem to vary so widely in the marketplace, as we've seen today.

We respectfully ask the FDA to do one of two things: either enforce the current statutes and hold the companies responsible for manufacturing and marketing these illegal products or we urge the secretary to exercise his authority under current statute to allow hemp-derived products such as CBD to be recognized as legal dietary ingredients, provided that an NDIN is submitted and all other applicable federal laws are met.

This will encourage responsible companies who follow the law, such as NOW Health Group, to potentially enter the market through the front door and perform the requisite safety studies, method validation, clinical studies and submit an NDIN for agency review to ensure that safe and effective

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products are available to the American public. This is in keeping with the FDA's mission and our company's mission and values.

We also respectfully ask the FDA to ensure that the rule of law is upheld by barring any company illegally marketing CBD or other hemp-derived dietary supplements from submitting an NDIN for a period of time equal to the time that their products have been illegally marketed.

If the FDA simply opens the door to hemp-derived ingredients and products containing CBD by exercising the secretary's authority without such a provision, then it effectively encourages companies to flout the law in the future, as the only consequence would seem to be a three- to five-year head start in the marketplace over companies who choose to follow the law.

We also respectfully ask the FDA to continue to explore the idea of master files relative to the NDIN process. We believe that this will help provide some IP protection to the companies that spend the precious resources of time and money to ensure the

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identity of the potentially new dietary ingredient, along with the requisite safety studies necessary to demonstrate to the agency that the ingredient is safe under the conditions of use.

We do not believe that the agency should accept self-affirmed GRAS as a way to circumvent the NDIN process as it relates to CBD and other hemp-derived ingredients. We also believe that it's very important for the FDA to ensure that there's federal preemption for any pathway forward for hemp-derived ingredients such as CBD as potential new dietary ingredients.

Varied and often contradictory state law makes it nearly impossible for responsible companies to enter the marketplace, which leads to subpar and possibly unsafe products on the marketplace. Thank you for your time.

MS. CRISTINZIO: Thank you. Next we have James Sharkey, number 88.

DR. SHARKEY: Good afternoon. I'm Dr. James Sharkey. A little bit about me, I have a doctorate in biomedical sciences and I am the director of research

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and development for hemp and CBD products for Dixie Brands and I'm also --

MS. CRISTINZIO: Can you move closer to the microphone please?

DR. SHARKEY: I'm sorry.

MS. CRISTINZIO: That's okay.

DR. SHARKEY: And I'm also the chief science officer for Therabis, which is a pet supplement brand. My talk today is going to primarily focus on the human supplement aspect of our businesses. But the written comments that we will be providing will also include animals.

Dixie Brands, we're based out of Denver, Colorado and we were one of the pioneers in the medical cannabis industry, which naturally brought along hemp and CBD products. We've been creating these products since 2009 under the regulatory environment of the Colorado -- state of Colorado, which is one of the most mature hemp and cannabis markets in the United States.

The reason why I'm employed there, unlike others in the space, is that we are very research-

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emphasis, very heavy research emphasis and providing products that are safe and have a degree of efficacy.

Recently we just announced actually yesterday that we partnered with a major university veterinary school to perform a clinical study on efficacy with safety in canine joint health.

So I'm going to proceed to go to -- now, we've heard today that there is a dearth of research in the space, specifically regarding safety. It's true and it isn't true. In the United States, it absolutely is true that very little of this work has been produced in the United States.

The majority of this are products from overseas. And I've selected just a few studies to show that we have side effect -- chronicling of side effects in humans, in oral administration since 1973 as well as across a broad range of dosages.

Now I just learned today from GW Pharmaceutical that they have shown adverse events as low as 1 mg/kg. It's in a bit of conflict and that is not publicly available. So I would strongly encourage that, for the benefit of all of us stakeholders, that

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these type of studies be made publicly available so that we can see and actually produce products, given if it is -- if the FDA does take a path towards a supplement category, that we can actually operate and provide safe products because there are a lot of us out there who do this, do want to ensure safety.

So beginning with Carneal, that was a relatively small study. But 40 healthy adult males and a dosage of 15 to 60 mg. So roughly that is sub 1 mg/kg. Hollister was 200 to 100. The more interesting one would be Consroe, which was a 15-week study in Huntington disease patients at 10 mg/kg/day that reported no significant side effects.

But the more recent data we have is the Epidiolex safety trial and the extended access program. A total of 607 patients were in the safety arm of the extended access program. Dosages got up to between 25 and 50 mg/kg/day and the dose range corresponded to 20 mg/kg/day for the study and 200 mg per day for the maintenance dose in a 10 kg child.

Primary findings, it was well tolerated. However, they did show some drug interactions, which

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we absolutely have to be concerned with because previous mouse work has shown inhibition of cytochrome P450s. And this was with clobazam and valproate. Valproate is known to have hepato -- to damage the liver and clobazam is known to have existing somnolence. As a matter of fact, the CBD of clobazam was predicted and characterized by Geffrey in 2015.

Then earlier today we learned from a previous group about this hepatotoxicity in mice. A lot of hard work has gone into that. But in reality, the test article they did, did not resemble anything that would be seen in a human being in the market.

Specifically regarding the THC levels and the fact that the residual solvents weren't characterized to a sufficient degree for a limit of quantitation. So we need some additional data and need to make sure that these studies accurately represent the products we're doing.

And then, here are just some conclusions based upon this. The FDA has done a clinical trial, a Phase III clinical trial and approved a drug in a vulnerable patient population of children. That is

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the most robust safety trials that exist. Further, we have empirical -- not empirical data, but anecdotal data and a lack of reporting of side effects in the general populace.

This lends to a degree that a concentration of 1 to 2.8 mg/kg, which would be the consumer available dose, that these supplements would in fact be relatively safe in an adult -- health adult population. Thank you for your time.

MS. CRISTINZIO: Thank you. Speaker number 89, Priyanka Sharma?

DR. SHARMA: Thank you. Good afternoon to my industry colleagues and distinguished guests. It is truly an honor and a privilege for us to be here today. We'd like to thank the Food and Drug Administration for providing us with this platform today and for hosting this public hearing on cannabis-derived compounds.

My name is Dr. Priyanka Sharma, and I'm joined here by Pulak Sharma. We're co-founders of Kazmira. I'm going to be explaining the left-hand side and Pulak will be talking about the remaining

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information.
Kazmira is a biotechnology manufacturing company operating in Colorado producing THC-free CBD raw extracts derived from industrial hemp. Our products are consistently free of residual solvents, heavy metals, pesticide and microbial contaminants, to name a few.
We develop these raw ingredients for product manufacturers who produce finished goods which are distributed online and within retail channels. We believe that setting high product quality standards will enable development of finished products that are safe for consumers.
Industrial hemp manufacturers throughout the U.S. have already implemented significant quality control and stringent manufacturing standards in the current processes of extracting the hemp biomass into oils containing a variety of cannabinoids.
Today we would like to discuss three quality metrics already followed closed by hemp-derived product manufacturers: consumer safety, quality management systems and validated testing.

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With added support from federal regulatory agencies, we can continue to create a brighter future state for the hemp-derived products industry. At Kazmira, we have focused our manufacturing processes on meeting the current applicable standards of CBD raw materials. This enables our customers to give consumers a product with non-detect levels of THC.
Working with regulatory agencies, we would support development of guidelines for consumer product specifications.
Second, current quality management systems allow complete traceability from farm to product. Many of the manufacturers here today have obtained ISO 9001 and are working towards self-regulating CGMP compliance certifications.
To further standardize process controls, infrastructure to support higher quality control on a federal level needs to be provided. We as manufacturers would support guidance on obtaining FSMA, GFSI or other food safety management compliance practices.
Third, cannabis-testing laboratories are

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available today to manufacturers where contaminant testing is performed on raw materials and finished products. Cannabinoid purity analysis, residual solvents, heavy metals, pesticides and microbial contaminants are among the testing performed currently on these products.
Manufacturers and testing laboratories would support a collaboration between industry and federal regulatory stakeholders to develop federal compliance guidelines and standardized testing methods for CBD products.
MR. SHARMA: Thank you, Priyanka. Performing at the highest level of manufacturing and product quality standards is going to give us stronger consumer safety infrastructure.
First there will be increased quality transparency with consumers being aware of contents of their hemp-derived products through updated packaging and labeling requirements. This will spark a healthy debate that encourages education on product quality.
Second, enabling a pathway for acceptance of CBD oils through the right channels as a dietary

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supplement and a food ingredient will create accountability with all stakeholders and drive deeper transparency and trust with consumers.
This has been successfully replicated with ingredients such as fish oils. As for the CBD industry, this model has been defined with successful deployment by the Colorado Department of Public Health and Environment.
Finally, ingredient safety will drive the conversation of product safety with rigorous process control, quality management and high compliance standards that enable higher quality products consumers can trust. For example, this can be pursued through USP monographs for dietary supplements.
Thank you very much for your valuable time and enabling this engagement to start the conversation on this important subject. We hope that with the presentations today, the regulatory agencies got a glimpse of the industry stakeholders' vested interests in making processes and standards for consumer safety.
We look forward to continuing this dialog and creating a sustainable pathway for manufacturers to

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serve consumers with the highest quality and safety standards for cannabis-derived compounds and products. Thank you.

MS. CRISTINZIO: Thank you. Our last presentation before the break, number 90, Thuy Vu.

MS. VU: Good afternoon. My name is Thuy Vu and I am -- I serve as the director of operations and regulatory affairs for Hammer Enterprises integrated solutions, located in Evergreen, Colorado.

Hammer Enterprises is one of the largest vertically integrated industrial hemp companies in Colorado and we serve as a custom white label manufacturer offering a full spectrum of products for oral ingestion, inhalation and absorption.

Hammer Enterprises is committed to strict quality control guidelines, ethical standards and high integrity to deliver pesticide-free, chemical-free and preservative-free pesticides -- I'm sorry, preservative-free products. Hammer Enterprises is devoted to setting the highest standards in the industry promoting public health, public safety and environmental stewardship.

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My perspective is unique in that I started my career as a lead foodborne illness outbreak investigator for the Denver Department of Public Health and Environment, Public Health Inspections Division.

After cannabis legalization in Colorado in 2010, I took the initiative to become the first environmental health investigator to specialize in marijuana investigations, spearheading inspections, investigations and enforcement of the Denver marijuana industry, implementing the first food safety recalls of marijuana-infused products and the first foodborne illness outbreak investigation of a licensed marijuana operation in 2014.

In addition to my regulatory background, I have five years' experience in the private marijuana industry as well as the industrial hemp industry, specializing in cannabis extraction and refinement processes, concentrated infused products manufacturing, food safety concerns and quality control of cannabis and cannabis derivatives and cannabis-infused products.

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Colorado has successfully regulated the legal marijuana and industrial hemp program. The Colorado Department of Agriculture regulates the regulation -- the registration and cultivation of industrial hemp, requiring all plants cultivated in the registered land area meet the standard identity of no more than 0.3 percent THC on dry weight basis, as well as setting forth criteria for pesticide usage.

In July of 2017, the Colorado Department of Public Health and Environment announced a new industrial hemp policy recognizing all parts of the industrial hemp plant, including cannabidiol as a food ingredient. CDPHE's industrial hemp policy is the first of its kind in the nation and it's the most progressive program applying current good manufacturing practices to a new food ingredient.

Excuse me. Let me get to the right slide. Okay -- as a new food ingredient. CDPHE's industrial hemp policy is the first of its kind in the nation and it's the most progressive program applying current good manufacturing practices to a new food ingredient and for a new emerging industry.

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Hammer Enterprises played a pivotal role in the successful implementation of CDPHE's industrial hemp program, committing to a professional partnership with CDPHE as well as other government and regulatory agencies in efforts to advocate for informed, balanced and fair regulations for the new industry.

CDPHE's industrial hemp policy requires all parts of the plant utilized in food to be sourced from a state with an established or approved hemp program or a country that inspects and regulates the commodity to ensure its safety for human consumption.

The producer or grower must be in good standing and compliant with the governing laws of the state or the country of origin and the raw material and finished products must be tested to ensure that it meets the standard of identity for industrial hemp and that documentation must be available upon request.

The policy also outlines labeling requirements citing all products meet both state and federal labeling guidelines by identifying hemp as an ingredient, the CBD potency, including the statement FDA has not evaluated this product for safety or

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efficacy, as well as clearly stating that no health benefit claims are to be made on the label or the extension thereof.

In order for these products to be considered approved sources, CDPHE requires a manufactured foods registration of all industrial hemp operations. At Hammer Enterprises, we lead the industry by voluntarily adhering to the strictest guidelines for quality control with a robust testing protocol of all products throughout the extraction, purification and manufacturing process.

As a vertically integrated operation, we have transparent oversight and complete control over every step of the process, from propagation to cultivation to extraction, refinement and purification and the manufacturing of finished products, achieving full chain traceability.

All manufactured products are accompanied by a product specification sheet and a certificate of analysis, either from our in-house proficiency tested analytical laboratory or a third-party laboratory. While Colorado -- sorry. While Colorado marijuana

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enforcement division has the list of solvents approved for marijuana extractions, some of which are not approved solvents for the production of human food. CDPHE requires the industrial hemp industry use only approved food solvents.

These extracts can be further refined into various forms of concentrates used to produce products for ingestion, inhalation and absorption.

Challenges are to be expected in any emerging industry that has little to no regulatory oversight. Conflicting regulations from state to state, no current standardized AOC testing methodologies for the various matrices allowing for variances in potency testing results and the lack of guidance from a higher authority.

While some markets are still budding and others like Colorado progressive and radical in its approach to the regulation of industrial hemp, there lies one common theme: the desire and duty to ensure safety, consistency and quality of the manufacturing products containing cannabis and cannabis-derived compounds which can be attained by creating a

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legitimate regulatory framework to streamline definitions, standards, required testing and full chain traceability.

At Hammer Enterprises, we are setting this standard by pursuing our ISO 9001, 22000 and 17025 accreditations. We have an onsite PCQI and follow CGMPs and FSMA guidelines to ensure the safety, consistency and quality of all manufactured products.

We conduct -- we conduct batch testing of all of our raw materials, intermediate ingredients and finished products for cannabinoid potency, terpene profiles, residual solvents, mycotoxins, heavy metals, pesticide residues, moisture analysis, water activity and microbial, which includes total yeast and mold, total plate count, total coliform E. Coli and salmonella.

