

Homeopathic
Medicine & Advertising



An FTC Workshop

Staff Report on the Homeopathic Medicine & Advertising Workshop
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Homeopathic Medicine & Advertising Workshop Report

Federal Trade Commission

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I. Introduction

On September 21, 2015, the Federal Trade Commission (FTC or Commission)¹ convened “Homeopathic Medicine & Advertising,” a one-day public workshop that explored advertising for over-the-counter (OTC) homeopathic products.² The rapid expansion of the homeopathic industry over the past few decades, and the corresponding growth in the marketing and consumer use of homeopathic products, prompted the workshop.

Dating back to the late 1700’s, homeopathy is based on the belief that disease symptoms can be treated by minute doses of substances that produce similar symptoms when provided in larger doses to healthy people. After homeopathy was introduced in the United States in the 1800’s, homeopathic products were often offered in formulations tailored for individual users. In the 1970’s, homeopathic products began to be sold in small health food stores and independent drugstores. By the late 1990’s, mass-market formulations were sold nationwide in major retail stores. What used to be a multimillion-dollar market a few decades ago is now more than a billion-dollar market.

A chief purpose of the workshop was to broaden the FTC’s understanding of the homeopathic marketplace and obtain information to assist the agency in determining how to apply its legal authority to the advertising and marketing of OTC homeopathic drugs. The workshop featured three panels made up of 18 stakeholders, including medical professionals, industry representatives, consumer advocates, private-practice attorneys, and government regulators. Panel topics included:

- The current state of the homeopathic market, advertising for homeopathic products, and consumer knowledge and understanding;
- Evaluation of the scientific support for homeopathy;
- The application of Section 5 of the FTC Act to advertising claims for homeopathic products;
- Public policy concerns about the current regulation of homeopathic products; and
- The effects of recent class actions against homeopathic product manufacturers.

This report provides an overview of the workshop and the FTC’s related work on homeopathy. Part II of the report summarizes the workshop. Part III describes consumer research commissioned by the FTC. Part IV describes the issues raised in public comments

¹ This report was prepared by FTC staff and does not necessarily reflect the views of the Commission or of any individual Commissioner.

² The workshop agenda and a transcript and videos of the workshop are available at: <https://www.ftc.gov/news-events/events-calendar/2015/09/homeopathic-medicine-advertising>.

submitted in connection with the workshop, including consumer research submitted by commenters.³ Part V discusses staff’s conclusions.

II. Summary of the Homeopathic Medicine & Advertising Workshop

A. Panel 1: Homeopathic Industry & Advertising

The workshop’s first panel sought to explore the homeopathic marketplace, as well as consumer understanding of homeopathy.

According to panelist John P. Borneman, the Chairman and CEO of Standard Homeopathic Company and Hyland’s, Inc., who gave an overview of homeopathy, the homeopathic manufacturing process is unique in pharmacy. Homeopathic medicines are made using a process called “dilution and succussion.” Dilution is the serial deconcentration of a substance, in steps of either one part in 10 or one part in 100. Each step of that deconcentration includes a vigorous shaking or succussion step. Homeopathic medicines are used according to the “law of similars.” That theory declares that if a large quantity of a substance causes symptoms in a healthy individual, and another individual presents with those symptoms from another etiology or cause, it is possible that a homeopathically prepared form of the substance that caused the symptoms in the healthy individual may have a mitigating effect in the afflicted individual. For example, an onion can cause runny eyes and a runny nose in a healthy individual, so according to homeopathic theories, *allium cepa* made from the red onion serially diluted and succussed may relieve seasonal allergy symptoms of runny eyes and nose. Although not discussed during the panel, another core homeopathic theory is the “law of infinitesimal doses” – that the more a substance is diluted, the more potent it becomes.

Mr. Borneman described the history of homeopathy in the United States. Homeopathy was first introduced in the United States in 1826. The first pharmacopoeia containing a list of homeopathic drugs together with their effects and directions for their use was published in the United States in 1842. Since the 1850s, consumers have been able to purchase prepared homeopathic products for self treatment. By 1970, a burgeoning consumer movement 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 such small retailers.

In 1988, the Food & Drug Administration (FDA) issued a Compliance Policy Guide (CPG) that permitted the distribution of OTC homeopathic products without FDA approval.⁴ The CPG recognized a product as a homeopathic drug if it is labeled as homeopathic, and it is listed in the Homeopathic Pharmacopoeia of the United States (HPUS), an addendum to it, or its

³ The Commission received over 530 public comments in connection with the workshop. They are available at: <https://www.ftc.gov/policy/public-comments/initiative-612>.

⁴ See FDA, CPG Sec. 400.400, Conditions Under Which Homeopathic Drugs May be Marketed, May 31, 1988, <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm>

supplements.⁵ According to Mr. Borneman, not all products marketed as “homeopathic” have met this requirement – for example, products containing human growth hormone and products containing combinations of homeopathic and non-homeopathic ingredients. Under the CPG, which is still in effect, the FDA permits a company to sell OTC homeopathic products without demonstrating their efficacy and to include claims on packaging about treating specific conditions. Only homeopathic products intended solely for self-limiting,⁶ non-chronic conditions amenable to self-diagnosis and treatment may be marketed OTC. The CPG requires that the labeling of homeopathic drugs display an indication for use. According to Mark Land, Vice President, Operations & Regulatory Affairs, Boiron, Inc., who was on the panel representing the American Association of Homeopathic Pharmacists (AAHP), the leading trade association for homeopathic medicines in the United States, homeopathic manufacturers view the CPG as giving them clear rules by which they can distribute their products.

As discussed by Mr. Borneman, in the early 1990s, some drugstore chains began experimenting with adding OTC homeopathic products to their product mix. By the end of the 1990s, most major drugstore chains in the United States carried a handful of homeopathic drugs. The number of OTC homeopathic market entrants grew, as did the number of distribution channels, which expanded to include grocery stores and mass merchandisers. During this period, retailers experimented with a variety of approaches to the shelving of homeopathic products: having separate homeopathic sections; having homeopathic products in separate natural product sections; merchandising by brand; and merchandising by disease or symptoms, mingling homeopathic products together with non-homeopathic, conventional OTC drugs (i.e., “allopathic” drugs). According to panelist Yale Martin, an independent retail consultant, homeopathic products are now typically organized on store shelves by symptom or ailment alongside conventional OTC drugs.⁷

According to Mr. Land, the HPUS requires that the labels of homeopathic medicines include the disclosure “homeopathic” in prominent type. He said that the AAHP has an advertising

⁵ According to Mr. Borneman, the HPUS was first published in 1897 by the American Institute of Homeopathy (AIH), a homeopathic physicians organization. In 1980, the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) was independently incorporated, separate from AIH. The HPCUS is a standard-setting body, not a regulatory body. 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 in 2015.

⁶ A self-limiting disease condition is one that resolves spontaneously with or without specific treatment.

⁷ When OTC products are organized by disease or symptom, dietary supplements, which pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA) are not permitted to claim to treat diseases or symptoms, have to be shelved separately, according to panelist Duffy MacKay, Senior Vice President Scientific & Regulatory Affairs, Council for Responsible Nutrition.

guideline that requires its members to include a disclaimer statement alerting consumers that claims for homeopathic medicines have not been reviewed by the FDA. Before accepting new members, the AAHP (the members of which are responsible for more than 90% of U.S. homeopathic sales) reviews representative labels of the potential members' products for consistency with its code of ethics. It also holds seminars and webinars on appropriate labeling practices. Mr. Land and Mr. Borneman acknowledged that advertising claiming that a homeopathic product was "regulated by the FDA" would be problematic.

