FTC Homeopathic Medicine & Advertising Workshop
September 21, 2015
Segment 2
Transcript

GREGORY FORTSCH: Good afternoon. We're going to move into the final panel of the workshop today. And I want to introduce myself, who is moderating this panel.

And you've met me already, and that's all I'm going to say about myself.

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

So we are going to follow the same structure that we followed in the other two panels, where we're going to ask each of the panelists-- and as you can see, we have a larger group than the other two panels, so we're going to strictly enforce the five minute or less rule, but I think everyone is very well versed on that one. We're going to ask everybody to give a five minute or less opening remarks, and then we'll do a number of questions. If we have time we'll take questions from the audience, but I'm going to start with my colleague, Michelle Rusk.

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

We do share jurisdiction with FDA over homeopathic, allopathic, OTC drugs, food, supplements, and certain other health products. And that means we need to coordinate our enforcement efforts, so we have in place a memorandum of understanding that spells out that FDA has primary responsibility over claims made in labeling, and the FTC takes the lead on claims in advertising and other marketing. And we do make every effort to be consistent in our actions. But there are some important differences in our legal frameworks.

The FTC is primarily a law enforcement agency, not a regulatory agency. And by that, I mean we don't engage in pre-market approval. The law requires an advertiser to substantiate advertising claims before they're made, but they don't have to submit ads to us in advance, and we don't pre-approve their claims, nor do we dictate how claims are worded or what specific disclosures are required.

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

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

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

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

So in my last minute, I want to make a few points about what exactly the FTC means when we say, competent and reliable scientific evidence. I have two minutes, apparently. Most importantly, we expect to see rigorous science. As Rich mentioned, there is some flexibility in the number and type of studies, the size, the duration-- but as a general rule, for treatment claims, we expect randomized, double blind, placebo controlled, human clinical studies. Not in vitro studies, not animal studies, not anecdotal evidence-- no matter how compelling it is.

Second, we expect the studies to be internally valid. That means well designed, reliably conducted, using procedures accepted in the field of research. It also means that results are not just statistically significant, but also strong enough to be clinically meaningful.

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

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

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

GREGORY FORTSCH: Thank you, Michelle. I'm now going to turn to Elaine Lippmann to speak about the FDA.

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

Products that meet the definition of "drug" under the Food, Drug, and Cosmetic Act are subject to regulation by the FDA, regardless of whether they are labeled as homeopathic. Since 1988, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval under our stated enforcement policies. FDA is now evaluating its current enforcement policies from scientific risk and process perspectives.

In April of this year, FDA began soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last approximately 25 years. FDA is, therefore, engaged in its own reexamination of its regulatory approach to homeopathic drug products, at the same time that the FTC is examining issues related to the advertising of these products.

Compliance policy guides explain FDA's policies on regulatory issues related to our laws or regulations. They also provide guidance to FDA's compliance staff and field investigators, on the agency standards and procedures to be applied when determining industry compliance. In 1988, FDA issued its compliance policy guide, or CPG, entitled, Conditions under Which Homeopathic Drugs May Be Marketed.

This CPG states that the FDA does not intend to take enforcement action against drug products labeled as homeopathic and marketed without pre-market review and approval, provided that certain conditions are met regarding ingredients, labeling, prescription status, and current good manufacturing practice. The homeopathic drug industry has continued on an upward growth trajectory since FDA issued the CPG in 1988, especially with respect to OTC drug products labeled as homeopathic.

The CPG noted that at the time of original publication in 1988, the homeopathic drug market was a multimillion dollar industry in the United States. In 2007, the National Health Interview Survey conducted by the Centers for Disease Control and Prevention estimated that adults spent about $2.9 billion on the purchase of homeopathic medicine. Drug products labeled as homeopathic are marketed and sold in a variety of dosage levels and forms, direct to consumers, through

magazines, the internet, and in both big box retail establishments-- like Target and Walmart-- and traditional retail pharmacies like CVS and Walgreens.

To date, manufacturers have listed with the FDA over 7,000 OTC drug products marketed as unapproved homeopathics. In light of the growth of the industry, and the passage of approximately 25 years since the CPG's issuance, FDA is evaluating its regulatory framework for these products. This past April, FDA held a public hearing to obtain information and comments from stakeholders about the current use of homeopathic drug products, as well as the agency's regulatory framework for these products.

FDA is seeking broad public input on the current enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health.

