FTC Homeopathic Medicine & Advertising Workshop
September 21, 2015
Segment 1
Transcript

GREG 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 either 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.

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Restrooms are located in the hallway just outside this conference room. 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 name tags, as well. The gentlemen 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 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 adviser 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 US Court of Appeals for the DC 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]

MAUREEN 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'll 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 test 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 believed that the manufacturers of homeopathic products tested their products in 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 its belief that consumers may be confused by retail store shelf placement of homeopathic products side by side with conventional medicine that impact 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 work 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 or 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 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, analysis, research or studies that have been conducted and evaluated in an objective manner by qualified persons, and our generally accepted in the profession to yield accurate and reliable results.

Competent and reliable 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 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 the 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 non-homeopathic 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 the 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 non-homeopathic 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]

GREG 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's now on stage, the Director of the Division of Advertising Practices here at the FTC.

MARY ENGLE: Good morning, everybody. And welcome again to our discussion of homeopathic medicine in 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. Candice Corlett, who's 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 in Scientific and 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? Mark? OK.

MARK 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% of homeopathic products 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 it requires advertisers of homeopathic medicines to include a disclaimer statement alerting consumers that claims made by homeopathic medicines have not been reviewed by the US Food and 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 entrusted 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 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% 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% 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 health care 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 free-standing 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% for the category. That was for homeopathic medicines. And the spend was only 2.5% 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% of all reports of exposures for pharmaceutical products involve a homeopathic medicine. And that more than 98% of these exposure reports result in no or minor effect.

As a leading industry association for homeopathic medicines, I'd like to leave you with a few final thoughts. These medicines have been part of American health care for generations. It's a small industry compared to other health care segments. But its 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 AHHP welcomes this opportunity to partner with FTC and the FDA. And I thank you for the opportunity to provide these comments today.

MARY ENGLE: Thank you, Mark. Now Jay?

JAY 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 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 is a field of medicine. It 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 and Tafel, today a brand owned by Schwabe North America, Luyties Pharmacal, Standard Homeopathic Company, and my great grandfather's firm, Borneman and 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 own 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 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 claim 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 that the industry association already has 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.

MARY ENGLE: Thank you, Jay. Candace?

CANDACE CORLETT: Okay. 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 1,000 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 health care in the US 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 health care.

Sharing information has created a widening circle of trust among shoppers for their health care. 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 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.

37% of shoppers have learned about their homeopathic medication through some form of recommendation. Another 18% have done their own online research. And 12% have learned about it through traditional advertising, in newspapers, ads, commercials.

Second point is that satisfaction is very high. We ask 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 60% to 73%.

More interesting even is that half the people who have chosen to use the 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 health care. They are more likely to use health websites, to subscribe to newsletters about health care, 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.

MARY ENGLE: Thank you, Candace. Now we'll go to Yale.

YALE MARTIN: Sure. Thank you. My name is Yale Martin. I spent 25 years in retail. During the last 10 of these years, until November of 2014, I specialized in over-the-counter products, basically everything nonprescription related to pharmacies, so cough/cold, allergy, antacids, laxative, 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 US 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 health care 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 a significant factor 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 upgrade their product offering. And items which fall in the lower quartile of their pure 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 the 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 America'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 the very aggressive marketing campaign 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 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 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 dead inventory.

Every retailer in America tracks the sales 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 a retailer, these dynamics police the marketplace, rewarding those who meet consumer expectations and punishing those who don't. Thank you.

MARY ENGLE: Thanks, Yale. Now we'll hear from Duffy.

DUFFY 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, and part of a trade association that represents both dietary supplements and functional foods and their ingredients.

And I'm going 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, integrated 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 and prevent 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 have 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 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 labelling themselves as homeopathic products. And in my opinion, without empirical evidence, it wasn't to 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?

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 actually are a homeopathic or you are a dietary supplement. But it's happening.

And then finally we also started seeing 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.

MARY 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, 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?

