# Homeopathy and the Federal Trade Commission: Policies for the 21st Century 1-2017

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**Homeopathy is an energy medicine giant** that is key to the health awakenings of the 21st Century. Current laws and public policy will have to be evaluated and designed with homeopathy's impact in mind.

**Homeopathic remedies are currently in a cross-fire between two federal agencies, the FDA and the FTC,** because health claims on homeopathic products bring up the direct overlap of current legal jurisdiction between these two federal agencies. **The overlap is based on this:** The FDA regulates the labeling of all food and drug products. Homeopathic remedies are considered drugs and thus their labeling is under the jurisdiction of the FDA. The FTC regulates advertising or labeling of products in commerce and prohibits unfair or deceptive acts in commerce. Homeopathic manufacturers advertise their products thus are under the jurisdiction of the FTC.

**The FDA has developed special marketing guidelines for homeopathy.** They have guidelines for regulation of over-the-counter (OTC) homeopathic products, based on the FDA's understanding that "*due to the uniqueness of homeopathic medicines*" they are deserving of clear conditions for marketing. These guidelines have resulted in protection of consumer access to these safe products. The FDA has specifically spelled out the requirements for the labeling of homeopathic products given their Hahnemannian principles of dilution. Since 1988, the FDA regulates homeopathic over-the-counter (OTC) remedies under their Compliance Policy Guide ("CPG") entitled "Conditions Under Which Homeopathic Drugs May be Marketed". It permits the marketing of homeopathic products "*intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment*" as OTC products. It requires that the labeling of OTC homeopathic drugs display an indication for use. And it acknowledges the existence of the homeopathic research procedure, called "provings", which is a homeopathic method of research employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms and used to determine the eligibility of drugs for inclusion in the Homeopathic Pharmacopeia of the United States (HPUS).

**But the FTC also claims authority over claims on products in commerce** under Sections 5 and 12 of the FTC Act, and their authority could conflict with the FDA's labeling requirements for homeopathy. For example, FDA's regulations require that OTC homeopathic remedies display an indication for use on the label. But FTC is now warning that they will require competent and reliable scientific evidence of statements made on labels. And that those statements will be held to a conventional drug standard. The FTC states as follows:

"Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in or affecting commerce, such as the deceptive advertising or labeling of over-the-counter (OTC) drugs. Section 12 prohibits the dissemination of false advertisements in or affecting commerce of food, drugs, devices, services, or cosmetics. Under these provisions, **companies must have a reasonable basis for making objective claims, including claims that a product can treat specific conditions, before those claims are made.**

*For health, safety, or efficacy claims, the FTC has generally required that advertisers possess "competent and reliable scientific evidence," defined as "tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results." Competent and reliable scientific evidence may take different forms depending on the type of claim being made. For some claims, the substantiation required may be one or more well-designed human clinical studies. Neither the FTC Act, nor any FTC rule or policy statement, exempts advertising claims for homeopathic drugs from these standards."*

**The FDA's regulations historically have been structured** in a way that has treated OTC homeopathic remedy health claims as if homeopathic remedies are safe. However, the FTC, appears to be considering them as dangerous drugs and is applying a conventional drug standard to speech regarding homeopathic remedy health claims.

**The problem is that FTC is using the wrong standard for assessment of the health claims for homeopathic remedies**. Here is why. As explained simply and clearly by leading homeopath John Melnychuk, RSHom (NA) CCH: "*Homeopathy has a scientific paradigm of its own, which is distinct from western scientific understandings. (Similarly, the science and paradigm that underlies Chinese Medicine and acupuncture are not readily explainable by western medical science. It is unwise and arbitrary to judge one system with the standards of another.) It is agreed upon by most that homeopathic medicines are not toxic, and therefore the rules for the necessity and method of proving safety are not relevant or reasonable in the same way as they are for dangerous drugs.*"

Conventional prescription drug health claims, because of the dangerous nature and known history of side effects of drugs, understandably require proof of any promise or health claims made, because the consumer has to choose between two possibilities: the dangerous side effects including sometimes possible death from a drug, or ongoing illness and potential death from a disease. It is important for consumers to have truthful information on whether there is a chance of getting cured by the product given those two options. Consumers need to know the effectiveness of pharmaceutical prescription drugs because they have to weigh the potential benefits against the danger to themselves.

But in the instance of a product that is generally regarded as safe, the proof that a substance is effective is not as crucial. If there is little risk in trying some approaches, consumers want to have broad access to many options based on their own research. That is why, for safe products like dietary supplements, food and homeopathic remedies, the consumer is most concerned with safety instead of proof of efficacy, and the role of government is not to ensure effectiveness, but rather to make sure that a product is not on the market that will hurt them. And if there is a potential fraud or misrepresentation regarding a health claim for a product on the market, it is the responsibility of the FTC to stop the fraud, and they have the burden of proof to show misrepresentation or fraud before banning speech.