On August 21st, the FTC submitted a comment to our docket. In it, FTC recommends that FDA reconsider its current regulatory approach to OTC products labeled as homeopathic. FTC states its concern that our policies conflict with the commission's advertising substantiation policy in ways that may harm consumers and create confusion for advertisers. FDA will consider FTC's comment, along with other comments submitted to our docket, as we determine whether and how to adjust our regulatory approach to products labeled as homeopathic, with the goal of protecting and promoting the public health.

GREGORY FORTSCH: Thank you, Elaine. I'm now going to turn it over to Al Lorman.

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

First, however, I'd like to make one brief point though about a key legal assertions by the FTC staff. I believe that a Compliance Policy Guide reflects FDA's recognition that Congress may well have adopted a different standard of effectiveness for homeopathic drugs. Whether that same standard also applies under the Federal Trade Commission Act is a legal issue which has never been decided by either the commission, nor court. Even were the FDA to revoke or revised the Compliance Policy Guide, as suggested by the FTC staff in its comments to FDA, that does not actually change the legal status of homeopathic drugs under the Food and Drug Act.

The FDA would still have to take some sort of legal action to establish that these drugs are not legal. In fact, since the drug amendments of 1962 were passed, the amendments which added the effectiveness requirements of the statute, FDA has been in the process of reviewing both prescription and over-the-counter drugs to determine their compliance with the effectiveness standard. There are still hundreds of OTC and RX allopathic drugs for which FDA has not made a final determination as to safety and effectiveness.

As a legal matter, homeopathic drugs are in no different position. And if we have to take our place in the line of FDA's review of drugs under the 62 amendments, I suspect they may reach it in the next century.

However, my main point today is that the AAHP believes that there is actually an appropriate path forward that not only gives consumers additional purchase information, but also satisfies the FTC's claimed legal standard. We would much rather cooperate than litigate. The AAHP adopted a voluntary advertising and labeling disclaimer program in 2012. That disclaimer was based on the one adopted by Congress in the DSHEA for diet supplements, which made structure function claims. Between the AAHP guideline, and court-approved settlements in some of the false advertising cases that have been brought against homeopathic manufacturers, we believe that a majority of the homeopathic products sold today bear some sort of disclaimer on labels and in advertising.

The AAHP has conducted a study about consumer understanding of FDA's role in the approval of a number of product categories. This study showed that 24% of the consumers tested believe that FDA approved homeopathic drug claims. This 24% is within the range found by the FTC in its study of a couple of years ago.

While 24% is not an inconsequential number of consumers to be confused, it is important to put that number in context. The AAHP study shows that fewer consumers believe that FDA approves homeopathic product labels than believe that FDA approves cosmetic, pet food, and grocery product labels. In fact, fewer consumers that we surveyed believed that FDA approved homeopathic product claims than any other product category tested.

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

In a separate study, the AAHP also studied consumer perception of product labels with one of three different disclaimers. This study, to the extent possible, was modeled on the study that the FTC commissioned several years ago.

We tested three different disclaimers. One, these statements have not been reviewed by the Food and Drug Administration. Two, the uses of our products are based on traditional homeopathic practice-- they have not been reviewed by the Food and Drug Administration. And three, the uses of our products are based on traditional homeopathic practice, and then a parentheses, see www.homeopathic.org, close parentheses. They have not been reviewed by the Food and Drug Administration.

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

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

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

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

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

ELAINE LIPPMANN: It's open until November 9.

GREGORY FORTSCH: OK, so we're in November. Everybody remember November if you want to file something. So I'm next going to introduce Paul for his opening remarks.

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

In 1938, Congress enacted the Federal Food Drug Cosmetic Act, or FFDCA, which contains a number of specific provisions applicable to the commercial distribution of homeopathic drugs in the United States. For example, the definition of a drug expressly includes articles recognized in the official homeopathic pharmacopoeia of the United States, or HPUS. Importantly, it's my understanding that the fundamental principles of homeopathy, including homeopathic claim support, have been generally consistent since the passage of the FFDCA. In other words, when the FFDCA was enacted, Congress knew how homeopathy claims are supported, recognized that homeopathic drugs are distinguishable from allopathic drugs, and clearly intended for consumers to have access to homeopathic drugs in the United States.

FDA's regulation of homeopathic drugs since 1938 has been consistent with this approach. FDA has long recognized the distinction between homeopathic and allopathic drugs, and has not applied new drug application or NDA requirements, or the OTC drug review to OTC homeopathic drugs. In 1988, FDA made this policy explicit when it issued a Compliance Policy

Guide, or CPG, still in effect today, explaining that OTC homeopathic drugs may be legally marketed in the absence of NDA approval, or inclusion on the OTC drug review, as long as a number of conditions are satisfied.

