



November 10, 2015

Gregory W. Fortsch
Bureau of Consumer Protection
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex B)
Washington, DC 20580

Re: Federal Trade Commission's Homeopathic Medicine & Advertising Workshop

Dear Mr. Fortsch:

On behalf of the United States Homeopathic Regulatory Commission (USHRC or Organization), we are respectfully submitting comments in response to the Federal Trade Commission's (FTC or Agency) workshop examining the advertising for Over-the-Counter (OTC) homeopathic drug products held on September 21, 2015 in Washington, DC. According to the FTC's Commissioner Maureen Ohlhausen, the goal of the workshop was to "examine the potential challenges that advertising for OTC homeopathic products pose for American consumers and possible solutions for addressing those challenges."¹

The USHRC is a non-profit organization whose mission is to provide a reliable, trustworthy and progressive system for determining commonly recognized homeopathic medicines. The USHRC has worked closely with the homeopathic community to establish a program for common national standards and methods as described by Samuel Hahnemann, the Homeopathic Pharmacopœia Convention of the United States (HPCUS), and the European Council on Classical Homeopathy. The goals of this program are to address two important issues facing the homeopathic community today: 1) defend the existing recognized homeopathic ingredients that are not listed in the Homeopathic

¹ See Transcript for the FTC's workshop on Homeopathic Medicine and Advertising at 3.

Pharmacopœia of the United States (HPUS), and 2) support innovative and new homeopathic materials and uses through valid provings and clinical verification.

Our Organization is dedicated to supporting the continued evolution of homeopathy in the 21st century in part by establishing a general repository of support for homeopathic materials recognized and commonly utilized in Homeopathy, but listed in non-U.S. homeopathic pharmacopeias, in *materia medica* references, and in textbook descriptions, as well as other appropriate and accepted channels.

Overall, the USHRC believes that homeopathic drug products are being appropriately regulated by the Food and Drug Administration (FDA) pursuant to the FDA's Compliance Policy Guide 400.400 (CPG 400.400) entitled "Conditions Under Which Homeopathic Drugs May be Marketed."² While we agree that a labeling disclaimer stating that homeopathic drugs are not approved by the FDA may be beneficial to consumers, research shows that consumers of homeopathic drug products are in fact very knowledgeable and savvy when it comes to determining what the best treatment is for their minor medical conditions, and appear to understand the difference between allopathic and homeopathic drugs despite shelf placement in pharmacies and other retail stores. The USHRC is submitting these comments to assist the FTC in its evaluation of advertising of OTC homeopathic drug products and hopes that the Agency carefully reviews all available data before taking action against products that have a very low-risk safety profile and provide consumers with alternative treatment options for minor conditions.

I. FTC's assessment of Consumer's Understanding of Homeopathic Drug Products

At the workshop, FTC expressed concerns about ensuring that consumers have "accurate and reliable information about the products they buy."³ Specifically, FTC questioned whether consumers knew what they were buying when purchasing a homeopathic drug product. FTC also expressed concern over consumers not understanding that homeopathic drug products are not reviewed and/or approved for safety and effectiveness by the FDA.

In trying to determine whether consumers were making informed purchases when buying OTC homeopathic drug products, the FTC staff conducted a copy test and assembled two small focus groups to assess consumers' understanding of homeopathy and homeopathic remedies. According to the Agency, this research suggested that "a significant percentage of consumers do not understand the nature of homeopathic products, how they are regulated, or the level of substantiation [needed] to support claims for those

² Available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>.