According to Mr. Land, the homeopathic industry is a small industry compared to the OTC drug, prescription drug, and dietary supplement industries in terms of revenues, advertising, and the number of marketed products. Although more than 7,000 homeopathic medicines are registered with the FDA, only about 1,000 are marketed on a routine basis, and fewer than 100 are marketed in mass distribution channels. Mr. Land said that many or most popular homeopathic medicines have been in the marketplace in the United States for 50 years or more. He also indicated that the U.S. market for homeopathic product sales is estimated to be \$1.1 billion to \$1.3 billion annually and is growing at roughly 5% per year. This is substantially less than the \$2.9 billion in 2007 homeopathic expenditures estimated by the National Health Interview Survey conducted by the Centers for Disease Control and Prevention.⁸ Mr. Land also said that the majority of homeopathic medicines are for cough, cold and flu, muscle pain, and children's ailments and that these represent less than 3.5% of all drug products offered OTC in popular drugstore chains.⁹

Mr. Land said word-of-mouth recommendations are a primary driver of homeopathic product sales; most paid homeopathic advertising is restricted to health-related print publications or targeted free-standing inserts (FSIs); broadcast advertising is limited to very few products. Mr. Martin also asserted that advertising plays a small role in the OTC homeopathic arena.

Ms. Candace Corlett, president of WSL Strategic Retail,¹⁰ which monitors changes in consumer thinking and behavior, described the results of an unpublished, mid-2013 survey that her company conducted of purchasers of homeopathic products. Of those surveyed, 37% learned about their homeopathic medication through some form of recommendation; 18% did their own online research; and 12% learned about it through traditional advertising. Over the course of a year, 52% purchased a homeopathic product from a drugstore, 48% bought from a mass merchant, about 30% purchased in a supermarket, 17% to 20% bought from a specialty food or

⁸ Richard L. Nahin et al., Nat'l Ctr. for Health Statistics, *Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007*, National Health Statistics Reports Number 18 (July 30, 2009), <https://www.cdc.gov/nchs/data/nhsr/nhsr018.pdf>.

⁹ With respect to OTC homeopathic product safety, Mr. Land noted that less than 1% of all pharmaceutical product exposures reported to the American Association of Poison Control Centers involved a homeopathic medicine. Of reported homeopathic incidents, more than 98% resulted in no effect or a minor effect.

¹⁰ WSL Strategic Retail is a company that provides research and marketing strategies to retailers.

vitamin store, and 14% made purchases on the Internet. There did not appear to be any geographic trends in terms of homeopathic usage. Thirty-eight percent of the homeopathic product purchasers surveyed felt that they clearly understood what “homeopathic” meant.¹¹ The survey found that 60% to 73% of homeopathic product purchasers were satisfied with the performance of the homeopathic treatment they used and half of the people who used a homeopathic medication for one condition went on to use a homeopathic treatment for other conditions. Mr. Land said that such levels of satisfaction would not be explained by the placebo effect based on his assertion that the “placebo effect ... is probably around 30%.”

B. Panel 2: Evaluating the Scientific Support for Homeopathic Advertising Claims

The second workshop panel discussed the principles of homeopathy, how homeopathic drugs are defined, and the substantiation of advertising claims for OTC homeopathic drugs. Introducing the second panel, the moderator noted the wide variety of conditions purportedly treated by homeopathic products. FTC staff had recently reviewed products on the Internet marketed as homeopathic and found products for, among other things, eczema, acne, psoriasis, heartburn, flatulence, pain, tendinitis, arthritis, menopausal symptoms, ADHD, flu, weight loss, anemia, gum disease, diarrhea, and the common cold.

Several panelists expressed the view that there is not competent and reliable scientific evidence of homeopathy’s effectiveness. Dr. John Williamson, Branch Chief, Basic and Mechanistic Research in Complementary and Integrative Health at the National Institutes of Health (NIH), said that the most rigorous clinical trials and systematic analyses and reviews of homeopathic research have concluded that there is little evidence to support ultra-high dilution homeopathy as an effective treatment for any specific condition. He cited, as an example, a 2015 comprehensive assessment of evidence by the Australian Government’s National Health and Medical Research Council (the Australian NHMRC report), which concluded that there is no reliable evidence that homeopathy is effective for any health conditions.¹² Dr. Adriane Fugh-Berman, Associate Professor in the Department of Pharmacology and Physiology at Georgetown University, agreed that homeopathic remedies are not supported by competent and reliable scientific evidence. She said that the effects of high dilution homeopathic products are placebo effects, and that this has been confirmed by most high-quality randomized, controlled, clinical trials (RCTs). Dr. Fugh-Berman acknowledged that there have been some positive RCTs involving some homeopathic preparations, but said that many of those trials had been done using homeopathically prepared drugs that actually have pharmacologically active doses of compounds. Dr. Freddie Ann Hoffman, the CEO of HeteroGeneity, LLC, a company that

¹¹ For comparison, 50% of the homeopathic product purchasers said they felt they had a clear understanding of what “natural” meant and 52% felt they had a clear understanding of “organic.” A panelist on a subsequent panel noted that the survey did not test whether consumers who thought they knew what “homeopathy” was actually did.

¹² See Australian Gov’t Nat’l Health and Med. Research Council, *NHMRC Information Paper: Evidence on the effectiveness of homeopathy for treating health conditions* (2015), https://www.nhmrc.gov.au/files_nhmrc/publications/attachments/cam02a_information_paper.pdf.

provides consulting services to the marketers of botanicals, probiotics, and complex products and who previously chaired the FDA's homeopathic working group, said that no homeopathic drug has been scientifically proven effective based on FDA standards.

Other panelists were more supportive of homeopathy's efficacy. Dr. Wayne Jonas, President and CEO of Samueli Institute Medical Center, a non-profit medical research organization supporting the scientific investigation of healing processes, responded to Dr. Williamson's reference to the Australian NHMRC report, asserting that an earlier analysis of homeopathy by the Swiss government, which was more favorable to homeopathy, was more "comprehensive."¹³ Dr. Paul Herscu, the founder and director of The New England School of Homeopathy, who represented the American Association of Naturopathic Physicians at the workshop, stated that homeopathic remedies work and should continue to be available OTC.

Dr. David Riley, who is on the Board of Directors of the HPCUS, explained that officially monographed homeopathic ingredients in the HPUS are supported by homeopathic "provings," clinical research, and/or the use of the ingredient in homeopathic products prior to 1962. Dr. Riley explained that provings involve giving a substance to healthy people and recording the symptoms they experience.¹⁴ He said that most contemporary provings involve a homeopathic, not an allopathic, dose of a substance.¹⁵ Homeopaths then apply the law of similars. They believe that a homeopathic dose of the substance will treat the symptoms produced by the substance in a proving. Drs. Riley and Jonas conceded that provings alone are not adequate to substantiate treatment claims for OTC homeopathic drugs. According to Dr. Fugh-Berman, provings are merely descriptions of symptoms that are elicited by substances and have absolutely nothing to do with the efficacy of a therapy. Any substance, she said, in a high enough dose, including water, will cause symptoms and those symptoms say absolutely nothing about the ability of that substance in any dose to help those or any other symptoms.

