

**HANP Testimony to Homeopathic Product Regulation:
Evaluating FDA’s Regulatory Framework After a Quarter-Century Hearing, April 20-21,
2015
Docket No. FDA-2015-N-0540**

**Testimony by the Homeopathic Academy of Naturopathic Physicians
By Lisa Amerine, ND, DHANP
April 20, 2015**

Introduction:

Thank you for the opportunity to speak today at this public hearing. My name is Lisa Amerine; I am a Naturopathic Physician and am board certified by the Homeopathic Academy of Naturopathic Physician (HANP) with diplomate status in Homeopathy. Since a very young age my life has been committed to homeopathy and for the past 11 years I have maintained a highly successful private practice exclusively dedicated to Homeopathy in Lafayette, Colorado. Currently I also sit on the board for the HANP and I am the HANP House of Delegates representative for the American Association of Naturopathic Physicians (AANP), in which I represent the specialty field of homeopathy. I am also a co-leader on what is known as the Materia Medica Pura Project, a collective 30,000 + hour project with the purpose of collecting any existing literature on each homeopathic medicine. This literature includes any proving publications, toxicology reports, and cured cases for every homeopathic medicine. This information is then compiled in one document, the “Materia Medica Pura” and serves as the most up to date information for homeopathic medicines. This on-going project insures that there is up to date and correctly referenced literature on every individual homeopathic medicine.

The Homeopathic Academy of Naturopathic physicians’ is a specialty field recognized with in Naturopathic Medicine. Naturopathic physicians lead our communities through out the US in natural health care. Physicians who specialize in homeopathy go over and beyond the already vigorous training received in homeopathy at naturopathic medical schools by undergoing further training in homeopathy. Upon completion of this process, which includes an additional board examination, they are awarded diplomate status. Practicing homeopathy is a true specialty in medicine and the diplomate status recognition rewards and acknowledges Physicians who have worked to achieve this status, setting them apart from any others who may be practicing homeopathy, thus Naturopathic Physicians with diplomate status in homeopathy are among the leading experts in homeopathy in the United States. The HANP also serves to further the excellence and success of homeopathy by providing continuing education that further sharpens the skill of not only the Diplomates but by physicians aspiring towards diplomat status. We also are committed to being an education resource for health care providers and the general public who may have questions regarding homeopathy.

Recommendations

HANP would like to respond to three particular questions posed by the FDA.

Question 1. What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

The licensed homeopathic medical professionals have a vast knowledge of the *Materia Medica*, which lists the properties of the medicines we use. This literature, when employed in conjunction with consideration of the unique totality of symptoms with which a patient presents, forms the basis for the accurate prescription of homeopathic medicines. Well-trained homeopaths will only prescribe based on these principles. Therefore, medicines labeled as homeopathic, regardless of their source – including human drug and biological products – will not be prescribed unless there is the proper literature found in the monographs to support the prescription. The homeopathic health care professionals, especially those with diplomate status have very busy practices. Frequently we will train our patients regarding basic homeopathic medicines that they can purchase over the counter to take care of simple non-dangerous conditions like an acute cold. The consumers love this because they can try some basic things at home that are often very effective, safe and inexpensive to use. The health care provider likes this because it empowers the patient and leaves time for the physician to treat more serious conditions.

Question 4. Are there areas of the current CPG that could benefit from additional clarity? If so, please explain.

The HANP serves to further the excellence in homeopathy. We do this by providing resources and continuing education for providers and the community. In an attempt to further the excellence in homeopathy the HANP believes that FDA's CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed, needs some clarification.

For example:

1. CPG Sec. 400.400 definition 2 states, “Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.” While the definition is clear, there is a loop hole that many products are taking advantage of. This loop hole provides manufactures the opportunity to put a substance in the “inactive” category while leaving the list in the active ingredients listed as HPUS homeopathic remedies that meets definition 2 per the FDA document. These inactive ingredients added are not always stabilizers but often a dietary supplement such as tea tree oil or aloe vera. This allows for manufactures to put products on the market and make an OTC drug claim when otherwise the product would be limited to a dietary supplement status. When this is done the product should not be considered a homeopathic drug, nor should be allowed to be marketed as such. The HANP believes this issue is a good example of where

additional clarification could be helpful.

Question 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?]

The Homeopathic Academy of Naturopathic Physicians serves to provide quality education not only to other health care professionals but also to the lay public. Physicians, in particular, those with diplomate status are on the front lines of homeopathic health care and daily field questions from the consumer and from other health care providers regarding homeopathic products. These experts, because of their extensive knowledge of homeopathy can easily provide information regarding products, which are labeled as homeopathic and comment knowledgably as to their efficacy and safety. There are many health care providers and consumers who know very little about homeopathy. Our goal with in the HANP is to be able to provide these people with quality information that can help guide them. Therefore the suggestion of the HANP is to maintain a team within the FDA that consists of experts in drug regulation, representative(s) of the American Association of Homeopathic Pharmacists (AAHP) and the Homeopathic Pharmacopoeia Convention of the United States as well as an expert clinical physician with diplomate status who is on the front lines of homeopathic health care and who is also committed to providing quality education to the public. A team comprised of such experts in the field is vital and will be able to help clarify any questions as to homeopathic labeling and most importantly help to ensure the safety of the consumer.

In closing today I would like to end with a story, 150 Years ago on a journey across the country on the Oregon Trail a group of explorers got stuck in the Cascade Mountains due to bad weather. They had to abandon their wagons and finish the trip on foot. They chose to bury their most valuable possessions so they could return to them when conditions were more favorable. Amongst one of those things buried was a small book written by a homeopathic physician, Constantine Hering, titled "*The Homoeopathic Domestic Physician*" and a small homeopathic medicine kit. For these people and people since then, homeopathic medicines have been effective and safe to use at home if their condition was intense enough to need attention but not severe enough for the care of a physician. There are many books such as this book that still guide the consumers in the lay public about making informed decisions regarding drug products labeled as homeopathic. Because homeopathy is safe and it is fairly easy for the consumer to understand what to buy should they have a minor health ailment, the HANP highly encourages that these homeopathic medicines continue to be available over the counter because they are so effective for helping improve the health of the population.

Thank you for your time and consideration