³ See Transcript for the FTC's workshop on Homeopathic Medicine and Advertising at 7.

products.⁴” In particular, the focus group results “suggested that many consumers choose homeopathic products based on incorrect and incomplete information” and that when given additional information; however, “they looked more critically at homeopathic treatments.⁵” With regard to the copy test, the Agency noted that the results showed that many consumer “mistakenly believed that the FDA had approved homeopathic products for efficacy,” and that homeopathic drug manufactures tested their products on humans for efficacy.⁶

Though we understand the concerns expressed by the FTC, we believe that the focus groups and the copy test data relied upon by the Agency is not really representative of the consumers that are in fact purchasing homeopathic drugs today. First, the Agency conducted two focus groups in Baltimore, MD in late 2010 and it only included 16 people (one group was composed of eight adults and another of eight parents). We strongly believe that a focus group conducted five years ago and limited to a very small number of participants in only one state is not sufficiently representative of how informed consumers are in this area. As such, it is difficult to use the data generated by the focus groups to support the overarching conclusion that consumers choose homeopathic drugs based on “incorrect and/or incomplete information” as stated by the Agency.

The copy test commissioned by the Agency presents similar problems. First, it is not clear from the materials submitted to FDA how many people actually participated in this online survey. The survey was conducted in 2012 and a “soft launch” of the online survey was “shut down” after approximately 100 people had completed it.⁷ There is no other mention as to whether the survey was reopened to more participants after the “soft launch.” Second, as with the focus groups, the data is old and did not inquire about the participants’ experience with the use of homeopathic products or their knowledge of homeopathy.

Moreover, the fact that people are confused as to whether OTC drugs are “approved” by FDA, can also be extrapolated to OTC allopathic drugs. There are many OTC allopathic drugs being marketed right now under monographs that have not been reviewed or finalized by FDA since the OTC monograph process started back in 1972. However, people are still under the assumption that all OTC drugs currently on the market have been “approved” by FDA. Therefore, the finding by the Agency, that “consumers have incorrect perceptions about human efficacy testing for homeopathic products,” is most likely not unique to homeopathic drugs.

⁴ See Comments of the Staff of the Federal Trade Commission submitted to the Food and Drug Administration on August 21, 2015 at 9.

⁵ See Transcript for the FTC’s workshop on Homeopathic Medicine and Advertising at 8.

⁶ *Id.* at 9.

⁷ See Exhibit C to the Comments of the Staff of the Federal Trade Commission submitted to the Food and Drug Administration on August 21, 2015.

Based on the above, we respectfully disagree with the Agency's conclusions based on this data. The fact is that consumers who purchase homeopathic drug products are knowledgeable and highly educated. These consumers know what they are purchasing and understand how to self-treat, either based on the information provided on the product labeling, internet or other research, and/or the guidance provided by a homeopathic drug practitioner.

According to the 2014 survey⁸ conducted by the American Medical College of Homeopathy Department of Research of over 1,000 homeopathic drug product users,⁹ the average consumer of homeopathic drug products today is a 51-year-old Caucasian female (85% of respondents) who is married (67% of respondents) and highly educated (36% have a masters or doctoral degree and 33% have a bachelors degree).¹⁰ The results also showed that the occupation for the majority of users of homeopathic drug products was health care providers (22.5%), with the majority of respondents learning about homeopathic treatments from their family and friends (33%).¹¹ When asked, "how well do you understand your homeopathic treatment and how homeopathy works?" 78% of respondents said that they had an "extremely high" or "high" understanding of the treatments they were taking.¹² Respondents also rated their overall satisfaction with homeopathic treatments at 77.5%.¹³

This survey provides significant evidence that purchasers of homeopathic drug products **DO** know the difference between OTC drug products and that the average purchaser is highly educated and most likely works in the healthcare field.¹⁴

As explained by Mr. Yale Martin, Independent Retail Consultant, during his presentation at the FDA hearing on April 21, 2015 and during the FTC Workshop, products (whether

⁸ This was a follow-up survey from a 2007 study conducted by the American Medical College of Homeopathy. The results of the 2007 survey are available at <http://www.amcofh.org/research/community>. The results of the 2014 survey are included with this submission as Attachment A. The American Medical College of Homeopathy plans to repeat these surveys every 7 years.