The moderator asked the panelists to explain what support there was for the law of similars. Dr. Riley analogized to allergy desensitization in conventional medicine, which in his view, does not make much sense but seems to help some patients. He cited the principle of hormesis which says that drugs can have an effect at one concentration and have the opposite effect at a lower concentration. In defending the possibility that miniscule doses of a substance could have the

¹³ See Gudrun Bornhöft & Peter Matthiessen, eds., *Homeopathy in healthcare: effectiveness, appropriateness, safety, costs*, Springer Sci. & Bus. Media (2011).

¹⁴ The concept of "provings" derives from the experience of Samuel Hahnemann, the founder of homeopathy, who, when he ingested the bark from which quinine is derived, experienced fever, shivering, and joint pain. These symptoms are similar to those caused by malaria, which is treated with quinine. Based upon this observation, Dr. Hahnemann came to believe that all effective drugs produce symptoms in healthy individuals similar to those of the diseases that they treat.

¹⁵ Dr. Riley said that the use of placebo controls in provings is recommended to minimize bias. He acknowledged, however, that the HPUS does not require quantitative statistical analysis of the results of a proving.

opposite effect of larger doses, Dr. Riley said that conventional researchers assume that drugs have a linear dose-response relationship and do not look at what happens at lower doses. Dr. Fugh-Berman said that although some drugs have different effects at low and high doses – 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 – this is not true for most drugs. Dr. Hoffman acknowledged that there are many examples, including anti-cancer drugs, interleukins, and gamma interferon, where drugs evoke a different response at high and low doses. Dr. Hoffman said, however, that the difference between homeopathic products and these drugs is the absence of data demonstrating such an effect.

The moderator asked about the appropriateness of marketing products containing homeopathic ingredients in combination with non-homeopathic active ingredients listed as “inactive” ingredients. Dr. Riley said that such combinations are scientifically indefensible, while Dr. Herscu said that they are not homeopathic products.

Regarding what is necessary to establish the efficacy of any specific homeopathic product, Dr. Fugh-Berman said that establishing the benefit of a therapy in humans requires RCTs, and that a control group is necessary to account for the fact that any therapy has nonspecific effects, also known as placebo effects. Dr. Hoffman agreed that the RCT is the gold standard for testing whether a particular product is safe and efficacious. Dr. Riley argued that RCTs are not the only reliable way to establish evidence of efficacy but declined to say that a scientific framework is unnecessary for proving efficacy. Dr. Jonas argued that the focus should be on safety and on “effectiveness” – how does a product work in the real world.¹⁶ He asserted that RCTs are a bad way to assess effectiveness and that health services research and observational studies provide the best evidence for effectiveness. Dr. Fugh-Berman disagreed with Dr. Jonas and responded that observational studies (as opposed to RCTs) are not an acceptable scientific standard for showing benefit and do not qualify as effectiveness studies. She noted that effectiveness research can be and usually is randomized and placebo controlled. Dr. Fugh-Berman said that although there are problems with RCTs, the answer is not to lower the necessary level of evidence.

The panelists also discussed the appropriate field of expertise for an expert evaluating the substantiation for a homeopathic product’s claims. Dr. Hoffman said that substantiation for a homeopathic claim should be evaluated by someone with expertise in the relevant condition, properly trained in the scientific method and in the current trial designs used for other products making similar claims. Dr. Fugh-Berman said that ideally any studies of homeopathic products would be done by people well trained in doing clinical trials and who are disinterested in the result. Dr. Hoffman agreed that potential conflict of interest and bias are significant issues.

Some panelists also expressed concerns about the contents and uniformity of homeopathic products. Dr. Richard Lostritto, the Acting Associate Director for Science and Division Director of the FDA’s Office of Policy for Pharmaceutical Quality, raised concerns about the quality of

¹⁶ Dr. Fugh-Berman explained that effectiveness research explores how a drug works in the general population and that effectiveness is lower than efficacy. She gave the example of the birth control pill which is more than 99% effective in clinical trials but only 95 or 96% effective in effectiveness trials because people do not necessarily take it as directed.

homeopathic products, including the lack of testing for content and uniformity in active ingredients and potentially inaccurate dilutions.¹⁷ He suggested testing intermediate dilutions, which would allow one to at least partially validate the dilution method. He also suggested that one could use standard chemical testing to confirm that the active ingredients in some products have been so diluted that they are no longer detectable. Dr. Hoffman said that because of difficulties in determining what is in a homeopathic product, when evaluating a particular homeopathic product's claim substantiation, it is extremely important to look for testing of the actual advertised product and not rely on testing of another manufacturer's product or of individual ingredients.

C. Panel 3: Legal and Regulatory Issues Presented by Homeopathic Advertising

The third workshop panel considered a variety of legal issues presented by OTC homeopathic drug advertising. These include the FDA's regulation of OTC homeopathic products, the application of Section 5 of the FTC Act to OTC homeopathic products, and the effect of recent class actions against homeopathic product companies.

One important legal issue discussed was the current and future status of the FDA's homeopathic regulation. Elaine Lippmann, an attorney in the FDA's Office of Regulatory Policy, explained that all products that meet the definition of a drug under the Food, Drug, and Cosmetic Act (FDCA) are subject to regulation by the FDA, regardless of whether they are labeled as homeopathic. Since 1988, however, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval under the CPG. The 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 good manufacturing practices.

In March 2015, the FDA began soliciting public comment about whether, and if so how, to adjust its enforcement policies to reflect significant changes in the homeopathic product marketplace.¹⁸ FTC staff submitted a comment saying that 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-related claims be substantiated by competent and reliable scientific

¹⁷ Dr. Lostritto also noted that a number of monographs in the HPUS call for levels of active ingredients that could fall within allopathic, pharmacologically, immunologically, or toxicologically active ranges.

¹⁸ See Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing and Request for Comments, 80 Fed. Reg. 16,327 (Mar. 27, 2015), <https://www.federalregister.gov/articles/2015/03/27/2015-07018/homeopathic-product-regulation-evaluating-the-food-and-drug-administrations-regulatory-framework>.

evidence.¹⁹ The FTC staff comment recommended that the FDA consider three possible approaches. These alternatives were for FDA to: (a) withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products; (b) eliminate the requirement in the CPG that an indication appear on labeling; or (c) require that any indication appearing on the labeling be supported by competent and reliable scientific evidence.

Al Lorman, an attorney representing the AAHP, criticized the FTC's recommendations to the FDA. He asserted that even were the FDA to revoke or revise the CPG, the FDA would still have to take additional legal actions to establish that homeopathic drugs were misbranded. Paul Rubin, a Ropes & Gray attorney, argued that the courses of action suggested to FDA in the FTC staff comment would pose legal and policy challenges for the FDA and be contrary to congressional intent or violate the FDCA.

Another legal issue discussed was the level of substantiation that should be legally required for advertising claims. Kat Dunnigan, an attorney with the National Advertising Division (NAD) of the Council of Better Business Bureaus, presented NAD's view that health claims for homeopathic products should be supported by competent and reliable scientific evidence, with RCTs considered the best evidence. She said that any treatment effect would need to be large enough to be meaningful to consumers. Ms. Dunnigan said that the presence of a product's active ingredient or ingredients in the HPUS is not sufficient substantiation. According to Ms. Dunnigan, NAD believes that homeopathic provings, in vitro studies, and animal studies do not qualify, on their own, as competent and reliable scientific evidence. Mr. Lorman expressed concerns that requiring homeopathic advertisers to have RCTs would be overly costly and could result in their ceasing advertising.

