

Statement: public hearing, “Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century.”

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Background

I am a board certified pediatrician practicing Pediatric Integrative Medicine at the Raby Institute for Integrative Medicine at Northwestern, LLC in Chicago. Previously I was associate professor of pediatrics at Loyola University medical center. At Loyola I was director of the Pediatric Integrative Medicine Program, medical director of pediatric nutrition and also director for the Pediatric Cystic Fibrosis Center. For the past 15 years I have been medical director of the Easter Seals DuPage Feeding Clinic. Practicing Integrative medicine for nearly 20 years I am board certified in Integrative medicine through the American Board of Integrative Medicine (ABloM), American Board of Integrative and Holistic Medicine (ABIHM) and Medical Acupuncture through the American Board of Medical Acupuncture (DABMA). My formal training has also included: mind/body medicine at the Harvard Mind/Body Institute; medical hypnosis through the American Society of Clinical Hypnosis and the Society of Behavioral and Developmental Pediatrics; functional medicine through the Institute for Functional Medicine;

My formal homeopathy training was through coursework sponsored by the American Institute of Homeopathy followed by a more extensive program through the Center for Education and Development of Clinical Homeopathy (CEDH - *A physician based homeopathic educational organization teaching courses in Clinical Homeopathy worldwide in over 20 countries. Over 1000 physicians have been taught through the CEDH since 2005*). I am a senior teacher in the CEDH physician training program and been teaching homeopathy through this program since 2008.

I have published in the area of integrative medicine: State of the Art Review article on CAM (*Pediatric Pulmonology 2011*) and a chapter on Clinical homeopathy in a forthcoming Naturopathic textbook (*The Foundations of Naturopathic Medicine – in press*) chapter on use of CAM for Parasomnias (2013); and co-editor of a book Nutrition in Pediatric Pulmonary Disease (2014). I have also lectured regionally, nationally and internationally on various topics pertaining to integrative medicine including homeopathy.

Role of Homeopathic Medicine in my practice

As an Integrative Medicine practitioner, an emphasis in my approach is education with a goal to establish improved diet and lifestyle. Other treatment interventions may include appropriate subspecialty referrals, pharmaceuticals, mind/body interventions, supplements and/or herbs and homeopathy; all based upon my knowledge and experience as what (combination) would be the most helpful. Homeopathy has come to play a major role in my treatment regimens particularly as I have gained experience in its use. It has proved to be exceptionally versatile and efficacious for many medical problems both simple and more complex. Nearly 80% of my patients receive a homeopathic medicine as part of their regimen.

Homeopathic medicines on the whole has played and invaluable role in my practice and has been exceptionally helpful for my patients. An important component of homeopathy is its feature of safety and lack of drug interactions, especially pertinent in young children. To me, FDA regulation guided by the HPCUS (Homoeopathic Pharmacopoeia Convention of the United States) is an important and reassuring aspect of ensuring proper guidelines in the manufacturing of homeopathic medicines.

Responses to Questions posed for this proceeding

(I feel capable of responding to these 3 questions):

Q#1: What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

A few patients (parents) will consult with me specifically because I use homeopathy in my practice. They have knowledge of it, have used it previously and prefer it over other interventions. However the majority of patients (and parents) that I encounter have no understanding of what homeopathy is and often confuse it with herbal medicine. Once it is explained, the great majority are very open to it. Many receive good to excellent results with homeopathy. With greater understanding they begin to rely on it for (self-care) acute self-limiting issues as well as seeking out (my) recommendations for other chronic or complex problems that they encounter.

My interaction with conventionally trained medical practitioners either through one-to-one contact or through lectures given (usually via grand rounds) has also revealed a lack of knowledge of homeopathy – what it is, how it works, safety issues and the supportive evidence. Once explained many I have encountered have been quite accepting of it. This is especially true for the younger practitioners. I have even prescribed homeopathic medicines (documented in the chart) for inpatient hospital care (though had to be obtained by patients as not on formulary) with acceptance of the various managing physicians.

Q#2: 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)?

The Primary source should be the HPUS as this organization is responsible for establishing standards for manufacturing with regards to safety and development of monographs with respect to the indications.

Other adjunct sources could include the American Association of Homeopathic Pharmacists, the American Institute of Homeopathy and the CEDH*. These organizations consist of pharmacist and medical practitioners who practice and are versed in the everyday use of homeopathic medicines.

**CEDH (Center of Education & Development of Homeopathy): A physician based homeopathic educational organization teaching courses in Clinical Homeopathy worldwide (over 20 countries). Clinical Homeopathy is designed for practicing physicians and can be incorporated in*

a busy practice setting as well as in the hospital. Over 1000 physicians in the US have been taught through the CEDH since 2005.

Q#8: 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?

An increasing number of health care practitioners are becoming more aware and therefore more open to its use by their patients. However, the majority of health care practitioners have little understanding of homeopathy (what it is, safety issues and regulation) with misperceptions (often confusing homeopathy with herbs).

For the consumer homeopathy has a definite place for symptomatic self-treatment of limited acute illnesses. Homeopathic drugs should be labeled as such along with cautions to see a health care professional should there be concerning changes in the condition or problem persist after a designated number of days. The labeling should be no different than from other over the counter/nonprescription medicines.

Prior to my coming to this meeting I reviewed several homeopathic products of well-known companies designated for acute self-limiting problems and found the labelling to be appropriately informative. In my opinion the current process of labeling is quite adequate and simply in need of ongoing monitoring and enforcement.