FEDERAL TRADE COMMISSION

HOMEOPATHIC MEDICINE & ADVERTISING

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Federal Trade Commission

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

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

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

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

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

OPENING REMARKS

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

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

Because of the recent growth in the marketing and use of homeopathic products, consumers have greater exposure to such products than ever before. But do consumers know what they are buying when they purchase a homeopathic product? Today's workshop will examine the potential

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

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

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

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

The copy test results revealed that many consumers

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-

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

Competent and reliably scientific evidence may take different forms, depending on the types of claims made. For some claims, the substantiation required may be one or more well-

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

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

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

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

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

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

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

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

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

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

Thank you so much.

(Applause.)

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

PANEL 1: HOMEOPATHIC INDUSTRY & ADVERTISING

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

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

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

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

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

MS. ENGLE: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

As the leading industry association for homeopathic

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

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

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

Physicians would not be taught homeopathy again

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

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

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

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

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

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

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

This trend to greater confidence and self-education and care is particularly strong among people who are more tech-savvy and are younger people in general, the ones who are in the life stage where they’re less likely to have --0.002 Tc 0.002 Tw 32.l