One of those conditions that OTC homeopathic drug labeling must bear at least one major OTC indication for use, stated in terms likely be understood by lay persons. This requirement is consistent with the FFDCA requirement that all OTC drugs must bear labeling containing adequate directions for use. In its recent comments to the Food and Drug Administration, FTC staff acknowledged the potential conflicts caused by FDA regulatory requirements applicable to homeopathic drugs. In an effort to address this conflict, the FTC proposed three options for the FDA.

I respectfully submit that, in my opinion, all three options are sub-optimal, and would pose legal and policy challenges for FDA as they would either be, in my opinion, contrary to congressional intent, or violate the FFDCA. Rather than those proposed approaches, I respectfully suggest that there is an alternative approach that should be capable of achieving the FDA's and FTC's goals, while avoiding vexing legal problems and which would seem to benefit all stakeholders.

That would be the use of disclaimers and qualified language. Effective disclaimers should be capable of addressing the FTC's concerns, and would be consistent with the FTC's guidance regarding claims for traditional use. Such an approach would have another crucial benefit, as well-- it would avoid offending First Amendment principles that strongly disfavor the suppression of commercial speech. This is now the clear trend in First Amendment jurisprudence involving claims for FDA regulated products.

Such issues arose, for example, in the Pearson v. Shalala decision, where the DC Circuit concluded that health claims lacking significant scientific agreement may be lawfully disseminated, consistent with First Amendment precedent, provided appropriate disclaimers are disseminated in order to avoid consumer confusion or deception. Similarly, in the recent FTC POM Wonderful decision, the DC Circuit acknowledged that an advertiser may lawfully disseminate a health related claim lacking robust substantiation, falling short of a randomized control trial, if the claim includes an effective disclaimer disclosing the limitations of the supporting research.

The use of disclaimers in this context would also be consistent with the recent First Amendment decision in the Amarin case, where the Southern District of New York held that commercial speech disseminated by a prescription drug company may not be just restricted by the government, if claims were accompanied by appropriate disclaimers reflecting limitations on claim support. Thus the existing case law, and the clear trend in such cases, strongly suggest that disclaimers would be more likely than other options to pass muster under the First Amendment.

Of course, according to FTC precedent, disclaimers will need to be presented in a clear and conspicuous manner, easily legible to consumers. In some, both the statutory requirements and constitutional considerations strongly suggest that use of carefully crafted disclaimers in qualifying language would be the optimal solution for addressing concerns about promotional claims for homeopathic drugs. Such an approach would be consistent with congressional intent,

FDA regulations, and FTC precedent, and would have the important benefit of adhering to the First Amendment's dictate that suppression of commercial speech should be a last resort.

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

GREGORY FORTSCH: Thank you, Paul. I next want to ask Christina to speak.

CHRISTINA SARCHIO: Thank you, Greg. Class action lawsuits can serve an important function in protecting consumers. And agencies, with great demand on their resources, sometimes rest a little easier knowing that consumers can enforce their rights through other vehicles.

Unfortunately, that has not been the case here. Where lawsuits filed against the homeopathic industry have done nothing more than decrease competition in the marketplace, while providing little value to consumers. Good afternoon, my name is Christina Sarchio.

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

I have represented manufacturers and retailers in a dozen of these cases, and have seen firsthand the impact that litigation has had on companies and consumers. The financial impact on companies as a result of this litigation has been significant, and in some cases, devastating-- with litigation defense budgets quickly reaching seven figures, even before the parties have reached trial. Now the three cases that have gone to trial have been wins for homeopathy. In each of these three cases, which included two bench trials and one jury trial, plaintiffs failed to prove in court that the homeopathic claims were false and misleading.

Most cases, however, never get to trial, with many of them either being dismissed or settled on a private basis. A handful of those cases have resulted in settlements, where homeopathic companies have volunteered to add disclaimers that plaintiff's lawyers have accepted and that judges have approved as adequate to address concerns of false advertising.

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

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

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

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

In another case I was involved in, we polled the consumers that submitted claim forms after settlement. 55 of those consumers went out and purchased either the same homeopathic product or a different homeopathic product, despite receiving money from the lawsuit that alleged that homeopathic products do not work as advertised.

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

GREGORY FORTSCH: Thank you, Christina. David?