⁹ The 2014 survey consisted of 41 questions and was primarily conducted online. The survey was reviewed by the American Medical College of Homeopathy's Institutional Review Board and distributed to homeopathic drug practitioners who were then asked to send the survey to their patients. There were 1054 participants in the survey (77% response rate). The study was conducted from January through March 2014.

¹⁰ See Attachment A, Summary of Survey Results at 6-8.

¹¹ *Id.* at 12.

¹² *Id.* at 17.

¹³ *Id.* at 15.

¹⁴ The test copy conducted by FTC did not allow participants that worked in marketing research, a grocery or a drug store, or for a drug or pharmaceutical company. See Comments of the Staff of the Federal Trade Commission submitted to the Food and Drug Administration on August 21, 2015, footnote 51 at 14.

homeopathic or allopathic) that fail to meet consumer expectations in terms of efficacy, safety, and quality do not last long in the marketplace and do not grow in sales volume.¹⁵ Mr. Martin specifically noted that retailers are quick to replace items that fail to meet their “minimum sales threshold.” Because shelf space is a “valuable commodity,” retailers do not continue to carry products that disappoint consumers or that have low sales. With regard to the placement of homeopathic drug products next to their allopathic counterparts, Mr. Martin explained that, based on his experience, these products are located next to allopathic counterparts as a way for retailers to provide consumers with all the available choices. He believed that if separated, consumers would be confused and would most likely have a hard time finding the product they want since most retailers group their product by symptom (not by ingredient). For example, all cough/cold medications will be on the same shelf to provide consumers with all the available treatment options. With regard to the advertising of homeopathic drugs, Mr. Martin noted at the FTC Workshop that:

While advertising plays a huge role in the OTC arena with allopathic drugs, **it is not significant** in the homeopathic area, simply because the manufacturers spend very little on advertising. While consumers address their more chronic health issues with their family practitioner, they have come to rely on the convenience of over-the-counter products to address noncritical health issues. They appreciate -- and some would say demand -- multiple options from their local retailer.¹⁶ (Emphasis added).

Moreover, Mr. Patrick Gibbons, of the Emerson Healthcare Group, provided valuable testimony at the FDA hearing about the repurchase rates for homeopathic drug products, as compared to their allopathic counterparts.¹⁷ Specifically, he compared the repurchased percentage rates for homeopathic drug products in the company’s portfolio to some of the major OTC national brands (i.e., Tylenol Cold, Mucinex, Alka Seltzer and Visine). The repurchase rates for homeopathic drugs were as follows: 42.2% in 2013, 41.9% in 2014, and 43.4% in 2015.¹⁸ These rates were on par with those of each of the national OTC brands for the last three years.¹⁹ This data is compelling in showing that consumers of homeopathic products are gaining the benefits they are seeking from the products they

¹⁵ See Summary of Mr. Yale Martin’s presentation to FDA, *available at* <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM443231.pdf>.

¹⁶ See Transcript for the FTC’s Workshop on Homeopathic Medicine and Advertising at 27.

¹⁷ See Presentation to FDA from the Emerson Healthcare Group at 3. *Available at* <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM443500.pdf>.

¹⁸ *Id.* Mr. Gibbons explained that the repurchase rates were based on AC Nielsen data collected from 125,000 panelists who agree to scan each of the products they purchase whether it is a Home Depot or CVS. He also noted that retailers obtain data from purchases made by consumers using their loyalty card programs.

¹⁹ According to Mr. Gibbons, about 80% of consumers were purchasing homeopathic drug products in conjunction with other traditional OTC therapies.

are purchasing and are not purchasing them due to “lack of information” related to the products.