We also have preliminary nutritional analyses of our raw CO2 extract, CO2 extract oil to split isolate and finished products. Thank you.

MS. CRISTINZIO: Thank you so much for your comments. At this time, we are going to take a 15-minute break. We will see you back here at 3:30.

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(Whereupon, the foregoing went off the record.)

MS. CRISTINZIO: Please take a seat. We're about to begin. Thank you, everyone. We are ready to move onto a new category. It is the coveted "Other" category. First up, we have speaker number 91, Aubrey Adams. Thank you, Aubree.

OTHER

MS. ADAMS: Thank you for this opportunity. My name is Aubree Adams, and I'm a former Colorado mom. I moved to Houston, Texas this past summer because marijuana changed my home.

My son started using marijuana edibles in the eighth grade, soon after legalization. He was self-harming. We did not know he was using marijuana because the industry makes these products in deceptive forms to disguise use.

By February 2015, my son was irrational, paranoid, repeating things that did not make sense and, one night, he was so violent towards my younger son that my younger son ran barefoot through the snow to get away from him. He attempted suicide and was

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hospitalized. When he was discharged, he was still suicidal and I took him back to the ER where I was told it's just marijuana and was sent home.

Within a few days, my son was hospitalized again in a different town because there were no available beds in our town. He told me he was using dabs and he knew they were making him feel crazy and he was trying to quit. He described dabs as strong marijuana and called them crack weed. Dabs are mass produced, marketed and called medicine.

I volunteered my family for crisis intervention with the Department of Social Services because I could not find treatment for marijuana abuse. My son had developed the pediatric disease of addiction. And by the next year, not only was he using marijuana, he was using meth and heroin.

Marijuana kills. It's a gateway to more drugs and pharmaceutical drugs. My son allows me to tell his story because he wants the nation to know that marijuana is deadly, harmful and can change you forever with delusional thinking, hallucinations and increased risk for suicide, depression and addiction.

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My husband also allows me to tell his story. He read that marijuana would treat his panic attacks. But marijuana harmed him and now he suffers from severe depression, anxiety and suicidal thoughts.

My old community of Pueblo, Colorado has pot scholarships for every high school senior. It's a brilliant marketing plan by the predatory marijuana industry to groom their future users. It's a way to advertise to kids under the radar.

One out of three Pueblo high school seniors now uses marijuana and they have a 27.6 chronic absenteeism rate. There is a marijuana head shop next door to an alternative high school where kids can see shiny bongs and pipes and clothing and advertising glorifying and normalizing marijuana. They even have a person waving a sign saying come get your free pipe.

The number one cause of death ages 10 to 24 in Colorado is suicide. The main drug the victims are testing for is marijuana, ages 10 to 19. In Pueblo, Colorado, we are exposed to marijuana smell and smoke everywhere we go, in schools, in stores, driving down the road, in our own homes and on our own property.

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Seventy percent of the marijuana shops in Colorado recommend marijuana to pregnant women. So my mom and I hung baby bibs on the marijuana shops in Pueblo that says don't hurt our future, Colorado kids. It's a campaign by the Marijuana Accountability Coalition.

These are some of the people that have been killed by the effects of marijuana in the state of Colorado. Marijuana-induced suicides, marijuana-induced psychotic murders and people killed by marijuana-impaired drivers.

Here is a quilt from Moms Strong of more people that have been killed by the effects of marijuana, including marijuana psychosis and we even have a marijuana-induced cardiac death.

Marijuana industry advertises psychotic experiences as being a bonus. The ad says, ever been so high you've shredded a pizza? We'll take you there. Well, our kids have been so high they've wanted to kill themselves and others.

Legalizing marijuana has made it more dangerous than ever. It is now a weaponized assault

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on the brains of our loved ones. Colorado has allowed a full criminal organization to flourish with pretty store fronts to sell their poison under the disguise of medicine with false claims, no warning and no accountability.

Colorado has allowed products to be marketed in the highest potency levels ever known and Colorado has allowed a predatory industry to profit of our children's demise. For the marijuana industry to survive, they need more and future users. Those users are the youth of our country.

Colorado has now turned into a third world country. We have criminal organizations from all over the world living in our neighborhoods. Why have drug dealers been allowed to break federal law for so long?

Every day I try to forgive those that have allowed this to happen. Drugs are winning the war on drugs and the war is now in our homes and in our neighborhoods. I am a witness to the fall of America and THC is the weapon of our destruction.

I hope -- I hope the House of Representatives in Illinois is listening to the testimonies from the

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industry. It is very obvious tax and regulation is not working and the people here are poisoning the people of Colorado. And it is my wish that federal law be enforced. Thank you.

(Applause.)

MS. CRISTINZIO: Thank you.

MS. ADAMS: I do have -- I have a minute, so I would like to just keep --

MS. CRISTINZIO: No, I'm sorry. You're actually over.

MS. ADAMS: Oh, I'm over?

MS. CRISTINZIO: Yeah.

MS. ADAMS: I'm so sorry.

MS. CRISTINZIO: That's okay.

MS. ADAMS: Thank you.

MS. CRISTINZIO: Next up, speaker number 92, is Susan Audino.

DR. AUDINO: Good afternoon. Thank you for the opportunity to address this critically important need to create a regulatory pathway for CBD and other cannabis products.

My name is Dr. Susan Audino and my testimony

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here is built upon my expertise as an analytical chemist and in testing methods. I'm also an A2LA lead assessor and an instructor to many ISO standards. I believe you are familiar with A2LA's dedication to quality control testing. And I'm also a board member of the Center for Research on Environmental Medicine here in Maryland.

I serve on several expert advisory panels for the cannabis industry and international organizations such as an including AOSC and ASDM. My consulting firm serves chemical and biological laboratories, including those that test cannabis.

With that as a background, I'm going to stay in my lane here today and ask you to focus on the role that adequate product testing plays in protecting patient safety. Of course testing and efficacy go hand in hand. We've been hearing that all day. However today I will focus on efficacy only in passing and instead highlight the safety benefits associated with adequate testing.

I believe that medical cannabis and cannabis-based products have a place in the lives of patients.

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However, to be clear, I do not believe that they should be used freely and at the sole discretion of the public. Rather I believe they need to be introduced and used responsibly and cautiously by all parties -- patients, physicians, the FDA and all other regulatory bodies.

All patients, particularly those that are immunocompromised and children, need to be cautious in the adoption of these products and await the results of solid and reputable testing.

For example, has science-based testing accurately and precisely analyzed a product's ingredients? Has it evaluated the product's potential therapeutic benefits and risks of toxins or other ingredients causing adverse effects? How do we know how much is in there? How do we know how much is too much or how much is too little?

As we know, rigorous testing can answer questions such as these, empowering patients and physicians to make truly informed decisions.

As with other products, cannabis-derived products should be developed using and under the

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processes central to and authorized by the FDA. Product manufacture also requires the scientific integrity of third-party testing labs to ensure that a product meets the expectations displayed on its label and in its marketing efforts.

This needs to be demonstrated for every product, on every label, every time. My firm provides scientific and technical guidance to cannabis dispensaries, testing labs, medical personnel and regulatory bodies.

We promote active research towards the development of official test methods and we advocate strongly for appropriate clinical research and product development consistently -- consistent within the rigors of the FDA processes.

For decades, centuries actually, there have been countless anecdotal reports promoting the benefits of cannabis and cannabis-based materials, although advancing scientific evidence needs to catch up with these attestations. The transparency and openness with which you're conducting today's hearing and soliciting additional testimony is a relief.

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I say this because now more than ever the public is gambling with its health. Product marketing is far ahead of the science needed to substantiate product claims and the media frenzy around CBD-based products is rapidly expanding the use of unregulated substances that people are ingesting without clear indication of known benefits and risks.

This is a very frightening situation. Today there are still many unknowns about the cannabis plants and in particular its interactions with the brain and other organs in order to allow these unregulated CBD products with or without THC to be so easily accessible.

Research is slowly emerging from the shadows and must rationally and aggressively continue on. And here are two more facts that could make you lose some sleep. Makers of CBD and cannabis products are susceptible to deception by laboratories that purport to do science-based testing.

In fact, some laboratories don't even perform quality control analyses of products for which they are charging the manufacturers.

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Second, there are product manufacturers that, when faced with state-mandated requirements, intentionally hire laboratories because of their reputation for doing substandard and ineffective product testing.

Patients and other consumers are at greatest risk from this negligent activity, and clearly you know that. Again, I commend you for today's hearing.

I close with good news. You have stepped into these waters before. The FDA has created an orderly process that brings benefits to all of society. And the FDA can tame this current Wild West of testing by requiring true quality standards.

For that to happen, we need regulators who are well-informed developing regulations that are science-based and consider the intricate interdependencies of accurate and reliable third-party testing, perhaps developing control standards would be a focus of a future FDA hearing.

When that day arrives, patients across the U.S. will applaud that effort as well. Thank you.

MS. CRISTINZIO: Thank you, Susan. Ur next speaker is James Beck, speaker number 93, from the Parkinson's Foundation.

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DR. BECK: Hi, there. Can everyone hear me? Great. As my slides --

MS. CRISTINZIO: Just one second while we pull your slides up.

DR. BECK: Great. No problem. I want to thank you for the opportunity to speak today. I'm James Beck. I'm the chief scientific officer with the Parkinson's Foundation. A little louder? It's deceiving.

So while my slides are coming up, the Parkinson's Foundation is the largest community for those living with Parkinson's disease. And there are a number of individuals in the United States have PD.

When the slides show up, I'll show you a map of the United States depicting the prevalence of those with Parkinson's disease in the U.S., based upon a current report that we had published recently.

MS. CRISTINZIO: Sorry about that. I can see your slide from my desk. But that's not helping anyone else here. Just one second. No? Try again.

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DR. BECK: Perfect. Okay. Well, I'll start again. So I'm from the Parkinson's Foundation, which, as I mentioned, is the nation's largest community for those living with PD.

Nearly a million people live with PD, underlining the urgency for what we do as an organization. This chart of the United States shows deep blue states which have more people with PD than the lighter colored states, based upon a recent report that we published as a group.

Many of you on the panel and in the room may not know what Parkinson's disease is. It's a neurodegenerative disease primarily characterized by loss of dopamine neurons that can lead to motor symptoms that include tremor at rest, bradykinesia, which is slowness of movement, or rigidity.

Many approved therapies already address these current symptoms. And levodopa shown up there on the right is that green pill is one of the classic examples. However, people with PD have many other symptoms that are not well-addressed by current approved therapies, problems with sleep, cognition,

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autonomic dysfunction, mood disorders, et cetera, which is why those in our community are seeking alternative ways with which to control these symptoms.

And cannabis is not surprisingly one of those choices. And when we surveyed our PD neurologists at our centers of excellence throughout the U.S. and the world, we found that 95 percent of them report being asked about medical cannabis from their patients.

That, along with the changing in the legalization in the United States, led to the Parkinson's Foundation to gather key stakeholders in at a meeting in Colorado earlier this spring.

The goal here, by bringing together people with Parkinson's disease, neurologists who specialize in PD, epileptologists, people who specialize in MS, is to understand what could cannabis be used for when it came to Parkinson's disease.

What are the gaps in knowledge? What are our safety concerns? What are health effects? And the idea here is to guide the patient as we wait for formal guidance from the government and further research and also to develop a research plan for

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moving forward with understanding how cannabis can be useful.

Key takeaways are, not surprising, that cannabis is unlikely to help the motor aspects. This is the tremor that current approved therapies are able to help.

It may be helpful at a targeted level for non-motor symptoms, the sleep, the anxiety issues. Bottom line is we really need more research to understand the utility of cannabis in Parkinson's disease. There's just not a lot known and the quality of research is rather limited that's available.

Diving deeper into some of the non-motor aspects, this survey that was again done in 2015 asking neurologists what they thought cannabis could be useful for. In blue shows where they think it could be a benefit and orange shows where neurologists thought it could actually cause harm.

Superimposed upon this is from a focus group in the patient community identifying their priorities. Pain, anxiety and sleep are issues that people with Parkinson's disease are dealing with and are seeking

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cannabis as a form of treatment.

But cannabis is a drug. And like any other drug, it has side effects that we need to be concerned about. Many of the side effects for cannabis are also symptoms of Parkinson's disease itself. So the issue here is that individuals who may utilize cannabis as self-treatment may be making their own PD symptoms worse.

Up there are dizziness and low blood pressure or hypotension. If a person with Parkinson's disease who was using cannabis too much led to a fall at the age where people with PD have Parkinson's disease is in the late 60s, early 70s, it could be catastrophic. And that's the last thing we want.

The other thing to just point out is that many of these adverse effects or side effects were discovered within a healthy population. It's important to consider a neurodegenerative population when trying to understand how side effects could be different in this community.

Routes of administration are a challenge. Inhalation is clearly the most rapid way with which to

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deliver it. But using raw plant material can lead to difficulties in dosing.

Oral forms are great. But they have a delayed effect and it's compounded by the fact that most people with Parkinson's disease have an issue with gastroparesis, which is delayed gastric entering and slow colonic motility, which can further compound any type of titration or even understanding how this can get delivered in an effective way.

Our community is concerned about lack of standards that has been talked about here, side effects and whether there's sufficient safety research that accompanies cannabis.

Take-home messages from our key stakeholder meeting is that we need objective safety and tolerability assessments at various stages of Parkinson's disease covering the symptoms as well.

We need more research within the neurodegenerative community. We need an evidence-based approach for treating and targeting symptoms.

And last but not least is what's been brought up before. We need ready access to the study drug for

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research in human subjects. It's too difficult right now to obtain the medication in order to use for people with Parkinson's disease and other diseases areas. Thank you for your time.

PANEL MEMBER: I had a question.

DR. BECK: Yes?

PANEL MEMBER: When you talk about cannabis use in Parkinson's patients, are you thinking primarily of the higher THC products or of the low THC, higher CBD products?

DR. BECK: So it's a mix. The problem is that many people with PD are trying to choose low THC, high CBD is what's often recommended if they're able to get the information because it's less psychoactive.

But you go to a dispensary and it could be hit or miss depending on what they could get. And so, people who have high THC cannabis could lead to problems with psychosis or delusions which are already problems with people with PD. Any other questions? Thank you.