The panelists discussed possible approaches to OTC homeopathic advertising and labeling in order to prevent consumer deception. Mr. Lorman said that the AAHP had adopted a voluntary advertising and labeling disclaimer program based on the first sentence of the DSHEA disclaimer adopted by Congress for dietary supplements, "This statement has not been evaluated by the Food and Drug Administration." He said that a majority of the homeopathic products sold bear such a disclaimer on labels and in advertising. According to Mr. Lorman, the AAHP had conducted a consumer survey showing that the use of label disclaimers on homeopathic product packaging would prevent consumer deception.²⁰ Mr. Rubin advocated for the FTC to approve

¹⁹ See Comments of the Staff of the FTC submitted to the FDA, DHHS in Response to a Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century, submitted on August 21, 2015, https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf.

²⁰ The AAHP also conducted another consumer survey about consumer understanding of the FDA's role in the approval of a number of product categories, including homeopathic drugs. Mr. Lorman said that the study showed consumers' ability to differentiate between homeopathic and allopathic OTC drugs. After the workshop, the AAHP submitted a comment to the FTC which

the use of disclaimers to address concerns about promotional claims for homeopathic drugs, arguing that such an approach would avoid offending First Amendment principles. David Spangler from the Consumer Healthcare Products Association, which represents manufacturers of OTC medicines, asserted that homeopathic advertisements are in compliance with the FTC Act if they disclose that the advertised product is homeopathic and not FDA-reviewed and describe the support for their claims – e.g., homeopathic literature. Ms. Dunnigan said that she believed that claims couched in terms of traditional use are acceptable as long as they are narrowly tailored not to imply that the products have been clinically tested for efficacy.

The final panel also engaged in a discussion of the impact of class action lawsuits on homeopathic manufacturers. In the past five years, approximately 75 lawsuits have been filed against homeopathic drug companies. Three lawsuits have gone to trial, resulting in rulings in favor of the companies.²¹ Several other lawsuits have resulted in settlements requiring the companies to add disclaimers on product packaging regarding the lack of FDA review or explaining dilution formulas. Christina Guerola Sarchio, an attorney with Orrick, Herrington & Sutcliffe, who has represented homeopathic manufacturers and retailers in class action lawsuits, and Antonio Vozzolo, an attorney with Faruqi and Faruqi, who has represented plaintiffs, offered differing views of these lawsuits. Mr. Vozzolo asserted that settlements have resulted in funds between \$1 million and \$5 million being made available to consumers, full reimbursement to consumers who submitted claims, and any non-claimed funds not reverting to the companies. Nevertheless, he described the settlements as fairly small given the revenues generated by the homeopathic companies and doubted that such suits had any significant impact on their marketing activities. Ms. Sarchio said that the lawsuits had resulted in at least two homeopathic manufacturers withdrawing from the U.S. market, other homeopathic companies stopping selling their lower priced and slower selling products, and some retailers reducing the number of homeopathic products that they carry. She also asserted that few consumer claims for reimbursement had been submitted in class action settlements, that many of those consumers who did submit claims continued to purchase homeopathic products, and that the consuming public has received little to no financial benefit from the class action cases brought on their behalf.

included a report fully describing both AAHP surveys. The AAHP submission is discussed in Part IV, below.

²¹ All three cases were based upon private rights of action for unfair or deceptive advertising or other practices under California law. In two cases, judges found that the plaintiffs, who had not presented any testing of the products at issue, had not met their burdens of proof. The third case was tried before a jury, and in light of the jury instructions provided, the court concluded that the jury implicitly found that the plaintiffs failed to prove by a preponderance of the evidence that the defendants' products cannot relieve the symptoms represented on their products' packaging. Unlike FTC actions, these cases were not based upon the theory that the defendants were required to have substantiation for their claims.

III. FTC's Homeopathic Consumer Research

As part of its efforts to understand the homeopathic marketplace and obtain information about consumers' knowledge and understanding of homeopathic products, the FTC commissioned consumer focus group research and a copy test. This research, which began in 2010, suggests that a significant percentage of consumers do not understand the nature of homeopathic products, how they are regulated, or the how much evidence there is to support their claims. The FTC's comment to the FDA was based in part upon this research.

A. Focus Group Results

FTC staff worked with Shugoll Research to conduct focus groups exploring the extent to which consumers understand the differences between various non-prescription health-related products including conventional, herbal, and homeopathic products.²² Shugoll Research conducted two focus groups in Baltimore, Maryland in late 2010. One focus group included eight general adults while the other included eight parents of young children.²³

Focus group participants in both groups were likely to group or categorize products in a number of ways including conventional versus non-conventional. They tended to group all non-conventional products, including homeopathic products, into a single category, using the terms "natural," "herbal," and "homeopathic" interchangeably. Most adults and parents struggled when asked to distinguish between herbal and homeopathic products. They did not understand what "homeopathic" means. Most participants associated homeopathic products with natural or "non-chemical" products.

Many adults and parents did not readily differentiate between different product types in terms of the evidentiary requirements for product claims or regulatory oversight. While they generally believed that manufacturers of conventional non-prescription products were required to support their claims with scientific evidence, they had varying opinions regarding the evidentiary requirements and federal oversight for herbal and homeopathic products. Some participants indicated there were no requirements, others insisted there must be some governmental oversight, and still others were unsure but hopeful that there were requirements.

The focus group results also suggested that there is a poor understanding of the principles underlying homeopathic products. Most adults and parents equated homeopathic products with natural and/or home remedies. Even those who had purchased homeopathic products were

²² Shugoll Research, *Homeopathy Focus Groups Report* (Jan. 2011), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitb.pdf and https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitb2.pdf (Shugoll). The focus group employed a qualitative research methodology rather than a quantitative one. The FTC employed the findings developed from these focus groups to undertake the quantitative research copy test discussed in Section III.B. below.

²³ The panel of general adults discussed products to treat their own cold symptoms, while the parents' panel discussed products to treat their children's cold symptoms.

unfamiliar with the principles underlying homeopathy. When those principles were explained to participants, they found them confusing; some parents were motivated by the relatively few side effects of homeopathic products, while the explanation of how homeopathy was supposed to work made other parents and adults question the effectiveness of homeopathic products. Furthermore, most adults and parents said they were more likely to continue to use the conventional non-prescription products with which they were familiar and unlikely to purchase homeopathic products without an express recommendation from a trusted source due to their skepticism about the effectiveness of such products.

These results suggest that many consumers may choose homeopathic products based on incorrect and incomplete information about them. 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.

B. Copy Test Results

Dr. Manoj Hastak, a professor of marketing at the Kogod School of Business at American University and a consultant for the FTC, designed a research study to investigate consumer understanding of claims made on homeopathic product packages.²⁴ The study tested three different homeopathic products: a Similasan product that claimed to relieve cold-related symptoms in children, a Boiron product called Oscillococcinum that claimed to relieve flu symptoms, and a Hylands product called Arnica that claimed to relieve pain. The study was conducted via an online panel.

