FEDERAL TRADE COMMISSION

HOMEOPATHIC MEDICINE & ADVERTISING

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FEDERAL TRADE COMMISSION

I N D E X

INTRODUCTORY REMARKS

MR. FORTSCH: Good morning. My name is Greg Fortsch, and I'm an attorney with the FTC's Division of Advertising Practices. I want to welcome all of you today to today's workshop and thank you for coming out in person or listening via webcast.

Before we get started today with our substantive program, I need to review some administrative details. Please silence any mobile phones and other electronic devices. If you must use them during the workshop, please be respectful of the speakers and your fellow audience members.

Please be aware that if you leave the Constitution Center building for any reason during the workshop, you'll have to go back through the security screening again. Please bear this in mind and plan ahead, especially if you're participating on a panel so we can do our best to remain on schedule.

Most of you received a lanyard with a plastic FTC event security badge. We reuse these for multiple events, so when you leave for the day, please return your badge to event staff.

If an emergency occurs that requires you to leave the conference center but remain in the building, follow the instructions provided over the building PA system.

In the unlikely event that an emergency occurs that

requires the evacuation of the building, an alarm will sound. Everyone should leave the building in an orderly manner through the main 7th Street exit, which is on that side. After leaving the building, turn left and proceed around 7th Street and across E Street to the FTC emergency assembly area. Remain in the assembly area until instructed to return to the building.

If you notice any suspicious activity, please alert building security. Please be advised that this event may be photographed. It is webcast, and it is recorded. By participating in this event, you are agreeing that your image and anything you say or submit may be posted indefinitely at FTC.gov or one of the Commission's publicly available social media sites.

Restrooms are located in the hallway just outside this conference. The cafeteria is currently open. It's open until 10:00 with a limited menu from 10:00 to 11:00. It opens for lunch at 11:00 and is open until 3:00, with a limited menu from 2:00 until 3:00.

If you're interested in submitting a comment for the panel to possibly address during their discussion, there are comment cards outside the conference room on the table where there are nametags, as well. The gentleman waving his hand right here will be walking around to collect those comment cards. If your comment doesn't make it to the panel,

never fear, there are comments that you can make online with the Federal Trade Commission until November 20th. And the links are available on the website.

And I should mention at the outset that any views I express today are my own and do not necessarily represent the views of the Commission, any other Commission official, or any individual Commissioner. And this goes for the other government employees serving as panelists and moderators today.

I now have the honor and pleasure to introduce Commissioner Maureen Ohlhausen, who has graciously offered to provide remarks and to open today's workshop. Commissioner Ohlhausen was sworn in as a Commissioner on April 4th, 2012. Prior to joining the FTC, the Commissioner was a partner at Wilkinson Barker Knauer, where she focused on FTC issues, including privacy, data protection, and cyber security.

She previously served at the Federal Trade Commission for 11 years, most recently as Director of the Office of Policy Planning from 2004 to 2008, where she led the FTC's Internet Access Task Force. She was also a Deputy Director of that office.

From 1998 to 2001, Commissioner Ohlhausen was an attorney advisor for former FTC Commissioner Orson Swindle, and she began her career in 1997 in the General Counsel's Office.

She has also served on the adjunct faculty at George Mason University School of Law, where she taught privacy law and unfair trade practices. Prior to working at the FTC, Commissioner Ohlhausen spent five years at the U.S. Court of Appeals for the D.C. Circuit, where she served as a law clerk for David B. Sentelle and also as a staff attorney.

She also clerked for Judge Robert Yock of the United States Court of Federal Claims from 1991 to 1992. She graduated with honors from the University of Virginia and from George Mason University School of Law.

Without further ado, I am glad to welcome and introduce Commissioner Maureen Ohlhausen.

(Applause.)

OPENING REMARKS

COMMISSIONER OHLHAUSEN: Well, good morning, everyone. I want to welcome you all to the FTC and thank you for being here with us today. Our workshop has a single focus: the advertising of over-the-counter homeopathic products. In convening this workshop, the FTC, as always, is furthering the goal of making sure that consumers have accurate and reliable information about the products they buy.

So, if any of you are looking for a discussion of the potential regulation of those who use or practice homeopathic medicine, you've come to the wrong place. We are just looking at issues related to advertising.

Because of the recent growth in the marketing and use of homeopathic products, consumers have greater exposure to such products than ever before. But do consumers know what they are buying when they purchase a homeopathic product? Today's workshop will examine the potential challenges that advertising for OTC homeopathic products pose for American consumers and possible solutions to addressing those challenges.

You will hear from stakeholders, including medical professionals, industry representatives, consumer advocates, and government regulators. They will discuss a variety of topics, including the evolution and growth of the homeopathic

industry, the scientific support for homeopathic advertising claims, and, finally, the legal and regulatory issues presented by the advertising of homeopathic OTC products.

The agency's interest in OTC homeopathic product advertising stems from our longstanding oversight of the marketing of health-related products and services. And although we began planning this workshop independently of the FDA's recent initiative to reevaluate its regulatory structure for homeopathic products, we are mindful of the FDA's role in this area.

As I'll discuss later, the FDA's current regulatory structure impacted our examination of homeopathic OTC product advertising, and the FTC recently provided comments to FDA, giving some thoughts on how we can work together better in this area.

FTC staff has used focus groups and copy tests to research what consumers understand about homeopathy and homeopathic products. As discussed in the comments FTC staff filed with the FDA, the focus group results suggested that many consumers choose homeopathic products based on incorrect and incomplete information. When given additional information, however, they looked more critically at homeopathic treatments and had a better basis on which to evaluate them in comparison to other remedies.

The copy test results revealed that many consumers

mistakenly believe that the FDA had approved homeopathic products for efficacy. They also indicated that consumers erroneously believe that the manufacturers of homeopathic products tested their products on humans for efficacy.

In addition to its research, FTC staff has observed other potential causes of consumer confusion. In our FDA comments, staff noted that it's its belief that consumers may be confused by retail store shelf placement of homeopathic products side by side with conventional medicine that, in fact, has been approved by the FDA for efficacy.

Staff also reports that confusion is likely created by the terminology used in homeopathic products -- product labeling regarding dilution, which results in a very small, nearly undetectable trace of the active ingredient in the water or alcohol substance that's provided to a consumer. Staff believes that it's highly unlikely an average consumer has an accurate understanding of what homeopathic labeling means in this regard.

Thus, the FTC is interested in ensuring that the advertising for OTC homeopathic products contains accurate and reliable information. In the past, pursuing this goal has been complicated by the potential conflict with the FDA's approach to regulating OTC homeopathic products. But for over 40 years, the FTC and the FDA have worked together collaboratively to regulate the marketing of OTC products.

With regard to OTC drug products, pursuant to a 1971 memorandum of understanding between the two agencies, the FDA focuses on product labeling, while the FTC focuses on product advertising.

With the exception of OTC homeopathic drugs, the regulatory approach of the two agencies has been remarkably consistent. The FTC's authority over disease and other health-related claims for all products is clear, straightforward, and not in dispute. It comes from Sections 5 and 12 of the FTC Act. Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in or affecting commerce. It covers the deceptive advertising of labeling of over-the-counter drugs.

Section 12 prohibits the dissemination of false advertisements of foods, drugs, devices, services, or cosmetics. Under these provisions, companies must have a reasonable basis for making objective claims, including claims that a product can treat specific conditions before those claims are made.

The FTC devotes significant resources, including enforcement and educational resources, to protect consumers from unsubstantiated and misleading health claims in advertising for OTC products. The FTC's well-established position on advertising substantiation was first announced in 1972 and has been repeatedly reaffirmed. For health, safety,

or efficacy claims, the FTC has generally required that advertisers possess competent and reliable scientific evidence, defined as tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

Competent and reliably scientific evidence may take different forms, depending on the types of claims made. For some claims, the substantiation required may be one or more well-designed human clinical studies. Neither the FTC nor any -- excuse me, neither the FTC Act, nor any FTC rule or policy statement, exempts advertising claims for homeopathic drugs from these standards.

Turning to the FDA's authority, all articles that meet the definition of a drug under the Food, Drug and Cosmetic Act, including homeopathic drugs, are subject to regulation under the FD&C Act. Specifically, the FD&C Act requires that drugs cannot be distributed in commerce until they are recognized by qualified experts to be safe and effective. Homeopathic drugs have never been regulated under the FD&C Act like other conventional drugs, however.

Prior to 1988, most homeopathic drugs were prescribed to individuals only after a private consultation with a homeopathic practitioner. The shift to offering homeopathic products on an over-the-counter, mass-market

basis began around the time that the FDA issued Compliance Policy Guidance 400.400, entitled “Conditions under which Homeopathic Drugs may be Marketed,” which permitted the distribution of homeopathic products without FDA approval.

Under the CPG, which is still in effect, the FDA permits a company to sell OTC homeopathic products without demonstrating their efficacy and, unlike both nonhomeopathic drugs and dietary supplements, to include claims in their packaging about treating specific conditions as long as the conditions are self-limiting and not chronic.

The CPG also requires that the labeling of homeopathic drugs display an indication for use. The FDA broadly defines “labeling” to include any article that accompanies a product. This can include websites and, under certain circumstances, advertising. Likewise, advertising is broadly interpreted under the FTC Act. Accordingly, the FDA’s requirement that labeling for homeopathic drugs display an indication for use, even when the product has not been demonstrated to be efficacious for that indication, creates a potential conflict with the FTC’s requirement that health claims be substantiated by competent and reliable scientific evidence.

This potential conflict does not exist with respect to dietary supplements or nonhomeopathic drugs because both FTC and FDA law require that advertisers have substantiation

to support efficacy claims for those products. As the FTC noted in the comments filed with the FDA, this potential conflict could be eliminated in one of three ways. First, the FDA could withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products.

Second, the FDA could eliminate the requirement in the CPG that an indication appear on the labeling. Companies could still include an indication in the label and would likely do so, but it would not be a specific requirement of the FDA's discretionary non-enforcement policy.

Finally, given that the CPG is a discretionary enforcement policy, a third way to eliminate the potential conflict discussed above would be for the FDA to require that any indication appearing on the labeling be supported by competent and reliable scientific evidence.

In conclusion, the FTC has been presented with a difficult problem. Although it is desirable that federal agencies with overlapping jurisdiction take a consistent regulatory approach, ultimately, the FTC must carry out its mission to ensure that advertising for OTC drug products, including homeopathic products, is truthful and not misleading. However, we are fully cognizant that there are many important unanswered questions in this area. As a result, we've convened this workshop on the advertising of

OTC homeopathic products. And the FTC looks forward to the thoughtful remarks and input from today's discussion.

Such input will help the FTC in formulating a path forward to ensure that consumers get truthful, non-misleading information on these products. So, we certainly look forward to hearing today's panelists and receiving comments, which may be submitted until November 20th.

Thank you so much.

(Applause.)

MR. FORTSCH: Thank you so much to Commissioner Ohlhausen for her thoughtful remarks, and I now want to welcome the first panel to come up to the stage. I think the only way to get up here is these stairs. The panel will be moderated by Mary Engle, who is now on stage, the Director of the Division of Advertising Practices here at the FTC.

PANEL 1: HOMEOPATHIC INDUSTRY & ADVERTISING

MS. ENGLE: Good morning, everybody, and welcome again to our discussion of homeopathic medicine and advertising. So, the first panel -- and I'll just repeat -- I'm Mary Engle, and I'm the Associate Director for Advertising Practices here at the FTC.

The first panel is going to discuss kind of the -- give you an overview of the landscape of the homeopathic medicine market, which has evolved quite a bit over -- I was going to say this century, but really starting last century, into this century.

And we have a great group of speakers here for you this morning. I won't read all of their bios because they're in the papers, but we have Jay Borneman, who is the Chairman and CEO of Standard Homeopathic Company and Hyland's. And he serves on the board of the Homeopathic Pharmacopoeia of the United States. Candace Corlett, who is President of WSL Strategic Retail. Mark Land, who is President of the American Association of Homeopathic Pharmacists. Yale Martin, who is an independent retail consultant. And Duffy MacKay, who is Senior Vice President, Scientific & Regulatory Affairs, Council for Responsible Nutrition.

We're going to have some brief opening statements before we get on to some questions and discussion, and we'll just start with Jay, actually -- or was Mark going to start?

DR. BORNEMAN: Mark. Yeah, I think it would be best.

MS. ENGLE: Okay.

MR. LAND: Thank you very much, Mary. Good morning, and I would like to thank the FTC and the organizers of this workshop for the opportunity to present comments today. My comments will address the market reality for homeopathic medicines in the United States and clarify some facts about the scope of the industry, its sales, and its advertising.

I'll start with the work of our association. The American Association of Homeopathic Pharmacists, or AAHP, is the leading trade association for homeopathic medicines in the United States. It was founded in 1923 and represents more than 90 percent of homeopathic product sales in the United States. All AAHP members must adhere to association guidelines, as well as pertinent regulations.

Perhaps of particular interest here, the AAHP has an advertising guideline which requires advertisers of homeopathic medicines to include a disclaimer statement alerting consumers that claims made by homeopathic medicines have not been reviewed by the U.S. Food & Drug Administration.

The homeopathic industry is a small industry compared to the OTC prescription drug and dietary supplements

industries in terms of revenues, advertising, and marketed products. However, it has a long history, and its medicines have been trusted in American homes for generations.

In large part, the story of homeopathy in the United States is that of families using medicines formulated by homeopathic companies -- excuse me -- to treat simple conditions in the home. Not surprisingly, publicity is overwhelmingly by word of mouth and based on consumer satisfaction.

Many or most popular homeopathic medicines have been in the marketplace in the United States for 50 years or more. Contrary to some published reports, the market for homeopathic product sales in the United States today is about $1.1 billion annually. The market is growing at roughly 5 percent per year, mimicking OTC drug products in general.

The majority of homeopathic medicines are indicated for cough, cold, and flu, muscle pain, and children’s ailments and represent less than 3.5 percent of OTC products offered in popular drug chains. The Homeopathic Pharmacopoeia of the United States requires that labels of homeopathic medicines prominently include the disclosure “homeopathic” or “homeopathic medicine.”

Turning to advertising, it’s safe to say that advertising is not a major contributor to the modest growth in the homeopathic market. I mentioned that word of mouth

has traditionally been the primary driver, and that remains true today. In fact, studies show word-of-mouth recommendations from satisfied consumers and healthcare practitioners consistently rank high for influencing trials of homeopathic medicines.

Conversely, advertising consistently ranks low as an influencing factor. Most advertising is restricted to print in health-related publications or targeted freestanding inserts in newspapers. Broadcast advertising is limited to very few products and brands, and digital media has only very recently started to play a role.

As a result, advertising spends are stable or even slightly declining. For example, review of the OTC topical pain relief category, one of the largest for homeopathy, shows a modest decline since 2010. In 2010, the advertising spend was 4 percent for the category that was homeopathic medicines, and the spend was only 2.5 percent in 2014.

Let’s talk about safety for just a few moments, since it’s the hallmark feature of homeopathic medicines. The American Association of Poison Control Centers has reported that less than 1 percent of all reports of exposures for pharmaceutical products involve a homeopathic medicine and that more than 98 percent of these exposure reports result in no or minor effect.

As the leading industry association for homeopathic

medicines, I'd like to leave you with a few final thoughts. These medicines have been part of the American -- of American healthcare for generations. It's a small industry compared to other healthcare segments, but it's popularity is largely due to word of mouth, due to satisfied consumers telling other consumers rather than mass advertising efforts.

Homeopathic medicines are marked by impressive safety overall, follow GMPs and labeling regulations from FDA, and are supported by literature-based medical evidence, which is the worldwide standard for substantiation of homeopathic claims.

To ensure consumers and advertisers are not confused, the industry has taken a proactive path by creating guidelines for label disclosures and disclaimers. And with that, I'd like to conclude by saying that the AAHP welcomes this opportunity to partner with FTC and the FDA, and I thank you for the opportunity to provide these comments today.

MS. ENGLE: Thank you, Mark.

Now Jay?

DR. BORNEMAN: Thank you, Mary. I noticed you looked at me when you said the 18th Century. I hope it's because I'm going to deal with history and not because of how old I am.

So, thank you for the opportunity to speak this morning. I'll talk a little bit about the evolution of

homeopathic pharmacy in the United States. It has mirrored the market generally, and it's been driven by consumer choice. Homeopathy, as a field of medicine, was first introduced in the United States in 1826. Homeopathic pharmacy began shortly thereafter in 1843. Within a few decades, many of the major homeopathic firms still in existence today began preparing homeopathic medicines, including Boericke & Tafel, today a brand from -- owned by Schwabe North America; Luyties Pharmacal, a standard homeopathic company; and my great-grandfather's firm, Borneman & Sons, which is now known as Boiron USA.

As one can see, the roots of homeopathic pharmacy run very long and very deep in the United States, as well as in my family. Let's talk a little bit about how the market developed. Throughout the 19th and 20th Century, the homeopathic pharmacy market was physician-driven as physicians trained in homeopathic medical schools and opened homeopathic hospitals.

With the publication of the Flexner Report in 1910, the medical schools were surpassed by their allopathic counterparts, and by the mid-20th Century, the last school, Hahnemann in Philadelphia, had ceased teaching homeopathy altogether. By the way, the last professor was my great-grandfather.

Physicians would not be taught homeopathy again

until the 1980s. Accordingly, the number of medical doctors utilizing homeopathy slowly declined from the early 20th Century peak until its low point in 1970, followed by a resurgence in the years that followed.

Consumer homeopathic medicines date from the 1850s, with Humphreys Pharmacal combinations and self-care kits from Luyties Pharmacal. By 1970, there was a burgeoning consumer movement that resulted in homeopathic products beginning to be sold in health food stores and independent drugstores. With few exceptions, retail sales of homeopathic medicines were the province of these small retailers.

In the mid-1990s, some drug chain pioneers, notably the Jack Eckerd Company, began experimenting with adding homeopathic drugs to their mix. And by the end of the 1990s, most major drug chains in the United States carried a handful of homeopathic drugs and had an appetite for more.

Shortly thereafter, the number of market entrants grew, as did the number of channels, expanding to grocery and mass merchandiser channels. And during this period, retailers undertook a series of merchandising experiments, trying a variety of approaches: natural product sets; some tried homeopathic sets; others merchandised by brand; and some merchandised by disease state or symptom. Different retailers made different determinations, and all of these approaches are still in use today.

Let's talk about pharmacopoeias. Of crucial importance to homeopathy, as well as conventional medicine, are the pharmacopoeias, so I'll talk about them for just a second. Pharmacopoeias are official publications that document the scientific substantiation, technical and quality standards for drug products. The first homeopathic pharmacopoeia was published in 1842 in the United States. The Homeopathic Pharmacopoeia of the United States, or the HPUS, which remains in publication today, was first published in 1897 by the American Institute of Homeopathy, the physicians organization.

In 1980, the Homeopathic Pharmacopoeia Convention of the United States, the HPCUS, was independently incorporated separate from the AIH. The HPUS was completely revised between 1980 and 2004 and now is an online publication containing 1,295 final drug monographs, along with guidelines for homeopathic manufacturing, standards and controls data, toxicology and safety data, and labeling guidelines. Its last update was this year, 2015.

The Commission has expressed concerns with homeopathic advertising in two particular domains: consumer confusion and claimed substantiation. Speaking for myself and for my firm, I believe that these concerns can be addressed in a straightforward approach. First, require that homeopathic drug products be clearly labeled and advertised

as homeopathic. Labeling is required by the HPCUS already.

Two, require that a notation that the product has not been reviewed by the FDA be clearly stated on labeling and advertising. This is -- the industry association already had guidelines in effect.

And, third, require that all OTC homeopathic drug ingredients be subject to a final monograph in the HPUS. This will ensure that the drug has been reviewed for quality and safety and that sufficient data concerning the drug appears in the homeopathic literature. These three requirements will significantly address the Commission's concerns and are in line with the industry's strong desire to be known and recognized as homeopathic among consumers.

Thank you.

MS. ENGLE: Thank you, Jay.

Candace?

MS. CORLETT: Thank you, everyone, for inviting me to contribute to the panel here today. My name is Candace Corlett. I'm President at WSL Strategic Retail. And the purpose of our business is to monitor changes in shopper thinking and behavior: how shoppers learn about products, how they decide where to buy them, how they decide what they will buy.

We monitor trends through ongoing surveys that are conducted online among national samples of men and women that

have at least a thousand participants in each survey. And all of our participants are shoppers in mass channels like supermarkets, drugstores, department stores, the mass merchants.

In the last two years, we have been doing a lot of work around the shoppers' interest in the wellness movement and in how they manage their short-term health conditions. It will come as no surprise to you that healthcare in the U.S. is in transition, and a lot of that transition is driven by the technology of the internet. Instant access to information, to ratings, to peer evaluations are building shoppers' confidence in their ability to learn about how to take better care of themselves, how to zero in on getting information about how to treat their conditions, whether it's common cold, arthritis, allergies, pain, even ear wax.

It was during these studies that we have studied how shoppers use and buy over-the-counter medications, homeopathic medications, and we've monitored their satisfaction and repurchase intent with these product categories for their healthcare.

Sharing information has created a widening circle of trust among shoppers for their healthcare. People consult and respect a wider variety of medical professionals, and they now have a broader portfolio of medications, including homeopathic medications, to treat their short-term illnesses.

This trend to greater confidence and self-education and care is particularly strong among people who are more tech-savvy and are younger people in general, the ones who are in the life stage where they're less likely to have -- visit a doctor regularly or to have conditions that require prescription medication.

Here's what we've learned about people who buy homeopathic medicines. First of all, most people who purchase homeopathic medications do their homework. They are avid about checking recommendations, and the number one way they learn about homeopathic medication is through word of mouth, recommendations from their friends, their family, their physician. Thirty-seven percent of shoppers have learned about their homeopathic medication through some form of recommendation. Another 18 percent have done their own online research; and 12 percent have learned about it through traditional advertising in newspapers, ads, commercials.

The second point is that satisfaction is very high. We asked people who use homeopathic medications for different conditions how satisfied they are with the performance of this treatment, and depending on the condition, the range of satisfaction is 60 to 73 percent.

More interesting even is that half of people who have chosen to use a homeopathic medication for one condition have gone on to use it for several other conditions. So,

once they're introduced to the concept, then they're buying similar products for other conditions.