MS. CRISTINZIO: Thank you. The next speaker is Scott Coates.

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MR. COATES: Thank you. Good afternoon. I am Scott Coates, the senior director for the AOAC Research Institute. That's a division of the AOAC INTERNATIONAL, and I also serve as the program leader for the cannabis analytical science program.

Before I start my presentation, I want to make an observation. We've probably had at least a dozen, maybe more, testimonies where there was concerns about label accuracy. And that comes as no surprise to me because we don't have any reference methods.

And without having reference methods, we don't know whether the label is accurate or the testing laboratory is accurate. You don't know. So we need to have reference methods. And that's one of the things that I think the analytical science program can help us with.

So just a little bit of background on AOAC INTERNATIONAL, we have a long history in food safety and involvement with USDA and FDA. We're consensus builders. We bring people and scientists together to decide on what the correct methods are, and that's an

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important function that we serve is that we publish the official methods of analysis.

So two years ago, in response to the concern from the states, we responded to regulators and we have taken action to convene experts and approve consensus methods for analysis of cannabis and hemp in feed, food, plant materials.

Those would be reference methods that everyone could use so that the testing laboratory and the producer could be using the same validated method.

We start by developing standard method performance requirements. We call them SMPRs for short. We started in 2017. We have one for cannabis, cannabinoids and cannabis concentrate and one for dried plant materials, one for chocolates and one for pesticides and cannabis.

Those documents give in great detail what cannabinoids and how many of the cannabinoids and at what level we're going to be testing.

We use those as a call for methods and we have two official methods now for cannabinoids in dried plant materials.

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After we did that exercise, we realized that that was too slow. We did two official methods, two reference methods in two years. Too much stuff was going on. So we just decided to develop CASS.

So CASS's objective was to facilitate a forum where the science of cannabis analysis could be discussed, develop and publication of cannabis and hemp-specific methods and standards, identify and develop cannabis and hemp reference materials, establish cannabis and hemp proficiency testing programs and provide resources and education to the regulators responsible for establishing rules and laws for hemp.

We do have a policy, because it's paid for. We do not advocate for or against the legalization of cannabis. Our mission is consistent with ensuring public health, and we do not accept any funding from any organization involved in the cultivation or manufacturing of cannabis or hemp.

We currently have three projects. The first one is microbiology in cannabis and they're focusing on aspergillus. A second one is the cannabinoids as

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consumables and their initial focus is on cannabinoids, in particular CBD and THC and hemp plant material. They're also missioned to give some kind of recommendations on reporting of total THC and also recommendations on how to calculate dry weight.

And a third working group is the one that reviews target limits of quantitation for pesticides. They all currently got started in May and they are doing their work and we expect to have some results by the end of the summer.

So those are the first three that we got started with. But we have many particular other options. Potency, pesticide residues, biological contaminants, chemical contaminants, untargeted testing profiles and method validation guidelines.

So what AOAC is doing, what we have been doing for 125 years, is set the standards for development of reliable analytical methods and what we're doing now is applying that to supporting programs for cannabis and hemp in food products and plant materials. And we feel that is critical. Thank you.

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MS. CRISTINZIO: Any questions from the panel? Thank you so much.

MR. COATES: Thank you.

MS. CRISTINZIO: Next up, we have speaker number 95, Daniel Fabricant.

DR. FABRICANT: Thank you. Good afternoon. I think I may be the only speaker here who was once part of the marijuana taskforce. So, it's good to see some of you again. I don't necessarily miss some of those meetings, and I can't imagine what -- I can't imagine what the next one is going to be like.

Now I represent the Natural Products Association, the oldest and largest trade association in the dietary supplement space. We represent about a thousand companies in 10,000 storefronts nationwide.

I think looking at how we got here, we've had about 1,500 products come on the market over the past three years. So clearly there's market confusion, so much so that I think we have a letter from a senator, a U.S. senator, which I'll submit for the record, where -- and this man has served since 1993, cannabidiol producer industrial hemp is considered by

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the Food and Drug Administration to be a dietary supplement and therefore legally used.

So if the Senate is not getting it right, I think there's a pretty high chance that the rest of America isn't getting it right and there's a lot more that needs to be done in terms of consumer education.

So while that's certainly one way to resolve the issue, I think the bigger way is this morning we heard from Dr. Sharpless that this is completely uncharted territory for the agency. That's not exactly accurate.

Currently active pharmaceutical ingredients are in nutritional products, dietary supplements, botanicals at levels that are established below an HHE, things like red yeast rice, Monascus purpureus, snake root and those products are allowed to stay on the market as dietary supplements.

That would seem to be, at least in the short term, because regulation writing, especially in this environment, and legislative action in this environment, which I think is deemed at best challenging, may be difficult.

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So FDA can at present, using an HHE process, establish a safe harbor, if you will, until other science comes online. And this isn't completely new territory for the agency. And other agencies have looked at CBD specifically and exposure CBD daily. WHO report has safe use up to 600 mg per day. No place preference and no indication of hepatotoxicity at those levels.

Mouse studies indicate somewhere between 8 to 10 mg/kg. That's including a safety factor. So for a 70 kg human, that would put the dosage range about that 600 level.

So currently none of this is happening. And furthermore, products aren't being screened for THC, which is something the agency can do. There's no planned activity code that I'm aware of that the agency is asking for funding to look at THC in products which would seem to be at odds with the public health mission of the agency.

So with that, I think it's incredibly important and you've heard from many people that time is of the essence that the agency establish a level

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via an HHE, allow for something to happen in the interim while a regulation is being written or a statutory solution is being sought.

And in the meanwhile, this is, while a confusing issue, it's not an impossible issue. This is food toxicology. I think there's a lot of streams being crossed here. I think when you look at the science, you hear a lot about drugs. You hear a lot about how these interact.

But we're talking about food toxicology. These are products that should be used by healthy populations. And so, you saw a recent study that said hepatotoxicity of a cannabidiol-rich cannabis extract in the mouse model. Well, this mouse model actually used a mouse that's used for cancer bioassays. Tumor was not an endpoint of this study.

And this mouse is so popular, it's actually -- Dr. Sharpless' lab used to use it at NCI in the mouse bioassay program for cancer. So I think looking at models like this in my time of running the division of dietary supplements and we saw food toxicology routinely on dietary supplements, we never saw any

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sort of animal models where the animal was already compromised.

So I think that that's important to note, that folks aren't getting the issues crossed. We're talking about use in a healthy population and the science should reflect that. And there's quite a bit already in the science that does reflect that.

So in closing, again, I think there's plenty of data out there that the agency can already use. A lot of smart people at the agency. A lot of smart people on this panel. A lot of people with background in toxicology.

It would seem to be that the exposure level drives this discussion and an unwillingness to set an exposure level doesn't seem to make a lot of sense for an agency charged with the public health. So with that, I'm happy to take any questions.

PANEL MEMBER: Hi. I'm wondering if you have any thoughts on labeling issues related to dietary supplements to address some of the risk factors and some of the risks you're seeing.

DR. FABRICANT: I mean, I think you --

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Sharon, you see standard for products with caffeine. Another joy we had at CFSAN. You saw levels for pregnancy, for children, things like that.

So I think those are generally labeled away. For adulteration, it's the use specified in the labeling or conditions -- normal conditions of use. So I think that's imparted into 402, into the law. Thank you.

MS. CRISTINZIO: Thank you. Next up, we have Jacqueline French, from the Epilepsy Foundation.

DR. FRENCH: Good afternoon. Thank you so much for allowing me to make remarks today. I'm Dr. Jaqueline French.

I'm the chief medical officer of the Epilepsy Foundation, as well as a professor of neurology at NYU School of Medicine in the epilepsy program and I do see many people with uncontrolled epilepsy. So I come here from both of those perspectives.

Next slide, please. I guess I can do it. There we go. So the Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the approximately 3.4 million

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Americans with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy and direct services.

Epilepsy, make no bones about it, is a serious and potentially life-threatening disease. And unfortunately, despite all of the therapies that are available right now, one-third of people with epilepsy do not have control of their seizures. Many of these are children. Many of them are young children.

Individuals with uncontrolled seizures live with continued risks of serious injuries. There is a condition called sudden unexplained death in epilepsy that can take people's lives. There's also the possibility of status epilepticus, which is continued seizures without stopping that can also be deadly.

For these reasons, I think that I speak in a unique position because CBD, we've been told, is not a drug. But we in the epilepsy community, obviously we know it is a drug and it is a lifesaving drug. It's been proven in randomized controlled trials of Epidiolex that CBD in high enough concentrations can

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stop seizures.
And people who are in my community know that. They've heard that. They understand that and they are looking for answers for their uncontrolled seizures.
So I'm just going to give you a little story, Laney's story. Laney was diagnosed with a type of epilepsy called juvenile myoclonic epilepsy as an adolescent in 2015.
She had already failed eight other seizure medications and had been told that therefore there was only about a 1 percent chance of ever getting control of her seizures.
She was started on CBD in September of 2017 and this is not Epidiolex because Epidiolex is not approved for her type of epilepsy. And she stopped having convulsions and has not had one since four days after starting the product.
And she is by no means alone. She uses a currently unregulated product. And believe me, listening to all of the other speakers today, that scares the bejesus out of me. But so far, it's been successful for her.

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So what happens if you, for example, go along the lines of what was just suggested and take all of the CBD off the market other than what has a low concentration? Laney and all the other Laneys in the world will suddenly lose access to the product that they've been using. And that literally could cause her and others to lose their lives.
So as much as I am afraid of what we have now, I am more afraid as a representative of my community of losing it. If she needed to get -- to, you know, take Epidiolex, it would be $32,000 per year because it would be off-label for her.
She takes Haley's Hope, which is a form of CBD that she gets that's been grown for this very purpose. And she pays $400 a month for that, which is still a lot of money, but it's affordable for her family.
So CBD has been proven to be an effective treatment for the most severe forms of pediatric epilepsy. And I don't know that there's very many other circumstances where you have a drug that is lifesaving as a medication and also available as a

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dietary supplement.
And in the best case scenario, obviously everybody would take the pharmaceutical grade product. But they just don't have access for it. It's not feasible for everyone.
So there are many, many people with epilepsy that are being medicated and often with their physician's assistance with CBD oil from various sources. So abrupt removal of CBD from these individuals could lead to seizure worsening, injury or death.
And the second thing that I think is very important for me to say is that these people are unaware of the variability of the drug they may be taking, although they look for the best supply. Some people seek it out and are unaware of the risk of liver injury and the potential for serious drug interaction.
So as the Epilepsy Foundation, we would like you to preserve access to CBD for those who need it as a lifesaving medication. But it is absolutely essential that there is consistency or people

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understand the consistency of their product, create some manufacturing standards, make sure that the horrible other things such as mold that might be in there are not in there and also increase availability of important information such as the potential side effects and drug interactions. And also, I totally agree that the access to this product for research is extremely important. Thank you.
PANEL MEMBER: I think you just said that, you know, in an ideal world, you would like the pharmaceutical quality of an Epidiolex-like drug to be more widely available.
But obviously you're saying preserve -- what I'm hearing you say is to preserve the other forms of it. And I guess my question for you is how would -- how does preserving those forms affect companies that might want to develop the pharmaceutical.
DR. FRENCH: Well, the issue is it's a little complicated. But there are probably a thousand different forms of epilepsy and nobody is ever going to have FDA approval for every single one of them. And that's true of all the other drugs that are on the

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market of course.
And again, I mean, you know, what would happen if the other approved drugs -- valproate we've heard, clobazam and other things -- were also available as a dietary supplement and people were taking them? It would be chaos.
So I didn't -- you know, I'm not saying that this situation is the one I would have picked. But, you know, if that were true, many of those people would be taking it. And if you yanked it away from them, they would get horribly worse.
So the situation is what it is. Many people are taking it and they need to have access to it now because no matter how many other manufacturers get FDA approval, they'll never get approval for everything. Thank you.
MS. CRISTINZIO: Thank you. Our next speaker is Jeffrey Gitto, from Vanguard.
MR. GITTO: Hello. Good afternoon, members of the committee. My name is Jeffrey Gitto. I'm an active attorney in the cannabis space for about six years, which is a very long time in the cannabis space

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for lawyers. Good to see a mix of lawyers on the panel too because I'm not going to be high science on this one.
But what I wanted to do was present to the committee the legal pathways that, in my opinion, would be more an immediate effect for the public to be more confident in purchasing these products.
One is a little more esoteric. I'm actually going to go through the three right now and then we'll go through them. But there's three, suggesting the FDA take a tripartite approach to the regulation of cannabis-derived products.
A public health approach, consistent with the FDA core principles of innovation and practical risk versus rewards. Two, the duality of market paths dietary supplements and prescription-based uses. Three is respect state determinations of regulating in-state commerce under minimum federal standards.
I won't get too much into commerce and dormant commerce clauses because that might get a bit too much. But to start off, number one, a public health approach. Here context must be given to

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cannabis' long history. We are not speaking of a more esoteric version of such back to BCBC eras.
But specifically the history of the U.S. and more specifically the relationship of the plan and what was considered to be its beneficial uses in the marketplace as an agricultural product, the context being you have to clear understand the past to understand the future.
The FDA holds a unique source of power in regards to public health. It is important that the committee recognizes this beneficial agricultural product that has been around for millennia, at least outside the confines of a post-prohibitionist mentality, alternatively focused on research, product accountability, tracking and standardizing consistency by the FDA in tandem with the USDA and state oversight down to the farm level.
Data analytics of supply chain is -- as everybody has heard the echoing of that -- crucial for traceability and safety. Regulating cannabis at a distance, at least at the moment, will allow the integrity of the currently 33 states and District of

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Columbia to continue their medical programs, as Mr. Fabricant and others have mentioned, the medical THC regime that each state has implemented has taken many state-specific factors into consideration for both its constituents, the state's needs and working within the regulated market.
I put a timeline here, but it's rather complicated. But you guys can review it later, of course. The second approach is a dual regulatory approach similar to alcohol. At least on the precipitous of a post-prohibition, the only other time the United States has seen this was with alcohol.
So to subject non-psychotropic cannabis-derived products to the two proven regimes that already exist.
Impose similar minimum standards as there is upon alcohol and tobacco such as purity, dosage, consumer age, known labeling with medical claims, health warnings, et cetera, on cannabis-derived products, more speaking of non-psychotropic of course. And regulate the products under the proven systems already in place at the federal and state level.