JAY BORNEMAN: Do you want me to take that? Do you want me start with that or do you want to take it?

MARK 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 and 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 were two things that happened. The first was that there was this growth and 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. It was developed over a long period of discussion between 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. 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, pharmacy 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.

And Jay, maybe you want to do add.

JAY BORNEMAN: Yeah. Just to add a couple points. First I think it's really important to de-link 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 or 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 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 a room with the duct tape 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 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 a great example is Thrifty Drug in Los Angeles-- that had carried Hyland's Teething Tablets back in the 1950s, didn't even know it was a homeopathic product. They just knew people wanted it.

Over time, as people clambered 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 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 do think we need to de-link that 1988 Compliance Policy Guide with the market.

MARY ENGLE: OK. Great. So even though the homeopathic medicine market 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?

MARK LAND: Yes. As I had mentioned, homeopathic market-- and this is at retail prices-- is estimated by commercial reporting firms at between $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%, 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 same for the dietary supplement market as well. So we're a very small fraction of those markets.

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

MARY ENGLE: OK. So when did the OTC homeopathic products first began 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?

JAY BORNEMAN: OK. 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 had a market area that was conducive to homeopathic medicine, 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 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 about 2000, '99 to 2001 in that bracket, it finally went into mass merchandisers, big-box stores.

MARY ENGLE: And I think now we have a short video clip that we'd like to play talking about--

[VIDEO PLAYBACK]

-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 solution. So they are looking for a natural alternative or complementary alternative to the conventional medicine that they're used to taking.

[END PLAYBACK]

MARY ENGLE: So to the folks on the panel then, generally, and I would say it's my anecdotal experience going into the store that 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.

JAY BORNEMAN: Do you want me to take this?

MARY ENGLE: Anybody.

JAY 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 a-- an analysis by one company, Boericke and 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 company's 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. Baby went in another category. Others were creating what were called natural sections. So dietary supplements and homeopathic medicine would be in one 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 what 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 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 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 do with the retailer read of what the customer wants, and then the retailer reacts to that. And does work they think is the appropriate way to go.

YALE MARTIN: I think, yeah. I think that's absolutely correct. Realistically, what the retailer is trying to do is 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 it will 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 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 basically takes items on a scaled 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.

CANDACE CORLETT: 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.

DUFFY MACKAY: And I think 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 were for treatment of a disease. And therefore the supplements would be sitting over here in the just for staying healthy aisle.

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

CANDACE CORLETT: Very much in the classic places where they shop for their health care. 52% will buy homeopathic in a drugstore in the course of a year. 48% will buy it in a mass merchant, like a Walmart or a Target over the course of a year. About 30% in a supermarket, and then there's a following in specialty food and specialty vitamin stores, where about 17% to 20% of shoppers choose those stores. And then of course the internet, which is at the time that we did this study, was 14%.

MARY ENGLE: So the internet is up to 14%?

CANDACE CORLETT: Yeah. That was as of about the mid 2013.

MARY ENGLE: OK. 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?

CANDACE CORLETT: You know, we did very much include that in our surveys. And we didn't ask people to say, to playback what they think homeopathic is. We asked them, do you feel that you clearly understand what the term 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% felt that they clearly understood what homeopathic meant. 50% said they clearly understood what natural meant. And 52% 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, than they re-buy the brand name.

So we've seen the high satisfaction rates for homeopathic. So they re-buy 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.

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

MARK LAND: Yeah. I'll take that. I think that first of all, homeopathic drugs are-- 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 non-conventional drug products, including herbs and diet supplements.

And so really the distinction is between an herb, for example, and a homeopathic medicine. And we are in now living in an era when we've 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 homeopathic drug label that differentiate those products from other products in the category.

MARY ENGLE: OK. 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?

DUFFY 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's crazy advertising like this for their supplement. And then I look 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 rumblings of companies saying, yeah this is great. 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 is a product where you sprayed it under your tongue, and it was vitamins and minerals. And you sprayed 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 look 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-- 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 actual 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 it. 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.