Survey respondents were invited to complete a screening questionnaire. Depending on their eligibility, respondents were assigned to view one of ten product packages.²⁵ There were three versions of the Similasan and Oscillococcinum packages and four versions of the Arnica package. The versions of the packaging for the Similasan and Oscillococcinum products consisted of the actual products available in the market at the time, versions that were more prominently labeled as homeopathic, and versions with a disclaimer statement, “This product has not been shown to relieve ...” either “cold symptoms” or “flu-like symptoms.” The four versions of the Arnica package consisted of the actual product (except company contact and some duplicative information was removed from the back panel to make space for a disclaimer), a version that was more prominently labeled as homeopathic, and versions with a disclaimer statement that read either “Notice: This product has not been shown to relieve pain symptoms” or “Notice: The ingredients in this product have not been tested for effectiveness.” After

²⁴ See Manoj Hastak, *Effects of Exposure to Packages of Several Homeopathic Products on Consumer Takeaway and Beliefs*, Report Submitted to the Federal Trade Commission (Aug. 2012), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitc.pdf (Hastak study)

²⁵ One thousand, seven hundred fifty-four consumers were surveyed, with approximately 175 consumers assigned to each treatment condition.

viewing a 3-D image of the assigned product, respondents answered a short questionnaire comprised of closed-ended questions.

The copy test results revealed that many consumers mistakenly believed the FDA had approved the homeopathic products for efficacy. After controlling for “yea saying,”²⁶ the copy test showed that between 10% and 29% of respondents exposed to the original product packaging for the three products indicated that they believed that a government agency like the FDA had approved the products for efficacy.²⁷ Although making the word “homeopathic” more prominent on the Similasan label significantly reduced the belief that the product was FDA approved (down to 11%), it did not have a similar effect for either the Oscilloccoccinum or Arnica products. Likewise, at least one of the two disclaimers used in this study significantly reduced the misperception of FDA approval for each product. However, after controlling for “yea saying,” the copy test showed that 19% of respondents exposed to the Similasan product packaging with the disclaimer still believed that a government agency like the FDA had approved the product for efficacy, as did 7% to 8% of respondents exposed to the other two tested products. As noted in FTC staff’s comment to the FDA, it is possible that different or more prominent disclaimers could further reduce the percentage of consumers with the misperception that homeopathic products are FDA approved.²⁸ This research suggests the persistence of mistaken consumer beliefs about government approval for homeopathic products.

The copy test results also showed that consumers mistakenly believed that the manufacturers of homeopathic products had tested their products on people in order to show their effectiveness. After controlling for “yea saying,” the copy test results showed that from 23% to 34% of respondents exposed to the original product packaging indicated that they believed the manufacturers had tested the product on people to show its effectiveness.²⁹ The disclaimers used in this study did not significantly reduce the misperception of human testing. After controlling for “yea saying,” the copy test showed that from 23% to 26% of respondents exposed to product packaging with the statement, “This product has not been shown to relieve ... symptoms” still indicated that they believed that the products had been tested on people in order to show their

²⁶ Affirmative responses to the FDA statement were adjusted by subtracting affirmative responses to a control statement asking consumers if they believed that the American Medical Association (AMA) certified that the product was more effective than other remedies in relieving the symptoms the product claimed to relieve. Control questions are used to control for measurement error, including yea-saying (i.e., the tendency to agree with questions regardless of content), inattention, and other noise factors that may result from a closed-ended question format. See J. Craig Andrews & Thomas J. Maronick, *Advertising Research Issues from FTC versus Stouffer Foods Corporation*, 14 J. PUB. POL. & MARKETING 305 (1995).

²⁷ Before controlling for yea-saying, responses ranged from 33% to 56%.

²⁸ As discussed below, in the second AAHP study, a disclaimer that directly addressed the lack of FDA approval and that respondents were expressly asked to read had a greater effect on reducing the belief that a homeopathic product was FDA approved.

²⁹ Before controlling for “yea saying,” responses ranged from approximately 45% to 57%.

effectiveness, as did 26% of respondents exposed to the packaging with the statement, “The ingredients in this product have not been tested for effectiveness.”³⁰ Again, it is possible that different or more prominent disclaimers could further reduce the percentage of consumers with the misperception of efficacy established by human testing.

IV. Public Comments

The FTC solicited public comments before and after the workshop and received over 530 written comments.

A. Comments from Individual Users or Practitioners of Homeopathy

The vast majority of the comments received were from individual consumers who had personally used homeopathic products. Over 400 consumers wrote to express their positive experiences with homeopathic products. In addition, over 30 individual homeopathic practitioners commented about their positive experiences or those of their patients. Many consumers and practitioners were concerned that the FTC might take action that would eliminate or reduce the availability of OTC homeopathic products. Many commenters stressed what they described as homeopathy’s safety. Some commenters noted that they did not rely upon advertising in choosing homeopathic products, while others said that existing product labeling was sufficiently clear. A few commenters who believed in the efficacy of homeopathy said that homeopathic products should not be labeled as treating specific diseases because that is not how such products work.

B. Comments from Individual Skeptics of Homeopathy

Approximately 50 individuals submitted comments questioning or denouncing homeopathic products. A number of these called on the FTC to subject claims for OTC homeopathic products to the same standards as any other drug. Others called for a prohibition on homeopathic efficacy claims or an outright product ban. There were suggestions that OTC homeopathic claims be accompanied by strong disclaimers, e.g., that the products be labeled as placebos, or that they be labeled to disclose their lack of active ingredients. Several commenters spoke of the placement of homeopathic products on store shelves next to allopathic drugs as leading to consumer deception. With respect to consumer injury, some commenters raised safety concerns and others raised the harm to consumers from relying upon homeopathic products instead of using potentially more efficacious allopathic alternatives.

C. Comments from Organizations Skeptical of Homeopathy

An organization called Sense about Science asserted that the scientific evidence shows that homeopathy acts only as a placebo and that there is no scientific explanation of how it could work any other way.³¹ It also submitted a link to its existing critique of homeopathy.

³⁰ Before controlling for “yea saying,” responses ranged from approximately 38% to 52%.

³¹ Comment #00063 (Sept. 8, 2015), <https://www.ftc.gov/policy/public-comments/2015/09/08/comment-00063>.

Three other organizations skeptical of homeopathy, The Society for Science-Based Medicine (SSBM),³² The Center for Inquiry, and the Richard Dawkins Foundation for Reason and Science (the RD Foundation),³³ also submitted comments. The comments argued that homeopathic products have no efficacy in treating illnesses and that there is no reasonable basis for homeopathic principles such as “like cures like,” the law of infinitesimal doses, or water retaining a memory of things that have been in contact with it.³⁴ They pointed to the Australian NHMRC report, to a report by the UK House of Commons Science and Technology Committee that “could find no support from independent experts for the idea that there is good evidence for the efficacy of homeopathy,”³⁵ and to a statement by the National Center for Complementary and Integrative Health that “There is little evidence to support homeopathy as an effective treatment for any specific condition.”³⁶ The SSBM asserted, based in part on its reading of individual public comments submitted to the FDA, that consumers do not understand the nature of homeopathic drugs or the support for their claims. The Center for Inquiry and the RD Foundation asserted that there was economic harm from homeopathy because such products are ineffective and that consumers were often relying on homeopathic products to the exclusion of proven scientific remedies. These commenters called on the FTC to require that homeopathic claims be substantiated by sound scientific evidence.