Furthermore, consumers are becoming savvier about their health and treatment options. Many consumers conduct some level of research and read reviews for particular medications before going to a drug store to buy a particular OTC drug, or even before they go to a doctor to be diagnosed. A 2013 survey conducted by the Pew Research Center’s Internet & American Life Project showed that “35% of U.S. adults have gone online to figure out a medical condition” In fact, both patients and doctors are turning to the Internet when researching medical conditions. A 2014 survey conducted by the IMS Institute for Healthcare Informatics found that about 50% of physicians search for health information on Wikipedia.²⁰ This has made Wikipedia the most popular source for medical information for both doctors and patients.²¹ Wikipedia has significant information on homeopathic drug products and is an immediately available resource to almost all U.S. consumers.²²

Based on the educational level of the average homeopathic drug consumer and the repurchase rates for these products, one can safely conclude that these consumers are not only generally informed about homeopathic drug products, but are probably one of the most sophisticated and highly educated consumers in the OTC market. Although it is sometimes stated that people use homeopathy in lieu of “lifesaving” traditional medicine, there is **no material data** to support that conclusion. The data shows that consumers are properly using homeopathic drugs, that they are satisfied with their choices for treating their self-diagnosable, self-limiting, and self-treatable conditions, and that they continue to purchase these products year after year.

II. Labeling of OTC Homeopathic Drug Products

In its comments to FDA, FTC suggested that FDA could eliminate the requirement in CPG 400.400 that an indication appear on the labeling of OTC homeopathic drug products. However, FTC also suggests in the same comments that “homeopathic product labels are confusing and do not conform with conventional product labeling.”²³ The Agency cannot have it both ways.

²⁰ See Engaging Patients Through Social Media, *available at* <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=ff71ad0087c73410VgnVCM10000076192ca2RCRD&vgnnextchannel=a64de5fda6370410VgnVCM10000076192ca2RCRD&vgnnextfmt=default>

²¹ See Doctor’s #1 Source for Healthcare Information: Wikipedia, *available at* <http://www.theatlantic.com/health/archive/2014/03/doctors-1-source-for-healthcare-information-wikipedia/284206/>.

²² See <http://en.wikipedia.org/wiki/Homeopathy>.

²³ See Comments of the Staff of the Federal Trade Commission submitted to the Food and Drug Administration on August 21, 2015 at 16.

Currently, CPG 400.400 requires that manufacturers of OTC homeopathic drug products include the information deemed necessary²⁴ (and required by the Federal Food, Drug, and Cosmetic Act (FD&C Act)) by FDA for a consumer to evaluate a product at the point of purchase (e.g., statement of identity, ingredients statement, directions for use, indications). Specifically, CPG 400.400 states that products must include “at least **one** major OTC indication for use, stated in terms likely to be understood by lay persons,” in accordance with Section 502(f)(1) of the FD&C Act. Therefore, asking FDA to not require an indication for use would violate the FDA’s main statute.

Moreover, the FTC’s suggestion that FDA not require indications or use on the labeling of homeopathic drug products contradicts the FTC’s statement that homeopathic drug products do not conform with conventional product labeling. All OTC drug products are required to have specific indications for use. Assuming that this could be an optional requirement for OTC homeopathic drugs, not having this information on the label would further confuse consumers that are trying to simply find the best product for their self-limiting, self-diagnosable, and self-treatable conditions.

Though the USHRC is confident that consumers are getting the information they need, we do understand that homeopathic drugs are marketed under a different regulatory structure and that some consumers may not be aware of this distinction. Therefore, **we would support the addition of a disclaimer similar to the one found on the labeling for dietary supplements.** For example, the American Association of Homeopathic Pharmacists Consumer Advertising Guidelines for OTC drugs suggest that the following disclaimer be included on the labeling of OTC homeopathic drugs: “These statements have not been reviewed by the Food and Drug Administration.”²⁵

III. Safety and Efficacy of Homeopathic Drug Products

Homeopathy has been widely and successfully practiced around the world for over 200 years, and was practiced in the United States before FDA issued CPG 400.400 in 1988. During the Workshop, the FTC raised many questions with regard to the substantiation needed to establish the safety and effectiveness for homeopathic drugs. The USHRC does not believe that the same standards for efficacy testing that are used for allopathic OTC drug ingredients can be applied to homeopathic drug ingredients.²⁶ Not only is the

²⁴ Homeopathic drug products are also clearly labeled as homeopathic, so the likelihood of a consumer (particularly the well-educated consumer described above) of being misled into purchasing a homeopathic product is low.