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

MARY ENGLE: Sure.

JAY BORNEMAN: As the pharmacopoeia guy here, I think that Duffy is 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 non-homeopathic 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 non-compendial products. They are not products that have been, 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 agita 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 regulars 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.

MARY ENGLE: And Candace, I think you mentioned maybe 16% of consumers are buying their homeopathic drugs on the internet?

CANDACE CORLETT: 14%.

MARY ENGLE: 14%. 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?

MARK 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 Walgreens, 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 1,000 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 are 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 and 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 a certain extent they all exist according to the same law of Darwinian theory that Yale has mentioned. If they don't sell, 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.

MARY 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-- a customer could figure out by themselves.

JAY BORNEMAN: That's my personal belief that the counsel's office at the retailers, the large retailers, are very much on top of what's being merchandised in their stores. Because they stand joint and severably liable for something to happen. 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.

MARK 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 it's sort of like a speeder going through a red light, pretty easy for the cops to identify.

MARY ENGLE: Yeah. And just that the FDA and FTC sent joint warning letters to various marketers of homeopathic HCG, weight loss, for weight loss. Yeah, and followed up with a couple of lawsuits.

JAY BORNEMAN: H1N1. There was lots of--

MARY ENGLE: Yeah, H1N1 as well. Yeah. I think we have some questions that have been passed up.

OK. The first question is kind of like a back to basics in terms of what is the definition, or should be the definition, of a homeopathic product. Maybe we-- we're 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.

MARK LAND: I know we have a lot of lawyers in the room too. But the homeopathic product-- or a drug is defined in the Federal Food, Drug and Cosmetic Act. And as it relates to homeopathic medicines, it is a product that is contained within the Homeopathic Pharmacopoeia of the 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.

JAY BORNEMAN: One modifications to that. The current 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?

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

JAY BORNEMAN: OK. So the homeopathic manufacturing processes 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 succusion. Dilution is the serial deconcentration, either one part in 10, or one part in 100, stepwise of the active principle.

Along each step of that deconcentration is a vigorous succussion, or shaking step. So there are two things that characterize the homeopathic manufacturing process. Homeopathic medicines are used according to the principles 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 prepared form of what would have caused the symptoms in a 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 deluded and succussed may relieve those symptoms. That is Homeopathy 101 in 15 seconds.

MARY ENGLE: Thank you, Professor. 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?

MARK LAND: 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%, depending on the therapeutic category. Placebo effect accounting for the Hawthorne, that component of that, is probably around 30%. And doctors can correct. So we can see that there's a wide difference between the satisfaction level for homeopathic medicines, and the placebo, the potential placebo effect.

JAY BORNEMAN: And I'll add another non-scientific 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.

CANDACE 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 par for both types of medication.

MARY 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.

JAY BORNEMAN: I wonder how one measures that. Is that a hard end point?

MARY ENGLE: Let's see. This may be a question for Candace or Yale. Curious about learning more about the profile of who buys-- and we touched on it a little bit, who was 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.

CANDACE 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 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 as at least we thought we would, and just a bit of a bump among African American consumers.

MARY ENGLE: The 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?

MARK 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 and Drug Administration.

MARY ENGLE: And exactly the disclaimer that, Jay, that you had-- I think, one of the three things you had recommended.

JAY 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 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 we're in the homeopathic pharmacy business.

Accordingly, announcing that our product is homeopathic on the principle 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 are proclaiming what we are. Actually it's 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's some truth to that. But to use it to sort of mislead a consumer is inappropriate.

MARY ENGLE: Well, and 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 it's just the word by itself in our research has suggested that people didn't really get what it was. So--

JAY BORNEMAN: I think it's a legitimate point. And I think reasonable people could discuss how large, 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.

MARY ENGLE: Thank you. Rich, are there more questions you want to pass up? OK. All right. Yeah. I don't understand this question either. Maybe you--

JAY BORNEMAN: Why did you give it to me?

