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DA/CFSAN PUBLIC MEETING

RESPONSIBLE INNOVATION IN DIETARY SUPPLEMENTS

Thursday, May 16, 2019

8:30 a.m.

US Food and Drug Administration

5001 Campus Drive

Wiley Auditorium

College Park, MD 20740

Court Reporter: KeVon Congo

JOB No.: 3391044

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## A P P E A R A N C E S

ANDREW SHAO

ASHISH TALATI

BERIT DOCKTER

BONNIE PATTEN

CARA WELCH

CHARLES JOLLY

DANIEL FABRICANT

DANIEL WANG

DAVE SCHONEKER

FREDERICK BLAKE

GABRIEL GIANCASPARO

GEORGE PARASKEVAKOS

HARRY RICE

JAY SIROIS

KEVIN BELL

LARISA PAVLICK

LAURA MacCLEERY

MACK MITCHELL

MARK BLUMENTHAL

MARK LeDOUX

MARK MILLER

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MICHAEL MCGUFFIN

NANA BAFI-YEBOA

NORMAN SHARPLESS

PIETER COHEN

SANDRA ESKIN

SCOTT BASS

STEVE MISTER

STEVE TAVE

WES SIEGNER

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1 P R O C E E D I N G S

2 DR. WELCH: Good morning. Good morning,  
3 everyone. Thank you for sticking with us while we get  
4 started. Welcome to FDA's public meeting on  
5 Responsible Innovation in Dietary Supplements. My  
6 name is Cara Welch from the Office of Policy,  
7 Legislation, and International Affairs in the Office  
8 of the Commissioner. And I'm so pleased to be working  
9 on today's meeting with ODSP. I have some  
10 housekeeping notes to get us started and then I'll  
11 turn it over to Dr. Sharpless.

12 This public meeting is being webcast and  
13 transcribed. The transcription and slide decks will  
14 be added to FDA's website once they're prepared for  
15 posting. I'm not sure on the timeline for this. It  
16 could be as much as a few weeks before they get  
17 posted. If you're interested in the transcription, I  
18 would suggest you monitor FDA's meeting page specific  
19 to today's meeting.

20 Wi-Fi is not available today. I'm  
21 sorry. Also please take a moment to confirm your cell  
22 phones and other devices are silenced as I do so

1 myself.

2 To ensure our webcast participants can  
3 hear, please be sure to speak your remarks or  
4 questions into the microphones. There are two mics  
5 about part way down the, the stairs and we would  
6 suggest that you use those. Also please introduce or  
7 start your comments or questions with your name and  
8 organization because of the transcription.

9 If, for the webcast participants, your  
10 phones sound be automatically muted. If you have a  
11 question to ask of our panelists during the Q&A  
12 sessions, please type it into the chat function. We  
13 have a few people monitoring that chat box and they  
14 can ask the questions on your behalf.

15 Restrooms, as you exit the auditorium at  
16 the top of the stairs, both the men's and women's  
17 restrooms are located down the corridor back towards  
18 security on your right.

19 Breaks and lunch. We have a couple  
20 short breaks and a lunch break scheduled. Snacks and  
21 beverages are available in the Wiley Building Cafe,  
22 which is outside of the building outside of security

1 to the left. Additionally, there will be food trucks  
2 available in the parking area for lunchtime. Seating  
3 is available in the café or in the courtyard area  
4 between the building and the parking lot if the  
5 weather is nice. I think it's supposed to clear.

6 Please use the front door to exit and  
7 enter. There is a door at the top of the auditorium.  
8 Please don't use that. We would get in trouble. And  
9 always wear your nametag because you will need to go  
10 back through security and that just indicates that you  
11 can go directly to Donna's corridor to the public  
12 meeting.

13 There are also two breakrooms available  
14 for our use. They are 1A001 and 1A002 and people at  
15 the registration desk can show you where those are.  
16 There are no food or drinks allowed in this room.  
17 Again, I'm sorry.

18 For any media or press questions, we  
19 should have Mariana Nam and Julie Manga (ph) attending  
20 the meeting. If they're in the room right now, they  
21 will indicate. I don't see either of them in the room  
22 right now. You can also find them at the registration



1 table. And then we will also have Lindsay Haik from  
2 our Office of Media Affairs available for other media  
3 questions.

4 The folders you were all provided when  
5 you checked in at the registration desk have some  
6 documents for the day. The agenda for today, bios for  
7 our presenters, both FDA and the panelists, and the  
8 photo register notice. July 15 is the deadline for  
9 submission of comments to the docket.

10 You were also able to pick up a list of  
11 persons making public comments at the end of the day.  
12 And speaking of which, the public comment session, we  
13 are having a public comment session at the end of our  
14 panels this afternoon. The list of persons who have  
15 requested an opportunity are on that sheet. We ask  
16 our commenters to target three minutes for their  
17 comments. If we have time at the end of the day, we  
18 could allow some extra unregistered people to give  
19 comments.

20 If you would like to have that  
21 opportunity, if we have time, please check in with  
22 Juanita Yates at the registration desk. Juanita, can

1 you step forward and make sure people know who you  
2 are? Very important for the meeting, Juanita Yates  
3 helps us keep moving smoothly. For questions and  
4 assistance, she is also probably your best source of  
5 information.

6 And with that, I am very please to  
7 welcome to the podium Dr. Ned Sharpless, Acting  
8 Commissioner of FDA. Thank you.

9 (APPLAUSE.)

10 DR. SHARPLESS: Good morning. Thank  
11 you, Cara, for that introduction. And thanks to  
12 everyone here for participating in today's meeting.  
13 Also for those of you online. The topic of today's  
14 session is of particular importance to protecting the  
15 public health and the work of the Food and Drug  
16 Administration. Although I'm relatively new to the  
17 FDA, I've been in the job about five weeks, protecting  
18 and promoting the public health has been central to my  
19 professional work and throughout my career.

20 As some of you may know, before coming  
21 to FDA I ran the National Cancer Institute at NIH, and  
22 before that I was a cancer researcher and a cancer

1 doctor treating patients with hematologic malignances  
2 for 20 years in academia. During that time I ran an  
3 NHI-funded lab studying the molecular mechanisms of  
4 cancer and aging and I was a director of a large  
5 comprehensive cancer center.

6 I'm thrilled to be at the FDA, to be a  
7 part of the team that uses science to develop policies  
8 and regulations that help make Americans more  
9 knowledgeable and safer. A few of FDA's  
10 responsibilities affect as many Americans on a daily  
11 basis as our work in the foods arena, which includes  
12 issues of food safety and labeling, but also issues of  
13 nutrition and diet.

14 As a physician, I've long seen the  
15 profound impact of diet and nutrition on human health  
16 and the importance of the food research in this area.  
17 A related aspect of this and a priority of FDA's  
18 oversight responsibilities is our subject of today's  
19 meeting, the dietary supplement market.

20 Today more than 75% of Americans use  
21 dietary supplements regularly. That number has grown  
22 significantly in recent years and the market and

1 products have changed and grown enormously as well.  
2 It's been almost 25 years since the majority of FDA's  
3 authority specific to dietary supplements were  
4 solidified in law with the passage of the Dietary  
5 Supplement Health and Education Act of 1994 or DSHEA.  
6 I think it's clear to everyone here today that the  
7 dietary supplement market does not look what it did in  
8 1994 when DSHEA was signed into law.

9           In October of 1994, the industry was  
10 estimated to be worth about four billion dollars.  
11 Today it's more like 40 billion dollars. And thanks  
12 in part to science and innovation, the range of  
13 products today is far broader than was on the market  
14 in 1994, having grown from about 4,000 products to  
15 perhaps more than 80,000 products. That's really  
16 significant and amazing growth.

17           Added to this fact that 25 years ago we  
18 didn't have the internet. We didn't have iPhones. We  
19 didn't, you know, had this global reach that's  
20 provided to the US consumer and you get some idea of  
21 the vast changes to this growing industry.

22           Against this evolving backdrop, the FDA

1 has worked to maintain an appropriate level of  
2 oversight within the authorities granted to us by  
3 Congress. It's essential that consumers are able to  
4 make informed and healthy choices about dietary  
5 supplements they may use. And there's an important  
6 public health need to make sure the products are safe  
7 and the labels are correct, and complete information  
8 about what's in them, and there's a scientific basis  
9 for claims that are made about these products.

10           These elements are central to FDA's  
11 mission to protect and promote the public health. I  
12 know this is a commitment that our stakeholders share,  
13 and in fact, many of you here today have been echoing  
14 from your platforms.

15           We all know that there are some  
16 companies who put consumers at risk and also risk  
17 damaging the reputation of the entire industry by  
18 distributing and selling dangerous and otherwise  
19 illegal products. In my career as an oncologist, I've  
20 seen all too clearly the unfortunate consequences of  
21 marketers selling fraudulent products that make claims  
22 to treat, cure, or prevent disease and which prey on

1 the desperation of patients and their families.

2 This is an area that I know the Agency  
3 has been active in for many years, will continue to  
4 protect consumers by cracking down on false,  
5 misleading, and potentially harmful claims.

6 We're also committed to taking action  
7 when products contain ingredients that render the  
8 products unlawful, including many drug ingredients and  
9 when they're not manufactured according, according to  
10 standards designed to ensure quality product.

11 But we also understand that dietary  
12 supplements are widely used, very popular with  
13 patients, and can be safe when responsibly produced  
14 and used. FDA has an equally important role to play  
15 in allowing these products to advance public health  
16 where possible.

17 DSHEA was deliberately crafted to  
18 establish a careful balance of protecting consumer's  
19 rights to access safe products and accurate  
20 information while also preserving the FDA's authority  
21 to protect those same consumers against unsafe and  
22 otherwise unlawful products.

1                   While the fundamental goals underlying  
2 DSHEA have not changed, the change, the challenge of  
3 realizing those goals has grown in magnitude far  
4 beyond what it once was. The realities of today's  
5 marketplace demand a renewed approach to this  
6 regulation and it's crucial that the FDA be nimble and  
7 adaptable as we advance our regulatory frameworks in  
8 keeping pace with this rapidly growing commodity.

9                   Now is the time to modernize our program  
10 to ensure better alignment with the realities of  
11 today's dietary supplement market. This past February  
12 FDA announced some steps were taken to advance our  
13 regulation of dietary supplements and modernize  
14 reform, and reform our oversight in this important  
15 segment of the health economy. I want to ensure you  
16 that this work remains a top priority and will  
17 continue with me as acting FDA commissioner.

18                   We are taking a close look at our  
19 dietary supplement program to make sure that we have  
20 the tools we need to keep consumers safe and that we  
21 are using these tools as effectively as possible.  
22 We've established an agency-wide dietary supplement

1 working group that is looking into our dietary  
2 supplement organizational structures, processes,  
3 practices, and procedures in identifying where we can  
4 make improvements. We've affirmed our commitment to  
5 using traditional law enforcement tools when we see  
6 products that are violative, but we also recently  
7 announced a new tool to address these potentially  
8 violative products.

9 Last month we announced the Dietary  
10 Supplement Ingredient Advisory List, a new rapid  
11 response tool that we'll use to alert the public when  
12 ingredients found in dietary supplements appear to be  
13 unlawful based on our preliminary determination. This  
14 is critical to protecting the public health. If an  
15 ingredient might be unlawful, consumers need to know  
16 so that they can avoid using those products with that  
17 ingredient and responsible industry participants need  
18 to know as well so they can avoid selling them.

19 We also recently announced a botanical  
20 safety consortium that we're kicking off with our  
21 industry, academic, and government partners to promote  
22 scientific advances in evaluating the safety of



1 botanical ingredients and mixtures in dietary  
2 supplements. This group, group will look at novel  
3 ways to use cutting edge toxicology tools to promote  
4 the goal of safety that we all share.

5 As a researcher, I'm thrilled to see  
6 these groups come together to collaborate and learn  
7 from each other while tackling these complex  
8 questions. Today's meeting is another piece of our  
9 renewed focus on dietary supplement regulation and our  
10 efforts to bring these into the 21st century.

11 The topic of today's meeting,  
12 Responsible Innovation in Dietary Supplements, really  
13 gets to the heart of the balance between access and  
14 safety that is the core of DSHEA. Our multipronged  
15 efforts to modernize the dietary supplement program is  
16 complicated, but so is this industry. I know that our  
17 Office of Dietary Supplements Program is looking  
18 forward to hearing your suggestions on how we might  
19 reshape our oversight of supplements.

20 I'm sure the conversation will be  
21 thoughtful, detailed, and productive with views from  
22 across the spectrum of stakeholders represented here

1 today. I'm please to see the broad interest in our  
2 efforts with participation from consumer health  
3 groups, industry trade associates, attorneys, and  
4 physicians. I know we all have representatives from  
5 our fellow regulatory agencies and other countries  
6 participating, which is very important given the  
7 global reach of these products.

8           Given the interest in the package that  
9 we had before, is I will turn this podium over now to  
10 Steve Tave, or director of the Office of Dietary  
11 Supplement Program and allow the conversations to  
12 begin.

13           Thank you for having me here today.

14           (APPLAUSE.)

15           MR. TAVE: Good morning, everyone. And  
16 thank you very much, Dr. Sharpless, for your remarks  
17 and for being here today. FDA is a big agency. They  
18 just figured to show that the Agency employs more than  
19 15,000 people spread across headquarters here in  
20 Maryland and the field, across the United States and  
21 now the world. And our jurisdiction spans a wide  
22 range of products used every day by every American.

1                   FDA encompasses six product centers  
2 covering commodities including foods, drugs, medical  
3 devices, biological product, veterinary products, and  
4 tobacco products. And there are a few people who now  
5 appreciate the full breadth of FDA's responsibilities,  
6 as well as Dr. Sharpless who brought a wealth of  
7 relevant experience with him to his role as acting  
8 commissioner and has since immersed himself in the  
9 full range of FDA's activities since he joined the  
10 Agency last month.

11                   Now although dietary supplements  
12 represent a small, relatively small, discrete segment  
13 of FDA's vast regulatory portfolio, these products  
14 remain an important part of the American lifestyle.  
15 Dr. Sharpless spoke about their prevalence and about  
16 the size of this industry. He also spoke about how  
17 the market has evolved and how those changes have  
18 created a need for FDA to ensure that our regulatory  
19 framework activities are up to date and reflect the  
20 realities of today's marketplace.

21                   Dr. Sharpless gave an excellent overview  
22 of the different steps that FDA is taking to

1 strengthen our oversight of dietary supplements  
2 through modernization and reform. And importantly  
3 while these steps were first announced in February  
4 before he arrived at the Agency, he also said that the  
5 intervening change in Agency leadership did not change  
6 the fact that his work, that this work remains an  
7 Agency priority.

8           Those words backed up by his personal  
9 presence here this morning despite the countless  
10 demands that come with leading an agency of this  
11 magnitude, including as I'm aware a telephone call  
12 that's starting any moment, send a very strong and  
13 clear message to all of our stakeholders that FDA is  
14 committed to moving our dietary supplement program  
15 forward.

16           So I'd like to take a moment to express  
17 my thanks to Dr. Sharpless for his continued support  
18 of our important work in the dietary supplement space  
19 and I know that you need to leave. So if, if you have  
20 other demands, this is probably an understandable time  
21 to go. Thank you.

22                           (APPLAUSE.)

1                   So we're already a few minutes behind  
2                   schedule, but I think with so many commercial flights,  
3                   we might make up time in the air and finishing on  
4                   schedule by the end of the day. Since Dr. Sharpless  
5                   already gave an overview of FDA's new efforts to  
6                   modernize our regulation of dietary supplements, I'm  
7                   not going to repeat that.

8                   And today's meeting isn't intended to be  
9                   a discussion of all of these new efforts, but it does  
10                  represent an important component of these  
11                  modernization efforts. So let's take a step back and  
12                  talk about why we're here today and what we hope to  
13                  accomplish.

14                  FDA's authority to regulate dietary  
15                  supplements was generally articulated by DSHEA, the  
16                  Dietary Supplement and Health and Education Act of  
17                  1994. We've talked before and Dr. Sharpless  
18                  reiterated about how DSHEA embodies two twin goals.  
19                  First, ensuring the right balance between preserving  
20                  consumer access to supplements that are safe, well  
21                  manufactured, and accurately labeled, while second,  
22                  still upholding our obligation to protect the public

1 from unsafe and unlawful products.

2 We embrace those goals and our strategic  
3 priorities for dietary supplements here at FDA,  
4 consumer safety, product integrity, and informed  
5 decision making, are in line with these twin goals.  
6 One of the critical elements of our modernization  
7 efforts is ensuring that our regulatory framework is  
8 flexible enough to allow for innovation and growth in  
9 the dietary supplement marketplace while maintaining  
10 and even strengthening our ability to efficiently and  
11 effectively evaluate product safety and protect the  
12 public health.

13 To be sure, DSHEA did not assume that  
14 the world would stand pat as it existed in 1994.  
15 Rather it clearly envisioned a dynamic dietary  
16 supplement market with a role for innovation. The law  
17 gave authority -- the law gave FDA authority to take  
18 action against dietary supplements on the market that  
19 are adulterated or misbranded.

20 Broadly speaking, though, DSHEA  
21 reflected a judgment that, and this is a quote from  
22 the congressional findings, dietary supplements are

1 safe within a broad range of intake and safety  
2 problems with the supplements are relatively rare. So  
3 DSHEA classified dietary supplements as foods subject  
4 to postmarket regulation by FDA, but with no premarket  
5 approval necessary before products can be introduced  
6 to the market.

7 As legislation goes, DSHEA is relatively  
8 short, but its provisions are there for a reason. And  
9 no one would argue that the law allows you to just  
10 stamp the words dietary supplement on any product and  
11 then market it lawfully. In fact, one way to read  
12 DSHEA is as establishing certain symbolic thresholds  
13 that must be crossed before a product is entitled to  
14 the presumption of safety that Congress bestowed on  
15 the class of dietary supplements.

16 Now I deliberately didn't use the term  
17 barrier there. I used threshold. Although FDA had  
18 the authority to take action when we can establish a  
19 violation by a product that is on the market, there is  
20 nothing to prevent a firm from disregarding these and  
21 introducing a product into the market anyway.

22 The route of administration is one such

1 threshold. For example, an injectable product cannot  
2 be a dietary supplement. Under the law to be a  
3 dietary supplement a product must be intended for  
4 ingestion. So while products that are swallowed like  
5 tablets, capsules, liquids, and powders can be dietary  
6 supplements, other products like products that are  
7 injected, inhaled, or applied topically cannot.

8 Can any ingredient be a dietary  
9 supplement? DSHEA imposes the threshold that a  
10 dietary supplement must bear or contain at least one  
11 dietary ingredient. The law then articulates six  
12 different categories of dietary ingredients. Or  
13 viewed another way, five different categories with a  
14 sixth category that captures different variations and  
15 innovations of the first five categories.

16 But are there limits to what these  
17 categories encompass? To take an extreme example,  
18 could you put gasoline in a six ounce bottle and sell  
19 it as a dietary supplement? Our first panel will  
20 discuss this very question. Maybe not the precise  
21 question of whether gasoline can be a dietary  
22 supplement. You never know with these folks. But the



1 question of how broadly the term dietary ingredient  
2 should be understood.

3 This is a question that has come up  
4 repeatedly in (inaudible). Synthetic copies of  
5 botanical ingredient is one. Dietary substances is  
6 another. But it also bears more generally on the  
7 question of innovation including with respect to  
8 certain classes of ingredients such as live  
9 microbials, as well as other contexts.

10 And as advances in technology lead to  
11 the development of novel ingredients with potential  
12 beneficial effects, the public health question of  
13 whether the safety of all dietary ingredients can be  
14 assessed equally using common criteria remains at the  
15 forefront.

16 Now not all dietary ingredients  
17 automatically qualify for the presumption of safety.  
18 DSHEA defines the term new dietary ingredient, which  
19 we often abbreviate as NDI, to mean a dietary  
20 ingredient that was not marketed in the United States  
21 before October 15, 1994. And like all definitions,  
22 there is a reason for this one. NDI status can

1 present another threshold to cross.

2 A dietary supplement that contains a new  
3 dietary ingredient is adulterated unless it satisfies  
4 one of two requirements. First, it contains only  
5 dietary ingredients which have been present in the  
6 food supply as an article used for food in a forum in  
7 which the food has not been chemically altered. And I  
8 apologize for reading that statute here. I'm not  
9 going to do that again. Or second -- but I think it's  
10 relevant in this case.

11 Second, that there is a history of use  
12 or other evidence of safety establishing that the  
13 dietary ingredient when used under the conditions  
14 recommended or suggested in the labeling of the  
15 dietary supplement will reasonably be expected to be  
16 safe, and at least 75 days before being introduced  
17 into interstate commerce the manufacturer or  
18 distributor of the product provides FDA with the  
19 information that is the basis for their conclusion  
20 that the product will reasonably be expected to be  
21 safe. Pause for breath.

22 The second prong is the premarket

1 notification requirement and we'll come back to that  
2 in a minute. But let's first focus on the other prong  
3 which is at the heart of today's second panel. Our  
4 second panel will discuss exceptions to the NDI  
5 notification requirement. That is, even some new  
6 dietary ingredients may not be subject to the  
7 premarket notification requirement.

8           Some of you will notice that I've  
9 skipped a step in the analysis. What does it mean to  
10 be new? For example as technology advances, when, if  
11 ever, do changes to manufacturing processes alter the  
12 character of an ingredient so much that it can no  
13 longer be considered the same ingredient that was  
14 previously on the market?

15           Our second panel will address this  
16 question along with what it means to be present in the  
17 food supply and the related question of how evolution  
18 over the past 25 years in how we regulate the food  
19 supply has impacted what this provision means in the  
20 broader framework of DSHEA.

21           Now back to the NDI notification  
22 requirement. This requirement when it applies is the

1 final threshold. In fact, an effective NDI  
2 notification process represents FDA's only opportunity  
3 to evaluate the safety of a new dietary ingredient  
4 before it becomes available to consumers. Our goal  
5 today is not to talk about the nuts and bolts of the  
6 NDI notification process. Although as an office, we  
7 certainly remain available to work with stakeholders  
8 who are interested in preparing to participate in that  
9 process.

10 And our goal overall is not to maximum  
11 the number of notifications that we receive. Rather  
12 our goal is to right-size the process to see that  
13 appropriate notifications are submitted for the  
14 products for which they are required. Our fourth  
15 panel will discuss ways to promote, to promote overall  
16 compliance with this requirement including challenges  
17 and opportunities associated with ideas like economic  
18 incentives and enforcement.

19 I went a little bit out of order there  
20 and I skipped from the second panel to the fourth  
21 panel and I did that because of the logical flow of  
22 this discussion, but it doesn't in any way reflect the

1 relative importance of the panels.

2 As Dr. Sharpless noted earlier, one of  
3 the biggest contributors to the changing dietary  
4 supplement marketplace has been globalization and  
5 we're very fortunate that today we'll be joined by one  
6 of our international regulatory partners from Health  
7 Canada who will offer a comparative perspective on how  
8 some of these same issues that we face are being  
9 handled abroad. So there is a lot to talk about  
10 today.

11 A few notes. First, although we have  
12 divided the discussion into separate panels for  
13 logistical purposes, there is inherently some overlap  
14 among the topics. We've asked our panelists to focus  
15 on the subject of their panel and they very kindly  
16 agreed, but we've also told them that we're not  
17 censoring any opinions. And so they may occasionally  
18 speak about something that is the subject of another  
19 panel and that's okay.

20 The goal of today's meeting is to  
21 facilitate discussions. After each panel has  
22 completed its presentations, there will be an

1 opportunity for question and answer both among the  
2 panelists and by the audience. And at the end of the  
3 day there will be an opportunity for open public  
4 comment.

5 As Dr. Welch said, there's also a docket  
6 to which you can submit written comments and that  
7 docket will remain open for 60 days after the meeting.  
8 We are here to hear from you and that's my one bad  
9 joke of the day.

10 In terms of what we hope to accomplish,  
11 we don't expect to walk out of here at the end of the  
12 day with all of our questions resolved. We do expect  
13 to all walk out of here. Okay, second bad joke. I'm  
14 done. I promise.

15 Some of these questions pertain to how  
16 the law should be interpreted. If the answers were  
17 obvious, we wouldn't need to have this meeting. The  
18 point isn't to convince one another that one view is  
19 the only correct one, but rather to articulate the  
20 parameters of the questions and then to ask on top of  
21 that what is the most desirable public health result  
22 consistent the DSHEA's twin goals of access and

1 safety. And then to try to identify areas of  
2 consensus about what we should do and how, and beyond  
3 that whether we currently have the authority to do it.  
4 And if not, to start to think about what it will take  
5 to achieve those desirable public health outcomes.

6 We have a wonderful array of panelists  
7 from a diverse range of stakeholder perspectives who  
8 have volunteered to be here to participate in today's  
9 discussion. We've also had tremendous interest in  
10 today's meeting. We reached capacity for in-person  
11 attendance here in the room and we have several  
12 hundred people participating remotely via webcast.

13 We've had a number of people sign up to  
14 share their thoughts during the open public comment  
15 portion of the meeting later and I expect that we'll  
16 have an active audience during the Q&A portion of our  
17 discussions today.

18 I want to thank you all for your  
19 interest in these topics and for your partnership in  
20 this important work. So without further ado, let's  
21 get started with our first panel and I'll invite our  
22 panelists for the first session to come gather at the

1 table and I'd like to invite Dr. Welch back up to  
2 podium to introduce session one. Thank you all.

3 (APPLAUSE.)

4 DR. WELCH: Good morning, everyone.  
5 Okay. So starting with our first panel. Let me get  
6 out my information here. We thought it was really  
7 important to sort of lay out FDA's definitions or  
8 working definitions of the dietary ingredients that  
9 are listed out. So the scope of dietary ingredients  
10 under DSHEA, some are more well established than  
11 others. Some less well established. And I think some  
12 of them, you know, we don't have a lot of questions  
13 from our stakeholders on.

14 I think the first four are pretty well  
15 accepted. You know, vitamin, a mineral, a vitamin,  
16 you know, and we're talking about the deficiency of  
17 which is, results in a clinically defined deficiency  
18 syndrome. Mineral, herb, or other botanical, for the  
19 most part we don't have questions on what an herb or  
20 other botanical is.

21 Amino acid, an alpha amino carboxylic  
22 acid, there, you know, some of those are fine if



1 they're synthetically produced versus pulled from  
2 nature. There's no such thing as a synthetic herb or  
3 botanical just in case we're, we're curious about  
4 that. Others of which, you know, we're still  
5 discussing 25 years later.

6           So a dietary substance, a dietary  
7 substance for use by man to supplement the diet by  
8 increasing the total dietary intake. Again, I realize  
9 I just read the statute to you all. So what do we  
10 mean by that? And I think in many instances it would  
11 be great if there was a well accepted definition.  
12 Taking it sort of on its face, what we have is a  
13 dietary substance for use by man. I'll let the man  
14 slide in today's world.

15           We'll go ahead and say a dietary  
16 substance for use by human. A substance that is  
17 commonly used as human food or drink. To supplement  
18 the diet by increasing the total dietary intake. As  
19 far as I'm concerned, I think this is further evidence  
20 it's intended to mean foods and food components that,  
21 that humans eat as a part of their diet. I don't know  
22 how usual the diet must be, but, you know, evidence

1 that this, this is part of the diet. It's part of the  
2 total dietary intake.

3 I think one aspect, I don't know if I  
4 need to clarify this, but use as a dietary supplement  
5 doesn't necessarily make something a dietary  
6 substance. That would be a pretty big loophole if you  
7 were to put something in a supplement, put it on the  
8 market and then say, well, because it's in a dietary  
9 supplement, it is not a dietary substance. I think it  
10 has to be a dietary substance first before it goes  
11 into the supplement and on the market.

12 I think some additional considerations  
13 is that something in food or in the food supply might  
14 not be a dietary ingredient either. I think there's  
15 that definition of consumed in food versus consumed as  
16 food. And you know how FDA likes to pick apart every  
17 single word as part of the statutory language. So  
18 and, and the exact wording that is used is important  
19 to us.

20 I think consumed in food you can, yeah,  
21 you can have contaminants or toxins versus consumed as  
22 food, something that was intended to be there. And to

1 be clear, I think synthetics have since this can be  
2 dietary substances if the synthetic version of which  
3 is what is in the diet. So that's, that's sort of our  
4 working definition.

5 And then I think the next one -- my  
6 little clicker is a little touchy in that it doesn't  
7 like to click. You know what? There's always a  
8 better way to do this. There. Okay. We'll do it  
9 that way. You all may need to use the mouse.

10 I think the constituent of a botanical,  
11 that's another one that we're still talking about  
12 today. So we've already defined herb or other  
13 botanical, right? We have a plant algae fungus, a  
14 part of a plant algae fungus or an effector, a  
15 secretion of a plant algae fungus. Again, sort of  
16 something that is from the ground from nature.

17 A constituent of and, and this, these  
18 are definitions, by the way, that are directly from  
19 our NDI draft guidance, the 2016 draft guidance. So a  
20 constituent, an article that is a physical part of the  
21 whole and can be isolated from the whole. So what  
22 we're talking about of course is a constituent of a

1 botanical, an article that is part of the botanical  
2 and can be isolated from the botanical.

3 I think that's something we -- that's  
4 sort of how we've been operating. We, I hope that our  
5 panelists can offer some different viewpoints. What  
6 we want to see, of course, as the conversation sort of  
7 to set ourselves off, ideally we can get some good  
8 conversation going during the panel. I don't want to  
9 take all of our time. I do want to turn it over to  
10 our panelists.

11 You know, we have, first we have Scott  
12 Bass, head of Global Life Sciences team at Sidley  
13 Austin. We were going to hear for Larisa. I'm sorry,  
14 from Loren Isrealson at UNPA. We are, he was not  
15 able to travel. So Larisa Pavlick from United Natural  
16 Products Alliance was very, very willing to step in.  
17 So we appreciate that.

18 George Paraskevacos from, the executive  
19 director from the International Probiotics  
20 Association. We really wanted to have a probiotics  
21 perspective. It's just such a huge area of the  
22 industry right now and we want to make sure that we

1 can recognize that. George was kind enough to work  
2 with the International Food Additives Council on his  
3 presentation. So the presentation while presented by  
4 George is actually coming from IPA and IFAC. So thank  
5 you for that.

6 And then Pieter Cohen, associate  
7 professor at the Harvard Medical School, Internists of  
8 Cambridge Health Alliance, and well known to the  
9 dietary supplement industry. So we are very happy to  
10 have them.

11 I'm going to turn it over to Scott here  
12 in a moment. I forgot I was supposed to give a few  
13 more housekeeping remarks if you aren't already sick  
14 of that. So I will turn it over to Scott. We're  
15 going to ask for about ten minutes from each presenter  
16 and then we'll open it up to Q&A. We would love to  
17 have questions from our audience. And again, the  
18 webcast participants can ask questions as well. We'll  
19 be monitoring that. We, we would like to see some  
20 sort of dialog happen. You know, FDA's definition  
21 versus other working definitions and, and make sure  
22 that we understand where everyone is coming from.

1                   With that, the couple housekeeping  
2 notices. Again, if you have mobile devices of any  
3 sort or every sort, please make sure they're silenced  
4 and I know we do have a number of people. There are,  
5 by the way, seats down in the front and in the middle,  
6 which is always fun to sit at.

7                   It is hot in here. I recognize that as  
8 much as everyone else. We are working on cooling it  
9 down. So stick with us. Webcast participants, you  
10 are very lucky to not be in our little sauna over  
11 here. So with that, I turn it over to Scott. He will  
12 then turn it over to Larisa, George, and then Pieter.

13                   MR. BASS: Good morning. Scott Bass.  
14 I'm heading the Global Life Science practice at Sidley  
15 Austin. So I want to first thank Steve Tave, Dr.  
16 Welch, Mr. Durkin, and Lawrence Silvus (ph) for  
17 putting this hearing on. I think it's a great, great  
18 message from FDA and I really commend the Agency.  
19 This is the first time, certainly in my career, where  
20 the Agency has reached out, acknowledging the value of  
21 dietary supplements and also seeking to allow science  
22 to lead the path forward in this very important

1 industry.

2 As many of you know, I had the honor of  
3 being asked many years ago by Sen. Hatch to lead the  
4 drafting on behalf of industry of this law and I  
5 worked with Loren Isrealson as lead negotiators for  
6 those two-and-a-half years, and we worked with Trish  
7 Knight in Hatch's office and with Peter Reinecke in  
8 Harkin's office to produce what is the law today.

9 As you heard before from Steve, we're  
10 looking today to see if the regulatory framework is  
11 flexible enough to also preserve product safety. And  
12 I just want to tell you up front that I think two  
13 things in answer to that question. First, the  
14 industry has not accepted its responsibility on the  
15 safety front in growing to 4 to 40 million, billion.  
16 And second, that FDA is inhibiting innovation and  
17 actually endangering consumer safety by the way it is  
18 interpreting this provision of the law.

19 So starting with the beginning, the  
20 beating heart of today's issue is, of course, FF1(e)  
21 and that was written. I will be producing this  
22 testimony in more detail in written form next month.

1 So I'm just going to go into highlights today in the  
2 remaining eight minutes. So I'm going to make three  
3 points this morning.

4           Number one, none of the things we're  
5 going to talk today about, not just this panel, but  
6 the other panels, is going to work unless we have four  
7 foundations.

8           The first is you have to have mandatory  
9 listing of dietary supplement products. You cannot --  
10 I am incredulous when I hear people say that they're  
11 willing to put a product on the internet or in a  
12 store, but they're not willing to tell the government  
13 they're selling it. It just makes no sense. There's  
14 no way we can have adequate enforcement, a working NDI  
15 system, or incentives for better science or for  
16 innovation unless FDA knows what's on the market.

17           Second, we need more enforcement money  
18 and it can't be earmarked anymore. That is a critical  
19 component. Third, we need incentives for responsible  
20 companies to innovate and spend money on science. And  
21 finally, and this is going to be another panel, other  
22 than grandfather products and foods that generally



1 were consumed as normal foods, everything else should  
2 go through an NDI. That was what we intended when we  
3 wrote the law and all of this talk about exceptions,  
4 which I can't wait to hear, is in my mind off the  
5 mark.

6           So let's get to point number two.  
7 201(ff)(1)(E), we now call it the innovation section.  
8 We drafted that, in fact I drafted it from one product  
9 at the time, coenzyme Q10, which ironically was a  
10 synthetic botanical. And after some court decisions,  
11 we made sure we wrote into the law the innovation  
12 section, meaning we didn't know what was coming down  
13 the road, probiotics being the biggest category now,  
14 but in that time we wrote something and FDA accepted  
15 it.

16           So it's a dietary substance and you  
17 should know that the word nutritional, that's really  
18 key to this entire discussion, was used in an earlier  
19 law. It was brought up several times by opposition  
20 and there was a constant fight to keep it out of the  
21 (E). So the words dietary substance were in there  
22 because nutritional was not. And that's why it's

1 written that way.

2           Because nutritional is basically  
3 circular. Is it commonly used in food? Read the  
4 recent NDI guidance. Oh, yes, it's commonly used in  
5 food. So it can't be a dietary ingredient unless it's  
6 not. So it's the opposite of innovation, which is  
7 creating something new. So we had vitamins, minerals,  
8 herbs or botanicals, amino acids, and the other stuff,  
9 the CoQ10s and innovative products.

10           So here's how FDA a couple years after  
11 DSHEA was passed themselves describe this section.  
12 Other dietary supplements comprise a broad and diverse  
13 group of substances that are neither of plant origin  
14 or could be viewed as nutrients within the common  
15 sense meaning of the term. This is what FDA said  
16 until 10 or 12 years ago.

17           And that make sense because coenzyme  
18 Q10, conjugated linoleic acid, glucosamine, melatonin,  
19 various enzymes, glandulars, and now probiotics, all  
20 are covered by that section. Within ten years later,  
21 a group of people at FDA with no regulation, no  
22 hearing, and no statutory change decided they would

1 quietly put the word nutritional back into the act  
2 through the -- you can read it in the NDI guidance.

3 And now FDA has said, and I don't think  
4 it's the ODS, by the way, Office of Dietary  
5 Supplements, that is responsible, that dietary  
6 substances now only include substances already present  
7 in foods, in food components, that humans eat as part  
8 of their usual diet. Does anybody here think that any  
9 innovative product could meet the definition? I  
10 don't.

11 And so here's the irony, the real irony  
12 that's caused by this distorted interpretation that's  
13 gone through no public hearing or regulation. There's  
14 actually caused the Office of Dietary Supplements now  
15 to adopt a tortured position that harms consumer  
16 safety. The very thing ODS was intended to protect is  
17 actually opening the floodgates to a bunch of products  
18 that will ever be reviewed for science.

19 And the reason is, here's the logic.  
20 Since nothing new can now get in under (E) under this  
21 wrong and I think ultra vires interpretation, FDA says  
22 go do a GRAS self-affirmation and without commenting -

1 - (inaudible) I have to be careful what I say here --  
2 on the quality of GRAS self-affirmation, which let's  
3 just say is not consistently great -- FDA says, oh,  
4 well now that you're a food, forget the fact we said  
5 in our guidance has to be usually in the diet -- we'll  
6 ignore that for the moment -- go on the market for six  
7 months and then you don't even have to file an NDI  
8 notice because it falls within the 413 catchall.