And who is the shopper for homeopathic medicine? All of them are much more involved in knowing about their healthcare. They are more likely to use health websites, to subscribe to newsletters about healthcare, to eat healthier now than they did five years ago. They say they exercise more and they buy more organic products. Overall, on a demographic profile, they are younger; better educated; more moms are likely to be buying homeopathic medications; and they're all pretty tech-savvy.

Thank you.

MS. ENGLE: Thanks, Candace.

Now, we'll go to Yale.

MR. MARTIN: Sure, thank you.

My name is Yale Martin. I spent 25 years in retail. During the last ten of these years, until November of 2014, I specialized in over-the-counter products, basically everything nonprescription related to a pharmacy, so cough, cold, allergy, antacids, laxatives, vitamins, et cetera.

In my final retail position, I managed the buying office for Walmart's OTC business. The buying team I led was responsible for merchandising more than 4,000 items in Walmart's 5,000 U.S. stores and included both allopathic and

homeopathic products.

My discussion today will center on the consumer, retailer, and manufacturer market dynamics from the perspective solely of a retailer. Consumers today, more than ever, seek to meet everyday noncritical healthcare needs at their local pharmacy. They're leveraging recommendations from friends and relatives, like "this worked for me," as well as utilize the internet for information.

They will also often compare various product labels while standing at the retail shelf. While advertising plays a huge role in the OTC arena with allopathic drugs, it is not significant in the homeopathic area, simply because the manufacturers spend very little on advertising. While consumers address their more chronic health issues with their family practitioner, they have come to rely on the convenience of over-the-counter products to address noncritical health issues. They appreciate -- and some would say demand -- multiple options from their local retailer.

The market dynamics of consumer products in a retail environment closely follow Darwin's survival of the fittest. Items must sell or turn or the products are quickly replaced. Shelf space is exceptionally valuable to every retailer, and each item must pay its rent or it faces elimination.

Retailers regularly update their product offering,

and items which fall in the lower quartile of their peer items are those first considered for deletion. Every retailer has a minimum expected level of unit or dollar sales per store per week or month, also known as a threshold. In many ways, the consumer herself chooses a product offering in today's retail stores.

Every sale is a vote for an item to remain on the shelf. Items which do not sell enough or get enough votes at the register are eliminated. This market dynamic has a positive influence for public in that items that fail to meet consumer expectations are not repurchased nor benefit from friend or relative recommendations. In other words, items that don't work typically do not last long on the shelves of American's retailers.

These marketplace rules apply to all products. There is no exception for homeopathic products, and it reinforces a positive, consumer satisfaction with these products. In spite of very aggressive marketing campaigns supporting allopathic products and little supporting homeopathic products, the homeopathic items have managed to maintain their place on the shelves of America's retailers.

The market dynamics that apply to items also apply to manufacturers. Manufacturers that have a history of supplying retailers with items that meet their expectations and are invited back to submit additional items for

incremental shelf space. Manufacturers that have a history of supplying retailers with items that have performed poorly find it difficult to get subsequent appointments with that retailer's buying staff.

Poorly performing items are costly for retailers. They take up shelf space that could be allocated to better selling merchandise. They usurp inventory open-to-buy dollars. And they require costly markdowns to eliminate that inventory.

Every retailer in America tracks the sale movement of their merchandise offering, often on a daily basis. The laws that apply to survival of the fittest with products and suppliers in the marketplace also apply to retailers, and those retailers who do not provide what the consumer is looking for seldom last long. But in the end, it's the consumer who benefits, whether it's a product, a manufacturer, or retailer, these dynamics police the marketplace, rewarding those who meet consumer expectations and punishing those who don't.

Thank you.

MS. ENGLE: Thanks, Yale. And now we'll hear from Duffy.

DR. MACKAY: Hello, everybody, and thank you for coming. And thank you, Mary, for having this event. I'm Duffy MacKay, and I represent the dietary supplement

industry. I'm part of a trade association that represents both dietary supplements and functional foods and their ingredients. And I'm going to talk a little bit about the similarities and differences between dietary supplements and homeopathic products.

Supplements were defined by statute in 1994, and our ingredients include vitamins, minerals, botanicals, herbals, amino acids, and also dietary substances that are used to supplement the diet. That's where things like CoQ10, carnitine and other things come in.

So, why am I here? Well, there's a lot of similarities. We have a similar type of consumer, and that's just my opinion, that's attracted to homeopathic products as well as dietary supplements. We have similar types of practitioners, integrative practitioners. I'm also a naturopathic doctor. I was trained in homeopathy, and I use dietary supplements. These are the types of tools that we might use in our practice.

We also have similarities in our ingredients. We use herbs and botanicals. So, I might have chamomile as a dietary supplement, but I also might have chamomile as a homeopathic remedy. So, you can see, again, more similarities. I might even use the same supplier of chamomile if I'm a homeopathic manufacturer versus a dietary supplement manufacturer.

However, there's a few key differences between the two categories, and I think one of the main differences is regulatorily. Dietary supplements are regulated as a category of food. So, therefore, because we're regulated as food, we cannot claim to treat, prevent, cure, or mitigate disease. Our claims can only be limited to supporting normal structure and function of the body.

Homeopathic products are regulated as drugs, and, therefore, as discussed, they make claims to treat, prevent, or treat and prevent, you know, sniffles and things like that, aches and pains, self-limiting diseases.

Again, the difference in claims is while we can only claim to support normal structure and function, we are required to have credible scientific evidence to support that claim. So, the Federal Trade Commission has a guidance document. They have a standard of science. It's a flexible standard. We don't always agree on that standard.

We often end up in court talking about that standard; however, we are required to have credible scientific evidence in the form that's the same kind that you use to get approval for a drug. You've got population-based evidence; you've got mechanistic evidence; and you have clinical trials. And I think homeopathic evidence is entirely different, and we'll learn more about the scientific substantiation later today.

You may ask why am I here. I'm here because about -- in 2010, we had actually wrote a letter to the Federal Trade Commission because we were noticing a pattern where companies were obviously attracted to making the kinds of claims that you can make for homeopathic products, as well as the low threshold for making those claims.

So, we started noticing products in the marketplace that actually were probably dietary supplements, and they were labeling themselves as homeopathic products, and in my opinion, without empirical evidence, it wasn't able to say for colds and flus. Everyone wants to be for colds and flus. No one wants to be for normal structure and function of the respiratory system. It doesn't make a lot of sense, right?

So, then, we had also products that were blending homeopathic ingredients and dietary supplement ingredients, again I think in an effort to make claims. None of this is legal if you follow the regulatory compliance documents, and you're in compliance, and you actually are a homeopathic or you are a dietary supplement, but it's happening.

And, then, finally, we also saw a more disturbing trend of ingredients that are not allowed to be dietary supplements, things like human growth hormone and other ingredients, being called homeopathic products. Why would we care about that? Because when there's complaints about those products people point to who? The dietary supplement

industry. And we take the heat for that kind of thing in the media, as well as in the court of public opinion.

And, so, our effort is to draw a bright line and say we are dietary supplements; we have a regulatory system; we have a substantiation doctrine, and that's what we follow, and homeopathics are different. And that's about it. That's all I'm here for.

MS. ENGLE: Great. Thank you, Duffy.

So, I was wondering if maybe Jay or Mark could expand a little bit upon what happened in the regulatory environment about, say, 25 or so years ago that really changed the market for homeopathic medicine. I mean, we heard a little bit from Commissioner Ohlhausen at the beginning. It started out that -- and for decades, maybe more than decades, maybe more than a century -- these medicines were largely done on a prescription basis. A patient would go to see their homeopathic practitioner and presenting with certain symptoms, and then something would be recommended for them.

And then in 1988, the FDA issued the CPG that allowed the over-the-counter sale of these products. And how did the market react to that?

DR. BORNEMAN: Do you want me to take that? Do you want me to start with that, or do you want to take it?

MR. LAND: I'll start, and then you can fill in. I

think that the intro that Commissioner Ohlhausen gave us was very accurate or mostly accurate, just a little bit of precision. First of all, I think it's really important to note that self-medication and self-medication products have always been part of homeopathy. Jay had mentioned in his talk that some firms date back to the mid 19th Century with self-medication products. And as I said, to a large extent, homeopathic medicine was really families using these medicines at home.

There was a resurgence in interest in homeopathy beginning in the 1970s, along with many other changes in lifestyle. And that came to the attention of FDA in the early 1980s. There was two things that happened. The first was that there was this growth in interest in homeopathic medicines; and there was also an influx of manufacturers from different parts of the world entering the market in the United States.

And, so, at that time, FDA was facing products being offered for importation that needed to be evaluated, so the market became more complex from that standpoint, and FDA found it necessary to define some controls for the market. That was developed over a long period of discussion between the FDA and the industry, and the document has been remarkably successful since that time.

It was promulgated in 1988; became effective in

1990; and what it did was it really defined the rules for the industry. And when rules become clear, business tends to grow. And as part of that growth, the business was expanded to new channels of distribution, having gone from primarily a distribution channel of the natural products industry into retail pharmacy, specialized pharmacies, pharmacies specializing in homeopathic medicine, and then eventually into national retailers.

So, I think that the effect of the CPG in 1988 and then later in 1990 was to give the clear rules by which business could expand distribution of these products, and it's worked very well since that time.

Jay, maybe you want to add.

DR. BORNEMAN: Yeah, just to add a couple points. First, I think it's really important to delink the compliance policy guide with the development of channels in the United States, channels being defined as retail channels, whether they be natural food stores, independent pharmacies, and so forth.

The Compliance Policy Guide is a relatively durable document if you think that it's 25 years old, and you think about what the world was like back in 1983 when it was originally conceived. I actually was there for that. I was the kid in the back of the room with the duct on my mouth when my father said don't say anything.

So, the world has changed a lot, and yet the Compliance Policy Guide, plus or minus a few tweaks that we probably could talk about, is a relatively durable, durable framework. The Compliance Policy Guide may have created the conditions under which the homeopathic pharmacies could have built their business -- there's no doubt about that, because regulatory frameworks are necessarily conducive to growth. But the channel development really developed for a different reason.

What happened, at least in my opinion, is that the core user of consumer homeopathic medicine that was in the natural food store and independent pharmacy began to ask for those products in other channels. And as the retailers, and the great example is Thrifty Drug in Los Angeles that had carried Hyland's Teething Tablets back from the 1950s, didn't even know it was a homeopathic product. They just knew people wanted it.

Over time, as people clamored and went back to the smaller drug chains and asked for it, they began to evaluate what are these products and should we sell them. So, it was really the channel shift was the consumer going to different channels and asking for the product. As that began to coalesce, then the channel shift develops. And, so -- and now we see a channel shift into Amazon. I mean, it's the same sort of thing.

The homeopathic medicine, the development of the market, is not distinct from the development of a market generally. It follows exactly the same patterns. And, so -- and I think that Mr. Martin makes a really good point, which is that there's no way the tiny little homeopathic pharmacies can force inventory into large drug chains or large retailers. Those decisions are made by the retailers for their consumer, who they have their connection with.

So, I don't think -- I do think we need to delink that 1988 Compliance Policy Guide with the market.

MS. ENGLE: Okay, great. So, even though the homeopathic medicine is following the general trends, though, I think, Mark, you said it's still very much smaller than the dietary supplement market. Is that right?

MR. LAND: Yes. As I mentioned, the homeopathic market -- and this is at retail prices -- is estimated by commercial reporting firms at $1.1 and $1.3 billion annually. And, you know, that's grown from about somewhere around $900 million about five years ago. So, growth has been about 5 percent, which is about the same growth rate as the OTC market in general. But just to put that in perspective, the OTC drug market is estimated at about $40 billion annually, and roughly the same for the dietary supplement market, as well.

So, we are a very small fraction of those markets.

We'd love to be that size, but we're just not that -- not there yet.

MS. ENGLE: Okay. So, when did the OTC homeopathic products first begin appearing in the national retailers? You mentioned they started out in kind of the smaller drugstores, and then people were demanding them more, and they started to shift. So, when did we start seeing them in the large mass-market retail chains?

DR. BORNEMAN: Okay, so, you have to remember what the world looks like with drug chains. We now have five -- probably four or five dominant players in the United States. And in the 1990s, there were five times that many. And, so, what happened was that the regionals where they were -- they had a market area that was conducive to homeopathic medicine in the Pacific Northwest. California and so forth started asking for products.

As those drug chains were subsumed and consolidated, it forced those medicines into other parts of the country. If you think about there's one major chain now that's made up of six chains through consolidation, and so that was one aspect of it.

So, it started -- I would estimate it started mid '90s. By the late 1990s, there were at least a handful in most of the regionals and small nationals. And within five years after that it had expanded out. And I guess at the --

about 2000, ‘99 to 2001, in that bracket, it finally went into mass merchandisers, big box stores.

MS. ENGLE: Okay. And I think now we have a short video clip that we’d like to play, talking about the placement of these products in the stores.

Are you ready?

VIDEO: The most important thing we’ve learned about, again, breaking down this barrier of people not being that involved in homeopathic medicines is the fact that you have to put them in next to the conventional remedies that are available. Wherever you find these products, and whether it’s drugstores, natural food stores, supermarkets, consumers tell, again, us in the focus groups the same thing. They say, when I have a problem, I need a solution, and I look in one area for my solutions. So, they are looking for a natural alternative or complimentary alternative to the conventional medicine that they’re used to taking.

MS. ENGLE: So, is that the experience of the folks on the panel, then, generally? And I would say it’s my anecdotal experience going into this store that the homeopathic remedies are placed side-by-side with the FDA-approved OTC drugs, whereas the supplements are in a separate section, whether it’s a drugstore or a supermarket.

DR. BORNEMAN: Do you want me to take it?

MS. ENGLE: Anybody.

DR. BORNEMAN: So, this video, I think -- I saw it last night. This video is probably between 10 and 15 years old, and it represents sort of an analysis by one company, Boericke & Tafel at the time, of a natural experiment that was going on at the time. Some retailers were what they call brand blocking, which is putting all of the companies products together on the shelf in one place. So, all of one Company A, Company B, Company C.

Others were going by disease state or disease category: cough/cold went in one category, maybe one in another category. Others were creating what were called natural sections. So, dietary supplements and homeopathic medicines were being in part of the store. What this fellow was talking about was they were doing focus groups and trying to find out what the result was, trying to follow the consumer. And what the consumer was saying, what she was saying is that she wanted to find them in a place where all the cough/cold was together wherever.

That’s not really how it all shook out. How it all shook out is that all of those -- all of those techniques are currently being used. And some retailers use more than one technique. So, it is true that we are adjacent to other cough/cold, you know, products in some retailers, but in other retailers, it’s by company and so forth. So, it sort of is all over the place.

For me, it has to do with the retailer -- and Mr. Martin will be able to talk about this -- it has to do with the retailer read of what the customer wants and then the retailer reacts to that and does what they think is the appropriate way to go.

MS. ENGLE: Anything?

MR. MARTIN: I think -- yeah, I think that's absolutely correct. Realistically, what the retailer is trying to do is to figure out exactly what the customer wants. How does the customer want to shop? And typically they're wanting to shop based upon some sort of symptom or ailment they have. And they expect to find the homeopathic items along with the rest of the items, and they want to make a choice at the shelf.

Mr. Borneman mentioned that sometimes they'll be brand blocked. That's correct as well. I think one thing to remember is that the retailer's real asset is that shelf space across the country, and it's exceptionally valuable. Those of you -- you probably -- a handful of folks in here understand this, but every square inch on a retailer's shelf is programmed.

There's a fairly sophisticated software program called ProSpace that is -- basically takes items on a scale level, so they're measured, and those items are entered into a computer program, and they're actually set on a virtual

shelf. And basically every square inch of that shelf is merchandise. So, sometimes, in order to leverage that space or to maximize that space, sometimes you have to put things where you don't necessarily want to put things.

I've done it. I was a buyer for years, and that's what I did. So, in most cases, you're looking at items that are in their exact location where the buyer wants to put them, and again, the buyer is trying to follow what is the customer expectation. We're all at the mercy of our customers, so...

MS. ENGLE: Yeah, and as people who follow shoppers, we're frequently advising our retail partners that shoppers shop by condition, and they would love to have everything, all their choices for a condition, presented all in the same place. Regardless of whether or not that's operationally efficient for the retailer, that's the way the shopper would like to see it.

DR. MACKAY: And on that I guess the one limitation would be that you wouldn't be able to put your supplements in a store by condition because then you would be implying they're for --

MS. ENGLE: Right.

DR. MACKAY: -- treatment of a disease, and, therefore, the supplements would be sitting over here in the just-for-staying-healthy aisle.

MS. ENGLE: And, so, Candace, what does your research show in terms of where most people are buying homeopathic products?

MS. CORLETT: Very much in the classic places where they shop for their healthcare. Fifty-two percent will buy homeopathic in a drugstore in the course of a year. Forty-eight percent will buy it in mass merchant, like a Walmart or a Target, over the course of the year. About 30 percent in a supermarket; and then there's a following in specialty food and specialty vitamin stores where about 17 to 20 percent of shoppers choose those stores. And then, of course, the internet, which is -- at the time that we did this study -- was 14 percent.

MS. ENGLE: So, the internet is up to 14 percent?

MS. CORLETT: Yeah. That was as of about mid-2013.

MS. ENGLE: Okay. The consumer research that the FTC staff conducted Commissioner Ohlhausen referred to at the beginning suggests that some consumers erroneously believe that homeopathic products are essentially synonymous with natural remedies or home remedies. They don't have a very precise understanding of it at all, really.

Do you have any indication that any research that consumers do understand when they are buying homeopathic products what they're getting or what the difference might be to the OTC drug that's next to it on the shelf?

MS. CORLETT: You know, we did very much include that in our surveys, and we didn't ask people to say -- to play back what they think homeopathic is. We asked them, do you feel that you clearly understand what the "homeopathic" means. And in order to put that in context, we included some other generic terms, like do you feel you understand what "natural" means, what "organic" means. And the responses for homeopathic was 38 percent felt that they clearly understood what "homeopathic" meant. Fifty percent said they clearly understood what "natural" meant. And 52 percent said they felt they had a clear understanding of what "organic" meant.

So, half empty, half full. Shoppers think they do, but then also they're not sure that they do. And what our recommendation to our clients is shoppers don't buy generic terms; they buy brand names. And then they buy a brand name and if they are satisfied with the performance, then they rebuy the brand name. So, we've seen the high satisfaction rates for homeopathic; so they rebuy the brands. And then they go on, and when they know that this type of product works for them in one condition, half of people who have purchased homeopathic then go on and buy a homeopathic remedy for another condition.

So, they may not have a clear understanding of what the term means, but they have a clear understanding of the benefits they're getting from the product.

MS. ENGLE: Great. Thank you.

The consumer research that the FTC staff conducted also suggested that consumers incorrectly think that homeopathic products have been tested for efficacy as OTC drugs have been. How can a consumer tell the difference between a homeopathic drug and an allopathic drug? Mark, do you want to take that?

MR. LAND: Yeah, I'll take that. I think that first of all homeopathic drugs, they're labeled as drugs. They do bear the mention of either homeopathic or homeopathic medicine on the label, so it's quite clear that this is a different type of product.

I think that FTC's own research demonstrates that consumers are able to make a clear distinction between conventional drugs and nonconventional drug products, including herbs and diet supplements. And, so, really, the distinction is between an herb, for example, and a homeopathic medicine.

And the -- you know, we are now living in an era when we have all been exposed to drug facts labeling and dietary supplement or food supplement facts labeling now for a generation. And we need to give the consumer a little bit of credit. There is a difference between a drug facts label and a dietary supplement label, be it an herb or otherwise, and I think consumers are able to understand that.

So, there are quite a few signals on a dietary -- or excuse me, on a homeopathic drug label that differentiate those products from other products in the category.

MS. ENGLE: Okay, thanks.

Duffy, you mentioned this -- alluded to this in your opening remarks, but could you expand upon the concerns that you have about dietary supplements who may decide it may be easier to present themselves as homeopathic than as a dietary supplement?

DR. MACKAY: So, I was actually just reading a magazine, and I saw a big, one-page ad for a homeopathic cold-and-flu product that was based on elderberry -- the herb elderberry. And I use the herb elderberry a lot, and I think it's a wonderful herb. And I just wondered, because everything to me just on first glance, I said, wow, this company is crazy advertising like this for their supplement. And then I looked closer and closer, and then I was like, oh, wait, it's a homeopathic. That's how they're able to do it.

And then I started to just ask questions around, like what's going on here, is everybody going to want to do this with their herbal products? This is a great opportunity. And I started hearing, you know, rumblings of companies saying, yeah, this is great, you know; you can make these claims if you call yourself a homeopathic. So, the draw was there.

I think if I remember, there may have been a warning letter or something along those lines, that seems to have settled down a little bit. But then again, there was a product where you sprayed it under your tongue, and it was vitamins and minerals, and you sprayed it in your mouth, and they made some pretty wild claims, weight loss, this, that, the other. And we had press calls, New York Times and others, calling us as a supplement trade association saying how do you account for this. And as I looked closer, the product was labeled as a homeopathic, and I was like, why are we taking the negative reputation sort of outcome of this.

And then, thirdly, there was sort of some interest in human growth hormone and some concerns it was showing up in supplement products advertised for bodybuilding. And, so, we deal with that, and we're always trying to work with FDA and other regulators to try to keep that as a minimal outlier practice and seeing what we could do to eradicate it, but then I noticed an alternative was they were labeling it as homeopathic, homeopathic human growth hormone, spray human growth -- and obviously there's a very vulnerable consumer that wants to get built and buff that's going to look at something like that and go for it. And my concern was is there human growth hormone in there. Who knows? And, so, that was just another concern.

So, we put all these concerns in a letter wrote in

2010 to the Federal Trade Commission, had a meeting, sat down and discussed, and just sort of became -- and our goal in that meeting was just to sort of say, hey, guys, this is not us. Let's be very clear; this is not dietary supplements. This should not be our reputation and so forth.

DR. BORNEMAN: Mary, can I jump in a little bit?

MS. ENGLE: Sure.

DR. BORNEMAN: As the pharmacopoeia guy here, I think that Duffy's making really good points. I think that if you look at our current regulatory framework, 400.400, the Compliance Policy Guide, the combination of homeopathic and nonhomeopathic ingredients is prohibited. If you look at the way the pharmacopoeia approaches things, these vitamins and supplements and growth hormones and things are what we call noncompendial products. They are not products that have -- or in our case drugs -- that have been reviewed by the Homeopathic Pharmacopoeia Convention of the United States, which is the experts.