D. Comments from a Homeopathic Manufacturer

Hahnemann Laboratories, Inc., a homeopathic product manufacturer, submitted the same comment that it had submitted to the FDA.³⁷ The company noted that its client base includes many plastic surgery and dermatology clinics, physicians, veterinarians, and dentists, asserting that such educated and experienced professionals would only purchase homeopathic products if homeopathy worked in their practices. It asserted that the FDA has never received an Adverse Event Report for a classical single remedy oral use homeopathic product with a “safe” dilution level of 6C (one part per trillion) or more. Hahnemann Labs said that almost 300 studies have

³² Comment #00513 (Nov. 20, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00513-99778.pdf.

³³ Comment #00517 (Nov. 20, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00517-99779.pdf.

³⁴ The purported ability of water to retain a memory of a dissolved substance is the explanation for why homeopathic drugs work even though they have been so diluted that no single molecule of the original substance remains.

³⁵ UK House of Commons, Science and Technology Committee, *Evidence Check 2: Homeopathy* (2010) <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament2005/homeopathy/>.

³⁶ NCCIH, *Homeopathy*, <https://nccih.nih.gov/health/homeopathy>.

³⁷ Comment #00370 (Nov. 12, 2015), <https://www.ftc.gov/policy/public-comments/2015/11/12/comment-00370>.

been conducted involving homeopathic treatments with positive results demonstrated in about 85% of the studies. The comment questioned the efficacy of products containing combinations of both homeopathic and non-homeopathic ingredients. Hahnemann Labs acknowledged that it may be difficult for people to find accurate information about homeopathic products and recommended that members of the public consult with a trained homeopath before purchasing homeopathic remedies.

E. Comments from Organizations Representing Homeopathic Companies or Practitioners

1. The Homeopathic Nurses Association

The Homeopathic Nurses Association (HNA) submitted a comment asserting the efficacy of homeopathy, citing the Swiss government's positive review of homeopathy, as well as several other studies. The HNA wanted consumers to continue to have OTC access to homeopathic remedies. It said that homeopathic ingredients combined with non-homeopathic ingredients should not be labeled as homeopathic and that homeopathic products should not be labeled as remedies for chronic illnesses or life-threatening issues, like asthma or diabetes.

2. The United States Homeopathic Regulatory Commission

The United States Homeopathic Regulatory Commission (USHRC), a non-profit association of health professionals whose mission is "to provide a system for determining commonly recognized homeopathic medicines," submitted a comment.³⁸

Among other things, the USHRC critiqued the FTC's homeopathic consumer research and argued that homeopathic purchasers have much greater understanding of homeopathic products than suggested by the research. It argued that because the focus groups commissioned by the FTC were five years old, conducted in just one city and involved just 16 individuals, they are not sufficiently representative of homeopathic product purchasers for their results to be the basis of policy decisions. With respect to the larger Hastak study, the comment noted the data was over three years old and that the survey did not inquire about the participants' prior experience with homeopathic products or their knowledge of homeopathy.³⁹

The USHRC asserted, based upon a 2014 survey conducted by the American Medical College of Homeopathy's Department of Research (AMCH) of over 1,000 homeopathic product

³⁸ Comment #00364 (Nov. 10, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00364-99550.pdf.

³⁹ FTC staff does not believe that the lack of information about survey respondents' experience with or knowledge about homeopathy is a shortcoming. The survey sought to assess the reactions to packaging by members of the general public as long as they were in the potential target audience for the product at issue.

The comment also incorrectly asserted that it is not clear how many people actually participated in the Hastak online survey. The study report shows that 1,754 people completed the survey.

users, that consumers who purchase homeopathic products are knowledgeable about what they are purchasing and highly educated.⁴⁰ Seventy-eight percent of survey respondents said that they had an “extremely high” or “high” understanding of the homeopathic treatments they were taking. Of those surveyed, 36% had a master’s or doctoral degree, 33% had a bachelor’s degree, and 23% worked as health care providers. FTC staff notes, however, that the AMCH survey was distributed to homeopathic practitioners who were then asked to send the survey to their patients. Therefore, not only was the survey not random, it is not representative of users of OTC homeopathic products who are not patients of homeopathic practitioners.⁴¹ Only 8% of those who completed the survey said that they did not use a homeopathic practitioner. FTC staff also notes the large discrepancy between the AMCH survey showing 78% of respondents having a high or very high understanding of homeopathic treatments and the 38% of homeopathic product purchasers in the WSL Strategic Retail survey who said that they felt that they clearly understood what “homeopathic” meant. Furthermore, it is not known whether the homeopathic product purchasers in either survey were correct in their understanding of homeopathy.

The USHRC asserted that there have been studies showing that homeopathy can be beneficial for the treatment of certain conditions and that many countries around the world recognize homeopathy as a therapeutic option that is both safe and cost efficient. The USHRC believes that homeopathic products should not be held to the same proof of efficacy standards applied to allopathic OTC drugs because the homeopathic industry would not be able to afford to test thousands of homeopathic ingredients and an entire class of products would be forced off the market. It argued that such a result would be contrary to the intent of Congress, which expressly included homeopathic drugs in the “drug” definition at the time that the FDCA was passed. The USHRC would support the use of a homeopathic disclaimer such as “These statements have not been reviewed by the Food and Drug Administration.”

3. The American Association of Homeopathic Pharmacists

The American Association of Homeopathic Pharmacists submitted a comment that recognized that consumers not familiar with homeopathy might not realize that homeopathic drugs do not undergo the same regulatory review process as allopathic OTC drugs.⁴² It believes that this concern can be addressed by disclaimers. AAHP’s advertising guidelines provide that consumer advertising for OTC homeopathic drugs should disclose, “These statements have not

⁴⁰ Manna Semby & Todd Rowe, North American Homeopathic Patient Survey – A Study Conducted by the American Medical College of Homeopathy Department of Research (June 2014), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00364-99551.pdf. The USHRC also asserted that repurchase rates for homeopathic products are on par with those for national allopathic OTC products, showing product satisfaction.

⁴¹ A potential additional bias is that each participant was invited to complete multiple, separate surveys for each child and animal in her or his household who used homeopathic treatments.

⁴² Comment #00524 (Nov. 20, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00524-99781.pdf.

been reviewed by the Food and Drug Administration.” The guidelines also allow for an additional disclosure explaining the homeopathic nature of the advertised product claim.

The AAHP comment recognized that an advertiser needs to have a “reasonable basis” for a product claim and noted that the determination of the necessary level of support for a claim requires an analysis of a number of factors including the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable (the *Pfizer* factors).⁴³

The AAHP sought to apply the *Pfizer* factors to claims for OTC homeopathic products. The comment asserted that because OTC homeopathic products are not claimed to treat life-threatening conditions, RCTs should not be required. With respect to the type of product, the comment claimed that homeopathic products have an unsurpassed safety profile. It said that the only consequences of a false claim for an OTC homeopathic product are minor discomfort and wasted money, and that the benefits of a truthful claim are relief from a condition while avoiding possible side effects. The AAHP said that the cost of Phase III clinical studies, which the comment said would cost almost \$2 trillion for testing 100 active ingredients, was greater than the homeopathic industry could bear.⁴⁴ The AAHP also argued that there are a significant number of qualified physicians who believe in the practice of homeopathy. The AAHP believes that the *Pfizer* factors support the conclusion that the traditional homeopathic literature provides adequate substantiation for appropriately qualified homeopathic advertising claims.