²⁵ See AAHP’s Consumer Advertising Guideline for Over-the-Counter Homeopathic Medicines, available at <http://www.aahp.info/position-statements/consumer-advertising-guideline-for-over-the-counter-homeopathic-medicines/>.

²⁶ Currently, the homeopathic community is in the process of developing standards for case studies to be prepared in multi-center clinics so that practitioners that utilize homeopathy can be part of a “functional and standardized” way to gather clinical data on the usage of homeopathic medicines. The USHRC also believes that there is a need for a system that can be used for determining recognized homeopathic medicines, and to support General Recognition of Homeopathic Status for commonly used homeopathic materials as noted in CPG 400.400. To that end, we have developed a framework to assist in determining

homeopathic model different in terms of how homeopathic medicines are tested (i.e., provings), there are thousands of homeopathic ingredients in common usage. The homeopathic drug industry would not be able to complete clinical trials for each of these ingredients, thus forcing an entire class of products, with a very low risk profile, off the market. This would be against the intent of Congress, which expressly included homeopathic drugs in the definition of a drug, at the time that the FD&C Act of 1938 was passed. This is of particular importance since Senator Royal Copeland, the main sponsor of the 1938 statute, was a homeopathic physician and of course was well aware of the basic principles of homeopathy. Moreover, even FDA has acknowledged the “uniqueness” of homeopathic drugs when it defer reviewing these types of products when implementing the OTC Drug Review process in 1972.²⁷

While, FTC is not a scientific agency, we believe that it is imperative to understand the risk safety profile of homeopathic drug products in an effort to understand why changes to the current regulatory structure are not necessary. As echoed by the entire homeopathic drug community during the hearing held by the FDA in April, few to no issues have been raised related to the safety and/or manufacturing of homeopathic drug products. In fact, homeopathic drug products have a multi-century safety record that would be the envy of many modern-day drugs. Mr. Edward Krenzelok, of the Rocky Mountain Poison and Drug Center, provided testimony at the FDA hearing showing that of 80,456 exposures to homeopathic drug products between 2006 and 2013 in the United States, 88.0% had no effects, meaning that the exposure²⁸ resulted in no adverse reactions, as compared to 55.7% for all pharmaceuticals (both OTC and prescription) for the same time period. Overall, the consensus from the majority of presenters at the FDA hearing and all available data, was that homeopathic drugs are safe and present a very low risk of interacting with other types of medications.²⁹

whether a substance could be commonly recognized as a homeopathic ingredient and are open to working with FDA to further define this framework. The costs of the review framework developed by the USHRC are fairly low (a few thousand dollars), and the framework allows manufacturers to submit an ingredient and to get a certificate of recognition as a “commonly recognized” homeopathic ingredient. We would be glad to provide the Agency with more information about the framework, upon request.

²⁷ See 80 Fed. Reg. 16,327, Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing, *citing to* “Procedures for Classification of Over-the-Counter Drugs,” 37 FR 9464, May 11, 1972. While FDA developed the OTC Monograph Process for allopathic OTC drug ingredients, the FDA does not have the resources to conduct the same review for homeopathic drug products, particularly since the Agency is still in the process of finalizing the OTC drug monographs, many of which were started back in 1972.

²⁸ As noted by Mr. Krenzelok during his presentation, an “exposure” to a drug product does not necessarily mean that the person exposed to the drug product had an adverse reaction to the substance.