So, I do think that there is a constellation of products out on the fringe that are causing odgena for both the dietary supplement people and the homeopathic people. It's a question of regulatory discretion and whether or not the regulators decide to do something about those products, but I do know that I think if any of the regulators went back and talked to industry about them, they would probably find

an inclined ear because the press spillover is bad for everybody. And, frankly, the folks in the press don't make a distinction between who the bad actors are and who the good actors are. Everybody gets tarred with it.

So, Duffy, I'm right there with you. I'm going to follow your parade.

MS. ENGLE: And, Candace, I think you mentioned maybe 16 percent of consumers are buying their homeopathic drugs on the internet. Oh, 14 percent. Do the panelists see a distinction between the kinds of products that are available on the internet versus those that will be stocked by a Walmart or a Walgreens or a Whole Foods?

MR. LAND: I'll start with that. Just to put things in perspective, there are about over 7,000 homeopathic medicines registered with FDA today. Now, not all of those products are marketed, that's for sure. Some of them may have been discontinued from the market. But in the mass distribution channel, so places like Walmart and Walgreen, et cetera, by our measurements, there are fewer than 100 products that are on the shelves in those kinds of outlets. Actually, we counted 78. So, in those channels, the number is small. The volume is probably larger individually for those products.

Probably in reality there's about a thousand homeopathic products that are marketed on a routine basis,

and the vast majority of those are in highly specialized either independent pharmacies -- and there are a handful of very important homeopathic pharmacies around the country that really specialize in homeopathic medicines, and they stock a very wide variety of products. And then there are retail stores like Whole Foods, et cetera, that probably stock in the neighborhood of hundreds of different products.

So, the question is where are those other 6,000 products that haven't been accounted for. And they're probably sold on the internet; however, it's really important to note -- or they could be dispensed through physicians' offices, as well. But it's important to note that when we talk about internet sales, we're talking about people like Amazon.com, Drugstore.com, CVS.com, et cetera, traditional pharmacy distribution channels, but they're just on the online version.

So, there's a filter there. They're not stocking a wide variety of products. There is some control, and to the certain extent, they all exist according to the same law of Darwinian theory that Yale has mentioned. If they don't sell, they don't -- they're not on the internet.

But I think that if we look at a chain like Amazon, for example, or a system like Amazon, they're probably merchandising something in the low hundreds of different products.

MS. ENGLE: And I think one of you mentioned in the call we had prior that you feel pretty confident that the major retailers, the products they're selling only contain ingredients that are listed in the homeopathic pharmacopoeia, and they're not making some of the claims that we've seen on the internet say for things like curing cancer, obviously not a self-limiting condition or one that could be, you know, a customer could figure out by themselves.

DR. BORNEMAN: It's my own -- it's my personal belief that the counsel's office at the retailers -- large retailers are very much on top of what's being merchandised in their stores because they stand joint and severally liable if something happens. So, they're on top of it. Whether every drug that's sold in a mass retailer is compendial, I don't know, but I would argue that most of them are, if not very close to all of them are.

Every industry has outliers. And, so, if you focus on the outliers, you sometimes miss the point. And I think the point is that maybe we need to clean up the outliers.

MS. ENGLE: Mm-hmm.

MR. LAND: Well, and I'll just step in because we've mentioned a lot about HGH, et cetera, and I think we do have to give the regulatory community some credit in that both the FDA and FTC have taken steps against these products rather swiftly. And the reason is is that they're easy to

identify in the marketplace. HGH, clearly it's not going to be within the homeopathic literature; it's not going to be used for indications that have traditionally been treated by homeopathic medicines. So, you know, it's sort of like a speeder going through a red light, pretty easy for the cops to identify.

MS. ENGLE: Yeah, and in addition, the FDA and the FTC sent joint warning letters to --

MR. LAND: Absolutely. Sure.

MS. ENGLE: -- various marketers of homeopathic HCG for weight loss.

MR. LAND: Exactly.

MS. ENGLE: Yeah. And followed up with a couple of lawsuits, as well.

MR. LAND: And H1N1.

MS. ENGLE: Yeah.

MR. LAND: That was lots of fun.

MS. ENGLE: H1N1, as well, yeah.

I think we have some questions that have been passed up. Okay, thanks.

Oh, so, the first question is kind of a like a back-to-basics in terms of what is the definition or should be the definition of a homeopathic product. Maybe we were assuming too much knowledge here. And I don't know; I mentioned the term "allopathic," which was one I hadn't heard

myself until fairly recently. So, maybe -- I don't know who'd want to take on defining that.

MR. LAND: I know we have a lot of lawyers in the room, too.

(Laughter.)

MR. LAND: But, you know, the homeopathic product -- or a drug is defined in the federal Food, Drug & Cosmetic Act, and as it relates to homeopathic medicines, it is a product that is contained within the Homeopathic Pharmacopoeia of United States or its supplements. And that's a very simplified view. In operation, it is probably simple to say that it's a product that's prepared homeopathically and that has historically been used as a homeopathic product.

DR. BORNEMAN: One modification to that. The Compliance Policy Guide says it's recognized as homeopathic if it is an article that has a final monograph in the Homeopathic Pharmacopoeia of the United States or is generally recognized as homeopathic. So, that "or" is an important modifier in the current regulatory framework.

Does that answer your question?

MS. ENGLE: Yeah, I think so. And I don't know whether -- are we going to get into the second panel about things about dilution and that topic, or would that be a good thing to address here? Address it here.

DR. BORNEMAN: Okay. So, the homeopathic manufacturing process is unique in pharmacy. It has some components to it that set it apart. First, homeopathic medicines are made using a process called dilution and succussion. Dilution is the serial deconcentration, either one part in ten or one part in 100 stepwise of the act of principle. Along each step of that deconcentration is a vigorous succussion or shaking step. So, there were two things characterizing the homeopathic manufacturing process.

Homeopathic medicines are used according to the principle of similars. That principle says that if a drug in a large quantity causes symptoms in a healthy individual, and another individual presents with those symptoms from another etiology, it is possible that a homeopathically prepare form of what would have caused the symptoms in the healthy individual may have a mitigating effect in the afflicted individual.

So, the idea is that you use a substance that may cause symptoms in a healthy person. Think of an onion causing runny eyes and runny nose. Homeopathically, if you have seasonal rhinitis, allium cepa made from the red onion serially diluted and succussed may relieve those symptoms. That is homeopathy 101 in 15 seconds.

MS. ENGLE: Thank you, Professor.

(Laughter.)

MS. ENGLE: The next question is whether the placebo effect has been studied in regard to consumer satisfaction with homeopathic products. It has been mentioned that largely marketing of these products has been done word to mouth over the years; there hasn't been a huge amount of traditional advertising. So, recommendations from friends, and then if people aren't satisfied, they wouldn't continue to buy it, and that's why you see continued shelf placement.

Of course, there is a potential placebo effect. We see that all the time with other products. Has that been studied with homeopathic remedies?

MR. LAND: You know, I know there's physicians that will speak later, maybe more eloquently about this, but Candace will tell us that our satisfaction rating for homeopathic medicines is between 60 and 80 percent, depending on the therapeutic category. Placebo effect accounting for the Hawthorne component of that is probably around 30 percent -- doctors can correct. So, we can see that there's a wide difference between the satisfaction level for homeopathic medicines and the potential placebo effect.

DR. BORNEMAN: And I will add another nonscientific point. And that is that homeopathic medicines are routinely used for small children who would not necessarily be subject to the placebo effect. I think trying to -- actually, the

idea of crafting a population-based placebo effect study is sort of a fascinating idea. That might be fun to do.

MS. CORLETT: And when we have asked shoppers about their satisfaction, if they're treating a condition, they're often treating it with both over-the-counter medication and homeopathic medication. And the satisfaction rates are about on a par for both types of medication.

MS. ENGLE: Although I will say there is a case involving an FTC product where the court noted the effect of a mother's kiss on a child's boo-boo.

DR. BORNEMAN: I wonder how one measures that.

(Laughter.)

DR. BORNEMAN: Is that a hard end point?

MS. ENGLE: Let's see, this may be a question for Candace or Yale. I'm curious about learning more about the profile of who buys -- we touched on a little bit who is buying, the sort of demographics of who's buying homeopathic products, particularly with maybe Latino or ethnic communities or other minorities. Are there particular communities that these particularly appeal to and are popular with? And kind of the role of maybe culture in these particular purchasing habits and beliefs.

MS. CORLETT: You know, we did look at that, and we did see a little bit of bump among African American consumers in terms of homeopathic medications, not dramatic. We also

looked, thinking maybe, you know, the West, the Northwest, or the Southwest would be particularly stronger in terms of use of homeopathic medications, and we didn't see as much geographic differences that we thought we would. And just a bit of a bump among African American consumers.

MS. ENGLE: This question states that homeopathic products often claim in their advertising that they're regulated by the FDA, and consumers believe this implies these products have been tested for efficacy. So, wouldn't this claim be inherently deceptive?

MR. LAND: I would recommend against that practice. I think that the trade association has made a very strong recommendation that all labelers and advertisers of homeopathic medicines use a disclaimer announcing specifically that the products have not been evaluated by the Food & Drug Administration.

MS. ENGLE: And is that the disclaimer, Jay, that you had -- I think one of the three things you had recommended was --

DR. BORNEMAN: Yeah. I mean, there are a number of variants that are out there right now, and I think that you may see some data later on on how they compare to one another. But I think there's a premise here that we need to make sure we understand. Most homeopathic firms -- my homeopathic firm -- is very proud of the fact that we're in

the homeopathic pharmacy business. Accordingly, announcing that our product is homeopathic on the principal display panel is not a hardship. It's what we want to do. It distinguishes us. It's what makes us different.

The proclaimer language, which is what my team calls it, not a disclaimer language, we're proclaiming what we are, actually is just another part of that. And, frankly speaking, were it mandated, I don't think that most homeopathic firms would find it problematic at all.

So, the FDA-regulated thing is a little problematic because, as drug companies we follow GMPs and all these other things, and we are regularly inspected by the FDA and blah, blah, blah, blah. So, there is some truth to that, but to use it to sort of mislead a consumer is inappropriate.

MS. ENGLE: Well, then, this next question kind of gets to the issue of the -- to the labeling on the package as homeopathic, and I guess there's two aspects to that, and one is whether it's prominent enough that consumers actually see and notice it. And the second is even if they do notice it, do they understand what it means. So, just the word by itself in our research has suggested that people didn't really get what it was.

DR. BORNEMAN: Yeah, I think it's a legitimate point, and I think reasonable people could discuss how large, how -- what the point size of the word "homeopathic" needs to

be. I don't know that that's particularly problematic. I know that from our own experience we put package inserts in our product that talk about homeopathy. We want our consumer to know more about it. And I think it goes back to Candace's research that says that people that are satisfied with the product and the brand and the idea go back and buy more. Homeopathic medicine is a very typical low-trial, high-repeat business.

MS. ENGLE: Thank you.

Rich, are there more questions you wanted to pass up?

MS. ENGLE: Okay, all right. Yeah, I don't understand this question either.

DR. BORNEMAN: Why did you give it to me?

MS. ENGLE: Maybe too much -- because you're the professor. It's too much technical terminology.

DR. BORNEMAN: The question says, if a product has an NDC code, then can a consumer tell if the product is an approved drug. The answer is no. An NDC code has nothing to do with drug approval. It's just a listing or registration.

MS. ENGLE: I don't know what an NDC code --

DR. BORNEMAN: A national drug code. It basically says you tell the FDA that you're going to sell the product, and you fill out the form.

MS. ENGLE: Okay.

DR. BORNEMAN: I mean, there is -- I mean, they review the form to make sure that the form is appropriate, but there's no level whatsoever -- that implies no level of scrutiny whatsoever. It's just a registration number.

MS. ENGLE: Okay. And does the -- we talked a little bit earlier about that some -- maybe some of the sellers on the internet are not really following the rules and so forth. They may be selling ingredients that are not really listed in the homeopathic pharmacopoeia and for indications that it's not appropriate.

Does the HPUS play any role in this? Is there any kind of self-regulatory body that would address kind of wild-west type of marketing?

DR. BORNEMAN: Yeah, the answer is no and yes. The HPCUS is a standard-setting body. It's not a regulatory body. And we don't hold ourselves out to be a regulatory body. But the standards that we set and the guidelines that we set could be used by regulatory bodies, should they choose to do so. So, we are a willing and happy partner in the process, but we are not a regulatory body, per se. That would be inappropriate relative to our role in federal law.

MR. LAND: From the trade association standpoint, we are not a regulatory body either; however, we do have procedures for reviewing and accepting new members. And part of that is to review representative labels of the products

that they market and to be consistent with the code of ethics of the association.

But more importantly and probably more effective than that is we conduct an education program that we call Compliance Through Education, and that's really aimed at trying to educate marketers and labelers of homeopathic products, very often on labeling and labeling issues, and our labeling seminars and webinars are the most widely attended of all the seminars that we offer. And they are generally taught by qualified experts. A few of them are here in the room, attorneys with a great deal of experience in labeling of drug products.

I would love to be able to say that we are reaching out to everyone. That's, of course, not true. But generally these labeling webinars, et cetera, exceed probably double or triple the amount of association membership. So, that means that we're reaching out to quite an audience beyond those that are members of our association.

MS. ENGLE: Okay, thank you.

Is there -- one more question? Okay. A couple more questions.

So, Duffy, I know that the Council for Responsible Nutrition has -- is pretty active in the self-regulatory space, and would you like to describe what you all do there?

DR. MACKAY: Yeah, we have a partnership with the

Better Business Bureau, the National Advertising Division, where we actually supply a grant that funds a position that helps review dietary supplement advertising through a process of challenge. So, what takes place is if anybody out there sees an advertiser that they feel has got false and misleading claims about it, they can do a challenge to that advertising where it's a voluntary process that's moderated by the National Advertising Division.

And, so, you would log your challenge through the NAD and say we saw this ad, we question its evidence to support. The NAD sends a letter to the manufacturer; the manufacturer has a certain given amount of time where they pull together their substantiation in the form of scientific evidence. They supply it back to the NAD, and there's a process; you know, it's an arbitration process that takes place.

And then, ultimately, the National Advertising Division comes up with a decision, and they look at that, and they sort of say, okay, Company X, you've been challenged and either, A, your claim is substantiated, good job; or, B, we think it needs to be modified for these reasons, and they give a very exhaustive definition of why the science doesn't meet the standard.

And then, at that point, the company has the choice to voluntarily comply. And if they choose to ignore the

decision of the National Advertising Division, there's a relationship with the FTC where they send a nice letter that says, you know, we've evaluated this case; these are the conclusions we've come to; FTC, if you get a chance, will you take a look at it.

And that usually has sort of its own strength to it. You know, people don't want, you know, their case teed up to the Federal Trade Commission within, and, so, therefore, there's a strong will to comply. And what's nice about the process is it's, you know, not the court of law, and it's not hugely expensive, and it's moderated very confidentially.

So, it's been really great for the dietary supplement industry. It's coming on nine years old at this point. We're about to have our ten-year anniversary of this. We've done, you know, over 150 cases. Some of these cases have gone up through the Federal Trade Commission and ended up to be big-deal cases. Lots of times, people get the first letter, and they say, holy, moly, we had no idea, and they change their advertising, and they get their act together. So, it's done a lot for cleaning up the industry.

MS. ENGLE: Yeah, and I do think -- I mean, just my perspective, when I see that it's a challenge that was brought by the trade association for the industry, I think, well, they probably looked into this, and, you know, there's

a good reason for this challenge to be happening.

DR. MACKAY: Yeah, and that's the other thing is that the competitors can challenge competitors, but we, as a trade association, have also agreed to do a certain number of challenges per year, just on our own, where we fund the challenge, and we challenge our own members, and we challenge others in the industry. And, so, you know, we're trying to do our part. And the whole idea is that the regulatory agencies are under-resourced, and we all support more resources, and we always like to say, FTC, you know, do your job more or, FDA, do your job more. But the bottom line is they have limited resources, so there's a role in the self-regulatory programs.

MS. ENGLE: Okay. And we will be hearing from Kat Dunnigan, who is the attorney at the NAD, in the last panel of the day.

All right, one last question, I think we have time for. Does the AAHP or the HPCUS play a role in identifying or reporting noncompliant products or outliers? Something similar to what Duffy described that CRN does.

MR. LAND: You know, this is an issue that the AAHP has struggled with for some time, and I'm actually very glad to hear what Duffy has announced because it's potentially -- or parts of it are potentially a model for the AAHP. At this time, we have actually not really filed -- our principal

regulator that we would point to would be the FDA in these kinds of issues. And we had a history of filing comments with FDA when we identified outlier products. And due to under-resourcing there, there was very little action that they were able to take, and that practice kind of fell off. But I'm very interested to speak with Duffy, as well as representatives of the NAD to see how we could enact something like that, like they're doing.

MS. ENGLE: All right, great. Thank you.

Well, we've run out of time, and I want to thank all the panelists for this very helpful and educational discussion.

(Applause.)

MR. FORTSCH: We are going to go right into our next panel. And as they come up to the stage, I just wanted to say a couple of brief things. If you're on the panel, you're welcome to come right on up. This is the panel that will examine scientific support for homeopathic advertising claims, and it's going to be moderated by Rich Cleland, who's an Assistant Director in the Division.

While they're assembling, I'm just going to point out that there are opportunities to make remarks, comments on FTC.gov until November 20th. I'm going to repeat this a number of more times, just so that if you feel frustrated that your question didn't make it or your comment didn't make

it, you do have an opportunity to provide that on our website until November 20th.

So, I'll let everyone assemble, and Rich will take over in a minute.

PANEL 2: SCIENTIFIC SUPPORT FOR HOMEOPATHIC ADVERTISING CLAIMS

MR. CLELAND: Good morning. My name is Rich Cleland, and I'm an Assistant Director in the Division of Advertising Practices. And last week, the FTC conducted a survey on the internet of products labeled as homeopathic. Among other things, we found products for eczema, acne, psoriasis, heartburn, flatulence, pain, tendinitis, arthritis, menopausal symptoms, ADHD, common cold, flu, weight loss, anemia, gum disease, diarrhea, and many more.

The question we're going to ask this panel is what kind of evidence constitutes competent and reliable scientific evidence sufficient to substantiate OTC homeopathic product claims. We have assembled a broad-based panel, and I'm going to introduce those people now.

To my left here is Dr. Richard Lostritto, the Acting Associate Director for Science and Division Director, Office of Policy for Pharmaceutical Quality at FDA, and he has a couple more titles, too, but those are in the bio.

At the end -- at the very far end is Dr. John Williamson, Branch Chief, Basic and Mechanistic Research in Complementary and Integrative Health at NIH.

Next to him is Dr. David Riley. He's board-certified in internal medicine, has conducted provings and clinical research, and is on the Board of the Homeopathic

Pharmacopoeia of the United States.

Second to the end down there on my right is Dr. Paul Herscu, who is the founder and Director of the New England School of Homeopathy.

Next to him, on his right, is Dr. Adriane Fugh-Berman, Associate Professor in the Department of Pharmacology and Physiology at Georgetown University. Next to me is Dr. Wayne Jonas, President and CEO of Samueli Institute Medical Center.

And next to him is Dr. Freddie Hoffman, CEO of HeteroGeneity. Dr. Hoffman was with the FDA for 13 years. And more expanded information is available about their bios. Right now, the procedure that we're going to use is that each panelist will have up to five minutes to make an opening statement, and then we will have a general discussion of issues related to science and homeopathy.

Let's start with Dr. Lostritto -- Lostritto, sorry.

DR. LOSTRITTO: Good morning. That's fine. Thank you.

Good morning and thank you for the invitation to participate on this scientific technical panel today. As a representative of the Office of Pharmaceutical Quality within CDER I am pleased to discuss product quality issues during this workshop as they may relate to products labeled as homeopathic. For clarity, today I will not be speaking to

FDA policy regarding homeopathic products.

Among many things, quality of a medicine includes the purity and grade of all ingredients that go into the product. Quality also includes the synthesis or isolation process and their controls to obtain the inactive -- excuse me, the active ingredients. Quality includes the methods of manufacture, that is, the processes by which raw materials are converted into a finished dosage form, which is then housed in a suitable container closure for distribution and use.

Data are required to support the stability of the product in that container closure to ensure adequate purity and potency over the shelf life. For sterile products, that includes sterility testing and, as appropriate, preservative effectiveness testing.

Conventional or allopathic drug products and biologics, whether prescription or over the counter, are required to meet certain standards of product quality before they may be marketed. By having quality standards in place, the intended, that is, the as-tested efficacy and safety outcomes, are more effectively assured.

Homeopathic products share many of the same desired quality-related outcomes as so-called allopathic products. These include a desire to manufacture consistent products of high quality that are properly made, which are stable

throughout the labeled shelf life and are without contamination from raw materials, processing, packaging, and so on.

However, there are some notable quality gaps between allopathic products and homeopathic drug products based on what is provided in the Homeopathic Pharmacopoeia of the United States. A brief listing of them includes, but is not limited to, the following general items: The controls of mother tinctures and triturates contain ambiguities and lacks testing for content and uniformity of the active principles, as in the case of botanicals, for example.

Dilution may be confounded by surface-active substances such that the real dilution may not always match the theoretical attenuation. This could be addressed, for example, by content testing at intermediate dilutions where low but measurable amounts of the active substances are present.

There is also confusion about the various succussion methods available for use. There appears to be no industry standard or basis for choice of method that is clearly evident. In the case of high attenuations, demonstrating a lack of active principle by normal chemical means may prove useful.

There are also concerns around several other quality issues, which I will mention only briefly for the

sake of time. These include but are not limited to testing and validation of sterility and preservative effectiveness where appropriate; and container closure integrity for vulnerable dosage forms such as injections, as well as liquid and semi-solid formulations for other routes of administration.

Although not strictly a quality concern, we do note for a number of monographs listed in the Homeopathic Pharmacopoeia that the lower attenuations listed in the Rx and in some cases, OTC use contain levels of active ingredient that could be thought to fall within allopathic, pharmacological, immunological, or toxicological active ranges.

Thank you very much for your kind attention, and I look forward to a productive discussion. Thank you.

MR. CLELAND: Thank you, Rik.

Dr. Williamson?

