Answers to Commonly Asked Questions About Homeopathy and the FDA

Updated December 2020

We are 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many members of Congress have responded to their constituents regarding the U.S. Food and Drug Administration's (FDA) Draft Guidance on homeopathy.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.

1. The FDA's proposed approach "prioritizes enforcement and regulatory actions involving unapproved drug products labeled as homeopathic that pose the greatest risk to patients" and the agency has stated that "many" homeopathic products will fall outside the risk-based categories described in the Draft Guidance. What is the problem with this approach?

The FDA will undoubtedly tell you that it is reacting to many instances in which homeopathic products appeared to cause harm. But, a review by Americans for Homeopathy Choice reveals no instance in FDA reports or data in which harm was caused by a PROPERLY manufactured and labeled homeopathic medicine which is by definition nontoxic. Yet, the FDA seeks the authority not just to pull specific defective products from the marketplace, but entire medicines across the board from every manufacturer, even from those manufacturers who are producing and labeling these nontoxic products properly!

How did we come to this conclusion? An analysis by our legal counsel confirmed the plain meaning of the language of the Draft Guidance which will allow the agency to:

1. Reclassify all homeopathic drugs as unapproved "new drugs" even though most pre-date the 1938 Food, Drug and Cosmetic Act.
2. Use that reclassification to treat all homeopathic drugs as "illegal."
3. Having decided to treat all homeopathic drugs as illegal, the FDA may withdraw any or all of them without notice and without any justification other than that they are illegal.

As confirmation of this analysis, the agency has publicly named specific popular, generic name homeopathic medicines such as Nux vomica and Aconitum napellus asserting that these medicines have "potentially significant safety concerns" and may be subject to enforcement action. Yet, any safety concerns are negated when homeopathic medicines

are properly manufactured and labeled. In other words, their highly diluted nature makes them nontoxic.

We would like the FDA to distinguish its claim that it may withdraw PROPERLY manufactured and labeled generic name homeopathic medicines across all manufacturers from the agency's authority to withdraw manufacturer-branded, distributor-branded, and store-branded homeopathic products or lots thereof which are IMPROPERLY called "homeopathic" on the label due either to manufacturing problems or improper labeling. Improperly manufactured and/or labeled products claiming to be homeopathic may, in fact, pose a danger to the public precisely because they do not meet homeopathic standards of dilution, administration and/or purity.

The legal position of Americans for Homeopathy Choice is that if the FDA were to reclassify all homeopathic medicines as "unapproved," the agency would be violating the Food, Drug and Cosmetic Act. The act already provides a process by which homeopathic medicines are approved for inclusion in the Homœopathic Pharmacopœia of the United States (HPUS). In our view treating homeopathic medicines as 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 medicines from the market. However, there is nothing that we see in the Draft Guidance that would prevent the FDA from removing every homeopathic medicine from the marketplace. This is especially worrisome as turnover at the FDA will eventually result in new people overseeing the regulation of homeopathic medicines, and those new people may not abide by this informal understanding.

It is puzzling that the FDA is now focusing on homeopathic medicines which have an enviable safety record, especially in the context of the agency's other responsibilities. According to an estimate based on FDA's own Adverse Event Reporting System, in one year between 2 and 4 million people sustained serious injuries including death from taking pharmaceutical prescriptions.[1] 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? [2]

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[1] 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

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

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

It is important to understand that the FDA never undertook an investigation to ascertain whether infants purported to have taken teething tablets containing Belladonna and who suffered adverse reactions were also on other medications or had other underlying causes that led to those reactions and deaths.

In fact, the FDA already has the authority to act when it believes medicines of any kind have caused serious previously unknown side-effects and deaths. That authority includes the right to conduct investigations into reports made to the agency and to others.

The FDA did perform a laboratory analysis of the teething tablets which showed that the highest amount of scopolamine (which is derived from the Belladonna plant) in the teething medicines 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 standard dose is 0.4 mg. That dose is 1,025 times higher than the amount found in the teething tablets.

Teething tablets with the amount of scopolamine found by the FDA's tests would have been nontoxic to anyone taking it including babies. Even so, the manufacturers of teething tablets voluntarily withdrew the tablets and reformulated them without Belladonna.