MARY ENGLE: Because you're the professor. It's too much technical terminology.

JAY 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 of registration.

MARY ENGLE: I don't know what an NDC code is.

JAY BORNEMAN: National Drug Code, it basically says you tell the FDA that you're going to sell the product, and you fill out the form. I mean there is-- 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.

MARY ENGLE: OK. And does the-- and we talked a little bit earlier about 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 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?

JAY BORNEMAN: The answer is no and yes. The HPUS 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.

MARK 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 our association membership. So that means that we're reaching out to quite an audience beyond those that are members of our association.

MARY ENGLE: OK Thank you. And is there one more question? OK. A Couple more questions. So Duffy, I know that the Council for Responsible Nutrition has been pretty active in the self-regulatory space. And would you like to describe what you all do there?

DUFFY 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 advertising 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 lob your challenge through the NAD and say, we saw this ad. We question its evidence to support it. The NAD sends a letter to 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. 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, OK, 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, 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. People don't want their case teed up to the Federal Trade Commission with an opinion. And so therefore there's a strong will to comply. And what's nice about the process is it's not a 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 10-year anniversary of this. We've done 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.

MARY ENGLE: Yeah. And I do think, I mean just from my perspective, when I see that it's a challenge that was brought by the trade association for the industry, I think well, they've probably looked into this. And, you know, there's a good reason for this challenge to be happening.

DUFFY 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 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 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.

MARY ENGLE: OK. And we will be hearing from Kath Dunnigan, who's 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 HPUS play a role in identifying or reporting non-compliant products or outliers? Something similar to what Duffy describes that the CRN does.

MARK 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.

MARY 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]

GREG FORTSCH: We're 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.

RICH 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 Listritto, 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 Mechanist 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. Adriene 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.

RICHARD LOSTRITTO: Good morning. 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 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.

RICH CLELAND: Thank you, Rik. Dr. Williamson?

JOHN 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 work, 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 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 co-funding of major studies such as AREDS, a study that showed that a dietary supplement containing high doses of vitamin 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 and 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 defined 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 is the nation's medical research agency, includes 27 institutes and centers. And it's a component of the US Department of Health and Human Services.

NIH is a primary federal agency conducting and supporting basic clinical and translational medical research. And it's 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 was 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.

And 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'm 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.

RICH CLELAND: Thank you, John. Dr. Riley?

DAVID 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's widely recognized as one of the key figures in evidence-based medicine, published an

article in the British Medical Journal, that he said, without clinical expertise practice risk becoming tyrannized 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 US, 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 condition, 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 desensitization 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 GNP 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 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, refer 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 in 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 of 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 home 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 index medical review. And 80 of those-- 137 of those where peer reviewed.

And in conclusion, I would 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.

RICH CLELAND: Thank you, David Dr. Herscu?

PAUL HERSCU: Good morning. And my name is Paul Herscu.

RICH CLELAND: Oh, I'm sorry.

PAUL 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 US Department of Education.

Naturopathic medical schools provide equivalent foundational course work as MDs in DO schools, including basing sciences as well specialties, such as cardiology and urology, et cetera. In addition, ND 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 NDs are extensively trained in pharmacology, NDs integrate naturopathic treatments with prescription medications, often working with conventional medical and naturopathic doctors to ensure safe and comprehensive care, and as such, have a unique perspective on questions of homeopathy in the United States.

Aside from my involvement with the AANP, I co-founded the New England School of Homeopathy, the largest and oldest continuous postgraduate study of homeopathy in the United States, training physicians in the art and science of integrating homeopathy into their medical practice. As well 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 just start by highlighting the reason I became a naturopathic physician, focusing primarily on homeopathy. At the time of my medical education in 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 it would help or not their own patients.

In other words, when we knew a drug was 60% effective, or 70% or 80% 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% likely to improve or in the 20% who is 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 patients suffer from horrendous side effects?