DR. WILLIAMSON: Good morning. I'm John Williamson from the National Center for Complementary and Integrative Health, NCCIH, at the National Institutes of Health. I'd like to begin my remarks by sharing a bit about my relevant background and where I worked before offering a few thoughts about the science regarding homeopathy.

First, I have a degree in pharmacy and hold a doctorate in medicinal chemistry and natural products

chemistry. I'm also an emeritus professor and former researcher in the field. At NCCIH, I serve as a Branch Chief in the Division of Extramural Research, and I oversee the Center's basic and mechanistic research efforts within our grantee community.

NCCIH's mission is to define through various rigorous scientific investigation the usefulness and safety of complementary and integrative health approaches. The Center's research priorities are driven by a strategic planning process, and the work we fund has to meet rigorous standards of scientific promise, amenability to study, potential for change -- potential to change health practice, and have a relationship to use and practice.

NCCIH's research portfolio focuses on two principal areas of research: first, mind and body practices such as meditation for stress, as well as yoga for pain conditions and secondly, natural products. Our research in natural products has ranged from basic mechanistic studies to the cofunding of major studies such as AREDs, a study that showed that a dietary supplement containing high doses of vitamins C and E, beta carotene and zinc may delay the development of advanced age-related macular degeneration in people who are at high risk.

Also, the GEM study. This is the Ginkgo Evaluation of Memory study of over 3,000 people, which showed that

ginkgo is ineffective at reducing the development of dementia and Alzheimer's disease in older people.

Key to the research of natural products clinical studies for NCCIH is our product integrity policy, which has strict criteria to ensure quality in natural products used in NCCIH-funded research and rigorous methods and design of clinical trials using practices to find as CONSORT, Consolidated Standards of Reporting Trials, which is an evidence-based minimum set of recommendations for reporting randomized clinical trials.

As I noted, the NCCIH is part of the National Institutes of Health, or NIH. NIH, as the nation's medical research agency, includes 27 institutes and centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic clinical and translational medical research and is investigating the causes, treatments, and cures for both common and rare diseases.

NIH-supported scientific studies range from laboratory research to large randomized controlled clinical trials to test the efficacy of medications to prevention trials. The research that NIH ultimately supports goes through a rigorous, two-tiered peer-review process, which is designed to evaluate the scientific merit of grant applications while avoiding bias and conflicts of interest,

which ensures that the researchers funded are held to the highest standards of scientific approach and methodology.

In speaking about homeopathy today, I'm addressing the potential study of ultra-high dilution homeopathic products. This is distinct from products that may be labeled as homeopathic but have active ingredients. Furthermore, I am not referring to homeopathic care or its delivery or the potential benefit of patient/provider interactions.

In regard to what the science shows about homeopathy, the scientific literature describing the most rigorous clinical trials and systematic analysis and review of the research have concluded that there is little evidence to support homeopathy as an effective treatment for any specific condition. A 2015 comprehensive assessment of evidence by the Australian Government's National Health and Medical Research Council, for example, concluded that there are no health conditions for which there is reliable evidence that homeopathy is effective.

As there is no accepted scientific method to measure the components in ultra-high dilution products, it would be difficult to meet the NCCIH's product integrity policy criteria for a study of these products.

Finally, given some products labeled as homeopathic may contain active ingredients, this does raise safety concerns as active ingredients in products should be studied

for efficacy and safety, including toxicity and interactions and would be amenable to rigorous scientific investigation.

Thank you very much.

MR. CLELAND: Thank you, John.

Dr. Riley?

DR. RILEY: I want to thank everybody for inviting me -- or the FTC for inviting me here to speak today. I wanted to step back for a second and say that in January 1996 David Sackett, who is widely recognized as one of the key figures in evidence-based medicine, published an article in the British Medical Journal, and he said, “Without clinical expertise, practice risks become tyrannized by evidence” -- and by that he meant external evidence -- “for even excellent evidence may be inappropriate for an individual patient.”

So, as previously described in the last panel, according to the Homeopathic Pharmacopoeia Convention of the U.S., which is kind of a mouthful, but it’s the HPCUS, homeopathy is the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes, and conditions when administered to healthy people in a homeopathic drug proving.

I would step back and just comment that this is kind of similar to what we do in allergy desensitivization in conventional medicine, which doesn’t make a whole lot of sense, but it seems to have a role to play in some patients.

Efficacy determinations for homeopathic ingredients that are officially monographed in the Homeopathic Pharmacopoeia of the United States, which is the HPUS, not to be confused with the HPCUS, are made by the board of directors of that organization. And officially monographed homeopathic ingredients in the HPUS are supported by one of three things: homeopathic drug provings and/or clinical research and/or the use of that homeopathic product prior to 1962 when the Kefauver-Harris Amendment came into play.

Labeling guidelines for OTC homeopathic products are available through the Compliance Policy Guide, and that covers both official and unofficial homeopathic drugs.

So, homeopathic drug provings are submitted to the HPUS -- or when they’re submitted to the HPUS those drug provings are conducted on subjects using a homeopathically prepared medication, prepared according to the GMP guidelines of the HPUS, and they adhere to all the current regulations for clinical practice.

These drug provings must follow -- there’s a bunch of things here -- the Helsinki Declaration, good clinical practice research guidelines, adverse event reporting, and they should -- they have to have IRB approval. Placebo controls are recommended to minimize bias. Contemporary homeopathic drug provings are essentially controlled qualitative trials, not quantitative trials, and the HPUS

homeopathic drug proving guidelines provide an outline for homeopathic drug-proving methodology that's acceptable to the HPUS. And this has been a recent effort of the organization to clarify and qualify the standards.

So, we talked a lot about scientific evidence and the scientific evidence frameworks commonly as a conventional internist refers to clinical practice guidelines and various treatment recommendation classification systems such as GRADE. And these recommendations help create a risk/benefit analysis based on expert opinion, case reports and series, cohort studies, observational studies, quasi-experimental designs, which are really controlled trials, and controlled trials which have multiple subcategories, from N of 1 trials to efficacy trials to pragmatic trials, and systematic reviews and meta-analyses.

So, there's all this whole ever-changing soup of evidence that's being used to evaluate effectiveness. So, there's a complete database of clinical evidence regarding homeopathy, not all positive -- some positive and some negative. It's available through the CORE-Hom database of clinical research in homeopathy. It's at no charge. And it currently includes 1,117 clinical trials of homeopathy.

Probably more relevant to easy access, except this is a database that's widely available now, there's 217 controlled clinical trials that were identified in a recent

review published by Robert Mathie in a peer-reviewed indexed medical review. And 80 of those -- 137 of those were peer-reviewed.

And in conclusion I would talk -- mention Gordon Guyatt, who is one of the founders of the GRADE analysis. He says, “High quality evidence” -- and by that he’s referring to systematic reviews and randomized controlled trials -- “don’t necessarily imply strong recommendations and that strong recommendations can arrive from low-quality evidence.” So, I think there’s a wide range of standards and a wide range of regulatory frameworks that are in place today.

Thank you.

MR. CLELAND: Thank you, David.

Dr. Herscu? (Mispronounced.)

DR. HERSCU: Good morning, and my name is Paul Herscu.

MR. CLELAND: I’m sorry.

DR. HERSCU: No, no problem. Thank you for the opportunity to present comments on behalf of the American Association of Naturopathic Physicians, the national professional association representing 4,500 licensed naturopathic physicians in the United States. Our members are physicians trained as experts in natural medicine, attending four-year, in-residence, full-time, graduate-level programs in institutions recognized by regional accrediting

bodies that are, in turn, recognized by the U.S. Department of Education.

Naturopathic medical schools provide equivalent foundational coursework as M.D. and D.O. schools, including basic sciences, as well as specialties, such as cardiology and urology, et cetera. In addition, N.D. programs provide extensive education unique to the naturopathic approach, emphasizing disease prevention and whole-person wellness, including general and specialty education in homeopathic medicine, leading to board certification in homeopathy, the DHANP.

Since N.D.s are extensively trained in pharmacology and these integrate naturopathic treatments with prescription medications, often working with conventional medical and osteopathic doctors to ensure safe and comprehensive care and as such have a unique perspective of questions of homeopathy in the United States.

Aside from my involvement with the AANP, I cofounded the New England School of Homeopathy, the largest and oldest continuous post-graduate study of homeopathy in the United States, training physicians in the art and science of integrating homeopathy into their medical practice; as well and sort of kind of interesting, I consult with conventional pharmaceutical industry to design -- in the design of clinical trials focusing on identifying and

removing confounders to clinical trials. And, so, I have a foot in both the pharmaceutical world and homeopathic world in terms of study design.

I wanted to start by highlighting the reason I became a naturopathic physician, focusing primarily on homeopathy. At the time of my medical education, the 1980s, I thought the current medical model had a blind spot that no one was looking at. Specifically, when prescribing a drug or therapy, clinicians have no idea, a priori, whether they would help or not their own patients.

In other words, when we knew a drug was 60 percent effective or 70 or 80 percent effective, we had no tools or even a way to approach the most basic salient point: Is the patient in front of me -- my patient -- is he going to fit the 80 percent likely to improve or in the 20 percent who's not likely to improve. And, more importantly, is my patient likely to be in the majority that are not going to experience any adverse events, or will my patient suffer from horrendous side effects?

There were no tools available to the clinician, and we all moved in lock step, as if this question did not matter, did not even exist, though it did and does to me. So, too, was this a question important to the originators of homeopathy who decided to create a better way to test pharmacological agents. Homeopathy gave us several

methodologies to testing medical agents and created what to this day still forms the backbone of the very best in clinical trial design in answering the most important question: Which of the many therapies available to me will my patient most likely benefit from?

I have a lot to say on this whole topic, but to the question at hand, I hear both state that homeopathic remedies work, are and should continue to be available OTC, and forgotten, homeopathic methodologies form a strong, vibrant science backbone and background that is currently used by all scientists, whether they know it or not. I hope to discuss some of that today.

Thank you.

MR. CLELAND: Thank you, Paul.

Adriane?

DR. FUGH-BERMAN: Homeopathic remedies are not supported by competent and reliable scientific evidence. Establishing a benefit of a therapy in humans requires randomized controlled trials, or -- also called RCTs. Randomization, excuse me, ensures that study subjects have an equal chance of being in a treatment or control group. In controls, which can be a placebo, or it can be a sham, or it can be a proven treatment, which are necessary to account for the fact that any therapy has nonspecific effects? Nonspecific effects are also called placebo effects, and

these are patient and practitioner factors that contribute to a therapy's benefits.

Diseases and symptoms get better, get worse, persist, or vanish for many different reasons. Expectation, will, and belief on the part of either the patient or the practitioner -- because if a practitioner believes in a therapy, it will work better for the patient -- the natural history of a disease and many other factors, some of which are known and some of which are unknown, all affect how a patient responds to a therapy.

A controlled study is necessary to determine whether a therapy's value lies only in provoking nonspecific or placebo responses. Is the placebo effect a bad thing? No. Placebo effects are genuine, and they're therapeutic. Placebo effects represent the patient's own self-healing powers. Every therapy, including conventional drugs and surgery, induces placebo effects that can amplify the physiologic effects of a therapy. If you believe in a therapy, it will work better for you. And if you believe in your healthcare provider, whatever therapy that healthcare provider uses, is going to work better for you.

But it's because of the placebo effect that RCTs are necessary. Only a randomized controlled trial can establish whether a therapy has an effect above and beyond its nonspecific effects. And only therapies that are better

than placebo or a sham or equal -- or are equal to proven treatments should be marketed with disease claims.

Therapies supported by scientific evidence have therapeutic effects over and above placebo. Here is where homeopathy fails. The effects of high dilution or what homeopaths call low-potency homeopathic products are placebo effects, and this has been confirmed by most high-quality RCTs of high-dilution products. Most of those high-quality RCTs of high-dilution products have found no benefit of homeopathy over placebo.

There are positive RCTs of some homeopathic preparations; however, many of these trials have been done with dosages of compounds that are pharmacologically active. In other words, because there’s no upper limit on how much of a substance can be in a homeopathic remedy, these preparations can contain measurable and pharmacologically active levels of ingredients, including drug-strength dosages of minerals, plant-based medicines, or prescription drugs.

A test of a pharmacologically active dose of a mineral is a test of a dietary supplement. A test of a pharmacologically active dose of a drug is a test of a drug.

I want to say a word about homeopathic provings. Careful observation is an important part of science, but so is reproducibility. And when we’re talking about looking at clinical benefit, we need to have a randomized controlled

trial. Provings, because they use pharmacologically active doses, may cause symptoms. Participating in a proving may also elicit symptoms that are not due to pharmacologic effects. But provings are not scientific; they're merely descriptions of symptoms that are elicited by substances.

More importantly, provings have absolutely nothing to do with the efficacy of a therapy. Any substance, including water, in a high enough dose will cause symptoms. That fact says absolutely nothing about the ability of that substance in any dose to help those symptoms or to help any symptoms.

Even if one believes that provings provide useful information, a proving provides diagnostic, not therapeutic, information. Homeopaths assess symptoms and match them with symptoms induced in a homeopathic proving. A proving may help a homeopath reach a homeopathic diagnosis, but it says absolutely nothing about therapeutic benefit.

I understand that the label on homeopathic products is the FDA's concern rather than the FTC's, but the question as to whether homeopathic remedies are supported by competent and reliable scientific evidence can't be rationally addressed if what is considered a homeopathic remedy can contain a drug-strength compound or materially nothing or anything in between.

Efficacy and safety claims can be promotional

claims. We've heard today that advertising contributes little to the sales of homeopathic products, but promotion can contribute a lot to the sales of products, and as Commissioner Ohlhausen noted, where a product appears on the shelf can be a promotional claim. Efficacy claims can be promotional claims. Safety claims can be promotional claims.

Most consumers have no idea what homeopathy is. That's already been brought up. And I would add even if they think they do. So, Ms. Corlett's survey did not test whether consumers who think they know what homeopathy is are actually correct.

MR. CLELAND: Adriane, could you --

DR. FUGH-BERMAN: Okay, yeah. Okay, there is no alternative science to establish therapeutic benefit. Only RCTs establish competent and reliable scientific evidence. Homeopathy has failed that standard.

MR. CLELAND: Thank you.

Dr. Jonas?

DR. JONAS: Thank you. I appreciate the opportunity to be here, and I appreciate the fact that the FTC is examining these areas. I think it's an important area for the public health, and I think the alignment of regulatory policy with good science and good evidence is exactly what we need in the interest of public health and that that's where we should be focused.

I run an organization that does science on healing and healing practices of various types, conventional and complementary or integrative, as they now call it. It includes some complementary and alternative practices, and I've had a particular interest in the area of homeopathy for many, many years, mainly because of its historical and methodological challenges that it provides.

Klaus Linde from the University of Munich and I did the first basic science criteria-based meta-analysis of homeopathy and published it in Human and Experimental Toxicology in 1995. We found out that there was no criteria for basic science quality assessment, and now those types of criteria have evolved and are now being used. That was while I was at Walter Reed Army Institute of Research.

I then went over and ran the Office of Alternative Medicine, one of the precursors, predecessors to the National Center for Complementary and Integrative Health. And during that time, we applied meta-analytic techniques to the clinical research in homeopathy. This was an emerging field. Cochrane was fairly new then. We started the Cochrane Interest Group in Complementary Medicine out of the NIH, which I think continues. And, so, the application of meta-analysis was evolving in that area.

To do this research, we brought in the person who literally wrote the book on meta-analysis, Larry Hedges from

the University of Chicago, as well as one of the first center directors for Cochrane, Gilbert Ramirez from the University of Texas. We did a systematic, comprehensive evaluation of homeopathy, including examining placebo and the placebo effect in that. And what we concluded out of that was that it was impossible to answer the overall question of does homeopathy work better than placebo just by taking a mixed bag of lots of different types of research.

In fact, we statistically calculated what would happen in the future if you invested more research in those areas, depending upon whether studies came out to be positive and negative, and we predicted that future meta-analyses would actually show mixed effects, depending upon how it was selected and conducted. Subsequently, over the last 20 years, that’s exactly what’s happened. There’s now been 14 systematic high-quality meta-analyses done in these areas.

They alternate in their claims. One claims it’s positive; the next one claims it’s negative; a few claim something in between. The Australian study that is the most recent of those, that was just mentioned, highly selected in those areas; if you want to go back, and what in my opinion is a much more comprehensive criteria-based analysis a few years before that, the Swiss Government did a health technology assessment on homeopathy, and it claimed exactly the opposite.

And, so, the whole issue of applying good science is a challenge in these areas, but -- and I agree with Dr. Berman -- Fugh-Berman and others on this panel that you have to do high-quality research, and there aren't different methods for these areas; there's just appropriate application of these methods. One of the reasons evidence-based medicine has evolved is because conventional medicine did expert opinion as the primary basis for making decisions, sort of like panels like this. And that ended up causing a lot of harm. I, as a conventional physician, actually prescribe many drugs that I found out later, after randomized controlled trials and others, were harmful and hurting patients in these areas. So, I think harm and safety needs to be really the foundation that's looked at.

Evaluations should be comprehensive, systematic, and they should apply very good bias reductio methods. These methods exist, but they are also evolving. The Samueli Institute works closely with the RAND Corporation and has evolved bias reduction methods that I think are the best in the world in these areas. There are the application of others that have published in this area, including standards from the Institute of Medicine, the Agency for Healthcare Research and Policy, Cochrane, the GRADE approaches, and others.

I'm not going to go into the details of those

methods, but I would like to lay out and recommend some principles that the FTC follow as they go into the evaluation of this area. I've already mentioned using good evidence-based approaches and not sort of the battle of the experts, if you will.

The second, I think that you have to match the evidence with the purpose of how that information is going to be used, and there are multiple decision-makers in clinical care, including scientists, including clinicians, but most especially the public. And, so, you need to be able to bring in public assessment and opinion and analysis into this area. Regulatory aspects are important, but they're only one type. The chemistry of it is only -- is only one type of evidence that you -- that you get. Great.

So, the public focus should be the primary one, and if you do that, there's a very clear path for evidence analysis that should be done. Number one, safety. You need to make sure you're not harming people. Number two, effectiveness, which is different than efficacy. It's does it work out in the real world, and health services research and observational studies are provided as the best evidence for that, comparative effectiveness trials, actually. And then efficacy in those areas. Mechanism informs those but shouldn't dictate those.

And, so, I think the FTC has an opportunity here,

not just to reassess homeopathy, but to really provide a great public service by breaking new ground in how we go about applying evidence to policy. You've all heard of patient-centered research. There's PCORI and other organizations around that are now focused on patient-centered research, and I suggest we need public-centered -- I'm sure you've heard of patient-centered care; we need public-centered research in these areas. And I think homeopathy provides us a great opportunity to do that.

So, thank you.

MR. CLELAND: Thank you, Dr. Jonas.

Dr. Hoffman?

DR. HOFFMAN: Thank you very much. I wanted to thank the Federal Trade Commission for inviting me here today. I am actually a consultant. HeteroGeneity addresses botanicals and probiotics and complex products. We have products from all realms, including homeopathy, which are not -- they come to us not to be homeopathic but to see what they can do in terms of the mainstream approaches. But I also served at FDA. I chaired the homeopathic working group in the late '90s. Then I left, and I joined the consumer healthcare group of Warner-Lambert, which became Pfizer, and I know that Pfizer was dealing with these issues, as well.

Let me start by saying that I am going to go back and talk about how the FDA's policy has brought us here

today. I think it's important to find out why we're here as to where we came from. The practice of homeopathy was deemed quackery back in 1906. It did not meet the current standards in 1906 for scientific evidence. These drugs came back into the Food, Drug & Cosmetic Act in 1938, with the addition of the single word to the law, the Homeopathic Pharmacopoeia of the United States being considered an official compendium.

When I joined FDA, the agency told me on the first day I walked in, in God we trust; all others must show data.

(Laughter).

DR. HOFFMAN: However, the FDA has never required data from this class of drugs. The FDA has singled out this particular group of drugs as unique from all other classes of drugs, warranting an exemption for deferment from the agency's -- the congressionally mandated oversight of U.S. drugs marketed post 1938.

The 1988 compliance guide, which has been alluded to, describes the conditions under which homeopathic drugs may be marketed, which serve to further distinguish them as a special class of drugs. This policy guide does require that these products bear the directions of use and at least one major over-the-counter indication. But it also allows these drugs dispensation from the legal requirements for new drugs, from the OTC drug ingredient monographs, and from certain key GMP requirements, such as the final determination of identity

and strength of the active components, and the expiration dating, all the while not imposing limitations on the amount of alcohol content. Nonhomeopathic drugs are limited to 10 percent or less; homeopathic drugs have no limit, sold direct to consumer.

Homeopathy may be unique as a practice, but it is no means alone in terms of practices that are still practiced today, which include TCM, which is traditional Chinese medicine, and Ayurveda, practiced by billions of people. These all arose prior to the modern era of science; however, there is no need to prove or to disprove the practice of homeopathy, because the practice of medicine is not under federal jurisdiction at this time. The practices are controlled by the states.

And I say this because today there are complex botanicals, fish oil products, marketed as prescription drugs in the United States under new drug applications, under NDAs, and acupuncture needles marketed as medical devices. These products came through the mainstream regulatory requirements. They were required to have scientific evidence in support of their marketing, which included scientific method, data collection, and analysis. How they work was not at issue. That they worked was at issue.

To date, no homeopathic drug has been scientifically proven safe and effective based on FDA

standards, and what is interesting is that actually would make them be health fraud under the FDA's definition of health fraud in CPG 400.400.

With regard to how the FTC should proceed, the FTC Act gives FTC a legal mandate to require that health and safety claims be supported by competent and reliable scientific evidence, which the FTC defines as tests, studies, or other scientific evidence that has been evaluated by people qualified to review it. The HPUS cannot be used to support material claims of health and safety. This is stated clearly within the CPG 400.400. It says, "A product's compliance with requirements of HPUS or even the U.S. Pharmacopoeia does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its use."

It is the 21st Century. It appears that the FDA may be rethinking its pronouncement of homeopathic drug exceptionalism. But I can see nothing produced so far by either the supporters or the detractors of homeopathy that calls for the absolution of homeopathic drugs from the laws of the known physical universe. More importantly, with the significant market expansion of homeopathic drugs in the U.S. in recent decades, along with the absence of compelling evidence of benefit or documented safety or efficacy, it is difficult to formulate with any basis, scientific or

otherwise, upon which FTC should ignore its legal responsibilities to the U.S. consumer to ensure that homeopathic drug ads are truthful, nondeceptive, and not unfair and are backed by sufficient scientific evidence.