DAVID SPANGLER: Good afternoon. I'm with the Consumer Healthcare Products Association, we represent manufacturers of OTC medicines-- both allopathic and homeopathic and dietary supplements. Thank you for having us here this afternoon.

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

Homeopathic products are one part of that spectrum of options of choices to help Americans address their everyday health care needs. That includes things like addressing cold symptoms, headaches, or heartburn.

For another example, the National Health Information survey found that nearly three quarters of Americans have used complementary and alternative medicine, as CDC defines it. One small part of that, around 2.6%, is homeopathy. So repeating, it's a choice among many options.

Second, yes, Section 5 of the FTC Act declaring unfair or deceptive acts or practices unlawful certainly applies the homeopathic product advertising, just as it would to other consumer health care product advertising-- or indeed, consumer advertising, in general. Third, well established and embedded within the prohibition against deceptive advertising is advertisers must have a reasonable basis for their claims-- or in other words, ads must be substantiated under the Pfizer factors, which take into account, as you know, the type of product, the type of claim, and the ease of developing substantiation for a claim.

As I know this audience is well aware, the Pfizer factors approach to substantiation is a flexible standard that recognizes the amount of evidence required depends on what the advertiser has said about that evidence. In general, the commission has not attempted to use substantiation doctrine to prescribe specific tests as the basis for particular classes of ad claims. To suggest otherwise, as the August 2015 FTC staff comments to FDA on homeopathic product regulations seem to suggest, is overreaching.

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

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

We are reassured that today, we've heard from neither FTC nor FDA, a suggestion that there's some basis to change this longstanding, widely understood agreement.

GREGORY FORTSCH: Thank you, David. Antonio?

ANTONIO VOZZOLO: Good afternoon. I'd like to thank the FTC for holding this panel today. Appreciate the invitation to come speak today.

I'd like to read off a couple of pretty interesting and noteworthy statements. "Many companies simply use regulation of homeopathic medicine as a cheap license to sell whatever they wish. Since the FDA in the United States, like many regulatory agencies, is underfunded, and since the public safety impact of enforcement of homeopathic regulation is seen as a low priority, there are no bodies in the streets, the FDA frequently does not enforce its own regulations, let alone those of the HoPUS-- HPCUS.

The results are that the US has become the victim of numerous so-called homeopathic medicines, which received big ad dollars but no clinical testing. Manufacturers have an obligation to customers to provide products that work."

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

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

What I've heard today are anecdotal evidence about surveys, about how customer satisfaction is somehow tantamount to efficacy. Somehow customer satisfaction implies that products work. Product placement implies efficacy-- you need to walk into these grocery stores, these pharmacies, and look at the actual packaging. There are efficacy claims made right on a packaging.

This is not simply packaging placed next to other OTC products. The deceptive and misleading advertising is actually on the packaging-- representations that these products are effective, that these products are fast acting, that these products work quickly.

And I'd like to point back to that last statement-- there's an obligation to provide truthful and accurate statements. Manufactures have an obligation to provide products that work. And this is the benefit of class actions. I thank Mrs. Sarchio for providing a wonderful interpretation of class action benefits that have occurred to date.

But the class action device is very powerful, particularly in this instance where there seems to have been a lack of action on behalf of numerous parties. And the value of class action litigation provides multiple benefits-- including deterrence effects; reimbursement and refunds to consumers; many of these settlements have provided monetary relief to class members-- they've received full reimbursement of the purchase price of their product; there have been funds made at anywhere between $1 dollars and $5 million for some of the smaller cases, which does not revert back to defending the homeopathic manufacture-- this is hard, real money for consumers to get back.

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

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

Some of the other injunctive aspects that have been proposed in class action settlements include dilution disclaimers-- explaining what these dilution formulas on a product packaging, what they

mean, and how to provide that information to consumers so they could make a reasonable and informed decision. There also have been the CPG disclaimer, where they place a link to the FDA Compliance Policy Guidelines, Section 400 400.

And also there have been proposed efficacy disclaimers, where defendants agreed not to use the words "clinically proven," "proven effective," or similar words unless at least two clinical trials have been performed by independent researchers, using random clinical trials to establish efficacy. I think that's all I have to say. I know we have limited duration.

GREGORY FORTSCH: OK, thank you, Antonio. And last, but not least, Kat Dunnigan from the NAD.

KATHLEEN DUNNIGAN: Hi, and hi over there. I came from New York this morning, and at 4:00 AM as I was headed out, I peeked into my kid's room and immediately my two-year-old said, "I'm awake! Yay!" Which is both adorable and unfortunate.