There are no tools available to the clinician. We all moved in lockstep as if this question did not matter. It 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, and 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'm here both to say that homeopathic remedies were, are, and should continue to be available OTC. And forgotten homeopathic methodology 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.

RICH CLELAND: Thank you, Paul. Adriene?

ADRIENE 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 ensures that study subjects have an equal chance of being in a treatment or a control group. And controls, which can be a placebo or it can be a sham, or it can be a proven treatment, 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 the 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 non-specific 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 health care provider, whatever therapy that health care provider uses, is going to work better for you. But it's because of the placebo effect that RTCs are necessary. Only a randomized controlled trial can establish whether a therapy has an effect above and beyond its non-specific effects. And only therapies that are better than placebo or a sham, 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 homeopathics 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 illicit 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 homeopathic 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.

There is no alternative science to establish therapeutic benefit. Only RCTs establish competent and reliable scientific evidence. Homeopathy has failed that standard.

RICH CLELAND: Thank you. Dr. Jonas?

WAYNE 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 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 a 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's 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, it was just mentioned, highly selected in those areas.

If you want to go back and do 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 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. Evaluation should be comprehensive, systematic, and they should apply very good bias-reduction 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. They're the application of others that are published in this area, including standards from the Institute of Medicine, the Agency for health care 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 one type of evidence 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, or provide us the best of 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. That's a-- there's PCORI other organizations around that are now focused on patient-centered research. I suggest we need public-centered-- I'm sure you've heard patient-centered care. We need public-centered research in these areas. And I think homeopathy provides us a great opportunity to do that.

RICH CLELAND: Thank you, Dr. Jonas.

WAYNE JONAS: So, thank you.

RICH CLELAND: Dr. Hoffman?

FREDDIE ANN HOFFMAN: Thank you very much. I want 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 health care 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, and 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. 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 exemption through deferment from the agency's congressionally-mandated oversight of US drugs marketed post 1938. The 1988 Compliance Guide, which has been alluded to, describes the conditions under which homeopathic drugs may be marketed, which serves 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 a 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. Non-homeopathic drugs are limited to 10% or less. Homeopathic drugs have had 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 that actually would make them be health fraud under the FDA's the 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 this 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 US 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. And 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 US 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 US consumer.

To ensure that homeopathic drugs ads are truthful, non-deceptive, and not unfair and are backed by sufficient scientific evidence.

RICH CLELAND: Thank you, Dr. Hoffman.

FREDDIE ANN HOFFMAN: Thank you.

RICH CLELAND: Well as sometimes happens on these panels, you meet and discuss what kind of questions you're going to ask or 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 basis on which products are included in the HPUS, and one of those was drug provings. Provings, no 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?

DAVID 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 a homeopathic--

RICH CLELAND: So these are people with no symptoms?

DAVID RILEY: People with no symptoms are given a diary. And the diary is collected. And it's a controlled qualitative study. And there's a guideline that have been produced that incorporate some of the contemporary scientific research methods that I discussed in terms of randomization, placebo controls, and such.

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

PAUL HERSCU: Yeah. There's a lot. 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, Adriene?

ADRIENE FUGH-BERMAN: Sure.

PAUL HERSCU: Sure. My colleague Adriene thought that clinical trials 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 effect.

So this has become part of clinical trials since 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. Here I have specific quotes here which are a little bit lengthy and I was asked not to go through all of those.

RICH CLELAND: OK. Thank you.

PAUL HERSCU: But, if somebody asks that question I'll be able to say it. Thank you.

RICH CLELAND: OK. So I want to understand, take a sub-- a group, 10 or so people, 20 people, divide them up into two groups. Give one of them a sham. And you let them record their subjective symptoms?

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

RICH CLELAND: OK. All right. We'll come back 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 where it went. And I think traditionally it was my understanding homeopathic remedies were individualized under the care of a treating physician who monitored the patient's 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?