MR. CLELAND: Thank you, Dr. Hoffman.

DR. HOFFMAN: Thank you.

MR. CLELAND: Well, as sometimes happens on these panels, you know, you meet and discuss what kind of questions you're going to ask and discuss in the panel, and then your panelists answer some of those questions in their opening statements. So, that's actually going to help me along here.

So, Dr. Riley, you indicated, and I think you indicated there were three bases on which products are included in the HUP -- or the HPUS U.S., and one of those was drug provings or provings -- not drug provings, but provings. I'm not sure everyone in this audience understands exactly what a proving is. They may have it actually confused with a clinical -- some type of clinical trial. Can you give us a description of what a proving is trying to prove?

DR. RILEY: A proving is trying to collect the symptoms experienced by people when taking a homeopathic, not an allopathic, dose of a homeopathic drug. So, homeopathic --

MR. CLELAND: Even people with no symptoms?

DR. RILEY: People with no symptoms are given a

diary, and a diary is collected, and it's a controlled, qualitative study, and there's guidelines that have been produced that incorporate, you know, some of the contemporary scientific research methods that I discussed in terms of randomization, placebo controls, and such.

MR. CLELAND: Paul, do you want to -- is there anything you want to add to that?

DR. HERSCU: Yeah, there's a lot.

(Laughter.)

DR. HERSCU: First of all, there's a lot to this question, and I guess Dr. Riley is answering it in the shortest possible way. But let me say that I think provings are a foundational scientific method. It is used, in one respect or another, by everybody running clinical research. And I guess I wasn't really supposed to talk about these things, but what the heck.

My colleague, Adriane?

DR. FUGH-BERMAN: Sure.

DR. HERSCU: Sure, okay. My colleague, Adriane, thought that, you know, clinical trials are -- should be -- should have placebo arms or sham arms or masking or blinding, which we all know adds to -- validity to remove -- to subtract biases as in removing Clever-Hans or Hawthorne effects. So, this has become part of clinical trials since the 1920s, 1930s. It's almost 100 years. It's who wouldn't

really do that.

What everybody has forgotten is that those things began with homeopathic clinical trials. Homeopaths began placebo trials. Homeopaths began masking and blinding. I have specific quotes here which are a little bit lengthy, and I was asked not to go through all of those, but --

MR. CLELAND: Okay, thank you.

DR. HERSCU: -- if somebody asks a question, I'll be able to say it.

MR. CLELAND: All right.

DR. HERSCU: Thank you.

MR. CLELAND: Okay. So, I want to understand, take a subgroup, 10 or so people, 20 people, divide them up into two groups, give one of them the sham, and you let them record their subjective symptoms.

DR. RILEY: Yes, generally, the placebo -- the symptoms experienced in the placebo group are not included in a report from a homeopathic drug proving. These are -- I'm talking specifically now about homeopathic drug provings that are submitted to support a monograph application and inclusion in the HPUS.

MR. CLELAND: Okay. All right, we'll come back to that in a minute. And I do want to ask a question in terms of just to get a slightly bigger picture here. Earlier, we heard a discussion about sort of the difference where

homeopathy came from and, you know, where it went. And I think traditionally it is my understanding homeopathic remedies were individualized under the care of a treating physician who monitored the patients progress and could make all sorts of adjustments based on that progress.

Does the removal of this learned intermediary from this process suggest that OTC remedies, homeopathic remedies, should be subject to a more traditional scientific framework?

David?

DR. RILEY: Well, I would say there are different levels of individualization in homeopathy, so you may have a professional homeopathic practitioner like Dr. Herscu who is going to be taking a fairly sophisticated level of individualization to picking out and selecting a medication. But a consumer walking into a pharmacy or a health food store wanting to self-manage, diagnose, and treat is also going to be individualizing. They're just individualizing on a cruder level. And if they have successes, they may come back; if they don't, they may go on to seek other therapies -- other therapeutic interventions for their problem.

I think that it's -- in this age, it's really disingenuous to limit evidence to a randomized controlled trial. I mean, the conventional scientific establishment is struggling with n-of-1 studies, pragmatic studies, comparative effectiveness studies. There are lots of ways we

begin to establish evidence, so individualization is one that's common in all of medicine now. And that's being recognized more and more. You look at some of the genomic and epigenetic influences of what we're doing. So, I think that individualization does occur when a consumer walks into a store to select a homeopathic remedy.

MR. CLELAND: So, your answer would be that a more traditional scientific framework is not necessary?

DR. RILEY: I did not say that. I just said that I think that there is a scientific framework to what goes on right now, and I'm always in favor of more evidence.

MR. CLELAND: Okay, let's go back to talk about provings, then. How are these -- how are the observations in a proving actually validated?

Paul or David? Either one.

DR. HERSCU: Oh, me?

MR. CLELAND: Either one.

DR. RILEY: You can go ahead.

DR. HERSCU: You want me to take it?

MR. CLELAND: He had the last one; you can have it.

DR. HERSCU: Okay, so, once we take the homeopathic -- once we take the symptoms of the provers, we categorize them into several categories. A very simple description of what a proving is just taking a very healthy person, of which it turns out there's no such thing as a very healthy person.

Everybody has symptoms to one extent or another. So, symptoms that we take within the proving fall into -- broadly speaking, into four different categories: new symptoms not previously experienced, unexpected recurrence of past symptoms, unexpected changes, improvement in ongoing or recurring symptoms, and unexpected changes in terms of worsening or aggravating symptoms. So, there's a confluence of information that's gathered, and we can provide a -- the framework that we use that HPCUS uses for approving provings.

MR. CLELAND: Okay. Someone, and I thought it was you, David, provided me with a copy of the HPUS clinical trial guidelines.

DR. RILEY: Proving guidelines, yes.

MR. CLELAND: Yeah, the proving guidelines. And I'm looking at Appendix 11 on -- in that, and it talks about analysis of efficacy. And it says efficacy measures do not apply to proving results in this type of analysis and is therefore not applicable to provings. And it goes on. The next section says, "Statistical analytical issues, not applicable."

And I'm wondering how if that's the case you actually determine whether your observations are due -- how do you determine that your observations are due -- are not due to just chance?

DR. HERSCU: Oh, okay, I'll take that. So, first,

as we mentioned, provings are -- there's placebo response; there's placebo separation; we're removing the placebo group and symptoms that have that. We use symptoms that are reproducibly found throughout the proving. In other words, multiple individuals that may or may not know each other but don't really communicate about the proving itself.

There have been numerous trials where the same proving was redone 50 years later, 100 years later, and showed the same exact symptoms. There's whole books written on that. And in the -- in the 1885 discussions on why we should mask and have placebo arms in clinical trials, they even gave the example that several individuals not only had the same symptoms develop but had the same symptoms develop in exactly the same tempo and the same timing -- different individuals, male/female, different ages. So, this is part of the answer, but provings are -- have a lot of science behind them.

MR. CLELAND: Yeah. I'm a little, though -- I mean, it's one thing to have a placebo and a control, but if you're not doing a statistical analysis, what difference does it make?

DR. RILEY: Well, there's a couple of things. First, that statement that you read out of the appendices was about quantitative statistical analysis. There's -- the four criteria that are used are not validated qualitative --

quantitative -- qualitative assessment tools, but, of course, you know, things like the PROMIS instrument really isn't validated either.

So, there's different levels of acceptance for that. So, there is not quantitative statistical analysis of the results of a proving. That is correct.

MR. CLELAND: Any other comments from the panel on that question?

Dr. Hoffman?

DR. HOFFMAN: Well, just simply, provings are really a collection of adverse events that are caused by these particular ingredients. And then the adverse events are translated into the target treatment. So, if somebody's getting nausea from, for example, ipecac at a certain dose, and it would be very, very reasonable for people to get the same nausea at the same dose, then to dilute it down to a homeopathic level under the principles of homeopathy, one should be able to treat nausea, and that is the principle. Whether it's backed by a rational basis in science is a separate issue.

MR. CLELAND: David, a couple of times you have mentioned that provings are qualitative, not quantitative. What does that mean in the real world?

DR. RILEY: It's a collection of information that's, A, going to be very useful for a professional

homeopath to prescribe, and it's probably going to -- somebody who is not trained in homeopathy is probably going to want to rely on other information, as well. It will not be sufficient.

MR. CLELAND: Is it -- in your view, though, it's sufficient to prove efficacy? Qualitative evidence alone?

DR. RILEY: Well, I tend to -- I tend to parse efficacy into several different categories. There's efficacy; there's effectiveness; there's pharmaco-kinetics. It's going to depend on what the potency is in the proving. There's lots of things that are going to qualify that. And I probably would not want to make a statement about that. It also depends on what kind of ancillary studies and research has been done on the remedy in question.

And several people have said here, and it seemed a little bit confusing, but most homeopathic drug provings are done with homeopathic preparations. They're not done with -- like with ipecac, in a homeopathic drug proving, you don't give full-strength ipecac, and then somebody gets nausea. That would not be done. You would use a homeopathic preparation.

So, I'm not sure what you mean by "efficacy." I mean, I tend to use the word "effectiveness," and then effectiveness by who. And it becomes --it becomes quite complicated to sort that out.

DR. FUGH-BERMAN: I just want to add, in defense of qualitative research, because I do some qualitative research, is that qualitative research isn't just bad research; it's -- it -- actually the analysis of qualitative research involves using academically accepted methods for analyzing material that you have. And, so, you know, one question here is whether the methods of analyzing provings are actually academically accepted methods for qualitative research, but, you know, more importantly than that, this kind of research has nothing to do with the therapeutic efficacy of the product.

MR. CLELAND: Dr. Jonas?

DR. JONAS: Yeah, I think the definitions here are really crucial, and I'm glad that Adriane brought up the point that you can do different types of research, and they can be good quality. Okay, so, you can have very good research that is not placebo controlled trials. It's just being done for a particular purpose.

The terms "efficacy," "effectiveness," "safety," have been well defined, actually, if you look at the Agency for Healthcare Policy and Research; they clarify that there are validity tools for those. Efficacy research primarily focuses on internal validity, thus the need to try to separate the particular groups to try to get at causal assumptions that you're testing. Those are called your

hypotheses.

Effectiveness research requires external validity, very different set of criteria. It's what happens when you stick it out in the real world. It still requires very good methods. You have to use good external validity methods to get good effectiveness research. And safety also requires a different type of an approach, large-scale surveillance depending upon the frequency and the type of side effects that are produced.

And I think it's very important that we not mix these things. You could decide which criteria you think are more important, but that's a value judgment, and it should be a value judgment that we receive input from those who are making the decisions, including, as I made a statement, the public.

MR. CLELAND: Thank you.

You know, we heard reference in the previous panel to the law of similars, and my question is why should we accept that if you give me a substance that causes a runny nose, that if I catch a cold, a product with this substance in it will stop my runny nose?

David?

DR. RILEY: Well, there are some examples in conventional medicine where we do that. That's one thing. And there's more than a few examples. There's also the whole

principle of hormesis in science where drugs can have an effect at one concentration and have the opposite effect at a lower concentration. So, those would be the main things that I would say would support the law of similars. I don't know; Wayne may have -- do you --

DR. JONAS: Well, I think, you know, if you look at dose-adaptive responses, which is what the hypothesis is -- the similar hypothesis was trying to get at, and you look at the basic science research around the adaptive responses, both in clinical and in basic science research, there's a huge amount of data in that. Some of it is classified as -- or talked about. Hormesis is in that area, but there are preconditioning studies or post-conditioning studies that look at those types of things, and they're all based on this idea that one can look at a physiological effect and induce or influence the response in its opposite direction or use it as a therapeutic or a scientific tool in those areas.

Now, is that the explanation for the law of similars? I don't know. Okay.

MR. CLELAND: Well, let me explore this a little bit, too.

DR. JONAS: Yeah, but that was -- that was the underlying hypothesis that I think the original homeopaths were trying to get at, or at least that's what they were claiming.

MR. CLELAND: Let's assume that in some idiosyncratic cases that may be true.

DR. JONAS: What may be true?

MR. CLELAND: That --

DR. JONAS: That dose-adaptive response? That is true.

MR. CLELAND: The law of similars.

DR. JONAS: That's not an idiosyncratic case.

MR. CLELAND: Well, no, no, no. Well, it's -- no, you're saying it's universally true across all substances?

DR. JONAS: Absolutely. We don't -- well --

MR. CLELAND: Every time you give a substance --

DR. JONAS: -- the only that -- the only one I've ever seen --

MR. CLELAND: -- that creates --

DR. JONAS: -- that doesn't actually produce an adaptive response, depending upon the dose and the sensitivity of the organism, is cyanide. There are a few others, okay, that have fixed responses that will -- actually don't have reversal, but if you look at just the hormesis literature, for example, Ed Calabrese from the University of Massachusetts, for example, huge, huge database across almost every substance you can name, almost -- almost every kind of organism that you can name, showing dose-adaptive responses, which he calls hormesis.

MR. CLELAND: What are the -- when you say “dose-adaptive responses,” what are you -- you’re talking about what? Remedy? Am I clearing up my runny nose? Is that a dose response?

DR. JONAS: So, most of this is basic science research, although there’s clinical research. It’s not therapeutic. The hormesis research comes out of pharmacological and toxicological fields, and only recently have they begun to look at and try to understand does this apply in the area of clinical components. So, is it an explanation for the law of similars? I don’t know, okay? But it is, in fact, a type of pharmacology that could be used to understand what’s going on in lose-dose effects.

DR. HERSCU: Can I just jump in?

MR. CLELAND: Yes, Paul, go ahead.

DR. HERSCU: So, first on the hormesis, Dr. Calabrese actually lives in my town, so I have a chance to have lunch with him. He’s not a homeopath; he doesn’t know much about homeopathy. What he does know is in his doctorate studies, and then for many, many years after that, he noticed that when he gave -- when he either gave a substance or exposed a plant to a substance it had a certain effect on it, but when he changed the dosage on it, meaning he made an ultra-dilute dose of that substance, the effect on the plant was exactly opposite.

So, back to your nose, your runny nose, the closest thing -- the closest and easiest way to describe this is if we look at the -- at the group here, there's a certain number of people that had allergy shots to -- something to some tree that they were allergic to and so on. That allergy shot is a very minute dose of the substance that they're allergic to, that causes that runny nose. That's isopathic medicine. That's using the same substance, regardless of the symptoms. Homeopathy-based is the cousin of isopathic medicine where we use substances that cause similar symptoms, rather than the same substance.

But everybody here that has had allergy testing and allergy shots has had an experience akin to homeopathy, in minute dose.

MR. CLELAND: Dr. Berman?

DR. FUGH-BERMAN: Just that for most drugs -- in drug testing, we're often looking for a dose-response curve, meaning that the higher the dose the more of a response you get. Now, there certainly are -- there certainly are drugs for which you get different effects at low doses and high doses. So, a classic example is estrogen, for example, which at low doses can cause growth of breast cancer cells but at very high doses will suppress the growth of those cells.

However, when we're testing drugs, we're looking for a dose-response -- we're looking for a dose-response

curve. And I don't think that it's true that for most drugs you get an opposite effect at low and high doses.

DR. RILEY: No, this is actually true, and it's been looked at. Usually what happens is that they don't look at the lower doses. They assume a linear effect down to the low doses, and that they assume then it dissipates out, and it goes away. But the vast majority of drugs in which this has been looked at -- okay, it's not looked at in most drugs -- you see an upturn right at the bottom of the dose-response. It's nonlinear. And that's pretty well established.

DR. HOFFMAN: Let me just state that there are lots of examples of, say, anti-cancer drugs where at the high end, of course, it's going to kill cancer cells or stop them, but at the low end it does stimulate the immune system. This is also true of biologic response modifiers, such as the interleukins, gamma interferon, et cetera.

I think the difference that we're talking about here, though, between homeopathy and these other products is really data. And I think if the homeopathic community can demonstrate in reasonable scientific experiments that this is the case, then that should be claimed. If they cannot, then it should be discarded, as simple as that.

MR. CLELAND: Okay, I'm going to move on to a slightly different subject. It's my understanding that

provings are generally conducted on individual ingredients. And many of the OTC homeopathic products contain combination ,ingredients and, in fact, some of the products that we looked at in our internet survey contained 14 or 15 different homeopathic ingredients in them. In your view, David, are the provings of individual ingredients of any scientific value when it comes to these combination products?

DR. RILEY: Well, I would say most homeopathic drug provings are conducted on individual ingredients. I'm not sure of ones that have been conducted on homeopathic drug provings, although -- on combination products, but it's not a regulatory requirement that homeopathic drug provings be limited to individual ingredients.

MR. CLELAND: No, I'm talking about from a scientific view. I'm not talking about the regulatory approach. From your point -- your view as a scientist, can you make that extrapolation from all these -- the results of the provings on these individual ingredients when you put them all into a bunch and pile them on the table?

DR. RILEY: Well, it would be nice to have -- it would be nice to have additional data there for a combination product.

MR. CLELAND: What about when these products are combined with dietary supplements that are then referred to as inactive ingredients?

DR. RILEY: Well, that's an illegal -- that's illegal to do.

MR. CLELAND: When they're inactive ingredients? Listed as inactive ingredients?

DR. RILEY: Well, that would be mislabeling, then. Yeah, so, that would be not --

MR. CLELAND: But it's not --

DR. RILEY: It may be done.

MR. CLELAND: Yeah, it wouldn't be scientifically -- again, we're not talking about the regulatory position. I'm talking about your position.

DR. RILEY: No, I would say it would be scientifically indefensible to do that.

MR. CLELAND: Thank you.

DR. HERSCU: But can I just jump in?

MR. CLELAND: Yes.

DR. HERSCU: So, FDA CPG Section 400.400 defines -- definition two states drug products containing homeopathic ingredients in combination with nonhomeopathic active ingredients are not homeopathic drug products. It goes on and so on. The homeopathic community, the HPCUS, has again and again taken that position that we -- these objects, these tablets, should not be called homeopathic.

As Duffy mentioned in the earlier panel, he has to deal with repercussions of things that are not in his domain.

It’s the same with these products. They really don’t belong in our domain. This is not -- we welcome FDA in consultation with HPCUS to deal with these issues.

MR. CLELAND: Okay. So, my next question is is there a valid scientific reason why efficacy or effectiveness claims, however you want to phrase them, for OTC homeopathic products cannot be tested using human clinical trials. Dr. Hoffman?

DR. HOFFMAN: No, only a short statement. There’s a difference, and I think one of the things I want to bring up is there’s a difference between showing how homeopathy works. Clinical practice guidelines are really to direct doctors how to practice medicine, and it’s based on available data. And it’s based on a range of different types of available data, which can be graded.

It’s a very different proposition to show that a product is efficacious for a claim, a labeled claim, a claim of efficacy, a claim of safety, a specific claim. And I think that is where people are sort of getting off track here, is that when it comes down to showing that something works, you have a hypothesis; you have objectives; you collect data; you analyze the data. And that systematic approach is what the scientific community has accepted for a century or so. And it translates into being able to say, yes, it does work; no, it doesn’t work, separate from

treating patients.

So, I think that -- the statement there is I cannot envision a case, and unless you're telling me that these products do not conform to the laws of physics and chemistry, then obviously they might not work, but otherwise, you should be able to control in some fashion. The acupuncture needles, for example, I was involved in that at the FDA; the agency had called for trials. There were more than 20 -- I think 20,000 trials that the agency received. But in looking at the quality of the trials and what could be used to actually say that the acupuncture needles did something was boiled down to about 20 trials in certain areas. It was that much of stuff out there, but the actual quality of the trials was very, very few to actually support the efficacy.

Now, the other thing is I deal with TCM all the time; I deal with Ayurveda. When the products come through, we're not trying to test Ayurveda. We're not trying to test whether Chinese medicine works. I'm pretty agnostic about that. But when we're trying to get a product to be able to conform to the U.S. medical system of finding out whether it's safe and efficacious and lot-to-lot consistent, yes, it has to conform to scientific methods. And the randomized controlled trial is really the gold standard at this time for that particular objective.

DR. FUGH-BERMAN: And I just want to add to that

that -- to clarify something about efficacy and effectiveness. So, efficacy is how a therapy works within a clinical trial, where things are quite controlled. And effectiveness is how it works in general population. And it's usually a lot lower. Effectiveness is lower than efficacy.

So, for example, the birth control pill. In clinical trials, it's more than 99 percent effective. In effectiveness trials, it's more like 95, 96 percent effective because people don't necessarily take it the way they're supposed to; they don't take it every day; or, you know, they might be late with pills or whatever. So, sometimes if we test something in a clinical trial, and it has to be taken five times a day, for example, once that gets into the -- once we do an effectiveness trial, it's less effective because it's difficult for people to take a drug five times a day, and the people who are in clinical trials are different than the general population.

So, effectiveness research is not observational studies. And observational studies can never prove benefit. Benefit can only be shown in randomized controlled trials.

DR. HOFFMAN: I'd like to add just one more quick thing. Having dealt with hyperalimentation, which is this complex solution of nutrients, which is given intravenously to patients, the mainstream cancer surgeons of the United

States for years thought that, gee, it works in surgical patients; it should work equally well in cancer patients. But it wasn't until randomized controlled trials were supported by the National Cancer Institute back in -- I hate to say back in the late '70s and early '80s, that demonstrated that hyperalimentation actually did not help most cancer patients but actually they died faster. And yet the surgeons, up until that point, were gung ho in feeling that what they were doing was reasonable.

So, I think there's a very important factor of trying to demonstrate whether something works or not in a very defined context.

MR. CLELAND: Dr. Jonas?

DR. JONAS: Yes. I definitely agree with Dr. Hoffman that we need to use clear, good, existing methods to test these products, especially if we're claiming that a particular product is producing a particular effect. That is efficacy training. If we know what's in the product, and we can isolate it, we have a hypothesis about that, that all goes into determining how you actually design the study, but it basically is the same thing.

I have to disagree again with Dr. Fugh-Berman that you cannot use effectiveness to determine benefit. In fact, effectiveness is an important way -- important type of information for determining benefit. And the benefit depends

upon who's making the decisions about it for which things. So, you have to really do comprehensive assessment of all of the evidence, including the product component randomized controlled trials, as well as its application to determine benefit of those particular areas.

