The End of Homeopathy in America?

It's Our Choice

An American Manufacturer of Homeopathic Medicines Speaks Out

By Mike Evans

The end of homeopathy in America is close-at-hand unless the homeopathy community acts quickly to challenge new proposed guidance from the FDA. The recent withdrawal of Compliance Policy Guide 400.400 by the agency has stranded the industry in a no man's land without protection from arbitrary action. Unless something changes, sometime in 2020 the FDA will be able to declare that all homeopathic medicines are unapproved new drugs and thus illegal. That means the agency would be able to withdraw any homeopathic medicine—not just a particular brand, but a generic remedy—from the marketplace without notice and without additional justification merely because it is illegal. And that means that many remedies such as Belladonna and Nux vomica—which the agency has had in its sights for years—could be gone from store shelves in the near future never to return. To find out more about why, read on. For steps you can take to support homeopathy, go to end of this article.

I am an American manufacturer of homeopathic medicines and I am very concerned that I won't be one for much longer. Many of my colleagues in the business have told me that they are just as concerned. But, they are worried about the possible consequences to their businesses if they go public with their fears.

Why do I feel so alarmed? Because the U.S. Food and Drug Administration (FDA) recently announced a path that could lead to the beginning of the end of homeopathy in America in the near future—and yet few people noticed. Consumers didn't notice because they were relieved that the FDA made minor changes in its proposed Draft Guidance on homeopathy to placate them and because the agency said that most of homeopathy would be left alone. Some manufacturers and distributors have also wrongly taken the FDA's recent actions and statements as an all-clear.

The much more consequential action taken by the FDA was the elimination of the administrative regime for homeopathy that the agency used for 30 years, one that allowed the industry to thrive while ensuring the quality and purity of homeopathic medicines. I am referring to the withdrawal of Compliance Policy Guide (CPG) 400.400 which has served the industry and consumers well.

Homeopathy in Limbo

Homeopathic medicines are now in limbo. There is no governing document that tells manufacturers what they must do to market homeopathic medicines in America. There is instead a newly revised Draft Guidance, which if adopted as currently written, will be a recipe for the destruction of homeopathy as we know it in America.

The difference between the FDA's old approach and its new one is stark. The full title of the now defunct CPG 400.400 is "Compliance Policy Guide 400.400, Conditions Under Which Homeopathic Drugs May Be Marketed." The title alone acknowledged a market space for homeopathic medicines. The guide itself provided manufacturers and distributors with a roadmap for staying within boundaries necessary to assure proper manufacturing and labeling of those medicines.

By contrast section three of the 2019 Draft Guidance reads as follows: "The issuance of this guidance, when finalized, is intended to provide notice that any product labeled as homeopathic that is being marketed illegally is subject to FDA enforcement action at any time."

A Funeral for Homeopathic Medicines?

The first thing you need to know is that under this newest guidance ALL homeopathic medicines will be considered illegal. This is because the guidance declares all homeopathic medicines to be "new drugs" which have not undergone the agency's pre-market approval process known as a New Drug Application (NDA). This designation is the linchpin of the eventual funeral of homeopathy in America. This is because homeopathic medicines are typically low-priced (and thus affordable), cannot be patented and therefore cannot justify the enormous expenditures that an NDA entails. Wherever the FDA insists that a particular homeopathic remedy must be put through the NDA process, the agency will essentially be issuing a de facto ban on that remedy in the United States.

Furthermore, because the agency provides no guidance whatsoever on what manufacturers and distributors *should* do, both are in the dark as to how they would proceed under the proposed guidance. The FDA's own words tell us that homeopathic medicines are in grave danger of disappearing from the marketplace. But the agency does not outline a path that would prevent this from happening. Nobody can say with any assurance what, if anything, the industry could do to avoid a countdown to zero homeopathic remedies in the United States.

If the Draft Guidance is adopted unchanged—and especially if the designation of all homeopathic medicines as "new drugs" is allowed to stand—consumers will likely begin to see homeopathic medicines disappear from store shelves and practitioners' offices as the FDA takes aim at one homeopathic medicine after another.

A Cunning Move

Under the authority of the Draft Guidance, which could become final as early as January 2020, the FDA would presumably have little trouble defending its actions in court if the court accepts the argument that homeopathic medicines are "new drugs" under the law. (I and many others believe that the FDA has no authority to designate homeopathic medicines as "new drugs" which is a specific legal definition and may be something a court will ultimately have to decide.) The designation of homeopathic medicines as "new drugs" makes all of them illegal and *the FDA can remove any illegal drug from the marketplace without notice and without additional justification merely because it is illegal.* The Draft Guidance is a cunning move that gives the FDA unfettered power to withdraw any and all homeopathic medicines from the marketplace tomorrow or the next day or any day after that if it so chooses.