9           You know why we wrote that catchall?  
10 Because if you have an orange and you extract  
11 bioflavonoids, it's a commonly consumed food, I want  
12 to take something out of it. It was not intended to  
13 let every new synthetic ingredient and every new  
14 ingredient on the market without any oversight of  
15 science.

16           It's a total distortion and it's  
17 precisely putting the word nutritional in (E), which  
18 is not allowed, that causes this to allow all these  
19 products in the market that are getting no FDA safety  
20 review.

21           That's not what Congress wrote. It's  
22 not what Congress intended. It turns the NDI process

1 on its head and it is dangerous for this industry's  
2 credibility and dangerous for FDA's regulation.  
3 Innovation is the key to growth and to public access  
4 and strong safety data is the only sustainable move  
5 forward.

6 Now Steve Tave said what about gasoline.  
7 Let me tell you the answer. No. And the reason is  
8 you can't retool (1)(ff)(1) in isolation, which is the  
9 problem here. We wrote that in conjunction with  
10 402(f)(1), the safety provision in what's now 301(v).  
11 We gave FDA lots of safety powers that didn't exist  
12 before.

13 Number one, (ff)(3), if it's a drug,  
14 forget it. It's not going to be a supplement. Number  
15 two, 402(f)(1)(b), if you didn't file NDI and you were  
16 supposed to, illegal, adulterated. Number three,  
17 301(v), you put out a product that's not safe, that  
18 didn't meet the standards of 413, illegal. FDA's  
19 never used those provisions to enforce. I'm not just  
20 looking at Dr. Frankos's here.

21 What we need here is to understand that  
22 we have great safe guards so you don't look at

1 something and say can this be a supplement and that  
2 stops. You look at it and say can this be supplement,  
3 does it meet the other safety thresholds that Steve  
4 Tate mentioned before. That's what you have to look  
5 at. So in conclusion, do we need legislation to  
6 create innovation under (ff)(1)(3)? No, we just need  
7 to remove this unlawful interpretation FDA's put on.

8 Number two, do we need legislation to  
9 provide real exclusivity incentives so companies will  
10 invest? Yes, we do. We need new legislation to  
11 create incentives for responsible companies to do good  
12 science. Thank you.

13 (APPLAUSE)

14 MS. PAVLICK: Good morning. Thank you  
15 all for being here. I am here today to present for  
16 you for United Natural Products Alliance. Loren  
17 Isrealson is, I'm honored to be supported by a  
18 ghostwriter that is a huge leader in our industry.

19 My name's Larisa Pavlick and I'm  
20 presenting on his behalf. And what we were asked to  
21 speak about today was the use of what has been termed  
22 synthetic botanicals. And from just this morning's

1 discussion, it feels as maybe there's just a  
2 terminology update that we could utilize to re-  
3 characterize these types of products that may be  
4 satisfying both sides of the industry because when we  
5 walk through this presentation together, I hope that  
6 in the end you're going to realize that innovation as  
7 Scott has mentioned, is really the key to all  
8 industries and all commodity areas. And dietary  
9 supplements is just one of those.

10           So as we walk through the slide  
11 presentation today, I want you to kind of reflect on  
12 where we were in 1994 and '92 when this law and DSHEA  
13 was being established and where we are today because  
14 as we have all recognized in the, the week that we've  
15 had here in Washington, DC with many supplement  
16 meetings, that there's a lot of changes in the  
17 industry.

18           So how can we all work together to  
19 ensure that moving forward we still maintain safe  
20 access to responsible dietary supplements that can  
21 improve the health and quality of life for many  
22 individuals? Okay. We'll do it this way.

1                   So within this presentation, we're going  
2 to cover a few items. We're going to talk about the  
3 FDA's goals. The FDA's goals in the public health  
4 importance of the NDI guidance, which was issued as a  
5 draft in August of 2016. As we approach August of  
6 2019, we may approach a final form.

7                   Dietary Supplement Health and Education  
8 Act, we're going to talk about some of the negotiation  
9 notes and regarding the synthetic ingredients that  
10 were discussed at that point. We'll also talk about  
11 the synthetic botanical ban and kind of where and when  
12 that may have taken place.

13                   We'll look at some of the congressional  
14 and industry responses to the synthetic botanical  
15 policy, talk about current issues and market realities  
16 for the use of synthetic ingredients, and some  
17 recommendations that we have itemized for, from United  
18 Natural Products Alliance, which is our members in the  
19 industry.

20                   So in looking at the first topic when  
21 we're talking about the FDA's goals for public health,  
22 and public health importance that was related to the



1 NDI guidance, the first aspect of that document was  
2 really to talk about the NDI process being the sole  
3 premarket opportunity for FDA and FDA staff to assess  
4 the safety of new dietary ingredients. And I think we  
5 all as a responsible industry agree with the  
6 intention.

7 We can talk about the improvement,  
8 improving the rates of NDI compliance through dietary  
9 ingredient notification and the compliance of those.  
10 And they're also looking at improving the -- the rate  
11 and the quality are two of those steps within that  
12 document.

13 And then we look at new dietary  
14 ingredient notifications and how it's serving as a  
15 preventive control, to borrow a term from FSMA, but to  
16 ensure that consumers are not exposed to any  
17 unnecessary public health and safety risks in the form  
18 of these new dietary ingredients with unknown safety  
19 profiles.

20 So as we walk through that, this term  
21 that has not been well accepted by some of the  
22 regulatory agencies and is often used in our industry,

1 is synthetic botanical or often referred to as  
2 synbots. And again, this is maybe where we update the  
3 terminology. If they're synthetic components, maybe  
4 there's a new terminology that we can come up and  
5 agree with and define so that all parties can agree to  
6 the functionality of these ingredients.

7 But synthetic botanical status is  
8 defined by its nutritional function and not by its  
9 state of matter. So as Cara mentioned, if it wasn't a  
10 plant, it was never a plant, and the component is  
11 extracted, or in this case, for a synthetic botanical,  
12 a chemically identical compound is developed, it's  
13 still not considered a dietary ingredient.

14 But if we look at this from other  
15 commodity groups within the FDA, we know that there's,  
16 there's drug compounds that are synthetic products and  
17 generics, which may be synthetic copies of those. And  
18 those are in the approved category.

19 We also have food additives that are  
20 synthetic copies, and if we want to take it to an  
21 extreme, we have, so we have food additives. We have  
22 drugs and we have chemical compounds being used in

1 cosmetics. They're all synthesized and the most  
2 recent and probably the most interesting to many of us  
3 in the natural products industry -- oh, and there goes  
4 the slides -- is that there's now approved synthetic  
5 meats. So if -- shazam. I didn't touch it. That's,  
6 and that's -- all right. Do you want me to switch to  
7 my own?

8 Now we have synthetic meat products. So  
9 if we have the ability to have approval in some of  
10 these other commodity categories, I think it's time to  
11 modernize the approach to synthetic compounds that are  
12 used in dietary supplement product regardless of their  
13 source. And I'm going to have to pose, pause a moment  
14 to pull up my own slides. You got me. Okay. And  
15 we'll continue. I'm sorry you're not going to be able  
16 to see the slides, but I'll just be working off of my  
17 copy and maybe you'll have access to them later.

18 A substance that has been synthesized in  
19 a lab or in a factory, has never been a part of an  
20 herb and a, or a botanical, and therefore, it's not a  
21 dietary ingredient. So that's, again, some of the  
22 rationale from FDA. Synthetic botanicals as my bullet

1 No. 3 are not part of the human diet, and therefore  
2 they cannot increase the total dietary intake of  
3 something that has not been part of, of the human  
4 diet.

5           So again, if we look at pre-DSHEA,  
6 there's many synthetic vitamins that have been on the  
7 market. It's not an orange and it's not an extract of  
8 an orange. It might be something else that was  
9 cheaper and easier to access or make. And again,  
10 making sure that the public has access to safe and  
11 affordable dietary supplements is the primary goal.

12           The rationale for FDA's position seems  
13 to date back to 2001 as a result of the ephedra and  
14 ephedra alkaloid synthetic products that were on the  
15 market that were causing a significant amount of  
16 illness and injury and consumer complaints, and in  
17 even some cases, death. And we can see as a  
18 responsible industry that that is a responsible step  
19 of the Agency to protect public health and safety, but  
20 it may not have been a fact of the synthetic  
21 composition of some of those alkaloids. It may be  
22 have been misuse of the product itself.

1           So if a synthetic botanical policy -- so  
2 then a synthetic policy was developed and in 2004 we  
3 had a regulation, which was prohibiting the use of  
4 ephedra and ephedra alkaloids in dietary supplements.  
5 But was this the right step?

6           So if you were able to see the slides,  
7 Loren has a great memo that was presented to Comm.  
8 Hamburg in 2011 and it was issued by two of the  
9 authors, or two of our chairs for the dietary  
10 supplement industry, our champions that were within,  
11 within government and helping us in the Agency. And  
12 this letter was addressed to Comm. Hamburg. It was  
13 dated on December 22nd of 2011 and it was in response  
14 to the initial guidance that was issued by the FDA.

15           And that guidance was called Dietary  
16 Supplement, New Dietary Ingredient Notifications.  
17 Excuse me. And related issues. And that document,  
18 that guidance document was published in January 2011.  
19 And within the document in paragraph number two, it  
20 states that they urge the FDA to withdraw the new  
21 guidance and to republish it. So as we know, the  
22 additional guidance was published in 2016, but have we

1 addressed all of the elements of, of concern and have,  
2 has the intent of DSHEA been pulled forward?

3 So the background of the guidance was  
4 that FSMA in 2011 asked FDA to direct, or asked the  
5 FDA to clarify the New Dietary Ingredient Notification  
6 process and to do that with means that were consistent  
7 with DSHEA. And instead what seems to have come out  
8 those guidance documents are a little bit adversarial  
9 to what we had in DSHEA.

10 So within this slide that you can't see,  
11 there's a quote that Loren has highlighted and the  
12 quote reads similar, similarly the draft guidance  
13 accept, accepts, attempt -- excuse me. The draft  
14 guidance attempts to assert this, that synthetic  
15 copies of botanicals can never be a dietary ingredient  
16 and an assertion that is wholly without statutory  
17 basis and in fact contradicts a longstanding FDA  
18 policy.

19 And again, the, kind of the punchline  
20 that you're not going to be able to see shows that  
21 this letter was signed by Tom Harkin and Orrin Hatch.  
22 So these are two of our champions in the industry that

1 were saying that this, the guidance and the current  
2 position of FDA regarding these synthetic compounds is  
3 opposed to the intent of DSHEA.

4 So what are the realities in our current  
5 industry? In 2019 if we look at the compounds and the  
6 ingredients that are being utilized, we have synthetic  
7 chemistry, we have synthetic biology, and we have --  
8 I'm sorry, Cara -- I'll say it one more time --  
9 synthetic botanicals. They've evolved dramatically  
10 since 1994, as has the rest of the world.

11 They're currently and they will continue  
12 to enter the food ingredient, spice, color, flavor,  
13 and the dietary supplement industry. And I have a  
14 great graphic that is going to show you all of the  
15 compounds that are available. This graphic is going  
16 to show you when you have access to that all of the  
17 different compounds that are currently being  
18 synthesized.

19 DR. WELCH: Hey, you guys, can you go to  
20 -- what is this -- slide 18, please?

21 MS. PAVLICK: All the compounds that are  
22 being synthesized and are available on the market

1 currently being processed with different yeast  
2 material. So if you look at this list and things that  
3 specifically effect our industry, you'll see caffeine,  
4 saffron, stevia, frankincense, mint. Look towards the  
5 bottom, ginseng, tumeric, all of these are being  
6 manufactured in large volumes in, and are -- well, to  
7 the market and in a much cheaper fashion. Still not  
8 moving. Oh, there we go.

9           So the synthetic botanical ingredients  
10 without sharing our personal opinion of our Agency,  
11 organization's opinion, but synthetic botanicals are  
12 causing an economic disruption. We have synthetic  
13 botanicals that are offering far less expensive  
14 options for buyers and if there's buyers that are not  
15 knowledgeable of the industry, it's hard to determine  
16 if it's price or if it's quality that's driving the  
17 operation.

18           Analytical detection is often difficult  
19 because, again, these might be chemically similar.  
20 Raw material pricing becomes skewed as the synthetic  
21 botanicals are added or replaced to ingredients and  
22 extracts and it encourages at times economic



1 adulteration, misbranding, mislabeling, and is a  
2 consumer deception.

3           So here's a couple slides from one of  
4 our MOU partners and this is talking about some  
5 examples that they've found in the market. This is  
6 from Loren Monahan (ph). He is from the trust and  
7 transparency group, but the Global Kierkenmen (ph)  
8 Association did a study to say what is the prevalence  
9 of synthetic compounds on the market.

10           And they purchased products off of the  
11 internet and from several brands, but they found that  
12 C14 testing was the only way to determine whether or  
13 not there was a synthetic compound. But they found  
14 that there is adulteration and it's happening pretty  
15 frequently. And typically they're not adulterating  
16 the entire product. They're only adulterating a  
17 portion of the product.

18           They're finding between 5 and 16% of the  
19 botanicals are including some sort of substitution or  
20 dilution by synthetic compounds, and when they looked  
21 towards the bottom in bullet No. 3, you'll see that  
22 this is affecting dramatically the prices of those

1 products and greater than 40% of the product that were  
2 tested online had some form of synthetic compound  
3 inside.

4 This is a summary of the data for some  
5 of those slides and you'll notice we don't have time  
6 to cover most of them, but if you look at the outer  
7 column in the colors, the blue indicates those that  
8 were 100% pure, natural products, but the others in  
9 red show that there were some amount of synthetic  
10 compound present.

11 So in summary, the synthetic botanicals  
12 are a growing percent of the dietary supplement  
13 market. It is our reality. FDA's current synthetic  
14 botanical policy should be updated because it's  
15 currently not consistent with the intent of DSHEA.

16 The genesis of new current synthetic  
17 technologies -- the genesis of the current synthetic  
18 policy -- was to remove synthetic ephedra alkaloids,  
19 and again, this policy is currently based on the 2004  
20 regulation, but in the present time if we're talking  
21 about modernization, it might not be helpful.

22 So UNPA has several recommendations for

1 the Agency, and that would be to revise the no  
2 synthetic botanicals as an NDI policy. But we're not  
3 saying that we're accepting of this as the way of the  
4 future. We're saying that let's recognize these  
5 synthetic copies as new dietary ingredients and allow  
6 it to go through the new dietary ingredient process,  
7 allow again safe access to products and consumers  
8 having the ability to make those decisions.

9           But with those making responsible  
10 decisions and providing public choice, we would need  
11 to have some sort of declaration on the labels -- just  
12 as you would see in a GMO or in a bioengineered  
13 product -- that you would be able to indicate that  
14 those products are synthetic and allow consumer  
15 choice.

16           And somebody's taking over the screen  
17 again. There we go. We want to make sure that  
18 products that have not gone through the new dietary  
19 ingredient process would have enforcement by the FDA  
20 and we would want to ensure that you were able to seek  
21 public comment regarding GRAS opportunities for these  
22 types of ingredients as Scott has suggested, that

1 self-affirmed GRAS may not be a strong of science as  
2 if it was reviewed otherwise.

3 With that, I want to thank you for your  
4 time and your patience while we got through these  
5 technical challenges.

6 (APPLAUSE.)

7 MR. PARASKEVAKOS: Well, good morning,  
8 everyone. Thank you again to Steven and Cara and the  
9 FDA for inviting us to present on probiotics. It's  
10 become quite an important category and I think it has  
11 its place in DSHEA. Today's presentation as announced  
12 earlier is a collaborative effort and on behalf of the  
13 International Probiotic Association, IPA, and the  
14 International Food Additives Council, IFAC.

15 So how do probiotics fit under DSHEA?  
16 So this presentation is going to underline some  
17 important aspects to show how probiotics actually do  
18 fit. Before going into the presentation, I'd like to  
19 underline and point why it's such an important  
20 category within the dietary and food supplement space.

21 So consumption of probiotics on a world  
22 level last year closed out at close to 44 billion US

1 dollars, up 6 billion from 2013. The way probiotics  
2 are consumed or the sources of consumed took was 71%  
3 was through yogurt, probiotic yogurts, 16% came from  
4 source and fermented milks, and then 13% was through  
5 dietary supplements. That's globally.

6 So let's look a little bit further into  
7 the dietary supplement space. Last year, 2018, the  
8 dietary supplement space closed out at 5.7 billion US  
9 dollar market value. It's projected to grow 19% by  
10 2022 to 7 billion. Important to note here, and that's  
11 why we are here today, that 5.7 billion dollar USD  
12 number, close to half of that number was consumed here  
13 in the United States. So quite an important category.

14 Does an important category like  
15 probiotics have an official definition? Not  
16 necessarily. It has a few recognized and referenced  
17 definitions globally from science communities,  
18 academics, government agencies. The most referenced  
19 one I would say is the WHO definition, which was put  
20 together by an expert panel in 2001 and you can see it  
21 up here. Live organisms when administered in adequate  
22 amounts will confer a benefit to the host. What about

1 in the US? Under DSHEA we have some reference or  
2 terms of reference to live microbial ingredients, but  
3 no official definition per se.

4 So what is a dietary ingredient? How  
5 does it fall within the scope of DSHEA? We heard the  
6 previous speakers talk about their vitamins, their  
7 minerals, their herbs, so on and so forth. We've,  
8 we've questioned where do probiotics fall under in  
9 many public meetings and in different exchanges we've  
10 had with government agencies.

11 And specifically we have heard that the  
12 FDA say in open meetings that probiotics would fall  
13 under (E). What is (E)? Let's look at the statement.  
14 The statement says it's a dietary substance for use by  
15 man to supplement the diet by increasing the total  
16 dietary intake.

17 What does this statement imply? On the  
18 first part, a need to increase the intake and to  
19 supplement the diet with that particular substance, in  
20 this case probiotics, to help the maintenance, and  
21 this is important, is the maintenance of health and  
22 normal body functions. And on the second part, it is

1 a dietary substance.

2                   So let's look at the first part of that  
3 statement. The need to increase intake and supplement  
4 the diet. We know the thousands of publications and  
5 articles in science that have been put out in the  
6 public domain around probiotics. We know, you know,  
7 their benefits and roles from healthy digestive  
8 support to immune. We know that humans from these  
9 publications and articles and research, we know humans  
10 are made of bacteria 10 to 100-fold more than human  
11 cells.

12                   We know that probiotics and life  
13 organisms are beneficial to the gut. They allow for  
14 better digestion of nutrients. They allow for better  
15 uptake in nutrients and they allow for synthesizing  
16 certain nutrients. They have very multifunctional  
17 roles within the gut, but also these research articles  
18 and publications have shown that they have benefits  
19 outside of the gut. Immune support, brain-gut access,  
20 skin microbiome, so on and so forth.

21                   At the end of the day, the aging process  
22 declines bacterial communities in our gut. So this

1 could possibly shift functions of the body. I can  
2 remember what I said previously; the maintenance of  
3 health is important. So it's key to understand this.  
4 The IPA is working on a meta-review and we're looking  
5 at two distinct databases of clinical trials that have  
6 been conducted.

7 We have a paper due out later this year  
8 from two databases, clinicaltrial.gov and the WHO, and  
9 we're, it's, it's quite interesting on how many  
10 clinical trials are ongoing at this point. Stay tuned  
11 for that paper.

12 Next, so probiotics are necessary like  
13 vitamins and minerals. So we, it begs the question,  
14 and we always ask, why did DSHEA not include a  
15 distinct line item. It would have made my life easier  
16 anyhow. So I would say a probiotic or a live  
17 microbial, they were prevalent in the US prior to  
18 DSHEA, prior to '94.

19 Some examples, an old dietary ingredient  
20 list which, you know, was published by a few  
21 significant associations in the US, we find genera  
22 species of probiotics. We have a food partial list



1 that we see for GRAS assessment and notifications.  
2 Probiotics also have prior sanctions for food  
3 manufacturing.

4 So they are prevalent. We have the  
5 evidence of that. And over and above that they've  
6 been also in the food supply for many, many years.  
7 One of the first papers that were written regarding  
8 probiotics was this, from the Russian scientist,  
9 Metchnikoff, who noticed Bulgarian peasants outliving  
10 royalty by a high ingestion of yogurts and cheeses.

11 So definitely have been around for a  
12 while. So how do probiotics fit under 20, 201  
13 (ff)(E)? So it's a dietary substance for use in man.  
14 The second part of that particular statement, it's a  
15 dietary substance. So a dietary substance. Let's  
16 take a look around the world how other government  
17 agencies looked at, you know, probiotics.

18 Clearly they exist in the food supply  
19 and there's many, many published lists or safe food  
20 lists that can be applied to be used for the, for  
21 probiotics within the food supply and in food  
22 supplements. Here's a few of the tests in Europe, the

1 IDS list. We have a natural health products monograph  
2 and many, many others as you see on the screen, too  
3 many to list.

4 So where do probiotics fall in the US?  
5 We know FDA has a partial list of organisms which have  
6 come from safety assessments from GRAS. I think the  
7 list is not comprehensive and I believe we can work on  
8 it. This is where IPA and IFAC can come into play to  
9 discuss on making a more comprehensive list or food  
10 list for live microorganisms or probiotics.

11 In conclusion, they fit under 201  
12 (ff)(E) because they've been in the food supply for  
13 thousands of years. There's a health benefit like  
14 vitamins and minerals to increase the total dietary  
15 intake of probiotics beyond the foods consumed. They  
16 were prevalent in the dietary supplements based prior  
17 to DSHEA in '94.

18 So how can we practically look at  
19 creating maybe a comprehensive list or a way forward  
20 for probiotics within DSHEA? How to be practical? We  
21 propose grandfathered or an exempted list. We propose  
22 the list, this exempted list would include a list of

1 species with a safe history of use. The manufacturers  
2 of these strains within the species would have the  
3 responsibility to, to establish safety based on  
4 abbreviated criteria of safety and identity similar to  
5 other requirements that we see around the world from  
6 other global regulatory agencies.

7 Now it's important to note that strains  
8 within the species of this list would not need to go  
9 through notifications. They could be grandfathered,  
10 but at the some time we must also maintain we cannot  
11 forgo, we cannot forgo the establishment of the safety  
12 assessments. Safety assessments still need to happen  
13 even though there would be a grandfathering process.

14 The second part on how to be practical  
15 and moving forward and adding probiotics within DSHEA  
16 are master files. The master file system or dossiers  
17 would provide FDA with enough information to avoid  
18 unnecessary notifications, but also reduce the burden  
19 and resources of FDA and industry to go through  
20 notifications on strains and species that have been in  
21 the food supply for many years and have a safe history  
22 of use.

1                   Establishing safety, I'd like to mention  
2 here that bacteria give us a very, very unique gift.  
3 Unlike chemical and innate substances, bacteria gives  
4 us a gift of a genetic code. That genetic code or its  
5 DNA allows us to look further into a bacteria organism  
6 or a probiotic so we can understand what it can or  
7 cannot do.

8                   From there things that we can establish  
9 from what can be used within the master file system  
10 would be whole genome sequencing from, from its DNA  
11 for proper identification. Genome, genome mining to  
12 make sure there's no production of virulence factors  
13 or toxin characteristics. Additionally, we can also  
14 look for antibiotic resistance profiling and make sure  
15 that these microorganisms do not have the gene that  
16 transfers this antibiotic resistance. So all this to  
17 say there is a very practical way forward by creating  
18 this practical list for, grandfather list for  
19 probiotics.

20                   So to finish, it's important to note  
21 that a master file system or dossiers with a  
22 grandfathered process from an exempted list is the

1 logical way forward for strains that have been in the  
2 food supply for many years and have a safe history of  
3 use. But at the same time, we have science which  
4 evolves and innovation continues.

5 So they'll definitely be new strains on  
6 the horizon and the NDI process or new dietary  
7 ingredient notification process should be reserved for  
8 these new, new strains.

9 I want to reiterate what was said  
10 earlier this week from Frank Yiannas, deputy  
11 commissioner. It's all about establishing consumer  
12 trust within our, and making sure that we put quality  
13 products to market. This is key for our category  
14 being probiotics.

15 So this is where IPA and IFAC are here  
16 to help. We like to be at the table and would like to  
17 sit with the FDA in regards to discussions within the  
18 working group and even possibly look at forming like  
19 botanicals a specific working group for probiotics.  
20 So with that, I want to thank you for your time.

21 (APPLAUSE.)

22 DR. WELCH: Can we get the screens up?

1 Thank you. Can you move one more slide? There we go.  
2 Whoops. Not break time yet. It is Pieter's time.

3 MR. COHEN: Thank you. Thanks so much  
4 for having me. It's an honor being here. Let me just  
5 share with you first what I do, which is I'm a general  
6 internist. So I see patients Monday, Wednesdays, and  
7 Fridays. And when I'm doing that I'm often --  
8 actually yesterday I was busy encouraging my patients  
9 to restart their supplements that they have forgotten  
10 to start. Starting other patients on supplements. We  
11 had discussions about B12, calcium, vitamin D,  
12 multivitamins that I was encouraging or making sure  
13 that my patients were adhering with.

14 But I not only think that supplements  
15 are essential for me and all physician to practice  
16 evidence-based medicine in 2019, I also think it's  
17 essential that my patients and all consumers have  
18 access to these products without seeing me. If  
19 everything was through me for every symptom of the  
20 human body, the system obviously would break down.

21 So I am so thankful that so many of my  
22 patients receive their care at, at pharmacies directly

1 without me involved. So I'm a big advocate for access  
2 and a big advocate for safety. I got interested in  
3 supplements because of harm that my patients were  
4 experiencing. And in the last decade we've spent a  
5 lot of time and energy studying the safety of, of  
6 supplements and particularly interested in the  
7 boundaries between pharmaceutical drugs and dietary,  
8 and what's found in dietary supplements.

9 Now this conversation is really exciting  
10 to me because what, what we're talking about  
11 publically today is something that's been going on  
12 sort of under the radar scene, under the radar gun.  
13 And it's just wonderful to have an opportunity to  
14 discuss it.

15 What I think's at the core of the  
16 question is, is what's, what's the difference between  
17 a new drug and a new dietary ingredient. So for the  
18 purpose of drugs, I'm not going to be talking about  
19 any legal definition. I'm just going to use common  
20 sense definition, which is a substance which when  
21 ingested has physiological effects.

22 So using that definition of drug, it's

1 clear that some dietary supplements, many, are drugs  
2 in the sense that they're to be ingested and have  
3 physiological effects. Vitamins and minerals across  
4 the board.

5 So the question is not whether or not  
6 there's a clear boundary between a pharmaceutical drug  
7 and dietary supplement. There's not and that's okay,  
8 and that's what DSHEA was put in place to define, to  
9 make sure that the FDA didn't regulate these types of  
10 substances in the same way they did with  
11 pharmaceuticals.

12 But what I think's very interesting is  
13 how do we -- let's now move to a new drug. So a new  
14 drug being a chemical that whether or not it's  
15 extracted from a plant or synthesized, but it's placed  
16 into a pill, powder, capsule, gel, ingested for  
17 physiological effects. And the question is what are  
18 the routes in the United States to market a new drug.

19 So over the last 25 years what's been  
20 happening is that new drugs have been marketed as  
21 dietary supplements or dietary ingredients in dietary  
22 supplements. There's a lot of different examples of



1 this and different routes that these new drugs have  
2 taken. Sometimes it's a drug that was actually well  
3 known prior to 1994. Yohimbine, for example. So  
4 yohimbe is the tree. The bark of it's extracted and  
5 used as extraction. One of the most active alkaloids  
6 is yohimbine. When that's either isolated from the  
7 bark in high quantities or synthesized, it was a  
8 pharmaceutical drug well before 1994.

9           So this distinction that there were  
10 things that were prescribed by physicians in 1990 and  
11 things that were sold over the counter, yohimbe bark  
12 extract prescribed by physicians, Yohimbine, was a  
13 clear distinction. And there was no effort that I  
14 understand for either consumers to demand or congress  
15 to say let's move these prescription drugs, even those  
16 that might have originated in plants, directly into  
17 the store shelves and be sold directly to consumers.

18           So one thing that we have seen over the  
19 years is that you take a product like a food like red  
20 yeast rice, but you formulate it in a way where it  
21 becomes a drug. You have high levels, monacolin K,  
22 exactly the same chemical that's the prescription

1 lovastatin. Or you take yohimbe bark extract,  
2 formulate it a way that you have pharmaceutical doses  
3 of yohimbine. But there's other ways that supplements  
4 have been formulated as new drugs. And this is where  
5 we're particularly concerned because we don't have  
6 evidence about its efficacy or safety in humans.

7           An example of this is finding a chemical  
8 in nature or purportedly finding in nature. DMAA, the  
9 stimulant, is a great example of this. You synthesize  
10 it, place into a pill, sell as a supplement to have  
11 physiologic effects. So here we have a new drug being  
12 introduced as a dietary ingredient.

13           So one pathway is using that old  
14 grandfather clause, but the other pathway is the NDI  
15 pathway. Vinpocetine is a great example of this. So  
16 the vinpocetine is a drug prescribed in countries,  
17 including Russia, for neurological conditions. It's  
18 never been found in nature. However, a chemical very  
19 close to it, vincamine, is very prevalent, for  
20 example, in lesser periwinkle.

21           So the idea was that since it's just a  
22 tweaked version of vincamine, we can sell vinpocetine

1 only synthesized, only pharmaceutically synthesized in  
2 supplements. That's how vinpocetine has found itself  
3 in hundreds of supplement products.

4 So there's been a -- and if we follow  
5 this thinking that has been proposed by some of the  
6 industry, that we can identify chemicals in any food  
7 or botanical and then synthesize them at whatever  
8 dosages and sell them for humans, this a, that's  
9 introducing a new drug into commerce in the United  
10 States.

11 Now does this matter? So I would argue  
12 it does for two reasons. Number one, I agree strongly  
13 with what Scott said. We need incentives for firms to  
14 create information, especially safety information, but  
15 also access to information such that consumers,  
16 physicians, and all of us regulators can just choose  
17 for ourselves what we want to use. So consumers can  
18 decide what to use.

19 If we don't have the research, a  
20 consumer can't make a wise decision for themselves.  
21 If we introduce a new drug in these pathways, there's  
22 no way that a consumer can decide if that's right,

1 especially when the label is not required if you mix  
2 it into a proprietary blend to include the quantity of  
3 the new drug. So I would argue that we need to have a  
4 system that insists on evidence at least of safety  
5 prior to marketing any new drug in the United States.

6 Now the second question is safety,  
7 consumer safety. Is this just a theoretical issue or  
8 are patients being harmed? My perspective as a  
9 physician is patients are being harmed. If you take a  
10 look at the studies, for example, the CDC's study that  
11 estimated that roughly 20,000 consumers end up in  
12 emergency rooms every year due to supplements, that  
13 more than 2,000 are hospitalized every year due to  
14 supplements, or at least the physicians caring for  
15 them believe it's from supplements, then, and you take  
16 a close look at what categories are causing the  
17 trouble, it's really categories that are doing more of  
18 this introduction of new drugs, introducing new drugs  
19 rather than nutritional categories.

20 Similarly, I wouldn't be surprised if we  
21 found out that the reason why ephedra led to 18,000  
22 adverse event reports including, of course, seizures,

1 heart attacks, and deaths, was that, not because they  
2 were, everyone was consuming a natural extract of  
3 ephedra, but rather that the ephedra alkaloids would  
4 either be highly concentrated or synthesized at  
5 dosages that were much higher than traditionally used.

6           So I do think there's serious safety  
7 issues. Another recent example just of one product,  
8 which is a mixture of these kind of new drugs,  
9 basically a synthetic version of a constituent of a  
10 botanical, is the OxyELITE Pro story, which when it  
11 was introduced in early 2013 before the end of the  
12 year had already led to 69 case of hepatitis, dozens  
13 of hospitalizations, three liver transplants, and two  
14 deaths.

15           So, and when scientists analyzed what  
16 was actually in it, it was exactly what was on the  
17 label, which is synthetic versions of botanicals mixed  
18 together in a new way that had never been consumed  
19 before.

20           So where does this leave us? I think  
21 that it's very fair that we have very thoughtful  
22 lawyers on both sides of the argument. I've read the

1 FDA's position on interpreting DSHEA in terms of  
2 synthetics. It seems extremely reasonable to me, but  
3 I sit down and listen or talk to Scott for an hour or  
4 two, his position also sounds very reasonable.

5 So I, I don't think that we have a clear  
6 guidance here, but we're going to have to make a  
7 decision on how we handle this. Do we want a two-  
8 tiered system where new drugs depending on their  
9 backstory, if they've been found somewhere in nature,  
10 in a food anywhere in a world, in a botanical, they  
11 can be introduced through the NDI process? Or, and a  
12 recent example for this would be CBD, might be in this  
13 pathway. Or are we going to have a system where the  
14 courts are going to make these decisions for us?

15 So I'm just delighted to be at a meeting  
16 where these issues that we have known about for years  
17 are now being publically discussed 'cause I think the,  
18 the conclusions we come to are going to be essential  
19 and I think they should be shared broadly with  
20 American consumers. Thank you very much.

21 (APPLAUSE.)

22 DR. WELCH: All right. Thank you.

1 Thank you, presenters. That's wonderful. I just want  
2 to note that it only took about 90 minutes for CBD to  
3 be brought up. So better than last two days ago. I  
4 intend to bring that up again. Okay. I actually  
5 would like to open it up for Q&A. I see they're  
6 turning on the mics. Thank you, guys. I appreciate  
7 that. If there are questions for our panel, I would  
8 fully encourage you to go to one of the two mics.

9 We do need to speak our questions into  
10 the microphone so that our webcast participants can  
11 hear, as well as our transcriber, because, again, the  
12 meeting is being transcribed. Also please begin with  
13 your name and affiliation. That will help the  
14 transcription process and so we all know who each  
15 other is. Our panelists, I, you have mics. I assume  
16 you push the button and it turns on. Great. Awesome.  
17 Thank you, George, for checking.

18 Also if you -- I realize there's only  
19 four of you. If you could try to remember to say who  
20 you are when you start answering the question. Our  
21 transcriber can't quite see you. So also he doesn't  
22 know who you are.

1                   So let's go ahead and start with the  
2 audience questions. Go ahead. Thank you.

3                   MR. GASTELU: My name's Dan Gastelu. I  
4 (inaudible). I've been working in the dietary  
5 supplement, food, and drug industry since the '80s.  
6 And can I ask a question? Like how many people were  
7 here for the dietary supplement (inaudible) Education  
8 Act (inaudible)? Anybody? All right. So very few.  
9 Because you got to really agree to have to live under  
10 that rule, FDA rule. I really appreciate the great  
11 work everybody's done with DSHEA because my life back  
12 then was, 'cause I started toward nutrition weight  
13 lose products was basically (inaudible) harassment by  
14 the FDA (inaudible) help build muscle.

15                   So the Dietary Supplement Health and  
16 Education Act just made my life normal. Everybody's  
17 life normal. (Inaudible) big products like I was  
18 involved in, well, condition categories, (inaudible)  
19 probiotics, ultra. And there's a lot of good stuff we  
20 have right now and the great part is all in the public  
21 health business. So that's (inaudible).

22                   So we have a (inaudible) selection of



1 products that are (inaudible) for health versus a lot  
2 of foods that, you know, are just snack foods and  
3 things like that that aren't necessarily made to  
4 promote people's health. I also work international  
5 and in Canada, places like that.

6 So one question I have is why not just  
7 adopt Canada's definition? It's a really familiar  
8 (inaudible) definition (inaudible) health products  
9 where it says bioactives of the above, which include  
10 botanicals? They also have fungi and things like  
11 that. That's question number one. Why not do that?

12 DR. WELCH: Do any of our panelists want  
13 to answer that? I would defer to the panel on this  
14 one. I am not --

15 MR. GASTELU: Reading it into the record  
16 (inaudible). (Inaudible.) I got a lot of stuff to  
17 read into the record.

18 DR. WELCH: George, it looks like you're  
19 going to answer Dan's question?

20 MR. PARASKEVAKOS: Yes.

21 MR. GASTELU: And also probiotics  
22 mentioned (inaudible). So (inaudible) FDA work

1 (inaudible). They use (inaudible). Work together  
2 closely (inaudible). I don't know the reason, how to  
3 answer that, but what's the general consensus?

4 MR. PARASKEVAKOS: George Paraskevakos.  
5 And your name was?

6 MR. GASTELU: Daniel Gastelu.

7 MR. PARASKEVAKOS: Daniel. It's really  
8 common. (Inaudible) Health Canada even developing  
9 that probiotic monograph. So I think it was well, the  
10 (inaudible) was well. We're a smaller (inaudible)  
11 time. It's a simple answer, but maybe not so simple.  
12 We love to see the model be (inaudible) across the  
13 globe with (inaudible) probiotics it works well, but  
14 within each country you got to understand that there's  
15 a very specific, you know, regulatory frameworks and  
16 structure that also need to be examined.

17 So I, from the regulatory perspective,  
18 from the government side, I also understand that, you  
19 know, it's not easy to fit a square into a circle.  
20 So, but the model does work and (inaudible).

21 DR. SHARPLESS: Well, we created it.  
22 The Dietary Supplement and Education Act didn't exist.

1 It was created by the industry (inaudible)?  
2 (Inaudible) that's a simple solution. Now the other  
3 thing I have, well somebody else (inaudible).