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

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

We also have a monitoring program were reach out and ask advertisers to send a substantiation for their claims. We do this in industries where competitors tend not to challenge one another-- the cosmetics industry, dietary supplements, and homeopathy. Especially with regard to homeopathic products, the types of claims we see over and over again are health claims.

And so just to call a few examples from prior cases-- prevents acne, clinically proven to reduce the duration of your cold, or, more seriously, to relieve symptoms of ADHD in children. These claims, and others like them, should be supported by competent and reliable scientific evidence. And just to say it again, the best being randomized, placebo controlled trials that are statistically significant to the 95% confidence level. There should also be evidence that the treatment effect is large enough to be meaningful to consumers, and that isn't always the same thing as statistical significance.

While NAD makes determinations on a case by case basis, generally speaking, the product of a presence active ingredient or ingredients and documents produced by the HPUS or the in a materia medica are not sufficient-- they are insufficient, not good enough to provide a reasonable basis for health related performance claims. Also, generally speaking, homeopathic provings, in

vitro studies, and animal studies are also not considered, on their own, to be competent, reliable scientific evidence.

And to understand why this is, you have to go back to the very beginning of claim analysis. And the first question we ask ourselves is what are the messages reasonably conveyed by this advertising? The types of messages conveyed drive the level of evidence required. And so if you're going to implicitly or explicitly say that your product has a specific effect on human health-- and I think we need to take a moment to just acknowledge that these claims can be very powerful, and have the potential to touch upon real fears and vulnerabilities in people's lives-- well if you're going to make that type of claim, consumers are reasonable in assuming that you have tested the product out on humans.

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

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

So in conclusion, the types of messages conveyed drive the level of evidence required. At NAD, it doesn't matter who you are. If you're an aspirin manufacturer, or dietary supplements, or homeopathy, what we look at are the messages conveyed, and the fit of the evidence to those messages. And so regardless of what product category you find yourself in, if you want to make health related performance claims, then the level of evidence is competent and reliable.

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

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

Now, as commissioner Ohlhausen said in her opening remarks-- and I would reiterate, and I think it's pretty clear at this point-- our workshop today is not about the practice of homeopathic medicine. It's about the advertising of products that are marked as homeopathic, or are homeopathic. And we also are here to talk about the FTC.

But it's hard to talk about this issue without talking about the FDA, because as we pointed out a number of times today, and in our remarks, comments that we filed with FDA, we work very well and very collaboratively with the FDA, because we have common interests in protecting the American public. And so my first question I want to direct to Elaine Lippmann from the FDA.

There's a few questions, but the first one is-- and I think you covered this a little bit in your opening remarks, but maybe a little more elaboration, if you can-- on why is the FDA reexamining its regulatory framework right now?

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

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

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

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

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

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

GREGORY FORTSCH: And this could be a challenging question, but I'll ask anyway-- because I don't know how I would answer it. But what options is FDA considering?

ELAINE LIPPMANN: Yes, it is a challenging question, and I'll answer with kind of a non-answer which is that we're still considering a range of options, and it's premature to discuss what we might do. We're still gathering feedback, we've gotten a lot of comments to our docket so far,

and we recently reopened the docket-- so now it is open until November 9. And we encourage any interested person who has not already submitted comments to go ahead and do so. So we're getting a broad range of feedback, and will consider all of that information in determining the best way to regulate homeopathic products.

GREGORY FORTSCH: So I honestly did not set up that question so that I could answer it myself, but we're also-- I would say the same thing for the FTC. We're really considering and looking at comments, listening to every single thing that's been said today, before we decide the path forward for us, as well. And so to turn more to the FTC, I wanted to ask my colleague Michelle a few questions.

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

MICHELLE RUSK: I think the answer to that is yes, clear and simple. If a claim that a product is effective to treat a certain condition carries with it the implied claim, the underlying claim, that the advertiser in fact has done the research to know that it's effective for that condition. And if they haven't done the research, and they don't know that it's effective, the claim's misleading. And we heard a lot of talk in the opening remarks about disclaimers as the way to fix that. And I have two thoughts about that.

One is saying the FDA has not approved the product doesn't really address that issue of correcting consumers' understanding that the claim is substantiated, that there's quality science behind it. It corrects a different misperception which is that the FDA regulatory approach is the same as for other products. But it doesn't correct the misperception about there being science to back up the efficacy.

