Five Answers to Commonly Asked Questions About Homeopathy and the FDA

We were very pleased to see that so many members of Congress have responded to their constituents regarding the U.S. Food and Drug Administration's (FDA) Draft Guidance on homeopathy. Americans for Homeopathy Choice has prepared this document in an effort to clarify statements made by these members in their responses. Many of those responses included language directly from FDA sources, language which is often inaccurate, incomplete and/or misleading. Here we correct the misleading impressions which the FDA has created in its documents on homeopathy.

Do the FDA's statements about the dangers of homeopathic teething medicines which contain belladonna stand up to scrutiny?

The FDA claims that homeopathic teething tablets for babies were somehow connected to serious side effects and even deaths. Doesn't that show that new guidelines for regulating homeopathic remedies are necessary?

No, new guidelines are not necessary. The FDA has the power to act when medicines of any kind cause serious previously unknown side effects and deaths. In this case the particular brand of teething tablets was voluntarily withdrawn and reformulated.

But, that's not the whole story. The teething remedy over which the FDA was so concerned contained so little of the active ingredient scopolamine (from the belladonna plant) that it would have been impossible for the remedy to cause the toxic reactions reported.

The results of the FDA's own testing showed that the highest amount of scopolamine in the teething remedies it tested was only 0.00039 milligrams (mg) of scopolamine. This is like taking a drop of water (50 mg) and dividing it into 128 thousand equal parts. One of those parts (or about 1 /1000 of 1 percent) is the amount of scopolamine the FDA claims it is concerned about.

For comparison, the FDA has already approved scopolamine as safe and effective for treating motion sickness. The dose is 0.4 mg. That dose is 1,025 times higher than the amount found in the teething tablets.

A parent would have to administer seven entire bottles of teething tablets to a baby in a short space of time just to reach the dose which the FDA already considers safe and effective for the treatment of motion sickness. This is merely a therapeutic level, not a toxic level.

This is a worst-case scenario since only one single tablet in an entire bottle that was tested was found to contain 0.00039 mg, the highest amount discovered. Most tablets contained undetectable amounts of scopolamine. It is worth noting that belladonna, the homeopathic remedy containing scopolamine, remains available today as there has been no specific showing that at homeopathic concentrations this substance is dangerous to anyone of any age.

While it is true that many substances found in homeopathic remedies can be toxic in high doses, homeopathic remedies—by definition—are made using extreme dilutions in which the concentration of any toxic substance is so small as to be unable to cause toxic effects in either adults or children. Any substance not properly diluted in accordance with the strict homeopathic definitions and guidelines found in the Homeopathic Pharmacopoeia of the US is not a homeopathic remedy.

If a manufacturer were ever to fail to dilute a homeopathic remedy properly and this led to a problem, the FDA already has the authority to take action under its current guidelines. Policing the quality and purity of homeopathic remedies has been and remains the proper role for the FDA.

Should homeopathic remedies be required to go through the FDA's New Drug Application process as is required for pharmaceuticals?

No, they should not. The New Drug Application (NDA) process is used by the FDA to regulate novel, potentially dangerous drugs containing pharmacologically active chemicals. The process requires thorough testing to prove both safety and effectiveness of new drugs.

Homeopathic remedies are inherently safe because of their extremely dilute formulas. They have a long history of safety without a single documented injury or death in 200 years of continuous use. These facts are recognized by the Food, Drug & Cosmetic Act and by FDA's current guidelines as reasons for exempting homeopathic remedies from the NDA process. In other words, since homeopathic remedies are safe, there are no risks with which to offset their benefits, and so homeopathy does not fit into the NDA process.

Unlike pharmaceuticals which act directly on the organs and physiological processes of the body, homeopathic remedies act indirectly by subtly eliciting the body's own healing response. As such homeopathic remedies are not drugs in the usual sense but belong in a separate category because of their inherent safety and unique mechanism of action. The FDA acknowledged this in 1972 saying, "Because of the uniqueness of homeopathic medicine, the [FDA] Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete."[1]

[1] 37 FR 9464, 9466 (May 11, 1972) See p.18 of the following PDF, 3rd column, item 25. http://api.fdsys.gov/link?collection=fr&volume=37&page=9464

NDA process is extremely expensive and rigorous and in all but rare cases is only undertaken on new pharmaceuticals that have been patented and thus offer the possibility of a financial return for the company seeking the approval. In the past the FDA has acknowledged that the NDA process was unnecessary for homeopathic remedies.

Homeopathic remedies are formulated using commonly available substances and therefore cannot be patented. Requiring an NDA for each homeopathic remedy would amount to a de facto permanent ban since no company seeking such an approval could ever obtain a patent that would allow it to recoup its investment.

How does the FDA currently regulate homeopathy?