4 DR. WELCH: Thank you, Daniel.

5 MR. GASTELU: (Inaudible.)

6 MR. PARASKEVAKOS: I would say  
7 (inaudible). One thing I struggle with is I see  
8 ingredients containing 7% (inaudible) acid and  
9 (inaudible) and pomegranate extract. I see ingredient  
10 from 90% (inaudible) claimed (inaudible) extract.  
11 When is a material, an extract, when does it become a  
12 pure compound?

13 MS. PAVLICK: Larisa Pavlick from United  
14 Natural Products Alliance. Looking at (inaudible) a  
15 little differently, especially with some our current  
16 market, market products. To define (inaudible) as a  
17 product transiting from an orange to an orange juice  
18 to ascorbic acid in a tablet. But the definition or  
19 the regulations have defined is that once there's  
20 chemical alterations, in that process, and it's no  
21 longer what was in (inaudible) 1994 (inaudible).

22 And I know that you and I share that

1 opinion. I think once we have that clinical  
2 alteration or manipulation for (inaudible) any one  
3 compound, that's when it needs to end of the  
4 (inaudible) ingredient pathway and goes through a  
5 notification process to unsure the safety of the  
6 product and then balancing access to innovative and  
7 modernized products and (inaudible) public health and  
8 safety.

9 MR. BASS: I look at it a little  
10 differently in the sense that I think it's a question  
11 of whether it's a new dietary (inaudible) or not and  
12 whether an extract or otherwise, it's something  
13 (inaudible). To determine in the first instance, but  
14 I think we really have to look at screens rather than  
15 how much (inaudible) under (E) or (f) and (inaudible)  
16 to safety and (inaudible) in terms of (inaudible).

17 MR. BLAKE: Rick Blake with Strategic  
18 Health Recourses. We represent (inaudible) and I, I  
19 urge the FDA and I know this is not (inaudible). I  
20 urge the FDA not to exclude patient and patient  
21 advocacy groups on the discussion because it's what  
22 we're talking about, protecting patients, patient

1 (inaudible).

2 Now, on the other hand, we also  
3 represent (inaudible) immune systems that are HIV  
4 (inaudible). So my question is it's really important  
5 in HIV (inaudible) to have supplements, dietary  
6 supplements that can help with comorbidities, co-  
7 conditions. Our patient groups are 30% more likely to  
8 have immune compromised systems, outside of just HIV.  
9 So my question to the doctors, as you see your  
10 patients and you recommend supplements, if you see HIV  
11 and AIDS patients, not just all the diabetics, or, or  
12 any, any immune compromised patients, how can we --  
13 it's very important.

14 How can, how can patients be assured,  
15 not just a safe, but the efficacies of, of what they  
16 take, particularly HIV patients (inaudible) retroviral  
17 drugs?

18 MR. COHEN: I, I thank you for that very  
19 thoughtful question. And I just want to say that  
20 personally I'm not a big fan of structure-function  
21 claims and I think that unfortunately they might not  
22 be the intent of the law, but it has permitted

1 companies to advertise products as if they have  
2 (inaudible) boost your immune system, even if there's  
3 not a single study in humans demonstrating that's the  
4 case.

5 So in addition to what we talked about  
6 earlier, I absolutely agree with you that we should be  
7 seriously thinking about the positive and negative  
8 potential health effects of structure function.

9 MR. GASTELU: Yeah, that's a category  
10 that frustrates a lot of us in the industry.

11 DR. WELCH: Daniel, can you get a little  
12 closer to the microphone?

13 MR. GASTELU: (Inaudible) nutrition  
14 together with (inaudible). But in regard to your  
15 comment on structure-function, that's, to me that's  
16 the life blood of the Dietary Supplement Education  
17 Act. You have to have substantiation. And the FDA  
18 did put together guidance documents (inaudible) you  
19 know, unfortunately it's left us (inaudible) health  
20 claim (inaudible). You go to Canada, they do, they do  
21 review. They have a lot of (inaudible).

22 So I think, I think it's a good time to

1 button things up. There are good models like Canada.  
2 There's a lot of good (inaudible). They have a lot of  
3 great products. And (inaudible) products, but getting  
4 back to this one specific issue here that we brought  
5 into it, 'cause we're talking about new dietary  
6 ingredients now and (inaudible) notification process.

7 If I'm going to create a new product, a  
8 new ingredient, you know, it's years before you  
9 (inaudible), especially now with safety data and  
10 things. So (inaudible) do anything. So I think you  
11 just need to have a forum to communicate officially  
12 when those dietary supplement says we're going to do  
13 this product. We think it's a (inaudible) ingredient  
14 for these reasons, and then have the FDA sign off on  
15 it so when they -- you know, so this is an example  
16 here.

17 So when they do the 70-day notification,  
18 they have documentation that says you've accepted the  
19 fact that it's a dietary ingredient, you know.  
20 (Inaudible) now this one (inaudible) here (inaudible).

21 DR. WELCH: Michael, do you want to jump  
22 in while Dan's looking for his glasses?

1 MR. MCGUFFIN: I think two quick  
2 questions. This is Michael McGuffin with the American  
3 Herbal Products Association. First to Larisa, when  
4 you say synthetic botanical, I don't think you mean  
5 somebody made a synthetic root of ginseng. I think  
6 you mean synthetic botanical constituent. Is that  
7 correct?

8 MS. PAVLICK: Thank you, Michael. This  
9 is Larisa, Natural Products Alliance. Yes, sir, that  
10 is a good clarification of the point. (Inaudible)  
11 compound.

12 MR. MCGUFFIN: And that's I think  
13 consistent (inaudible). Let's get the language really  
14 clear.

15 DR. WELCH: I would actually say  
16 synthetic copy of a botanical constituent.

17 MR. MCGUFFIN: That'll work too. And  
18 then I'd like to pose to Scott. Larisa also said that  
19 UNPA's considering a policy that we would require to  
20 make a synthetic (inaudible) when you put it in your  
21 product you've identified it because (inaudible) did  
22 not come out of a plant, whether you call it a



1 synthetic or whatever word is used. Did I understand  
2 correctly?

3 MS. PAVLICK: Correct. Yes, sir.

4 MR. MCGUFFIN: But it's also looking at  
5 a thoughtful process around that same issue. If you  
6 put an artificial flavor in your food, you call it  
7 artificial. So I'm curious, Scott. I know you  
8 advocate for the allowance for synthetic botanical  
9 constituents. Does it make sense? Would that be a  
10 service to consumers to, for companies that sell those  
11 to be required to acknowledge that it did not come out  
12 of a plant on the product label?

13 MR. BASS: Thank you, Mike, for putting  
14 me on the spot. Let's put it this way. Go back to  
15 Section 411 which was passed in 1973 where the  
16 congress said we're not going to distinguish between  
17 synthetic and actual sources (inaudible) minerals. So  
18 move forward from a regulatory standpoint (inaudible)  
19 matters.

20 So it's really a commercial standpoint  
21 and something that you would argue fairness to  
22 consumers and disclosures. So without taking a final

1 position on that, I would say there's a good argument  
2 on disclosure which goes to, I think, my colleagues'  
3 comments earlier that people want to know what they're  
4 getting. (Inaudible.)

5 MR. MCGUFFIN: Thanks very much.

6 MR. POLINSKY: Scott Polinsky, attorney.  
7 Thank you for the great presentations. I wanted to  
8 bolster Larisa's point and Scott's as well on the  
9 distinction between synthetic and natural substances.  
10 Actually the Food and Drug Act (inaudible) regulations  
11 (inaudible) synthetic versions of vitamin and minerals  
12 equally. 21 CFR 109, subsection or paragraph K, in  
13 that section the FDA considers a food to be misbranded  
14 if it makes a label claim stating or implying that a  
15 natural vitamin is superior to a synthetic one.

16 And I have a, a comment on Dr. Cohen's  
17 remarks. What percentage of people who visit  
18 emergency rooms as a result of something used to have  
19 taken too much of a supplement way in excess of the  
20 labeled directions because they want to loose a lot of  
21 weight or hit a homerun? And what percentage of those  
22 ER visits and emergency situations are a result of

1 taking a product that is not actually a supplement?  
2 (Inaudible) that is a product masquerading as a  
3 supplement?

4 MR. COHEN: Those are great questions,  
5 but I think what we're getting at, especially  
6 (inaudible) because as I'm interpreting what we're  
7 hearing, we take synthetic versions of botanicals and  
8 food and place them into dietary ingredient. And the  
9 last comment that (inaudible) these are not  
10 (inaudible) masquerading as supplements. These are  
11 counter to what we've been talking about. So I'm not  
12 quite understanding that position you're taking.

13 MR. POLINSKY: Thank you.

14 MR. MILLER: Yeah, Mark Miller. INW  
15 Manufacturing. I just want to ask the panel about the  
16 (inaudible) definition of synthetic regarding a  
17 bioidentical because often what we're thinking about  
18 is something that's got the same chemical structure  
19 and you write it simply, but there are variances in  
20 it's 3D structure and (inaudible), which we've  
21 (inaudible). And if something does have the right  
22 three D structures, it's likely to have quite

1 different effects involved (inaudible).

2 DR. WELCH: I would still defer to the  
3 panel first. Sorry.

4 MR. COHEN: I completely agree. This is  
5 why we need, we're introducing a new chemical  
6 (inaudible) function, that we need evidence. We need  
7 data. We need to know what it actually does in the  
8 human body.

9 MR. MILLER: But I give a thought is  
10 some of the interesting examples. Astaxanthin is in  
11 the food supply for salmon colorant, but the natural  
12 product has a different 3D structure. All the  
13 (inaudible) chains and (inaudible) as opposed to SIS  
14 bonds makes it all bent and clearly less functional  
15 Also affects absorption.

16 So there are circumstances where it  
17 looks to be the same, but it's not the same. And  
18 therefore, it has a very different biological effect.  
19 Should they be treated equally?

20 MS. PAVLICK: Larisa with the United  
21 Natural Products Alliance. If a dietary supplement  
22 (inaudible) appropriately (inaudible) it does have

1 expectation of developing specifications (inaudible)  
2 and potential contaminants. And (inaudible) 111-75,  
3 you're also verifying the (inaudible) specifications  
4 are being met. So a (inaudible) is being used  
5 appropriately, it would address the system  
6 transference of a chemical compound. So within a new  
7 dietary ingredient notification application as part of  
8 the process, it should be identifying product  
9 appropriately using all examples and analytical tools  
10 available.

11 MR. GASTELU: I would just like to jump  
12 in (inaudible). He's talking about different chemical  
13 structures of a biological activity. I would use an  
14 example of vitamin E. It's a natural or synthetic,  
15 but our government says astaxanthin has a different  
16 chemical structure, the natural, the synthetic. So  
17 would (inaudible) what the biological activity is?  
18 Even, even natural source things like some of the  
19 omega 3 fatty acids that are reproduced are a  
20 different source. Naturally it could have different,  
21 you know, chemical structures that make the biological  
22 activity just a little different.

1           So even the natural depending upon the  
2 source could, could have different -- so there's the  
3 chemical side and biological activity side. I think  
4 we're trying to get at one (inaudible) biological  
5 activity side (inaudible).

6           MR. MILLER: Part of it is when you're  
7 looking at the chemistry, there are levels of, and I  
8 don't think in the discussions, certainly the public  
9 understands (inaudible) and things like that. So we  
10 tend to stop at a very top level and not take it all  
11 the way through. And I think that things are slipping  
12 through are inappropriate and the consumers can't tell  
13 the difference.

14           DR. WELCH: Thank you. So we only have  
15 about one more -- oh, Scott, you want to say  
16 something?

17           MR. BASS: I just want to comment it's a  
18 matter of law. You're right and the reason I said  
19 earlier that (inaudible) NDI was grandfather was  
20 common food is (inaudible) rewrote a lot of the  
21 (inaudible) to F1 safety health regs because of the  
22 tryptophan disaster in 1989. Precisely because of

1 that. So you can't rely upon (inaudible) structure  
2 and even if NDI is one line, it would be under the  
3 master classes (inaudible) licensing out product  
4 (inaudible) one line (inaudible). On something like  
5 you're talking (inaudible).

6 DR. WELCH: One quick question from  
7 Taylor.

8 MR. WALLACE: So we talked a lot about  
9 dietary supplements that might or might not have a  
10 direct effect in individuals. I'm really anxious to  
11 see what George has to say about this 'cause I have  
12 had the opportunity to now start the second clinical  
13 trial on a bacteria (inaudible) supplement that might  
14 not have a direct effect on human health, but if you  
15 were to have a certain maybe higher level of a  
16 problem-causing bacteria in your gut and you introduce  
17 that, there's a possibility that there could be a  
18 release of exotoxins from those bacteria that are, I  
19 guess, should say naturally present in the gut and how  
20 do you begin to incorporate that. (Inaudible) FDA  
21 (inaudible) those things in the '50s.

22 DR. WELCH: George?

1 MR. PARASKEVAKOS: So just (inaudible)?

2 MR. WALLACE: Well, I'm asking, you  
3 know, we talked a lot about, you know, I take ephedra  
4 that's got a direct effect on humans. If I study  
5 bacteriophages in healthy people that maybe don't have  
6 a high level of pathogen or whatever bacteria of  
7 interest, you won't have any negative health effect.  
8 There comes a (inaudible) a higher level, that  
9 bacteriophage would kill that bacteria, they would  
10 create an exotoxin and could harm the constituent. I  
11 see a lot of these hitting the market and how those,  
12 how does this go into DSHEA 2.0?

13 MR. PARASKEVAKOS: So (inaudible)?

14 MR. WALLACE: We actually make the  
15 virology behind (inaudible) specific strains of  
16 bacteriophages, but we didn't find any adverse events.  
17 Again, we were targeting inorganic (inaudible) coli  
18 which is found in very small levels to support a  
19 structured function (inaudible) healthy individuals --

20 DR. WELCH: I'm actually going to -- I'm  
21 sorry. I think this is a great conversation that you  
22 two may want to have in private because George is



1 getting all down in the details here. I don't, I just  
2 one quick editorial note and I said I wasn't going to  
3 answer the questions. But I would make the argument  
4 that DSHEA 1.0 addresses that, specifically the safety  
5 document.

6 So with that, I think its time to take a  
7 break. Well, we really do need to take a break. So  
8 I'm going to break, but you by all means can come up  
9 and talk to the panel. Could, could you fit it onto  
10 comments at the end of the day? We have 15 minutes  
11 for break. Fifteen minutes for break. So we'll start  
12 again at 10:40, 10-4-0, you all. Thank you.

13 (BREAK.)

14 MS. WELCH: All right. Thank you all.  
15 I'm going to ask everyone to be quiet, please.  
16 Everyone, I need you to come in and take your seats  
17 and -- thank you. Thank you. I feel like I'm  
18 corralling children here. Basically, yes. A few  
19 notes because I just can't stop giving housekeeping  
20 notes.

21 I feel like the temperature has really  
22 cooled down in here. So I'm sure everyone is grateful

1 for that and they will do their best to keep it  
2 somewhat temperate for the rest of the time. It's  
3 even hotter under these spotlights. So feel bad for  
4 your speakers.

5 The, this door down here is really just  
6 for FDA employees. So please continue to use the one  
7 at the top of the stairs. And I think that's it for  
8 now. We have session two beginning. This is talking  
9 about understanding exceptions to the NDIN  
10 requirement. This panel discussed issues related to  
11 when an NDI notification is not required for new  
12 dietary ingredients and whether evolution in the  
13 supplement marketplace has altered the impact of this  
14 provision.

15 We're going to be hearing from about  
16 three speakers about ten minutes each and then we'll  
17 open it up for a Q&A session again. Hopefully it'll  
18 be as popular as our last one was. But these speakers  
19 are between you and lunch. So I'm sure they'll keep  
20 that in mind.

21 First we're going to be hearing from  
22 Michael McGuffin, President of the American Herbal

1 Products Association, then Ashish Talati, partner, and  
2 Amin Talati Upadhye. And then Laura MacCleery, policy  
3 director at the Center for Science in the Public  
4 Interest.

5 I don't want to take up their time, so  
6 I'm going to turn it over the Michael right away.  
7 Thank you.

8 MR. MCGUFFIN Thank you very much, Cara.  
9 Thank you, Steve. Thanks for the opportunity to be  
10 here today and discussing these issues that of course  
11 have been troubling us and confusing us and hopefully  
12 leading to some progress for us over the last 25  
13 years.

14 And so I was asked to address this issue  
15 of the exception for filing of a notification for an  
16 article that is a new dietary ingredient, but that is  
17 also identified as an article used for food in a form  
18 in which the food has not been chemically altered.  
19 And this is the language from the law. When DSHEA  
20 amended the Food, Drug and Cosmetic Act, it clearly  
21 stated that a supplement that contains an NDI is  
22 adulterated unless it meets one of these conditions.

1           The first one being that it is an  
2 article used for food in a form of which the food has  
3 not been chemically altered, and the second option is  
4 submission of a new dietary ingredient notification.  
5 And the implementing regulations used exactly the same  
6 language, no reinterpretation here at all, very  
7 clearly adopted the language from the law.

8           And then so the first question that we  
9 have to ask I think is the first phrase, an article  
10 used for food. What is an article used for food?  
11 It's defined in the Food, Drug and Cosmetic Act in the  
12 United States Code at 321(f). Food means an article  
13 used for food or drink for man or other mammals,  
14 chewing gum, or articles used for components in any  
15 such article.

16           And there is another place in regulation  
17 where this is addressed on the requirements for prior  
18 notice of an imported food. FDA gives some examples  
19 of foods and I think it's good to just have this list.  
20 The Agency does not in this regulation say this is  
21 the, this is an entire list, but these are examples  
22 and this is what, there's nothing at all surprising

1 here. These are articles that we think of as food.

2 And there are many, many such articles  
3 and one thing that is, that needs to be remembered, in  
4 the, this tolerance for an article used for food,  
5 there's no geographical limit and there's no time  
6 limit. So it's not an article used for food in the  
7 United States. It's an article used for food. And  
8 it's not an article used for food prior to the passage  
9 of DSHEA. It's an article used for food.

10 I'm clear in conversations with the  
11 Agency over the years that there's agreement at least  
12 on that first part. The Agency's never taken a  
13 position that this means articles used for food in the  
14 United States. I'm not sure that there's been that  
15 same degree of clarity on, if it's an article  
16 introduced for food in 2018, does that grant the  
17 exception? I think industry thinks it does, but I  
18 don't know that the discussion has ever been had.

19 But these are just examples of where  
20 we'll find articles used for food identified in  
21 federal regulation, and Bill Frankos brought these up  
22 at a meeting a couple of days ago that these are

1 clearly all old dietary ingredients. These are fairly  
2 set regulations. The Agency hasn't added to these in  
3 decades. And there are 120 botanicals in the natural  
4 flavoring. Another 80 in spices and other natural  
5 flavorings; although, there is some duplication there.  
6 Some more in essential oils. I like the one at the,  
7 at the end, 182-50. You can, if you can get your musk  
8 or your civet oil in there, which is used to make  
9 things smell good or smell like that, those are  
10 clearly articles used for food.

11 Now I don't know that they would fit one  
12 of the definitions of a vitamin, a mineral, amino  
13 acid, or an herb or other botanical, but they would  
14 fit the dietary supplement for use by man to  
15 supplement the diet apparently. So I can see a musk  
16 CBD supplement coming in soon just to make the second  
17 mention.

18 Interesting too, so food additives and  
19 one of the things that DSHEA clarified is that dietary  
20 supplements are not food additives, but are food  
21 additives, articles used for food for the purposes of  
22 recognizing that we would have an exemption from an

1 NDI, from a notification if our NDI is a permitted  
2 food additive and there are a number of them,  
3 including synthetic flavoring substances and adjuvants  
4 and direct food substances affirmed as GRAS.

5 Well, I find it interesting that in  
6 FDA's 2016 NDI guidance, they gave us an example in  
7 asking the question, the one that I'm discussing here,  
8 is an NDI notification required for an NDI if it's an  
9 article used for food and form of food and it's not  
10 been chemically altered? No.

11 And then they give as an example if  
12 ingredient X is a food additive that was approved for  
13 use to sweeten baked goods in 1993, but was never  
14 marketed as a dietary, in a dietary supplement,  
15 clearly it's an NDI, but it says because it was, but  
16 it's not required to submit an NDI notification  
17 because ingredient X has been present in the food  
18 supply.

19 I'm not sure that the Agency intended to  
20 mean that broadly, that food additives in the food  
21 supply can be used in a, can be acknowledged as a new  
22 dietary ingredient and skip the notification. But

1 again, this example in the 2016 guidance, which don't  
2 forget we have rejected out of hand. So we shouldn't  
3 say, but we love this paragraph. But nonetheless,  
4 this is what was stated by the Agency at that time.

5 I also -- this is a place that I go.  
6 Somebody calls me and says, hey, can you find me a  
7 recipe that has schisandra in it, you bet I can. So  
8 you can see that there are 4,853 cookbooks available  
9 at archives.org. You got to love the way-back machine  
10 and all of these things are out there. Some of them  
11 you can directly download. Some of them you can  
12 borrow. But it's really a great reference for finding  
13 old recipes and new.

14 I organized this in two different ways,  
15 one by these thumbprints or thumbnails, and the other  
16 by just you can organize it by listing. I organize  
17 both of these from oldest to newest, but I think that  
18 was a little bit of an oversight 'cause I do want to  
19 make the point that a new food use apparently also  
20 would establish that it's an article used for food.

21 But again, this is a great reference if  
22 you just need to go find a recipe that establishes



1 that an ingredient, especially a botanical ingredient,  
2 is an article used for food. You can find plenty of  
3 recipes for hemp here. I have. I have them in a  
4 file. I can't find any recipes for CBD, though.

5 So then what is chemical alteration?  
6 I'm going to move to the second half of the sentence.  
7 In the, in the congressional statement of agreement  
8 was quite clear. It said that chemically altered does  
9 not include the following physical modifications,  
10 minor loss of volatile components, dehydration,  
11 lyophilization, milling, tincture, or solution, water  
12 slurry, powdered, or solid in suspension. I say clear.

13 When you read this and you look at the  
14 placement of the commas, it gets a little hard to  
15 understand quite what a tincture or solution in water  
16 slurry, powdered, or solid in suspension means or where  
17 the comma break should be, but I think the Agency  
18 grappled with this in the 2016 guidance. Again, we  
19 can take some learning from that.

20 What the Congress did not say is and  
21 that's the end. And so is this a list of examples or  
22 is it the list of all modifications that do not

1 constitute a chemical alteration? And that's another  
2 issue that we're still trying to sort out, I think.

3 I'm actually going to skip a couple of  
4 slides because I think it's better to start here.

5 What, this is, again, from FDA's NDI guidance. And  
6 the balance of my presentation is not to try to sort  
7 out all of these things in the ten minutes that I was  
8 given, but to report a snapshot of where we are based  
9 on FDA's view of what constitutes chemical alteration  
10 from the 2016 guidance.

11 And so here are a couple of slides of  
12 what processes for manufacturing or dietary  
13 ingredient, article of food present in the food  
14 supply, do not result in chemical alteration. And you  
15 can see that first bullet point is that FDA says that  
16 they consider the list in the congressional statement  
17 of agreement to represent examples, but not  
18 necessarily a complete list. That's good.

19 And then if you go read the rest of  
20 them, the Agency did not add any to the list that FDA,  
21 or that was in the Congress. So even though they've  
22 conceptually stated there may be some, they didn't

1 offer here's, here's an example. All of the rest of  
2 these were already in that congressional statement  
3 from, from 1994.

4 A couple of these that I do want to  
5 comment on, I think the, not on this page, but on this  
6 page. Changing agriculture or fermentation conditions  
7 to alter the chemical, molecular, or composition, or  
8 structure. We're a little nervous about what that  
9 means.

10 If I'm harvesting my camomile usually in  
11 June, but I start to harvest it in May even though my  
12 yield will be a little less, but I know that the  
13 senecio hasn't germinated by then and I really don't  
14 want the senecio in my camomile, I hope that the  
15 Agency doesn't say, oh, that's a new, a change in  
16 agricultural practice that results in a new dietary  
17 ingredient.

18 I think this is, these kinds of attempts  
19 in the guidance to, in my view, broaden as many  
20 ingredients as possible, but could be defined as  
21 needing an NDIN and not surprisingly industry would  
22 rather narrow that, and I think that kind of -- we, we

1 need to find the balance on those things. We need to  
2 still go back to these examples that we're given and,  
3 and clarify them.

4 Use of a botanical at a different life  
5 stage, you know, the example given here, even this  
6 one, I'm not so sure that an unripe apple or a ripe  
7 apple, I mean certainly there are some different  
8 measures of compounds in those, lesser sugars,  
9 whatever other constituents. But again, it may be a  
10 bit of a strained example. The last one on mycelium,  
11 that's actually not a, it's more of a part of the  
12 plant which we're all required to address anyway.

13 I'm going to move back up then to the,  
14 several slides on examples of processes that the  
15 Agency has said do constitute chemical alteration, a  
16 process that makes or breaks chemical bonds. You  
17 know, I bake bread every once in a while. There's an  
18 awful lot of chemical bonds broken there. Is that  
19 what we meant? I'm not sure there's clarity here.

20 Removal of some components from a  
21 tincture. So if I remove the pyrrolizidine alkaloids  
22 from my comfrey extract, is that chemical alteration

1 that results in, that would require a notification? I  
2 think it's hard to argue that it would not and I know  
3 that FDA has commented that that exact example  
4 probably would be an NDI.

5 Use of solvents other than water or  
6 aqueous ethenol. There must not have been an  
7 herbalist working on writing this guidance because  
8 they would have known that we might use vinegar. We  
9 might use oil. We might use a food grade oil. There  
10 are other solvents, food grade solvents that we would  
11 not consider that represent chemical alteration that,  
12 anymore than water or aqueous ethenol would.

13 There's an application of  
14 nanotechnology. I know that's one that the Agency has  
15 asked about not just in a supplement area, but also in  
16 foods and concerns about what do we know about the  
17 safety of those.

18 There was one other that I thought the -  
19 - but I can't find it right now. So I'll skip it and  
20 hope I've given you enough to think about.

21 I think kind of the takeaway is all  
22 these issues are unresolved. And, you know, we saw a

1 2011 guidance. We commented. We saw a 2016 guidance,  
2 we commented. There hasn't been any discussion since.  
3 I'm going to give some credit to when Bill Frankos was  
4 here and I think Susan Walker may have still been  
5 here, and we were working on the GMP rule and there  
6 was a meeting requested that we all come in and sit  
7 around tables and talk to each other a line at a time  
8 and see if we could get consensus in that kind of  
9 framework.

10           You know, the, the process now is it's  
11 like the doors are closed between us and we don't have  
12 a forum in which we sit and talk to each other. And I  
13 don't mean just industry. We would invite the public  
14 health agencies, the consumer groups, but I think some  
15 of this needs to be resolved in a more, more of a  
16 dialogue than an exchange of papers with months and  
17 months or years and years between them.

18           Because we do need to get these things  
19 resolved if we're going to move forward in the whole  
20 issue of recognizing the new dietary ingredients that  
21 actually do require notifications. Thank you very  
22 much.

1 (APPLAUSE.)

2 MR. TALATI: Good morning. Thank you,  
3 FDA, Steve, and Cara for giving us the opportunity to  
4 provide our comments. I'm Ashish Talati, a partner at  
5 Amin Talati law firm that specializes in food and  
6 supplements. I've been working on GRAS and NDI issues  
7 for a long time. So I really appreciate the  
8 opportunity. Let me see if I can --

9 All right. Thank you. So I know  
10 Michael gave a good overview of these exceptions.  
11 I'll try to dig into it a little more and give my  
12 perspective. Certainly it's an important topic. You  
13 know, 2019 is, is certainly 25 years from 1994 and a  
14 lot has changed. What we're seeing in the  
15 marketplace is a line's been blurred between  
16 conventional foods and dietary supplements.  
17 Functional foods, what's called better for you, is a  
18 huge category.

19 We have a lot of our clients that used  
20 to be, you know, just marketing dietary supplements,  
21 but they certainly have products in the conventional  
22 foods or functional foods categories as well.

1                   So we certainly think that the  
2                   exception, you know, where a company certainly does  
3                   not have to file an NDI notification, is a significant  
4                   opportunity for companies that, you know, even based  
5                   on their limited resources, certainly does, and can  
6                   take advantage of that.

7                   So one of the things is on the GRAS or  
8                   approved food additive. In 1958 Congress passed a  
9                   food additive amendment act where a company or a, you  
10                  know, supplier can self-affirm GRAS or file a GRAS  
11                  notification, or at that time it was an approval  
12                  process with FDA, or can do without any FDA approval  
13                  process, meaning they can self-affirm on their own.

14                  Since then in 2016 FDA has finalized a  
15                  GRAS rule and the independent conclusion of GRAS is  
16                  certainly written in the law. So companies don't have  
17                  to file GRAS notifications with FDA.

18                  So I'd like to walk you through a  
19                  scenario. If a company works with Office of Food  
20                  Additive Safety, OFAS, files a GRAS notification, has  
21                  an ingredient in the food supply, they have a product,  
22                  and then they would like to market also as a dietary



1 supplement, dietary ingredient, does that company need  
2 to file a GRAS notification? The law clearly says  
3 they can use the exception and they don't have to.  
4 And that is a huge, huge opportunity. It saves a  
5 number of resources with FDA and certainly the safety  
6 standard, which a lot of times does not get enough  
7 attention, but the GRAS safety standard is reasonable  
8 certainty of no harm. The dietary supplement, dietary  
9 ingredient standard is reasonable expectation.

10 I would like to get some more clarity on  
11 what the difference is with OFAS review and GRAS  
12 notification, and ODSP reviewing and NDI notification.  
13 Is there a difference in their analysis? But  
14 certainly someone doing a GRAS notification or a self-  
15 affirmed independent conclusion of GRAS, they have to  
16 meet that standard.

17 So right here basically the, the  
18 process, the way it should work is you have a GRAS or  
19 approved food additive ingredient or it's in the food  
20 supply for many, many years, we certainly think it  
21 should be before 1958 if you don't do a GRAS or food  
22 additive petition. And then it's available in the

1 food supply and then you can have it as a dietary  
2 ingredient without chemical alteration, meaning you're  
3 not making any changes to that ingredient.

4           So there are three bullets here. One of  
5 them I'll start that's not on here is having in the  
6 food supply. The one question we often get is, you  
7 know, if there was a, let's say, indigenous tribe in  
8 Brazil and they were using this ingredient, does that  
9 qualify as a food supply? We certainly think it needs  
10 to be very widespread and, you know, that also means,  
11 you know, if you find a cookbook that mentions it,  
12 there's no documentation of that ingredient being sold  
13 or marketed, does that qualify as food supply?

14           So those are some questions that, you  
15 know, certainly come up all the time. But a company  
16 can do a GRAS notification. They can do independent  
17 conclusion of GRAS or food additive petition. Those  
18 are opportunities. Those are the pathways. And then  
19 have it legally marketed anywhere in the world. And  
20 has been introduced to the food supply.

21           So, again, it's very important where it  
22 does not have to be in the US. It could be anywhere

1 in the world. The timeframe comes into the picture.  
2 You know, let's say someone does an independent  
3 conclusion of GRAS or a GRAS notification, can they  
4 simultaneously introduce a dietary supplement, have it  
5 in the food supply, and it's a dietary supplement? Is  
6 there a timeframe? No one knows. There has not been  
7 a clarity on that. So it could be six months, one  
8 year, one day, but, again, those are some of the  
9 important issues to be addressed.

10 And this chemical alteration issue, it  
11 does not get enough attention, but at the end of the  
12 day certainly FDA has provided a lot of details as to  
13 what they consider as chemical alteration. Certainly  
14 it involves only physical steps and it does not  
15 selectively increase the concentration of any  
16 ingredients that would modify the bonds.

17 We don't see chemical alteration as, as  
18 of an issue. The bigger issue is what's in the food  
19 supply and how do you, you know, come up with, you  
20 know, what's acceptable to the FDA in terms of  
21 duration of the ingredient being in the food supply.  
22 The GRAS pathways, and either you do a GRAS

1 notification to FDA or do it on your own, we certainly  
2 think that the safety is paramount, but we have not  
3 seen or are aware of any ingredient that has been  
4 self-affirmed and was pulled from the market because  
5 of safety concerns. Thank you so much.

6 (APPLAUSE.)

7 MS. MacCLEERY: Hi. I'm Laura  
8 MacCleery. I'm policy director for Center for Science  
9 in the Public Interest. We're a nonprofit  
10 organization that's been around for about 50 years. I  
11 appreciate the sincere and earnest effort today to  
12 come together with all this range of stakeholders and  
13 I would enthusiastically accept any invitation from  
14 Michael or others to engage in a consistent dialogue.  
15 I agree that these sort of sporadic events are not  
16 enough to resolve the kind of issues that we're facing  
17 in this marketplace and I do think that agreement is  
18 possible.

19 This is an example of a recent -- well,  
20 this is last year actually. We just did one, smoking  
21 cessation, dietary supplements, and we're doing these  
22 as a repeated sort of service to FDA. We write

1 enforcement letters. We actually query companies that  
2 are selling products making disease treatment claims.  
3 I ask them for their evidence of efficacy and can you  
4 believe that some of them write back and admit that  
5 they don't have any?

6           And so we put that information in a  
7 chart with all the responses and give the particular  
8 product names to FDA as part of its enforcement, a  
9 policy which says that they're going to prioritize  
10 enforcement around disease claims. They did issue  
11 warning letters in response to this and found even  
12 more violations than we have alongside the FTC.

13           We think consumers are obviously  
14 entitled to a safe marketplace and there's some basic  
15 consumer protections around transparency, efficacy  
16 claims, accuracy, adulteration, and other things that  
17 are actually reflected in the law, but aren't often  
18 honored and practiced due to a number of sort of  
19 slips. And these are the kind of things we'd love to  
20 work with industry to address.

21           I think they're basic to any consumer  
22 product and they're a particular issue with

1 supplements given the size of the marketplace and the  
2 list of resources for effective regulation.

3           These are some of the things that we  
4 think we could accomplish working together. We see  
5 this as like sort of the low hanging, common ground  
6 fruit that we could work on including product  
7 registration and additional transparency measures.  
8 And then some safety checks where we know that there  
9 are problems with particular product categories, like  
10 weight loss and other places where we're seeing a lot  
11 of tainted supplements. We think that there's an  
12 enhanced enforcement mechanism that you could use  
13 there. And obviously improving resources for FDA and  
14 its oversight.

15           We've heard a little bit about GRAS. I  
16 want to talk for a minute and you'll just have to bear  
17 with me about the arcana of the way that generally  
18 recognizes safe operates as a category within the food  
19 system. In the food system, and you, many of you  
20 probably know this, there is a process for approval  
21 called a food additive petition where you have to file  
22 for that approval with FDA, and that triggers an

1 internal review. It's actually not a public notice  
2 and comment. But FDA publishes a notice in the  
3 federal register that they're asking these things  
4 under advisement for a food additive petition  
5 consideration.

6 And then there's an alternative to that  
7 and Congress in its wisdom in 1958 provided a large  
8 category that has, we think, taken over the law over  
9 time. And substances, GRAS, if it is generally  
10 recognized as safe by experts based on common  
11 knowledge. So it's not public perspective. It's  
12 expertise end scientific, and then it's supposed to be  
13 common knowledge. I'll note that no other country in  
14 the world has this category of an exemption for  
15 generally-recognized-as-safe substances. It's  
16 unusual, at least that I know of.

17 And the way that you establish a  
18 general, an ingredient generally recognized as safe is  
19 through scientific procedures where a safe history of  
20 use. Safety is a reasonable certainty in the minds of  
21 competent scientists that the substance is not  
22 harmful. That means that there, there should be some

1 body of evidence, scientific evidence. There's a book  
2 called the Redbook which lays out FDA's methodology  
3 for assuring the safety of GRAS substances. And that,  
4 you know the standard is to animal testing in  
5 different species, toxicological testing. There's  
6 also other evidence. It's a weight of the evidence  
7 approach.

8           You're supposed to rely on published  
9 data and the common knowledge element is really  
10 important. If it's just your own, as an industry for  
11 putting forward a GRAS substance, your own data and  
12 it's not public data, it not published data, it's not  
13 sort of a commonly known, then the general recognition  
14 element is not met. That's the idea of GRAS anyway.

15           This is a really boring history of, of  
16 GRAS and the precursor to the 1997 rulemaking that  
17 changed the parameters of how the industry processes  
18 GRAS notifications, but there, there has been attempts  
19 over time to put all the substances that are GRAS on a  
20 list. Those lists still exist and they still have  
21 legal force. And then before 1997, there was the GRAS  
22 affirmation process.



1           The takeaway here is that there were  
2 very few GRAS determinations that were made in private  
3 even though no showing this might have been a quote,  
4 unquote, voluntary process, for liability reasons they  
5 would often ask for affirmation by FDA under GAP.

6           And then in 1997 because of pressure on  
7 the system, there was a significant revision to the  
8 requirements for GRAS. And what happened in the 1997  
9 notice was that FDA essentially authorized self-  
10 affirmed GRAS and laid out some additional parameters.  
11 And this stayed a draft rule for 20 years until the  
12 Center for Food Safety sued them to finalize the rule  
13 and they finalized it in 2017.

14           We're going to, I'm going to criticize  
15 GRAS, but I also want folks that are relying on GRAS  
16 to be aware that there is a significant amount of  
17 science that's supposed to be required for a GRAS  
18 notification or for a GRAS self-affirmation. And if  
19 you, if you look at the particulars of the '97 rule,  
20 you'll see what those are.