DR. FUGH-BERMAN: I didn't say anything --

DR. JONAS: I think the --

DR. FUGH-BERMAN: -- against effectiveness research. What I said was that observational studies cannot show benefit. Are you saying that observational studies can show benefit?

DR. JONAS: They show benefit all the time. Surgical research does it all the time. Psychotherapy research does it all the time.

DR. FUGH-BERMAN: It's not an acceptable standard.

DR. HOFFMAN: It really isn't, and --

DR. JONAS: Okay, so, you don't believe that --

DR. HOFFMAN: -- I think that that's going --

DR. JONAS: -- back surgery should be allowed, is that right?

DR. HOFFMAN: There's a lot of issues with how surgeons do trial --

DR. FUGH-BERMAN: Yeah, really.

MR. CLELAND: Well, let's not go there.

DR. FUGH-BERMAN: There are very few sham-

controlled --

DR. JONAS: But this is the essence of the comparative component, because if we're saying we need to use good quality research standards that are the state of the science in terms of what's used, then we have to say what is the state of the science as what's used and do that in an appropriate, comparative way.

MR. CLELAND: Well, let me put you on the spot, then, and ask you whether or not in your opinion provings alone are adequate to substantiate treatment claims for OTC homeopathic drugs.

DR. JONAS: No. They're completely different. A proving test and an efficacy test are a completely different type of study.

DR. RILEY: I would concur with his statement.

DR. HERSCU: But just to fill in -- just can I jump in?

MR. CLELAND: Yeah, oh, absolutely.

DR. HERSCU: So, first of all, many OTC conventional drugs have not been held to RTC method. There's this review process under way for the past 40 years. I think it's useful to think of homeopathic products as the past and the future. The vast majority of homeopathic drugs currently in use in OTC in the United States have a large body of clinical data. When I think our colleagues said provings are

not enough, they meant there's a lot of data already collected supporting the primary indications for each of the medicines. Medicines have a high amount of documentation. All of this can be read and found in the pharmacopoeia of the HPUS.

That said, and I've been waiting 30 years to say this, so --

MR. CLELAND: Okay.

DR. HERSCU: -- while randomized controlled trials have propelled science forward and propelled medicine forward, it is, in a sense -- and this is not a homeopathy comment; it is a scientific comment -- it is a blunt, vague instrument. It does not correspond to reality very well. Simply put, it fits within the model of the 1950s and the 1970s, not in the medicine of 2015.

In 20, 30 years, that might change. I can give you multiple examples, but just take the fact that currently to get marketing approval for FDA you'll have to do two phase three successful trials. Even if the drug trial failed two, three, four, seven times, once you get your second one, you might be able to get marketing approval. Look at Prozac as an example.

Randomized controlled trials typically have a wide bell curve of distribution of effect. We believe that's just the way it is. Drugs might have a small effect size,

receiving approval, and yet in reality many people will not have any benefit or have adverse events. So, when we're talking about effectiveness, we actually mean effectiveness rather than efficacy where efficacy is quite useful to pass a drug through marketing approval. It may not conform to reality.

I can give you many examples on the homeopathy side, but I also work in the pharmaceutical industry, and I can give you examples there. We can see what I mean specifically. There are -- there are -- there is this -- you know, we're using randomized controlled trials as if it's a done deal, and it's perfect and so on.

It's far from perfect. It is continuously changing in skill and ability, and the closest thing to what might be heading as good clinical trials is adaptive trials, which eventually will lead us to where homeopaths have been doing provings for many, many years. I'd love questions on this because I could talk about this all day. So, if anybody wants to pass questions along, that would be great.

DR. WILLIAMSON: I would make a comment that we -- I believe that clinical trials -- random and clinical trials have changed quite a bit --

DR. HERSCU: Absolutely.

DR. WILLIAMSON: -- in the past 65 years.

DR. HERSCU: Absolutely.

DR. WILLIAMSON: I wasn't alive to know what was going on 65 years ago, but I can guarantee you it has changed, and it's changed for the better. We have very strenuous regulations associated with this. This is why when you compare a 2015 study to a 1995 study the rigor is different, quite different, than it was 20 years ago. And, certainly, when you are comparing anecdotal evidence to the 1800s, it is quite different than the strenuous research that we require today.

DR. HOFFMAN: Yeah, the observational studies go back to the 19th Century. You might as well just move back there, because that's what they were using.

DR. JONAS: That applies, though, to any type of study you're doing. There's been significant improvement in the methodology that's gone on in -- in everywhere, you know, basic science research, observational, and epidemiological studies, comparative effectiveness research, randomized controlled trials.

DR. WILLIAMSON: I believe in medical research, though, I would not say that there's been very little significant or infinitesimal advancement in science. Medical research has advanced quite a bit in just a few years, and if you think about what was going on just five years ago and how different things are, I think that becomes quite obvious. And, again, that is based on very rigorous research done on

the standards that we have today in 2015.

DR. JONAS: I think that's absolutely right, and you have to look at the quality of the research when you're analyzing this, you know, in order to determine that, regardless of when it was done. I think this is one of the problems with the Australian study, is that they set a certain set of lines, and they actually didn't go back and individually evaluate the quality of the research that they bundled or selected in those areas. So, that type of thing has to be done.

DR. FUGH-BERMAN: But the answer to problems with random -- yeah, there are some problems with randomized controlled trials, but the answer is not to go to a lower level of evidence. And, you know, to paraphrase the famous quote about democracy, yeah, randomized controlled trials are the worst way to assess efficacy except for everything else.

DR. HOFFMAN: The other thing I just want to bring in --

DR. JONAS: They're a bad way to assess effectiveness. And safety.

DR. FUGH-BERMAN: Effectiveness research can be randomized and controlled, and it usually is. Do not confuse effectiveness research with observational studies.

DR. JONAS: That's correct. It's not placebo.

MR. CLELAND: Okay, Dr. Hoffman.

DR. HOFFMAN: There's one other issue about trials, though, with homeopathy and with other complex products, is that they're complex. And the biggest question that I've always had in this area, one can impose a very clean-cut trial. It can be methodologically correct. However, there's been no standard, no standard set by FDA, in terms of determining what's in the bottle. And lot-to-lot differences, batch-to-batch differences are very key, in particular for botanicals and complex products.

You may not get the same answer. I think the NIH's studies didn't get the same answer by switching manufacturers. So, I think it's extremely important that when FTC looks at this that they look at it product by product, that the manufacturer who is bringing in the claim or the data, it needs to match up. It can't be someone else's product. It can't be just on the individual ingredients, not on the whole. And this is -- and these are important concepts with complex products.

MR. CLELAND: Okay. We have just a few more minutes, and I'm going to move on to a couple of questions here left on my list. You know, one of the factors that the FTC considers when it determines a level of substantiation required for a claim is what experts in the relevant field would generally require.

Dr. Hoffman, in the case of homeopathic drugs,

should the relevant field be limited to homeopathic experts?

DR. HOFFMAN: I would say no, but the thing is this, homeopaths, if they have expertise in the claim that they're trying to evaluate, fine, but I think, for example, if someone is making a sinus claim, if someone is making a headache claim, the most important part of that is to be using the standard approaches for the United States.

There are validated instruments to determine pain, for example, or how people feel following sinus medications. So, I think it's extremely important that it's a case-by-case what that individual brings to the table in terms of their own expertise. If it's ENT, if it's a neurology, if it's urology, I think it's very important that that person be properly trained in the scientific method and in the current trial designs that people are using for all other products making similar claims.

MR. CLELAND: Any other --

DR. FUGH-BERMAN: I would add that, you know, ideally studies would -- whether they're of homeopathy or drugs or surgery or whatever, would be done by people who are well trained in doing clinical trials and who do not care about the result.

DR. HOFFMAN: Yep.

DR. JONAS: Well, then, nobody would do them.

(Laughter.)

DR. HOFFMAN: Well, there has to be -- I mean, conflict of interest is a big deal, and bias.

DR. JONAS: Yes you have to manage conflict and bias. There's no question about it, which is, you know, why we try to do rigorous research, placebo controls, et cetera, et cetera. I think it's absolutely right, as well as product consistency, product --

DR. HOFFMAN: Yep.

DR. JONAS: -- measurement in terms of that. I mean, we were doing -- I'll give you an example. You have to have a way of trying to say this is the product and it's the same thing over and over again in those areas. We worked with the NCI to try to replicate a pilot study for a homeopathic product for mucositis in a large, multi-center randomized controlled trial. And we needed a way of determining that particular -- what was in that particular product. It ended up we had to develop an enzyme assay in order to distinguish between those so that we could determine that there was a quality component before we could even put it into a placebo control trial.

DR. HOFFMAN: Let me also just quickly add the size of trials are very important. The average drug is approved on no less than about 700 people, generally more. It depends if it's an orphan indication, of course, and things like this. But I think the size of the trials -- a lot of the

trials that are used, I have to say, for dietary supplements and for foods can be very small trials, not for health claims, but for structure/function claims. But for drugs in the United States, mainstream drugs really have to prove several hundred people in these pivotal studies. And the size of the trial is really -- yeah, and thousands of people in some case. There was a -- one of the major pharmaceutical companies just lost a phase three trial; it did not work out -- 16,000 people. It depends on the indication. But I think it's important that the size of the trial match the claim. That's the most important --

MR. CLELAND: Yeah, and I'm going to throw in a comment there. I think your reference to FDA, and I just want to point out that I think the FTC has a whole lot more flexibility when it comes to evaluating, you know, how many people need to be in a trial and how many trials you need, so, you know, we have a very flexible standard when it comes to evaluating.

DR. HOFFMAN: But they have to be reproducible.

MR. CLELAND: Yes, absolutely. They have to -- and it's even better -- they not only should be reproducible, I like it when they're actually -- been reproduced.

DR. HOFFMAN: Sounds good.

MR. CLELAND: So, I have a little more confidence in the results. I have one last question and one minute.

And, so, I'm going to ask this. Rik, you get this question; it was yours, and if you have -- to the extent that you didn't address it in your opening statement, what are the primary differences in product quality between FDA-approved drugs and homeopathic products prepared per the HPUS? I think you touched on that in your opening statement.

DR. LOSTRITTO: I did, thank you. And I'll try to go a little bit in direction with it and in one minute. So, there's a number of substantive quality differences between allopathic products and homeopathic products, but I'll touch on just three: one in the area of raw materials; a second in the area of manufacturing process; and a third in the area of end-product testing.

In the area of raw materials, I think an area particularly of interest would be to quality control of mother tinctures and triturates. So, right now, when you read the HPUS, there is not a lot of testing for the consistency of composition, say of the active constituents from a plant.

We know that some of the plants that are used nowadays may be endangered species, that other factors -- other species may be used as substitutes, that depending upon the climate, the altitude, the amount of sunshine, et cetera, the ratio of active constituents can vary. I think there should be some consideration for testing, for shelf life and

storage and so forth of these mother tinctures and triturates.

In the area of manufacturing process, you know, we read about the dilution and attenuation and succession process. It appears to be largely based on a common-sense approach but untested. Testing of intermediate dilutions to validate the final attenuation, which you may not be always -- always be able to measure, but testing at intermediate dilutions allows one to at least partially validate the dilution method.

And, also, if you read about various succussion approaches, which we use to shake up, potentize, the preparation, there's a number of various approaches there. So, I think there would be some interest in that manufacturing process approach that homeopathic products are unique to.

In the area of end-product testing, it would be very interesting to show that at high attenuations that there actually is a lack of the active principal that you diluted away. Again, I pointed out some anomalies that could take place during the dilution process. And, certainly, sterility for those products that are named -- labeled to be sterile, and also you'd want to avoid contamination from other things associated with the product besides the active material, excipients, container closures, and so on.

So, that's just the three top ones I could think of.

MR. CLELAND: Paul, you indicated -- did you want to respond to that, any of that?

DR. HERSCU: Well, I would jump in a little bit. I think a lot of these questions are best served by a meeting with the HPCUS, the organization that actually deals with creating the pharmacopoeia. And I'm sure they would be a willing partner to discuss any of these points. For example, before all the different standards of deciding on the different levels of a plant at different times of the year, that was already included in the pharmacopoeia, so when you pick any plant, it says, you know, grown at this time of the year, at this time, this -- and so on. So, there are actually methods. But that said, questions which are important questions are best served by asking and interacting with HPCUS.

MR. CLELAND: Okay, thank you, Paul. And that is all the time we have. And I want to thank all my panelists for a great discussion. And we'll be back starting at 1:35.

(Applause.)

(Lunch recess.)

PANEL 3: LEGAL/REGULATORY ISSUES PRESENTED BY HOMEOPATHIC ADVERTISING

MR. FORTSCH: Good afternoon. We're going to move into the final panel of the workshop today. And I want to introduce myself, who is moderating this panel. And you've met me already, and that's all I'm going to say about myself.

(Laughter.)

MR. FORTSCH: So, the more important part of the panel is who's on it and the graciousness that they've all agreed to come today and speak on the panel. And I'll first introduce, directly to my left, Michelle Rusk, who is a colleague in the Division of Advertising Practices; and then Christina Guerola Sarchio from Orrick, Herrington & Sutcliffe; and continuing on to my left, David Spangler from the Consumer Healthcare Products Association; Antonio Vozzolo from Faruqi and Faruqi -- I hope I pronounced that right; and then going all the way to my far right, Kat Dunnigan from the National Advertising Division, and you heard a bit about the NAD, as it's known, in an earlier panel; Elaine Lippmann from the FDA; Al Lorman from the Law Office of Alvin J. Lorman; and Paul Rubin from Ropes & Gray.

So, we are going to follow the same structure that we followed in the other two panels, where we're going to ask each of the panelists -- and as you can see, we have a larger group than the other two panels -- so we're going to strictly

enforce the five-minute-or-less rule, but I think everyone is very well versed on that one. We're going to ask everybody to give a five-minute-or-less opening remarks, and then we'll do a number of questions. If we have time, we'll take questions from the audience, but I'm going to start with my colleague, Michelle Rusk.

MS. RUSK: Thanks, Greg. Okay, so, today, now that everybody's awake, I'm going to touch quickly on the FTC's shared jurisdiction with FDA, how we coordinate, but also how our legal frameworks differ in some important respects. And then I'm going to explain what exactly the FTC law requires in the way of scientific support for claims, not just for homeopathic products but for any health-related product.

We do share jurisdiction with the FDA over homeopathic, allopathic OTC drugs, foods, supplements, and certain other health products, and that means we need to coordinate our enforcement efforts, so we have in place a memorandum of understanding that spells out that FDA has primary responsibility over claims made in labeling and the FTC takes the lead on claims in advertising and other marketing.

Now, we do make every effort to be consistent in our actions, but there are some important differences in our legal frameworks. The FTC is primarily a law enforcement agency, not a regulatory agency. And by that I mean we don't

engage in pre-market approval. The law requires an advertiser to substantiate advertising claims before they're made, but they don't have to submit ads to us in advance and we don't preapprove their claims, nor do we dictate how claims are worded or what specific disclosures are required.

Also, the FTC law makes no distinction between product categories. It doesn't matter under our approach whether you position yourself -- your product as a food, a supplement, a drug. You will be held to the same substantiation standard for the claims that you make, and there's no exemption under FTC law or policy for products in the homeopathic pharmacopoeia.

Finally, the FTC doesn't make bright-line distinctions between disease claims, health claims, structure/function claims, or other treatment claims. So, for every claim, we're asking the same questions: What message does the ad communicate to consumers? Is it truthful and accurate? Is it backed by science?

Our authority for the approach comes from two very simple sections of the FTC Act, not a lot of regulations you need to be familiar with. Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in commerce. So, Section 5 would prohibit deceptive marketing of homeopathic or any other product or service marketed to consumers.

Section 12 applies to products that are also regulated by the FDA, like foods, drugs, supplements, devices, and it prohibits dissemination of false ads for these products. But under both of these sections a marketer has to have a reasonable basis for any objective claim that they make about their product. And the FTC's made it clear in case law and warning letters and policy statements and guidelines that when you're talking about the benefits of a health-related product the reasonable basis standard means that you have to have competent and reliable scientific evidence.

So, in my last minute, I want to make a few points about what exactly the FTC means when we say "competent and reliable scientific evidence." I have two minutes, apparently.

Most importantly, we expect to see rigorous science. As Rich mentioned, there is some flexibility in the number and type of studies, the size, the duration, but as a general rule for treatment claims, we expect randomized, double-blind, placebo-controlled human clinical studies, not in vitro studies, not animal studies, not anecdotal evidence, no matter how compelling it is.

Second, we expect the studies to be internally valid. That means well designed, reliably conducted, using procedures accepted in the field of research. It also means

that results are not just statistically significant but also strong enough to be clinically meaningful.

Third, the evidence has to match the product and the specific claim. Is it the same active ingredient, in the same form and dose? Are there other ingredients in the product that could alter the effect? Does the degree and nature of the effect match the claim? So, for instance, a study that shows a product might shorten the duration of a cold for a day or two is not support for a claim of cold prevention.

And my final point, the FTC will look at a marketer's studies in the context of the larger body of evidence, not just in isolation. We ask how does it fit and is it consistent with the scientific literature as a whole. If the larger body of evidence suggests a product may not be effective, then that's going to be a very high hurdle for an advertiser to overcome.

So, that's our analysis. Whether you're advertising a homeopathic drug, an allopathic supplement or something else, do you have one or more quality studies? Does the evidence match the product and the claim? And how does it fit into the science as a whole?

MR. FORTSCH: Thank you, Michelle.

I'm now going to turn to Elaine Lippmann to speak about the FDA.

MS. LIPPMAN: Good afternoon. I'm Elaine Lippmann. I'm in the Office of Regulatory Policy at the FDA. FDA is pleased to be participating in the FTC's workshop to examine advertising of over-the-counter homeopathic products. The two agencies share an interest in drug products marketed as homeopathic. While the statutes and regulations we enforce differ, both agencies share the goal of implementing policies that are in the best interest of the public. We, therefore, welcome the opportunity to add our perspective to the FTC's exploration of the issues under its purview, as well as to hear from the FTC and others.

Products that meet the definition of drug under the Food, Drug and Cosmetic Act are subject to regulation by the FDA, regardless of whether they are labeled as homeopathic. Since 1988, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval under our stated enforcement policies.

FDA is now evaluating its current enforcement policies from scientific, risk, and process perspectives. In April of this year, FDA began soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last approximately 25 years. FDA is, therefore, engaged in its own reexamination of its regulatory approach to homeopathic drug products at the same time that the FTC is

examining issues relating to the advertising of these products.

Compliance policy guides explain FDA's policies on regulatory issues related to our laws or regulations. They also provide guidance to FDA's compliance staff and field investigators on the agency's standards and procedures to be applied when determining industry compliance. In 1988, FDA issued its compliance policy guide, or CPG, entitled Conditions under which Homeopathic Drugs may be Marketed. This CPG states that the FDA does not intend to take enforcement action against drug products labeled as homeopathic and marketed without pre-market review and approval, provided that certain conditions are met regarding ingredients, labeling, prescription status, and current good manufacturing practice.

The homeopathic drug industry has continued on an upward growth trajectory since FDA issued the CPG in 1988, especially with respect to OTC drug products labeled as homeopathic. The CPG noted that at the time of original publication in 1988, the homeopathic drug market was a multimillion-dollar industry in the United States. In 2007, the National Health Interview Survey conducted by the Centers for Disease Control and Prevention estimated that adults spent about $2.9 billion on the purchase of homeopathic medicine.

Drug products labeled as homeopathic are marketed and sold in a variety of dosage levels and forms direct to consumers through magazines, the internet, and in both big-box retail establishments like Target and Walmart, and traditional retail pharmacies like CVS and Walgreens. To date, manufacturers have listed with the FDA over 7,000 OTC drug products marketed as unapproved homeopathics.

In light of the growth of the industry and the passage of approximately 25 years since the CPG's issuance, FDA is evaluating its regulatory framework for these products. This past April, FDA held a public hearing to obtain information and comments from stakeholders about the current use of homeopathic drug products, as well as the agency's regulatory framework for these products. FDA is seeking broad public input on the current enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health.

On August 21st, the FTC submitted a comment to our docket. In it, FTC recommends that FDA reconsider its current regulatory approach to OTC products labeled as homeopathic. FTC states its concern that our policies conflict with the Commission's advertising substantiation policy in ways that may harm consumers and create confusion for advertisers.

FDA will consider FTC's comment, along with other

comments submitted to our docket, as we determine whether and how to adjust our regulatory approach to products labeled as homeopathic with the goal of protecting and promoting the public health.

MR. FORTSCH: Thank you, Elaine.

I'm now going to turn it over to Al Lorman.

MR. LORMAN: Thank you. Good afternoon. I appreciate this opportunity to speak to you today on behalf of my client, the American Association of Homeopathic Pharmacists. The issues that the FTC staff have asked this group to address are both important and complex. In the five minutes that each of us have been allotted, I'm going to focus on the use of disclaimers in labeling and advertising.

First, however, I'd like to make one brief point, though, about a key legal assertion by the FTC staff. I believe that the FDA Compliance Policy Guide reflects FDA's recognition that Congress may well have adopted a different standard of effectiveness for homeopathic drugs. Whether that same standard also applies under the Federal Trade Commission Act is a legal issue which has never been decided by either the Commission nor a court.

Even were the FDA to revoke or revise the Compliance Policy Guide, as suggested by the FTC staff in its comments to FDA, that does not actually change the legal status of homeopathic drugs under the Food and Drug Act. The

FDA would still have to take some sort of legal action to establish that these drugs are not legal. In fact, since the drug amendments of 1962 were passed, the amendments, which added the effectiveness requirement to the statute, FDA has been in the process of reviewing both prescription and over-the-counter drugs to determine their compliance with the effectiveness standard.

There are still hundreds of OTC and Rx, allopathic drugs, for which FDA has not made a final determination as to safety and effectiveness. As a legal matter, homeopathic drugs are in no different position, and if we have to take our place in the line of FDA's review of drugs under the '62 amendments, I suspect they may reach it in the next century.

However, my main point today is that the AAHP believes that there is actually an appropriate path forward that not only gives consumers additional purchase information but also satisfies the FTC's claimed legal standard. We would much rather cooperate than litigate.

The AAHP adopted a voluntary advertising and labeling disclaimer program in 2012. That disclaimer was based on the one adopted by Congress in DSHEA for diet supplements which made structure/function claims. Between the AAHP guideline and the court-approved settlements in some of the false advertising cases that have been brought against homeopathic manufacturers, we believe that a majority of the

homeopathic products sold today bear some sort of disclaimer on labels and in advertising.