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I've heard a few questions from the panel about incentivizations, required prescriptions. I can get into incentivizations if you guys would like my opinion on that.

For higher doses purity of cannabinoid and subject such approval to abbreviated review process, thereby increasing incentives for the research which assists in the necessary data collection.

With data being collected by the states and Canada, it will not be so much as just proving what may be harmful, the known about the plant, but also the unrealized potentially, the known unknown, if you will.

For the moment, farmers should only be able to isolate specific cannabinoids on a prescription dosage purity level with the benefits of insurance, medical industry and FDA support. And the inverse would be social, religious, familial support groups for the people who may abuse that from a dietary supplement aspect.

Third is to clarify the confusion. As we all know, having one drug violate the FD&C Act, CBD, and

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the same drug not violate the act, Epidiolex, in a way that would be understood from an agency level down to the state and federal enforcement departments as well as producers, vendors and consumers.

And then three may be controversial to some. It's to allow the states to guide and support state legislation, regulation in tandem with the USDA for the farmers and the FDA. Each state should be allowed to regulate both their respective non-psychotropic and THC cannabis markets while operating under FDA minimum standards and guidelines.

The state's commerce may be required to stay within the state to be exempt as a temporary compromise to accommodate this theory. If so, companies who wish to operate in multiple states would need to be based out of each state.

If any intrastate pacts are made, transfers of raw plant materials, flower would need to be agriculturally exempt through the act, the agricultural act, in crossing state lines, allowing farmers access to larger out of state markets.

I did not mention in the beginning. I

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represent quite a few hemp farmers and THC farmers as well as hemp seed cultivars. The industry will be better kept inherently within the states while the FDA and other agencies learn more about the challenges and successes through the states, with the states always being their own experiences in each of themselves.

The FDA's workload can be more focused on its current regime of regulatory experience. Each state has agricultural departments that must comply with the USDA. States can regulate and enforce according to minimum federal standards with their own thresholds as they do with other heavily regulated industries like alcohol, tobacco and gambling.

Plus they are collecting the tax revenues in order to fund this. Cannabis is actually taxed more than alcohol and tobacco and gambling.

MS. CRISTINZIO: Sorry, sir. You're quite over. Can you wrap up, please?

MR. GITTO: Oh, am I quite over? Sorry. I was into it.

MS. CRISTINZIO: Please don't forget to submit all your comments to the docket.

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MR. GITTO: Absolutely. Thank you so much.

MS. CRISTINZIO: Thank you.

MR. GITTO: Any questions? I thought I could get into the Tenth Amendment there for a second. Thank you.

MS. CRISTINZIO: Mayne another time. Next up we have Brian Malkin.

PANEL MEMBER: Garrett Graff, yeah.

MS. CRISTINZIO: Sorry about that. I'm ahead of myself. Garrett Graff.

MR. GRAFF: No problem at all. Good afternoon, and thank you for allowing us all the opportunity to speak before you here today.

My name is Garrett Graff. I am the managing attorney of Hoban Law Group, a Denver-based law firm that almost exclusively serves both the marijuana and the hemp industries.

We have been extensively involved for several years now with respect to helping set definitive parameters around regulatory guidance at the state and local levels, as well as at the federal level.

So with respect to this afternoon's

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commentary, four takeaway points. First, to compel and request that the FDA provide interim guidance as it continues to evaluate regulatory schemes in the forthcoming months and years. Second, the need to reconcile and unify existing state regulations.

With respect to the 2014 farm bill, perhaps both a good and bad thing is that it encouraged states to create regulatory schemes. But now with federal oversight through the 2018 farm bill, there's great need to reconcile and unify those.

Third, in order to so reconcile state and local laws, we can use existing FDA mechanisms to do so. Product classifications, testing, labeling and other standards are all applicable and able to be extrapolated here to hemp products. There is no need to reinvent the wheel.

And fourth, for the answers to -- in order to get answers to questions that are yet unanswered, we need to encourage research because to date it's been stifled in many respects by federal agency rhetoric, including that from the DEA.

With respect to the existing marketing and

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sales of hemp products, there again are existing mechanisms already in place. Labeling conventions for foods, supplements, cosmetics and other product types already regulated by the FDA are sensible and provide an appropriate way to disseminate information to consumers.

Warnings, such as those for use with medications or when suffering from other medical conditions or when pregnant, many other conventional warnings of those types may be well applicable here too for hemp products as well and can be replicated.

Secondly, manufacturers have a great onus in these industries already. So you look at calcium, vitamin C and other supplement manufacturers.

In many respects, it's their requirements or their obligation to comply with FDA requirements and to disseminate information to consumers. There should not be any different standards adhered to or applied to hemp product manufacturers.

And lastly, as I commented before, we have this great need to reconcile state laws. States like Colorado and their department of health have

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implemented regulatory schemes that treat hemp products just as if you're manufacturing any other food or dietary supplement product. Excuse me. The same registration is used. We need not any different registration regulatory scheme, but rather can simply use the same registrations, the same GMP requirements and all of the same typical methods for the existing product types.

Next, with respect to the manufacturing of hemp products for public consumption, again, GMPs are in place for foods, supplements, cosmetics and other product types. Solvent-based manufacturing is not new. Plant-based products are not new.

There are -- there is no need to specifically regulate hemp differently akin to how vapes or tobacco or other product types have been regulated by FDA in one-off ways in the past. But instead this fits squarely within existing regulatory schemes for products.

Testing, there's been commentary so far today with respect to the availability of testing. There are testing companies that are testing food additives

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and dietary ingredients and finished products and have been doing so for decades. And they are applying those same exact standards, knowledge and wherewithal as to hemp products today. For potency, for contaminants, for heavy metals.

Now again, I don’t expect everything to be perfect. I ordered food this morning at my hotel and there were bits of plastic in it. So clearly not all regulation is perfect. But those same standards can be applied to hemp products in successful way, in a sensible way and in a way that provides confidence and certainty to both consumers and regulators alike.

I note on the slide before you with respect to terminology -- and I note that the panel has asked questions about terminology being used. Currently there's approximately four different types -- four different phrases widely used: full spectrum hemp extract, broad spectrum hemp extract, isolate, CBD in this case or perhaps other cannabinoids in other cases, and hemp seed oil for those products derived from hemp seed.

Now I also note importantly as well that the

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panel should not just be considering CBD. That's of course the hot topic for today. But there's over a hundred cannabinoid compounds within cannabis. So these are issues that we're going to have to replicate time and time again or we can take this opportunity to try and handle that for all the different cannabinoids now.

With respect to those various phrases, full spectrum represents a full representative profile of the entire cannabis plant and the compounds and cannabinoids that are in. Broad spectrum is a broad but not yet full representative profile. Isolates of course mean isolated profiles and hemp seed oils.

And lastly, with respect to research, you know, obviously there's been a great deal of research presented here today and that's a testament to those that have conducted that research. But yet there are still those that are rejecting the ability to do and conduct research.

We have clients that have been requesting to do so for years and institutions of higher education that remain -- continue to cite DEA and other rhetoric

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saying that IND applications are required. Now, while none of us may agree with that or some of us may not agree with that statement, that rhetoric is still out there. And so, clear and definitive guidance from the FDA that would encourage, not stifle research would answer the questions yet unknown. Thank you for your time this afternoon.

MS. CRISTINZIO: Thank you.

(Applause.)

MS. CRISTINZIO: Next we have Brian Malkin, from Arent Fox.

MR. MALKIN: Good afternoon. All right. Good afternoon. My name is Brian Malkin. I'm an attorney. And today I'm not speaking -- I'm speaking on my own behalf. I'm not speaking on behalf of my firm, any client or association.

I'm a food and drug attorney and an IP attorney. My background's biochemistry. I worked at the agency. I've worked at FDA and IP boutique firms and currently I'm at Arent Fox.

And one of the things I'm active in now in some bar association where there's a direct

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relationship to cannabis is the New York State Bar Association. I'm the co-chair for the committee on cannabis law. I also am the chair for the food, drug and cosmetic law section and I'm also involved in their activities on legislative affairs. And for the Food and Drug Law Institute, I'm also on a new committee they have, the cannabis-derived products committee.

So there's increasing interest obviously now with FDA and FDA attorneys looking at how FDA is regulating cannabis. And within cannabis law from such as myself, my current firm, there's a cannabis industry group which we're seeing happening more and more at different law firms as there are more and more products in the space.

So this is the overview I'm going to talk about today, sort of how I got involved in cannabis and FDA law, what I'm seeing happening in terms of the overlay of cannabis clients and FDA and the interaction there, what that relates to in terms of the questions that are coming up in law firms that have these cannabis industry groups or dealing with

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cannabis clients and what kind of guidance I would see that's helpful for FDA to spell out as you're looking at lawmaking right now.

So I got involved back in 2015 as the chair of the food, drug and cosmetic law section. Someone approached me and said, you know, there's a new law within medical marijuana in New York. What kind of program can you do in your FDA group? And I was like, I didn't know. It's not an FDA-regulated product at that moment.

I said let's do something on ethics of representing cannabis clients because there's a lot of ethics issues that come in which gives the interplay between federal and state laws because federal law was saying it was illegal, state laws were saying it was legal. So we thought that was a good topic to talk about at the time.

Also what we started seeing is that within our association, there were different programs. Every section was doing it different. They're different legal disciplines. So it's not just food and drug. It's IP. It's labor law. It deals with real estate.

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You know, there were all these different disciplines that were coming into play.

And so, what I saw, there was a need that we had to create some sort of thought leadership in the space of cannabis generally. FDA is just one part of that.

And so, back in June 2017, I pitched to the state bar to create a committee and it was approved. And so, now we have a committee on cannabis law. And I'm a co-chair for that. And we also added an academic advisor, the first professor who wrote a textbook for law schools on cannabis law.

So this is the mission of our committee and essentially what we're really trying to do is provide good thought leadership within the space for laws as well as advising other lawyers who want to get into the space to properly advise their clients in terms of what's going on in regulatory law. And that's relevant here in terms of what FDA is considering to do for cannabis and CBD-related products.

So far we've put on a number of CDLE programs. This is giving a little bit of an overview

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of the ones that had some interplay with FDA and you can take a look at those sort of later.

What has happened since 2015 and that initial program, what I'm seeing happening is there's an increasing client base. First there was a lot of international activities going on in regulation because there wasn't a lot of guidance in what you could do in the U.S. Everything was considered illegal.

And so, the research had to be done overseas. And there was a lot of frustration. The University of Mississippi was the only source. It was a difficult source to get ahold of the product. It was not a very high quality source for doing cannabis research.

And so, and then there's the interplay between whether it was legal or not. And so, again, it was very frustrating and there's banking issues and marketing issues for the products that were very complicated.

So now what's happened since the farm bill that came into play is that basically more companies want to enter the market. Their first goal is to

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enter the state friendly markets and then interstate commerce. And that's fine. They're looking for more FDA review and guidance. I want to sort of get actually in terms of -- my time is coming into place -- what kind of questions we see would be helpful for FDA to give guidance on.

So a lot of the questions now is like what is legal. We get that question all the time. Is what I'm doing legal? Can I do this? Is it appropriate? We're struggling with definitions about CBD extract, broad, full spectrum, things like we've talked about earlier today.

What is hemp extract? Is it from the hemp seed or from the plant? That's not clear all the time. What does THC-free mean? What are these -- what kind of laboratory tests are appropriate to use? Are they state testing authorities?

Are there some national authorities for that? What kind of intermediary processing comes into play? If your THC level above 0.3 percent in your biomass, what does that mean? Can you transport that in interstate commerce or not?

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And then, what kinds of products can be used in FDA-regulated products? So these are some things where we thought FDA could be helpful with the dosage forms, whether there's need for allergen testing, guidelines for CGMPs that are relevant to cannabis, specific to it.

Import/export implications with the Border Patrol and advertising as FDA relates to the THC and developing more uniform labeling standards. Thank you. Any questions? All right. Thank you.

MS. CRISTINZIO: Thank you. Next we have speaker number 100, Robert Morgan.

MR. MORGAN: That's not mine, no. That's mine. Thank you. Thank you, and good afternoon. My name is Bob Morgan, and on behalf of ASTM International, I would like to thank the FDA for giving us the opportunity to provide some comments concerning our scientific and consensus-based driven efforts to develop technical standards that advance the safety, manufacturing and product quality of cannabis products and processes.

ASTM International was established 120 years

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ago to enable industry, consumers and regulators to work in public and private collaboration in the development of consensus standards that ensure product quality and performance while protecting the consumer and the environment. Over this time, ASTM has developed nearly 13,000 standards for 90 different industry sectors. Over 6,000 ASTM International standards have been adopted or referenced in regulations in the United States and around the world.

ASTM standards are known and trusted for their technical quality and relevance because they are developed in an open and transparent form, with all stakeholders having an equal voice in the process.

These standards range from ensuring the performance of jet fuel used in airplanes to the steel and concrete used in our infrastructure, as well as for the safety of children's toys.

ASTM and the Food and Drug Administration have a long history of working together for the development of standards for all types of medical devices. As an active stakeholder, the FDA contributes its technical and regulatory expertise to

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help inform and shape ASTM consensus standards because they can be developed more efficiently by a collaborative effort among regulators, manufacturers and users.

They can be more easily updated to reflect changes in technology or new product development and because they can be recognized and utilized globally as international standards.

In response to a request for standards from a cannabis cultivator, ASTM met with key industry stakeholders and, in 2017, formed committee D37 on cannabis. The scope of this technical committee is the development and maintenance of standards and guidance materials for cannabis and its products and processes.

D37 has grown to 600 members from 14 countries representing all aspects and components of the cannabis and hemp industries. Partnerships have been created with key industry organizations bringing in research and stakeholder participation. Subcommittees on cultivation, laboratory testing, quality management, processing and handling and

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transportation have been actively working on standards for their part in this industry.

To date, ASTM has developed six full consensus standards addressing water activity, cleaning and sanitation, packaging and labeling, waste management and managing hazard analysis critical control points.

Our efforts are already having an impact as U.S. states are working towards referencing the water activity standards, ensuring product stability in the marketplace.