DAVID 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's 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 or other therapeutic interventions for their problem.

I think that it's-- 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 the homeopathic remedy.

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

DAVID 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.

RICH CLELAND: OK. Let's go back to talk about provings then. How are the observations in a proving actually validated?

DAVID RILEY: Well it--

RICH CLELAND: Paul or David, either one? Either one?

DAVID RILEY: You can go ahead.

PAUL HERSCU: Do you want me to take it?

RICH CLELAND: He had the last one. You can have the--

PAUL HERSCU: OK. 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, 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 withing 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 the information that's gathered. And we can provide the framework that we use that HPCUS uses for approving provings.

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

DAVID RILEY: Proving guidelines, yes.

RICH CLELAND: Yeah. The proving guidelines. And I'm looking at appendix 11 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 you determine that your observations are due or not due to just chance.

PAUL HERSCU: Oh. OK. I'll take that. So first, as we mentioned, provings are there's placebo response. There's placebo separation where 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 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, the same timing, different individuals, male, female, different ages. So this is part of the answer.

But provings have a lot of science behind them.

RICH 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?

DAVID RILEY: Well, it's a couple things. First that statement that you read out of the appendices was about quantitative statistical analysis. The four criteria that are used are not validated, quantitative-- qualitative assessment tool, but of course, things like the promise instrument really isn't validated either. So there's different levels of acceptance for that. So is not quantitative statistical analysis of the results of provings. That is correct.

RICH CLELAND: Any other comments from the panel on that question? Dr. Hoffman?

FREDDIE ANN HOFFMAN: 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 principal, whether it's backed by a rational basis in science is a separate issue.

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

DAVID 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 have somebody who is not trained in homeopathy-- is probably going to want to rely on other information as well. It would not be sufficient.

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

DAVID RILEY: Well I tend to parse efficacy into several different categories. There's efficacy. There's effectiveness. There's pharmacokinetics. 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 people, several people have said here, and it seemed a little bit confusing. But most homeopathic drug provings are done with homeopathic preparations. They are not done with like with Ipecac. In an 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 quite complicated to sort that out.

ADRIENE 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 that it actually-- the analysis of qualitative research involves using academically accepted methods for analyzing material that you have.

And so one question here is whether the methods of analyzing provings are actually academically accepted methods for qualitative research. But more importantly than that, this kind of research has nothing to do with the therapeutic efficacy of the product.

RICH CLELAND: Dr. Jonas?

WAYNE JONAS: Is it automatic? OK. Thank you. Yeah. I think the definitions here are really crucial. And I'm glad that Adriene brought up the point that you can do different types of research and they can be good quality. OK. 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 health care 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 two 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 a 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.

So 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.

RICH CLELAND: Thank you. 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 that with this substance in it, will stop my runny nose. David?

DAVID 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--

WAYNE JONAS: Well I think if you look at dose-adaptive responses, which is what the hypothesis, this 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 they're 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.

RICH CLELAND: Well-- let me Let me explore this a little bit about that too.

WAYNE JONAS: 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.

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

WAYNE JONAS: What may be true? The adaptive response? That is true. That's not an idiosyncratic case.

RICH CLELAND: Well it's no-- are you saying it's universally true across all substances?

WAYNE JONAS: Absolutely don't--

RICH CLELAND: Every time you give a substance it creates--

WAYNE JONAS: The only one I've ever seen that doesn't actually produce an adaptive response, depending upon the dose and the sensitivity of the organism, is cyanide. OK. There are few others that have fixed responses that 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 almost every substance you could name, almost every kind of organism that you can name, showing dose-adaptive responses, which he calls hormesis.

RICH CLELAND: What are the-- when you say dose-adaptive responses, you're talking about what? Remedy? My clearing up my runny nose? Is that a dose response?

WAYNE 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 does it-- is it an explanation for the law of similars? I don't know. OK? But it is in fact a type of pharmacology that could be used to understand what's going on in low-dose effects?