21           So GRAS now operates in a two pathway  
22 system. You can voluntarily submit safety data to

1 FDA. Those are called GRAS notifications, and FDA may  
2 raise questions, and then if they don't have any  
3 further questions, they may issue a no questions  
4 letter, but that actually doesn't have the status of a  
5 regulatory approval. It's just that they ran out of  
6 questions to ask you.

7                   And those of us in the consumer  
8 community who work on this issue a lot think that FDA  
9 does a decent job of asking some questions, but also  
10 that there are key aspects of the safety standard that  
11 they don't typically ask about including around  
12 cumulative effects of something that is, is it, is it  
13 part of a chemical class of substances about which  
14 there have been raised concerns? Does it have  
15 pharmacological effects that, that should be looked at  
16 in view of other substances in the diet that have  
17 small pharmacological effects? So we don't think even  
18 the GRAS notification process is adequate for safety.

19                   In addition, after the '97 rule it was  
20 very clear that companies can secretly self-assess the  
21 GRAS status of something. I would suggest humbly to  
22 you that it is not a system, the secret GRAS

1 affirmation process, that can be defended publically  
2 with a straight face. It doesn't provide any adequate  
3 assurances that an ingredient is safe. It's so  
4 conflicted that if you look at any guidance on  
5 addressing conflicts of interest and scientific  
6 determination from the national academies, anything,  
7 that you cannot view the process of a, a paid  
8 consultant or employee of a company that has a direct  
9 financial stake in the outcome of a decision assessing  
10 the science as being a process that's free of  
11 conflicts of interest.

12 So what happened after '97 was that, and  
13 this is not secret GRAS. This is just GRAS  
14 notifications versus food additive petitions. You can  
15 see the, the, the GRAF notification sort of take over  
16 the whole game. And this is another failure that we  
17 think is, is a part of FDA's approach to this. We  
18 think that part of what's going on is that FDA's  
19 allowing things to proceed as GRAF notification when  
20 they're really deserving of a food additive petition  
21 and possible Burger might be an example of that.

22 They went through the GRAS process.

1 Really that science was proprietary to their  
2 particular heme-protein that they were developing and  
3 putting in their meat substitute product. That's a  
4 food additive petition. Any novel substance that  
5 doesn't have a public, published record of safety  
6 that's available and cognizable to experts is a food  
7 additive petition, not a GRAS process substance.

8           So this was a report in JAMA that showed  
9 the conflicts. And again, these are just what we, we  
10 know that we know. We can't look at the unknowns,  
11 which are the secret GRAS. This is notifications to  
12 FDA who makes these decisions, 22% were made by an  
13 employee of the additive manufacturer, 13% by employee  
14 of the consulting firm to the manufacturer, and 64% by  
15 an expert panel selected by the manufacturer. There  
16 were ten experts that were on 27 or more panels and  
17 one expert who was very busy was on 128. Very well  
18 compensated, I'm sure.

19           So is the opposite of what the law  
20 intended, said Mike Taylor. He was very interested in  
21 this when he was deputy FDA commissioner. He said,  
22 you know, this really is supposed to be about general

1 recognition, not about private science.

2           So we sued. We joined Earthjustice and  
3 a whole cadre of other organizations. We're in the  
4 2nd Circuit. We survived the motion to dismiss. This  
5 is a case against that FDA's final rule on GRAS. It  
6 makes the argument that it illegally sub-delegates to  
7 private companies the safety of the food supply. And  
8 that is still pending.

9           So how does this apply to dietary  
10 supplements? Well, as we saw from Michael's slide,  
11 FDA's answer is that you can apply a GRAS designation  
12 to be an exemption from the NDI requirements. There  
13 was a bit of a shift that was sort of subtle in the  
14 way the Agency positioned this issue. In the 2016  
15 guidance, they dropped the reference that was in the  
16 2011 guidance to food self-affirmed as GRAS.

17           So that suggests to me that the position  
18 of the Agency is that a self-affirmation for GRAS is  
19 actually not adequate, that you're supposed to go  
20 through notification. If you look at the question for  
21 2016, it has been listed or affirmed. So we know  
22 things can be GRAS listed or affirmed. Affirmed is

1 not quite the right language. It should be notified  
2 under the notification process because FDA doesn't  
3 actually approve substances.

4 But, you know, that suggests to me that  
5 there's some shift here going on and that there's some  
6 discomfort at FDA around self-affirmed GRAS. I think  
7 that should, that's an area where we could look at  
8 additional clarification that would be very useful.

9 I would say also that even our speakers  
10 today have acknowledged that GRAS self-affirmations  
11 are not what was the best science, right? We think  
12 it's far worse than that obviously. But, but I do  
13 think it provides the kind of assurances of safety  
14 that, that the law had in mind. And Scott's comments  
15 earlier suggested that when they were thinking about  
16 the exemption to the NDI requirement for DSHEA, they  
17 were not contemplating that it would be an end-run  
18 around the NDA requirements to have things go through  
19 this GRAS process.

20 And I would -- if you think about the  
21 legislative calendar, you have DSHEA in '94, the  
22 regulations changes to GRAS don't happen 'til '97. So

1 it's really not conceivable that it would, would have  
2 been part of the legislative design in '94 to think  
3 about self-affirmed GRAS as the main pathway.

4 Here's some differences just from a  
5 regulatory compliance perspective between GRAS and  
6 NDI. We know that GRAS is being used by the industry.  
7 Our colleague, Loren, at the last public meeting said  
8 it's six to seven times more GRAS affirmations than  
9 there are NDI notifications. This is from the  
10 transcript of that meeting.

11 And I would suggest to you a GRAS self-  
12 affirmation or even GRAS more generally is not an  
13 adequate substitute for an NDI. It certainly, I think  
14 based on the changes to the guidance FDA put and  
15 should clarify that, that an NDI is required if you  
16 are relying on self-affirmed GRAS as opposed to a GRAS  
17 notification. That seems to be to me, to be sort of a  
18 de minimus clarification.

19 Also we're concerned about the fact that  
20 it could be legally marketed but not actually used in  
21 food. We think that if not accurate, that, you know,  
22 we've heard stories of people short of putting things

1 into marketing for food abroad and not actually using  
2 it in food. That's a clear end-run around the NDI  
3 requirement. And same for outside the US.

4 GRAS also critically fails to address  
5 the safety of mixtures. And I actually think the  
6 DSHEA language is a little bit better about the NDI  
7 review process which contemplates that people will  
8 submit safety information on combinations of  
9 ingredients. GRAS really looks at each ingredient in  
10 isolation, which has been one of its major issues.

11 GRAS, the GRAS notification is also for  
12 the food use typically, right? It's not going to  
13 consider the application of the conditions of use for  
14 dietary supplements. So it actually is totally  
15 inappropriate on the face of the document to then turn  
16 around and say we've got, we've got a GRAS  
17 notification, submitted GRAS notification based on  
18 this particular condition of use in food and we're  
19 going to cross-apply that to a different condition of  
20 use.

21 DSHEA also recognizes the need to have  
22 conditions of use specified as to the NDI. And then I



1 do think that the GRAS notification is supposed to  
2 take into account exposures and typically would not,  
3 because you're filing it for food to put it into  
4 presence in the food supply, it's not going to take  
5 into account the exposures that might be part of the  
6 picture from a supplement perspective.

7 So you have an application for a GRAS  
8 notice that doesn't take into account adequate  
9 exposures or conditions of use for the supplement  
10 context. That, for that reason I don't think it's  
11 actually appropriate.

12 So we do know that substances that are  
13 withdrawn from the FDA GRAS notification process show  
14 up in foods and supplements anyway. This is a report  
15 by an NRDC. These were substances that had been put  
16 as part of a GRAS notification, FDA raised questions,  
17 the substances were withdrawn from the notification  
18 process and, you know, they had serious safety issues.  
19 And then they showed up in products anyway and a lot  
20 of the products that they showed up in were dietary  
21 supplements or functional foods.

22 In addition, we think GRAS is just

1 generally broken. That's why we're in court and we  
2 don't think that it should be expanded or used to also  
3 undermine the safety of dietary supplements. There's  
4 a lot of things that are sort of wrong at the level of  
5 the, what's required for a GRAS notification.

6 Here's also a kind of cautionary tale.  
7 So here we have percummin, is going through the GRAS  
8 notification process at this moment. There's an  
9 example of supplements that are already selling the  
10 substance. And then we looked at the effectiveness  
11 data for our nutrition action health news letter and  
12 we found that there isn't really any. There's,  
13 there's a, one study that has some equivocal data, but  
14 really the stuff is being marketed all over the place.

15 And so, you know, I think we're focused  
16 on GRAS and NDIs and the pure safety of it, but  
17 there's a whole host of other issues around efficacy  
18 and claims that we could also usefully talk about.  
19 That's my presentation. Again, I'm very happy that --

20 (APPLAUSE.)

21 DR. WELCH: All right. So Q&A. Again,  
22 if you want to ask a question, please go to the mics

1 on either side. I will ask that we just have one  
2 question per questioner until everyone has sort of  
3 cycled through. I, I appreciated the robust  
4 discussion last time, but I want to make sure everyone  
5 has a chance. And Adrian might be coming down to turn  
6 the mics on. So thank you for that. Quite quickly,  
7 in fact. All right. So first question for our panel.

8 MR. GASTELU: At it again. I just want  
9 to get my money's worth. This is a rare opportunity  
10 (inaudible - off mic).

11 DR. WELCH: Right. I would remind you  
12 to speak your name and affiliation into the mic before  
13 your question and answer, please.

14 MR. GASTELU: Daniel Gastelu (inaudible  
15 - off mic). So anyway, only one question now?

16 DR. WELCH: Please.

17 MR. GASTELU: Will it rotate like it did  
18 before?

19 DR. WELCH: Mm-hm, yeah.

20 MR. GASTELU: The first one is  
21 (laughter). There's companies selling synthetic  
22 isoflavone. So that would be a synthetic of a

1 botanical bioactive. So did that go around in the  
2 GRAS process somehow? Are you familiar with that  
3 whole --

4 DR. WELCH: Push the button right there.  
5 Thank you.

6 MR. MCGUFFIN: The question is  
7 isoflavone being sold --

8 MR. GASTELU: It did --

9 MR. MCGUFFIN: So then the question  
10 would be was synthetic isoflavone being sold as a  
11 dietary ingredient prior to 1994, if yes, then it's  
12 not a new dietary ingredient? If no, then it is? And  
13 and then the next question is, is synthetic  
14 isoflavones being sold in foods or are we finding it  
15 in --

16 MR. GASTELU: Well, how would it qualify  
17 to be a food ingredient to begin with if you wanted to  
18 go that route. It's (crosstalk). But you're saying  
19 wait a minute. I just picked up on something there.  
20 So if I have proof on what a manufacturer is doing,  
21 'cause I work with companies that are manufacturing,  
22 obviously synthetic isoflavone like beta-sitosterol,

1 that that was before 1994, that basis, you go use a  
2 synthetic? It's a basis to use a synthetic bioactive?

3 MR. MCGUFFIN: Well, again, the test is  
4 was it a lawful ingredient at the time? So  
5 (crosstalk).

6 MR. GASTELU: (Crosstalk) that's another  
7 one. So around that loophole, how do you (inaudible)  
8 if somebody (inaudible) GRAS and it's not being used,  
9 how does that whole thing, that puzzle work? Do you  
10 have any -- I gave you a specific example of an  
11 ingredient I know about. Does it make sense to you  
12 that that's a legal dietary ingredient?

13 MR. MCGUFFIN I, I couldn't comment on  
14 that from here (inaudible), but I think the,  
15 (inaudible) our comments is if it's a synthetic  
16 constituent, you have to assume that it's a new  
17 dietary ingredient unless you have a history of use of  
18 that exact synthetic prior to '94. And then you  
19 probably have to file a notification unless it's  
20 already used in food and that's, those are all  
21 discoverable facts.

22 MR. GASTELU: So you just correspond

1 (inaudible) dietary supplements (inaudible) question  
2 probably?

3 DR. WELCH: I would encourage you to  
4 correspond with her, yes.

5 MR. JAKSCH: Frank Jaksch, ChromaDex. I  
6 guess can we (inaudible) as an industry maybe start to  
7 agree to not overcomplicate the NDI process and, in  
8 the sense that it's actually pretty easy to navigate  
9 the process and understand what you're having. A lot  
10 of it starts with understanding what it is that you're  
11 introducing to commerce itself.

12 So if you understand the chemistry of  
13 the ingredient that you're introducing to commerce,  
14 then you know where you stand in terms of what you  
15 need to file in terms of NDI. I don't care if it's a  
16 synthetic, is that you understand that chemistry. It  
17 goes back (inaudible) exception as well. Three  
18 dimensional chemical structures, understand ingredient  
19 isomers, yeah, of course. You, you owe it to  
20 understand the chemistry of what you're introducing to  
21 commerce.

22 If you're introducing something that is

1 noticeably different, notably different than what is  
2 natural, which is easy to understand by knowing the  
3 chemistry of it, then you should understand whether or  
4 not you need to file an NDI (cross noise). And, so I  
5 just wanted to make sure that, you know, label or  
6 anything you guys want to comment on can we, you know,  
7 potentially stop over-complicating that process.

8           If the goal is to get the Agency to  
9 define down to every possible combination and detail  
10 or nuance of what is, what they mean by the guidance,  
11 it's actually fairly simple to understand where it  
12 fits.

13           MR. TALATI: No, I agree. We certainly  
14 think the GRAS issue is not the bigger issue. The  
15 issue is enforcement. There are a lot of TGIs (ph) in  
16 the marketplace. The FDA had enough resources and  
17 tolerance enforcement, is probably the bigger issue.

18           MR. JAKSCH: One other comment on the  
19 GRAS as well as that. The case (inaudible) use of  
20 self-affirmation process is definitely there, but in  
21 reality the one major fail point if you look at the  
22 GRAS self-affirmations that are, the data underlying,

1 they aren't going to know the chemistry or the  
2 substance or whatever it is that they have, so it  
3 fails right out of the gate. And the same thing again  
4 in understanding whether or not you need an NDI or  
5 not.

6 MR. MCGUFFIN: You know, that issue on  
7 that identification of the ingredient, you try to  
8 keep, probably notice is the single most observation  
9 by FDA in NDI notifications where the Agency says they  
10 have significant concerns, the most common identified  
11 significant concern is that you did not clearly  
12 identify the ingredient. And it's got to be  
13 (inaudible) GRAS what are we talking about. You know,  
14 there are two words in the statute that are not hard  
15 to understand. I don't think we need, you know --  
16 these are not complicated. It's ingredient and an  
17 (inaudible), and if you don't know exactly what that  
18 ingredient is, then I don't know how to go forward.

19 MS. OESTERLING: This is Janet  
20 Oesterling from Novozymes. My question is for Laura.  
21 You mentioned in the GRAS requirements that you have,  
22 have a limit on how much you consume and there has to



1 be safety evidence to provide for that consumption.  
2 And in the NDI guidance they talk about the  
3 adulteration standard and that you must also consider  
4 the addition of consumption and also chronic use when  
5 you look at your GRAS assessment as compared to NDI.  
6 And I'm just wondering what your thoughts are on that.

7 MS. MacCLEERY: I'm not sure I follow.  
8 Are you saying that the NDI application process  
9 accounts for the consumption as a food item?

10 MS. OESTERLING: What it does is there  
11 is an adulteration standard in the guidance that talks  
12 about the level of use in the GRAS assessment and  
13 whether or not that level of use is consistent with  
14 your NDI consumption and pattern of use. You have to  
15 make adjustments for that if it does not.

16 MS. MacCLEERY: So you're, you're saying  
17 if you're filing an NDI, you have to account for the  
18 GRAS uses of that same substance.

19 MS. OESTERLING: What I'm saying is that  
20 the, the use of your substance as affirmed as GRAS,  
21 the level of use and the consumption pattern must be  
22 taken into consideration when you're using it in an

1 NDI as a dietary supplement. You have to make  
2 adjustments for that consumption pattern, chronic use,  
3 and level. So you have to increase your safety  
4 assessment?

5 MS. MacCLEERY: Yeah. So that would be  
6 true if you're filing an NDI, but if you just file, if  
7 you've just gone through GRAS and you see, viewing  
8 that as an exception to the NDI requirement, then you  
9 wouldn't taken that step. So my point was for, the,  
10 the assumptions in the GRAS notification are around  
11 the conditions of use in food typically. I haven't  
12 gone to look at some of the details of some of the  
13 supplements like GRAS notifications, but --

14 MS. OESTERLING: It's already an  
15 exception. It's number three in the exceptions, the  
16 rule?

17 MS. MacCLEERY: Yeah. So those food  
18 uses are what's the subject of the safety analysis for  
19 the GRAS status and there, if you're using the GRAS  
20 exemption to bypass the NDI process, there wouldn't be  
21 a place where you actually account for the conditions  
22 of use of the, of the supplement in addition to

1 whatever food uses there may be. So they're not good  
2 substitutes for one another. They're actually looking  
3 at different conditions of use. One is looking at  
4 conditions of use in food and the other one is looking  
5 at applications of use in supplements, plus any  
6 additional uses that may be in a food environment, in  
7 food.

8 MS. OESTERLING: Thank you.

9 MR. POLINSKY: Scott Polinsky, attorney.  
10 Thank you again for your comments. So I have a brief  
11 discussion on the use of foreign data for self-  
12 determination of GRAS. FDA's clearly leery of  
13 independent conclusions of GRAS in addition to  
14 requiring the level of data on par with GRAS with  
15 notifications. For those seeking an independent  
16 conclusion for GRAS, the final rule of 2, 2016  
17 includes more stringent requirements for evidence of  
18 use outside the United States.

19 So for the example of indigenous  
20 populations in Brazil or adherence of higher data in  
21 India, the outside use must be corroborated by  
22 qualified US experts in addition to foreign sources.

1                   Number two, FDA states that a person who  
2 concludes that a substance is GRAS based on use in  
3 food outside the United States should notify FDA of  
4 that view. And this seems to contradict or eviscerate  
5 the notion that an independent conclusion is truly  
6 independent.

7                   So I'd like to ask the FDA of their  
8 current view of the foreign source requirement and  
9 the, the notion that an independent GRAS determination  
10 is truly independent.

11                  DR. WELCH: So I'd, I'd rather not  
12 address that right now. Kind of puts me on the spot  
13 there. I, does anyone on the panel have a response  
14 while I formulate my thoughts?

15                  MR. TALATI: I can add that it can  
16 certainly be GRAS notification or independent  
17 conclusion on the standard safety (inaudible - room  
18 noise), i.e., the same amount of data, need the same  
19 amount of (inaudible) GRAS dossier over (inaudible).

20                  MS. MacCLEERY: I would think that the,  
21 the information required for a GRAS notification would  
22 be potentially more than is required for an NDI, but

1 actually put them side-by-side and look. I, I do  
2 think that obviously the global marketplace is a great  
3 business source of ingredients and to find ingredients  
4 that are of interest to consumers on a global health  
5 perspective. I worry that some of the additional  
6 requirements that FDA's put in place are inadequate to  
7 really ensure that merely having a food be present for  
8 long term use in a, in a food environment like India  
9 or Brazil where it hasn't been well characterized or  
10 well studied in terms of its effects on human health,  
11 may not be an adequate basis for ensuring its safety  
12 for US consumers.

13 And so I think some additional actual  
14 safety data would be important, not just data on the,  
15 the history of use of an ingredient. There are lots  
16 of ingredients and, you know, that have been used for  
17 a very long time but that are still poorly understood  
18 from a scientific perspective.

19 MR. MCGUFFIN I can't answer Scott's  
20 question directly but just in bringing up this issue  
21 of different regulatory approaches around the word and  
22 as we find ourselves in a global marketplace,

1 certainly a move towards greater harmonization would  
2 be of value on issues.

3 For example, like CGMP, there's an  
4 awfully good regulation in Australia. But if I make  
5 my target in Australia, going to be inspected under  
6 111 if I try to sell it in the United States, is that  
7 necessary? Is it a pride of ownership in every  
8 country? Are the regulations any good?

9 I would encourage some further  
10 discussion of harmonization of the regulations where  
11 it would work, including safety evaluations. Of  
12 course by that I don't mean how about (inaudible) the  
13 question (inaudible). But some further discussion of  
14 working globally since the marketplace already is  
15 global would be a benefit for all.

16 DR. WELCH: And I would just add a few  
17 thoughts. I think this panel is focused on the  
18 exceptions to the NDIN requirements. So, and getting  
19 back to the questions from Novozymes, whether a  
20 notification is required is, is one aspect, and then  
21 whether it's, the ingredient as it's being used in a  
22 supplement is, is a different aspect. And so the, the

1 premarket notification and the NDI guidance does  
2 address this question which I think is what you were  
3 referencing.

4           So the, the notification, the premarket  
5 notification to FDA for use of an ingredient in a  
6 supplement might not be required, but you still have  
7 to know that conditions of use of your ingredient in  
8 your product are safe. Just whether or not you  
9 proactively premarket, tell FDA that information. So  
10 some of that is ensuring that the, the, the marketers,  
11 the manufacturers, and distributors know that  
12 information.

13           It's really nice when FDA knows that  
14 information. So sometimes we are playing a bit of  
15 catchup. So, and if, this has come up a couple times.  
16 So I would just sort of put in a plug for, for greater  
17 communication with FDA. And I know our, our Office of  
18 Dietary Supplement programs has put a lot of effort  
19 into this and we do want to be open to communicate  
20 with folks that are thinking about an NDI  
21 notification, thinking about an ingredient even before  
22 they realize if it's new or old.

1                   There's, there's a lot of questions that  
2 come up as you're formulating a new product I can only  
3 imagine. And, and so we do want to make sure we have  
4 those open lines of communication. I think it helps  
5 everyone. Manufacturers, distributors understand the  
6 requirements, but also FDA understands the safety of  
7 the products that are being out there.

8                   It is hard just from personal experience  
9 when you find a product and you turn it over and you  
10 read the label, what are we dealing with. What is the  
11 actual ingredient, again a concept that has come up a  
12 couple times already, and then is it, is it safe in  
13 the levels.

14                   And so I think those are great aspects  
15 to mull over as we break for lunch here shortly. A  
16 thank you to our panel. I appreciate that. Thank you  
17 to the Q&A. It's, I appreciate folks coming up to the  
18 mic. It's wonderful. We are going to break for lunch  
19 now and we are going to reconvene at one o'clock.

20                   Our session three, before everyone runs  
21 out of the room, our session 3, we will be hearing  
22 from Health Canada. So I think that's a great



1 opportunity to hear one of our counterparts. Again,  
2 we are starting at 1 p.m. sharp. We have a big  
3 afternoon ahead of us. So thank you and we'll see you  
4 soon.

5 MR. TAVE: Good afternoon, everyone. If  
6 we could begin to come back to order, please. I never  
7 quite reached the pinnacle of where I'm being a judge,  
8 but I can call the room to order and maybe I'll get a  
9 gavel for the next session. Wow. That was more  
10 effective than I thought it would be.

11 So for those, for those online, one  
12 thing I've observed is that the Wiley Auditorium can  
13 function something like a theater before we come back  
14 from intermission in that the lights went down and  
15 then up, and went back down again, which I think is  
16 why everybody is so neatly shuffling to their seats so  
17 we can get back on track with our schedule.

18 One administrative note and then we'll,  
19 we'll move right into the important fun stuff. For  
20 those who are participating remotely via webcast, we  
21 understand that you had some questions that came  
22 through during the earlier sessions and we didn't do a

1 very good job of responding to those in a timely  
2 manner. We have been going through those questions.  
3 We are going to be a little bit more attentive to that  
4 as we get through the next sessions in the afternoon,  
5 but we're also going to go back and try to address  
6 some of those questions that came in later on either  
7 during the open public comment session or otherwise as  
8 we have time.

9                   So we appreciate your attention. We  
10 know it's always a challenge to participate when  
11 you're not in the room, but we are going to continue  
12 doing what we can to make it a little bit easier for  
13 all of you.

14                   Okay. I hope everybody enjoyed their  
15 lunch. Thank you all. The next session is a bit of a  
16 departure from the rest of today's agenda and I'm  
17 particularly excited for it because I think it might  
18 be the only time all day where nobody talks about how  
19 wrong FDA is on one of those positions; although,  
20 maybe I shouldn't speak too soon. We'll see.

21                   In all seriousness, I think that, that  
22 this next session is going to be particularly

1 informative as well as interesting. We talked about  
2 it this, this morning, but globalization has been one  
3 of the biggest forces driving change in the dietary  
4 supplement marketplace, as well as probably every  
5 commodity that's in commerce over the past 25 years.

6 American firms regularly source raw  
7 materials and other ingredients from abroad and just  
8 as many firms sell their finished products overseas to  
9 foreign jurisdictions. So as regulators we are very  
10 fortunate to enjoy a really wonderful working  
11 relationship with our neighbors to the north from  
12 Health Canada.

13 And during the course of some of our  
14 discussions, we realized that we grapple with many of  
15 the same issues and we face many of the same  
16 challenges. And even though we operate under  
17 different regulatory schemes, there's still a lot of  
18 relevance to the differences, as well as to the  
19 similarities.

20 And so in light of that we thought it  
21 would be useful for today's proceedings to introduce a  
22 comparative perspective to this discussion and to hear

1 how some of these issues are being addressed in  
2 Canada, as well as what has worked successfully for  
3 them and what has not.

4 Our next speaker is Manon Bombardier.  
5 She's the Director General of Natural and Non-  
6 prescription Health Products, directorate health  
7 products and food branch of Health Canada. It's a  
8 role she's held since October 2016.

9 Manon has years of experience as a  
10 regulator including as the Chief Compliance and  
11 Enforcement Officer at the Canadian Radio, Television,  
12 and Telecommunications Commission and before that at  
13 Environment and Climate Change Canada. She holds an  
14 MBA and a PhD in environmental toxicology.

15 Manon will be speaking. She's got a  
16 presentation that will take about 10 or 15 minutes, I  
17 think, and then she has very nicely agreed to be  
18 available for Q&A. She has a colleague, Nana, here  
19 who much like I don't answer technical questions  
20 without my staff using a normal heart rhythm. I think  
21 Manon is relying on expertise as well to complement  
22 what she brings to the table.

1           So after her presentation, Manon and I  
2 will -- or Nana and I will, will go to the table.  
3 We'll go through the Q&A and then we will continue on  
4 with the rest of the afternoon. So we are very  
5 grateful that Manon has agreed along with Nana to  
6 travel here today from Ottawa to share Health Canada's  
7 experience and perspective with us. It's my pleasure  
8 to introduce Manon Bombardier.

9           (APPLAUSE.)

10           MS. BOMBARDIER: Thank you very much,  
11 Steve. Good afternoon, everyone. Pleasure to be here  
12 on behalf of Health Canada, and as Steve mentioned,  
13 I'm here with a manager in our Product Evaluation  
14 Bureau, Nana Bafi-Yebo, who will join me after for  
15 questions.

16           So as Steve mentioned, we do have a  
17 regime in, in Canada for, for dietary supplements and  
18 I'm very happy to provide the highlights of what the,  
19 the, the regime looks like and provide the regulator's  
20 perspective. I know there are some companies have  
21 sort of industry stakeholders in the room. Probably  
22 some of you do business in Canada and have experience

1 with our regime. So the, I think if, if you want to  
2 bring some insight from an industry perspective at the  
3 end, that would be helpful as well. I'll try to move  
4 the slides. Oh, that works. Okay.

5 So what I want to provide is first the  
6 regulatory context. So how, how we regulate them with  
7 the regime that governs dietary supplements in Canada,  
8 talk to what we do on the pre-market review and some  
9 of the work we're doing on the post-market review.

10 As with the US FDA, we do have a good  
11 size of our regime, but there's also other areas that  
12 have not evolved as quickly as the market in terms of  
13 policy development. So we're doing some work to  
14 improve in those regards. I want to say a few words  
15 in, on those as well at, at the end.

16 So in terms of the regulatory context,  
17 dietary supplements fit under a category of drugs  
18 under the Food and Drugs Act. In Canada the Food and  
19 Drugs Act govern all foods and all drugs and those  
20 include natural health products and within the natural  
21 health products we have dietary supplements.

22 So there's three sets of regulations

1 under the Food and Drugs Act. Dietary supplements  
2 like vitamins, minerals can fit under any of the, of  
3 the three regimes. It could be used in cosmetics; it  
4 could be used in natural health products; it could be  
5 used in drugs.

6           Depending on what the intended use is  
7 and whether it requires prescription or medical  
8 oversight, depending on what other ingredients are in  
9 there, the requirements would change and the  
10 regulatory framework would, would change as well. But  
11 it's all under the Food and Drugs Act. So three sets  
12 of regulations that govern cosmetics, natural health  
13 products, drugs, other drugs, and food.

14           The natural health product regulations  
15 were put in place in 2004 and they came into effect in  
16 2004, but actually came into force in 2014. So ten  
17 years after, ten years of transition for the industry  
18 to bring their products legally to market. And so the  
19 -- what was the impetus for the regulations was a  
20 report that was provided to Senate Committee on  
21 Health, one of the cabinet committees, the government  
22 of Canada, because of the routine use of natural

1 health products in the daily diet of Canadians. Three  
2 out of four Canadians use natural health products on a  
3 daily basis and that is on the rise.

4           Given the propensity of the use of these  
5 products, there was definitely a call for having the  
6 proper regime to regulate them in, in Canada. So  
7 they're considered as drugs, but they're subject to  
8 requirements that are not as stringent as what exists  
9 for prescription drugs for instance or non-  
10 prescription drugs. So, so we have a, a level of  
11 oversight that's properly to address, to address the  
12 level of risk of natural health products with are,  
13 which are considered lower risk.

14           Under the Food and Drugs Act there's  
15 three main outcomes that we're trying to achieve,  
16 safety, efficacy, and quality. So natural health  
17 products including dietary supplements are subject to  
18 requirements and we want to make sure that they're  
19 safe, they do what they say on, on their labels, and  
20 they're manufactured consistently in accordance with  
21 the quality standards that apply to them.

22           So those three elements apply to all



1 food and drugs products including dietary supplements.  
2 And the purpose of the regulations is to make sure we  
3 apply the right balance of oversight while maintaining  
4 access to these products for Canadians.

5 So the, the scope of the products is, is  
6 quite large under, in the natural health products, and  
7 the actual groups of products that are acceptable to  
8 be regulated and, and regulated under the natural  
9 health product regulations are listed in our  
10 regulations. So probiotics are in there, vitamins,  
11 minerals. So we have all, all the, the, the product  
12 types which you see here on, on the list. Homeopathic  
13 products as well, and traditional Chinese medicines  
14 are also covered by our regulations.

15 All product must be assessed for safety,  
16 quality, and efficacy prior to reaching the market.  
17 All products need a market authorization from Health  
18 Canada and that market authorization is notified to  
19 Canadians on the labels by an NPN number, which you  
20 see in the picture at the bottom left. So there's an  
21 NPN number that says Health Canada has approved this  
22 product. It's a natural product number.

1           Similar to what exists for drugs, we  
2     have a DIN, drug identification number. So NPN is for  
3     dietary supplements and other natural health products.  
4     There's over 150,000 products that have been approved  
5     for market in, in Canada to date.

6           I, I know that there was some interest  
7     into synthetic duplicates. So synthetic duplicates of  
8     natural ingredients including vitamins and, and  
9     minerals are actually listed as acceptable ingredients  
10    in natural health products. So as long as the  
11    activity of the synthetic substance is the exact same  
12    as, as the natural substance, but those are allowed to  
13    be used in natural health product and therefore are  
14    regulated under the natural health product  
15    regulations. Vitamin C is, is a great, is a common  
16    example.

17           We also, probiotics is also part of the  
18    scope. We have what we call a monograph. Basically  
19    it's a standard that Health Canada has established.  
20    It's published on our website and it specifies all the  
21    conditions under which a probiotic can come in for an  
22    application. If it meets all the requirements of the

1 monographs, and we do verify those, so the proper  
2 name, the common name, the, the source material, the  
3 conditions of use, the dosage form, the dose, risk  
4 information if any applies.

5           If all the requirements of the monograph  
6 are met and appear on the label as such, the company  
7 receives a, a license for that product. So monographs  
8 have been -- they love to facilitate more timely and  
9 efficient processing of applications that come in and  
10 it's based on established standards that we've  
11 reviewed, like as an organization and we've deemed to  
12 be acceptable. So we have one for probiotics and I  
13 have the link at the bottom of the slide which I  
14 understand will be made available so you can access  
15 it.

16           There's, there's three pathways for  
17 product licensing under the natural health product  
18 regulations and I know what is of most interest here  
19 would be captured under the modern natural health  
20 products. So vitamins, fish oils, for example. The  
21 level of evidence that's required to support the  
22 safety and efficacy of these products is based on

1 risk. So we have lower risk, medium, and high risk,  
2 depending on the level of risk of the ingredients, the  
3 intended use, if, if it requires some assistance from  
4 a health professional, for instance. All of those are  
5 taken into considerations when assessing the level of,  
6 of, of risk and then the, the level of evidence that's  
7 required. And in some cases it could be clinical  
8 trials. In other cases such as homeopathic product,  
9 it could be a reference, a pharmacopeia reference as  
10 long as it meets all the requirements of, of the  
11 monograph and there's only specific, very specific  
12 claims that can be used.

13 So we have a three class system and it's  
14 based on the use of, of monographs that I mentioned.  
15 So a product, for instance, that comes in an  
16 application and all the requirements of the monograph,  
17 it's a single monograph -- let's say it's, it's a  
18 probiotic -- and all the requirements of the monograph  
19 are met, it could come in as a Class I and in 60 days  
20 the company would get the license for market  
21 authorization.

22 If the product is supported by two or

1 more monographs, entirely monograph supported, it is  
2 still reviewed and the timeline there is 90 calendar  
3 days. If anything goes beyond the monograph, it's a  
4 new ingredient or it's a new condition of use that  
5 we've not seen before, we don't have the data so it  
6 has to be provided by the applicant, it requires a  
7 full review by our scientists including members of  
8 Nana's team. It's a 210 day to get the license.

9           So we have the classification system  
10 which allows flexibility to the companies and you can  
11 come in and if you meet all the pre-established  
12 standards, your product can go quickly on the market  
13 as long as your label meets all the requirements as  
14 well, and if it's a new ingredient, then there's a  
15 review and there's, and there's -- we have a lot of  
16 policies on our website that describe what's required  
17 in terms of level of evidence to support a particular  
18 product and condition of use.

19           The other element that's key in our  
20 process is we have an NHP ID which is the natural  
21 health product identification database. It's a list  
22 of medicinal ingredients and non-medicinal ingredients

1 that are deemed to be acceptable in natural health  
2 products. So no application will be accepted unless  
3 the ingredients are listed in that database.

4 Listing does not mean that the  
5 ingredient is safe and effective. It still needs to  
6 be reviewed, but it is acceptable to submit an  
7 application. So it's a key tool and it's available.  
8 It's very transparent for applicants to use.

9 So I spoke a lot about safety and, and  
10 efficacy. The other key element, of course, is the  
11 quality. So applicants must provide to us a product  
12 specification form that describes the quantity, the,  
13 the identification, the quantity of the ingredients,  
14 their level of purity, and the testing methods that,  
15 that were used with the level of sensitivity of that  
16 method. So we have a product specification form,  
17 again, that's available on our website and, and that  
18 comes in with the application.

19 What I, I want to talk about just for a  
20 few minutes is some of the challenges that we've had  
21 with safety, efficacy, and, and quality to date. We  
22 had been relying on attestation forms from companies.

1 So when the regulations came into force 2014, we had  
2 about 60,000 products on the market, natural health  
3 products that were already on the market that needed  
4 an NPN to be legally on the market. So we've  
5 introduced what we call an attestation model where  
6 companies would come in and provide us an application  
7 with an attestation form that the product met all the  
8 requirements of the monograph, and in ten days they  
9 would get, they would get their license.

10 In 2017, we did an audit of a number of  
11 files that we had received applications for and that  
12 we had licensed, and we found out that 70%, 7-0  
13 percent of the applications actually did not meet the  
14 requirements for safety and efficacy. So we adjusted  
15 our approach and we said that doesn't work. We need  
16 to review these diligently line by line and make sure  
17 that all the requirements are met.

18 Ultimately it's our obligation to make  
19 sure that products that reach the market are safe for  
20 Canadians and we were not doing this. So we changed  
21 our approach and now we have a pre-market review. So  
22 the applications come in and we review everything

1 that's in the application.

2 On quality, we're not there yet. We're  
3 going there. So right now we're doing a similar audit  
4 on product specification forms and other material that  
5 were provided us for applications for quality and  
6 we're finding similar results.

7 So, so far we've reviewed a number of  
8 applications and, and we've identified gaps on  
9 specification forms, information that's missing.  
10 Stability, no indication that the product has been  
11 tested for shelf life, instability over a certain  
12 period of time, and gaps in terms of quality assurance  
13 having a QA person in place, having the proper  
14 training, proper methodologies and, and procedures in  
15 place to make sure that the quality standards is met  
16 on a consistent basis.

17 So given those gaps, we are going to  
18 reintroduce a quality review in the coming months, but  
19 we're still looking at the results to figure out where  
20 exactly we're going to focus our, our assessment.