In addition to these approved standards, the stakeholders are driving dozens of standard test methods that will impact laboratory testing for pesticides, residual solvents, heavy metals, cannabinoid and terpene analysis, compliance auditing as well as security and transportation processes.

Our newest subcommittee on industrial hemp has opened the door for the many issues of hemp as a food supplement and as a construction material.

The efforts of ASTM members clearly demonstrate a commitment to raise the bar for this

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industry through consensus standards that ensure product quality and safety.

Moving forward, ASTM committee D37 is eager to work with the FDA and others from state and federal regulatory bodies and all stakeholders on the development of high quality consensus standards that support every step in the production and processes for these emerging class of products.

Thank you for this opportunity to share these comments, and I look forward to answering any questions you may have. Thank you.

MS. CRISTINZIO: Thank you. Next, we have Sheri Orlowitz, speaker number 101.

MS. ORLOWITZ: Good afternoon. I'm Sheri Orlowitz, and I'm honored to be here and I'm pleased to be representing MPP in my role as an officer and board member.

I'm a businesswoman. I'm a former Justice Department lawyer who was recruited through the honors program. And I'm a former federal prosecutor who was charged with enforcing the drug laws.

We change lives. That's a pretty bold

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statement. But for the past 25 years, MPP has been working to decriminalize cannabis because cannabis has ruined more lives than people use cannabis today. We need and we welcome the FDA regulation and we suggest that the FDA take note of the state markets and the state regulatory schemes as a starting point.

As MPP's legislative counsel said to me, the FDA should pave the cow path. So today, I'm going to give you a little view of the cow path, our broad recommendations and how we might be able to assist.

Changing state laws. It's hard to fathom how fast things are changing today. Yesterday 33 states, including 10 states that are adult use cannabis. Today Illinois just passed adult use, 46 against, 66 for.

The landscape is unbelievable. The reality is cannabis is used by millions of people. One report estimates that close to 25 million people are using cannabis today. They're doctors. They're lawyers. They're legislators. They're Fortune 500 CEOs. In fact, perhaps there are some FDA administrators and some of the most successful people in the world.

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What we know over the 80 years that cannabis has been illegally -- has been used illegally, there have been few reported incidents of serious adverse effects.

To the contrary, they are far outweighed by more and more evidence that cannabis has many legitimate medical and wellness uses, as well as for recreation, with less deleterious effects than alcohol.

Unprecedented change. Cannabis moved from the back alleys to beautiful dispensaries and this is an opportunity for oversight and control by the FDA. But we caution against an unduly restrictive scheme that can drive another illegal and unsafe market. That is something we do not want.

We have already seen incidents of synthetic CBD using rat poison ingredients which hundreds of people, I've been told, died from. This is something that must stop. No more back alley dealing. Retailers should have confidence in what they are selling and the populace needs to have confidence in what it is buying.

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Regulation now falls largely to the states. And again, that is where MPP has done most of the work. Our knowledge of the state and regulatory schemes that we have helped create over the past few decades is unparalleled.

We have been assembling a council of experts which includes scientists, some former FDA, academics, lawyers as well as industry people from outside the U.S. who have no stake in the U.S. regulatory scheme to help us understand the landscape and shape our advocacy work.

We've taken great pains to assemble this council so that there are people without conflicts of interest in the current U.S. regulatory scheme.

The broad range of products is mindboggling and gives rise to so many dichotomies in the states. Some states allow flower. Some states don't allow flower. Some states allow infused drinks. Some states don't allow infused drinks.

Aside from the state and federal illegal dichotomy, I give you an example in California which arose out of an FDA edict which just threw more

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confusion into the way. CBD from hemp was illegal for food products. But CBD for marijuana was legal from food products -- in food products, excuse me.

Now how can that be enforced? As far as I have researched, there is no test that can discern the difference between CBD from marijuana and CBD from hemp. FDA. FDA looms large over all of the states. These -- wrong page. So we suggest that the FDA work hand in hand with the states and not against the states.

Consider we agree with Commissioner Gottlieb's statement in early April. The path that the FD&C allows for such substances to be added to foods or marketed as a dietary supplement is first by the FDA issuing a regulation through notice and comment rulemaking allowing such use and through bifurcating the regulation of cannabis to both drug pathway and supplemental pathway at lower doses, the FDA can provide Epidiolex a protected path and provide for usage for health, wellness and recreational use.

As we go forward, MPP is a veteran of the drug war and 25 fighting it has made us experts. We

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know overregulation created the largest illegal industry and this war has cost more and created more American casualties than all wars combined. So we give the following recommendations. We recommend a dual path be created for cannabis. We recommend --

MS. CRISTINZIO: Briefly, please, because you're over.

MS. ORLOWITZ: Okay. Thank you very much.

MS. CRISTINZIO: Thank you.

PANEL MEMBER: Can I just ask a quick question? You said that you have a vast knowledge of all the state laws and regulations. If you have compilations and analyses or comparisons of those laws that you can put on the record, that would be very useful for us.

MS. ORLOWITZ: In fact, we were going to allow -- ask that you allow us to provide a comprehensive report on the state laws along with some recommendations of how to proceed. If you would like, we would be happy to submit such.

PANEL MEMBER: Yeah. Thank you.

MS. ORLOWITZ: Thank you.

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MS. CRISTINZIO: Thank you. Next up, speaker number 102, is Steve Mister.

MR. MISTER: Good afternoon. I'm Steve Mister, with the Council for responsible Nutrition. CRN is the leading trade association representing the dietary supplement and functional food industry. We start with the acknowledgement that we hear FDA's position.

FDA currently considers CBD to be prohibited for use in dietary supplements and foods because of the exclusionary provision of section 321, a provision that's somehow referred to as the IND exclusion.

This provision was included in DSHEA to protect the commercial interests of pharmaceutical firms and to incentivize drug development by assuring that years and millions of dollars of research for a drug would not be diminished by allowing food and dietary supplements to come in and use an article if it was first studied as a drug.

It's important to realize that this provision is grounded in protecting the commercial interest of pharmaceutical research, a worthy objective. But it

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is not a safety question, but rather a race to market, or more appropriately, a race to investigate.

Even so, Congress gave FDA the discretion by statute to permit an article to be used in food and supplements irrespective of the race to investigate because it foresaw circumstances that might arise that would justify mutual use and deny an indefinite monopoly to a drug company should that article have other intended uses than just the drug claim.

So it is worth reiterating that the IND exclusion is not a safety question. FDA has plenty of processes and standards in place to examine the safety of any ingredient and it should use those tools and aggressively demand evidence of safety. But the initial determination of whether CBD is a dietary ingredient is not a safety question. It's a commercial one.

FDA needs to trust its own processes for examining safety in due time with respect to the requirements for each of the regulatory channels where CBD would appear, whether food, cosmetic, supplement, OTC drug or prescription medication.

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One of the advantages of considering the definitional issue first and independent of the safety consideration is that it allows FDA to more quickly clear up the regulatory confusion and then consider safety for each individual product rather than trying to adopt a "one size fits all" broad safety standard dosage ceiling across all of these products.

Such a broad safety standard developed at the beginning of the process would be ill-fitted for the vast range of CBD-containing products that are already in the market.

It would fail to provide flexibility as new research emerges and it would not take into account the wide range of dosage forms, delivery systems, dosage levels, cautionary level statements and other differences among all of these products that would factor into whether individually they would be considered safe.

For FDA and for industry, consumer safety is always job one. But that doesn't mean that sequentially it's the first job we do. Providing a predictable and lawful path to market is.

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Particularly when it comes to products that are already in the marketplace, FDA needs to act swiftly.

The agency must also act boldly to assure that products comply with the rules for whatever regulatory lane they are swimming in. If a CBD-containing product is marketed as a dietary supplement, if it contains a dietary supplement statement of identity on the label, if it carries a supplement facts box, then the marketer of that product has implicitly signaled to FDA and to consumers that it should be held to the regulatory framework for dietary supplements.

And so, these products should be made in a facility that is registered with FDA. They should be subject to GMP inspection. The label should comply with all general regulations for supplements. The marketer should have a system in place for reporting adverse events.

All CBD-containing supplements should be treated as new dietary ingredients, subject to notification. And then, questions about identity of the product, identity, purity, potency and composition

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should be addressed with adequate characterization of the product in the NDI notification and then followed up with product testing.

And FDA should strongly enforce these category-wide requirements on these CBD requirements as they would for any dietary supplement, using the range of tools provided by DSHEA like warning letters, import alerts, product seizures, mandatory recall and even criminal sanctions to send a clear message.

FDA will still have the opportunity to evaluate safety though. And while I will not get into specific safe levels identified in the ongoing research, FDA should find some comfort that well-respected authoritative reviews have already found CBD to be safe.

Demanding adherence to the NDI notification requirement in DSHEA will give FDA, in due time, the ample opportunity to insist upon, to analyze and to evaluate the safety data that's specific to each product.

Indeed, CBD research has already generated several systematic reviews that support the potential

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of CBD to be used in the general population without the requirement of the intervention of a health professional. These early studies have found CBD to be well-tolerated and appropriate for use.

Ironically if a company submits an NDI notification today to FDA, complete with all of that safety data, it would have the notification returned because the ingredient is not recognized as a legitimate dietary ingredient.

But if the FDA creates a predictable path to market, then the safety research that the agency so craves will materialize because then the nutrition community, academia and government agencies like NIH will all join in the symphony of research.

So, and then I'm going to provide you with some references to some of those safety data. In summary, CRN urges FDA to act quickly and decisively to resolve the definitional issues by conducting a notice and comment rulemaking to allow hemp and hemp-derived CBD to be used in food and dietary supplements and, in the meantime, to demand that products that are marketed as food or dietary supplements comply with

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all of the requirements long-established and expected of any product in those channels. Thank you.

PANEL MEMBER: Given your knowledge of the dietary supplement industry, I'm curious of your opinion about whether you believe that most of the supplements, particularly the CBD supplements, are produced by companies that already exist.

In other words, it's an additional product to an existing facility, or whether you think there'll be numerous additional facilities that will need to be inspected.

MR. MISTER: Well, I think that's the irony of the CBD situation in the marketplace that has exploded over the last three years. Typically when a new ingredient comes to market, it comes through existing companies who are already in the dietary supplement space. And as a result, they're well-equipped and familiar with all of those requirements.

I believe what's happening in the CBD space is that the majority of these companies who are bringing CBD to market as supplements are not companies that are traditionally in the supplement

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space. So they're not even aware of the requirements to have an adverse event system in place, where a dietary supplement company that's been in this space knows well that that's been around since 2008. So I think that is creating an added requirement why the agency needs to be aggressive in enforcing the other requirements for supplements.

PANEL MEMBER: Do you have any estimates of how many additional facilities you think are out there beyond what we're aware of with these existing dietary supplement facilities?

MR. MISTER: I would have no way of knowing that. Thank you.

MS. CRISTINZIO: Thank you. Our next speaker is Matt Sica, speaker number 103.

MR. SICA: I'm Matthew Sica. I'm the accreditation manager at ANAB, responsible for cannabis labs. ANSI National Accreditation Board is a recognized international body that does assessment activities around the world to various standards.

We're asking that FDA consider the adoption of the international conformity assessment model

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pertaining to testing activities for the cannabis space. This testing may include aspects such as content of cannabinoids, pesticides, heavy metals and microbiological organisms.

ANAB encourages the use of accredited laboratories, 217025, the international standard for the general requirements of competence of laboratories. We respectfully ask FDA to consider not using terms such as meeting the requirements of or in compliance with 17025. We stress that conformity assessment and accreditation to 17025 is more appropriate as it includes an independent review of the competence of the laboratory.

Acting as impartial entities, internationally recognized accreditation bodies evaluate the competence of the lab. The accreditation body approach and assessments provide a credibility to the conformity assessment activities such as testing and that goes beyond a self-declaration of meeting the spirit of the standard.

The conformity assessment model is structured to give confidence through the attestation of

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competence. Accreditation is the formal recognition of competence of the laboratory to carry out specific activities in accordance with the standard as described in a scope of accreditation.

Accreditation provides the attestation that laboratories offering testing have technical competence and impartiality to check conformity of products to relevant specifications.

Lab accreditation provides a ready means for customers to identify and select reliable testing services. The competence is determined through an ongoing cycle of assessments, onsite and offsite, by technical competent experts and through participation in proficiency testing on an ongoing basis.

The conformity assessment model provides several levels of impartiality throughout the process. Regulators may set requirements for specific products. The producers of those products use testing services to determine conformance to specific requirements.

Conformity assessment bodies, in this case laboratories, test the products where those conformity assessment bodies are assessed for competence by the

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accreditation bodies. This is strengthened when accreditation bodies are peer-evaluated and are members of mutual recognition arrangements among accreditation bodies. In the United States, there are several ILAC signatory accreditation bodies to promote choice through an established competitive market.

Accreditation is based on the laboratory demonstrating compliance with specified requirements for competence, independence and impartiality. Competence is determined through the experience and technical skills of the staff, as well as review of equipment and the methods utilized.

Independence is determined through a review of the business framework of the accredited body and any related bodies to show autonomy between the laboratory and organizations to which it provides service.

Impartiality is demonstrated through the absence or management of conflicts of interest with the laboratory to whom they are providing the services.

Benefits of accreditation include for

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regulators the use of the conformity assessment model can support implementation of national legislation to confirm compliance with standards and accepted requirements, reduce bureaucracy by eliminating a number of administrative obligations and limit costs and resource needs by reducing the need for regulators to employ their own specialized assessment personnel.

For consumers, it can create trust, where consumers have confidence that the market is enhanced knowing that products and services they choose are regularly evaluated and checked by independent and competent third parties.

For business, accreditation can boost efficiency where accurate measurement and testing performed in accordance with best practices can help limit errors and control product costs and contributions. By relying on accredited tests, regulators --

MS. CRISTINZIO: Sir, please wrap it up. Please wrap up.

MR. SICA: Yeah. Regulators obtain independent evaluation which is a transparent process

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and allows for the product to go through. Please consider the use of ILAC MRA signatories.

MS. CRISTINZIO: Thank you for that. Please submit the rest of your comments to the docket for consideration. Our next speaker is David Steinberg, 104.