PAUL HERSCU: Great. Can I just jump in?

RICH CLELAND: Yes, Paul. Go ahead.

PAUL HERSCU: So first on the hormesis, Dr. Calabrese actually lives in my town. So I had 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 you change the dosage on it, meaning you made an ultra-dilute dose of that substance, the effect on the plant was exactly the opposite.

So back to your nose, your runny nose. The closest thing, the closest, easiest way to describe this is if we look at the group here. There's a certain number of people that had allergy shots to something, to some tree that they're 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 is the cousin of isopathic medicine where we use substances that cause similar symptoms, rather than same substance.

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

RICH CLELAND: Dr. Berman?

ADRIENE FUGH-BERMAN: It's 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 are testing drugs, we're looking for 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.

WAYNE JONAS: 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 that it dissipates out, and it goes away. But the vast majority of drugs in which this has been looked at, it's not looked at in most drugs, you see an upturn right at the bottom of the dose response. It's non-linear, and that's pretty well-established.

FREDDIE ANN 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 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, than it should be discarded. As simple as that.

RICH CLELAND: OK. 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. In fact, some of the products that we looked at in our internet surf 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?

DAVID 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 on combination products. But it's not a regulatory requirement that homeopathic drug provings be limited to individual ingredients.

RICH 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 pound them on the table?

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

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

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

RICH CLELAND: When they're inactive ingredients, listed as inactive ingredients?

DAVID RILEY: Well that would be mislabeling then. Yes. So that would be not--

RICH CLELAND: But it's not.

DAVID RILEY: It may be done.

RICH CLELAND: It wouldn't be scientifically? Again we're not talking about the regulatory position. I'm talking about your position.

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

RICH CLELAND: Thank you.

PAUL HERSCU: Can I just jump in?

RICH CLELAND: Yes.

PAUL HERSCU: So FDA CPG Section 400.400, definition 2 states, drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients and non-homeopathic drug products, it goes on and so on-- the homeopathic community, the HPCUS, has again and again taken that position.

That 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.

RICH CLELAND: OK. 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?

FREDDIE ANN HOFFMAN: No. On 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 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, unless you're telling me that these products do not conform to the laws of physics and chemistry that 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, 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 will 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 what we're trying to get a product to be able to conform to the US 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 control trial is really the gold standard at this time for that particular objective.

ADRIENE 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% effective. In effectiveness trials, it's more like 95-96% effective. Because people don't necessarily take it the way they're supposed to. They don't take it every day. Or 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 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.

FREDDIE ANN 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 the-- 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, very defined context.

RICH CLELAND: Dr. Jonas?

WAYNE JONAS: Yes. I definitely agree with Doctor 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 Doctor Fugh-Berman that you cannot use effectiveness to determine benefit. In fact, effectiveness is an important way, an 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 control trials, as well as its application to determine benefit, in those particular areas.

ADRIENE FUGH-BERMAN: I didn't say anything against effectiveness research. What I said was that observational studies cannot show benefit. Are you saying that observational studies can show benefit?

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

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

FREDDIE ANN HOFFMAN: It really isn't it. And I think that that's going--

WAYNE JONAS: And also you don't believe that back surgery should be allowed? Is that right?

FREDDIE ANN HOFFMAN: There's a lot of issues with how surgeons do trials actually.

RICH CLELAND: Let's not-- let's not go there.

WAYNE 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 it's what's used, and do that in an appropriate and comparative way.

RICH CLELAND: 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.

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

DAVID RILEY: I would concur with his statement.

PAUL HERSCU: But just to fill in, just can I jump in?

RICH CLELAND: Yeah. Absolutely.

PAUL HERSCU: So, first of all many OTC conventional drugs have not been held to RTC method. Is this review process underway 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 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-- while randomized control 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 1950s and 1970s, not in 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 3 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, what 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 in the homeopathy side. But I also work in the pharmaceutical, and I can give you examples there where you can see what I mean specifically. There is this-- 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 of questions on this. Because I could talk about this all day. So if anybody wants to pass questions along, that would be great.