21 We've also started a proactive  
22 inspection regime which is fairly new for NHPs. In



1 the previous years the, the approach to compliance  
2 verification was very reactive and complaint based.  
3 We've moving into a more proactive approach which  
4 I'll, I'll give you a bit more details. But some of  
5 the findings were particularly concerning based on 46  
6 inspections that have been done to date, which  
7 represents about 6% of the, the market, the sites that  
8 had received a license, 'cause we do issue site  
9 licenses. For any site that produces or imports NHPs  
10 in Canada, they need a site license and there's a  
11 review process in place for those.

12 And when our colleagues from our  
13 enforcement branch inspected, they found problems at  
14 all the sites and some of which were quite concerning,  
15 again, no specifications, unavailable or incomplete,  
16 no data on stability, QA person was not there or was  
17 (inaudible) person who had no training, cracks in the  
18 walls, contamination fungus. You name it; we found  
19 it.

20 So with those results we said we need to  
21 adjust our approach to pre-market and, and post-  
22 market. So we're making significant changes. The

1 results of the compliance verification are available  
2 in that report at the link at the bottom of the, the  
3 slide there if you're interested.

4 In terms of processing -- so I spoke  
5 about the ten day standard and the, the lack of pre-  
6 market review prior to 2017. So we've made some  
7 changes as a result of the findings of our audits on  
8 applications and the gaps that we found. And we've  
9 updated our policy in April of 2019 with new  
10 performance standards. So instead of 10, 30, 210 for  
11 Class I, II, III, it's now 60, 90, and 210. So for a  
12 Class I and II we're taking the time that we need to  
13 do a proper review of those applications.

14 Also we have provided the industry with  
15 a web form that instead of sending us a pdf and we  
16 would get five or six different forms. Companies were  
17 even creating their own form and sending that to us.  
18 And we had to stop and had to manually enter the data,  
19 which is totally unsustainable. So we've created a  
20 web form and, and as of June 2019 it will be mandatory  
21 for companies to submit us that form for their  
22 application.

1                   We also have provided more clarity on  
2 criteria for refusals. If an application is deficient  
3 in certain areas, it's going to be automatically  
4 refused; whereas, before we would help the, the  
5 company develop their application to be compliant.  
6 With the volumes that we get, we get about 7,000 per  
7 year applications, there's no way we can do that. We  
8 can't continue to do that. So we are refusing if  
9 there's substantive gaps. If the form is not  
10 complete, it's, it's refused.

11                   So with those changes we hope to be more  
12 efficient and to get to the market the products that  
13 meet the requirements in, in the most efficient way  
14 possible.

15                   On the post-markets I said we, we have  
16 been quite reactive. An area where we need to  
17 continue to be reactive is when we get adverse  
18 reaction reports from patients or from hospitals or  
19 health professionals. So when we get those, of  
20 course, we review, we have colleagues in our market  
21 health products directorate that can help us do safety  
22 assessment of the signals that we get. And then if we

1 find that there's enough evidence to suggest that  
2 there's a high, a risk that outweighs the benefit of  
3 the product, then we take action. It could be a  
4 recall. It could be labeling changes. We've done  
5 that recently on green tea where we found we had a lot  
6 of signals of liver toxicity.

7 We did a safety assessment. We  
8 published a report on our website and we're now  
9 working with companies to adjust their labels to make  
10 it very clear and prominent in the warning section  
11 that if you have jaundice or symptoms of liver  
12 toxicity, you need to consult your health practitioner  
13 or doctor right away.

14 So those activities will continue, but  
15 we're moving more and more into proactive monitoring  
16 and we're focusing not only on site inspections, but  
17 also on false and misleading advertising. So we have  
18 a prohibition in the act against false, misleading  
19 advertising. We've been quite reactive to date, but  
20 we're moving into a more proactive approach, again  
21 with our colleagues and we're working with pre-  
22 clearance agencies.

1                   We have agencies in Canada like the  
2 Advertising Standards Council who help industry make  
3 sure that their labels don't provide misleading claims  
4 and that comply with our regulations. So we do work  
5 very closely with them to indicate and promote  
6 compliance with that provision of the legislation.

7                   In terms of modernization efforts, so we  
8 -- for natural health products, the area that we're  
9 working on now from a regulatory change perspective is  
10 on the labeling. We have on the non-prescription drug  
11 side, we've just implemented changes to require plain  
12 English labeling with a drug facts table, product  
13 facts table for drugs. And so we're looking at  
14 implementing a similar approach for the labeling of  
15 natural health products similar to what exists for  
16 dietary supplements in the US. We've looked at that  
17 model and borrowed quite a bit from it as well.

18                   And the approach that we're -- so NHPs,  
19 as part of our modernization effort, NHP is there, but  
20 we're also looking at non-prescription drugs in  
21 cosmetics and bringing improvements there as well.  
22 Non-prescription drug side -- I know this is not the

1 focus here, but just to say that we have non-  
2 prescription drugs that are cosmetics like toothpaste  
3 with triclosan in it. It's considered a non-  
4 prescription drug and it's held to the same standard  
5 right now as prescription drugs and companies are  
6 saying it doesn't make sense and we agree with them.  
7 We need to make sure the regulatory burden and  
8 oversight is appropriate for the level of risk. So  
9 that's what we're doing right now for non-prescription  
10 drugs.

11 So for labeling for NHP, so we're  
12 looking at three key requirements for all labels of  
13 NHPs. I will go in the regulatory proposal that will  
14 be consulted on in the spring 2020. First is minimum  
15 font size. So size six for non-medicinal ingredients  
16 we're looking at, at font size five point five and  
17 we're allowing condensing. Minimum contrast, meaning  
18 black on white is, is also something that we're going  
19 to require and standardization. So a product fact  
20 table with the headings in bold and the, the, the  
21 text, again, making sure that the text is in font size  
22 six and proper contrast and, and in the same order.

1                   We have some exemptions for a very small  
2 package. We're about to publish proposed guidance for  
3 labeling of natural health products in May. I could  
4 share the link if you're interested when it comes out.  
5 And our proposal will lay out some of the  
6 flexibilities that we're proposing to industry to  
7 implement those changes.

8                   In Canada we have French and English and  
9 a lot of companies are telling us both languages won't  
10 fit. So what flexibilities can you give us to make  
11 sure we don't have to resize our packages or resort to  
12 innovative labels? So we're working on flexibilities  
13 and that includes an exemption for small, very small  
14 packages. Anything less than 12 square inches would  
15 be exempted from the product fact label. And that's  
16 what it would look like. So very similar to what  
17 exists on the dietary supplement side in the US.

18                   For questions we're providing, you know,  
19 a phone number or an e-mail address, and we're also  
20 allowing some information to go on a URL. So for  
21 very, very low risk products, one of the flexibility  
22 that we've introduced is for point of views warnings

1 such as if, if you get a rash when you apply it, stop  
2 using it. Those types of warnings would be able to be  
3 moved to a URL, again, to save space on the label. So  
4 we're consulting on that proposal. The policy will go  
5 up for consultation in, in the month of May, near the  
6 end of the month, with a regulatory proposal in 2020.  
7 That's it.

8 MR. TAVE: So now we have an opportunity  
9 for questions and just like this morning anybody who  
10 wants to come down to the microphone, please feel  
11 free, and I think we have somebody monitoring remote  
12 questions through the broadcast and we'll have  
13 (inaudible) monitor, please tell us your name and  
14 affiliation before your questions.

15 MR. FRANKOS: Hi, there. Is this on?  
16 Okay. Thank you for your presentation. My name's  
17 Bill Frankos of Herbalife and my question has to do  
18 with whether there is any propriety given to a  
19 manufacturer who has developed the data, the safety  
20 data of that ingredient they submitted, and can other  
21 people use that information that's, that was submitted  
22 by another company to support their adding that



1 ingredient to their product?

2 MR. BAFI-YEBOA: Nana Bafi-Yeboa. Thank  
3 you for the question. Part of that really comes down  
4 to what an ingredient is because by our regulations  
5 the medicinal ingredients, the source won't have to  
6 appear on the label. So in terms of the provisions  
7 around it, you're in a space where you have to declare  
8 enough to the regulator for them to know exactly what  
9 that ingredient is and to then provide the evidence  
10 that supports the safety and efficacy of that  
11 ingredient. There is no provision of use of a master  
12 file, which can keep certain pieces of information  
13 confidential and, and not in the public domain. But  
14 there isn't a way to mask the identity of your  
15 ingredients on the label.

16 MR. FRANKOS: But as far as, for  
17 instance, the manufacturing specifications, the let's  
18 say all of the steps that go into manufacturing, is  
19 that protected?

20 MR. BAFI-YEBOA: So if it's within the  
21 context of the master file, that is confidential. The  
22 issue then in practical terms is whether someone else

1 can represent the ingredients in a way that appears to  
2 be similar to yours and have enough publically  
3 available information to substantiate the safety and  
4 efficacy of your ingredients.

5 Now whether indeed it is a, a sort of a  
6 certain trademark issue that you may have, that would  
7 be the role of the, I guess, manufacturer to enforce  
8 that, that piece. In terms of our role as the  
9 regulators strictly looking at do we have enough  
10 information regarding the ingredients and then enough  
11 information concerning its safety, efficacy, and  
12 volume to issue a license.

13 MR. FRANKOS: Okay. Thank you.

14 MR. TALATI: Hi. It's Ashish Talati  
15 from Upadhye. Thank you so much. Are you able to  
16 share with us the number of employees in your office  
17 and your, your budget?

18 MS. BOMBARDIER: Number of employees and  
19 --

20 MR. TALATI: Budget size.

21 MS. BOMBARDIER: Oh. The number of  
22 employees is about 150 people and the budget is about

1 17 million. (Inaudible) responsible for pre-market  
2 (inaudible) other programs that are involved in the  
3 post market (inaudible).

4 MR. TALATI: Thank you.

5 MS. MCENROE: Hi. It's Diane McEnroe  
6 from Sidley Austin. In terms of what we call  
7 structure function claims here, the claims are C  
8 claims, what does it look like in, in, you know, my  
9 own decision of what is an appropriate structure  
10 function claim? If you look at the science, if you  
11 come up with something that is solid for a company to  
12 rely upon and then look at is as is it something that  
13 we can model here in the United States, would that be  
14 a, a particularly long process?

15 MR. BAFI-YEBOA: I think there's two  
16 parts to it. I think the experience basically had the  
17 benefit of what had happened with respect to DSHEA in  
18 1994 because our regulations came into effect in 2004.  
19 So we had that ten years to really look at what was  
20 working and what was, could be improved and perhaps  
21 use that model.

22 In terms of also structure function

1 claims, it would be very similar to what you have for  
2 vitamins and minerals and these type base claims.  
3 You're, you can also have some structure function  
4 claims that you see in with the probiotics where you  
5 have source of probiotics with probiotics to help wt,  
6 you know, promote, you know, like a favorable  
7 (inaudible).

8                   So it really depends on the type of  
9 ingredients and the evidence that's available. What  
10 we do is we publish monographs so we're satisfied that  
11 there is sufficient information regarding some of  
12 those claims and our monographs do not only relate  
13 back to the structure function claims, they will have  
14 full range of claims.

15                   Granted there are certain conditions and  
16 diseases that products intended for self-care should  
17 not really go forth. So our monographs do not speak  
18 to those whatsoever. It, it's, it's just a way of  
19 understanding that it's always based on what the  
20 evidence is and what that ingredient is, that we then  
21 use to leverage to label for safety, efficacy, and  
22 then what the quality standards are. So that also

1 takes into account the nature of the ingredients.

2 MR. TAVE: I don't see anyone at the  
3 microphone. So are there any questions coming through  
4 the webcast?

5 MR. BOLAR: Paul Bolar of Pharmavite.  
6 My question is, well, twofold. First of all, I'm  
7 wondering how effective are these, the regulatory  
8 schemes that you have with respect to products sold  
9 over the internet? Does it effectively -- are  
10 products sold over the internet effectively controlled  
11 and do they comply with the requirements?

12 MS. BOMBARDIER: So any product that's  
13 sold on the internet, I mean it's a challenge for an  
14 individual organization to make sure they comply  
15 because the reach outside of jurisdiction is always  
16 challenging because it's no different and health  
17 products are no different. So we, we do work with our  
18 colleagues in order as it is CSA (ph) Agency. So  
19 (inaudible) agency to verify and monitor (inaudible).  
20 When we see claims that are egregious (inaudible)  
21 product with the disease claim that's illegal in  
22 Canada and we do take action. We do take those things

1 seriously (inaudible).

2 MR. BOLAR: And the, the second question  
3 is I'm, I'm wondering with respect to the system that  
4 requires numbers and every product needs to be  
5 submitted. How effective is that system in preventing  
6 drug adulterated products or tainted products from  
7 entering the market, which is a huge problem here in  
8 the US?

9 MR. BAFI-YEBOA: That, that really is a  
10 post-market type of issue and it really goes back to  
11 what is the circumstance, the intensity of activities  
12 related to both proactive and random verification of  
13 standards. Because as much as you can introduce  
14 certain things on the pre-market side, unless you have  
15 the ability to balance that out and verify on the  
16 post-market side, you, you really do not have the type  
17 of (inaudible - sneezing) in my opinion to kind of  
18 make a difference.

19 MR. TAVE: We have time for one more  
20 question and looks like we have one ready to go.

21 MR. MACKAY: So this is Doug MacKay  
22 from CV Sciences. I'm just curious from both your

1 perspectives. The arbitrary line that we have here in  
2 the United States that products can only support  
3 normal health, and then you guys were able to venture  
4 into this area with natural products can actually have  
5 a therapeutic benefit. That seems to translate a lot  
6 of the issues that we talk about, even getting the  
7 right kind of evidence to make a claim becomes  
8 difficult if we can't talk about lowering cholesterol  
9 or changing hemoglobin A1C.

10 So just philosophically, how much does  
11 that shape the regulatory paradigm and what advice  
12 would you give to the United States on that topic?

13 MS. BOMBARDIER: Well, one of the, the  
14 key elements for health regime for drugs to ensure  
15 that claims are well-supported and well supported by a  
16 level of evidence, scientific evidence. While we do  
17 have traditional Chinese medicine, homeopathic  
18 medicines as well, that's for the purpose of  
19 maintaining a process of ingredients and proper  
20 balance (inaudible - room noise) allowed to have  
21 general claims without the scientific evidence  
22 especially monographs and establish (inaudible) these

1 health claims are adequate in, in Canada.

2           What is most important for these  
3 products is the safety and any other operation we do  
4 look at safety and, and, and adulteration. So we do  
5 look at safety and quality more than anything else for  
6 these (inaudible). For high risk ingredients, then  
7 there's, we have what we call a pathway for licensing,  
8 which is our policy that establish what evidence  
9 that's required. It can be on the level of the claim.

10           And if the claim doesn't work  
11 (inaudible) we do think (inaudible) and the functions  
12 of use and it requires (inaudible). So those are all  
13 factors that are considered. And that's everything.  
14 You want to add?

15           MR. BAFI-YEBOA: I would just add on the  
16 philosophical aspects I think regardless of where you  
17 stand, there will be a line that you'll have to draw  
18 and that may seem arbitrary at times. The more  
19 important pieces that you have safety for who have a  
20 say speaking to where that line should be. And  
21 agreement that once that line is established, you have  
22 the tools in place to move it as the evidence changes



1 or the assumption that led to that establishment also  
2 changes.

3 I think these type of forms are very,  
4 very important because at the end of the day the  
5 markets do not exist unless they can meet a consumer  
6 need. And when we talk about innovation, you know,  
7 innovation is the meet what consumers want or  
8 consumers need. That's, that's an ability to meet  
9 than need, but it's also an ability to impact the  
10 health of, of consumers. Obviously the health of  
11 communities, but the health of Americans.

12 And that's, that's a very, very  
13 important thing and the more you can engage in these  
14 type of forums, I think that you do actually start  
15 making progress and landing where you really want to  
16 be.

17 So it's -- thank you for the opportunity  
18 to speak at this type of, you know, meeting, and to  
19 really hear all of the voices that are, you know, have  
20 an interest in improving where we currently are.

21 MR. TAVE: And I want to say thank you.  
22 I know that the session after lunch from this morning

1 was (inaudible) I can tell you with certainty today  
2 (inaudible). This has been incredibly informative.  
3 We, we are (inaudible) to both of you. So we do not  
4 have (inaudible).

5 (APPLAUSE.)

6 ADRIAN FROM AUDIO DEPARTMENT: One  
7 question from online.

8 MR. TAVE: Okay. We have one question  
9 from online.

10 UNIDENTIFIED FEMALE SPEAKER: Hi. I  
11 hope everyone can hear me. We have one question  
12 online. Can you please share information about the  
13 percentage of products so that an NPN in Canada are  
14 registered with Health Canada and have an NPN number?

15 MS. BOMBARDIER: So the question is, is  
16 the question whether there is any actual (inaudible)  
17 products on the market in Canada without an NPN  
18 number?

19 UNIDENTIFIED SPEAKER FROM AUDIO: I'm  
20 having trouble hearing you.

21 MS. BOMBARDIER: So --

22 UNIDENTIFIED SPEAKER FROM AUDIO: I, I

1 want to say, yes, that's the question. Okay.

2 MS. BOMBARDIER: So products that don't  
3 have an NPN first are illegal in Canada. So there  
4 needs to be an NPN which says that Health Canada has  
5 approved this product. If there's any point that  
6 comes to our attention that a product is on the market  
7 without an NPN, we take action. So if you have any  
8 examples you can provide them.

9 MR. TAVE: Okay. Thank you again. I  
10 think we can have our, our panelists come down. Okay.  
11 So, so as our panelists find their seats, I'm going to  
12 start talking to encourage everybody to, to keep  
13 things moving. Place on mute in the background as we  
14 switch off. All right. I'm going to get started.

15 So we've now reached the last panel of  
16 the day, but certainly not the least, and the topic of  
17 this panel is promoting compliance with the NDI  
18 notification requirement. And the title sort of begs  
19 the question and maybe it's obvious to some people,  
20 but why do we think that there isn't already adequate  
21 compliance with the requirement? I've got to ask.  
22 The answer is twofold.

1           First we hear it anecdotally and I'm  
2           sure we'll hear it anecdotally later during Q&A and  
3           public comment, but it's not at all uncommon for  
4           stakeholders to say to us that FDA, and to others,  
5           that FDA needs to do a better job of enforcing the NDI  
6           notification requirement. And we hear complaints from  
7           firms, typically those firms who have successfully  
8           navigated the notification process who feel that their  
9           competitors are getting a free pass.

10           And like I said, I think we're going to  
11           hear a few pretty compelling examples before the end  
12           of the day of firms that have made significant  
13           investments in being transparent and coming through  
14           the front door and complying with their understanding  
15           of the law and, you know, there's, there's a degree of  
16           sympathy to that view.

17           All right, but second, we can look to  
18           the data and this is somewhat challenging because we  
19           don't know what we don't know. Specifically, we, we  
20           don't really have any way of measuring how many firms  
21           are marketing products for which an NDI notification  
22           should have been required, or should have been

1 submitted, but it wasn't.

2 So we can start with what we do know.  
3 And what we do know is that in 1994 when DSHEA was  
4 enacted, there were approximately 4,000 dietary  
5 supplement products on the market. And we don't know  
6 exactly how many products are on the market today, but  
7 the prevailing estimates range from 50,000 to 80,000  
8 different products.

9 So for purposes of this exercise, let's  
10 take the most conservative assumptions and let's use  
11 the low end of that range and suppose that there are  
12 50,000 products on the market today. If you subtract  
13 out the 4,000 that were on the market when DSHEA was  
14 enacted in 1994, that means that approximately 46,000  
15 new products have been introduced to the market in the  
16 past 25 years.

17 Now clearly not all of those new  
18 products contain new dietary ingredients as it's  
19 defined in the statute that are subject to the  
20 notification requirement. Some of them might be new  
21 brands of old ingredients, some might be new  
22 combinations of old ingredients like a reformulated

1 multivitamin, and some might be exempt from the  
2 notification requirement because of presence in the  
3 food supply or otherwise.

4           So let's take a conservative assumption  
5 again and let's suppose that 90% of the new dietary  
6 supplements that have been introduced to the market in  
7 the past 25 years were not subject to the notification  
8 requirement. So let's say 90% of these products did  
9 not require notification. That still leaves 10% of  
10 the products that did require notification and 10% of  
11 the 46,000 new products is 4,600.

12           So by that math we should have received  
13 approximately 4,600 new dietary ingredient  
14 notifications since 1994. In fact, the number that  
15 we've received is quite a bit lower. To date we've  
16 received just over 1,100 notifications. So in other  
17 words, even using the low end of the estimate for the  
18 number of products on the market today, and even  
19 assuming, assuming that 90% of the new products that  
20 have been introduced were not subject to the  
21 requirement for notification, we still find that the  
22 number of notifications submitted is less than 25% of

1 where we expect it should be. And you can quibble  
2 with the math, but I think the orders of magnitude are  
3 probably fairly accurate. The point is that  
4 compliance clearly needs to improve.

5 So this panel initially began as two  
6 separate panels and if you look back at the federal  
7 registry notice announcing the meeting, and there's no  
8 reason you should do this, but if you do look back  
9 you'll see that we listed four separate topics for  
10 discussion.

11 And as we started planning out the  
12 agenda and talking to speakers and thinking through  
13 the flow of the day, we realized that two of the  
14 topics, potential commercial or marketing advantages  
15 to incentivize responsible innovation, as well as  
16 promoting overall compliance with the pre-market  
17 notification requirement through enforcement we're  
18 really opposite sides of the same coin.

19 Effective enforcement by itself provides  
20 something of a marketing advantage for products that  
21 have successfully gone through the notification  
22 process and at the same time commercial incentives

1 won't really be worth anything if there isn't  
2 effective enforcement to prevent non-compliant copycat  
3 products from free riding. So you can't really  
4 discuss one without the other.

5           Now as it turns out these companion  
6 issues are particularly challenging. We've heard  
7 stakeholder calls for economic incentives and  
8 marketing advantages, but unlike with some other FDA  
9 regulated commodities, there is no statutory  
10 intellectual property protection in play. So we're  
11 open to the concept, but we want to hear ideas about  
12 whether this is something that can be done under  
13 existing authorities, and if so, how.

14           Similarly, it's easy to call for more  
15 enforcement and it's certainly fair to do so. But  
16 even in a straightforward case, unfortunately it can  
17 be time consuming and resource intensive. That  
18 doesn't mean it's not worthwhile. But these cases  
19 present some unique challenges. For one thing, a  
20 competitor product might not have submitted an NDI  
21 notification, but as you heard in session two before  
22 lunch, it might be on the market by virtue of the GRAS



1     loophole via self-affirmation. And because DSHEA  
2     places the burden on FDA to show that a dietary  
3     supplement is adulterated under Section 402(f), we  
4     wouldn't necessarily know that until we had travelled  
5     well down the path of an enforcement action.

6                     Well let's suppose that the competitor  
7     product hasn't even done that much. The case is still  
8     far from a slam dunk. Recall that we're typically  
9     being asked to bring enforcement action to protect a  
10    product or an ingredient that has successfully gone  
11    through the notification process. That means that  
12    when we reviewed their data, we had no objections to  
13    the notifier conclusion that the product is reasonably  
14    expected to be safe. So it follows that a knockoff  
15    product that is identical or very similar to that  
16    product is probably at the very least not clearly  
17    unsafe.

18                    So even assuming that we can satisfy our  
19    burden of proving a product is technically adulterated  
20    under DSHEA, there's still a practical question of  
21    resources. And to make the best use of our finite  
22    resources, we've established three strategic

1 priorities. I mentioned them this morning: consumer  
2 safety, product integrity, and informed decision  
3 making would always be consistent with those  
4 priorities to investing an enforcement action against  
5 a product that is closely similar if not identical to  
6 one that is expected to be safe.

7 Now there is a lot of value to upholding  
8 the integrity of the regulatory process and you can  
9 say that that's part of promoting consumer safety. So  
10 let's, let's say that a case like this is consistent  
11 with our strategic priorities. When we issue warning  
12 letters, which some call for us to do and we have  
13 done, it's important for us to be able to follow them  
14 up with judicial action if we don't achieve  
15 compliance. We can't be a paper tiger. But FDI, FDA  
16 can't bring cases in court on our own.

17 We have to rely on the Department of  
18 Justice to bring them for us. And they have limited  
19 resources and competing priorities. Would DOJ be  
20 willing to take on a case that faces all of the  
21 obstacles that I just mentioned?

22 And I haven't even mentioned one of the

1 bigger obstacles. As you'll hear in a few minutes  
2 during this panel, there's a legal argument that once  
3 one firm has submitted a notification for a new  
4 dietary ingredient, anyone can freely market that  
5 ingredient.

6 I'm not saying that I agree with this  
7 position, but it's one that we have to acknowledge and  
8 recognize, and it's one of that we have to respect at  
9 least as a potential defense that we'd encounter in  
10 any enforcement action.

11 So there's no doubt that the public  
12 health is best served when we have a robust effective  
13 NDI notification system working as DSHEA intended.  
14 And we know and we'll hear it today that it's possible  
15 for firms to use this process to introduce innovative  
16 new ingredients that are reasonably expected to be  
17 safe. So the question becomes what can we do to get  
18 firms to see the value and to realize the value in  
19 this process rather than having firms exploiting it  
20 through loopholes or, or ignoring the requirement  
21 altogether.

22 And for those easy questions we'll turn

1 to our panel. And so before we begin, I'm going to  
2 introduce each of our panelists and we've got a pre-  
3 established order of presentation. So I will  
4 introduce them all and then we'll, we'll call up our  
5 first panelist to speak.

6 So we'll start with Dan Fabricant,  
7 President and CEO of the Natural Products Association.  
8 He'll be followed by Andrew Shao, Interim Senior Vice-  
9 President of Scientific and Regulatory Affairs from  
10 the Council for Responsible Nutrition. Then we'll  
11 hear from Wes Siegner, Senior Counsel at Hyman, Phelps  
12 & McNamara. Then Jay Sirois, Senior Director of  
13 Regulatory and Scientific Affairs Consumer Healthcare  
14 Products Association. And finally Sandra Eskin,  
15 Project Director of Food and Dietary Supplement Safety  
16 at The Pew Charitable Trust.

17 So with that, let me turn the mic over  
18 to Dan.

19 MR. FABRICANT: Steve, you're kind of a  
20 low talker. I was worried I was going to end up  
21 wearing a puffy shirt or something, but -- and the  
22 only thing people -- the last time we were in this

1 room we were talking about old dietary ingredient  
2 lists and the only thing that the ODSP staff remembers  
3 was that I was talking about a claims question. They  
4 said it's like porn, you know it when you see it and  
5 they just liked seeing that up there on the, on the  
6 board. So there it is again for, for -- we aim to  
7 please.

8 Daniel Fabricant, President and CEO of  
9 Natural Product Association. And this is an  
10 interesting topic; though, it's not that interesting  
11 in some ways 'cause you're, you're talking about a  
12 statute that's in existence for 20, 25 years and in  
13 the crux of -- and there's a lot of NDI topics that  
14 are unresolved and we'll touch some of them here. I  
15 think IP ties in. Steve did a really nice tease up to  
16 kind of where, where these issues are, but it really  
17 comes down to -- and these meetings are, are kind of  
18 formulated on getting the guidance out and we'll talk  
19 more about that later this afternoon.

20 But that's kind of the, the basis of  
21 these meetings, is the Agency wants to get the  
22 guidance out and this is a, you know, everyone feels

1 good. We had meetings and let's get the guidance out  
2 and everyone will hate the guidance again. That's  
3 that.

4 But more importantly is I think the, is  
5 the lack of enforcement. You have, you really have a  
6 disconnect I think in terms of -- and I understand  
7 people may make a legal argument that, okay, if one  
8 person submits an NDI, then everyone can ride on that,  
9 but I don't think that's how the statute reads at all.  
10 And I heard Scott, you know, the, the framer of the  
11 constitution down there. What was Patrick Henry like,  
12 Scott?

13 Anyway, but I think that important, it's  
14 important that it's, it, you know, the law is pretty  
15 clear and, and, you know, and then you hear about  
16 resources and there's also ways that the Agency's  
17 enforce using a very low resource burn and I think  
18 we'll touch on that right now 'cause what does it buy  
19 you? And this is the key thing. By notifying the  
20 Agency it's on the, the burden is then on the Agency.

21 But by not notifying the Agency, who's  
22 the burden on? The burden's on the company to say,

1 hey, this was either -- and they may not have to  
2 necessarily provide that information to the Agency.  
3 They either have to have it in their back pocket  
4 saying it was on the market pre-94 or some other basis  
5 for which they're exempt from filing an NDI.

6 So without notifying the Agency, and the  
7 law was clear on this and introduced a new  
8 adulteration clause, that if the product is in fact  
9 adulterated, the ingredient is in fact adulterated for  
10 not notifying the Agency. That simple.

11 And, you know, not getting into the  
12 safety data part of it, 'cause while you may be able  
13 to, and I heard Steve say, you may be able to  
14 reasonably conclude that if someone says it's the  
15 same, it's safe. Okay, but someone says it the same,  
16 says it's the same doesn't provide the Agency or  
17 anyone else specifications that the product is exactly  
18 the same, that it's made the same, that it doesn't  
19 have solvents that could be a problem, impurities that  
20 could be a problem, etc. and so forth.

21 So I think this is really the biggest  
22 challenge when we talk about NDIs is, are the

1 knockoffs. There's 900 NDIs filed and, Steve, I  
2 think, you know, I, I like the mathematical exercise.  
3 I don't know that I agree with it, that 4,600 that  
4 should have filed, but okay, the bottom line is this,  
5 I don't think that people are going to file unless  
6 there's a strong enforcement component.

7           And it's really simple. These are all  
8 enforcement components the Agency has. Some of them  
9 are actually NDIs. The claim on kratom, it's not that  
10 it's unsafe. It's actually, it's actually held  
11 because it doesn't have an NDI, under 402(f)(1)(B).  
12 Sorry. I hate, I like to walk. This mic doesn't walk  
13 with me.

14           These are all import alerts that the  
15 Agency has in place that, again, there's, there's  
16 really -- this is on firms to show they're compliant  
17 with the law, not for the Agency to show that firms  
18 are noncompliant with the law. This can be done. It  
19 has been done already in NDIs, but not specific NDIs,  
20 not in kind of a bolus or broad fashion on anyone who  
21 has an NDI. If there is someone knocking them off,  
22 why aren't they held up until they show the Agency



1 that it is the same?

2 Simple. Not a big resource burden and  
3 for the life of us we can't understand why this isn't  
4 being done on a frequent manner. I understand there  
5 may be some legal arguments, but if someone has the  
6 product, the product is the same as what's been  
7 submitted, it should be relatively easy import to show  
8 the Agency that it is the same. That shouldn't be a  
9 big ask on routine in other parts of the Agency too.  
10 So, and again, these are all import alerts that are  
11 currently proffered that, again, very little resource  
12 burn on the Agency.

13 So, and if we go through them, so 5411  
14 import alert references NDIs, androstenedione, and  
15 again they never filed androstenedione. So it gets  
16 held up, 350(b)(A)2 and 21 CFR 190.6. So this is,  
17 again, there's precedent there. It's just not being  
18 done in a more routine fashion to other NDIs.

19 Dietary supplements as well. You know,  
20 this is where I think there should be some concern  
21 because if it's not a priority of the Agency they go,  
22 well, wait a second, it's adulterated, but it's not

1 adulterated. Well, it's a technical adulteration.  
2 Failing to file is a technical adulteration. Not  
3 meeting GMPs is also a technical adulteration. So  
4 there's an import alert for all products that don't  
5 meet GMPs. It seems that there's somewhat of a  
6 picking favorites of which part of the statute people  
7 choose to enforce or not enforce and I think that that  
8 should cause some concern here. And there's  
9 Mitragynine speciose, and again, kratom, and again the  
10 kratom charge is failing to file an NDI. While there  
11 is information on the safety, it is that they didn't  
12 file an NDI.

13 So -- and I'm very lucky. We've got a  
14 very good board chair, Mark LeDoux, and he's going to  
15 make some comments later, but I think certainly when  
16 you're hearing from groups in the industry that feel  
17 like this is the appropriate time, while Mark is the  
18 leading provider of this particular amino acid, there  
19 are others out there making it, bringing it into the  
20 country routinely, and we don't know what's in it.  
21 And yet it comes in the country freely and no one  
22 seems to mind. Kind of a problem. Knockoff

1 ingredients may purport to be the same, but there's no  
2 way of knowing until they provide the Agency with that  
3 sort of information.

4 So we'd like to and certainly look  
5 forward to working with the Agency on submitting some  
6 other NDIs or a bolus import alert for NDI so this  
7 happens in a matter of course routinely. We think  
8 it's important and we think it's really the only way  
9 you get at some of these issues that are present as it  
10 pertains to the guidance, and more importantly what's  
11 in the statute.

12 So with that I will shut up and turn it  
13 over to Andrew.

14 MR. SHAO: Let's see. Is this working?  
15 There we go. All right. Good afternoon, everyone.  
16 How's everyone doing? Good? All right. Well, I'm  
17 Andrew Shao with the Council for Responsible  
18 Nutrition. Grateful for the opportunity to have CRN  
19 provide some perspective on the topic here in this  
20 session. I'll be talking about three areas, three  
21 main areas you see here up on the slide to improve  
22 compliance with the notification requirement. One is

1 providing intellectual property protection, then  
2 reducing the NDI notification burden, and then finally  
3 conducting meaningful and effective enforcement.

4 So first is the challenges in this area,  
5 which I think is no secret to anybody, a lack of data  
6 protection, and previous speaker I think alluded to  
7 this a little bit. Past commenters have as well.

8 It's a disincentive for companies that  
9 do actually invest in generating science behind their  
10 ingredient, but the lack of protection of that data is  
11 a disincentive for them to participate in this process  
12 for the fear of having their ingredient get knocked  
13 off or the data that they use they've invested in  
14 generation of to be pirated by other ingredients that  
15 have no assurance of safety or maybe very little and  
16 not relate to the actual ingredient at all that was  
17 subject of a lot of research on safety. They get the  
18 benefit of pirating, pirating their data.

19 Another thing I'd like to bring up is  
20 the fact that it seems that FDA sees itself first and  
21 foremost as a protector of public safety, but not a  
22 protector of intellectual property. But these don't

1 have to be mutually exclusive. Incentivizing more NDI  
2 notifications fosters better assurance that these new  
3 ingredients and the products that contain them are  
4 safe. So actually ultimately public safety can be  
5 served by protecting the investments that ingredient  
6 manufacturers make in generating safety data.

7 So as an opportunity here you see the  
8 concept of the master file, which maybe is not so much  
9 of a concept anymore. So the opportunity is  
10 incentivizing ingredient manufacturers by vigorously  
11 protecting their investment in the generation of  
12 safety data. So the master file is a means of  
13 collecting and protecting data investments made by  
14 ingredient manufacturers specific to their products,  
15 and the master file can be used or cited by subsequent  
16 filers with permission or with licensing agreement as  
17 opposed to just showing up at the dock unannounced and  
18 claiming to be the same thing.

19 Another thing we might recommend is  
20 allow companies to reference NDI notification numbers  
21 of successful ones on labeling any marketing  
22 materials, that this may provide an incentive for

1 compliance with this provision. But really the most  
2 important thing is to vigorously defend and enforce  
3 the proper use of the master file to maintain its  
4 integrity and utility.

5 And I do also want to point out that  
6 when we talk about IP protection, it's not the same as  
7 exclusivity. It's protecting the investment that's  
8 made in the generation of safety data. It's not  
9 giving exclusivity on the ingredient itself. That's  
10 not what we're talking about with this concept.

11 Okay, next. Reducing the burden of NDI  
12 submissions, NDI and submissions. So I think, Steve,  
13 you addressed this in your opening remarks, so maybe  
14 this isn't so relevant now, but there I, I would say  
15 has been a misperception that every new dietary  
16 supplement contains an NDI and requires a separate  
17 notification. We just heard that that's really not  
18 FDA's view.

19 So we've seen some of these statistics  
20 before of the past, vast majority of the growth that  
21 we've witnessed here in the industry, it doesn't come  
22 from new dietary ingredients and for those that do

1 contain NDIs, duplicative finished products should not  
2 have to be notified if a valid notification already  
3 exists on file. So it provides little additional  
4 public protection and it's another thing that creates  
5 a barrier to participation in this process.

6 Another thing that's a barrier is  
7 industry is not clear when a, a notification is  
8 required and also what exactly needs to go into a  
9 notification. There's a number of notifications that  
10 are filed that are woefully incomplete. So for  
11 opportunities is permit ingredient manufacturers to  
12 determine the scope of their new dietary ingredient  
13 notification, establish a reasonable expectation of  
14 safety of the new dietary ingredient under a range of  
15 conditions of use that would cover different finished  
16 products.

17 There's also a confusion here between  
18 the, the NDI notification process and the GRAS  
19 process. We heard a little bit about it earlier today  
20 where foods that come under the market that contain a  
21 GRAS ingredient don't have to be notified, so there's  
22 a little disconnect there between these two processes.

1           Finally is to provide clarity in the  
2 guidance addressing requirements for new dietary  
3 ingredients to reduce objections due to lack of  
4 completeness. So some sort of template that walks the  
5 submitter through the specific areas of information  
6 that are needed to be included so that we avoid  
7 situations where there are objections due to  
8 incomplete notifications.