**We need to ask the important question** as to whether the manufacturers of safe products be required to prove by conventional scientific methods that the health claims that they make about their products are truthful and not misleading before they have the freedom to market their product and speak about them, or should the government have the burden of proof to show that a statement is dangerous or fraudulent before taking a product off the market? We believe that since the FTC regulates deceptive trade practices and wishes all statements to be truthful, the burden of proof of fraud must remain on the government for a product that is generally regarded as safe. Otherwise most safe products would be banned and there would be a massive infringement on freedom of speech. If that were the case nothing positive could be said about a product unless the manufacturer was a multimillion dollar company that could go through the high standard of proof that the FTC is suggesting. Statements about the benefits of food and homeopathic products for sale have been made for hundreds of years, and the wisdom of the culture on these products must not be

stifled by demanding the type of scientific proof required of dangerous drugs, costing millions of dollars, before one speaks.
**If something is safe, all citizens of the world should always be able to speak about it and have access to it.** And if a fraudulent commercial claim is made about a safe product, the government has the duty and the burden of proof to prove fraud before pulling from the market.
**NHFC opposes the following FTC recommendations based on our discussion above:**

FTC recommends the following: "For the vast majority of OTC homeopathic drugs, the case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product's efficacy. Accordingly, marketing claims that such homeopathic products have a therapeutic effect lack a reasonable basis and are likely misleading in violation of Sections 5 and 12 of the FTC Act.14 However, the FTC has long recognized that marketing claims may include additional explanatory information in order to prevent the claims from being misleading. Accordingly, the promotion of an OTC homeopathic product for an indication that is not substantiated by competent and reliable scientific evidence may not be deceptive if that promotion effectively communicates to consumers that: (1) there is no scientific evidence that the product works and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts. To be non-misleading, the product and the claims must also comply with requirements for homeopathic products and traditional homeopathic principles. Of course, adequately substantiated claims for homeopathic products would not require additional explanation."

FTC's requirement to add a statement to labels that "***there is no scientific evidence that the product works***", is based on the FTC's conventional scientific knowledge and methods, without recognizing the massive library of research and literature available in the homeopathic medical community regarding Hahnemannian principles and homeopathic research. FTC's requirement to add a statement to labels that "***the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts***" is a denigration of a healing system used by millions world-wide. It is promoting one system of medicine over another based on its dominance in the culture. It has nothing to do with positive education of consumers. It is based on an unwillingness to allow access by consumers to a minority system of healing, and ignores the potential benefit of simply ensuring safety, and providing education to consumers.
**In addition to these concerns, there is an additional, and much larger issue that the FDA and the FTC must eventually address regarding homeopathic products: that is the issue of the advancement of the understanding of the universe.** How does continued access to the broader conventionally un-proven truths of the universe interact with the current regulatory standard of "*competent and reliable scientific evidence"?* The FTC refers to "modern medicine" and "reliable science". How can the research scientists, inventors and innovators experiencing and probing the complexity of the human experience and the universe, and consumer access to the knowledge that is forthcoming from them, be protected and encouraged, when government authorities attempt to block speech about, and access to, products unless healing efficacy has been proven based on conventional scientific methods? Conventional science has expanded and grown over the years, but it may be said that conventional science is in the early stages of understanding when it comes to truths such as the foundations of homeopathy, the Hahnemannian principles, the law of similars and the process of dilutions and succussions.

In the case of homeopathic remedies, there is agreement in government and civil society that thousands of homeopathic remedies and products do not pose an imminent risk of harm to individuals or the public. We need to protect and encourage access to these safe products. And we need to protect our personal freedoms to speak about health options and to make health care choices. We must never allow government to quash speech and advertisements about safe products that are basically innovative applications of natural truths.

It is our position at NHFC and NHFA that individuals should always be able to speak about and have access to all health care options that they desire that are generally regarded as safe and that government has the burden of proof to show misrepresentation or fraud when it comes to any health claim. It is noticeable that these larger glaring issues were not addressed by the FTC. That fact alone causes much consternation within the healing community.

**In Conclusion: In this complex situation between FDA and FTC,** the FDA has been doing a good job of walking the line effectively by protecting access for consumers to homeopathic products, while at the same time, making sure that consumers are obtaining safe products with appropriate labeling. The FTC continues to have the authority to challenge fraudulent statements, and that is appropriate.

We deeply hope that the FDA will uphold its homeopathic policies and protect consumer access to homeopathic remedies, and tell the FTC that they have over-stepped their jurisdictional boundaries. Citizens need to ask the FDA to hold fast to their 1988 Compliance Policy Guide providing reasonable treatment(regulation) of homeopathic remedies.

There is no need to denigrate homeopathy by forcing the additional requirements of disclosures to labeling or advertising that FTC proposes.

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