

Statement to FDA re: “Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework after a Quarter-Century.” April 21–22, 2015

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Credentials:

I am a full time attending physician at a tertiary academic teaching hospital, Ann & Robert H. Lurie Children’s Hospital in Chicago, and am on faculty at Northwestern University Feinberg School of Medicine. I am also board certified in Integrative Medicine (American board of Physician Specialties), Medical Acupuncture (American board of Medical Acupuncture), and a diplomate of the CEDH (Center for Education & Development of Homeopathy) which is a teaching organization active in the U.S. and over 20 countries around the world.

What led me to Homeopathy:

During my tenure as director of Pediatric Pulmonary Medicine and Cystic Fibrosis Center at two tertiary care teaching hospitals in Chicago in the 1990’s, I was intrigued by the idea of treating asthma by more natural means such as nutrition, acupuncture, and other Complementary & Alternative modalities (CAM) that are in use by some other cultures around the world. This was more pressing as patients as well as medical students were asking these questions.

I first turned to acupuncture. After formal medical acupuncture training in 1987, I was integrating acupuncture into my practice and discovered that yes, there are other ways to help treat asthma as well as other pulmonary diseases beyond drugs alone. I also knew that even within CAM modalities, there was more than one method that was useful. This led me to homeopathy.

My experience with homeopathy:

What was attractive about homeopathy was its inherent safety unlike herbal supplements. My use of homeopathy does not interfere with standard of care practice. For example, for my patients who seek integrative medicine for asthma, I prescribe all the standard drugs and may add homeopathic medicines to lessen the intensity of the symptoms, prevent triggers or alleviate the comorbid conditions. The goal I have with my patients is to decrease their reliance on drugs.

I also found homeopathy to be valuable for medical conditions where we have no effective treatment: For example, I had great results with homeopathic medicines to relieve persistent whooping cough (during paroxysmal stage), a cough that is notoriously unresponsive to inhalers, steroids or cough suppressants. Parents are extremely relieved and

grateful to see cessation of their child's cough. Recurrent croup prevention is another common indication for me to add homeopathic medicines.

Patients' attitudes toward homeopathy:

When I have suggested trying a homeopathic medicines for my pediatric patient, parents are almost always willing to use it as I provide them information on what homeopathy is, how it is made, for what purpose we would use it and its limitations. Some examples of my patient's parents comments include: "I can't believe those small pellets are so powerful", "it worked so well I want to take homeopathic for myself, for my other child..." Etc.

I often have patients seeking consultation from me specifically because they know I use homeopathy. I now find it personally unethical to not offer homeopathic medicine in situations where I think it may be appropriate and helpful.

Now I want to address the specific questions:

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

Many health care providers are unfamiliar with homeopathy and confuse it with herbal supplements. To make matters worse, there are products labeled "homeopathic" that are being sold, but have herbal or other botanicals mixed in. This is a problem as herbs or botanicals can have side effects. Consumers also need to know that they need to seek guidance from a homeopathic practitioner for chronic medical conditions.

What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of homeopathic drug products (HDPs)?

They need to have a consulting group from various organizations: for example, the Homeopathic Pharmacopoeia Convention of the United States (HPCUS); major homeopathy educational organizations such as CEDH (Center for Education & Development of Homeopathy), AIH (American Institute of Homeopathy); and also industries like Boiron, the largest manufacturer of homeopathic products in the world.

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic? If not, what information, including, for example, information in labeling, would allow consumers and health care

providers to be better informed about products labeled as homeopathic?

Physicians are not well informed at all about homeopathic medicines as it is not routinely taught during their training. For consumers, certain reliable brands do provide basic information about how and when to use a homeopathic, but they may not know which brand is reliable and this is an issue as there are products labeled “homeopathic” but are in fact not pure homeopathic.

Information in labeling should be no different from other OTC products. Any product that is a mixture of homeopathic with non-homeopathic ingredients should not be labeled “homeopathic” as this is misleading for the consumer.

Closing statement:

From my experience of using homeopathic medicines, I can attest to the fact that homeopathics are not just safe but offer extremely valuable therapeutic option for a wide range of clinical problems. It is one of the most widely used complementary/alternative modalities in the world. Fortunately in the United States we have regulatory agencies to assure good quality of medicines including homeopathic medicines which increasing number of physicians and consumers are finding to be a valuable complement to their medical care.