9           Okay. Finally is meaningful and  
10 effective enforcement. So there's a lack of perceived  
11 consequences for those who fail to comply with the  
12 provision, the NDI provision. That creates a  
13 disincentive for others to participate and contributes  
14 to a lot of confusion as we've already heard.

15           So another challenge is that FDA has  
16 limited resources. So if something doesn't pose a  
17 safety concern, it's unlikely to be addressed. I  
18 think that's a, a challenge we'll have to continue to  
19 work on, also mentioned earlier by Steve.

20           Another thing is discovery of a, of a,  
21 an API in a product results in referral to that  
22 product over to CDER because it's not a food and it's



1 not a supplement. It's an unapproved drug and so it  
2 goes over to CDER and then CFSAN seems to lose  
3 control, lose continuity of the enforcement process.

4 And then there's the perceived stakes  
5 in, of pursuing full investigation, prosecution. It  
6 discourages FDA legal action beyond some basic steps  
7 because it's resource-intensive. So the first  
8 opportunity, consider using mandatory recall might be  
9 a stretch. FDA has mandatory recall authority under  
10 FSMA. Products containing NDIs as we just heard from  
11 Dan that have not been notified are adulterated, may  
12 be considered adulterated.

13 There is a second requirement for a  
14 mandatory recall and that's establishing, the acronym  
15 is SAHCODHA or a serious adverse health consequence.  
16 That could be challenging for certain new dietary  
17 ingredients.

18 The next opportunity, mandatory product  
19 listing. So this is not a cure all, it's not a catch  
20 all, it's not a, a complete solution in and of itself,  
21 but it would in concept allow for easier  
22 identification of noncompliant products. But there

1 have to be consequences. If there is a mandatory  
2 listing there have to be consequences for lack of  
3 participation. So a voluntary system that everyone  
4 knows about of course, supplement OWL, certainly a  
5 worthy effort, but not very effective without  
6 consequences for failure to list. So this is a very  
7 important thing that we all have to keep in mind. FDA  
8 has to be prepared with the resources and the resolve  
9 to address violators if a mandatory product listing  
10 is, requirement is created.

11 Finally, wrapping up with meaningful  
12 effective enforcement. FDA should utilize its other  
13 enforcement tools including, but not limited to  
14 warning letters such as untitled letters, seizure,  
15 authority to initiate misdemeanor proceedings,  
16 administrative detention, fines, disgorgement of  
17 profits. That should, that's a typo. That should be  
18 debarment, not disbarment; although, maybe there are  
19 some attorneys that should be disbarred for advising  
20 their clients not to file notifications. But that  
21 should be debarment, not disbarment, and then  
22 injunction.

1           FDA should enforce through CFSAN all  
2 products that are represented to be dietary  
3 supplements. So even if they are products  
4 masquerading as dietary supplements because they have  
5 unapproved drugs in them, they shouldn't be kicked  
6 over to CDER. If they represent themselves with a  
7 supplement facts panel, we should treat them  
8 accordingly and CFSAN should retain control over that  
9 for more consistent enforcement.

10           Work with state partners such as  
11 attorneys general to increase enforcement activity.  
12 And FDA itself should, the Agency overall should be  
13 requesting additional funding to the Office of Dietary  
14 Supplement programs.

15           So with that I thank you for your  
16 attention and thank you very much, Steve.

17           MR. SIEGNER: Well it's an honor, an  
18 honor to be here and I'd like to thank Cara and Steve  
19 for organizing this meeting. I began practicing in  
20 the food and drug area in 1986 and primarily spent my  
21 first four or five years litigating cases against FDA  
22 on, on GRAS food additive issues and that was mainly

1 surrounding evening primrose oil which it's, it's a  
2 longer story I won't get into here, but led to the  
3 black currant oil decisions that helped kind of lead  
4 to DSHEA. And I'm, I'm just curious, how many people  
5 here, show of hands, had some input into the drafting  
6 of DSHEA? Maybe paying legal bills as this business  
7 person or writing? So we, we have a fair number.

8 A couple of people that haven't been  
9 mentioned here I would like to mention. One is Peter  
10 Reinecke, who is with us today, was the point person  
11 on Harkin, Harkin's staff during this whole exciting  
12 time. The other I would mention is Steve McNamara, my  
13 partner, who is, when he was practicing one of the  
14 giants in, in food and drug area. He's a great man.

15 So my assignment here today is pretty  
16 narrow and I've already heard four people who I would  
17 view as experts, either agree or disagree with the  
18 position I'm about to take. So it's interesting that  
19 we're still 25 years out debating some of these kind  
20 of basic concepts within DSHEA and what is an NDI and  
21 what isn't an NDI and when do you need to notify, so.

22 Okay. Let's see. Which button am I

1 supposed to push here? Okay. So I put this -- I, I  
2 originally drafted a long answer to this question. I  
3 said, well, okay, everybody knows lawyers can give  
4 long answers. Why don't you just put a short answer  
5 in. So my job here today is to explain whether I view  
6 that there is a, some type of market exclusivity  
7 provided under DSHEA, specifically in the present in  
8 the food supply exemption to notification filing and  
9 I'd say, no; although, being a lawyer I, I would put  
10 an asterisk there and I'll explain where, what the  
11 asterisk means later.

12 So a little, a little bit of history.  
13 I, I, I say here that FDA has struggled with how best  
14 to address dietary supplements. The other way you  
15 could frame that is FDA is truly in kind of an  
16 uncomfortable position. With respect to supplements  
17 if you have a, as a continuum a pre-market here, and  
18 pre-market approval here I'm getting, you know, it  
19 just easier for FDA to talk about products and, and  
20 agree with products and to support products that are  
21 pre-market approved.

22 Well, we're somewhere in the middle

1 here. Okay? We're expecting FDA to assure safety of  
2 the products without pre-market approval and that  
3 obviously has led over decades up to some difficulties  
4 for FDA and some attempts to kind of say, well, how  
5 can we get a better grip on this.

6 Congress has a couple of times pushed  
7 back with the Proxmire Amendments. Back in the '70s  
8 FDA came up with the idea that dietary supplements  
9 over, or vitamins and minerals over a certain dosage  
10 amount should be drugs. And basically Congress said  
11 no.

12 And then it was actually a, a partner of  
13 mine who before being a partner was a commissioner at  
14 FDA -- I'm sorry, general counsel at FDA, Tom  
15 Scarlett, who came up with the idea, well, we could  
16 use the food additive amendments to better confine the  
17 industry and declare some of these ingredients that  
18 are coming out that are new as unapproved food  
19 additives, which led to the whole GRAS food additive  
20 litigation and, and eventually to DSHEA.

21 And if I, I have a link to our blog and  
22 there's a post on here that kind of goes more into the

1 depth of that history. So, you know, it's -- given  
2 where we are, and we're kind of in this continuum with  
3 FDA pushing toward approval and industry and others  
4 may be pushing toward more of a free market, we're  
5 still debating a lot of these issues.

6 So it's important to understand when  
7 we're talking about this concept of market protection  
8 or exclusivity to understand where did, where did the  
9 -- you know, DSHEA did evolve from something and it  
10 really did evolve from the whole concept of GRAS  
11 affirmations, GRAS, GRAS self-affirmations, FDA  
12 affirmations, food additive approvals, and that these  
13 are ingredient-based ideas, okay?

14 So what we're trying to assure here is  
15 the safety of an ingredient and the identity of the  
16 ingredient is very important. Now sometimes the  
17 identity is very easy, albeit there may be SIS  
18 transformations and I think those are important, but  
19 when we're dealing with herbal extracts it, it can be  
20 much more difficult. But ,nonetheless it's still an  
21 ingredient-based concept and in my view that leads us  
22 into this presence of the food supply, it's the

1 ingredient that is the issue here.

2           So what is -- just, quickly, this slide  
3 just quotes the exemption. So you do not need to file  
4 a notification for a dietary supplement that contains  
5 only the dietary ingredients which have been present  
6 in the food supply as an article that is used for food  
7 in the form -- okay. The rest of that deals with  
8 chemical alteration and I don't want to get into that.

9           But there's, this -- you could base a  
10 whole legal career on this one sentence. I mean  
11 there's so many ways that I can be creative with this.  
12 But I think one way that I, I don't need to be  
13 creative is the question when we talk about food  
14 supply and we talk about used for food, what does that  
15 mean because the Food, Drug, and Cosmetic Act defines  
16 the term food as a dietary -- sorry. Defines the --  
17 states that a dietary supplement shall be deemed to be  
18 a food within the meaning of this act.

19           So in my view this is actually part of  
20 the simple part of this definition or this sentence.  
21 When we're talking about foods and food supply, we  
22 don't just mean conventional foods. We mean both



1 conventional foods and dietary supplements and  
2 dietary, dietary ingredients in dietary supplements.

3           Now I, and I'm not going to go into at  
4 length what FDA has said about this, but briefly  
5 they've said that this is not, that the case -- sorry.  
6 The slide -- I am ahead of myself here. That  
7 basically it's just conventional foods. Food supply  
8 is conventional foods. In this -- if you follow that  
9 interpretation it would provide some market incentive.  
10 You go ahead and file an NDI for your ingredient and  
11 you go on the market, then the subsequent manufacturer  
12 making the same ingredient would need to also file a  
13 notification.

14           Now there's ways to make that easier.  
15 It's not a great protection to the market, but in my  
16 view it's actually no protection because in my view  
17 the subsequent manufacturer can go onto the market as  
18 long as the ingredient is identical to the ingredient  
19 that's already been notified. So again, once an  
20 ingredient's been notified, in my interpretation you  
21 can go ahead and market.

22           And I'd like to point out that this is,

1 it's not a novel concept. This is how the GRAS  
2 process works. This is how the food additive process  
3 works. The importance, again, is ingredient safety  
4 and it's not an exclusivity issue.

5 So I, I, I do want to say kind of in  
6 closing that we're talking here about promoting a  
7 compliance overall and the important thing to me in  
8 promoting compliance is to try to simplify what the  
9 NDI process is and what is and is not an NDI and how  
10 to go through notification, what you need to, to  
11 submit to FDA and when you need to submit it.

12 Unfortunately, what we're seeing here is  
13 there's so much confusion surrounding these draft  
14 guidances that it is forcing companies seeking  
15 alternative routes to go through the GRAS process.  
16 And ironically DSHEA was intended to cure that process  
17 and to avoid having to, people to go through the GRAS  
18 process.

19 I, I have different view of the GRAS  
20 process than some other speakers here. I actually  
21 think it's a very good process. I think it works  
22 well. I think as one speaker noted even through the

1 kind of secret GRAS affirmation, self-affirmation  
2 process, we've had very few instances of safety  
3 issues. I think, you know, PHOs are maybe the only  
4 exemption section I can think of where ingredients  
5 have gone through self-GRAS and then subsequently been  
6 determined by FDA to be something that should be  
7 pulled back. And with that, thank you.

8 MR. SIROIS: So good afternoon,  
9 everyone. I'm Jay Sirois with the Consumer Healthcare  
10 Products Association, one of our five major trade  
11 associations in the dietary supplement space. I'd  
12 like to thank the FDA for holding this important  
13 public forum today to discuss responsible innovation  
14 and also for providing me an opportunity to present.

15 CHPA is a 138-year-old member-based  
16 association representing companies that market OTC  
17 drugs, some of whom are also involved in the dietary  
18 supplement space. We have a very active dietary  
19 supplements committee comprised of companies committed  
20 to manufacturing high quality products and marketing  
21 them in a responsible manner.

22 We appreciate the Agency's efforts in

1 looking at potential new pathways to strengthen  
2 regulation and perhaps develop new pathways for  
3 innovation. We share the commitment frequently  
4 espoused by the Agency that consumer safety, product  
5 integrity, and informed decision making by consumers  
6 are paramount.

7 I'd like to briefly share with you some  
8 of the items our supplement committee has been  
9 discussing over the past year and I will note first  
10 that these are topics of discussion within our  
11 association, and again, I'll note that we share the  
12 Agency's commitment to, to safety, integrity, and  
13 informed decision making. We have initiated outreach  
14 efforts to other stakeholders in the supplement  
15 industry to discuss these items as the industry seeks  
16 to chart a path of responsible growth while ensuring  
17 that consumers have access to appropriately labeled  
18 quality products marketed in a responsible fashion.

19 In the spirit of the statement issued by  
20 Dr. Gottlieb back in February and, and, and reiterated  
21 this morning by Dr. Sharpless, we believe an  
22 appropriate balance can be struck between fostering

1 the development of innovative products while  
2 maintaining the, the commitment to FDA's three  
3 priorities.

4 So mandatory product listing, of course,  
5 as you've heard, has been a hot topic of discussion in  
6 the industry and FDA is noted that they are unable to  
7 determine what products are sold in the US market  
8 hampering their ability to act against dangerous  
9 and/or illegal products. Listing could provide  
10 greater transparency into the marketplace and perhaps  
11 FDA allow them to better enforce against violative  
12 products.

13 FDA has estimated that there are over  
14 9,000 dietary supplement facilities worldwide and in  
15 fiscal year '18, 2018 inspected less than 10% of  
16 those. Poor quality or adulterated products can lead  
17 to greater consumer safety risk, a black eye for the  
18 whole category, and a significant increase of FDA  
19 inspections through authorization of, FDA  
20 authorization of third party GMP inspectors could  
21 perhaps increase the number of inspections and make  
22 certain of the retailer requirements that have

1 proliferated become unnecessary.

2                   We know that FDA devotes approximately 5  
3 million dollars to regulate the 40 billion dollar  
4 dietary supplement industry and we know that  
5 insufficient FDA oversight due to a lack of funds can  
6 diminish consumer confidence in the industry. So I  
7 think there's widespread support for increased funding  
8 for the Agency throughout the associations.

9                   Innovation. We know that that is  
10 hampered by the current NDI process since companies  
11 are reluctant to take on the expense of testing as  
12 Andrew described, that it's required for an NDI  
13 application as the data subsequently become public.  
14 FDA has also expressed concern as you just heard that  
15 the number of NDI submissions is far below what they  
16 would expect.

17                   So one proposed fix to both of these  
18 issues is for FDA to implement the master file process  
19 whereby FDA would hold data submitted in support of an  
20 NDI notification confidential and require subsequent  
21 companies wishing to market that ingredient to either  
22 submit their own data in support of, of an NDI or to

1 obtain permission from the innovator company and  
2 submit a one page NDI, or NDI notification informing  
3 FDA that they have permission from the innovator  
4 company to rely on that information.

5 This would foster innovation and occur  
6 as a development of conduct of high quality safety  
7 studies and provide an innovation incentive as the  
8 initial company would have early entry into the  
9 market. It would also address FDA's stated desire for  
10 all companies submitting an NDI to submit  
11 notification. And I'll speak more on this in a bit.

12 The definition of a dietary ingredient,  
13 or excuse me, a dietary supplement, includes a dietary  
14 substance for use by man to supplement the diet by  
15 increasing the dietary intake. We know that Congress  
16 removed the term nutritional substance from the  
17 definition in order to not restrict ingredients to  
18 those substances with nutritional value where they  
19 were naturally occurring, and you heard Scott Bass  
20 speak of this, this morning.

21 FDA's restrictive interpretation of what  
22 constitute a dietary substance, to mean a substance

1 that's commonly used as food or drink, limits  
2 innovation and requires clarification.

3           Structured function claims right now we  
4 know comprise the majority of, of the claims that are  
5 found on supplement products. However, many dietary  
6 supplement products are used to help manage conditions  
7 and their symptoms without direct claims. Product  
8 innovation and the public health would be better  
9 served if claims for these specific benefits were  
10 permitted, of course, with the appropriate level of  
11 substantiation and the demonstration of safety.

12           And lastly, we encourage the FDA to  
13 finalize the authorization of an old list, or the list  
14 of old dietary ingredients and to consider moving the  
15 date for inclusion on the list to perhaps a more  
16 recent time for those ingredients with a demonstrated  
17 history of safety.

18           So at the risk of sounding repetitive,  
19 and I promise that Andrew and I did not copy term  
20 papers, I'm going to, I'm going to talk about the NDI  
21 master file process.

22           So we're convened here today to discuss



1 possible ways to foster innovation while increasing  
2 compliance with the notification requirement, and  
3 again we know the cost associated with preparing and  
4 submitting an NDI notification including the cost of  
5 safety studies can be hundreds of thousands of dollars  
6 and companies are often reluctant to incur these as  
7 subsequent entrance to the market can basically market  
8 the ingredient without having to incur the costs.

9           So one possible mechanism to encourage  
10 innovative safety studies and to enhance NDI  
11 notifications submitted was to -- this was described  
12 in the 2016 NDI guidance on NDIs. Under this master  
13 file concept the innovator company would conduct the  
14 appropriate safety studies, submit the notification,  
15 and the FDA would keep the data and information  
16 confidential in a quote, unquote, "master file."

17           Following the receipt of a good day  
18 letter by the innovator company, subsequent companies  
19 wishing to enter the market and to market the new  
20 ingredient in a supplement would have to do one of two  
21 things. Either perform their own safety studies on  
22 the ingredient, defining the conditions of safe use,

1 followed by the subsequent submission of a  
2 notification, or alternatively they could obtain a  
3 right of reference from the innovator company. And in  
4 the latter case that company would submit a one page  
5 notification to FDA signifying that they had been  
6 granted access to the master file from the innovator.  
7 This would reduce the burden on industry in terms of  
8 submitting duplicative NDI notifications, but it would  
9 also satisfy the FDA's call for increased numbers of,  
10 of notifications.

11 The NDI master file process would also  
12 provide for a de facto marketing advantage for those  
13 companies filing a, a, a, an innovator NDIN and would  
14 ensure that any responsibility for companies marketing  
15 an NDI to submit notification could potentially not be  
16 too onerous.

17 To implement the NDI master file process  
18 FDA would need to ensure that the safety information  
19 contained in the master file is treated as  
20 confidential and trade secret beyond the 90 day pre-  
21 market filing period so that it is only relied upon by  
22 those who are authorized, and as you've heard, needs

1 to take enforcement action as authorized under the  
2 Food, Drug, and Cosmetic Act against any entity  
3 marketing an NDI without a notification on file. Full  
4 implementation of the NDI master file would result in  
5 a de facto marketing advantage for the innovative  
6 company filing the initial notification.

7 We believe the NDI master file would  
8 allow for efficient filing of notifications and would  
9 also provide transparency into the NDI marketplace  
10 allowing FDA to better identify industry outliers.  
11 Similar to master files for other FDA regulated  
12 products, an NDI master file could contain information  
13 such as the owner's name, as well as composition and  
14 manufacturing information, and any unpublished safety  
15 studies on the NDI. Again, FDA would be responsible  
16 for protecting all of this confidential information.

17 Okay. There we go. Lastly, we believe  
18 this type of process would encourage the development  
19 and conduct of high quality safety studies supporting  
20 the marketing of the innovative products, but  
21 importantly there would be no lessening of the current  
22 requirement for demonstration of a reasonable

1 expectation of safety. Of course as with all the  
2 topics we've discussed here today, the devil's in the  
3 details, and in this case perhaps the most important  
4 devil would be how to prevent companies from marketing  
5 the me-too ingredients without either relying on the  
6 innovator company master file or through the  
7 performance of their own appropriate safety studies  
8 and subsequent submission of a notification. We  
9 believe that FDA and industry must work together to  
10 find solutions to this.

11 To conclude, by implementing the  
12 previously described NDI master file concept, FDA  
13 could allow for the development of responsible  
14 innovation by the industry while ensuring that  
15 notifications were submitted for all products  
16 containing a new dietary ingredient. To do this FDA  
17 would need to ensure that the contents of our master  
18 file are treated as confidential trade secret  
19 information including unpublished safety studies, and  
20 would need to commit to a robust enforcement action  
21 against entities marketing dietary supplements  
22 containing NDIs that have not been a subject of a

1 notification. Thank you.

2 (APPLAUSE.)

3 MS. ESKIN: You're just going to have to  
4 stare at the slide 'cause I don't have any. Good  
5 afternoon. I, too, would like to begin by thanking  
6 FDA for holding this meeting and for inviting Pew to  
7 participate.

8 I'm often asked what is The Pew  
9 Charitable Trusts. It is a public charity. The  
10 funding came from the children and grandchildren of  
11 the founder of Sun Oil or Sunoco. We focus on  
12 evidence-based solutions to today's greatest  
13 challenges, and maybe not the greatest, but important  
14 ones like how to figure out NDI compliance and  
15 incentives.

16 So our focus on food safety on -- I do  
17 food safety too. Our focus on supplements is on  
18 safety, which has to be an essential component of  
19 innovation. It will be the focus of my comments and  
20 it has been raised by many other speakers today.

21 So consumers who use dietary supplements  
22 should have assurances that the products they buy are

1 safe, high quality, and accurately labeled. I will  
2 focus on three points today. Again, there's been a  
3 lot of, of common points raised and so you've probably  
4 heard some if not all of these before.

5 One is the general concept of marketing  
6 advantage in this context. The importance of  
7 effective enforcement and one thing that I think began  
8 the discussion this morning thanks to Scott's  
9 presentation, mandatory product listing.

10 So again, first, regarding market  
11 advantages, if FDA comes up with a way to create a  
12 marketing advantage whether it's a master file or some  
13 other concept to incentivize compliance with the NDI  
14 system, we ask that along with it, the, the Agency  
15 explore ways to incentivize research related to  
16 ingredient safety. It is absolutely critical that  
17 that be encouraged.

18 At the very least any marketing  
19 advantage should in no way dilute the safety standard  
20 in the NDI notification process. We've heard what  
21 that standard is. The product should be, it should  
22 reasonably expect it to be safe under the supplement's

1 labeled conditions of use.

2 And I think Larisa mentioned it this  
3 morning in her presentation. Only the NDI safety  
4 standard, which is provided in the NDI process, right,  
5 provides FDA with pre-market authority to stop the  
6 sale of a supplement that includes a potentially  
7 unsafe new dietary ingredient. All the other safety  
8 provisions, and there are numerous, are all post-  
9 market.

10 Second, regarding enforcement and its  
11 role in promoting compliance, I think everybody  
12 believes that it needs to be strengthened and I'm  
13 going to mention two things that have been mentioned  
14 before, but they bear repeating, please finalize the  
15 August 2016 guidance on NDIs. This will give needed  
16 clarity and it will make, it will hopefully enable  
17 companies to meet the requirements of the law easy,  
18 more easily.

19 Number two, you need to have more  
20 resources. Not endless resources, but more resources  
21 than the Agency has currently provided to ODSP. And  
22 Pew has been working with other advocacy groups like

1 CSPI. We've been working with CRN and other trade  
2 associations and CHPA to work to get FDA's supplement  
3 program more money. I think we've had some success in  
4 the last year and I think we have to continue to do  
5 that because that is the only way you will see  
6 anything that looks more robust than what you're able  
7 to do in the current resource environment.

8 Okay. So third, mandatory product  
9 listing. A number of the panelists here this  
10 afternoon have mentioned it. To do its job, FDA needs  
11 to have a comprehensive picture of what's on the  
12 market. As we've heard, we've gone from 4,000 or so  
13 products in 1994 to as many as 80,000 products. The  
14 tool that will enable FDA to effectively carry out its  
15 existing authorities -- again, it's not greater  
16 authority, it's just a tool that let's it exercise  
17 what the law currently provides it -- is a listing  
18 requirement.

19 Every manufacturer would be required to  
20 provide the Agency with basic information such as the  
21 product name, the ingredients, and the labels for  
22 every product that is sold. This tool is a win-win



1 for almost everyone. It will enable FDA to determine  
2 compliance probably pretty quickly with NDI  
3 notification process and other requirements.  
4 Consumers would be able to identify reputable  
5 supplement products, and retailers would have an  
6 assurance with being able to only sell products that  
7 are produced by companies that are on FDA's radar  
8 screen and that are compliant with the law. Thank  
9 you.

10 (APPLAUSE.)

11 MR. TAVE: Thank you to each of our  
12 panelists for the (inaudible) and for taking part in  
13 Q&A. (Inaudible.) So that is before we (inaudible)  
14 and I will pay attention (inaudible) questions that  
15 are (inaudible). So we can start with Mr. Bass. And  
16 again, just a reminder, please, give name and location  
17 (inaudible).

18 MR. BASS: Scott Bass, Sidney Austin.  
19 It's a kind of question; though I would say it's  
20 rhetorical, but can I ask you all. We all agree that  
21 Section 413 -- is there anybody in the room who  
22 disagrees it's a horribly written section? Nobody.

1 That was the subject of so much (inaudible), but when  
2 I hear people say that nobody else has to file, I just  
3 want you to understand today the responses I hear.

4 This section came about because a year  
5 earlier there was a version that said everything was  
6 grandfathered before '93. Everything after it had to  
7 have (inaudible) approval. This was the compromise,  
8 but the word everything is the key and the one word  
9 that tells you why everybody has to file an NDI is L-  
10 tryptophan.

11 Are you going to relay upon a sleazy  
12 second comer and say, oh, it's identical? No. FDA  
13 has to know the manufacturing method because if it's  
14 different from the first product that got an NDI, we  
15 could have another L-tryptophan episode. If the FDA  
16 does not know full composition and manufacturing  
17 method (inaudible) filing, they're letting product on  
18 the market with the manufacturer saying it's  
19 identical, but you have no proof of that.

20 And that's why the entire scheme -- and  
21 to say -- and I, I know we have a legal disagreement  
22 here, that a dietary supplement is food under 413's

1 exemption for commonly food that's used by humans and  
2 not chemically altered, but that writes 413 out of  
3 existence (inaudible).

4 So I just wanted to ask, Steve, if the  
5 FDA believes other than what the (inaudible) that  
6 calls itself GRAS that if there's any reason not to  
7 require everybody to file even if it's a one line NDI  
8 saying I'm filing pursuant to the master file  
9 (inaudible) the first company.

10 MR. TAVE: Well, that's a broad  
11 question. I don't know if I can give an authoritative  
12 answer to everything. I mean, I, I think -- you know,  
13 I said before it's not (inaudible) that everybody on  
14 the market needs to file a notification. Our view is  
15 that a notification should be filed for the products  
16 (inaudible) and that's a somewhat circular answer.

17 I want to ask something about your  
18 question. I want to open it up to the panelists, but  
19 it, it sounds like you're suggesting that a  
20 manufacturing process change requires a new  
21 notification requirement, and that was my  
22 understanding of stakeholder positions after we

1 released the draft guidance in 2016. So I'm curious -  
2 -

3 MR. BASS: Depends on the change. It  
4 depends on the change. It's mostly a GMP issue. If  
5 you have filed a full NDI notification GMP is supposed  
6 to cover major changes especially (inaudible)  
7 controlled, controlled guidance which applies to  
8 drugs, devices, and food.

9 MR. TAVE: But is it mostly (inaudible)  
10 and can we use that (inaudible) cooperation charge for  
11 (inaudible)?

12 MR. BASS: Not if it's somebody who  
13 already filed a full NDI. But certainly for a  
14 subsequent company who didn't file, absolutely.

15 MR. TAVE: (Inaudible.)

16 MR. FABRICANT: I don't even think you  
17 need that. It's a subsequent, it's, it's not --  
18 there's nothing in the statute that says if somebody  
19 files everyone just gets to ride on it. I mean I  
20 don't know where the heck that interpretation's coming  
21 from. It, it's specific to the ingredient.

22 You can talk about safety, that's fine,

1 but there's an identity to any ingredient. If one  
2 person makes an ingredient, Cara makes an ingredient,  
3 (inaudible) makes an -- she can say it's the same  
4 ingredient, but I guarantee you (inaudible) different.  
5 That's part of the 190.6. So that's the trigger. You  
6 don't need to know the trigger.

7 MR. BASS: That's a better answer than  
8 mine. Thank you.

9 MR. FABRICANT: I know. You're an  
10 attorney.

11 MR. SIROIS: So I, I don't, you know,  
12 one, another way to look at this is, okay, so you have  
13 the whole GRAS process. You know, obviously we're all  
14 concerned about L-tryptophan. Scott and I and a few  
15 others were involved in trying the parse out the, you  
16 know, the, the destruction of the, of everything after  
17 that and, and how to figure out how do we assure that  
18 things are safe, particularly when I don't think we  
19 ever really pinned down exactly what, what caused the  
20 L-tryptophan problem in, in the first place.

21 So there was a time where nobody wanted  
22 to market L-tryptophan because it, you know, we didn't

1 know for a long time, and eventually, you know, L-  
2 tryptophan came back on the market and it's, it's  
3 there (inaudible).

4 So we, we have, we have these issues, L-  
5 tryptophan may be a, an outlier, but that doesn't mean  
6 we don't worry about them and we worry about them in  
7 the context of GRAS self-affirmation also. But, you  
8 know, in -- we have ways, much better ways these days  
9 of determining which, what the ingredient is and how  
10 it's made. I, you know, I, I still think the law's  
11 pretty clear in terms of what, who, who's (inaudible).  
12 Maybe Justice Scalia would agree. (Inaudible.)

13 MR. SCHONEKER: Dave Schoneker from  
14 Colorcon. I'm also very involved with the  
15 International Pharmaceutical Excipients Council and I  
16 guess I, I'd like to sort of do an analogy here a  
17 little bit and get your thoughts. Let's not reinvent  
18 the wheel, okay? A lot of what we've heard here about  
19 the concepts of master file exclusivity, etc., I have  
20 to say (inaudible).

21 We've already got the same system on the  
22 drug side that we could just incorporate here. It's

1 all about ingredients, right? So if you look at  
2 excipients, we're very familiar, okay? We already  
3 have a typed (inaudible) excipient or master file that  
4 is used for exactly what we're talking about here.  
5 Anybody who develops a novel excipient, it's never  
6 been used in a drug before, it's going to have to be  
7 reviewed by the Agency as part of drug a application,  
8 or at some point you do massive amounts of safety  
9 studies, etc.

10           You have a lot of, you know, innovation  
11 and a lot, a lot of investment by a particular  
12 excipient company. They put all that safety data in  
13 (inaudible) drug master file it is, it doesn't give  
14 you any exclusivity, but your safety studies are  
15 protected in a drug master file. Your specifications  
16 are, are protected in a drug master file until such  
17 time that you want to get a monograph or make it  
18 public, which is at your bidding whenever you want  
19 that, okay?

20           And then if anybody else wants to make  
21 that material, they have to file (inaudible) drug  
22 master file, do their own safety data and their own

1 specifications, and, and get reviewed in, in, in, in a  
2 drug application later on.

3 So it seems to me that you've already  
4 got a system that does almost exactly what I heard Jay  
5 outline and I know Andrew is pretty much in line with  
6 that, which seems to give us everything we're looking  
7 for to help give innovation.

8 I could tell you from an excipient  
9 company's perspective if we didn't have that type 4  
10 drug master file system, there would be no new  
11 excipients. Nobody is going to do millions of dollars  
12 (inaudible) studies and expose themselves to somebody  
13 just taking notes and using them. And, and, you know,  
14 the master file system we have works very well in  
15 terms of protection of the data and, and allowing a  
16 company (inaudible) that information.

17 And we have some other issues  
18 (inaudible) in terms of having the ability to have an  
19 independent qualification of that data like in the  
20 new, in the I (ph) system. We wish we had that there  
21 in the drug side. You got to put all of it in there.  
22 Then you have to wait for some drug company to



1 actually decide they want to put in a drug  
2 application, and at that point your file gets  
3 reviewed.

4 That part I don't like and isn't  
5 working, okay? But the concept of protecting the data  
6 and, and, and providing that protection and innovation  
7 incentive is already there.

8 So what would it take to put a system  
9 like that in place here? It seems like to me the  
10 (inaudible) there. It's a matter of is there some  
11 sort of legislation that's needed to do this? Is it  
12 just a matter of somebody coming up with a system to  
13 manage the DMF?

14 We could learn from the CDER guys. They  
15 already have it. It's all electronic (inaudible)  
16 master file system. You just copy and paste. So I'd  
17 be interested, especially, Steve, your thoughts about  
18 what would it take to institute a system basically  
19 copying a type 4 (inaudible) master process and put in  
20 place for this and why not. Let's learn from what  
21 we've already got (inaudible).

22 DR. TAVE: Thank you for your question.

1 (Inaudible) we'll make sure everybody has a chance.  
2 So I, I don't know (inaudible) to the extent that I've  
3 worked (inaudible), but I, I (inaudible) had a  
4 question earlier (inaudible). And that is a point  
5 that I didn't get a chance to linger over, but we were  
6 never a one size fits all (inaudible) explaining again  
7 the differences from a previous (inaudible).

8 Andrew had some points during his  
9 presentation especially on master files to where  
10 (inaudible). We probably couldn't have done a better  
11 job of (inaudible) some of these things are things  
12 that (inaudible) and so we encourage firms to submit  
13 (inaudible) and it doesn't have to be (inaudible)  
14 product (inaudible).

15 We have no problems at all with firms  
16 (inaudible) their notification letting other people  
17 use that so there are ways to use the (inaudible) that  
18 are already in practice and we certainly (inaudible)  
19 and other communication with our office if somebody is  
20 interested.

21 One challenge (inaudible) is  
22 confidentiality and I think, you know, where we accept

1 is the statutory system under 413 requires us to  
2 disclose an application (inaudible) or 90 days after  
3 we receive a completed application (inaudible).

4 And so when we want the master file to  
5 be reviewed that there is an obligation on our part to  
6 (inaudible) as possible and I understand that. I  
7 don't know (inaudible) the Agency necessarily because  
8 (inaudible) and we wouldn't be able (inaudible). So I  
9 think, you know, in terms of what's not in place right  
10 now, but that could be different (inaudible).

11 MR. SHAO: The, the only thing I would  
12 say -- this is Andrew with CRN, and I would say follow  
13 up comment is a big question is what does, what, what  
14 would the FDA do if an ingredient manufacturer went to  
15 market and failed to file a notification assuming it  
16 was identical to a previously notified (inaudible)  
17 ingredient that the confidential information which was  
18 maintained in the master file.

19 So in other words, would FDA go out and  
20 enforce to maintain the integrity and the utility  
21 master file in that situation, or would it say, well,  
22 you know, the ingredients appear to be the same, so

1 we'll just let it go? More of a question than a  
2 comment.

3 MR. TAVE: No, it's a fair question and  
4 I think, you know, it's impossible to answer  
5 (inaudible) with certainty that philosophically that's  
6 a case where we would want to take enforcing action.  
7 The (inaudible) between philosophy and reality is  
8 where it gets difficult and becomes less, you know,  
9 (inaudible), you know. And, and so we have the  
10 likelihood that we would be able to prevail the  
11 willingness of (inaudible). So there's a lot of  
12 (inaudible), but it certainly is a fair question.

13 MR. SIROIS: So I'll, I'll reiterate a  
14 couple of points (inaudible) and Andrew (inaudible)  
15 said this in his comments, the use of the E word.  
16 We're definitely not talking about that in this  
17 context. It's an, it's an incentive for a company to  
18 have to do this, to do these innovative (inaudible)  
19 studies and to be the first to submit a notification,  
20 but in no way would this be, you know, I want to use  
21 the word (inaudible) and I can't, can't say the study,  
22 study number or it's an innovation incentive for that

1 company that files the initial notification, but I'll  
2 leave this to the lawyers in the room to argue about  
3 how to, you know, go about the provisions in 413 and  
4 whether, you know, what needs to be disclosed or not,  
5 but there are many other master files.

6           You know, Dave, you alluded to the  
7 (inaudible) master file and I know there are several  
8 other examples of master file concepts that are, that  
9 are viewed as (inaudible). This requires a little  
10 more discussion, but we've heard from several folks  
11 here today (inaudible) mentioned it early in his, in  
12 his talk. Dan talked about it, Andrew, and myself so  
13 I think the discussion should be continued.

14           MR. MILLER: Mark Miller at INW  
15 Manufacturing and I've, I've enjoyed the discussion  
16 on, on primarily safety and, and the master file, but  
17 I'm drawn to the title of the event today which is  
18 innovation and who does innovation? Truly  
19 entrepreneurs. And they do it for a marketing  
20 advantage and I think that we haven't probably spent  
21 enough time thinking about either protecting or  
22 fostering some marketing advantage based on

1 innovation.

2 And so there's a sort of general  
3 question related to that and specifically just to sort  
4 of narrow it down, I think that we have a great need  
5 for clinical research to give us some comfort in both  
6 safety, but also efficacy and consumer responses and  
7 that should be encouraged.

8 Is there a way to sort of protect a  
9 company that devotes it's, it's efforts into really  
10 decent clinical research given the context that many  
11 consumers still want peer reviews so it's going to be  
12 in the public place? So there's no sort of hiding it  
13 in the file buried somewhere and, and allow you to  
14 have some degree of the E word.

15 So how do we, how do we engage with the  
16 consumers in an innovative way that, that, and  
17 encourage companies to do clinical research to, to  
18 show benefits as well as safety?

19 MR. TAVE: Nobody's jumping to answer  
20 that one. Is there a (inaudible) question.

21 MR. FABRICANT: I'm always happy to put  
22 my foot in my mouth. I think as far as FDA goes, that

1 the NDI process does -- and maybe not for, for, to  
2 some degree clinical research, but does -- I think the  
3 DNI process does have an, an avenue to, to reward  
4 people who are doing research and I think more and  
5 more you're seeing cases get turned over to FDC when  
6 folks are out there making claims and have no  
7 research.

8 So now that that's said, necessarily a  
9 way to incentivize, but I think you're dealing with a  
10 regulatory agency there. They're fresh out of  
11 carrots. They generally deal (inaudible). So I don't  
12 know that that would be something that (inaudible).