MR. STEINBERG: Okay. I guess I've got the microphone right. I'm David Steinberg. I am the founder of Steinberg & Associates. We are a consulting firm that deals in the chemistry and regulations of cosmetics and topical drugs.

I titled my presentation "The Coming Crisis," and that may give you a slight comment which is to explain why I think it's a crisis and why I'm so concerned.

My wife and I have a 38-year-old son who, when he was five months old, was diagnosed with infantile seizures. He outgrew this because he got to be two years old. So it became Lennox-Gastaut syndrome and you've already heard something about this. I'll talk a little bit more about it later.

I thought by now someone would have put this

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slide up. But no one did. What is CBD? I haven't heard anyone say what it is. I've heard everyone talk about it. CBD is a chemical. It has a CAS number. It's commonly called CBD. It has an IUPAC name. It has a definitive structure right here, which you've already seen.

Oh, I went the wrong way. This is what CBD looks like. I don't know how many of you have ever seen pure CBD. Not too many people. It's horrible. I sort of describe it as a mixture of molasses with soft margarine. It is yucky is the best way to describe it. It sticks to everything. As a chemist, it's very difficult to handle.

As you know, we've already heard that it has an approved legal use that came out last June. The important comment that I want to make here is on the label it is not stable after being opened for 12 weeks. It's available by prescription only.

The other term I hear constantly is CBD oil and I have no idea what CBD oil is. Every company that I've asked about what it is, I heard a different story, the term. And I have a typo mistake here. It

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should be CBD oil. It has become generic. I've asked manufacturers what is it. Well, it's CBD in oil. Petroleum oil? Mineral oil? Sesame oil? Not disclosed. So this has become a generic term and this has led to some of the crisis that I am concerned about.

At the Lennox-Gastaut Foundation meeting three weeks ago in Seattle, I was talking to many parents of children with LGS. And some of them were taking the legal drug and some of them for other reasons were taking the generics, which claim to have the same effect. And their children suffered from it.

But they told us it was CBD oil, just like the real stuff.

Okay. This, everyone knows the uses of CBD. So what is CBD? Does it have specifications? Do we have solvents present? What is the purity? The sample that I showed you before was measured at about 98.2 percent purity. What are the contaminants? Does it have THC in it? What trace contaminants are? And of course we have the unintended use of imitations which have caused all sorts of bad consequences.

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Okay. My principal chemistry issue with CBD is that it's not stable. Everyone needs to understand it's not stable. It has a maximum temperature of about 25 degrees Celsius, which is 77 degrees Fahrenheit. Above that, it starts to break down or form other compounds. You can't store it cold because below 4 degrees Celsius, around 39 degrees Fahrenheit, you have other problems.

It is packaged in dark brown glass. We now have a place for recycled beer bottles. It is not pH very stable. It's stable most at about 6.5 to 7. That's not where we want to use it in cosmetics. Most cosmetics are lower than that. The degradation products possible include THC. So stability is a critical question.

So what I want to say is that the FDA needs to establish specifications for CBD. Get a USP monograph and have that be the law of the land for any use of CBD, whether it's in foods, drugs, cosmetics or in dietary supplements.

So here it is. Let's have the percent of CBD on the label and also, because of the instability of

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it, the date of the manufacture of the CBD raw material on the label. Thank you.

(Applause.)

MS. CRISTINZIO: Thank you very much. Our next speaker is Youn Lee, 105.

DR. LEE: Hi. My name is Youn Ok Lee and I'm a social scientist at RTI International, a nonprofit, independent research institute and I --

MS. CRISTINZIO: Please move the microphone down a little bit.

DR. LEE: And I've led many studies in tobacco regulatory science. However, today I'm going to be presenting data from my NIDA-funded study of adult cannabis user behavior. I just wanted to acknowledge my collaborators and funding source.

And I'll just start by saying what everybody has said before, which there are many, many cannabis products currently available on the market. The degree to which the mode of administration of cannabis may affect both individual and population health risks is currently unknown. And national surveys do not capture this range of cannabis product on the market,

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which severely limits the population surveillance necessary to monitor the population health effects that may occur as a result of some of these products.

Furthermore, prior studies show that concurrent use of cannabis and tobacco is prevalent. But less is known about the potential effects of this concurrent use of cannabis with tobacco or nicotine. Such co-use may complicate the regulatory approach needed for such products.

And finally, there's reason to expect that the use of the range of the available cannabis products varies by subpopulation, in part because of the ease of targeted digital marketing, many brands and retailers can increasingly tailor and target market to specific groups in the population.

For example, here are a couple of screenshots. You see the brand Kandypens at the top, which I think is clearly positioned to appeal to younger adults. And then below, you have a CBD product line whose ad features older individuals and explicitly markets to what they say seniors and veterans with a discount.

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So my purpose is threefold. First, I wanted to look at what types of cannabis products are used by consumers, especially those in mature markets. Second, I wanted to know does preferred THC versus CBD concentration vary across sociodemographic groups. And third, I wanted to look at what motives for use are associated with high CBD products compared with high THC products.

So just very quickly in the interest of time, we collected original data. We surveyed 2,978 past 30-day cannabis product users in the legally -- the recreational legal states at the time of survey. We collected this data in November and December of 2018 using a protocol approved by the RTI IRB. It was a convenience sample, but we did calibrate based on past 30-day cannabis use using the 2016-2017 BRFSS.

All right. So results. So here you can see the 30-day prevalence of each type of cannabis product that we measured along the bottom. Now one thing to note is that these categories are not mutually exclusive. So they won't total to a hundred percent. But you can see by the percentages that these indicate

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a high degree of multi-product use. A large proportion of our adult sample reported using multiple modes of cannabis administration in the past 30 days.

Overall, if you look at the left side, you can see that joint, edible, pipe and vape were the most prevent reported products, though many current cannabis users did also use or co-use with tobacco as well, indicated by the yellow bars.

So we can see evidence of the co-use that's been reported in prior surveys and show some of the relative prevalence that may be driving the introduction of nicotine-cannabis products onto the market.

Now here we added information about use frequency, indicted by the orange line. You can see that shows the average number of days in the past 30 each product type was used. And so, I won't go through all of the results.

But you can see for pipe, for example, it was the most frequently reported number of days at 11.5 days of the past 30 compared to 4.3 days of the last 30 for co-vaping with nicotine. But there's a decent

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amount of variation here that should be considered when assessing the health effects, dose or exposures of these different modes, certainly when people are using multi-modes.

So we also wanted to examine cannabis product type and demographic characteristics. So here you can see as an example we were comparing people who reported they usually use a high THC, low CBD product versus a low THC, high CBD product versus equal amounts of THC and CBD and we included I don't know because in this case I think the response of I don't know can be meaningful because there may be knowledge gaps in the public that need to be addressed with proper public education.

We see relatively high percentages compared to don't know responses to other items in the survey which suggests that many consumers may not really know some of these differences.

MS. CRISTINZIO: Please wrap up.

DR. LEE: Oh, all right. Let me go really quickly then. So finally I just wanted to share some of the motives and show you that they differ a bit by

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the high THC, low CBD, especially you treat a health problem. You'll see that those scores are higher for the CBD responses.

So just to wrap up, our data suggests that regulation of cannabis involves understanding variation among products and consumers or users. Protection of public health requires considering population health in addition to individual health and this can inform approaches for regulating these products in the protection of public health.

Thank you. And we look forward to doing more research like this in support of the decision-making of you and other stakeholders.

PANEL MEMBER: Just a question. Will those data be available in the public docket in any greater detail? That would be really useful information for us.

DR. LEE: We can submit some summary, I believe.

PANEL MEMBER: Thank you very much.

MS. CRISTINZIO: Thank you. Our next speaker is in the "Patient" category. We have James Werline.

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PATIENTS

DR. WERLINE: Good afternoon. My name is James Werline. Greenwich Biosciences supported my travel, but I have not been paid for my time.

I took off of work and traveled here today from San Antonio, Texas because I feel it is important for the FDA and the public to understand what an FDA-approved CBD oil has done for my daughter and family.

I am a husband and father of a child with a rare disease known as Sturge-Weber syndrome. And I am also a doctor of pharmacy. So I look at today's hearing issue, a regulatory pathway for cannabis and cannabis-derived products, through two lenses, one as a pharmacist, the other as a dad.

Those two lenses provide me with a single clear vision for what I believe the FDA must do to support the needs of people with rare diseases, people like my daughter, Camilla.

In this photo, my wife Marla is holding Camilla. We will celebrate her second birthday in about six weeks. Camilla is as sweet as any little girl you'll ever see. She's also a fighter. Camilla

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started having seizures when she was only nine months old.

When a child has debilitating seizures, the entire family suffers. As time went on, her seizures increased to 20 to 25 attacks every day and were considered drug-resistant. We tried to ease Camilla's suffering and we fought to give her every chance to have a better quality of life through a combination of treatments.

At one point, we were pumping six medications into our little girl twice a day, every day and still the seizures continued. My worries grew significantly because I didn't know if Camilla's development delays were due to her disease or the medicines prescribed as treatment.

My wife and I took Camilla to some of the country's leading pediatric neurologists and epileptologists. She underwent all the tests you can imagine. We received three different diagnoses for three different types of epilepsy and we didn't have an answer and neither did the doctors. We even considered a brain surgery that is too complicated and

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too gruesome to describe during my brief time with you today.

As the months dragged on, our frustration turned to desperation. About a year ago, my wife and I thought about trying CBD oil on Camilla. We planned to drive from San Antonio to Colorado to buy a CBD product from a dispensary. Desperation can make you do some crazy things.

For the first time during Camilla's illness, we were considering giving an untested, unproven, unregulated product to our little girl. Sure, there were anecdotal reports of children with epilepsy getting better with CBD.

But I wouldn't know how to monitor for interactions or how to adjust other medications that she was already taking and who knows what would be in the bottle that we bought and gave to Camilla. Its ingredients and its impurity would be unknown. It could contain THC or toxins or other substances that could worsen her condition. And that is today's world of unregulated and inadequately controlled CBD oil.

On Thanksgiving eve, just six months ago, we

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have Camilla her first dose of Epidiolex, which the FDA had recently approved as the only prescription CBD medication. And we watched in wonder as our prayers were being answered right before our own eyes.

I am forever grateful to the FDA and the company that invested in the clinical trials and manufacturing processes needed to bring a new medication to patients and families like ours.

I'm not testifying to promote the product. But I have to share that Camilla hasn't had any seizures since she's been on the medication. She's also been able to wean off of five medications and continues to reach new development milestones. Even now, after living her best life for the past six months, it still seems unbelievable.

FDA determined that the company demonstrated safety and efficacy to the agency's satisfaction and that means that families like ours can have conversations with our doctors to determine if a product is indeed the right drug for the right patient at the right time.

FDA, I'm asking you to accept your

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responsibility and exercise your authority to meaningfully assist patients, their families and health professionals with a few simple yet important questions.

What is in a bottle containing CBD that is purchased in a retail store or online? What does a label say about what's in that bottle? And what can it do to the patient, both good and bad? These are -- well, there are families out there that will benefit from FDA-approved prescription CBD medications just like we have.

Patients and their healthcare professionals should have as much information and assurances as possible in order to make informed decisions about a substance that might be beneficial. They deserve to have a clear vision for navigating their individual health journey. Today they're flying blind. They don’t know what they're taking or what they're giving to their little girl or boy.

FDA, please require that these drugs are subject to robust clinical trials and good manufacturing processes to demonstrate safety,

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efficacy and purity. Every patient deserves a chance to receive the same blessings that our family has received over the last six months. Thank you for your time.

(Applause.)

MS. CRISTINZIO: Thank you. Next up, we move to the "Public Safety" category. We start with number 107, Heather Despres.

PUBLIC SAFETY

MS. DESPRES: I'd like to thank you for giving me the opportunity to speak here today. My name is Heather Despres, and I am the director of patient-focused certification at Americans for Safe Access. It is a nonprofit organization whose mission is to ensure safe and legal access to cannabis for therapeutic and research.

The patient-focused certification program is an independent compliance program whose goal is to ensure that cannabis businesses are operating in compliance with state regulations as well as other regulations.

Today I'd like to present to you information

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about manufacturing and product safety as it relates to validated analytical testing, product standards and safety concerns. We will be presenting comments based on everything that we present here today in much more significant detail.

One of the questions presented centered around current standards needed to address safety concerns related to manufacturing of cannabis and cannabis-derived products. And we would like to address this by identifying industry standards that already exist.

The American Herbal Products Association and the American Herbal Pharmacopeia have issued best practices for cannabis business, including cultivation, manufacturing, distribution and laboratory operations. From these standards, the patient-focused certification program was created in order to ensure compliance.

In addition to these standards, we would recommend that personnel working in the cannabis industry and regulators inspecting these businesses have the education and training needed to safely

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perform the job that they are hired to do and that to ensure that there are adequate numbers of inspectors available to support the industry.

Validated analytical testing is a key factor in ensuring safe products. Mandatory testing is required in almost every state that has a cannabis program and yet this testing is not consistent from state to state.

This is a table of a subset of over 70 different pesticides that are required to be tested for in various different states. And as you can see, only six are the same throughout. Also all of the limits are different. So for operators working in various states, there's not consistency.

With consistent testing and limits, the safety profile of cannabis products can get better. Some of the major safety concerns for cannabis and cannabis-derived products are the use of pesticides and solvents in cultivation and manufacturing.

The majority of recalls that have been issued have been for the use of non-permitted pesticides or for exceeding the limits of allowable pesticides.

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Four different states have applied for a special local needs registration, none of which have been approved by the EPA. The type of solvents approved for use also varies by state.

For example, some states will permit the use of hydrocarbons such as butane, while others will only permit the use of carbon dioxide. Additionally, the equipment used in cannabis extraction is often operated at high pressures and requires specific training for safe operation.

We would encourage that operators be required to obtain this special training prior to being able to use the equipment.

While pesticides and solvents are major concerns, the potency of THC-rich products is also a concern. People have varied reactions to this, to the THC present in cannabis and cannabis-derived products as many factors may play into how this person reacts, including their weight and rate of metabolism, the amount and type consumed, the method of consumption and their personal experience with cannabis.

Some states require that products containing

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THC be tested for homogeneity and we would encourage this type of testing for all products, not just THC-rich products.

