FDA's Proposed Changes to Homeopathy Regulation

A Briefing

After almost 30 years of regulating inherently safe homeopathic medicines under its current guidelines, the U.S. Food and Drug Administration (FDA) proposed new guidelines. In December 2017 the agency issued a draft of its proposed new "guidance." "Guidance" is the word the FDA uses to describe guidelines which characterize how the FDA expects to regulate a particular industry under its jurisdiction.

What "Guidance" Means

Guidance documents do not carry the force of law as regulations do. The FDA states that it is neither bound by what it says in its guidance nor are the standards outlined in the guidance enforceable in court. The FDA reserves the right to follow all, none or some of the guidance in any particular situation. As a general rule, the FDA tends to adhere to the guidance it issues fairly closely.

Current Homeopathy Regulation

Currently, homeopathy in the United States is governed under the Food, Drug and Cosmetic Act of 1938 which specifies homeopathy as a distinct form of medicine and provides a method for obtaining approval of new medicines.

Homeopathy is also governed under guidance issued by the FDA in 1988 referred to as Compliance Policy Guide (CPG) 400.400. This guidance established clear conditions under which homeopathic medicines may be marketed. The guidance dictates that those medicines must meet the quality and purity standards set out in the Homeopathic Pharmacopoeia of the United States (HPUS) which is recognized by law as the official listing of approved homeopathic medicines. This list now numbers over 1300. Homeopathic medicines formulated in accordance with the standards outlined in this compendium typically have the letters HPUS on their labels.

In order for a proposed medicine to be accepted into the HPUS, it must go through what are called "provings" under the direction of the Homeopathic Pharmacopoeia Convention of the United States which oversees the HPUS. The CPG 400.400 also states that the potencies of homeopathic medicines are specified in terms of dilution and must only contain diluents commonly used in homeopathic preparations. 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 medicines.

The FDA's New Draft Guidance

The FDA's draft guidance for homeopathic medicines would give it the power to ban properly formulated homeopathic products currently legal under the Food, Drug and Cosmetic Act which governs the FDA.

Furthermore, the FDA proposes withdrawing CPG 400.400. Under the draft guidance alone the role of the FDA in policing quality and purity would become uncertain at best. This could open a regulatory loophole that could lead to poorly manufactured and improperly labeled products.

New Enforcement Priorities

The proposed guidance states that the FDA will prioritize enforcement actions against homeopathic medicines containing the following:

1. Infectious agents with the potential to be pathogenic.

2. Controlled substances, that is, drugs for which one must get a doctor's prescription.

3. Multiple ingredients that, when used in combination, raise safety concerns due to possible interactions, synergistic effects, or additive effects of the various ingredients.

4. Ingredients that pose potential toxic effects, particularly when those ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are not adequately controlled in the manufacturing process.

These broad categories suggest that the FDA is aiming at removing a significant number of currently available medicines from the market—though as we contend below these categories completely miss the mark.

These Priorities Make No Sense

We believe that none of the priorities mentioned by the FDA makes sense in the context of homeopathy. We know of NO product properly labeled homeopathic which contains an agent that:

- Has the potential to be pathogenic.
- Could be considered a controlled substance.
- Is dangerous because it combines multiple homeopathic ingredients.

- Poses potential toxic effects because of concentrated ingredients. If such a product exists, it would not be a homeopathic product which is always diluted. Low dilution during a manufacturing process which is "not adequately controlled" would point to a manufacturing problem, not a problem with a properly formulated and manufactured homeopathic medicine.

If the FDA were to discover a product containing such agents or high concentrations, it would mean the product is not homeopathic and is therefore improperly labeled. The FDA already has ample authority under CPG 400.400 to take action against such products. This is a key reason we are urging the agency to withdraw its proposed new guidance and why we are seeking legislation that uses CPG 400.400 as its framework.

If You Use It, You May Lose It

In a strange twist the FDA's proposed guidance would allow the agency to ban a particular homeopathic medicine simply because an increasing number of people are using it. This is because such medicines "may cause users to delay or discontinue medical treatments [that is, pharmaceuticals] that have been found safe and effective." The implication, of course, is that the FDA now believes that homeopathy is either *not* effective or not *as* effective as pharmaceuticals for many conditions. But, this argument could be made for many over-the-counter medications. Taking a pain reliever to address a headache caused by a brain tumor might very well delay treatment. But, no new policy is being announced for over-the-counter pain relievers.

Nevertheless, the FDA singles out homeopathy as a threat to public health if people choose to try an inherently safe homeopathic medicine BEFORE resorting to a pharmaceutical product that may list serious and even fatal side effects. Yet, homeopathic medicine labels advise users to consult a doctor if symptoms do not improve within three days—very much like over-the-counter medications do. Despite this the FDA implies that if consumers in great enough numbers choose to try homeopathic medicines for "the prevention or treatment of serious and/or life-threatening diseases and conditions," that alone could trigger a move by the FDA to ban some of those medicines because their use "raises public health concerns." Would the agency do the same with over-the-counter pain relievers?

It's important to note that homeopathic medicines do not treat serious and/or life threatening diseases and conditions in the manner that pharmaceuticals do. Pharmaceuticals act directly on the physiology and organs of the body. Homeopathic medicines, on the other hand, seek to engage the natural healing ability of the body itself to resolve disease.

Medicines Would Become "Unapproved"

The proposed guidance would also change the status of homeopathic medicines from a special category of medicine and put them into a group considered "unapproved." This means that all homeopathic medicines would become technically illegal and could be banned at any time by order of the FDA.

Any homeopathic medicine which is withdrawn from the market by the FDA could not return unless it undergoes the agency's New Drug Application (NDA) process, a costly process designed to weigh the risks and benefits of chemical drugs which may have toxic effects. It makes no sense for homeopathic medicines—which are by definition nontoxic and therefore pose no toxic threat to humans—to go through a process that can cost millions of dollars and take many years to complete in order to find out if they are toxic. In 200 years of use there has never been a documented death or injury from a properly formulated homeopathic medicine. (For information on safety and effectiveness, see our briefing entitled "The Evidence for Homeopathy's Safety and Effectiveness" which can be accessed at this address: http://tinyurl.com/yyrnlh2m)

Moreover, since homeopathic medicines cannot be patented—they consist of commonly available substances—there would be no incentive for a company to pay for such an approval process. This is because any company can manufacture an unpatented FDA-approved medicine regardless of who pays for the approval process. *Therefore, the requirement that a homeopathic medicine undergo the NDA process would result in a de facto permanent ban.*

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 Homeopathic Pharmacopoeia of the United States which is administered by the Homeopathic Pharmacopoeia Convention of the United States. In our view declaring homeopathic medicines technically illegal would be illegal itself, and we would fight to overturn such a finding.

Read the Draft Guidance Yourself

To understand why we've said what we have in our analysis of the FDA's draft guidance, we invite you to read it yourself. The guidance can be accessed at the following link:

http://tinyurl.com/yxamssm3

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