The AAHP comment pointed to an FTC staff guidance document, Dietary Supplements: An Advertising Guide for Industry, which states that claims based on historical or traditional use should either be substantiated by scientific evidence or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of a product for a particular purpose. The AAHP asked the FTC to apply the same principle to OTC homeopathic

⁴³ If an advertiser has not claimed that a particular level of evidence underlies its claim, the Commission considers a number of factors articulated in the 1972 *Pfizer* case to determine the appropriate level of support for a claim. *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972).

⁴⁴ This estimate is based on the incorrect assumption that only RCTs that meet the requirements of a Phase III clinical trial would be considered reliable substantiation. The FTC has never espoused that position. In fact, the vast majority of published peer-reviewed clinical trials do not satisfy all Phase III requirements. There is no reason to assume that these studies are unreliable for the purposes of substantiating advertising claims based solely on their failure to satisfy the Phase III requirements.

According to the AAHP, an RCT is not suited to test the efficacy of homeopathic drugs because, among other reasons, homeopathic medicines are individualized for a specific constellation of symptoms. Although homeopathic treatment was traditionally individualized, staff notes that it is not individualized with respect to OTC homeopathic products, which are claimed to have the same effect across the population. The other purported reasons suggested in the AAHP comment why RCTs are ill-suited to homeopathic treatments, such as the wealth of existing product data, do not preclude their use.

products and asserted that the AAHP disclaimer about the absence of FDA review, together with a statement that the claims are based upon traditional homeopathic practice, should be sufficient. Nevertheless, the AAHP said that OTC homeopathic medications should never be marketed so that they “could lead consumers to forego other treatments that have been validated by scientific evidence.”

The AAHP argued that the use of appropriate disclaimers that qualify and explain the therapeutic claim made by an OTC homeopathic product is an adequate means of providing consumers with truthful and non-misleading information and that to reject such an approach would offend the First Amendment. It also argued that if the FTC adopted a significantly different position from the FDA’s and prevented consumers from receiving information about homeopathic products, it would create a significant disharmony in federal regulation.

To measure any confusion about homeopathic products and the effectiveness of disclosures in remedying any FTC concerns, the AAHP commissioned two consumer research studies designed by Dr. Thomas J. Maronick, a professor of marketing at Towson University.⁴⁵ Both studies were conducted online with samples drawn from Internet panels.

a. The first AAHP study

The purpose of the first AAHP study was to determine consumers’ perceptions of the FDA approval status of labeling claims for a variety of product categories, including homeopathic products. The survey population was a nationwide sample of adults.⁴⁶ Respondents were asked a closed-ended question about their understanding of whether the FDA approves labeling claims for each of the product categories.

A total of 159 respondents completed the first AAHP study. As reported, 78% of the respondents had previously purchased a homeopathic product and another 11% did not know or were not sure if they had done so. The vast majority of consumers surveyed (85%) believed the FDA approves prescription drug claims, while 76% of respondents believed the FDA approves claims for over-the-counter medicines. Less than a quarter of respondents (24%) believed the FDA approves claims made for homeopathic products, which is lower than the percentage of consumers who believe the FDA approves claims for every other product category, including pet foods (39%), cosmetics (40%), dietary supplements (48%), and grocery foods (64%). According to Dr. Maronick, these results indicate that consumers have a better understanding of the FDA approval status of claims made for homeopathic drugs than the FDA approval status of claims for other product categories that are not approved, such as grocery foods, dietary supplements, cosmetics, and pet foods. According to the AAHP comment, the study suggested that most consumers can differentiate between allopathic OTC products and homeopathic OTC products.

⁴⁵ Thomas J. Maronick, *An Empirical Analysis of Consumers’ Perceptions of the FDA Approval Status of Labeling Claims and of Disclaimer Language on a Homeopathic Remedy for Heartburn* (Oct. 13, 2015).

⁴⁶ Respondents had to have purchased a product to relieve cold symptoms, pain, heartburn, or flu symptoms in the prior year. Because the survey did not concern such symptoms, it is unclear why individuals who had not purchased such products were excluded.

FTC staff notes a number of concerns with respect to the first AAHP study. There is no indication that the survey respondents actually knew what a homeopathic product is. The survey found that 78% of respondents had previously purchased a homeopathic product, yet two other surveys described in the AAHP comment show much lower levels of homeopathic usage. According to a report by the National Center for Health Statistics and NIH, as of 2012, only 2.2% of the U.S. population had used homeopathy within the past year, and in a survey by Mintel, 37% of “mainstream” shoppers reported having ever used homeopathic medicines. Also, to the extent that consumers believe that homeopathic products are home remedies, they would not expect them to be approved by the FDA. In the Shugoll focus groups, most adults and parents equated homeopathic products with natural and/or home remedies.

Contrary to the AAHP’s assertion, nothing in the first AAHP survey suggests that consumers can differentiate between allopathic and homeopathic OTC products on the store shelf or in advertising.⁴⁷ Furthermore, whether or not consumers think that homeopathic product claims are approved by the FDA is not dispositive as to whether consumers are misled about the support for homeopathic claims.

b. The second AAHP study

The second AAHP study was intended to examine consumers’ perceptions of one of three disclaimers included on the back panel of a package of a fictional homeopathic product, Acidux, purportedly for the relief of heartburn, bloating, and upset stomach. One disclaimer was “These statements have not been reviewed by the Food and Drug Administration”; a second was “The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration”;⁴⁸ and a third was identical to the second other than it included a referral to a fictitious website, “(See www.Homeopathy.org.)” where consumers could presumably obtain information on homeopathy. The survey population was a nationwide sample of adults who had purchased a product to relieve heartburn over the prior year. Approximately 450 respondents completed the study, with approximately 150 exposed to each of the three different disclaimer statements.

⁴⁷ The rating scale used (“Definitely are approved by the FDA,” “Are Approved by the FDA,” “Are not approved by the FDA,” “Definitely are not approved by the FDA,” and “Don’t know/Not sure”) may have biased the results. Respondents who thought that a product was probably approved by the FDA but were not sure may have opted for the “don’t know” option. This possibility could have been avoided by using the scale: “definitely approved ..., probably approved ..., probably not approved.”

⁴⁸ To the extent that consumers do not know what a homeopathic product is or do not understand homeopathic principles, the reference to “traditional homeopathic practice” is unlikely to be informative. As reported, 60% of the respondents in the study had purchased a homeopathic product and 20% did not know if they had done so. These results suggest a lack of understanding by the respondents of what a homeopathic product is. See discussion on page 17, *supra*. In addition, in the Shugoll focus groups, even those who said that they had purchased homeopathic products were unfamiliar with the principles underlying homeopathy. In the WSL Strategic Retail survey, only 38% of self-identified homeopathic product purchasers said that they felt that they clearly understood what “homeopathic” meant.

After looking at a flattened Acidux package showing the back, front, and side panels, survey respondents were asked separate questions about what the package said or suggested “about the uses of this product” and about “testing done on/for this product.” Dr. Maronick did not report the responses to the question about product uses. In response to the question about what the package communicated about “testing done,” only between 6% and 12% of respondents said “not FDA approved/tested,” which could suggest that very few respondents noticed the disclaimer statements.