Proper testing with representative sampling will ensure that products are labeled accurately, allowing the consumer to know exactly what cannabinoids and how much are in the products that they are consuming.

There are many challenges facing the cannabis industry. However there are solutions available. We have worked with state regulators to develop and implement these standards and we look forward to working with you together to help implement these standards as well. Thank you.

PANEL MEMBER: Just one quick question. You mentioned recalls. Any data that you have on the recalls that have occurred in states or the processes surrounding it would be greatly appreciated, if you could submit that.

MS. DESPRES: We do plan on submitting that.

PANEL MEMBER: Fantastic. Thank you.

MS. DESPRES: Thank you.

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MS. CRISTINZIO: Thank you. Our next speaker is John Redman.

MR. REDMAN: Good afternoon, and thank you for allowing me to speak today. I'm John Redman. I'm the CEO of Community Alliances for Drug Free Youth.

We're a non-for-profit organization based out of California that focuses -- that was created during the parent movement of the late '70s/early '80s and focusing on youth drug prevention. We focus and support sound drug policy not only at the local, but state, national and international levels. CADFY holds consultative status at the United Nations and we work on global drug policy at that level.

We're not here to really discuss or argue the merits of the medicinal use of CBD. What we are concerned about however is the amount of THC that will be allowed as an adulterant within CBD products that negatively impact our youth.

If you take a look at this picture, I took that only weeks ago in my hometown. That is water that's being sold to businesses and homes that says it has CBD products in it and I have no idea what's in it. We have no idea what the THC levels are. And it is vastly unregulated compared to our municipal water that I don't drink.

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Our request for action is that the FDA should proceed with extreme caution and treat any levels of THC as unsafe, especially for vulnerable populations. And to protect the public health and safety, we urge the FDA to prohibit THC in CBD containing consumer goods, that is any amount.

I won't go over all of the concerns of the harmful effects of CBD -- or THC, I mean. You've heard that ad nauseam today. But suffice it to say that we know that THC significantly impacts youth much more than adults. And the question is how much THC is too much.

We have no idea of the THC amount percentage by weight consumed that causes dependency or addiction. We have no idea of the THC amount that causes first-time episodic psychosis or other chronic adverse health effects. We also know that THC permanently changes brain structure in the developing mind.

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One thing to look at is how much THC is too much. If we take a look at some of the states, or if we just take a look at Oregon, Oregon has stated that 5 mg of THC will produce psychoactivity. So that means no more than 5 mg of THC in a serving. But when we take a look at the hemp bill, we have 0.3 percent by dry weight.

Well, what does that mean? If you take a look at a joint that contains 63 mg, 17 mg of THC is ingested into the body. An edible that contains 50 mg packaging, a serving is 5 mg of THC.

If you take a look at a 30-count bottle that can have 360 mg in a single 4 g CBD gummy bears, those can have -- a single gummy bear can have 12 mg of THC for a CBD product. For 30 mL bottles that contain CBD oil, that could contain 82 percent mg in a single serving of 2.73 percent. All you do have to take two servings and you're over Oregon's limit.

Some available products, I looked on the website. Here's one product on the left that has 2.8 mg. If you multiple that times the 0.3 percent you get at the bottom what they say is 84 mg of THC in

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that CBD product. Another one, that 2.89 percent of THC, you have 86 mg.

When we take a look, it's been said that all we have to do is just put an age limit on it. It didn't work for alcohol, folks. It didn't work for tobacco. We know that putting age restrictions on products doesn't work and we also know that the most abused drugs in our youth, number one, alcohol, number two, tobacco. It's not going to be any different for marijuana products.

The three things that come together to increase youth use is attitude, advertising and availability. I've heard all of those talked about today. All three of those will create a perfect storm.

All one has to do is look at the permissive drug policies of certain states that have legalized marijuana and look at the higher youth use rates in those states than those that don't have it. And yes, we have the data on that.

Our request for action is the FDA should proceed with extreme caution and treat any levels of

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THC as unsafe, especially for vulnerable populations. To protect the public health and safety, we urge the FDA to prohibit THC in CBD-containing consumer goods, any level.

Please treat this as a drug and not as a commodity. Please look at this as a public health issue and not as a profit issue. We urge the FDA to look at this and strictly regulate it. Our youth deserve it. Our nation demands it. Thank you.

(Applause.)

MS. CRISTINZIO: Thank you. Our next speaker is Denise Valenti.

DR. VALENTI: Good afternoon. I know it's been a long day. But I've found it pretty exciting because I've learned quite a bit from many of the previous testimonies, and I hope you have also.

I'm Dr. Denise Valenti. I'm an optometrist. I'm a CEO and president of IMMAD. IMMAD is Impairment Measurement Marijuana and Driving. Our current funding source comes from NIH, NIDA in the form of an SBIR. We have our first prototype of a technology that is intended for roadside use by law enforcement.

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And it works quite well. It measures the retina using a visual field technology in a virtual goggle, smartphone and Bluetooth response.

However, it is my previous roles in previous careers for which I am offering my testimony today. Prior to doing research, I spent 20 years as a clinician specializing in vision loss and blindness. Under that capacity, I did see many multi-handicapped children, much like some of the children you have heard described today. They are complex and the parents are very challenged in identifying treatments and care for their children.

I'm also a parent. I stopped seeing patients because, at the age of 36, after I had my family, I was diagnosed with idiopathic familial dilated cardiomyopathy. It's familial because even though the clinicians had determined I was beyond the potential of risk of having the disease, I had lost a 17-year-old sister to cardiac health and a 19-year-old sister to cardiac death.

When I was diagnosed, I couldn't walk up a flight of stairs. I was worked up for a heart

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transplant. But that's not the worst.

Two years later, the next generation. The oldest child in our family was diagnosed. He was 15 years old. He died three months later. So it was with horror we realized that the disease that we thought was only affecting one generation was autosomal dominant. It meant my two-year-old had a 50 percent chance of potentially not surviving to the age of 21.

So I know the desperation and the feelings of some of these parents that would do anything and go to any lengths to solve and improve the health of their children. And I would never suggest that these severely impaired children that are having some of their quality of life significantly improved by CBD go off the CBD.

But we do need to do more research because there are side effects that are treatable. One of them is that there is increased pressure in the eye with CBD. While we often hear about marijuana being able to lower the pressure in the eye, that's only with THC, only with THC. We never hear about the CBD

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causing an increase in the IOP.
The very research papers that were put forward by proponents to advocate for glaucoma as one of the treatment -- diseases to treat with CBD actually had research in them demonstrating that CBD elevates the pressure of the eye.
Glaucoma is painless. Glaucoma is a disease that it creeps up on you and steals your vision and you don't know it before it's too late. Why is CBD potentially doing this? Well, there are cannabinoid receptors in multiple parts of the eye, every layer. It's in the retina. That's why we're able to identify vision loss and develop technology. But it's also in the anterior chamber.
In neurologic systems, and particularly in the eye, THC and CBD tend to have opposite effects. And the THC acts on the ciliary body as does the CBD. But they can do it in opposite ways. The one human study that I talked about earlier found a dose-dependent response. And these doses, relative to what we hear about are being used to treat many diseases, aren't that high.

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These are some of the doses that are suggested for many diseases. As you can see, they are beyond the dose of risk, the 40 mg that was found in this study.
However, there are additional studies. There is a rabbit study that I don't cite here. On the other hand, a colleague of mine, when I wanted somebody to look into this, used some of his funding to investigate it further and he definitely found CBD causes an elevation in IOP in his mouse model.
We need to investigate this further. Again, I'm not suggesting that anybody go off a lifesaving drug. But if there is an elevation of IOP, it can be treated. But we don't really know exactly what's happening in humans.
I'm concerned that there is going to be a new generation of needless vision loss because we did not look closely at CBD. Thanks.
MS. CRISTINZIO: Thank you.
DR. VALENTI: Oh, there's a good ending. My son was negative. And we developed a mouse model for my own disease and we developed treatments for me.

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(Applause.)
MS. CRISTINZIO: Any questions?
PANEL MEMBER: Absolutely please submit your data. Thanks.
MS. CRISTINZIO: Thank you. Our next speaker is Shawn Hauser.
MS. HAUSER: Hi. Good afternoon. I'm Shawn Houser. I'm an attorney with the Vicente Sederberg LLP and here today on behalf of the Cannabis Trade Federation.
The Cannabis Trade Federation is a national coalition of cannabis businesses representing all aspects of what has primarily been a state-based marketplace. Our companies include large multistate operators who have been subject to stringent regulations under these state systems for the better part of the past decade.
We're eager to share today with the FDA data arising from our many years of operation and our views on federal regulation.
We believe the appropriate regulation of products containing lawful cannabinoids already exist

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under the framework of DSHEA and that the data arising out of these state-regulated regimes supports such regulation. The evidence of CBD safety is clear, as acknowledged today and by agencies such as the World Health Organization and DEA and their findings that CBD is safe, well-tolerated and non-addictive.
State-controlled cannabis regulatory regimes provide years of evidence demonstrating that consistent quality products containing cannabinoids can be safely and transparently sold in a manner like dietary supplements.
Our operators are familiar with the complexities of issues faced by consumers, regulators and businesses when compliance means navigating a patchwork of state regulations and differing legal interpretations.
However, whether right or wrong, the current situation has created a perceived regulatory vacuum and it opens the door to bad actors and allows for substandard products, often available to the most vulnerable of our population.
We produce products containing lawful

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cannabinoids and desire to market these products. But the lack of a federal pathway for regulation, particularly the refusal to accept NDI notifications for CBD and other regulatory impossibilities, remains a barrier to proper regulation. Our industry is ready to meet FDA requirements and, in many cases, already complies with the elements of FDA regulations.

In virtually every regulated state market, most businesses are required to apply for and obtain a state and local license for each facility they operate. These facilities are subject to rigorous and regular inspections by various agencies. These state regulatory frameworks increasingly require the implementation of CGMP systems for the manufacturing of cannabis products.

For example, cannabis businesses in Florida must employ CGMPs, pass a food safety GMP inspection by a nationally accredited certifying body. If they don't pass, they can't process until they demonstrate corrective action. Similarly, New York requires CBD supplement manufacturers to adhere to FDA standards for the production of CBD products, including CGMP and

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packaging and labeling.

Truth in labeling is at the core of our state cannabis regulatory regimes. In addition to comprehensive labeling regulations in most states, many states like Indiana, Utah and Texas require that hemp -- CBD product labels include scannable bar codes linked to information regarding the manufacture of the product such as batch IDs, ingredients and a link to certificates of analyses.

Use of independent third-party testing labs to verify label content for each production batch is standard. Using accredited and independent testing laboratories to confirm the accuracy of labeled information including potency and to ensure compliance with state requirements helps ensure consumer confidence in the product being sold by standardizing the analysis procedure and eliminating the risk of bias.

Warning labels for vulnerable subgroups, particularly children, is a virtually universal requirement in our state-regulated cannabis regimes, with labels generally requiring both written

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statements and symbols indicating the presence of cannabinoids and instructions that the products be kept away from children. As demonstrated by the chart, these requirements are effective.

In California and Colorado, product manufacturers have achieved an average 90 percent passage rate for mandatory testing for label accuracy in the presence of microbial, pesticide and heavy metal contaminants. This data demonstrates that cannabis manufactures can and do comply with DSHEA-like standards to protect consumer safety.

Many states also follow the FDA's approach with recall and adverse event reporting, requiring a review and investigation of consumer complaint that extends to all relevant batches and records.

Based on investigative findings arising out of adverse event reporting, manufacturers and regulatory authorities issue public notifications and recall the affected products where appropriate.

In sum, cannabis products can be safely regulated under the existing DSHEA framework and, where products are intended for non-medicinal

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purposes, it's appropriate to regulate them as such. The years of data from these state regulatory regimes are a very important source of data for the agency to consider in determining the appropriate regulatory pathway here.

We stand ready as the Cannabis Trade Federation to advance to the next level with FDA an effective regulation of cannabinoid products to ensure consumer safety.

MS. CRISTINZIO: Thank you.

PANEL MEMBER: Hi. As we've asked in other instances, if your organization has a report that details some of those findings at the state, could you make sure that they get into the docket?

MS. HAUSER: Absolutely.

PANEL MEMBER: Thanks.

MS. CRISTINZIO: Great. Our next speaker is speaker number 111, Dana McMurchy.

RETAILERS/DISTRIBUTORS

MR. MCMURCHY: Yes. Thank you for inviting me. I'm here in Washington by your invitation. My challenge is will you listen. The authority that I'm

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given to speak comes from the constitution of the United States of America which grants me and every person I this room the right to life, liberty and the pursuit of happiness.

Why did I start that way? I believe that a balanced endocannabinoid system is fundamental for human life. That's why I ended up supporting Yes on 788 in Oklahoma. We also demand liberty to decide what laws and regulations we're willing to live under without interference from anyone, including law enforcement because they don't create law. We do.

Oklahoma has a population of under 4 million people. In the vote that we gave -- that we did, we surpassed all election turnouts for any kind of vote and there were 507,000 voters that approved medical cannabis.

So I represent those voters. Those are people in chronic pain, in despair over their opioid dependence, patients with MS, lupus, Alzheimer's, Parkinson's, cancer or the veterans with PTSD.

We're joining 32 other states that have already approved cannabis either recreational or for -

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- sorry, medically or for reasonable adult use. I am the voice of the people without the money to buy or influence the practices of medical provider.

You might have noticed that I was a pharmaceutical and medical device rep. So I have a lot of experience in that area.

And then, not to gain -- I'm the voice of people who do not have the money to gain privileged access to the FDA and the demands of people for access to cannabis and our parents and grandparents who are the number one use of medical cannabis.

And if you look, American College of Pediatrics, Journal of Prevention Medicine and national survey on drug use shows that in youth, most of that use has gone down with a slight use there.

So why did I get so involved in this? Ten years ago, if you told me I'd be promoting medical cannabis, I'd have said nonsense, there's no medical proof. They just want to get high.

And then, I found this patent in addition to much other research. We funded this information. This is Patent Number 6630507 and I assume that you

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all know this really well. But I'm shocked and constantly impressed that people do not know about this.

We funded it from the department of health and human services. It was assigned in the United States and it was assigned in 2003. Okay. What do they claim? They claim that cannabinoids are antioxidants and neuro-protectants.