The other thing I would say about disclaimers is that our research-- not just for homeopathics, but over the years looking at things like qualified health claims for food products and supplements-- has shown us pretty vividly that it's very difficult to craft a disclaimer that really communicates there is no science to back up this claim. So I think we have to be careful when we think about disclaimers as a remedy in making sure that they really effectively correct the misperception.

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

AL LORMAN: I'll accept your invitation. We have more data on that, and we have not had an opportunity to fully digest it. Unfortunately the study that we commissioned exists at this point-- we have the raw data, but the analysis of the data is in draft form. But we did actually inquire about the level of understanding of what kind of support there is behind these claims, because we

recognize that the FTC is looking at this. The initial data shows that consumers do recognize that there's a difference between that-- and as I cited-- between the level of data supporting allopathic products regulated by FDA, and homeopathic products.

I'm not prepared to say more about that at this point. And it may well be that additional surveys are necessary to further elucidate that point, and we're perfectly happy to do that.

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

PAUL RUBIN: Well, I can start with that. So I think the issue really, I think, the best source of this is the FTC's guidance, the advertising guidance for dietary supplements for traditional use-- which I think All alluded to a few minutes ago. And in essence, yes, there's an indication for use that FDA requires companies to use, and they would include that on your label. But you can have a disclaimer that can go in many different directions.

You've seen some that talk about FDA approval. You could see some that address the substantiation, from the principles of traditional homeopathic principles. You can see references to educational websites, with significant information.

One of the problems I think we see, when we think about disclaimers, is that it is exceedingly difficult to have a comprehensive disclaimer explaining the depth of homeopathic regulation and how that contrasts to the OTC drug review, or NDA OTC drug products, in a disclaimer on a product or advertising. It'll be way too confusing. So from my perspective, I think the key is to signal consumers that there is a fundamental difference. And as long as consumers are signaled, and then they're armed now-- that fortunately we live in an era where via the internet and other sources you can obtain a tremendous amount of information.

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

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

MICHELLE RUSK: I do. As somebody who was very involved in the writing of the dietary supplement guides--

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

MICHELLE RUSK: Yes. I have noticed that it's one of those documents that can be quoted to support whatever you want, unfortunately, sometimes. But you are right that we do address traditional use medicines in the guidelines. But I think I want to make it very clear what the

guidelines say about traditional use, because it's a very limited situation where we would consider it appropriate to talk about how something has been traditionally used.

And what our guidelines say is that any discussion of traditional use also needs to clearly convey that the efficacy of the product has not been confirmed by research, and that traditional use doesn't establish that the product will achieve the claimed results. And that's a standard of-- does the consumer get those messages? One that it hasn't been backed by research, and that the fact that's it traditionally used doesn't mean it will have the claimed results.

I think that's a pretty high standard. We're not saying-- and we wouldn't say under the First Amendment-- that under no circumstances could you communicate that effectively. But as I said before, I think it's very challenging to say, "traditional use for colds." We don't have any science, and traditional use doesn't mean it works for colds. I think that's a message that just-- there's a disconnect there that makes it very difficult for consumers to reconcile.

The other thing our guideline says is that traditional use claims, even with that kind of very clear and strong disclaimer about efficacy, shouldn't be made for serious diseases. That at that point, the analysis shifts. And when you're talking about cancer, for instance, you really can't make a claim and just disclaim away the lack of science.

PAUL RUBIN: Can I jump in, Greg?

GREGORY FORTSCH: Yes, but quickly.

PAUL RUBIN: Sure, I'll be very quick. So I agree with that last point, that was a very good segue, Michelle. Just to remind everyone that we're talking about OTC homeopathic drugs, which, pursuant to FDA rules, must be marketed for the treatment of a self-limiting condition amenable to self-diagnosis. And in the traditional used guidelines, I'll quote, it says, "The FTC in the determining the level of substantiation necessary to substantiate a claim, the FDA will assess, among other things, the consequences of a false claim."

And I think in this context, that should be factored in. We're talking about things they basically are self-limiting. They go away on their own, they're OTC conditions. It's not cancer. These are not significant diseases. So I would respectfully submit that that should be factored into the analysis, as well.

GREGORY FORTSCH: So as we have moved a little bit into the issue of substantiation, I want to ask the question. The science panel this morning talked a lot about substantiation, and I want to direct this to Al, initially, with questions from others, or comments from others, if there are any.