There is also the question of how manufacturers will fare in this new regulatory and legal environment if the Draft Guidance as it currently stands becomes final. For many years homeopathy has been the target of frivolous lawsuits. These lawsuits come from opportunist lawyers, either acting on their own accord or funded by organizations implacably opposed to homeopathy and wishing to wipe it out as a medical practice.

With an FDA declaration that homeopathic medicines are "illegal," this litigation will almost certainly intensify since attorneys will be handed a potent new weapon with which to attack homeopathy.

Increased Liability

Increased liability will also threaten the insurability of those who manufacture homeopathic medicines and those who prescribe or sell them to patients.

It should be no surprise to anyone familiar with the challenges of being a manufacturer that many homeopathic manufacturers will simply choose to exit the business. They will do this rather than endure the added liability and insurance costs while facing a

persistent reduction in their product line as the FDA removes one homeopathic medicine after another from the marketplace. Such developments could have an immediate and dramatic effect on the availability of homeopathic medicines in America.

Despite assurances from current FDA personnel that most of homeopathy will remain untouched, nothing in the Draft Guidance would prevent the FDA from attacking all homeopathic medicines. The people who currently work at the FDA will not be there forever. If the Draft Guidance is not changed in ways that explicitly protect genuine homeopathic medicines, new FDA personnel—ones who have made no assurances of any kind to the homeopathy community—could very well eliminate a large portion of those medicines soon after arriving. We would be foolish to rely on assurances from the FDA that are not in writing and incorporated into the agency's guidance.

The FDA's guidance documents are by its own admission not regulations and not the law. But in practice, every manufacturer knows that deviations from the guidance can lead to the end of careers and companies. That is the power of the FDA's pronouncements in the marketplace. For unscrupulous operators who threaten the public's well-being, this power is both a deterrent and a method for closing them down.

Manufacturers at Risk

But the FDA Draft Guidance on homeopathy so thoroughly misconstrues the tenets of homeopathy that even those manufacturers who properly produce and label homeopathic medicines are at risk.

Let me be frank. Some in the industry are afraid that speaking up about the Draft Guidance will only stir the ire of the FDA and lead to retaliation. It's hard to understand what kind of retaliation would be worse than the end of homeopathy in America for domestic manufacturers of those products. And that's where we are currently headed because of this fear or because of our failure to understand the gravity of the situation or both.

I could here cite the evidence that homeopathy is entirely nontoxic; that it has a 200-year history without verified evidence of any deaths associated with its use; that it has shown excellent clinical results and is backed by an extensive medical literature including hundreds of clinical trials which demonstrate its safety and effectiveness.

But none of that will matter if the homeopathy community does not stay united in seeking a better framework from the FDA. Many in the homeopathy community have in the past adopted a strategy of keeping their heads down and hoping for the best. That strategy will simply not work this time. We cannot save homeopathy by cowering in a corner.

It is important to note that the fight for homeopathy is just one aspect of the fight for health freedom. Freedom to choose how we want to care for our own health is central to

maintaining our autonomy in a free society. Every bit of control we give up over our own health care is given to someone else, someone who is not particularly interested in expanding health care choice for the public.

We manufacturers of traditional and alternative health products should not deceive ourselves that acquiescing to the FDA on homeopathy will somehow secure us peace. The fight will simply shift to whatever other lines of products we may produce. And, our capitulation will only embolden our opponents across the board.

Today, we must as a community join together for the tough fight ahead to save homeopathy.

We can win that fight if we stay united in our effort to preserve the entire range of genuine homeopathic medicines that have been serving us well. Settling for a war of attrition with the FDA where one side, namely our side, takes all the losses is simply not an alternative.

We can save homeopathy in America if we act with intelligence and resolve. We can save homeopathy if we focus on our strength and commitment instead of our fear. We can save homeopathy if we give the necessary support to those who are on the front lines of this battle.

It's really up to us. It's our choice.

About the Author

Mike Evans is Chief Executive Officer of Grato Holdings, Inc., a manufacturer of private label homeopathic and natural health products in the United States. He is a military veteran with 20 years of service in the U.S. Air Force.

What You Can Do

Tell the FDA where you stand. Visit the FDA comment page on the Americans for Homeopathy Choice website where you can learn more about efforts to save homeopathy in America.

Tell everyone you know about the threat to homeopathy and the steps they can take to protect it.