

# Spotlight on Homeopathic Regulation - And How You Can Help



By Stephen Barrett — February 9, 2018



The FDA has proposed new rules for homeopathic product labeling. Do these constitute a historic strategy to tame the homeopathic marketplace? Or will they merely perpetuate the *status quo*.

Homeopathy is nonsense. Its fanciful "law of similars" asserts that substances that can cause symptoms in healthy people will treat health problems that produce such symptoms. Its fanciful "law of infinitesimals" asserts that the greater the dilution, the more potent the product and that even products so dilute that they contain no molecules of the original ingredient can be potent drugs.

Despite all this, a provision of the 1938 Federal Food, Drug, and Cosmetic Act (FDC Act) recognizes all substances included in the *Homeopathic Pharmacopeia of the United States* as drugs subject to FDA regulation. But the FDA has paid very little attention to homeopathic wrongdoing.

Federal laws and regulations require that drugs marketed in interstate commerce be approved by the FDA as safe and effective for their intended purposes. No homeopathic product has ever been FDA-approved, and there is no logical reason to believe that any ever will be. In fact, the vast majority of substances in the *Homeopathic Pharmacopoeia* have never been tested.

The current version of the *Pharmacopeia* contains 1-page "monographs" that describe physical characteristics and manufacturing procedures for about 1,300 substances of plant, animal, and mineral origin. The monographs contain no information about how the products should be used. Their intended uses are determined by manufacturers and prescribers, based mainly on the results of "provings," most of which were conducted more than a century ago. During "provings," people record what they feel during a predetermined period time after swallowing a substance.

More than 100,000 symptoms noted during provings have been compiled into books called “*materia medica*” that are used to guide remedy formulation and selection.

Although all drugs marketed in interstate commerce are within the FDA's scope, the agency did not adopt a formal homeopathic policy for nearly fifty years. From 1938 onward, the FDA essentially relied on informal "understandings" between the agency and homeopathic industry leaders. The 1962 Kefauver-Harris amendments to the FDC Act requires that all drugs be effective as well as safe. This law triggered an extensive review of prescription drugs that was followed by an extensive review of over-the-counter (nonprescription) ingredients. However, homeopathic products were exempted from these reviews.

In the 1980s, discussions between members of the FDA's Compliance Office and industry leaders led to the development of a formal policy. The resultant Compliance Policy Guide, implemented in 1990, permits homeopathic products to be marketed over the counter for "self-limiting disease conditions amenable to self-diagnosis (of symptoms)."

While the discussions were taking place, the FDA's chief enforcement official told me that if the agency required all homeopathic products to meet drug-approval standards, none could be legally marketed, but Congress would probably rescue them. I believe that the negotiated policy guide was intended to protect the public against homeopathy's most serious dangers while protecting the FDA from political controversy. Unfortunately, it also opened the floodgates to thousands of products that were falsely claimed to provide symptomatic relief.

Since the original policy guide was issued, the FDA has taken about 60 regulatory actions related to homeopathic products. Most have been warning letters to companies that claimed that products were effective against serious diseases or equivalent to approved vaccines. There have also been a few recalls of products that were found to contain toxic ingredients.

In December 2017, the FDA proposed new "risk-based guidelines" that give enforcement priority to homeopathic products with the greatest potential risk to patients—those that are unsafe or are intended for the treatment of serious diseases. Major media outlets have headlined the proposal as a “crackdown” on homeopathy. But it is not. It merely spells out what the FDA has been doing since its compliance policy guidelines were issued—which is not enough.

### **Your Help Is Needed**

If the FDA really wants to protect consumers, it needs an enforcement policy that is so efficient that unsubstantiated claims can be deterred or quickly driven from the marketplace. The key strategies are to (a) limit the products to single-ingredients that strictly comply with the *Homeopathic Pharmacopeia* and (b) ban health claims and indications for use that have not been approved through the FDA's standard drug approval process. The only statements permissible in labeling should be the chemical name, the dilution, and that fact that the product is homeopathic. Products consistent with the *Pharmacopeia* could still be marketed, so consumers who want homeopathic products could still obtain them. But unapproved claims—including implied claims in product names—should be banned.

Armed with such a policy, the FDA, the FTC, and state attorney generals could efficiently demand

that Internet outlets (such as Amazon.com) and retail stores stop offering homeopathic products that make any efficacy claim.

The FDA has called for public comments until March 20, 2018, but might extend the date if there is public interest in doing so. If you agree with my suggested strategies, please visit [http://www.homeowatch.org/reg/fda\\_hearing\\_2015/comment.html](http://www.homeowatch.org/reg/fda_hearing_2015/comment.html) [1] for further details and submit a comment in your own words through the FDA comments page at <https://www.regulations.gov/document?D=FDA-2017-D-6580-0002> [2]

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