



IHPC Testimony/Response to FDA Hearing
April 20-21, 2015

Homeopathic Product Regulation:
Evaluating the Food and Drug Administration's Regulatory
Framework After a Quarter-Century

Alyssa Wostrel, MBA, DiHOM
Executive Director
Integrative Health Policy Consortium
P.O. Box 491
Conifer, CO 80433



Pursuant to the Food and Drug Administration (FDA) Federal Register Notice of public hearing (Notice) Docket No. FDA-2015N-0540, the Integrative Health Policy Consortium provides the following views that will be presented on behalf of consumers and providers of homeopathic products at the April 20-21, 2015 public hearing.

Thank you for the opportunity to speak today. My name is Alyssa Wostrel, and I am the Executive Director of the Integrative Health Policy Consortium or IHPC.

As background, IHPC is a national nonprofit 501(c)(4) created in 2001 as requested by Congressional members who sought a consensus voice in complementary and integrative healthcare for legislators, policy makers and federal agencies. Our mission is "to advocate for an integrative healthcare system with equal access to the full range of health-oriented, person-centered, regulated healthcare professionals."

IHPC represents 16 organizations and educational institutions, over 400,000 providers, including Chiropractors, Acupuncturists, Holistic Nurses, Certified Professional Midwives, Massage Therapists, Naturopathic Physicians, and conventional physicians trained in integrative practice. They provide clinical care services to millions of Americans each year. IHPC is here to assure safety and quality in CAM. With assured safety and quality, we expand the effective choices for doctors and patients in healthcare.

Now, a quick word about my background. Prior to joining IHPC as Executive Director, I served as an executive and a consultant with several homeopathic manufacturing companies. I interacted with thousands of licensed practitioners who used homeopathic products for their patients, regarding FDA approved product use and medical education programming. I coordinated closely with Quality Assurance and Quality Control departments to assure product-labeling compliance with labeling regulations and the Compliance Policy Guide. I always consider the FDA an important guide in promoting the safety of the public health. Today, issues about safety and quality will inform the 3 key agenda questions that I will address. Safety and quality of homeopathic products is a constant in our professions. Safety and quality of homeopathic products is a focus of advocacy by IHPC. It is through the lens of safety and quality that I deliver my remarks today.

Q1. What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

Positive consumer attitudes about high quality, safe homeopathic products can be seen through quantity and frequency of use. Homeopathic products accounted for an estimated \$1 billion in out-of-pocket expenditures in the US in 2012 according to research by Mintel¹. A 2008 NCCAM survey listed homeopathy in the top 10 most utilized CAM therapies². A Stanford study of CAM use among the fastest growing segment of the population, found that 5.8% of seniors surveyed use homeopathy, and experienced greater symptom relief compared to other CAM options³. A 2014 survey of homeopathic patients noted efficacy and safety as the top two 'best liked' attributes of homeopathy⁴.

Providers that IHPC represents have favorable attitudes toward both availability of homeopathic services through trained and credentialed practitioners, and patient access to homeopathic products. These providers incorporate safe, high-quality homeopathy in patient care during consultations and also for ongoing patient self care. Therefore, access to homeopathic products is important as a therapeutic choice for both the provider and the consumer. Access

to the licensed or certified healthcare provider of one's choice is a central tenet of Sec 2706, the Non-Discrimination Provision of the Affordable Care Act. IHPC advocates for the full implementation of Sec 2706 through CoverMyCare, a consumer-facing initiative.

The FDA's effective guidance of the manufacturing, labeling, marketing and sales of homeopathic products has been in place since 1938. Compliance requires that manufacturers must register with the FDA and are subject to FDA inspections. IHPC has always fully supported this guidance.

The healthcare providers represented by IHPC who practice homeopathy, and who refer to homeopathic practitioners, understand that individual homeopathic ingredients marketed for sale in the US have been thoroughly reviewed. They have been reviewed for homeopathic efficacy, toxicology, adverse effects, and clinical use by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS). This informs the attitudes of these providers that utilization of homeopathic products is in accordance with best practices for safety and effectiveness. This rigorous review by HPCUS guided by the FDA has been an essential in safety and quality of homeopathic products.

My professional experience in this field assures me that the current regulatory system, based on the FDA Compliance Policy Guide, has been effective for safely regulating homeopathic products.

Q2. What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic?

References from the World Health Organization and the Swiss Government report are suggested. Both address similar questions to those the FDA is asking in this hearing. Links to documents are provided.

- [Swiss Government Report: http://link.springer.com/book/10.1007%2F978-3-642-20638-2](http://link.springer.com/book/10.1007%2F978-3-642-20638-2)
- WHO Report: <http://www.who.int/medicines/areas/traditional/Homeopathy.pdf>

The IHPC can be utilized by the FDA as an information source to engage with the leaders in complementary and integrative healthcare in the US to access recommendations of data to review. Such an information channel can create a center for FDA discussions with providers about real-time safe usage of effective, quality products in a clinical or therapeutic setting. IHPC's consumer-based site, CoverMyCare, may also provide a similar channel to patient populations.

In order to increase the FDA's already deep understanding of homeopathy and to foster clarity, the FDA could consider having a homeopathic expert on staff to serve as a liaison with the homeopathic community.

Q3. Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

Regarding health care providers, the breadth of licensed and certified providers and their patients who safely use homeopathic products have been well served for many decades. This service is underpinned by the robust educational standards of training, licensing and certifying bodies in homeopathic education, and their professional development symposia and literature. Licensing and certification boards for the practice of homeopathy have express standards of ethics and informed consent for the education of their clients/patients. It assures the knowledge to make informed decisions. It assures quality care.

Consumer educational outreach is the focus of the National Center for Homeopathy, an IHPC member organization, whose 5000 plus members are informed via newsletter, magazine, webinars and annual conferences. Media articles on

homeopathic self care are published in reputable wellness journals, such as Mothering Magazine and Yoga Journal. Homeopathic organizations and product manufacturers also provide education and online tools to prepare consumers to make informed choices about homeopathic products for self-limiting conditions. Even before the recent new world of consumer-driven health care, our industry has been educating consumers so they can make better-informed decisions.

IHPC's member organizations that represent providers and consumers of homeopathic products are vigilant in ensuring that consumers have safe and clearly identified homeopathic products to choose for their health care needs and access to the providers of their choice. In the end, safe, effective choices for healthcare providers and their patients are about assuring quality. Quality products. Quality care. Quality of life.

Thank you for your attention.

¹ Mintel Executive Summary report, March 2013 “Homeopathic and Herbal Remedies”

² “The Use of Complementary and Alternative Medicine in the United States” NCCAM December 2008
<https://nccih.nih.gov/sites/nccam.nih.gov/files/camuse.pdf>

³ “Complementary and Alternative Medicine Use Among Elderly Persons: One-Year Analysis of a Blue Shield Medicare Supplement” John A. Astin, Kenneth R. Pelletier, Ariane Marie and William L. Haskell Stanford Center for Research in Disease Prevention, Stanford University School of Medicine, Palo Alto, California. University of Southern California, School of Medicine, Los Angeles. Journal of Gerontology: Medical Sciences 2000. Vol. 55A. No. 1. M4-M9

⁴ North American Homeopathic Patient Survey 2014” American Medical College of Homeopathy, Dept of Research, Todd Rowe, MD, MD(H), CCH, Dht. <http://www.amcofh.org/sites/default/files/2014%20Homeopathic%20Patient%20Survey%20Results%20-%20Summary.pdf>