

The Food and Drug Administration (FDA) Proposed Rule: [Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing](#)

ID: FDA-2015-N-0540-0001

I wish to offer my perspective on the regulation of homeopathic remedies by the FDA. As both a healthcare consumer and as a practicing veterinarian, I see the marketing and use of homeopathic products without legitimate scientific evidence of safety and efficacy as a danger to human and animal health. These products should be held to the same standards of evidence as any other drug if they are to be marketed with claims that they can treat or prevent disease in humans or animals.

The current regulatory structure effectively allows most homeopathic products to be marketed and used in humans and animals, with or without the guidance of a physician or veterinarian, without any of the scientific evidence of safety and efficacy required of most drugs regulated by the agency. This is a result of historical and political factors, but it leaves the public without the scientific information and guidance needed to make effective and informed decisions about the use of these products. The FDA itself acknowledges that "'FDA is not aware of scientific evidence to support homeopathy as effective." (<http://labels.fda.gov/>)

Even National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health, which is specifically charged with investigating alternative therapies, acknowledges the lack of scientific evidence for efficacy:

Most rigorous clinical trials and systematic analyses of the research on homeopathy have concluded that there is little evidence to support homeopathy as an effective treatment for any specific condition.

The scientific evidence is overwhelming and unequivocal that homeopathy provides no therapeutic benefit beyond the placebo effect of the consultation with a homeopath. Despite over 150 years of use and extensive research, no convincing evidence of a specific treatment effect has been produced. And there is also evidence that despite containing no active ingredients, homeopathic remedies can be harmful. When such products are mislabeled as homeopathic when they actually contain biologically active chemicals, or when they are used to treat serious illness in lieu of effective medical care, they can cause injury and death. Below I have provided a brief overview of this robust scientific evidence concerning homeopathy.

The evidence that homeopathic remedies are ineffective is an internationally accepted scientific consensus rejected only by dedicated practitioners of homeopathy and those they have misled. Given this consensus, it is an abrogation of the FDA's responsibility to protect human and

animal health to allow therapeutic and prevention claims to be made for these products. I recommend the agency take the following steps.

1. Draft and submit to Congress a report identifying homeopathy as ineffective and recommending changes in the agency's authorizing legislation to prohibit the marketing and use of homeopathy without fulfillment of the same new drug licensing requirements applied conventional drugs.
2. Produce educational materials for healthcare providers and patients in both human and animal health fields identifying the ineffective nature of homeopathy for the treatment or prevention of human and animal disease.
3. Require all OTC homeopathic products to carry a label similar to that required for dietary supplements under DSHEA, "This/these statement(s) have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."
4. Vigorously enforce regulations in both human and animal health fields prohibiting treatment and prevention claims for homeopathic remedies without fulfillment of the requirements of a NDA.

Thank you for your attention,

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