INTEGRATIVE HEALTH POLICY CONSORTIUM

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

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

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.

Prior to joining IHPC as Executive Director, I worked in national sales and marketing with several homeopathic manufacturing companies. I interacted with thousands of licensed practitioners who used homeopathic products for their patients, regarding product promotion 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.

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

Positive consumer attitudes can be seen through quantity and frequency of use. Homeopathic products accounted for 8.7% of $2.9 billion out of pocket CAM costs for American adults in 2007 according to the CDC.[1] A 2008 NCCAM survey listed homeopathy in the top 10 most utilized CAM therapies.[2] 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 options.[3] A 2014 survey of homeopathic patients noted efficacy and safety as the top two 'best liked' attributes of homeopathy.[4]

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 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.

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[1] "Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007" by Richard L. Nahin, Ph.D., M.P.H., National Institutes of Health; Patricia M. Barnes, M.A.; Barbara J. Stussman, B.A.; and Barbara Bloom, M.P.A., Division of Health Interview Statistics Pg 3 http://www.cdc.gov/nchs/data/nhsr/nhsr018.pdf

[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,1 Kenneth R. Pelletier,1 Ariane Marie,2 and William L. Haskell1 '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

IHPC recognizes that the manufacturing, labeling, marketing and sales of homeopathic products have been subject to FDA guidance and compliance since 1938, and that manufacturers must register with the FDA and are subject to FDA inspections.

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 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.

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
- 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 usage of these products in a clinical or therapeutic setting. IHPC's consumer-based site, CoverMyCare, may also provide a similar channel to patient populations.

Q8. Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?

The breadth of licensed and certified providers and their patients who use homeopathic products have been well served for many decades 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.

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. 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.

Thank you for your attention.