²⁹ See Endrizzi, C. et al. *Harm in homeopathy: aggravations, adverse drug events or medication errors?* Homeopathy (2005), available at <http://www.ncbi.nlm.nih.gov/pubmed/16226201>; see also, *The Safety of Homeopathy, An European Council for Classical Homeopathy (ECCH) Report (2009), available at <http://www.nationalcenterforhomeopathy.org/files/TheSafetyofHomeopathy2009.pdf>.*

Although the efficacy of homeopathic drugs is a controversial issue, we do not believe that every benefit purported by consumers who use homeopathic drug products is related to a placebo effect. There have been some studies to show that homeopathy can be beneficial for the treatment of certain conditions³⁰ (e.g., allergies, influenza, childhood diarrhea), and many countries around the world recognize homeopathy as a medical therapeutic option that is both safe and cost efficient.³¹

For example, France, rated as the #1 medical system by the WHO, recognized homeopathy as a “medical therapeutic method,” and 39% of French doctors have prescribed homeopathic medicines.³² Moreover, a five-year comprehensive review completed by the Swiss government examined efficacy, real-world effectiveness, appropriateness, safety, and economy of therapies and concluded that homeopathic interventions were “effective under Swiss conditions, safe, and as far as could be judged from the trial situation, also cost effective.”³³ Homeopathy is also a major source of healthcare in India.³⁴

IV. Conclusion

The USHRC thanks the FTC for the opportunity to provide these comments with regard to the regulation and advertising of homeopathic drug products. Our main points are listed below:

- The focus groups and test case data presented by FTC is not representative of the types of consumers that use homeopathic drug products.

³⁰ See e.g., Bell, IR, et al., *Homeopathic medications as clinical alternatives for symptomatic care of acute otitis media and upper respiratory infections in children*, Glob Adv Health Med. (2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/24381823>; see also, Chauhan, VK, *Efficacy of homeopathic intervention in subclinical hypothyroidism with or without autoimmune thyroiditis in children: an exploratory randomized control study*, *Homeopathy*. 103(4):224-31. (October 2014) (Attachment C).

³¹ See April 20, 2015 Presentation to FDA from Wayne B. Jonas of the Samueli Institute, see also Attachment B, *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review by the World Health Organization (WHO)* (2001).

³² See F. Bouchayer, *Alternative Medicines: A General Approach to the French Situation*, *Complementary Medical Research*, May, 1990, 4(2)4-8.

³³ Bornhöft, Gudrun, Matthiessen, Peter (Eds.). *Homeopathy in Healthcare: Effectiveness, Appropriateness, Safety, Cost* (2011), available at <http://rd.springer.com/book/10.1007/978-3-642-20638-2/page/1>.

³⁴ A 2007 paper by Lancet states that over 100 million Indians use homeopathy as their sole source of healthcare. See Prasad R. *Homoeopathy booming in India*. *Lancet*, 370:November 17, 2007,1679-80. Also, according to *MedIndia*, there are 185 homeopathic colleges and 11,000 homeopathic hospital beds in India. See Manohar, Rathi. *Homoeopathy Popular in India*. *Alternative Medicine News* available at <http://www.medindia.net/news/homeopathy-popular-in-india-82548-1.htm>.

- Consumers of homeopathic drug products are in fact knowledgeable and very savvy when it comes to determining what the best treatment is for their minor medical conditions and would not continue to purchase products that are of poor quality or simply do not work.
- The USHRC would support the addition of a disclaimer similar to the one found on the labeling for dietary supplements.
- Homeopathic drugs have a very low-risk safety profile and provide consumers with a safe and affordable treatment option for minor conditions.
- Both FDA and FTC need to consider the intent of Congress when it added a reference to the HPUS to the definition of “drug” in the FD&C Act of 1938.

We look forward to additional opportunities to work with the FTC as it seeks to further understand the homeopathic drug market.

Sincerely,


Todd Rowe, MD, MD(H), CCH, DHT
Acting President
United States Homeopathic Regulatory Commission