13 MR. TAVE: Please feel free to plant a  
14 garden for us (inaudible). I, I think it was an  
15 excellent question (inaudible), but your question is  
16 (inaudible) there are people out there who (inaudible)  
17 research and, and develop quality products and  
18 (inaudible) and that would make that worthwhile. So  
19 (inaudible). It was a good question. Let's -- I  
20 think take a few more questions and then (inaudible).

21 MR. GIANCASPARO: My name is Gabriel  
22 Giancasparo and I'm from US Pharmacopeia (inaudible)

1 here that product specifications are a way to compare  
2 different products in determining whether to stick  
3 with it or not.

4 So it is important then to have  
5 transparency about the (inaudible) specifications  
6 because otherwise what do people know about the same  
7 product or (inaudible) submit another NDI or who we  
8 intended (inaudible) NDI? So it's a possibility of  
9 considering also that within the (inaudible)  
10 information (inaudible) the specifications that make  
11 up (inaudible).

12 And therefore that way also the people  
13 (inaudible) can also get protection (inaudible) and  
14 somebody else comes in, it doesn't (inaudible) and it  
15 doesn't (inaudible) that product again (inaudible) our  
16 product specifications (inaudible) safety needs to be  
17 demonstrated (inaudible).

18 MR. SIEGNER: I think -- I'm not sure I  
19 completely understand that. I think -- so one of the  
20 things that when I was talking about the word he won't  
21 use, exclusivity, the -- or, or any kind of market,  
22 you know, advantage. I mean there are -- I think what



1 you've pointing at is that there are things that are  
2 important to ingredient safety such as an, and  
3 particularly in the herbal extract area that  
4 (inaudible) some of those (inaudible) where you can't  
5 make your ingredient unique.

6 It would also be important to the safety  
7 of the ingredient, but would also cause FDA to want to  
8 file your NDI notification. And, you know, so I'm  
9 not, I'm not trying to suggest that that's not  
10 important or that that could not lead to some kind of  
11 advantage for your ingredient under the way the law is  
12 written now. I'm not sure that that fits specifically  
13 what you're asking.

14 MR. GIANCASPARO: Yeah. (Inaudible)  
15 information, information goes into process, how and  
16 (inaudible) ingredient in the reviews and that doesn't  
17 need to be disclosed of course, but in terms of the  
18 determining the equivalency (inaudible) those things  
19 should not be (inaudible) in, in, in our reviews. It  
20 should be a (inaudible) specification so that, that  
21 the (inaudible) also the, the -- have the ability to  
22 know whether or not (inaudible) because the, the drug

1 ID (inaudible) specifications of an impurity requiring  
2 (inaudible) another safety (inaudible).

3 MR. SHAO: My name is Andrew Shao  
4 (inaudible). So today let's say companies that are  
5 paying attention see a notification is filed because  
6 it's public record, see that FDA hasn't objected, and  
7 then purport that their ingredient is the same and  
8 they go to market. So they are paying attention.  
9 They do know that a competitor has already filed a  
10 notice of successful notification.

11 So in a situation where specifications  
12 may make a difference between whether something is the  
13 same or different, they can go and contact that  
14 manufacturer and say, can we, you know, we're, we're  
15 trying to decide if we should file or not. You know,  
16 that's an approach that could be made. And if they  
17 had a master file system, they'd have to request  
18 permission. So they'd have to come to some sort of  
19 agreement.

20 So the, the process would require some  
21 amount of transparency for those companies that are  
22 paying attention already and deciding not to file

1 because the competitor already took care of it for  
2 them. So if we had the right system in place, they  
3 would have to go to that company and they'd have to  
4 exchange information before doing that.

5 MS. MACCLEERY: Laura MacCleery with  
6 Center for Science in the Public Interest. So I think  
7 we have a bit of a (inaudible) thing on GRAS. So I've  
8 heard several times that because there hasn't been any  
9 things that have been de-GRASed over time that there's  
10 no problem, and I would say, in fact, that is evidence  
11 of a problem.

12 You know, we all want to see absence of  
13 evidence of (inaudible), right. We filed a citizen  
14 petition which is what you have to do to De-GRAS a  
15 substance. (Inaudible) had 20 years before it  
16 actually was taken out of the GRAS-listed substances  
17 and FDA took interim steps of putting it on the label  
18 first. There's actually no systemic (inaudible)  
19 approach for reevaluating the safety of an approval of  
20 a GRAS substance or a food additive once it's put onto  
21 the listing or whether once, once there's been a  
22 notification filed on the GRAS case.

1                   And so that lack of a systemic look back  
2 has been a problem that we are trying to address as a  
3 community, with (inaudible) organizations. We filed  
4 petitions to withdraw approvals on food additives in  
5 recent years on perchlorated compounds, which was  
6 successful on perchlorate and potassium bromate which  
7 has been caught up in Agency delay. There's some  
8 interest in (inaudible). We won one on carcinogenic  
9 flavors and we have a pending petition on sugar 'cause  
10 we think that condition of use for sugar-sweetened  
11 beverages, of excessive amounts of sugar, is actually  
12 already (inaudible).

13                   But to get the Agency to do these  
14 things, at least the food additives side, you have a  
15 petition process and you're supposed to have a process  
16 by moving the decisions. On the GRAS side, you just  
17 set up the files (inaudible) petition and FDA can take  
18 as long as a week unless you sue them for delay.

19                   So I, I think there's a whole host of  
20 things that could be de-GRASed if there was an  
21 adequate system of look back, but there just isn't.  
22 And I don't want there to be a misunderstanding that

1 that absence of action by FDA, which we view to be  
2 deeply problematic, is actually evidence that the  
3 system works fine.

4 MR. TAVE: Okay. I'm, I'm looking  
5 (inaudible) to see if we have any questions from our  
6 monitor. We want to try to keep us a little bit on  
7 schedule and I'm not seeing any, but if we have any we  
8 can get them and we review them over time.

9 So we're already at the time where we  
10 were going to begin session five. How about, how  
11 about if we take a break and come back at 3:10; is  
12 that (inaudible)?

13 (SESSION BREAK.)

14 MR. TAVE: If we could start moving to  
15 our seats so we can move to the open public comment,  
16 please? That way we can make sure we get everybody  
17 out of here on time and on schedule. The lights are  
18 flickering. Wonderful. If we could get our panelists  
19 to the table and our speakers lined up and we'll do a  
20 very short introduction. (Inaudible - background  
21 noise). We will enforce that judicially. So if you  
22 need to enforce that judiciously. So if you need

1 three minutes and three seconds, we're not going to  
2 stop you, but if you will (inaudible - background  
3 noise).

4 So with that, let me first introduce our  
5 panelists very quickly so you all know their faces  
6 that are up here. Everybody's tired of hearing from  
7 me all day. (Inaudible) Dr. Welch this morning. I  
8 don't know a few people who have responsibility in  
9 (inaudible) Office of Dietary Supplements (inaudible).  
10 Dr. Sybil Stretch (ph) is the special assistant here  
11 at USD and (inaudible) policy adviser.

12 So we will (inaudible) your questions,  
13 taking comments, and I believe our first speaker is  
14 Frederick Blake. And again, just as (inaudible) if  
15 you could please identify your name and affiliations  
16 for those who are following along via webcast. Thank  
17 you. And for those who are next, feel free to come on  
18 down to the microphones just so we can (inaudible).

19 MR. BLAKE: Okay. The word innovation  
20 was used (inaudible - background noise and crosstalk).  
21 And I think the innovation is going to be enforced on.  
22 It's not, it's not something, -- it's something that

1 industry is responding to the government to be  
2 (inaudible). Patient groups and (inaudible -  
3 coughing), dietary supplements along (inaudible) drug  
4 (inaudible) and it's just, they're not (inaudible).  
5 So what do you do here is, okay. I think this is a  
6 great (inaudible - coughing).

7           Physicians' groups need to be here,  
8 Patient advocacy needs to be here. This needs to be  
9 way more open in terms of what, what's actually done  
10 here 'cause this is not a -- it was an in-house thing.  
11 It thought it was interesting and people were very  
12 friendly. (Inaudible.) I, I just think that  
13 (inaudible) a zillion patient advocacy groups and  
14 representing federally qualified health centers and,  
15 and (inaudible) hospitals, it's, you've got to open up  
16 the conversation to make this worthwhile for patients  
17 know where it's at.

18           Having said that, this is particularly  
19 important for those who are threatened with life-  
20 threatening diseases like HIV and AIDS and the  
21 gastrointestinal conditions that present themselves in  
22 these communities. And we are not going to have these

1 communities included in substantive dialogue with the  
2 FDA and the industry.

3 More than 30% of all HIV medications  
4 show gastrointestinal symptoms with a high prevalence.  
5 And in fact, those gastrointestinal symptoms greatly  
6 impacts the quality of life in the HIV patients in  
7 this era of highly active antiretroviral therapies.  
8 And, and we know very little about the interaction of,  
9 of, of dietary supplements in these kinds of  
10 (inaudible). People who are so, so diminished.

11 These and other patients communities  
12 must have guidance of physicians. It's, HIV  
13 physicians aren't here either for physicians and  
14 patients at the point of care because they need that  
15 guidance. There are a (inaudible) nutritional  
16 supplements and medical foods on the market that  
17 support the restoration of the intestinal barriers of  
18 people living with AIDS and HIV.

19 This can, this can help prevent  
20 nutritional absorption and (inaudible) Michael Biota  
21 (inaudible) symptomatology in the HIV community such  
22 as insulin tolerance, intestinal infections,



1 (inaudible) constipation and diarrhea. These are  
2 ongoing problems with long term AIDS survivors and you  
3 have no idea the suffering that goes on in this  
4 community. Maybe you do. I hope you do.

5 The majority of these conditions are  
6 experienced a higher prevalence in the HIV positive  
7 community. We would like to work with the FDA to  
8 ensure that people living with AIDS and HIV and other  
9 diseases are (inaudible) safe and effective  
10 nutritional (inaudible) food choices to better their  
11 condition, and that the FDA develop (inaudible)  
12 guidance and other means of communications to  
13 physicians, the HIV community, and the general public  
14 concerning nutritional supplements and medical foods  
15 that can be used in the HIV community to restore, help  
16 restore their health.

17 We view this as a, a priority for the  
18 president's efforts at (inaudible) HIV and AIDS as he  
19 stated in the Union Address. Thank you.

20 MR. TAVE: Thank you, Mr. Blake. Just a  
21 quick response. We really appreciate you being here.  
22 You made some good points. And (inaudible) it's not

1 the end (inaudible). So we would love to hear from  
2 patients (inaudible) message at our office is open and  
3 (inaudible).

4 MR. BLAKE: Well, if you know the HIV  
5 community, reaching out is not going to be an issue.

6 MR. TAVE: Our next speaker is Berit  
7 Dockter.

8 MS. DOCKTER: Hi, everybody. Ms. Berit  
9 Dockter. I represent the International Food Additives  
10 Council. IFAC is (inaudible) association representing  
11 manufacturers and users of food ingredients including  
12 life microbiotics ingredients, cultures, and  
13 probiotics, and dietary supplements. Thank you for  
14 the opportunity to provide comments today and  
15 recommendations to work with IPA to share (inaudible -  
16 coughing) on behalf of our organizations.

17 Today I want to highlight a few of our  
18 points from a letter I faxed, submitted to FDA last  
19 month regarding the dietary supplement work. I've had  
20 supports (inaudible) the FDA's involving new ways of  
21 altering, alerting consumers to concerns regarding  
22 dietary supplements that contain potentially unsafe

1 ingredients. IFAC suggests that FDA be the only,  
2 about these specific producers and/or exact  
3 ingredients involved when an issue arises unless they  
4 can prove the issue is more broadly applicable.

5 In regards to the new dietary ingredient  
6 notifications promotions statement, IFAC has concerns  
7 regarding the use of the term exclusivity for dietary  
8 supplements. We believe this (inaudible) applicable  
9 to drug manufacturers where (inaudible) is required  
10 for the introduction of new products into the  
11 marketplace which is not (inaudible) for dietary  
12 supplements.

13 Regarding the safety of ingredients on a  
14 permitted list, IFAC would like to restate our  
15 recommendation provided launch letter to FDA to use  
16 the existing FDA food master file system to develop a  
17 similar process for live microbial dietary ingredients  
18 and probiotics.

19 We strongly support FDA permission for  
20 dietary supplement manufacturers to label the quantity  
21 of probiotics in their products in calling for unit,  
22 CFUs, a more scientifically appropriate measurement of

1 viability regarding to our letter on CMU labeling  
2 submitted to the docket.

3 We would also like FDA to be aware of  
4 California Assembly Bill 1178 which was referred to by  
5 the Senate Health Committee this month and would  
6 require GMP labeling at the state level. IFAC  
7 encourages FDA to consider a national regulatory  
8 change on this topic since the issue is being raised  
9 by states.

10 In regards to the modification of DSHEA,  
11 IFAC is concerned that changing the law would require  
12 an act of congress, which may be difficult or  
13 unlikely. So we seek clarification from the FDA if  
14 there are non-legislative changes that could be made  
15 to DSHEA.

16 We also would like to remind FDA of our  
17 letter submitted to the docket on February 27th, this  
18 year, regarding annulment of a pre-DSHEA exact  
19 ingredient database.

20 In summary, IFAC strongly supports the  
21 work of a dietary supplement working group and we're  
22 glad that it will continue under Acting Commissioner

1 Sharpless. So I'm happy to answer any questions.

2 MR. TAVE: Thank you very much. And  
3 we'll have time for people to ask questions after  
4 we're done. We appreciate the offer. Harry Rice is  
5 next on the list.

6 MR. RICE: My name is Harry Rice. I'm  
7 from Global Organization for EPA and DHA (GOED), which  
8 represents the worldwide industry for the Omega 3  
9 fatty acids, EPA and DHA. GOED is interested in  
10 ensuring that consumers continue to have access to  
11 safe, high quality EPA and DHA rich ingredients. That  
12 said, GOED thanks the Agency for the opportunity to  
13 provide public comments concerning responsible  
14 innovation in dietary supplements.

15 While the market for EPA and DHA rich  
16 dietary supplements does explode on the passage of  
17 DSHEA in 1994, the first fish oil, cod liver oil, in  
18 Wisconsin (inaudible) was launched in 1790 of the  
19 United States and continues to be marketed; thus  
20 representing what GOED believes to be the oldest  
21 continuously marketed dietary supplement in the US.

22 In addition to cod liver oil, prior to

1 October 15, 1994 multiple forms of fish oil was  
2 launched, including fish body oil concentrates, both  
3 ethyl esters and (inaudible) triglycerides in salmon  
4 oil. In common to all passage of the (inaudible) is  
5 it that the primary composition of EPA, DHA to make  
6 sure it monitor fatty acids.

7 GOED believes the major sources of EPA  
8 and DHA ingredients including concentrates are being  
9 lawfully sold since they were marketed as dietary  
10 ingredients prior to October 15, 1994. To support  
11 this position, GOED has a considerable amount of  
12 documentation including, but not limited to, patents,  
13 (inaudible) press articles, advertisements, labels,  
14 peer-reviewed scientific articles, and information  
15 from the NIH and biomedical fish oil test materials  
16 program from the '80s and '90s.

17 For years EPA and DHA rich ingredients  
18 have been sourced from multiple organisms and species.  
19 Since the FDA issued its final rule on June 5, 1997  
20 affirming the hidden oil generally recognized the same  
21 with limitations on maximum use levels (inaudible -  
22 coughing) categories in order to ensure the daily

1 intakes of EPA and DHA did not exceed 3 gm per day.  
2 EPA and DHA are considered valuable components from  
3 which these oils are standardized.

4 The products are principally comprised  
5 of EPA, DHA in a mixture of fatty acids. Subsequent  
6 to the final rule, more than ten companies (inaudible)  
7 marketing fish oils for addition to food have received  
8 letters of no objection from the FDA despite minor  
9 differences among the oils of fatty acid composition,  
10 FDA (inaudible) no potential safety issues (inaudible)  
11 intake EPA and DHA would not exceed 3 gm per day.  
12 From a whole food perspective, consider the single  
13 serving of salmon, today's (inaudible) EPA, DHA  
14 (inaudible) fatty acids, (inaudible) fish oil  
15 supplements on the market today.

16 Over the years innovation has resulted  
17 in manufacturing changes to make the same or similar  
18 products on the market, but such changes should not be  
19 altered in NDI. These manufacturing changes should be  
20 addressed on a final rule for current manufacturing  
21 practice, the manufacture packaging, labelling, or  
22 holding operations for dietary supplements.

1 GOED believes the focus should be on  
2 whether or not the change to the manufacturing process  
3 alters the safety profile or identity of the  
4 ingredient do not be specific to manufacturing changes  
5 (inaudible). After all, the principal ingredient  
6 (inaudible) omega 3 fish oil with prominent fatty  
7 acids being EPA and DHA, along with a mixture of minor  
8 fatty acids. That's all I have. Thank you.

9 MR. TAVE: Thank you. Our next speaker  
10 is Mark LeDoux.

11 MR. LEDOUX: You want me to go up there?

12 MR. TAVE: Yeah, if you wouldn't mind  
13 'cause because (inaudible).

14 MR. LEDOUX: Good afternoon, everyone.  
15 My name is Mark LeDoux. I'm the chairman of the board  
16 of Natural Alternatives International, as well as the  
17 Natural Products Association.

18 First of all, I want to thank the Office  
19 of Dietary Supplements for hosting this meeting,  
20 including my old friends Cara and Steve, and Mr.  
21 Durkin, who is not here today. Nice to see you as  
22 well, Sybil and Laura, and it's great working with you



1 guys.

2 I'm, I'm standing here because I want to  
3 encourage companies to do the right thing. Our firm  
4 spent million of dollars and went through the front  
5 door of the FDA and we brought in our dossiers and we  
6 had our meetings, and we had our pre-meetings and we  
7 had our subsequent meetings. This is not a difficult  
8 process to do the right thing.

9 Filing an NDI notification should not be  
10 considered too difficult; however, spending those  
11 kinds of resources as either a private or public  
12 company begs the question we're a good citizen, now  
13 what.

14 So by helping the government do its job,  
15 which is to promote the safety of consumer products in  
16 our space, we're looking at ways to work together with  
17 the Agency to arrest those products that are in  
18 commerce that I believe are deficient in not only  
19 scope, content, but are, in fact, per se, adulterated  
20 because they have not gone through the font door of  
21 the FDA. They have not spent their money. They have  
22 not identified the toxicological implications or the

1 pharmacological significances of their particular  
2 products.

3           They are unwilling or unable to address  
4 issues such as diet problems such gave rise to altered  
5 DeFang in that fiasco in 1989. So what I'm suggesting  
6 is that there have been some great ideas shared here  
7 today. One is the master file concept. The other  
8 which needs to be addressed quite frankly is more  
9 alerts and (inaudible).

10           My company was started in 1980 by me. I  
11 am telling you right now there are many companies like  
12 mine that are willing to pay the FDA user fees to  
13 enforce the law, which means identifying products that  
14 are in the marketplace that are clearly adulterated  
15 per se under statute and either make it very difficult  
16 for them to enter the United States by eliciting the  
17 service of the customs officers and officials at the  
18 ports of entry, or by subsequent post-market  
19 surveillance when we provide to you lists of companies  
20 that are abusing the privilege of our efforts.

21           Recently your office has sent out, I  
22 believe, eight warning letters to different companies

1 involving DMHA, which I believe is appropriately  
2 identified by you as an illegal substance without  
3 adequate NDI work.

4           It's interesting to note that most, the  
5 majority of those products were also combined with  
6 beta-alanine not Pearson beta-alanine, which has NDI  
7 No. 1103, but just beta-alanine. So we've asked  
8 counsel to send them information to say, oh, by the  
9 way, not only is DMHA not appropriate, we feel that  
10 you're abusing the privilege even further by placing  
11 generic beta-alanine in inferior products under the  
12 guise that somehow the work that NAI has done with 55  
13 clinical studies, not to mention appropriate  
14 pharmacologic data and toxicology profiles, you are  
15 free-riding on our efforts.

16           That's got to stop. So responsible  
17 industry is willing to work with you at the Agency  
18 level the fix this mess, but you have got to think  
19 about private industry getting a return on investment  
20 for doing the right thing. We're here partnering with  
21 you. We're here to support you.

22           One of the reasons you have an Office of

1 Dietary Supplements is because of the efforts of  
2 myself, Steve Mister, and many of the colleagues in  
3 this room, Dan Fabricant, and listed in the halls of  
4 congress to get you out of the watercooler and into a  
5 bona fide office.

6 So we believe in what you're doing. We  
7 are just encouraging you take some risks, go further.  
8 Start making it difficult for miscreants to prosper  
9 based upon work of solid citizens in our industry.  
10 And I thank you for this opportunity.

11 (APPLAUSE.)

12 MR. TAVE: Thank you, Mark. Next is  
13 George Paraskevakos.

14 MR. PARASKEVAKOS: Good afternoon,  
15 again. I'm George Paraskevakos, the director of the  
16 from International Probiotics Association. On behalf  
17 of our 110 member companies (inaudible - off mic)  
18 thank FDA for holding this important meeting and for  
19 allowing the IP the opportunity to present.

20 As discussed earlier today, probiotics  
21 have been part of people's diets around the world for  
22 centuries. Their common ingredients in dietary

1 supplements in the United States prior to the passage  
2 of DSHEA, they're one of the most (inaudible)  
3 categories of dietary ingredients from safety to  
4 health (inaudible - coughing) consumer's desires to  
5 supplement their diets with probiotics is undeniable.

6 As a general matter, IPA believes that  
7 while perhaps not perfect, DSHEA and FDA's regulations  
8 implement DSHEA have been and continue to be workable  
9 and effective, legal and regulatory framework to  
10 ensure that consumers have access to probiotics that  
11 are safe and effective dietary ingredients. But it's  
12 not perfect.

13 One probiotics (inaudible) regulatory  
14 requirement with the amount (inaudible) ingredients in  
15 a dietary supplement be declared (inaudible). As  
16 discussed (inaudible) petition (inaudible) vitamins,  
17 minerals and other categories of dietary ingredients,  
18 a way to provide a supplement and not provide  
19 consumers with useful information. In general  
20 (inaudible - coughing) a particular exceptions like  
21 cold culturing for probiotics.

22 Labeling the quantity of probiotics is

1 that there's something (inaudible) in terms of  
2 (inaudible) provides consumers with relevant  
3 information (inaudible). While we appreciate the  
4 FDA's willingness to allow (inaudible) in addition to  
5 milligrams, such dual labeling can be effectively  
6 challenging.

7 Of course the issue of what ingredients  
8 you require for the submission of (inaudible)  
9 notification is also very complicated and we  
10 appreciate the FDA's continued efforts to clarify that  
11 (inaudible). Along those lines, a qualitative list of  
12 the ingredients including probiotics would be  
13 extremely useful.

14 Similarly, as discussed earlier, the  
15 master file system is extremely useful as well to  
16 make, to make the process more efficient and  
17 effective. We appreciate the steps that FDA has taken  
18 (inaudible) exploring what a master file (inaudible)  
19 and we look forward to working with the FDA to make  
20 (inaudible).

21 In conclusion, IPA supports the work of  
22 the dietary supplement working group and hopefully

1 will continue (inaudible). We look forward to  
2 (inaudible) collaborating (inaudible). Thank you.

3 (APPLAUSE.)

4 MS. MacCLEERY: Laura MacCleery, Center  
5 of Science in the Public Interest. I think the really  
6 good news today is that I feel there's been a real  
7 shift since the last public meeting in terms of  
8 specific proposals to be put on the table to address  
9 some of the major issues facing the dietary supplement  
10 industry.

11 CSPI has a long concern about issues in  
12 this industry. We care most, first and foremost about  
13 safety and ensuring that consumers are not facing  
14 particularly acute or even chronic risks with regular  
15 consumption of dietary supplements (inaudible) the  
16 guidance again (inaudible) drugs out to consumers.

17 And we also care about efficacy. We  
18 haven't talked much about claims today, but we do see  
19 that there are (inaudible) disease and treatment  
20 claims being made in the dietary supplement  
21 marketplace. These tend to exploit vulnerabilities of  
22 consumers. So the additional ones like opioid

1 cessation addiction, or tobacco cessation addiction.

2           And the real tragedy there is that  
3 consumers come to these products with their best  
4 intentions and these are ineffective. And so they may  
5 blame themselves for the failure for them to, to get  
6 rid of their addiction even though it's the product  
7 that's actually failed them.

8           We see the same problems with weight  
9 loss supplements, for example, as a whole category and  
10 there are being additional problems, but these often  
11 contain drugs. And so we think in addition the  
12 proposals that have come to the table, FDA should have  
13 mandatory vehicles for the (inaudible) containing  
14 unapproved drugs. Right now those are classified as  
15 drugs and so therefore (inaudible) ironically.

16           So I, I also think that we've identified  
17 a number of really important low hanging fruit on the  
18 ground type proposals that we can all get behind,  
19 including product listing and registration with some  
20 teeth behind it. So failure to list a product, it  
21 actually renders the product illegal. And that will  
22 create obviously visibility for the Agency.



1 I think we would be in favor of closing  
2 the GRAS loophole not only because we are, you know,  
3 skeptical about the value of GRAS as a mechanism  
4 assuring consumers of safety and the (inaudible) for  
5 consumer trust. But also because that would assure  
6 that the mechanism that was designed in DSHEA to  
7 provide visibility on dietary supplements, which is  
8 the NDI mechanism, would actually do its job.

9 Then we would love to see specific  
10 oversight in a, in a more constituted way of high risk  
11 categories of supplements so we know that there are  
12 protein with drugs where they are targeting  
13 particularly vulnerable groups of consumers like  
14 infants or people with addictions where we know that  
15 there is a history of contamination or susceptibility  
16 to adulteration.

17 So those, those product classes  
18 (inaudible) high risk could be subjected to some third  
19 party system of audits and I think that would be  
20 preferable to trying to propose to roll back the clock  
21 in DSHEA and say everything needs pre-market testing.  
22 We know where the problems are and we could just

1 target with FDA's discretion our own high risk  
2 categories (inaudible) nation.

3 We also think there could be some  
4 improvements on product labeling including changes to  
5 the clarity and contents of disclaimers, warning  
6 labels pertaining to drug interactions, and then a 1-  
7 800 number for consumers to directly report adverse  
8 events to the FDA, which would be a lot more  
9 transparency than we currently have around adverse  
10 events and supplements.

11 And then mandatory reporting of all  
12 adverse events like we have on the medical device side  
13 so that FDA can really see what's going on in the  
14 marketplace and it's not the manufacturers that are  
15 deciding what's serious or not serious in terms of  
16 reportable events.

17 Then we also agree with (inaudible) FDA  
18 needs more resources. We'd certainly be in favor of  
19 user fees or some other mechanism to naturally  
20 quadruple or quintuple the budget of ODSP regardless  
21 of what the budget was for Health Canada, and that's  
22 just a premarket side, but it's already three times

1 the ODSP's budget. We've been working with  
2 (inaudible) to double the budget to ten million for  
3 this year for ODSP (inaudible).

4 And then lastly I think we're not  
5 opposed to a master file particularly if it was part  
6 of the package that included all these additional  
7 (inaudible) preventions for consumers. I think that's  
8 an idea that incentivizes more research on safety is  
9 worth exploring. So that's what I have. Thank you.

10 (APPLAUSE.)

11 MR. TAVE: Thank you, Laura. There's no  
12 objection between that, but you went a little bit  
13 overtime, but I didn't want to interrupt you while you  
14 were talking about the (inaudible - laughter). Next  
15 we have Daniel Gastelu, but I think Mr. Gastelu may  
16 have left. If he's not here, then we'll move on to  
17 Bonnie Patten.

18 MS. PATTEN: Good afternoon. My name is  
19 Bonnie Patten and I'm with Truth in Advertising.  
20 Thank you for the opportunity to provide comment today  
21 on behalf of TINA.org. We are a nonprofit consumer  
22 advocacy group that works to out stuff and prevent

1 deceptive marketing. While we focus on advertising of  
2 all kinds and in all sectors of the economy, we pay  
3 particular attention to the marketing of supplements.

4 From autism to Alzheimer's, Ebola to  
5 epilepsy, there is a supplement that is being marketed  
6 to cure, treat, mitigate or prevent almost any disease  
7 we can think of. On our website, TINA.org, we  
8 currently have more than 3,000 examples of companies  
9 and marketers promoting supplements with inappropriate  
10 disease treatment claims. With the marketing hype  
11 surrounding CBD, a growing scepticism and distrust of  
12 the medical establishment and the rise of the wellness  
13 industry to (inaudible) right (inaudible), there can  
14 be no doubt that deceptive and misleading marketing of  
15 supplements is a problem that's only going to get  
16 worse.

17 Given this growing problem, TINA.org  
18 appreciates the FDA's focus on the issues before us  
19 today. The unfortunate reality, however, is that the  
20 FDA will never be able to eradicate all of the  
21 deceptive product including use of (inaudible)  
22 supplements. As such, we would urge the Agency to

1 take (inaudible) where consumer harm is greatest.

2 By way of example while (inaudible) the  
3 FDA's work with regard to brain health supplements,  
4 more needs to be done. One in three people over 70  
5 suffer from some form of memory loss and a new poll  
6 indicates that nearly 75% of adults report engaging in  
7 some kind of activity to help with dementia, including  
8 taking supplements.

9 Of the countless memory supplements on  
10 the market, one stands alone on the industry's self-  
11 proclaimed leader, Prevagen. It first became  
12 available to consumers in 2007 and has since sold  
13 these pills to hundreds of thousands of aging  
14 Americans. This product is available in more than  
15 40,000 stores across the nation with more than 2  
16 millions bottles sold to date.

17 In TV commercials and on its label,  
18 Prevagen promises to improve memory despite the fact  
19 the experts in the field have concluded that it is  
20 biologically inconceivable that a protein taken by  
21 mouth would have any effect on memory. As I'm sure  
22 this panel knows, Prevagen is no stranger to the FDA.

1                   In 2007 after an NDIN was submitted, the  
2                   FDA said it had significant concerns regarding the  
3                   safety of the ingredient and it reiterated those  
4                   concerns in July of 2012.

5                   In October 2012, this Agency sent a  
6                   warning letter to the makers of Prevagen indicating  
7                   that not only was the product marketed as an  
8                   unapproved new drug, but the sole ingredient in the  
9                   product, synthetically produced apoaequorin, did not  
10                  meet the definition of a dietary ingredient such that  
11                  Prevagen could not be marketed as a dietary  
12                  supplement. And yet seven years later the company  
13                  continues to market Prevagen as a supplement that  
14                  improves memory.

15                  It is critical that more be done to rein  
16                  in supplement companies that use inappropriate disease  
17                  treatment claims to take advantage of susceptible  
18                  populations like the elderly. Tina.org thanks the FDA  
19                  for its efforts to date and looks forward to working  
20                  with the Agency to help ensure development can be done  
21                  (inaudible). Thank you.

22   (APPLAUSE.)

1 MR. TAVE: Thank you very much, Bonnie.  
2 Our next speaker is Dan Fabricant.

3 MR. FABRICANT: Thank you for having me.  
4 National Products Association. Thank you for the  
5 time, time to make a few comments. We recognize  
6 (inaudible) important and it's a set for FDA box to  
7 check in getting out the final guidance or the draft  
8 guidance, whichever the Agency would have to pursue.

9 But with that said, I'm reminded of an  
10 important part of regulation 21 CFR 10.115, good  
11 guidance practices where it says that FDA will  
12 (inaudible) would have to follow up guidance standards  
13 and simply (inaudible). While guidance is incredibly  
14 important, the statutes makes it more important  
15 (inaudible) here today.

16 There is (inaudible) makes (inaudible)  
17 relatively simply, especially as resources or  
18 (inaudible) resource by itself. We look forward to  
19 having those discussions first and foremost  
20 (inaudible) discussions on guidance and things like  
21 that that are not (inaudible) where the statute is.  
22 Thank you.

1 (APPLAUSE.)

2 MR. TAVE: Charles Jolly is our next  
3 speaker.

4 MR. JOLLY: Thank you, Dan. Charles  
5 Jolly. Thank you. I want to thank you for the  
6 opportunity to participate in this important  
7 discussion. I'm going to try not to go over time, but  
8 I will talk about resources (inaudible) in developing  
9 countries. I'm Charles Jolly. I'm an attorney with  
10 the Baltimore office of Baker Donelson Bearman  
11 Caldwell & Berkowitz.

12 I spent my entire career of more than 50  
13 years working in food and drug law matters. It has  
14 been my privilege over that period of time to advise  
15 and represent some of the most iconic and well known  
16 dietary supplements ever offered in this country. So  
17 I'm not sure whether I'm here as a public commentator  
18 or historian, but I do wish to warn you that I'm not  
19 speaking today on behalf of my clients or even for my  
20 firm. Rather I'm going to offer a personal  
21 perspective and offer some suggestions for making  
22 contributions to a business that makes an important



1 contribution to public health and wellbeing.

2           The, there's been a common theme today  
3 and I think the common theme is enforcement resources.  
4 And Mark LeDoux commented -- I don't know Mark. I've  
5 just heard him for the first time, really struck a  
6 cord with me, but I, in thinking about this over the  
7 more than 50 years that I've been practicing, I have  
8 given some thought to why the FDA is so under  
9 resourced in the area of dietary supplements and what  
10 possibly could be done about it.

11           There is a policy which is part of the  
12 1938 act, which is the core of, of, you know, the  
13 statute that we all follow that prohibits private  
14 rights of enforcement of the food and drug in  
15 (inaudible). And in 1938 when that statute was  
16 adopted, there were good and sufficient reasons for  
17 that. Remember in 1938 -- and no, I wasn't practicing  
18 in 1938 -- that came a little later -- the, there was  
19 concern that if there was a private right to enforce  
20 federal food and drug (inaudible), you would wind up  
21 with a hodgepodge of inconsistent decisions around the  
22 country. There would be burdens on discovery that

1 would prevent FDA from doing its job and, you know,  
2 and on balance, that policy has served the country  
3 well.

4 As you know, Peter Hutt and the  
5 commissioner put in the OTC review in 1971. Now  
6 almost 50 years later we're still not quite done with  
7 all that process, but a huge part of what, what is the  
8 administrative burden of the Agency in 1938 is now in  
9 a different posture. The no private right to enforce  
10 model works best if FDA has premarket approval. And  
11 in a context where we're talking about dietary  
12 supplements, and I was parenthetically the same  
13 concept applies to monograph drugs, the Agency is  
14 really dependent on the regulated industry self-  
15 execution against known and public standards.

16 This is not a serious process. Law  
17 firms like Baker Donelson are asked every day to  
18 assess a particular set of facts and circumstances  
19 regarding ingredients, claims, training, procedures,  
20 processors for products that are not subject to  
21 premarket approval. And we do, I think on balance, a  
22 pretty good job of advising our clients as to what the

1 factors are for compliance.

2           The fabric of self-regulation for these  
3 products which so much depend on the determination of  
4 the regulated industry depends on FDA's actually being  
5 predictable, consistent, and uniformly applied. In  
6 fact, we look at the Code of Federal Regulation, we  
7 look at administrative practices, look at the statute,  
8 and yet scarcely a month goes by when I have had a  
9 dietary supplement marketing manager come to me saying  
10 so and so is doing this and you told me I couldn't.

11           And the problem is there really isn't  
12 any recourse. Now, yes, I can send a letter to FDA  
13 or, yes, I can pick up the phone and call, but it is  
14 on balance a non-satisfactory system. And in many  
15 cases I have to say because dietary supplements are  
16 largely safe products, there's not a huge overhang of  
17 public health concern which mandates, you know, an  
18 immediate alarm.

19           And so the frustration of the regulated  
20 industry, and I would distinguish myself from Scott  
21 Bass a little bit, to there is no one profile for the  
22 regulated industry. There are careful, precise

1 factors, and there are wild, wild west (inaudible).  
2 And if the industry doesn't have one profile; however,  
3 the responsible members of the dietary supplement  
4 industry really want double lines where it's no  
5 pasture. They want solid fences. They want solid  
6 rules and understandings.

7           So I come to the question of what could  
8 be done to look to, to find more compliance in the  
9 industry. And my, my answer is one that is somewhat  
10 familiar to HHS and that is the Qui Tam lawsuit.  
11 Under the Qui Tam theory, the complainants were able  
12 to put the HHS on notice that there is a violation and  
13 allow the Agency to taken over the case if it has the  
14 sort of merit that the Agency thinks deserves it, or  
15 they can leave it to private litigants to, to go  
16 ahead.

17           I am not suggesting an abandonment of  
18 the no private rights of enforcement by FDA either for  
19 NDIs or for new drugs or in general. Rather I am  
20 suggesting that there be an appropriately structured  
21 private enforcement permitted for qualified  
22 stakeholders in the dietary supplement community, and

1 I think it would do wonders to enhance good product  
2 law.

3 MR. TAVE: Mr. Jolly, I'm sorry to cut  
4 you off, but you're well over time. I do hope you'll  
5 submit written comments of your full thoughts.

6 MR. JOLLY: I shall.

7 MR. TAVE: Thank you very much. Mark  
8 Miller will be next.

9 MR. MILLER: On behalf of three minutes.  
10 I just want to follow up on a question I really posed  
11 earlier about stimulating research because for such  
12 data, it will give you information, it will give you  
13 familiarity, it'll give you context, and they're all  
14 good things. And what can we do to stimulate research  
15 in this industry that will help everybody share  
16 information and improve consumer responses? And I  
17 think we kind of struggled with that a little bit  
18 earlier when I kind of posed it, but I think there is  
19 an answer here today. But it may not be terribly  
20 helpful, but I'm going to pose it anyway.