JOHN WILLIAMSON: I would make a comment that we, I believe that clinical trials, random clinical trials have changed quite a bit in the past 65 years. 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 start comparing anecdotal evidence to the 1800s, it is quite different than the strenuous research that we require today.

FREDDIE ANN HOFFMAN: Yeah. The observational studies go back to the 19th century. Might as well just move back there. Because that's what they were using.

WAYNE 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 everywhere, basic science research, observational and epidemiological studies, comparative effectiveness research randomized controlled trials.

JOHN WILLIAMSON: I believe in medical research, though, I would say that there's very little insignificant, or infinitesimal advancement in science. Medical research has advanced quite 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.

WAYNE JONAS: I think that's absolutely right. And you have to look at the quality of the research when you're analyzing this in order to determine that, regardless of when it was done. I think this was 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.

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

FREDDIE ANN HOFFMAN: The other thing I just want to bring in--

WAYNE JONAS: They're a bad way to assess effectiveness and safety.

ADRIENE FUGH BERMAN: Effectiveness research can be randomized and controlled. And it usually is. Do not confuse effectiveness research with observational study.

WAYNE JONAS: That's correct. It's not placebo though.

RICH CLELAND: OK. Dr. Hoffman.

FREDDIE ANN 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 could be methodological 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 look 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 these are important concepts with complex products.

RICH CLELAND: OK. We have just a few more minutes. And I'm going to move on to a couple of questions here left on my list. One of the factors that the FTC considers when it determines the level of substantiation required for 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?

FREDDIE ANN 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 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.

RICH CLELAND: Any other?

ADRIENE FUGH-BERMAN: I would add that 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 results.

WAYNE JONAS: Then nobody would do them.

FREDDIE ANN HOFFMAN: Well there has to be-- I mean conflict of interest is a big deal.

WAYNE JONAS: Yes. You have to manage conflict and bias. There's no question about it, which is 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 measurement in terms of that. I mean we're 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 multicenter 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 controlled trial.

FREDDIE ANN HOFFMAN: Let me also just quickly, the size of trials are very important. The average drug is approved on no less than about 700 people, generally more. 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 accrue several hundred people in these pivotal studies. And the size of the trial is really-- and thousands of people in some case. There was one of the major pharmaceutical companies just lost a Phase 3 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 thing.

RICH 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 how many people need to be in a trial, and how many trials you need, so we have a very flexible standard when it comes to evaluating.

FREDDIE ANN HOFFMAN: But they have to be reproducible.

RICH CLELAND: Yes, absolutely. And it's even better that they not only should be reproducible, I liked it when they've actually been reproduced. 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 haven't-- 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.

RICHARD LOSTRITTO: I did. Thank you. And I'll try to go in a little different direction with it 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 the third in the area of end-product testing.

In the area of raw materials I think particularly interest would be the 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 the plant. We know that some of the plants that are used nowadays may be endangered species.

That other factors-- the 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, we read about the dilution, attenuation, and succussion 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 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 the various succussion approaches, which are used to shake, to potentize the preparation. There's a number of various approaches there. So I think there would be some interest in that manufacturing process approach of homeopathic products are unique too.

In the area of end-product testing it would be very interesting to show at high attenuation that there actually is a lack of the active principle 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 or 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.

RICH CLELAND: Paul, you indicated-- did you wand to respond to any of that?

PAUL HERSCU: Well, I would jump in a little bit. I think a lot of these questions are best served by 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 level of a plant at different times of the year. That was already included in the pharmacopoeia. So when you pick any plant, it says, grown at this time of year, at this time and so on.

So there are actually methods. But that set of questions which are important questions are best served by asking and interacting with HPCUS.

RICH CLELAND: OK. 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?

SPEAKER: 1:30

RICH CLELAND: Or 1:35.