Respondents were then reshown an enlarged version of the back panel of the package and asked to note the disclaimer language, which was highlighted. Respondents were then shown three statements, based upon three statements tested in the Hastak study, and were asked whether they believed each statement was true. Between 16% and 29% of respondents said that they believed that a government agency like the FDA had approved Acidux as being effective, a statement that is inconsistent with the disclaimers. These percentages are lower than the 23% to 45% of respondents in the Hastak study exposed to disclaimers who said they believed that the product claims were FDA approved. That may be in part because the respondents in the AAHP study were directed to read the disclaimer and in part because the AAHP study disclaimers expressly addressed the lack of FDA review. In the AAHP study, between 22% and 30% of respondents agreed with Dr. Maronick’s control statement, that the “AMA had certified Acidux as effective.” This appears to be greater than the 13% to 26% of respondents in the Hastak study exposed to a disclaimer who agreed with the control statement in that study. This may be because the Hastak study control asked about the AMA certifying the product to have “greater efficacy” rather than simply certifying it “as effective,” the latter being easier for respondents to believe and not as good a control. After adjusting for yea saying, using his control, Dr. Maronick found that there was no net belief in FDA approval.

In the AAHP study, between 49% and 54% of respondents said that they believed that the manufacturer of Acidux had tested it on people to show that it was effective. This is comparable to the 45% to 58% of respondents in the Hastak study who saw labels without disclaimers who thought that the products in that study had been tested on people to show their effectiveness. Because the AAHP disclaimers did not address the lack of proven efficacy or the lack of testing and the Hastak study disclaimers did, it is expected that the results for the packages with the AAHP disclaimers would be comparable to the Hastak results for packages without disclaimers. After Dr. Maronick applied his control, which as discussed above may have been flawed, between 24% and 30% – substantial proportions of respondents – believed that the product manufacturer had tested the product for effectiveness. Also, even if only these percentages of respondents believed the manufacturer had tested the product on people, higher percentages of respondents still may have believed that the manufacturer had a scientific basis for its claims.

Respondents were asked to select from several possible answers the one that best represented their understanding of what the disclosure statement they saw said or suggested about the testing the product manufacturer may have done.⁴⁹ Between 6% and 14% of respondents said the

⁴⁹ This and all subsequent questions about the disclaimer statements repeated the full disclosure statement as part of their question language. Therefore, the questions themselves asserted the lack of FDA review. This may have biased the results. Also, it may have been inappropriate or confusing to ask this question, which asserted the lack of FDA review, of the 16% to 29% of

disclaimer statement they saw said or suggested that the manufacturer had conducted scientifically controlled studies with humans, 8% to 16% said the statement meant at least one human study that was not necessarily scientifically controlled was conducted, 21% to 51% said homeopathic studies with humans were conducted, 13% to 21% said that the product had been provided to people and its efficacy was tracked, and 18% to 32% did not know. Dr. Maronick asserted that these results mean that consumers do not necessarily believe that scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed, but rather mean that the manufacturer conducted homeopathic studies on humans, with consumers holding different views as to what type of testing on humans was conducted. Staff notes that this survey question did not ask about consumer beliefs about the product but rather asked about the meaning of a disclosure statement that was quoted in the questions asked. Also, some of the closed-ended answer choices may have confused consumers. For example, is not clear what consumers understood “homeopathic studies with humans” to mean. The responses to this question do not answer the degree to which consumers expect there to be reliable scientific or other evidence underlying product efficacy claims.

Respondents who saw the second or third disclaimers were asked an open-ended question about what that disclaimer statement said or suggested about the scientific support the product’s manufacturer had. Only 14% to 23% said the disclaimers suggested there was no scientific support for the claims.⁵⁰ When asked closed-ended questions about what these disclaimers said or suggested about scientific support, between 28% and 29% said the disclaimers suggested there was either the same evidence or more evidence than for similar non-homeopathic products and only 22% to 29% said there was less evidence, with the remaining respondents either not knowing or giving other answers. The proportions of respondents saying there was the same or more evidence than for non-homeopathic products are substantial. Staff notes that even those consumers who interpreted the disclaimers to mean there is less evidence than for non-homeopathic products might still expect scientific or other reliable evidence for the product claims. Similarly, respondents who did not know how to answer the question may have expected there to be scientific or other reliable evidence for the claims.

The second AAHP study does not demonstrate that the tested disclaimers would be effective without forced exposure, and does not demonstrate that even with forced exposure they stop consumers from expecting a product’s efficacy claims to be supported by scientific or other reliable evidence. To the contrary, the results suggest that at least a significant proportion of consumers would be deceived despite directed exposure to the disclaimers.

respondents who had just said they believed that a government agency like the FDA had in fact approved Acidux as being effective.

Dr. Maronick reports that this question was limited to those who said they believed the product was tested on people, but according to the questionnaires attached to his report, that was not the case for those seeing the first disclaimer.

⁵⁰ Although almost half of the respondents who saw the first disclaimer were asked an open-ended question about what, if anything, the disclaimer statement said or suggested about the type of testing the product manufacturer may have done, the responses to this question were not reported.

4. A European trade association

Omeoimprese, the Association of Italian Homeopathic Companies, submitted a comment describing the regulation of OTC homeopathic products in the European Union (EU).⁵¹ In the EU, homeopathic products must be registered, using either a “simplified” registration procedure or a “normal” registration procedure very similar to the registration procedure for conventional medicine. A product registered using the simplified procedure must be for external or oral use, may not make any therapeutic claims, and must be sufficiently diluted to ensure safety. These products are not sold “over the counter,” but rather are delivered under license per practitioner advice. Only homeopathic products registered pursuant to the normal procedure may make therapeutic claims and only based on proof of efficacy similar to that required of conventional medicines. The comment suggested that the U.S. government consider a simplified authorization procedure similar to the EU’s.

F. Comments from Other Organizations Supportive of Homeopathy

Two organizations, the Center for Medical Freedom⁵² and The Senior Citizens League,⁵³ both associated with the same individual, submitted separate comments. The Center for Medical Freedom comment questioned the FTC’s jurisdiction over homeopathy, the legitimacy of administrative agencies, and the FTC’s longstanding policy of placing the burden on marketers to have substantiation for their claims. The Senior Citizens League comment said that the “government has no business effectively preventing senior citizens from purchasing homeopathic products.”

V. Conclusion

The FTC workshop and related public comments provided valuable insight into the dynamic OTC homeopathic drug market. No convincing reasons have been advanced either in the comments or the workshop as to why efficacy and safety claims for OTC homeopathic drugs should not be held to the same truth-in-advertising standards as other products claiming health benefits. Efficacy claims for traditional OTC homeopathic products are only supported by homeopathic theories and homeopathic provings, which are not accepted by most modern medical experts and do not constitute competent and reliable scientific evidence that these products have the claimed treatment effects. For these reasons, the vast majority of OTC homeopathic drugs lack adequate substantiation for their efficacy claims.

To address concerns that many consumers are likely being misled by current marketing claims, the Commission is issuing an Enforcement Policy Statement, making clear that marketers of OTC homeopathic drugs must either have adequate substantiation for their efficacy claims or

⁵¹ Comment #00069 (Sept. 28, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/09/00069-97591.pdf.

⁵² Comment #00537 (Nov. 20, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00537-99785.pdf.

⁵³ Comment #00530 (Nov. 20, 2015), https://www.ftc.gov/system/files/documents/public_comments/2015/11/00530-99783.pdf.

effectively communicate the lack of scientific evidence backing them and that their claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts. This approach is fully consistent with the First Amendment, does not limit consumer access to OTC homeopathic products, and does not conflict with FDA's current regulatory stance because it would allow a marketer to include on labeling an indication for use that is not supported by scientific evidence so long as the marketer effectively communicated the limited basis for the claim in the manner described above.