So that now makes sense as to why it can have application in a wide variety of oxidative diseases such as ischemic, age-related -- I don't know anybody who's getting younger -- inflammatory and autoimmune diseases.

They have particular application as neuro-protectants. And I will specify that in this case they took the THC out. They made some changes. But they're claiming on behalf of the American people that this has potential in 2003. 2003.

I had to do educational seminars. I had to debate physicians who said what's the urgency, what's the emergency. The opioid crisis that we face, the number of deaths in the U.S. exceeds what we lost in

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World War II. Okay. Twenty-two veterans committed suicide. Twenty-two today. Twenty-two tomorrow. And cannabis prohibition has been a big part of the problem.

So proceedings of the National Academy of Sciences, 1995 -- that's a long time ago. CBD and THC is antioxidants and neuro-protectants. The endocannabinoid system is our master balancing and homeostasis system and it was discovered in the 1990s. How come our doctors don't know about this? Only 13 percent of physicians are trained in the endocannabinoid system in medicine right now.

We demand a new model, not the pay-for-play science funded by corporate money. We have paid the price of corporate greed and I carry some weight on that. The opioid crisis. That's how I got to retire at age 50. It pays really, really well.

Sixty percent of our U.S. biomedical research is funded by the for-profit pharmaceutical industry. And of course this is the best slide of all. March 1973, cannabidiol and other cannabis compounds could reduce hippocampal seizures. It took 45 years using

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the model we currently have to reach patients. I'm thrilled that Epidiolex got approved. But I beg you not to wait 45 years for the next one.

And you asked about full spectrum hemp oil. It's not CBD. It's cannabidiol, terpenes, flavonoids, fatty acids, vitamins and minerals. Okay. And I think it's important that we regulate cannabis as generally regarded as safe and the regulations should match other products out there. And I just think this is helpful.

MS. CRISTINZIO: Please wrap up.

MS. MCMURCHY: Yes. Thank you. I'm the home grower who makes my food -- sorry, my food my first and best medicine. I trust -- oh, sorry. Okay.

And we the people in the United States have claimed back our rights to this whole plant medicine from generally ill-guided federal policy, not necessarily just the FDA. I'm not saying you guys did that. But we require and respectfully require the FDA to respect our common voices and self-governance.

MS. CRISTINZIO: Thank you.

(Applause.)

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MS. CRISTINZIO: We are now on speaker 112, Valentina Milanova.

MS. MILANOVA: Good afternoon. Thank you for the opportunity to be here today. We are Valentina Milanova and Dr. Harry Baxter from Daye. We are a UK-based female health company. And we are delighted to present our research on CBD-coated feminine hygiene tampons as well as the quality standards we're implementing in our supply chain and manufacturing.

Let's start with the supply chain. The CBD we use is extracted through a proprietary process capable of separating all cannabinoids from one another. Importantly the process fully removes -- oh, I think there's an issue with the clicker. Oh, there it is.

Importantly the process fully removes any and all traces of THC, THCA, making the end extract suitable for medical and consumer uses. The advantages of the method are that the synergetic effects of CBD, CBN and CBG are retained while THC is fully removed to ensure that the tampons do not cause a high. Importantly the extract prepared in this way has no impurities and no traces of solvent.

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Further we're using cottonized industrial hemp fibers to make up the absorbent body of our tampon. To achieve cottonization, the fiber is soaked in purified water and then treated with high voltage electric process, separating and softening individual fibers.

The advantages of using cottonized hemp are that the porous structure of the fibers allows for improved absorption and moisture retention, thus reducing the size of the tampon and the likelihood of vaginal abrasions which often occur from the insertion and removal of a dry tampon. We take great care to ensure our tampons are produced safely by introducing clean room manufacturing and gamma ray sterilization.

Vaginal applications of CBD are quite novel. And here is what we know so far. Unlike other forms of CBD, vaginally applied CBD works by binding to cannabinoid receptors in the vaginal epithelium, working locally and mechanically. Oops, sorry.

The endocannabinoid system is being discovered in many organs, including the vaginal canal, where it plays an important physiological role, as we have heard today. A few promising studies in rats, rabbits and human volunteers so far have shown the lubricating and skin conditioning properties of topical CBD.

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These are advantageous for vaginal use again as the dry surface of tampons is known to cause abrasions in the vaginal canal which are associated with a heightened risk of toxic shock syndrome. Moving on to how we -- sorry. Is there are a --

DR. BAXTER: Where are we pointing the clicker?

MS. MILANOVA: It's not working. The next slide should be about manufacturing standards. Should we click? Yes, down please. Further down. Down. Down. Down. Here it's perfect. One up. Thank you.

All right. How we ensure quality in our supply chain. So first we have three years agreements for the supply of CBD and cottonized hemp which ensures that we get a consistent quality of raw materials and can build long-term relationships with our partners.

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Second, each and every batch of CBD that we receive is tested in two independent labs for concentration, toxic shock syndrome, staph, Escherichia coli, candida, total anaerobes, total yeast, arsenic, nickel, lead and mercury.

Third, we have strict conformity agreements with our suppliers, ensuring that they are incentivized to continuously provide the best quality product or face liability.

Moving forward to manufacturing standards, if I can have the next slide please, we use FDA-approved, medical grade machine parts in all of our proprietary CBD tampon coating machines which are housed in ISO 8, Grade D certified clean rooms. We also sterilize the CBD-coated packaged tampons -- perfect. We sterilize the CBD-coated packaged tampons using gamma rays, ensuring no harmful bacteria or contamination are left on the tampon surface when it reaches the consumers.

Next slide, please. Shelf-life testing and stability are really important questions when it comes to CBD. We've conducted accelerated shelf-life testing on our raw materials as well as the finished

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products to ensure that our CBD tampons have a 12-month shelf-life.

To ensure product stability in natural consumer environments, we wrap our tampons in medical paper with a lacquer finish and then place them in heat-sealable, airtight plastic pouches.

When it comes to labeling -- next slide, please, thank you -- we have clear indications on our packaging and in informational pamphlets on the risk of toxic shock syndrome as well as the risk of CBD allergies.

We don’t recommend that first-time tampon users employ the CBD tampon and we limit sales to over 18-year-olds. We can do that through our e-commerce business model -- as the data on CBD's impact on the development of the vaginal tract is still limited. We're currently thinking about marketing our product simply as CBD tampons, with the view of expanding to soothing, lubricating and finally cramp-fighting as we obtain regulatory approvals and more peer-reviewed clinical data.

At present, we will not be making any medical

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claims with regards to our products. It's important to note here as well that we've received clearance from the European Medicines Agency to market our products in the EU.

Dosing is another issue in CBD products, as we heard today, that deserves further research. How we chose the dose that we use today was based on extensive peer-reviewed literature reviews as well as volunteer trials with self-reported efficacy outcomes. That's the next slide. Thank you. Next slide.

MS. CRISTINZIO: Please wrap up.

MS. MILANOVA: So from the studies that we've seen so far, CBD was tolerated really well in all volunteers with no signs of toxicity or serious side effects. The reported minor side effects that we had included tiredness and diarrhea. Finally --

DR. BAXTER: And finally, we are prioritizing high quality research to ensure our products are safe and effective. We've demonstrated that CBD suppresses E. coli, Staph aureus and E. coli growth at therapeutic levels in vitro and we have completed preclinical trials including CBD showing that it does

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not irritate vaginal epithelium and is pH-balancing.

Finally, we have undertaken extensive volunteer trials with CBD-coated tampons which were well-tolerated and so far have shown no adverse events. In our oncoming research pipeline, we are currently undertaking further preclinical trials with animal models to interrogate other potential rare adverse events.

We are currently undertaking a double-blind, multicenter RCT at an EMA-certified facility with 80 patients using CBD tampons for menstrual symptoms. And finally, we are investigating the effect of CBD on the vaginal microbiome using qualitative PCR analysis.

In conclusion, we look forward to working with the FDA on ensuring a stable regulatory framework for CBD, especially in women's health, is put in place in the future. We will be submitting all our written testimony and quoted research for submission.

MS. MILANOVA: Thank you. I'm sure you must have questions.

PANEL MEMBER: Do you have data -- do you have data on absorption through the vaginal mucosa?

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MS. MILANOVA: So what we have data about is CBD binding to endocannabinoid receptors in the vaginal epithelium. And we're currently conducting blood plasma tests to see the absorption of CBD through the vaginal mucosa.

What we know is that in rat models, CBD is well-absorbed through the skin. But what we've seen in the vaginal canal from in vitro studies with vaginal epithelium cells is that it tends to bind to the endocannabinoid receptors.

DR. BAXTER: And we're currently undertaking it in a rabbit model to assess vaginal absorption.

PANEL MEMBER: And were you saying that the CBD coating was leading to a lower risk of TSS than with standard tampons? I couldn't tell if that's what you were saying or not.

MS. MILANOVA: So the research on toxic shock syndrome shows that the main reason for it is the dry surface of the tampon causing minor incisions on the vaginal entrance and the vaginal walls from the friction from the insertion and the removal of the tampon. And through these incisions, bacteria can

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enter the bloodstream and toxic shock syndrome happens.

Now, there's two ways in which we believe we're reducing the risk of toxic shock syndrome. The first one is that by being infused with CBD on the outer layer, on the protective sleeve of our tampon, it's effectively lubricated, so significantly reducing the risk of those ulcerations happening from friction from insertion and removal.

And then second because we sterilize the tampons using gamma rays which is the standard in surgical tools. That's where we borrowed that from. We ensure that there's no bacteria that could enter through any ulcerations or abrasions.

MS. CRISTINZIO: Great. Thank you so much.

DR. BAXTER: Thank you.

MS. MILANOVA: Thank you.

MS. CRISTINZIO: Sorry for the technical difficulties with your slides.

MS. MILANOVA: No worries. Thanks for helping.

MS. CRISTINZIO: Our last presenter today

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before we close is Craig Brand, from Folium Biosciences, for five minutes.

MR. BRAND: Dale told me I could speak until all of you fell asleep. But five minutes shouldn't say that. Anyway, I literally asked -- my name is Craig Brand. I'm general counsel for Folium Biosciences in Colorado Springs, Colorado.

I asked to be the first speaker. That way, when I sat down, I was literally the best speaker. So I got moved all the way to the back where everything I wanted to talk about is pretty much gone now.

So I would like to start off first by thanking the FDA for this day, thanking the stakeholders for this day, thanking all who are listening on Wi-Fi for being present with us, thanking all that are in the room with us. Thank you for sharing your birthdays. Thank you for sharing beer 30. Thank you for all the time that everybody has given to these issues.

Now, given the fact that almost everything I did want to say has already been said or I should just button my lips, let me repeat what I did hear. I did

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hear that what we're here today to discuss is about a product that is a pharmaceutical product or a dietary supplement or a food ingredient or even a dispensary product. Yes, it is.

I did hear that we're talking about issues of adulteration, of diversion, of mislabeling, of improper product manufacturing. Yes, we did. I did hear us talk about safety, conformity, standards and protocols. Yeah, we did that too.

I heard people mentioning about the farming business, the genetic business, the harvesting, the extraction, the production, the fulfillment and even pharmaceutical interest. Yeah. We did that as well. I heard people talk about competition, global intervention. There's even, if you look just across the pond, a new category for CBD called novel foods that maybe the FDA needs to direct some attention to. But yes, we did.

So we have an industry. We have an American-made industry. Now, let's do everything we can that we keep this American-made industry, that we don't let this American-made industry go bye-bye to the world as

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we know it.
Let's look to work in harmony, bring all of what I just discussed, whether it's a pharmaceutical product, a dietary supplement, a feed ingredient or dispensary product, let's figure out a way to make it work and let's come up with solutions.
So Folium Biosciences is located in part in Colorado Springs, Colorado. There are -- I'm going to give a shout out to all of the other Colorado companies that came up here today and talked before me because, one, they deserve the shout out and, two, I love my state.
But all of us here are here for a single purpose. There were people that came up and I heard a lot of badmouthing about CBD. I heard badmouthing about THC. Guys, it's an industry. It's a business. We're all here to make it better. We're not here because we want to do things wrong. We're in this room. We're listening over the Wi-Fi. We're listening over TV, whatever it is, because we're trying to get it right. With you or without you, we're moving forward and we're doing a really, really

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good job.
So I ask you how many of you sitting on the panel have even ever tried CBD. You don't have to say anything. I ask you the following. How many of you sitting on the panel have even come out to one of Colorado's best or any other state's best and even seen how the industry actually works? It should be first base or home plate.
And I invite you, and I'm sure my Colorado brethren would probably have no objection as well to come out and see us. See what it is we do.
Folium Biosciences is one of the largest seed-to-sale facilities in the entire world, with facilities going around the world, with our product going around the world. So it's first base for you. It's the way that you get your answers to your questions.
So I know that my time is almost up. But let me say the following. All that we talked about today, from the labeling issues, from the diversion issues, from the adulteration issues, does it go on? Yes, it does.

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But let's not kid ourselves. It goes on in every single business. For those who know me also know that I was healthcare attorney of the year. I'm a senior partner in one of the largest healthcare law firms in the country. I also was CEO of a very large pharmaceutical chain.
So there's a lot about the history of this building, of what is done here that I have firsthand knowledge about. So what happened, all you have to do is look just a few years back.
Look to the illegal drug diversion issue and look how the states got smart and created all the solutions to counter that, to prevent that and to move forward going forward in the future. And all of what we saw here today, from the labeling issues, from the people making improper products --
MS. CRISTINZIO: Please wrap up.
MR. BRAND: -- to people improperly fulfilling, all of that has been answered. All we have to do is look to the states and look to the laws that they've written. Thank you very much.
(Applause.)

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CLOSING REMARKS
MS. CRISTINZIO: Thank you. That concludes the end of our public comment and formal presentation. I want to remind everyone that the docket is still open. It remains open until July 2nd. Please submit comments to the docket. Thank you to everyone who joined us in person today and on webcast. And this concludes our public hearing. Thank you very much.

(Whereupon, the foregoing was concluded.)

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I, KEVON CONGO, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am n f any counsel or attorney hereto, nor financially e outcome of this action.

KEVON CONGO
Notary Public in and for the
STATE OF MARYLAND

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I, BENJAMIN GRAHAM, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

BENJAMIN GRAHAM

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