It would take seven entire bottles of teething tablets to equal the dose in one motion sickness tablet, a dose which the FDA considers safe and effective. This is merely a therapeutic level, not a toxic level.

And, it 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 medicine 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 both pharmaceuticals and homeopathic medicines can be toxic, homeopathic medicines—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. This is not always the case with pharmaceuticals which often have toxic side-effects in many individuals.

To be clear: Any substance not properly diluted in accordance with the strict homeopathic definitions and guidelines found in the Homœopathic Pharmacopœia of the United States is not a homeopathic medicine.

If a manufacturer were ever to fail to dilute a homeopathic medicine properly and this led to a problem, the FDA already has the authority to take action to enforce Current Good Manufacturing Practices. Policing the quality and purity of homeopathic medicines has been and remains the proper role for the FDA.

3. Should homeopathic medicines 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 was designed for and is used by the FDA to regulate novel, potentially dangerous drugs containing pharmacologically active chemicals. Conversely, homeopathic medicines are nontoxic and 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 and Cosmetic Act and by the FDA's previous guidelines as reasons for creating an approval process for homeopathic medicines separate from the NDA process.

Homeopathic medicines are generally individualized to the patients—that is, two patients presenting the same conventional diagnosis are often given *different* homeopathic medicines depending on their total health picture in order to treat the whole person and not just the identified condition. Since an NDA by definition requires that all patients in the experimental group of a clinical trial for a particular drug be given that drug, homeopathy does not fit the NDA process. Instead, homeopathic medicines, which are designated as drugs in the Food, Drug, and Cosmetic Act, are subject to the provisions of the Homœopathic Pharmacopœia of the United States through which they are evaluated for safety and efficacy. To see a comparison chart of the approval and regulatory frameworks for homeopathic medicines and pharmaceuticals, click here.

Unlike pharmaceuticals which act directly on the organs and physiological processes of the body, homeopathic medicines act indirectly by subtly eliciting the body's own healing response. As such, homeopathic medicines 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."[3]

Homeopathic medicines are formulated using commonly available substances and therefore cannot be patented. Requiring an NDA for each homeopathic medicine would amount to a de facto permanent removal from the marketplace since no company seeking such an approval could ever obtain a patent that would allow it to recoup its investment. That means consumers could lose access to a wide array of these inherently safe, nontoxic, effective and affordable medicines.

4. How does the FDA currently regulate homeopathy?

Homeopathic medicines are designated as drugs in the Food, Drug, and Cosmetic Act and subject to the provisions of the Homœopathic Pharmacopœia of the United States (HPUS).

Federal law recognizes the HPUS as the official listing of approved homeopathic medicines. To be eligible for inclusion in the HPUS, the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS) must have determined that the drug is 1) safe and effective; 2) has been prepared according to the specifications of the General Pharmacy and relevant sections of the HPUS; 3) has been submitted with documentation in an approved format; and 4) has demonstrated efficacy in clinical provings,[4] clinical trials or therapeutic experience.

As with any drug manufacturer, the FDA is responsible for inspecting homeopathic production facilities to ensure that manufacturing and labeling standards are met as set forth in the Code of Federal Regulations.

Over the last 30 years the agency has done an excellent job of ensuring the quality and purity of homeopathic products under its Compliance Policy Guide (CPG) 400.400 which served as a manufacturer's guidebook for adhering to the applicable regulations.

Given this, it is puzzling that the agency decided to repeal its highly successful CPG 400.400 and set homeopathy adrift on October 25, 2019 without any concrete guidance. While it is understood that as an industry grows, an agency may need to issue a new guidance to clarify existing policy, the proposed guidance takes a completely different approach. Not only does it target for enforcement action medicines many Americans rely on for their health, but it also removes all of the clear guidance included in

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[3] 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

[4] 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."

CPG 400.400 to help manufacturers understand what they SHOULD do in order to adhere to the law and meet the FDA's expectations for quality and purity. This sudden shift has created a tremendous amount of concern and uncertainty for both manufacturers and consumers.

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