The AAHP has conducted a study about consumer understanding of FDA's role in the approval of a number of product categories. This study showed that 24 percent of the consumers tested believed that FDA approved homeopathic drug claims. This 24 percent is within the range found by the FTC in its study of a couple of years ago. While 24 percent is not an inconsequential number of consumers to be confused, it is important to put that number in context.

The AAHP study shows that fewer consumers believe that FDA approves homeopathic product labels than believe that FDA approves cosmetic, pet food, and grocery product labels. In fact, fewer consumers that we surveyed believe that FDA approved homeopathic product claims than any other product category tested.

The study also suggested that most consumers can differentiate between allopathic OTC drugs and homeopathic OTC drugs. The study showed that 76 percent of consumers understood that FDA reviewed the claims for allopathic OTC products but, as noted, only 24 percent thought the same about homeopathic products. These were -- this was a study that did not show consumers labels. This was based solely on the use of the terminology.

In a separate study, the AAHP also studied consumer

perception of product labels with one of three different disclaimers. This study, to the extent possible, was modeled on the study that the FTC commissioned several years ago. We tested three different disclaimers: (1), “These statements have not been reviewed by the Food and Drug Administration;” (2), “The uses of our products are based on traditional homeopathic practice -- they have not been reviewed by the Food and Drug Administration;” and, (3), “The uses of our products are based on traditional homeopathic practice,” and then a parentheses, see www.homeopathic.org, closed parenthesis; “They have not been reviewed by the Food and Drug Administration.”

I should add that that is not a real website, or if it is, it’s not one controlled by us. We used that as a signal to consumers that more information was available. And there was some indication from the person who helped design the survey that signals can help consumers understand that perhaps this is out of the ordinary.

The key finding of this survey is that when a homeopathic drug bears one of the three label disclaimers that we tested, only between 1 percent and 8 percent of consumers believed that homeopathic drug claims are approved by FDA. That is a dramatic decline from the 24 percent who believed that FDA approved these claims when not presented with a label showing a disclaimer.

In addition, only 14 percent of the consumers we surveyed believe that homeopathic drugs had the same level of scientific support as allopathic drugs. The report and the analysis of these studies are still in draft form, unfortunately. We will be submitting them as part of our written comments to the FTC and, actually, we will also submit them to the FDA.

The data, however, we believe clearly speak for themselves. We believe that when you have a chance to review the data in detail you will agree that the use of appropriate disclaimers on homeopathic products helps consumers make informed purchasing decisions while complying with the applicable legal standards. And we look forward to working with the FTC staff on this issue.

Thank you.

MR. FORTSCH: Thank you, Al. And I should elaborate a little bit as you mentioned about the comments. Just to reiterate again, people are probably tired of hearing this, but by November 20th, we will accept comments at the FTC and will welcome the comment that Al has referenced here. And I know the FDA has also extended their comment period. I don't know the exact date.

MS. LIPPMANN: It's open until November 9th.

MR. FORTSCH: Okay. So, we're in November. Everybody think of -- remember November if you want to file

something. So, I will also -- I'm next going to introduce Paul for his opening remarks.

MR. RUBIN: Great. Thank you, Greg. I first would like to thank the FTC for hosting this public workshop and providing the opportunity for a wide range of stakeholders, including government regulators, medical professionals, industry representatives, and consumer advocates, to share their views on this important topic.

In 1938, Congress enacted the Federal Food, Drug & Cosmetic Act, or FFDCA, which contains a number of specific provisions applicable to the commercial distribution of homeopathic drugs in the United States. For example, the definition of a drug expressly includes articles recognized in the official Homeopathic Pharmacopoeia of the United States, or HPUS.

Importantly, it's my understanding that the fundamental principles of homeopathy, including homeopathic claim support, have been generally consistent since the passage of the FFDCA. In other words, when the FFDCA was enacted, Congress knew how homeopathic claims are supported, recognized that homeopathic drugs are distinguishable from allopathic drugs, and clearly intended for consumers to have access to homeopathic drugs in the United States.

FDA's regulation of homeopathic drugs since 1938 has been consistent with this approach. FDA has long

recognized the distinction between homeopathic and allopathic drugs and has not applied new drug application, or NDA, requirements or the OTC drug review to OTC homeopathic drugs. In 1988, FDA made this policy explicit when it issued a Compliance Policy Guide, or CPG, still in effect today, explaining that OTC homeopathic drugs may be legally marketed in the absence of NDA approval or inclusion on the OTC drug review as long as a number of conditions are satisfied.

One of those conditions is that OTC homeopathic drug labeling must bear at least one major OTC indication for use, stated in terms likely to be understood by laypersons. This requirement is consistent with the FFDCA requirement that all OTC drugs must be labeled containing adequate directions for use.

In its recent comments to the Food and Drug Administration, FTC staff acknowledged the potential conflict caused by FDA regulatory requirements applicable to homeopathic drugs. In an effort to address this conflict, the FTC proposed three options for the FDA. I respectfully submit that in my opinion all three options are suboptimal and would pose legal and policy challenges for FDA as they would either be, in my opinion, contrary to congressional intent or violate the FFDCA.

Rather than those proposed approaches, I respectfully suggest that there is an alternative approach

that should be capable of achieving the FDA's and FTC's goals while avoiding vexing legal problems and which would seem to benefit all stakeholders. That would be the use of disclaimers and qualifying language. Effective disclaimers should be capable of addressing the FTC's concerns and would be consistent with the FTC's guidance regarding claims for traditional use.

Such an approach would have another crucial benefit, as well. It would avoid offending First Amendment principles that strongly disfavor the suppression of commercial speech. This is now the clear trend in First Amendment jurisprudence involving claims for FDA-regulated products. Such issues arose, for example, in the Pearson v. Shalala decision, where the DC Circuit concluded that health claims lacking significant scientific agreement may be lawfully disseminated consistent with First Amendment precedent, provided appropriate disclaimers are disseminated in order to avoid consumer confusion or deception.

Similarly, in the recent FTC/Pom Wonderful decision, the DC Circuit acknowledged that an advertiser may lawfully disseminate a health-related claim lacking robust substantiation, falling short of a randomized controlled trial, if the claim includes an effective disclaimer disclosing the limitation of the supporting research.

The use of disclaimers in this context would also

be consistent with the recent First Amendment decision in the Amarin case, where the Southern District of New York held that commercial speech disseminated by a prescription drug company may not be restricted by the Government if claims are accompanied by appropriate disclaimers reflecting limitations on claim support. Thus, the existing case law and the clear trend in such cases strongly suggests that disclaimers would be more likely than other options to pass muster under the First Amendment. Of course, according to FTC precedent, disclaimers would need to be presented in a clear and conspicuous manner, easily legible to consumers.

In sum, both the statutory requirements and constitutional considerations strongly suggest that use of carefully crafted disclaimers and qualifying language would be the optimal solution for addressing concerns about promotional claims for homeopathic drugs. Such an approach would be consistent with congressional intent, FDA regulations, and FTC precedent and would have the important benefit of adhering to the First Amendment's dictate that suppression of commercial speech should be a last resort.

By utilizing carefully crafted disclaimers and qualifying language, the First Amendment right of companies to inform consumers in advertising and promotion regarding claims lawfully included on product labeling would not be infringed. Thank you.

MR. FORTSCH: Thank you, Paul.

I next want to ask Christina to speak.

MS. SARCHIO: Thank you, Greg.

Class action lawsuits can serve an important function in protecting consumers, and agencies with great demand on their resources sometimes rest a little easier knowing that consumers can enforce their rights through other vehicles. Unfortunately, that has not been the case here, where lawsuits filed against the homeopathic industry have done nothing more than decrease competition in the marketplace while providing little value to consumers.

Good afternoon. My name is Christina Sarchio. I have been practicing law for 20 years, and in the past five years, I have seen a huge spike in the number of class action lawsuits filed against homeopathic companies and the number of lawyers that are attacking homeopathic companies and profiting from these lawsuits. In fact, in the five years past alone, 75 lawsuits have been filed against homeopathic companies in federal and state courts throughout the country.

I have represented manufacturers and retailers in a dozen of these cases and have seen firsthand the impact that litigation has had on companies and consumers. The financial impact on companies as a result of this litigation has been significant and, in some cases, devastating, with litigation defense budgets quickly reaching seven figures, even before

the parties have reached trial.

Now, the three cases that have gone to trial have been wins for homeopathy. In each of these three cases, which included two bench trials and one jury trial, plaintiffs failed to prove in court that the homeopathic claims were false and misleading. Most cases, however, never get to trial, with many of them either being dismissed or settled on a private basis. A handful of those cases have resulted in settlements, where homeopathic companies have volunteered to add disclaimers that plaintiff lawyers have accepted and that judges have approved as adequate to address concerns of false advertising.

So, what has been the impact of this litigation on consumers? First, these cases have served to limit competition in the marketplace. Some homeopathic companies have stopped selling in the U.S. altogether, while others have stopped selling their lower priced and lower selling products because the cost of litigation is greater than their sales.

In addition, retailers, worried about suits or the negative publicity of these suits have reduced the number of homeopathic drugs they carry on their store shelves. Thus, the choices that consumers have are being limited, and not because a court has ordered them off the shelf or because there was any finding of wrongdoing.

Second, because a majority of these cases are either dismissed or they settle on an individual basis, consumers mostly receive nothing at all from the lawsuits that are brought on their behalf. The individuals that bring these suits often have a familial or close connection to the lawyers that also bring these suits. And these folks quickly abandon their efforts to stop the "offending" conduct for the want of $5,000 they can get in a private settlement and the handsome fees their attorneys can get.

Third, in the rare instance a case survives dismissal or is certified by a judge, the settlement that follows typically yields very little value to consumers. A settlement usually provides reimbursement through a fund, but very few consumers actually get any money from it. In one lawsuit I was involved in, where the sales totaled $350,000 over a four-year period, the company spent over $1 million in litigation before deciding to settle. Less than 10 percent of the class members submitted requests for reimbursement. So, at the end, consumers received about $33,000, while their lawyers received $750,000 in fees.

In another case I was involved in, we polled the consumers that submitted claim forms after settlement. Fifty-five of those consumers went out and purchased either the same homeopathic product or a different homeopathic product, despite receiving money from the lawsuit that

alleged that homeopathic products do not work as advertised.

In conclusion, what I have seen is that the cost of litigation has been devastating to many companies, typically small companies that are forced to defend their products. No plaintiff has been able to convince any judge or any jury at trial that these claims are false or misleading, and the consuming public has received little to no benefit from the class action cases brought on their behalf.

Thank you.

MR. FORTSCH: Thank you, Christina.

David?

MR. SPANGLER: Good afternoon. I'm with the Consumer Healthcare Products Association. We represent manufacturers of OTC medicines, both allopathic and homeopathic, and dietary supplements. Thank you for having us here this afternoon. I'd like to make four points this afternoon.

First, consumers want choice and control over their health. For instance, in a survey this year by -- for CHPA by the market research firm GS Strategy Group, they found that while three-quarters of Americans agree they have sufficient choices in consumer healthcare products today, that same percentage would like to have even more options to treat their conditions. Four out of five respondents agree that finding a product that works for them means they need

multiple choices.

Homeopathic products are one part of that spectrum of options of choices to help Americans address their everyday healthcare needs. That includes things like addressing cold symptoms, headaches, or heartburn. For another example, the National Health Information Survey found that nearly three-quarters of Americans have used complementary and alternative medicine as CDC defines it. One small part of that, around 2.6 percent, is homeopathy. So, repeating, it’s a choice among many options.

Second, yes, Section 5 of the FTC Act declaring unfair or deceptive acts or practices unlawful certainly applies to homeopathic product advertising, just as it would to other consumer healthcare product advertising or, indeed, consumers advertising in general.

Third, well established and embedded within the prohibition against deceptive advertising is that advertisers must have a reasonable basis for the claims or, in other words, ads must be substantiated under the Pfizer factors, which take into account, as you know, the type of product, the type of claim, and the ease of developing substantiation for a claim.

As I know this audience is well aware, the Pfizer factors approach to substantiation is a flexible standard that recognizes the amount of evidence required depends on

what the advertiser has said about that evidence. In general, the Commission has not attempted to use substantiation doctrine to prescribe specific tests as the basis for particular classes of ad claims. To suggest otherwise, as the August 2015 FTC staff comments to FDA on homeopathic product regulation seem to suggest, is overreaching.

I say that because under the approach of the American Association of Homeopathic Pharmacists ad guidelines, homeopathic ads disclose the product as homeopathic, they can disclaim the product as not FDA-reviewed, and they reference the support for their claims, such as homeopathic literature. An ad following this approach is squarely within the Pfizer factors. The type of claim ties to the strength of support.

Fourth and finally, we would note that going back decades, and as Michelle Rusk noted, there’s been the clear delineation between FTC and FDA where, in the interest of clarity and efficiency, FDA has primary responsibility with respect to regulation of advertising of foods, drugs, devices, and cosmetics. And in the absence of an express agreement between the two agencies to the contrary, FDA exercises primary jurisdiction over all matters regulating the labeling of these products.

We are reassured that today we’ve heard from

neither FTC nor FDA a suggestion that there's some basis to change this longstanding, widely understood agreement.

MR. FORTSCH: Thank you, David.

Antonio?

MR. VOZZOLO: Good afternoon. I'd like to thank the FTC for holding this panel today. I appreciate the invitation to come speak today. I'd like to read off a couple of pretty interesting and noteworthy statements.

May companies simply use regulation of homeopathic medicine as a cheap license to sell whatever they wish?

Since the FDA in the United States, like many regulatory agencies, is underfunded, and since the public safety impact of enforcement of homeopathic regulation is seen as a low priority, there are no bodies in the streets, the FDA frequently does not enforce its own regulations, let alone those of the HPCUS, HPCUS. The results are the U.S. has become the victim of numerous so-called homeopathic medicines which receive big ad dollars but no clinical testing. Manufacturers have an obligation to customers to provide products that work.

Now, this statement is not a statement from a class action attorney. The statement is not from a consumer advocate. This is from a prominent CEO of one of the major homeopathic manufacturers in this country. And this statement was made in 2001.

So, the question you have to ask, what has occurred between 2001 and 2015? And that's why I thank the FTC for holding this panel because there's obviously an issue with the marketing of homeopathic products in this country.

What I've heard today are anecdotal evidence about surveys, about how customer satisfaction is somehow tantamount to efficacy. Somehow customer satisfaction implies that products work. Product placement implies efficacy. You need to walk into these grocery stores, these pharmacies, and look at the actual packaging. There are efficacy claims made right on the packaging. This is not simply packaging placed next to other OTC products. The deceptive and misleading advertising is actually on the packaging itself, representations that these products are effective, that these products are fast-acting, that these products work quickly.

And I'd like to point back to that last statement. There's an obligation to provide truthful and accurate statements. Manufacturers have an obligation to provide products that work. And this is the benefit of class actions, so I thank Ms. Sarchio for providing a wonderful interpretation of class action benefits that have occurred to date, but the class action device is very powerful, particularly in this instance where there seems to have been a lack of action on behalf of numerous parties.

And the value of class action litigation provides multiple benefits, including deterrence effects, reimbursements and refunds to consumers. Many of these settlements have provided monetary relief to class members. They've received full reimbursement of the purchase price of their product. There have been funds made, anywhere between $1 million and $5 million, for some of the smaller cases, which does not revert back to defendant homeopathic manufacturers. This is hard, real money for consumers to get back.

Now, the problem with the amount of claims has to do with the way the products are marketed. These products are sold in pharmacies. There is a claims-made process where people have to submit claim forms. It's just the function of the system. It has nothing to do with the efficacy or value of class action litigation.

The other benefits of class action litigation involve what I call injunctive relief or labeling changes, and we have gone through a litany of some of the labeling changes. FDA disclaimers has been mentioned as an important disclaimer, although the regulatory body has claimed benefit of imposing the FDA disclaimer, that is a function out of -- a function of some of the lawsuits that had been filed early on. That was one of the proposals made by plaintiff class action attorneys on how to address some of the misleading

advertising.

Some of the other injunctive aspects that have been proposed in class action settlements include dilution disclaimers, explaining these dilution formulas on the product packaging, what they mean and how to provide that information to consumers so they can make a reasonable and informed decision. There also have been the CPG disclaimer, where they place a link to the FDA Compliance Policy Guideline of Section 400.400.

And, also, there have been proposed efficacy disclaimers, where defendants have agreed not to use the words “clinically proven,” “proven effective,” or similar words unless at least two clinical trials have been performed by independent research using random clinical trials to establish efficacy.

I think that’s all I have to say. I know we have limited duration.

MR. FORTSCH: Okay. Thank you, Antonio.

And last but not least, Kat Dunnigan from the NAD.

MS. DUNNIGAN: Hi, and hi over there. I came from New York this morning, and at 4:00 a.m. as I was headed out I peeked into my kid’s room, and immediately my two-year-old said, I’m awake, yeah! -- which is both adorable and unfortunate. But, so, I say to you in a similar vein, at the end of this long panel, I’m the last one, yeah!

And, so, just to get right to it, if there's one thing I would want you to take away from anything I have to say today is that at NAD, the National Advertising Division, if you want to make health-related performance claims about your homeopathic product, then you must have confident and reliable scientific evidence to support those claims. And just so we're on the same page, I'm also including claims that appear on the label.

And just a quick background about NAD, the National Advertising Division, we are one of several forums an advertiser can find themselves in, be it legal, regulatory, self-regulatory, where an advertiser will be called upon to provide a basis for their claims. NAD is a self-regulatory forum, where competitors have the -- competitors challenge the truthfulness of one another's advertising.

We also have a monitoring program where we'll reach out and ask advertisers to send us substantiation for their claims. We do this in industries where competitors tend not to challenge one another, the cosmetics industry, dietary supplements, and homeopathy.

Especially with regard to homeopathic products, the types of claims we see over and over again are health claims. And, so, just to cull a few examples from prior cases, prevents acne, clinically proven to reduce the duration of your cold, or, more seriously, to relieve symptoms of ADHD in

children. These claims and others like them should be supported by competent and reliable scientific evidence, and just to say it again, the best being randomized, placebo-controlled trials that are statistically significant to the 95 percent confidence level. There should also be evidence that the treatment effect is large enough to be meaningful to consumers, and that isn't always the same thing as statistical significance.

While NAD makes determinations on a case-by-case basis, generally speaking, the presence of a product's active ingredient or ingredients in documents produced by the HPUS or in a materia medica are not sufficient. They are insufficient, not good enough to provide a reasonable basis for health-related performance claims. Also, generally speaking, homeopathic provings, in vitro studies, and animal studies are also not considered, on their own, to be confident and reliable scientific evidence.

And to understand why this is, you have to go back to the very beginning of claim analysis, and the first question we ask ourselves is what are the messages reasonably conveyed by this advertising. The types of messages conveyed drive the level of evidence required. And, so, if you're going to implicitly or explicitly say that your product has a specific effect on human health -- and I think we need to take a moment to just acknowledge that these claims can be

very powerful and have the potential to touch upon real fears and vulnerabilities in people's lives -- well, if you're going to make that type of claim, consumers are reasonable in assuming that you have tested the product out on humans.

And at the present time, and admittedly painting with a broad brush across different health fields, scientists concur that the most reliable way to do this is to gather a sample of population of people that look a lot like the people you're advertising to and to have clinical endpoints that are clearly defined; test your ingredient or product against a placebo; and then conduct a statistical analysis to make sure that what you're seeing is due to the intervention and not just due to random chance.

I don't mean to sound so grim. I'm certainly not saying that in the absence of this evidence there are no claims to be made. And as also has been said before me many times, traditional use types of claims are popular in this field and are generally provable, as long as they're narrowly tailored to not imply that they've been clinically tested for efficacy.

So, in conclusion, the types of messages conveyed drive the level of evidence required. And at NAD, it doesn't matter who you are. If you're an aspirin manufacturer or dietary supplements or homeopathy, what we look at are the messages conveyed and the fit of the evidence to those

messages. And, so, regardless of what product category you find yourself in, if you want to make health-related performance claims, then the level of evidence is competent and reliable.

Thank you. And thank you to the FTC for having this panel and for having me today.

MR. FORTSCH: So, thank you for all your opening remarks and, again, thank you for participating. We're going to now go into a number of different questions that are raised by the FTC, including issues that have come up earlier today.

Now, as Commissioner Ohlhausen said in her opening remarks and I would reiterate, and I think it's pretty clear at this point, our workshop today is not about the practice of homeopathic medicine; it's about the advertising of products that are marked as homeopathic or are homeopathic. And we also are here to talk about the FTC, but not the -- but it's hard to talk about this issue without talking about the FDA because as we pointed out a number of times today and in our remarks, comments that we filed with FDA, we work very well and very collaboratively with the FDA because we have common interests in protecting the American public.

And, so, my first question I want to direct to Elaine Lippmann from the FDA. There's a few questions, but the first one is, so, and I think you covered this a little

bit in your opening remarks, but maybe a little more elaboration, if you can, on why is the FDA reexamining its regulatory framework right now.

MS. LIPPMANN: Yes, so, as I stated in my opening remarks, our current policy has been in place for about 25 years, during which time the homeopathic industry has grown significantly. So, we're gathering information about whether it's the right time to adjust the current enforcement policies to better reflect the variety, the volume, and complexity of the products -- homeopathic products that are on the market today.

In addition to the industry's significant growth, there have been some emerging safety, quality, and policy concerns that we've become aware of in recent years. For instance, there's a common misconception that homeopathic products are necessarily safe because they're natural. Unfortunately, FDA has become aware of some safety issues associated with some of these products, which demonstrates that the safety of these products depends upon a multitude of variables, just as it does with all drug products, things like how much ingredient there is, manufacturing quality, that sort of thing.

So, for all these reasons, FDA is taking another look, gathering stakeholder input, and determining the best way to regulate these products.

MR. FORTSCH: So, Elaine, I think another question I had for you was -- which I think would be helpful to make a distinction, if you can, between -- and I'm sure it's complicated, of course -- but what is FDA's regulatory enforcement approach to other nonhomeopathic marketed unapproved drugs, you know, to provide a contrast between homeopathic and nonhomeopathic?