Since 1988 the FDA has regulated homeopathy according to guidelines formally known as Compliance Policy Guide (CPG) 400.400. These guidelines established clear conditions under which homeopathic remedies may be marketed. The guidelines dictate that homeopathic remedies must meet the manufacturing standards set out in the Homeopathic Pharmacopoeia of the US (HPUS) which is recognized by law as the official listing of approved homeopathic remedies. Remedies formulated in accordance with the standards outlined in this compendium typically have the letters HPUS on their labels.

In order for a proposed remedy to be accepted into the HPUS, the remedy must go through provings[2] under the direction of the Homeopathic Pharmacopoeia Convention which oversees the HPUS. The CPG 400.400 also states that the potencies of homeopathic drugs are specified in terms of dilution and must only contain diluents commonly used in homeopathic remedies. Suitable diluents include alcohol, purified water, and/or glycerin.

Thus, through CPG 400.400 the FDA maintains oversight of both the manufacturing and labeling of homeopathic products. This oversight regime has resulted in 30 years of effective policing of homeopathic remedies.

Why does Americans for Homeopathy Choice object to the FDA's "risk-based approach" outlined in its recently released proposed guidelines ("Draft Guidance") for regulating homeopathic remedies?

A plain text reading of the FDA's proposed risk-based approach, as outlined in its Draft Guidance regarding homeopathic remedies, indicates that under this new approach every single homeopathic remedy currently on the market—whether over-the-counter or

[2] According to the New York School of Homeopathy, "A proving is conducted on volunteers who are in a reasonable state of health (provers), and who do not know what substance it is they are taking. Doses are repeated until provers start to experience symptoms of a change in state. The provers record everything they experience, whether physical, emotional, mental, or even spiritual, as long as the change in state persists. At the end of the proving all the records are compared to find the physical symptoms, states of mind, feelings, and experiences that the provers have had in common, which can reasonably be attributed to the emerging signature resonance of the substance."

prescription—would be considered "unapproved" and therefore technically illegal. This means that any homeopathic remedy could be banned at any time by order of the FDA. It is our belief supported by legal counsel that such a move would contravene the approval process that Congress has already established for homeopathy in the Food, Drug & Cosmetic Act.

If the FDA is permitted to finalize its Draft Guidance on Homeopathy, any homeopathic remedy which is withdrawn from the market by the FDA could not return unless it undergoes the agency's New Drug Application (NDA) process. This process can cost tens of millions of dollars and take many years to complete. But, since homeopathic remedies cannot be patented—they consist of commonly available substances—there would be no incentive for any company to pay for such a process. The requirement that a homeopathic remedy undergo the NDA process would be a de facto permanent ban.

The legal position of Americans for Homeopathy Choice is that if the FDA were to reclassify all homeopathic remedies as "unapproved," the agency would be violating the Food, Drug & Cosmetic Act. The act already provides a process by which homeopathic remedies are approved for inclusion in the Homeopathic Pharmacopoeia of the US which is administered by the Homeopathic Pharmacopoeia Convention of the United States. In our view declaring homeopathic remedies technically illegal would be illegal itself and would result in a vigorous court challenge.

On March 29, 2018, Americans for Homeopathy Choice heard from FDA officials during a face-to-face meeting that the FDA would not seek to withdraw the "vast majority" of homeopathic remedies from the market. However, there is nothing that we see in the Draft Guidance that would prevent the FDA from banning every homeopathic remedy. This is especially worrisome as turnover at the FDA will eventually result in new people overseeing the regulation of homeopathic remedies who may not abide by this informal understanding.

Why the FDA is now focusing on homeopathic remedies with their enviable safety record is puzzling, especially in the context of its other responsibilities. According to an estimate based on FDA's own adverse reaction reporting system in one year between 2 and 4 million people sustained serious injuries including death from taking pharmaceutical prescriptions.[3] Why is the FDA diverting limited enforcement resources for the review of inherently safe homeopathic medicines when it has its hands full with millions of adverse reactions and more than 100,000 deaths each year from pharmaceuticals, an estimate cited on FDA's own website?[4]

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[3] 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

[4] 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

Homeopathic remedies are non-toxic and inherently safe without a single documented death or injury in 200 years of use. A set of remedies with such a safety record does not require the type of risk-based approach to policing proposed by the FDA**.**

Why is a homeopathic advisory committee at the FDA a good idea?

According to the FDA, "Advisory committees provide FDA with independent advice from outside experts on issues related to human and veterinary drugs, vaccines and other biological products, medical devices, and food." It is clear that the FDA could use additional expertise concerning homeopathy in order to help it make better decisions concerning its regulation.

Such committees provide advice to the agency on important technical and policy questions though all final decisions rest with the FDA. FDA currently list 50 advisory committees. Because of the unique nature of the homeopathic system, professionals who are educated and skilled in the use of homeopathy should be a part of the committee. We believe regular users of homeopathy should also be included since a significant portion of homeopathic sales are over-the-counter.

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