Assuming the FTC required human clinical trials to substantiate treatment claims for over-the-counter homeopathic drugs, or determined that provings were not sufficient competent and reliable scientific evidence to substantiate such claims, what would be the effect on the OTC homeopathic drug industry?

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

Elaine mentioned that there are 7,000 homeopathic products registered with FDA. If each of them were to be the subject of two clinical trials, that's 14,000 clinical trials. This is where my math starts to break down. If each clinical trial costs roughly $1 million to conduct, I calculate that that's a commitment of $1.4 trillion for an industry whose annual sales, at retail, are slightly above $1 billion.

Even if that money was available, I find it inconceivable that any regulatory agency would spend the time and energy to review 14,000 clinical trials. The practical effect of any kind of clinical trial requirement of that extensiveness is that-- assuming that you're just going to apply it to advertising, it means there's not going to be any advertising, basically. And that, therefore, consumers are going to be denied a way of knowing about the existence of these drugs, assuming they're still available under FDA's compliance policy guide. And so that the manufacturers then face a much more difficult task in presenting to consumers any information about these products.

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

GREGORY FORTSCH: I don't-- I know Michelle probably wants to comment on that, but I also wanted to ask Elaine if it's something that you can weigh in on. And particularly the OTC comments that Al mentioned initially.

ELAINE LIPPMANN: Which?

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

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

Now, I'm not sure how any change in the FTC's requirement for substantiation-- I'm not sure how that would affect FDA's regulatory authority. I will say that the homeopathic CPG of the FDA is not intended to bind the FTC, or to impact its enforcement of its own statutory authority.

It's merely an articulation of FDA's enforcement policies with regard to requirements of the FD&C Act.

GREGORY FORTSCH: Michelle?

MICHELLE RUSK: I'd like to respond to the statements Al made about what the effect would be on the industry, and what the cost of doing clinical studies are. First all, those 7,000 products-- I think we heard this morning, in terms of what's really in retail, it's more like 100 products, maybe 1,000 at most. More importantly, I think, nobody said today that you need to do $2 million trials.

And we regularly investigate companies in all kinds of product categories who are making similar claims to the homeopathic industry, claims about colds, claims about weight loss-- and the studies that are done are significantly less expensive than $1 million studies. And they are definitely financially feasible, given the profits the companies are making.

PAUL RUBIN: May I respond?

GREGORY FORTSCH: I actually want to-- we're limited in time, so I would love to have you respond, but we must keep moving. So one of the questions that I have for both Paul and David is about qualified claims. They can be difficult to communicate, and may not be commercially attractive. But what would a qualified claim for an over-the-counter homeopathic product look like?

A qualified claim must communicate, unambiguously, that the evidence is non-conclusive, or that additional research is necessary. Something that we think might apply to a homeopathic product, or at least some of them. So I wanted to see if either of you had a response to that. I might start with David, and then go to Paul.

DAVID SPANGLER: I think Paul already, earlier, talked about a lot of that when he was talking-- there are a lot of different ways to disclose and qualify. So I don't know that there's a magic bullet, and I don't know why, then, one would say that a qualified claim must unambiguously communicate that the evidence is inconclusive, or that additional research is necessary. It seems to me, your qualifier or your disclaimer is simply trying to make sure that you're getting across the context in which the claim is made-- be that a reference to a website, be that pointing out its traditional literature, or traditional use, or that it's based on homeopathic literature. But accurately characterizing what the claim is based on, as opposed to trying to communicate what it's not based on.

PAUL RUBIN: And I think just to add to David's comments, which I agree with entirely, I think it's important to keep in mind the fact that FDA regulated products are very diverse. And if you want to delve into comprehensive disclaimers that address complex regulatory regimes are just not going to work. I mean, think about all the different products where that could be required-- you have class one devices, that are not reviewed or approved or cleared by FDA at all; class two medical devices that are cleared, but not approved, only deemed to be substantially equivalent to a lawfully marketed predicate-- do you have to make that disclosure and say, some of those cases

there are no clinical studies, other cases there are? Do you really need to get into that level of detail?

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

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

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

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

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

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

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

[LAUGHTER]

If they're not already friends. I have several questions, so I'll go back and forth on who I start with, or we'll let the discussion take its course. First, what has been the overall impact of class action litigation on the homeopathic industry? And I know, I think at least, Christina, you covered this, but I think you may have different answers to that question. So I'd like to hear both of you and your thoughts on that.