MS. LIPPMANN: Sure. First, let me step back and explain that any new drug requires approval by the FDA before it can be marketed in the U.S. And this is true whether it's prescription or over-the-counter. Now, some new drugs are marketed without FDA approval, and recognizing that we're not able to take immediate legal action against all illegally marketed products, we have to prioritize and figure out how to best use our resources. So, we've had to prioritize our enforcement efforts with regard to drug products that require FDA approval but are marketed without it.

And these priorities are spelled out in our FDA guidance call Marketed Unapproved Drugs Compliance Policy Guide, which was issued in September of 2011. And FDA has other compliance policies in place, as well, for example, the homeopathic CPG. But I want to just make clear that any drug product that requires FDA approval but is marketed without it is subject to FDA enforcement.

MR. FORTSCH: And this could be a challenging

question, but I'll ask anyway, because I don't know how I would answer it, but what options is FDA considering?

MS. LIPPMANN: Yes, it is a challenging question, and I'll answer with kind of a non-answer, which is that we're still considering what options -- we're considering a range of options, and we -- it's premature to discuss what we might do. We're still gathering feedback. We've gotten a lot of comments to our docket so far, and we recently reopened the docket, so now it is open until November 9th. So -- and we encourage any interested person who has not already submitted comments to go ahead and do so.

So, we're getting a broad range of feedback, and we'll consider all of that information in determining the best way to regulate homeopathic products.

MR. FORTSCH: So, I honestly did not set up that question so that I could answer it myself, but --

(Laughter.)

MR. FORTSCH: -- we're also -- I would say the same thing for the FTC. We're really considering and looking at comments, listening to what -- every single thing that's been said today before we decide the path forward for us, as well.

And, so, to turn more to the FTC, I wanted to ask my colleague, Michelle, a few questions. FTC consumer research suggests -- and I'm talking about, in part, the research that we reference in our comments that we filed with

FDA in August -- FTC consumer research seems to suggest that there are a significant number of consumers who think homeopathic products have been tested for efficacy. Now, Al -- and I -- Al has different research, which I look forward to reviewing, and I know there are differing opinions on this, but based on our agency's research, are consumers misled when that is not the case?

MS. RUSK: I think the answer to that is yes, clear and simple. If a claim that a product is effective to treat a certain condition carries with it the implied claim, the underlying claim that the advertiser, in fact, has done the research to know that it's effective for that condition, and if they haven't done the research and they don't know that it's effective, the claim's misleading.

And we heard a lot of talk in the opening remarks about disclaimers as the way to fix that. And I have two thoughts about that. One is saying the FDA has not approved the product, doesn't really address that issue of correcting consumers' understanding that the claim is substantiated, that there's quality science behind it. It corrects a different misperception, which is that the FDA regulatory approach is the same as for other products, but it doesn't correct the misperception about there being science to back up the efficacy.

The other thing I would say about disclaimers is

that our research is not just for homeopathics but over the years looking at things like qualified health claims for food products and supplements has shown us pretty vividly that it's very difficult to craft a disclaimer that really communicates there is no science to back up this claim.

So, I think we have to be careful when we think about disclaimers as a remedy and making sure that they really effectively correct the misperception.

MR. FORTSCH: I suspect there might be others on the panel who have a question or comment on that. If not, I'll move on to the next question. Does anyone to my -- the two people to my right want to --

MR. LORMAN: I'll accept your invitation.

MR. FORTSCH: Okay.

MR. LORMAN: We have more data on that, and we have not had an opportunity to fully digest it. Unfortunately, the study that we commissioned exists at this point. We have the raw data, but the analysis of the data is in draft form, but we did actually inquire about the level of understanding of what kind of support there is behind these claims because we recognize that the FTC is looking at this.

The initial data shows that consumers do recognize that there's a difference between that and as cited between the level of data supporting allopathic products regulated by FDA and homeopathic products. I'm not prepared to say more

about that at this point. And it may well be that additional information -- additional surveys are necessary to further elucidate that point, and we're perfectly happy to do that.

MR. FORTSCH: Since we're on the topic of disclaimers, I have a question from the audience. For those who think disclaimers are an answer to the problem, how do you balance FDA's requirement of indications of use, for example cold or flu, with an actually effective disclaimer, and how do you disclaim what the product is sold for?

MR. RUBIN: I can start with that.

MR. FORTSCH: Okay.

MR. RUBIN: So, I think the issue really -- I think the best source of this is the FTC's guidance, the advertising guidance for dietary supplements for traditional use, which I think Al alluded to a few minutes ago. And in essence, yes, there's an indication for use that FDA requires companies to use, and they would include that on your label, but you can have a disclaimer that can go in many different directions. You've seen some that talk about FDA approval; you could see some that address the substantiation from the principles of traditional homeopathic principles; you can see references to educational websites with significant information.

You know, one of the problems I think we see when we think about disclaimers is that it is exceedingly

difficult to have a comprehensive disclaimer explaining the depth of homeopathic regulation and how that contrasts to the OTC drug review or NDA OTC drug products in a disclaimer, on a product or advertising. It will be way too confusing.

So, from my perspective, I think the key is to signal consumers that there is a fundamental difference. And as long as consumers are signaled and then they're armed now, you know, that fortunately we live in an era where via the internet and other sources you can obtain a tremendous amount of information.

So, I think the signaling effect is really what's critical for disclaimers, and I think there are many ways of getting there, but I don't think there's inherent tension between having an indication for use and having some disclaimer addressing it. And I think that's consistent with the FTC's principles established in the traditional use guidance.

MR. FORTSCH: Since we teased that question out a little bit after I initially asked, I wanted to see if Michelle had a response to the --

MS. RUSK: I do. And as somebody who was very involved in the writing of the dietary supplement guides --

MR. RUBIN: I spoke to you about it years ago.

MS. RUSK: Yes. I have noticed that it's one of those documents that can be quoted to support whatever you

want, unfortunately sometimes. But you are right that we do address traditional use medicines in the guidelines, but I think I want to make it very clear what the guidelines say about traditional use, because it's a very limited situation where we would consider it appropriate to talk about how something has been traditionally used. And what our guidelines say is that any discussion of traditional use also needs to clearly convey that the efficacy of the product has not been confirmed by research and that traditional use doesn't establish that the product will achieve the claimed results.

So, and that's a standard of does the consumer get those messages, one, that it hasn't been backed by research and that the fact that it's traditionally used doesn't mean it will have the claimed results. I think that's a pretty high standard. We're not saying -- and we wouldn't say under the First Amendment that under no circumstances could you communicate that effectively, but as I said before, I think it's very challenging to say traditional use for colds, we don't have any science and traditional use doesn't mean that it works for colds. I think that's a message that just -- there's a disconnect there that makes it very difficult for consumers to reconcile.

The other thing our guideline says is that traditional use claims, even with that kind of very clear and

strong disclaimer about efficacy, shouldn't be made for serious diseases, that at that point the sort of analysis shifts. And when you're talking about cancer, for instance, you really can't make a claim and just disclaim away the lack of science.

MR. RUBIN: Can I jump in, Greg?

MR. FORTSCH: Yes, but quickly.

MR. RUBIN: Sure. I'll be very quick. So, I agree with that last point. I thought it was a very good segue, Michelle. Just to remind everyone that we're talking about OTC homeopathic drugs, which pursuant to FDA rules must be marketed for a self-limiting -- for the treatment of a self-limiting condition amenable to self-diagnosis.

And in the traditional use guidelines, I'll quote, it says, "The FTC in determining the level of substantiation necessary to substantiate a claim, the FDA will assess among other things the consequences of a false claim." And I think in this context that should be factored in. We're talking about things that basically are self-limiting. They go away on their own. They're OTC conditions. That's not cancer. These are not significant diseases, so I would respectfully submit that that should be factored into the analysis, as well.

MR. FORTSCH: So, as we have moved a little bit into the issue of substantiation, I want to ask a question.

The science panel this morning talked a lot about substantiation. And I want to direct this to Al initially, with questions from others -- or comments from others if there are any. Assuming the FTC required human clinical trials to substantiate treatment claims for over-the-counter homeopathic drugs or determined that provings were not sufficient, competent, and reliable scientific evidence to substantiate such claims, what would be the effect on the OTC homeopathic drug industry?

MR. LORMAN: Well, first, I would like to point out that requiring 2015 clinical trials for OTC homeopathic drugs would essentially be requiring a standard that was never required of allopathic OTC drugs during the OTC review when, in fact, panels of experts largely relied on their own sophisticated and medical expertise to decide which drugs would be recognized as generally recognized as safe and effective. It was never a two-clinical-trial requirement during the OTC drug review, and so you'd actually be requiring of us something that is not required of allopathic OTC drugs.

Elaine mentioned that there are 7,000 homeopathic products registered with FDA. If each of them were to be the subject of two clinical trials, that's 14,000 clinical trials. This is where my math starts to break down. If each clinical trial costs roughly $1 million to conduct, I

calculate that that's a commitment of $1.4 trillion for an industry whose annual sales at retail are slightly above $1 billion. Even if that money was available, I find it inconceivable that any regulatory agency would spend the time and energy to review 14,000 clinical trials.

The practical effect of any kind of clinical trial requirement of that extensiveness is that assuming that you're just going to apply it to advertising it means there's not going to be any advertising basically and that, therefore there's -- consumers are going to be denied a way of knowing about the existence of these drugs, assuming they're still available under FDA's Compliance Policy Guide, and, so, that the manufacturers then face a much more difficult task in presenting to consumers any information about these products.

It seems to me that it's both -- it's an unworkable requirement, given the number of homeopathic drugs, and I might add the price of homeopathic drugs. We're talking about products whose -- at retail range from $3 to maybe $10. I mean, the clinical trial requirement that you're talking about today is essentially the clinical trial requirement required in new drug applications where they're -- where pharma is hoping to hit a $1 billion-a-year sale. That's essentially what our entire industry does.

MR. FORTSCH: I don't -- I know Michelle probably wants to comment on that, but I also wanted to ask Elaine if

it’s something that you could weigh in on, and particularly the OTC comments that Al mentioned initially.

MS. LIPPMANN: Which the --

MR. FORTSCH: The extent to which so many OTC products are not subject to what we’re asking homeopathic products to be subject to.

MS. LIPPMANN: Well, like I said, any drug -- if you meet the definition of a new drug, you need to be established as safe and effective, whether it’s through the OTC monograph or through an application -- an NDA application. So, as I said before, we have enforcement priorities that we articulate in any number of ways, but under the statute, all new drugs, in order to be marketed in the U.S., are required to be established as safe and effective.

Now, I’m not sure how the -- any change in FTC’s requirement for substantiation -- I’m not sure how that would affect FDA’s regulatory authority. I will say that our -- the homeopathic CPG of the FDA is not intended to bind the FTC or to impact its enforcement of its own statutory authority. It’s merely an articulation of FDA’s enforcement policies with regard to requirements of the FDNC Act.

MR. FORTSCH: Michelle?

MS. RUSK: Yeah, I’d like to respond to the statements that Al made about what the effect would be on the

industry and what the cost of doing clinical studies are. First of all, the 7,000 products, I think we heard this morning, in terms of what's really in retail, it's more like 100 products, maybe 1,000 at most. But, more importantly, I think nobody has said today that you need to do $2 million trials.

And, you know, we regularly investigate companies in all kinds of product categories who are making similar claims to the homeopathic industry, claims about colds, claims about weight loss. And we don't -- the studies that are done are significantly less expensive than million-dollar studies, and they are definitely financially feasible given the profits the companies are making.

MR. LORMAN: May I respond?

MR. FORTSCH: I actually want to -- we're limited in time, so I would love to have you respond, but we must keep moving.

So, one of the questions that I have for both Paul and David is about qualified claims. They can be difficult to communicate and may not be commercially attractive, but what would a qualified claim for an over-the-counter homeopathic product look like? A qualified claim must communicate unambiguously that the evidence is nonconclusive or that additional research is necessary, something that we think might apply to a homeopathic product, or at least some

of them.

So, I wanted to see if either of you had a response to that. I might start with David and then go to Paul.

MR. SPANGLER: I think Paul already earlier talked about a lot of that when he was talking. There are a lot of different ways to disclose and qualify, so I don't know that there's a magic bullet and I don't know why, then, one would say that a qualified claim must unambiguously communicate or the evidence is inconclusive or that additional research is necessary.

It seems to me your qualifier or your disclaimer is simply trying to make sure that you're getting across the context in which the claim is made, be that a reference to a website, be that pointing out its traditional literature or traditional use, or that it's based on homeopathic literature, but accurately characterizing what the claim is based on as opposed to trying to communicate what it's not based on.

MR. RUBIN: And I think just to add to David's comments, which I agree with entirely, I think it's important to keep in mind the fact that FDA-regulated products are very diverse, and if we -- if you want to delve into comprehensive disclaimers that address complex regulatory regimes, they're just not going to work.

I mean, think about all the different products

where that could be required. You have Class I devices that are not reviewed or approved or cleared by FDA at all; Class 2 medical devices that are cleared but not approved, only deemed to be substantially equivalent to a lawfully marketed predicate. Do you have to make that disclosure and say some of those cases there are no clinical studies; other cases there are? Do you really need to get into that level of detail?

So, I would again submit that I think that the key is to signal to consumers. You know, even the OTC drug review we've been talking about, I mean, consumers don't appreciate that that's an ingredient-based review, not a product-specific review. Those products, in general, have not been individually reviewed for safety and efficacy. They're deemed generally recognized as safe and effective based on ingredients.

So, I think that based on all that, the key is to signal consumers that there is something unique and special about homeopathy and that the claims are based on a very different standard. And I think there are many ways of accomplishing that.

MR. FORTSCH: I'm going to beg the panel and the audience's indulgence. I'd like to go on for a few more minutes. I have a few questions for Antonio and Christina and Kat. So, if you wouldn't mind a few more minutes, I'm

going to beg your indulgence for that.

Kat, I had a question for you. Is the NAD requiring a level of substantiation that is not required by the Federal Trade Commission?

MS. DUNNIGAN: The short answer is it doesn’t seem to be -- there doesn’t seem to be any indication that NAD’s approach to claim substantiation is at odds with the FTC’s thinking on the matter. And then the slightly less short answer is that NAD has enjoyed -- we’re very privileged to enjoy an open relationship with the FTC, and we know that if an advertiser chooses not to participate or chooses not to comply with our recommendations that when we send the referral to the Federal Trade Commission that they will communicate with the advertiser and also then communicate the status of the referral -- the results of that referral.

And, so, there is a dialogue between the two -- these two institutions, and I think that if they were going in very separate directions we would know.

MR. FORTSCH: And, so, I just had a couple of questions for Antonio and Christina, who I hope will be friends after this panel today.

(Laughter.)

MR. FORTSCH: If they’re not already friends. So, I’ll start -- I have several questions, so I’ll go back and forth on who I start with, but -- or we’ll let the discussion

take its course. But, first, what has been the overall impact of class action litigation on the homeopathic industry? And I know -- I think at least, Christina, you covered this, but I think you may have different answers to that question, so I'd like to hear both of you and your thoughts on that.

MR. VOZZOLO: Sure. I'm not sure it's actually had a significant impact on the marketing or activities of homeopathic companies. I'm not aware of any companies that have gone out of business as a result of class action litigation. The class action lawsuits that have been brought so far have resulted in fairly small settlements.

I think there's a misnomer or a misunderstanding about the types of -- or the size of the manufacturers that sell these products in the U.S. They're very large manufacturers. They generate significant revenues, and you could tell that by the quality of the counsel that they hire. Every lawsuit I've seen has hired a white-shoe law firm to defend it. These are very expensive lawyers. They have significant funding. So, I do not think it has had an impact whatsoever in the industry.

MR. FORTSCH: Christina?

MS. SARCHIO: So, in 2014, the CEO of Heel announced in a press release that's publicly available that one of the major reasons that Heel was withdrawing from the

North American market was “the substantial cost of litigation.” I want to make sure I got that right.

So, it has had at least two homeopathic companies have completely withdrawn from the U.S. company [sic] and I have seen homeopathic companies lay people off, not be able to invest in research and development, and, more importantly, not wanting to change or improve their advertising practices or educational campaigns for fear that if they change anything then the plaintiffs’ lawyers will come in saying, aha, you changed it because you did -- you admit you were doing something wrong.

And, so, we’re really at a standstill at sort of improvements in the homeopathic industry because litigation has chilled the desire of the companies to really reinvest in their product and in educational campaigns.

MR. VOZZOLO: Greg, I’d just like to follow up on one point. You raise the fact of R&D for homeopathic companies, and are you aware of homeopathic companies actually spending significant dollars on R&D for homeopathic products? Because I challenge you to say that statement. It is -- it is a complete fictitious answer. There is no such word as R&D in a homeopathic business.

MR. FORTSCH: Well, I’m going to -- I know Al had a comment, and I did also have a couple more questions in this field before we close.

Al?

MR. LORMAN: I just wanted to follow up on something Antonio said earlier about that the class actions lawsuits have contributed to the disclaimers that appear on labels and in advertising. And, in fact, the truth is just the opposite. The American Association of Homeopathic Pharmacists, long before the first of these cases was ever filed, was discussing ways to adopt a disclaimer program to provide additional information to consumers about the homeopathic nature of the product -- of the products that we sell.

And, in fact, that effort basically stopped when the lawsuits were filed, precisely because we were concerned that were we to then adopt it, it would be cited against us in the lawsuits as proof that we knew we weren't adequately warning people before. So, the reality is that an adequate disclaimer program would have been adopted many years ago had there not been these class actions against the companies.

MR. VOZZOLO: Just one followup point, Greg, and it's just a well known concept in law that subsequent and remedial measures are inadmissible in a court proceeding, so I take that with a grain of salt.

MR. FORTSCH: Well, Christina and Antonio, in terms of settlements, some companies have agreed to include a disclaimer that the claims have not been approved by the FDA.

How, if at all, does that disclaimer address the Federal Trade Commission's concern with adequate substantiation? And I'm going to ask Michelle to address that after you both provide answers.

MS. SARCHIO: If I can jump in and start?

MR. FORTSCH: Go ahead.

MS. SARCHIO: So, as you can see, in litigation, we hotly debate each and every issue that comes up.

(Laughter.)

MS. SARCHIO: And, so, when we get to the negotiation table and talk about settlement and talk about disclaimers, the disclaimers that plaintiffs' lawyers and defense lawyers have agreed to have been hotly contested. Where are we going to put the comma? Where are we going to put the period? Which letter is going to be capitalized? Each and every issue has been carefully vetted by the plaintiffs' lawyers that are aggressively defending their clients' interests. And we on the homeopathic industry side are carefully vetting to make sure that these disclaimers comply with all the federal rules and regulations that apply to the companies.

And, so, once we finally agree to the language, not only do we agree to the language, but then we have to make sure that a judge approves it. And, again, the judge doesn't just rubber stamp settlement agreements. I have been in many

cases where at the final hearing we are debating because there's an objector or there's somebody that's come in at the last minute, trying to champion consumer rights, saying that, wait a minute, is this -- is this class action settlement fair and reasonable. And we have had to defend our position and bring in experts to support the disclaimers that, again, we have so vigorously fought for and agreed to.

And court after court has approved these disclaimers. In fact, I had a case that went all the way up to the 9th Circuit Court of Appeals, where a settlement was challenged, and one of the items that was challenged were whether the disclaimers were effective. And the 9th Circuit Court of Appeals felt that the District Court judge did his job in carefully evaluating the benefits to consumers and the benefits of the settlement and approved that settlement with the disclaiming language.

MR. VOZZOLO: I tend to agree with Ms. Sarchio, surprisingly, but I do think disclaimers are important. I think the whole goal behind consumer class actions and civil litigation is to provide the consumer with full information, accurate information, truthful information. And I think that is a critical step in at least providing that consumer with the necessary information.

MR. FORTSCH: Michelle?

MS. RUSK: Okay. So, I'll just reiterate one thing

I said earlier about disclaimers, which I think to the extent we're talking about disclaimers that say a homeopathic product has not been approved by FDA, we still believe that that's not really getting at the issue that we're most concerned about, which is that consumers need to understand that the efficacy claim hasn't been established by accepted scientific procedure, meaning randomized controlled trials.

And this afternoon -- or before the break, when we had this panel about the science, there seemed to be a lot of disagreement on a lot of different points, but when we narrowed it down to the specific issue of should there be randomized controlled trials to support specific claims about specific products, I think there was very wide agreement that that was what was called for. So, when there's not that level of evidence, that's really what the disclaimer needs to go to.

And I want to go back to something that David mentioned about referring to a website as a way of letting consumers know what the evidence is. Under our policy, disclaimers have to be clear and prominent. They have to be put in a place where consumers are going to see them. They have to be worded in a way that consumers are going to understand. And you can't leave the important qualifying information in another place. It has to be close to the claim that you're qualifying.

So, any disclaimer that uses an approach of referring to a website and putting the important qualifying information there would not be acceptable under FTC law.

MR. FORTSCH: So, as much as I would like to go on longer -- and I do enjoy these sorts of things, since I'm a lawyer -- I think we do have to conclude. But fortunately, as I mentioned and I will mention once again, we can accept your comments. We didn't get to take questions from the audience. It's even important of those who weren't able to get their comments or questions up here to file them with us at FTC.gov on or before November 20th.

I want to thank so much the panelists on my panel today and the panelists that served on the panels moderated by Mary Engle and Rich Cleland. I just have a couple of very quick housekeeping items, not nearly as long as the ones that I provided in the morning.

First of all, on a nonsubstantive basis, security badges can be passed to the people at the desk on the way out. They do reuse them, so if you got one, please pass in one on the way out, right outside the door.

And I should also -- I can't fail to thank all of the people at the agency who worked so hard to put on today's workshop, especially our dedicated Division of Consumer and Business Education, my colleagues in my division and managers, and our Office of Executive Director, who organized

the workshop so that everything was functioning.

And, most importantly, I just want to thank you so much for taking the time to come out to today’s workshop. And I will now adjourn the workshop. Thank you.

(Applause.)

(At 2:55 p.m, the workshop concluded.)

C E R T I F I C A T I O N O F R E P O R T E R

MATTER NUMBER: P154502
CASE TITLE: HOMEOPATHIC MEDICINE AND ADVERTISING WORKSHOP
DATE: SEPTEMBER 21, 2015

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the Federal Trade Commission to the best of my knowledge and belief.

DATED: OCTOBER 5, 2015

JENNIFER METCALF

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

SARA J. VANCE