Safeguarding the Freedom to Choose
Homeopathy for All Americans

Americans for Homeopathy Choice: Our FDA Petition

A Briefing

Recent moves by the U.S. Food and Drug Administration (FDA) could deliver a potentially fatal one-two punch to homeopathy in America. A proposal put forth by the agency, if adopted, would seriously undermine trust in homeopathic medicine by deregulating its manufacture while simultaneously curtailing access through unwarranted bans on many products.

We believe that the way the FDA regulates homeopathy will also set the direction for its regulation of other alternative and complimentary treatments. So, at its base our concern is the freedom of all Americans to choose alternative treatments if they wish to.

Preserving the Right to Choose

To prevent the FDA from fatally undermining the right to choose homeopathic medicines, we at Americans for Homeopathy Choice have filed a petition with the agency explained in more detail below. We also want to make sure that the quality and purity of homeopathic medicines remains assured so that those taking them can do so with confidence.

Manufacturing Guidelines Not Replaced

The high quality and purity of homeopathic medicines which practitioners and users have come to expect under the current FDA guidelines could be compromised if the FDA adopts the new guidelines it proposed in December 2017. (Technically, such guidelines are called "guidance.") The guidelines would entirely eliminate current manufacturing standards without replacing them. That would open a giant regulatory loophole which could lead to poorly manufactured, improperly labeled and even fake products. That's why we say the FDA proposal is a deregulatory wolf in sheep's clothing. We don't believe this is what the FDA intended, but it is what would result.

Our Petition

By filing a Citizen Petition under the Administrative Procedure Act, Americans for Homeopathy Choice (AFHC) is forcing the FDA to reconsider the agency's proposed guidelines. Without our petition there would be nothing to impede the adoption of the guidelines. With our petition the FDA is obliged to slow down and respond to our proposals and concerns. In the petition we ask the FDA to do the following:

1. Form an FDA advisory committee on homeopathy made up of homeopathy professionals, academics and users to provide needed input into FDA policies and practices regarding homeopathy.

2. Withdraw the Draft Guidance on Drug Products Labeled as Homeopathic dated December 2017 which threatens to restrict severely the availability of homeopathic medicines and at the same time open up a giant regulatory loophole for unscrupulous, fly-by-night manufacturers.

3. Convert a slightly modified Compliance Policy Guidance (CPG) 400.400 which currently governs FDA actions on homeopathy from mere guidance into a regulation. This is the policy that has guided the agency since 1988 and resulted in high standards of quality assurance in the manufacture of homeopathic medicines even as choice and availability continues to grow. It has never been formally adopted as a regulation, making it vulnerable to the whims of changing administrations and FDA staff turnover. A regulation would essentially make it the law of the land.

   (One indication of those high standards can be found on the FDA's own website. Of the 23,682 recalls issued by the FDA in fiscal years 2016 through 2018, exactly seven were of homeopathic products. Compare that to 3,737 for drugs and 8,630 for medical devices during the same period. The data is through August 2018.)

4. If the FDA fails to grant this petition, AFHC requests a public hearing with the FDA before enacting its proposed new guidelines (referred to as Draft Guidance on Drug Products Labeled as Homeopathic dated December 2017).

What Safety Concerns?

The FDA claims that its proposed guidelines will address ongoing safety concerns. It is hard to understand what safety concerns the agency is referring to. Since the beginning of homeopathy more than 200 years ago, there has never been a single documented case of injury or death attributable to homeopathic medicines. This record stands in grim contrast to the more than 100,000 Americans who die each year from adverse reactions to pharmaceuticals, an estimate cited on FDA's own website.[1] Altogether between 2 and 4 million people sustained serious injuries including death from pharmaceuticals in the course of one year, an estimate based on the FDA's adverse reaction reporting system.[2]

All of the instances of concern the FDA cites in its proposal are for products that are not actually homeopathic and therefore improperly labeled. It follows that much of the impetus for the FDA's proposed new guidelines comes from improper labeling and not from the use of properly formulated and manufactured homeopathic medicines. The FDA already has ample authority under its current policies to take action on such labeling violations. This is a key reason we are urging the agency to withdraw its proposed new guidelines and turn its current policy called CPG 400.400 into a regulation.

A New Legal Limbo for All Homeopathic Medicines

Of particular concern is the FDA's proposal to move all homeopathic medicines into what the FDA calls a pre-approval process. This means that the FDA may at its discretion require any homeopathic medicine to be vetted through a New Drug Application (NDA). The agency may also withdraw or ban any such medicine at its discretion if the medicine has not been approved under the NDA process. Right now the number of homeopathic medicines that are approved under this process is zero. This puts homeopathic medicines already on the market into a legal limbo; they would technically be considered illegal until they complete the NDA.

We at Americans for Homeopathy Choice believe that requiring homeopathic medicines to undergo the NDA process would itself be illegal under the Food, Drug and Cosmetic Act. The Act provides an explicit evaluation process for homeopathic medicines separate from the NDA process. Once they are approved under that process, homeopathic medicines are listed in the Homeopathic Pharmacopoeia of the United States which is administered by the Homeopathic Pharmacopoeia Convention of the United States.

Read Our Petition for Yourself

To understand our concerns and responses in detail, read our petition to the FDA which you can find at the following link:

https://www.regulations.gov/document?D=FDA-2018-P-2962-0001

You can read the FDA's draft guidance at the following link:

https://homeopathychoice.org/wp-content/uploads/2017/11/FDA-Draft-Guidance-Dec-2017.pdf

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[1] U.S. Food and Drug Administration, "Preventable Adverse Drug Reactions: A Focus on Drug Interactions," U.S. Food and Drug Administration, March 6, 2018. https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm110632.htm

[2] Institute for Safe Medication Practices, *Monitoring FDA MedWatch Reports: Anticoagulants the Leading Reported Drug Risk in 2011* in "QuarterWatch," T. J. Moore, M. R. Cohen, and C. D. Furberg, eds. (Horsham, PA: Institute for Safe Medication Practices, May 2012), 11. https://www.ismp.org/quarterwatch/anticoagulants-reported-drug-risk

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