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

I think there's a misnomer, or a misunderstanding, about the types of, or the size of the manufacturers that sell these products in the US. They're very large manufacturers. They generate significant revenues, and you can tell that by the quality of the counsel that they hire. Every law suit I've seen has hired white shoe law firm to defend it. These are very expensive lawyers, they have significant funding.

So I do not think it has had an impact whatsoever in the industry.

GREGORY FORTSCH: Christina?

CHRISTINA SARCHIO: So in 2014, the CEO of Heal announced in a press release, that's publicly available, that one of the major reasons that Heal was withdrawing from the North American market was quote, "the substantial cost of litigation." Want to make sure I got that right. At least two homeopathic companies have completely withdrawn from the US company, and I have seen homeopathic companies lay people off, not be able to invest in research and development-- and more importantly, not wanting to change or improve their advertising practices, or educational campaigns, for fear that if they change anything, then the plaintiff's lawyers will come in saying, ah-ha, you changed it because you admit you were doing something wrong.

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

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

GREGORY FORTSCH: Well, I'm going to-- I now Al had a comment, and I did also have a couple more questions in the field before we close. Al?

AL LORMAN: I just wanted to follow up on something Antonio said earlier about that the class actions lawsuits have contributed to the disclaimers that appear on labels and advertising. And in fact, the truth is just the opposite. The American Association of Homeopathic Pharmacists, long before the first of these cases was ever filed, was discussing ways to adopt a disclaimer program to provide additional information to consumers about the homeopathic nature of the products that we sell. And in fact, that effort basically stopped when the lawsuits were filed, precisely because we were concerned that were we to then adopt it, it would be cited against us in the lawsuits as proof that we knew we weren't adequately warning people before.

So the reality is that an adequate disclaimer program would have been adopted many years ago, had there not been these class actions against the companies.

ANTONIO VOZZOLO: Just one follow-up point, Greg-- it's just a well known concept in law that subsequent remedial measures are inadmissible in a court proceeding. So I take that with a grain of salt.

GREGORY FORTSCH: Well, Christina and Antonio, in terms of settlements, some companies have agreed to include a disclaimer that the claims have not been approved by the FDA. How if, at all, does that disclaimer address the Federal Trade Commission's concern with adequate substantiation? And I'm going to ask Michelle to address that after you both provide answers.

CHRISTINA SARCHIO: If I can jump in and start. So as you can see in litigation, we hotly debate each and every issue that comes up. And so when we get to the negotiation table, and talk about settlement and talk about disclaimers, the disclaimers that plaintiff's lawyers and defense lawyers have agreed to have been hotly contested. Where are we going to put the comma? Where are we going to put the period? Which letter is going to be capitalized?

Each and every issue has been carefully vetted by the plaintiff's lawyers that are aggressively defending their client's interests. And we, on the homeopathic industry side, are carefully vetting to make sure that these disclaimers comply with all the federal rules and regulations that apply to the companies. And so once we finally agree to the language-- and not only do we agree to the language, but then we have to make sure that a judge approves it.

And again, the judge doesn't just rubber stamp settlement agreements. I have been in many cases where at the final hearing, we are debating-- because there's an objector, or there's somebody that's coming in at the last minute trying to champion consumer rights, saying that, wait a minute, is this class action settlement fair and reasonable? And we have had to defend our position, and bring in experts, to support the disclaimers that, again, we have vigorously fought for and agreed to.

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

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

MICHELLE RUSK: OK, so I'll just reiterate one thing I said earlier about disclaimers, which I think-- to the extent we're talking about disclaimers, let's say, a homeopathic product has not been approved by FDA-- we still believe that that's not really getting at the issue that we're most concerned about, which is that consumers need to understand that the efficacy claim hasn't been established by accepted scientific procedure, meaning randomized, controlled trials. And this afternoon, or before the break, when we had this panel about the science, there seemed to be a lot

of disagreement on a lot of different points. But when we narrowed it down to the specific issue of should there be randomized, controlled trials to support specific claims about specific products, I think there was very wide agreement that that was what was called for.

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

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

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

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

First of all, on a non-substantive basis, security badges can be passed to the people at the desk on the way out. They do reuse them, so if you got one, please pass in one on the way out right outside the door. And I should also-- I can't fail to thank all of the people at the agency who work so hard to put on today's workshop, especially our dedicated division of Consumer and Business Education, my colleagues in my division, and managers, and our office of executive director, who organized the workshop so that everything was functioning. And most importantly, I just want to thank you so much for taking the time to come out today's workshop. And I will now adjourn the workshop. Thank you.