21 I really was enthusiastic and, and, and  
22 tickled to see that you invited our colleagues from

1 the north, Canada, who reviewed what was happening  
2 with our industry for ten years and designed their own  
3 system, and included in that system is a reward for  
4 research that you can get albeit being somewhat tepid,  
5 but you can get some claims associated with a study or  
6 research effort that you've done.

7 So the question is even though it's very  
8 difficult under the current regulations, there is an  
9 attractiveness to encourage more research and  
10 collection of information by giving a reward at the  
11 end and that is about validated structure of function  
12 (inaudible).

13 MR. TAVE: Thank you very much. Mark  
14 Blumenthal, you're next.

15 MR. BLUMENTHAL: Howdy. Good afternoon,  
16 everybody. I'm Mark Blumenthal, founder and executive  
17 director of the American Botanical Council. I want to  
18 thank the Agency, my good friends here, of course, for  
19 putting on this event and for allowing me to take a  
20 few moments to offer comments.

21 The American Botanical Council is an  
22 independent, broad research organization 30 years old.

1 We're a science organization with members in 80  
2 countries, which 3,000 or so members, Canada. So we  
3 have a global perspective on what's going on in  
4 research and education, quality control of dietary  
5 supplement industry, the herbal medicine industry,  
6 etc., and the communities that use these products.

7 About nine years ago we started a new  
8 project called the botanical adulteration prevention  
9 program out of our concern about what appears to be  
10 rising incidents of the attachment of adulteration of  
11 various botanical products, herbs, botanical  
12 materials, extracts, essential oils, etc. I'm not  
13 just talking about technical adulteration we referred  
14 to earlier back to items not having -- actual  
15 adulteration where the identity of these materials  
16 have been altered for fraudulent purposes by the  
17 seller or the reseller in a nondisclosed manner  
18 according to USP definition of adulteration.

19 Our program has over 200 supporters over  
20 the last nine years and support our work in this area,  
21 and we've published over 50 peer-reviewed publications  
22 identifying adulteration problems and dealing with

1 analytical methods to determine the fitness for  
2 purpose and the robustness of various analytical  
3 methods dealing with technical adulteration, and to  
4 help guide industry and regulatory, laboratory as to  
5 which analytical methods are appropriate.

6           We're finding out that more people seem  
7 to be concerned about this and we're grateful for that  
8 concern. We're grateful for all the partners and  
9 other stakeholders who help promote the information  
10 that we are putting out so that we can try to reduce  
11 or hopefully element, maybe idealistic, the idea of  
12 these type of adulterations going on in the world. We  
13 know that the, the GMPs prohibit the use of  
14 ingredients without specification, but for regulations  
15 they're silent on guidance for disposition of  
16 materials.

17           So consequently we come up with a best  
18 practice SOP for the disposal and destruction of what  
19 we call irreparably defective materials and my friends  
20 and colleagues in the room have already heard to  
21 discuss this (inaudible) as we put this out for public  
22 comment previously. We're concerned that when



1 companies reject irreparably defect materials, it goes  
2 back into supply and it gets rerouted somehow back  
3 into the supply chain. And that we believe is  
4 unacceptable.

5 And we believe we have a self-regulatory  
6 mechanism that can reduce any burdens that might be on  
7 the Agency and its resources that need to go into  
8 enforcement, but we believe that responsible, honest,  
9 ethical members of the herb and dietary supplement  
10 industries, of which there are many, many of whom have  
11 already come forward and endorsed and/or supported our  
12 draft proposal on this matter.

13 There are many companies that are  
14 willing to do what it takes, which includes if they,  
15 even if they qualify their supplier, they still  
16 receive what they consider to be irreparably defective  
17 material, as in our articles as we defined it under  
18 the SOP, which is something that is adulterated beyond  
19 mediation or reconditioning, contaminated beyond  
20 remediation, or contains illegal ingredients.

21 Those would be the factors that make for  
22 an irreparably defective article. Those should kept

1 under quarantine, they should be tested by an  
2 appropriate third party laboratory, by appropriate  
3 validated and with valid scientific methods, and then  
4 that material should be disposed of or destroyed by a  
5 qualified third party that is experienced in this  
6 matter.

7 We have also draft contract language for  
8 suppliers that industry members can require as a  
9 priority stipulation that in order to supply them with  
10 any kind of botanical or other kind of material, that  
11 the supplier must agree to this contract claims so you  
12 have an agreement between the two that if there's a  
13 problem like, and there's the detection of irreparably  
14 defective materials, that this material can be  
15 destroyed. The supplier doesn't get their money back.  
16 They don't get their material back. They have to pay  
17 for the extra testing. They have to pay for the  
18 destruction or the disposal and doesn't require  
19 anything (inaudible - sneezing). So it's really based  
20 on a contract agreement.

21 We put this information out in public  
22 comment. ABAC members, past members, that was the

1 acronym for our botanical adulteration prevention  
2 program. In the fall of this last year we received  
3 106 what we consider substantial comments. By the end  
4 of this month we hope to have all the documents  
5 revised with those comments and responses to those  
6 comments including a new document of FAQs, which has  
7 all of the 106 comments listed and how we resolved  
8 them and/or revised the language of the contract  
9 language and of the SOP and response to the comments.

10 So we're doing this in an extremely  
11 transparent and open manner so that anybody can see  
12 this. After this review and revision of our legal  
13 community and voluntary attorneys from the industry  
14 who review it, and then at that point we'll determine  
15 whether we want to put it out as a proposal final or  
16 put it out for review again from stakeholders to see  
17 how they can review the revised version before I  
18 finally (inaudible).

19 Again, this is being driven by and  
20 supported by responsible elements in this community,  
21 responsible health industry, including suppliers and  
22 manufacturers. Ironically, it's those companies that

1 probably least have to ever resort to use of this SOB  
2 because responsible suppliers test their material  
3 before they ship it as they're supposed to do so  
4 they're not shipping bad material, irreparably  
5 defective material. And responsible manufacturers  
6 have robust quality control systems and also properly  
7 and adequately qualified as suppliers.

8 So these are the companies that are the  
9 least likely to have to use this SOB and they're the  
10 ones that are supporting us. We welcome the Agency's  
11 input in this matter. We welcome anybody else's input  
12 that's interested in this because we believe that we  
13 can help increase consumer confidence in this area, as  
14 well as industry and other component stakeholders  
15 including health professionals and researchers if the  
16 industry fully adopts this SOB and basically does it  
17 on a self-regulatory basis. Thank you for your time.

18 (APPLAUSE.)

19 MR. TAVE: Thank you, Mark.

20 (Inaudible.) So Daniel Wang is our next speaker.

21 MR. WANG: Can you hear me? I'm Daniel  
22 Wang, CMU associate, and associates for science-based

1 consulting (inaudible) pharmaceutical and consumer  
2 health companies all the time (inaudible) development  
3 and (inaudible) assessments of (inaudible) drugs and  
4 other products. We also advise the dietary supplement  
5 industry on (inaudible) filings and the (inaudible)  
6 guidance association. (Inaudible) input into my  
7 comments today or (inaudible) meeting. And we'll be  
8 submitting more written comments later as well.

9           So as we've heard today, millions of  
10 people use dietary products every day in order to  
11 support their health and wellbeing. Globalization  
12 seems to be introducing us to more and more of these  
13 (inaudible). Many consumers find these products to be  
14 helpful (inaudible) and in some cases with few or less  
15 destructive side effects (inaudible). However, the  
16 products that affect how people feel and function,  
17 (inaudible) CNS effects, are a particular challenge to  
18 regulate.

19           With that (inaudible) understanding of  
20 mental health (inaudible) use of these products for  
21 health and wellbeing and attributing to disease  
22 (inaudible). FDA's evaluations of CNS drugs can

1 impact scheduling status, which in turn can  
2 drastically affect consumer and patient access.

3 FDA has suggested that drugs with  
4 consultation activity undergo abuse potential  
5 evaluations. How does this inform how FDA will  
6 evaluate CNS active dietary products like (inaudible)?  
7 While there are limited data on the health effects and  
8 risk of these products, surveys suggest that millions  
9 of Americans use them similarly to other dietary  
10 products to treat minor aches and pains, dealing with  
11 energy, (inaudible).

12 For some (inaudible) a (inaudible)  
13 opioids. They find it to be effective and  
14 substantially easier to access than FDA approved  
15 treatments for their pain and mental health  
16 (inaudible). When regulating these product we urge  
17 FDA to focus on, of course, the risks, but also to  
18 their potential public health benefits. We also  
19 encourage FDA to be more active and communicate the  
20 Agency's approach to assessing the CNS effects of  
21 dietary ingredients, including what evidence to  
22 include in any item to support a product's safe use

1 and acceptable claims for CNS active dietary  
2 ingredients. All at the same time while recognizing a  
3 few companies are able to amass hundreds of millions  
4 of dollars required to develop their products  
5 (inaudible).

6 We believe that a perspective approach  
7 to policy making around dietary supplements,  
8 additional active engagement by FDA and with consumers  
9 and industry, and additional guidance by FDA can help  
10 to avert problems before they happen, and to ensure  
11 consumers get the information they need to guide  
12 (inaudible) sponsors crossing the often (inaudible).

13 MS. PAVLICK: (Inaudible - off mic.)  
14 But in an effort to support modernization and  
15 innovation in our industry and to allow continued  
16 access to safe, quality, compliant, and affordable  
17 dietary supplement products, UNPA members,  
18 investigator training should be addressed.  
19 Investigators are our first line and the filter to  
20 which responsible innovation is monitored. They must  
21 have an in depth understanding of DSHEA. They need to  
22 understand dietary supplement GMPs, and most

1 importantly with need data to understand our industry.

2 This month the Food and Safety  
3 Modernization Act has identified preventative controls  
4 role, and it does mention for a qualified auditor,  
5 qualified auditors and individuals with the  
6 appropriate background, training, education, and  
7 experience. If you continue to look at the definition  
8 (inaudible) you'll find a qualified individual not  
9 only has the education and training, background, and  
10 experience, but they also have specific training  
11 related to knowledge, background, and risks of the  
12 product for which there are working with. And food  
13 safety risks including (inaudible).

14 They also have to have standardized  
15 training using the standardized curriculum that's been  
16 developed by (inaudible) compliance. (Inaudible)  
17 comment we do not have the time to share with you the  
18 differences between a four day dietary supplement  
19 training compared to an approximate ten weeks of  
20 training received by a drug investigation. But after  
21 that time they're being qualified for the  
22 investigations to which they conduct.



1                   In the times of limited resources in the  
2                   FDA, we suggest that the FDA and responsible industry  
3                   are allowed to collaborate with the FDA by people in  
4                   the drug industry to provide additional technical  
5                   there for the investigators.

6                   We've heard a lot of discussion today  
7                   about the need to enforce and to separate the good  
8                   actors from the bad actors. Another constant refrain  
9                   has been that FDA simply doesn't have resources it  
10                  needs to focus and market the, to police the  
11                  marketplace adequately. UNPA's devoted considerable  
12                  resources toward ensuring quality manufacturing and we  
13                  believe that there's a role for industry (inaudible)  
14                  bolster FDA's work in this regard.

15                  Let's work together to provide  
16                  solutions, to ensure qualified auditors are conducting  
17                  the audits, to provide consist audits with the same  
18                  mission between industry and the FDA, which is to  
19                  protect public health while allowing safe access and  
20                  consumer choice to safe, quality, compliant, and  
21                  scientifically based supplements. Thank you.

22                  MR. TAVE: Thank you, Larisa.

1 (APPLAUSE.)

2 MR. TAVE: We'll hear now from Frank  
3 Jaksch.

4 MR. JAKSCH: Good afternoon. I'm Frank  
5 Jaksch, the cofounder of ChromaDex and (inaudible)  
6 present at this meeting. I'm here today with our CEO,  
7 Rob Fried, because we have transformed the science and  
8 chemistry company most of you have known for many  
9 years to become a consumer product dietary supplement  
10 company that does develop responsibly with innovation,  
11 science, and safety at our core.

12 Enforcement of dietary supplement  
13 regulations and their modernization is critical.  
14 ChromaDex like other innovative science-based  
15 companies we consider as peers supports NDI or the NDI  
16 notification process, at least about our products,  
17 champions the integrity of our industry, and most  
18 importantly protects consumer safety.

19 However, without enforcement the door is  
20 open for bad actors to ignore NDIs, to steal  
21 intellectual property from responsible companies who  
22 have made their science public through the process,

1 and then bring a product to market with limited  
2 substantiation or consumer safety protections.

3 By enforcing our current regulations,  
4 incentivizing clients, and modernizing policies, we  
5 could recognize a number of important benefits, such  
6 as IP protection, more robust science, enhanced  
7 consumer safety protections, intentional expanded  
8 health claims. Companies who invest in research and  
9 resources to developing their IP should be able to  
10 protect it.

11 The second step is to introduce to new  
12 incentives for compliance and investment and good  
13 science. For example, the same approach to the FDA  
14 use of drug companies who afford exclusivity rights  
15 could be applied to the dietary supplement industry.  
16 While the exclusivity rights have definitely been a  
17 hot topic or a hot word to be using around here, but  
18 one thing I'll comment on to assure you is if you  
19 can't find a way to incentivize companies to make an  
20 investment in science, then the NDI process, the  
21 number of NDI applications isn't going to go up; it's  
22 going to go down. It's going to go down probably

1 lower than the rate that you're seeing today.

2 This approach would not only provide  
3 intellectual property protections, but it would also  
4 incentive investment in science which would in turn  
5 elevate the integrity of the entire industry and we'd  
6 have companies (inaudible) substantiation for their  
7 projects. Consumers are looking for products that  
8 promote health, support their health and wellness,  
9 should be able to trust the market and the companies  
10 providing them with those options and the safety of  
11 what they're consuming.

12 And we should explore providing  
13 consumers with deeper understanding about benefits  
14 that are supported by sound, well-documented science.  
15 This would allow consumers to be better educated about  
16 the steps they can take today to improve the quality  
17 of their life.

18 The landscape has changed dramatically  
19 since DSHEA was written. The size of the industry is  
20 expanding and the speed in which supplements are  
21 brought to the market has, has been accelerating  
22 greatly. The sales channels are dynamic. The science

1 and business information is now conveniently available  
2 on the internet. Through strike enforcement of  
3 current regulations and modernization of DSHEA,  
4 responsible companies would be the norm, not the  
5 exception.

6 Our industry, it's our industry, it's  
7 our science, it's our health, it's our responsibility  
8 to protect them and by working together we can grow a  
9 thriving marketplace in which good science is  
10 rewarded, compliance is attractive, and public safety  
11 is protected. Thank you.

12 (APPLAUSE.)

13 MR. TAVE: Thank you very much, Frank.  
14 Jack Mitchell is next.

15 MR. MITCHELL: Good, good afternoon.  
16 I'm Jack Mitchell from the National Center of Healths  
17 Research, a nonprofit think tank which analyzes and  
18 researches identifications for public health patients  
19 and consumer safety. We strongly support FDA's recent  
20 efforts to crack down on manufacturers who make false  
21 or misleading claims about dietary supplement  
22 products. We were given a good example this morning

1 with supplements masquerading as legitimate opioid  
2 treatments.

3 Last fall a team from the California  
4 Department of Public Health concluded that there were  
5 unproven and sometimes dangerous drugs in almost 750  
6 dietary supplements, most them marketed for sexual  
7 enhancement, weight loss, or muscle growth. Numerous  
8 representatives would respond it's not fair to compare  
9 these so-called fringe products to legitimate vitamins  
10 and other more conventional dietary supplements.

11 (Inaudible) the public mind, these products are all  
12 part of the same family.

13 For it's own protection, the dietary  
14 supplement industry has made substantial progress in  
15 weeding out the bad actors since the so-called wild,  
16 wild west days of the advent of DSHEA in the 1990s.  
17 At that time I worked in the commissioner's office and  
18 my office conducted an investigation of the industry,  
19 responded to reported harm to consumers, and the gross  
20 underreporting of adverse events.

21 The senior FDA pathologist told me at  
22 the time that this substantial number of adverse

1 events reports made FDA regarding dietary supplements  
2 probably represented only 5 to 10% of the true number.

3           Nonetheless, there is substantial  
4 progress being made and I thank you for holding this  
5 meeting today. As the recently departed FDA  
6 Commissioner, Scott Gottlieb, told the New York Times  
7 in February people have (inaudible) framework to  
8 address this case in really decades. I think it's  
9 time we do so, close quote. The promise online,  
10 online watching this specific dietary supplement  
11 ingredients that the Agency was concerned about has  
12 recently been published and that's a good step  
13 forward.

14           However, there's a long and not always  
15 encouraging history involving the ingredients in  
16 dietary supplements and I'm here talking about safety,  
17 not innovation. In 1997 with the instruction of the  
18 then commissioner, I helped organize the Scientific  
19 Advisory Committee on the safety of the supplement  
20 ephedra, which was widely use in supplements. The  
21 committee after reviewing the evidence overwhelmingly  
22 voted there was no safe level of ephedra in these

1 products. Nevertheless, it took FDA seven years to  
2 remove or ban ephedra for these dietary supplement  
3 products.

4           And something that dangerous is not  
5 required to report serious adverse events to the FDA  
6 until 2007. The regulatory environment did not change  
7 substantially a dozen years later. In 2010, 16 years  
8 after the passage of the DSHEA law, I helped convene  
9 the senate committee oversight hearing which the DA  
10 identified numerous examples of misleading or false  
11 advertising by dietary supplement vendors. FDA also  
12 discovered phonetically hazardous contaminants in no  
13 less than 37 of the 40 products they tested.

14           The chief executive (inaudible) consumer  
15 lab (inaudible) and a former FDA official also  
16 testified that fully one quarter of 2,000 supplement  
17 products tested had a quality problem. The hearing  
18 concluded that senior citizens be especially vigilant  
19 about the potentially hazard interaction of dietary  
20 supplement ingredients with drugs they may be taking.

21           Again, certainly with this history  
22 there's been substantial progress over the last decade



1 or more and there are a lot of legitimate players here  
2 today who want to give safe, well-approved products to  
3 their customers, but unfortunately questionable  
4 marketing, phony claims with some phony control  
5 problems, fairly or not, are associated with some  
6 elements of this industry even after 20 plus years.

7 After a quarter century with the  
8 industry, it's a dozen times bigger than it is in  
9 1994, the FDA still has to prove harm before  
10 regulatory actions taken (inaudible) industry.  
11 especially with, in this online age with limited  
12 control over both internet marketing and advertising  
13 such that FDA needs to move more quickly to keep up  
14 with the explosion of products and ingredients and  
15 claims made by suppliers in this industry.

16 The DSHEA law is now 25 years old and  
17 the Agency will struggle to keep up with the explosion  
18 of new ingredients, question of ingredients in the  
19 global marketplace. We need to all work together to  
20 better protect consumers and tighten oversight of this  
21 industry. The consumers include 50% of American  
22 consumers. Thank you for the opportunity to talk to

1 you.

2 (APPLAUSE.)

3 MR. TAVE: Thank you. (Inaudible.)

4 MR. MISTER: Good afternoon. My name is  
5 Steve Mister. I'm the president of the Council for  
6 Responsible Nutrition. I want to express my thanks  
7 first of all to FDA for hosting this dialogue and for  
8 the opportunity be here hear and present earlier  
9 today. And so these comments will respond on what we  
10 heard today and I'll try not to repeat Andrew's  
11 remarks from earlier this afternoon.

12 The question of whether an article is a  
13 dietary supplement is not a safety question, nor is it  
14 a question of whether an article is a new dietary  
15 ingredient, a safety question. Now whether or not it  
16 gets objected to because it's not safe, that is a  
17 safety question. But I think we'll get to safety, but  
18 we don't need to let it color these other decisions  
19 that are inherently not safety decisions.

20 And as I said on Tuesday in another  
21 context, safety is always job one, but it isn't always  
22 the first job. And here I do realize that I sound, my

1 remarks sound a little similar to something I made,  
2 some comments I made on Tuesday regarding a certain  
3 three letter ingredient in it that I promise not to  
4 mention today.

5 But, you know, as I'm listening today,  
6 perhaps the issues that Scott Bass raised this  
7 morning, maybe it makes us wonder if this additional  
8 condition about adding nutritional value to the  
9 criteria was originally injected by those of FDA  
10 because of a distrust of the ability to be NPI and GMP  
11 provisions to address safety questions on their own.

12 And so there was this effort to  
13 interject safety into an earlier stage in the global  
14 market flow chart. I suggest that we use this moment  
15 to restart and determine what is the role of each step  
16 in the regulatory path to the market for old  
17 ingredients, the market for new ingredients, the  
18 pathway to market for synthetic ingredients and, yes,  
19 even for (inaudible). There, I said it.

20 So my message to FDA not unlike the  
21 Philadelphia 76ers is trust the process. You will get  
22 to safety and when you do, that evaluation should

1 absolutely be a robust one, but for companies to  
2 invest in safety they have to know there is a pathway  
3 to market and that the ingredient is a viable one.  
4 They have to know that their investments will be  
5 protected. And these issues need to be resolved first  
6 in order to incentivize the kinds of investments in  
7 safety that FDA wants.

8           Even if the (inaudible) synthetics,  
9 we've heard some interesting questions today about  
10 whether it's going to (inaudible) whether it's  
11 bioequivalent, again, a synthetic ingredient fit  
12 within the six categories in the law. If it can, then  
13 a synthetic copy of a botanical constituent is  
14 definitely a dietary ingredient as much as a synthetic  
15 vitamin is a vitamin. And at that point the Agency  
16 can and should demand an NDI notification and a full  
17 demonstration that that particular ingredient is  
18 reasonably expected to be safe. And then we'll let  
19 the chips fall where they may. But you have get to  
20 that point first.

21           The second point I want to make is  
22 regarding the NDI guidance process. I think we can

1 also use this as a moment for clarity because it's  
2 taken far too long to resolve. And if FDA believes  
3 that there are deficiencies in the statutory provision  
4 for NDIs, then maybe this is the time to have that  
5 conversation with the industry and see if we can  
6 address it through legislation and clarifying the  
7 expectations. But we need, need to move to a period  
8 of certainty and predicability if we want to foster  
9 innovation and investment in the industry.

10 And then the last thing I will say,  
11 we'll underscore something that Andrew mentioned  
12 earlier, and that's enforcement. Whatever we do,  
13 there needs to be meaningful enforcement, enforcement,  
14 enforcement. We can't say that enough. I note that  
15 FDA is quick to lament that the NDI process is, quote,  
16 "the only method by which to evaluate the safety of  
17 new ingredient before they get to market" and often  
18 that's made to sound like it's a hindrance to the  
19 Agency that it's the only way they can monitor safety.

20 But at the same time I note that the FDA  
21 is typically unwilling or unable to use the robust  
22 tools that were given to it with the NDI provision to

1 go after companies that blatantly violate it.

2 Any successful effort in this area  
3 requires enforcement, enforcement, enforcement. Thank  
4 you.

5 (APPLAUSE.)

6 MR. TAVE: Thank you, Steve. Robin  
7 Marles.

8 MR. MARLES: Hi. I'm Robin Marles. I'm  
9 the volunteer chair of the USP Botanical Dietary  
10 Supplement (inaudible) medicine expert committee along  
11 with my colleague, Dennis (inaudible) chair of the  
12 (inaudible). We have a team of about 40 international  
13 experts working on all of the issues around dietary  
14 supplements and setting monographs that have legal  
15 standing in the USP. However, I also wear another  
16 hat. I am an employee of Health Canada where I'm a  
17 senior scientific advisor and a food director at  
18 advising on the addition of dietary supplement  
19 ingredients to foods, and prior to that I worked in  
20 the group that (inaudible) now chairs as the science  
21 on writing the NHG regulations. So I'm very familiar  
22 with how we worded the definition for a synthetic.

1                   We also wrote in mandatory compliance  
2 with pharmacal standards for quality of which USP is  
3 one of our key sources. So the irony here is that in  
4 Canada USP quality standards are mandatory along with  
5 European (inaudible) choose, while being less, they're  
6 voluntary.

7                   So in terms of innovation, what I'd like  
8 to suggest is a much greater focus on the quality of  
9 when you look at adverse reactions. Most adverse  
10 reactions to dietary supplements are due to issues of  
11 quality, whether it is identity, purity, strength,  
12 accidental contamination, or deliberate adulteration.

13                   And in terms of rewarding industry for  
14 being compliant with a reliable source such as the  
15 monograph, which are harmonized to a very large extent  
16 of those of Europe and other countries as well, which  
17 facilitates international trade. But if you were then  
18 able to link that quality assurance to targeted FDA  
19 verification and link that to the number on the label,  
20 you would then greatly increase the consumer's comfort  
21 in using products if they were assured it had the  
22 quality and that creates fertile ground for innovation

1 when consumers really can have some confidence in the  
2 products there.

3 Now we've people express concerns about  
4 the challenges with implementing numbers on labels and  
5 as you heard from my colleague (inaudible) earlier,  
6 the Health Canada way to do that using a very simple  
7 electronic system for registering products. We've  
8 also looked at the Australian therapeutic foods  
9 administration's electric listing facility, the  
10 (inaudible) which is also very efficient.

11 So it's not actually a difficult thing  
12 to achieve. And then with the licensed natural health  
13 products database, there is a public listing of all  
14 those numbers so that consumers can actually check  
15 because, of course, when you have a mandatory number  
16 on the label, there are people who will fit those  
17 numbers. But by posting the list, this then makes it  
18 easy to verify.

19 And so you have the opportunities for  
20 increasing consumer confidence in high quality  
21 products which will resolve a lot of the adverse  
22 reaction issues and you also have a chance to become



1 more harmonized with other country's systems. And I'm  
2 sure my colleagues, (inaudible) and I will be happy to  
3 provide any advise or assistance in seeing how our  
4 system works, learning from our mistakes, and making  
5 your system better. Thank you.

6 MR. TAVE: Thank you, Robin.

7 (APPLAUSE.)

8 MR. TAVE: Karen Howard.

9 MS. HOWARD: Good afternoon. I'm Karen  
10 Howard, CEO of Organic and Natural Health Association.  
11 We're a unique trades association representing the  
12 interest of health-minded consumers and the best  
13 companies in the dietary supplement chain. Our tenets  
14 are really supper demand for access to the safest and  
15 highest quality products available, a demand our  
16 industry members subscribe (inaudible).

17 Even with an amazing safety record, I  
18 believe statistically it's more dangerous to eat foods  
19 or fill your prescriptions. Opportunity still exists  
20 for bad actors who sell inferior or dangerous products  
21 to unsuspecting buyers. Or in the lab (inaudible)  
22 resources to fund enforcement against most egregious

1 players that sell products online, in gas stations, in  
2 convenient stores, (inaudible) weight loss, energy or  
3 sexual performance. They cause the most harm. Let's  
4 fully fund the effort to clean our house with the laws  
5 we have.

6           Second, we see through innovation and  
7 modernization there is an intellectual flaw in the  
8 definition of health claims, vis-a-viv structure  
9 function claims, most also be addressed. Dietary  
10 supplements are, in fact, a category with no change in  
11 definition (inaudible) supplement and pharmaceuticals.  
12 However, it is far too easy to create a new disease.  
13 Osteoarthritis, the result of wear and tear on our  
14 joints, is a condition that will impact virtually  
15 everyone in this room as they naturally age, yet this  
16 categorizes disease in a supplement that may reduce  
17 their pain of this malady can only tend to support  
18 bone and joint health.

19           Circuitous label claims achieve  
20 technical compliance, but keep customers confused.  
21 With regard to health claims, existing regulation  
22 chokes often even science to document how

1 supplementation can reduce the incidents of disease.  
2 For instance, the FDA (inaudible) formal petition to  
3 allow health claims, saying that increased vitamin D  
4 serum levels reduces the risk of preterm birth by 60%.  
5 By the way, the Agency's response was that as an  
6 indicator of vitamin D status, serum levels do not  
7 meet the definition of substance. Serum levels are  
8 not found, are not food or components of food.

9           Given the strength of the research  
10 undertaken with the Medical University of South  
11 Carolina, it leaves one curious and then outraged to  
12 contemplate how existing regulations exclude health  
13 claims about the correlation of well-established  
14 nutrient levels with a well-defined health status.

15           Fundamentally it is not sufficient or  
16 accurate to define a supplement simply as a dietary  
17 substance produced by man or pregnant woman to  
18 supplement the diet by increasing the total dietary  
19 intake. This definition needs to be updated and  
20 modernized.

21           Lastly, dietary ingredients produce  
22 using genetic engineering and novel methods of

1 synthetic biology should be evaluated as new dietary  
2 ingredients even when similar natural ingredients  
3 exist. If in addition to designs of process of  
4 creating novel compounds and formulating products with  
5 them, then full disclosure through the entirety of the  
6 supply chain must be required as part of the  
7 regulatory process.

8 Anything less than 100% transparency  
9 completely fails consumer's desires and expectations.  
10 This misstep can potentially instill consumer distrust  
11 in a helpful category of dietary supplement  
12 ingredients, just as we have seen happen in food  
13 products. Lesson learned.

14 Any dietary supplement company that's  
15 confident in its products and respectful of its  
16 customers will not object to full, honest disclosure  
17 of how its products are made. Thank you for this  
18 opportunity.

19 (APPLAUSE.)

20 MR. TAVE: Thank you. Bernie Landes?  
21 Not here. And our next speaker and our final speaker  
22 for today is Kevin Bell.

1 MR. BELL: You know, (inaudible) I I  
2 think the guy between you guys in a bar would be a  
3 problem. So I'll try to keep this brief. I am  
4 (inaudible) my practice as primary (inaudible)  
5 litigation and regulatory enforcement. I'd like to  
6 thank the FDA (inaudible) fantastic. (Inaudible)  
7 equivalent of facing your accuser, your constitutional  
8 right, but I appreciate it, especially their existence  
9 in managing my procrastination (inaudible).

10 In February (inaudible) used the phrase  
11 idiotic within about ten words of IP. I got very  
12 interested because I do view NDI as the equivalent of  
13 some form of an IP right to proved the intellectual  
14 property protection (inaudible) exclusive protection  
15 (inaudible) use, but it really is almost the  
16 equivalent of what you would see when you file for a  
17 patent or for a trademark.

18 It gives you a period of exclusivity or  
19 a right to exclude others absent a license for a  
20 period of time and you dedicated that to the public.  
21 That's a patent issue. Trademarks can last longer. I  
22 do know this. Eighty percent of this discussion today

1 has been about enforcement and I think 100% of people  
2 agree that, maybe not 100, but pretty close, but if  
3 you do not have NDI for something, you run the risk of  
4 having a technical adulteration of the food, drug or  
5 cosmetic. Whether calling it a misdemeanor or a  
6 felony, it's a violation of the law.

7                   And so when I hear about all of the  
8 things that need to be done to afford enforcement, I  
9 see a much more simple path on this that doesn't have  
10 to involve researches by the FDA. I think you should  
11 always have more money of researchers. But I don't  
12 think it's something that we have to spend a lot of  
13 time on as far as what can be done to move forward  
14 with enforcement without the FDA having to do it  
15 themselves through the Department of Justice.

16                   I think there are opportunities where if  
17 the AKL letter that you receive on NDIN from the FDA,  
18 which is a government document, is treated as  
19 equivalent as when someone gets a patent issued by the  
20 Commissioner of Patents or the patent office, that is  
21 a government document and has a presumption of  
22 validity to it.

1           The patent office doesn't go out through  
2 DOJ and enforce patents. People who own them do. Mr.  
3 LeDoux's remarks if you stifle that opportunity, you  
4 will see a decline in those filings because there is  
5 no market benefit even at this point. When you go to  
6 try to say, hey, I have an issue don't have a problem,  
7 the response is but the FDA's not going to come after  
8 me.

9           And so it should never be about whether  
10 someone only stole a VCR or also stole the jewelry, or  
11 killed someone in the process, to be a misdemeanor to  
12 a felony, the size of the crime or the adulteration  
13 should not be the decision. If it violates the Food  
14 and Drug Cosmetic Act, it violates the Food and Drug  
15 and Cosmetic Act. That's it. And we don't need the  
16 FDA, in my opinion, to have to go out and do that  
17 enforcement on behalf of the people that own NDIs.

18           That document should be enough. I have  
19 one; you don't. I'll go deal with it and the FDA  
20 doesn't have to wade in on it. I'm want to hear about  
21 what the attack would be on ingredients and whether an  
22 old dietary ingredient, that is the equivalent in

1 patent law of a prior (inaudible). We file patent  
2 cases all the time and end up in the world of somebody  
3 finding a doctoral thesis from a Russian institute  
4 from 1949 that says I did this before you. All right?  
5 I can tell everyone in this room if they saw one of  
6 their products, someone, someone using something that  
7 wasn't theirs, but had their trademark or their logo  
8 or their symbols on it, it would incense them beyond  
9 belief.

10 And so I believe NDIs need to be treated  
11 the same way. If they are not, they will be treated  
12 just like patent and trademarks are when they are not  
13 enforced. People will steal; people will knockoff.  
14 It that's, it is that simple. I believe the  
15 mechanisms then for how do you do it, certainly import  
16 alerts and import bans. If it's as simple as here's  
17 my NDI notification and that trips a standard import  
18 alert or import ban, I think that would show there's  
19 no more additional effort to meet everything else as  
20 to how safe something is.

21 It doesn't have to play into the  
22 decision making process at that point, but it does



1 give the stakeholder that has it the ability to move  
2 forward on their own because if they were all spending  
3 money on the NDI, trust me, I can tell you as usual,  
4 they're willing to spend the rest of the money to  
5 enforce it.

6 I, I believe that in the same way that  
7 we can register trademarks at customs through IP  
8 enforcement, and if someone brings something that  
9 violates your trademark and if you help monitor with  
10 customs your trademark, at customs, they'll pull those  
11 things over. I've watched it happen like lightning.  
12 When it comes to patents, import alerts or alert ban,  
13 patents, that's where you go to your district courts.  
14 You go to the International Trade Commission. And  
15 that's how you stop it; you get injunctive relief.

16 And I think here it's the same thing. I  
17 think, I think if anyone's going to start needing more  
18 assistance in enforcement, it might be the folks at  
19 the border. I don't think that (inaudible), right? I  
20 think, I think your job should be making sure that the  
21 NDIs that are put in are the NDIs that should come out  
22 with the letters that you guys send. And I think that

1 letter should mean something.

2                   You've really got to put a lot of effort  
3 into this. Those are (inaudible). I appreciate all  
4 the effort you put in and I think that's your job. On  
5 the enforcement side, I think it's time to let the dog  
6 off the leash and just -- that, that document gives  
7 you what you need to move forward upon enforcement.  
8 You're not, you don't need us. You don't need OCI and  
9 you don't need DOJ. All right? Go do it. This mean  
10 the same, the equivalent as if I got a patent. It's a  
11 government document.

12                   So anyway, thank you for your time. I  
13 appreciate it.

14                   (APPLAUSE.)

15                   MR. TAVE: Am I on? Good. So we're  
16 actually reasonably close to schedule. At 4:30 I was  
17 supposed to come up here and give closing remarks.  
18 It's 4:35. I will be appropriately brief.

19                   First I want to start with thank you to  
20 everybody who provided comment during the final  
21 session. Thank you to everybody who asked questions,  
22 offered thoughts during the panels. Thank you very

1 much to all of our panelists. Thank you to our  
2 audience who, who traveled from near and far to be  
3 here today.

4 I think we mentioned this earlier. The  
5 meeting has been transcribed. The slides that were  
6 presented, as well as the transcript will appear on  
7 the webpage, on FDA's webpage at some point. It won't  
8 be instantaneous, but it will be in the relatively  
9 near future. Keep an eye out. There is an open  
10 docket to which you can submit written comments. I  
11 think everything that we heard today was, was  
12 constructive and useful.

13 I would encourage everybody who has  
14 comments whether they shared them or not to think  
15 about submitting written comments to the docket.  
16 Everything that is submitted will be reviewed and will  
17 be considered. The docket is open until July 15th of  
18 this year.

19 I want to express some thanks to, to our  
20 team here who helped, Dr. Cara Welch who did a lot of  
21 work and even aside from figuring out the clicker  
22 issues, this meeting would not have happened with her.

1 Laura and Sybil who are on panel and were doing a lot  
2 of behind the scenes work today. Lori Papadakis, who  
3 is not in the room right now, and Juanita Yates who  
4 many of you encountered on your way in who, who did an  
5 enormous amount of work in helping this meeting happen  
6 so successfully. And our friends in, in the  
7 communications team, Julia Manges, (inaudible),  
8 Lindsey Hake. I'm sure there are names who I've  
9 forgotten to mention that is entirely my fault and not  
10 a reflection on their contribution.

11 I think that's it for the day. Thank  
12 you very much to all of you. We really appreciate  
13 everybody's partnership and participation and we look  
14 forward to continuing to work together. We are at  
15 ODSP@FDA.hhs.gov if you don't know how to reach us.  
16 The address is on the website. Most of you know how  
17 to reach us, but we will always be responsive.

18 Thank you very much.

19 (APPLAUSE.)

20 (Whereupon, at 4:37 p.m., the meeting  
21 concluded.)

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15 Penny Knight  
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