CLOSE THE HOMEOPATHIC LOOPHOLE: REQUIRE HOMEOPATHIC MEDICATIONS TO PROVE THEIR EFFECTIVENESS

INTRODUCTION

Consumers assume that medication must have scientific support for claims of safety and efficacy before such claims can be placed on the product's packaging. For the most part, this is true.[1] However, because of a dubious twist in the development of medication regulation,[2] there is one type of over the counter medication that can advertise effectiveness against diseases without scientific proof: homeopathic medication.[3] As it stands, medications labeled as "homeopathic" advertise misleading "health claims"—

disseminate "any false advertisement" for their products.[16] To comply with the FTC requirements, drug manufacturers must be able to scientifically

homeopathic medication contains the equivalent of one drop of active ingredient in an ocean of water is not hyperbole, but actually an understatement. A dilution of 30X[37] is "equivalent to placing one drop of water in an ocean more than fifty times the size of earth, mixing well, and removing one drop for administration to the patient."[38] These are the same products sold alongside traditional medications. Occasionally, markets will create a special display or section selling exclusively homeopathic products.

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B. Labeling Requirements of Homeopathic Medicine and Traditional Over-the-Counter Medication

Regulations for labeling homeopathic over-the-counter remedies are less stringent than for any other medication. In the early 1900s, homeopaths developed the Homeopathic Pharmacopeia of the United States (HPUS) to

37. This dilution is thirty successive 1:10 dilutions, or 10^{30} dilutions. PRAY, *supra* note 24, at 195.

38. *Id*.

39. The photographed image is a display in Gelson's Supermarket containing mostly homeopathic remedies, including products sold by

develop a uniform literature for homeopathic treatment.[40] In the 1938 passing of the Federal Food, Drug, and Cosmetic Act (FDCA), "homeopathic drug products in the HPUS were stipulated to be drugs" and "were subject to the drug requirements of food and drug law."[41] The FDCA recognizes substances contained in three sources to be defined as "drugs."[42] The official HPUS is one of those sources, alongside the official United States Pharmacopeia (USP) and the National Formulary.[43]

Homeopathic medications are subject to different standards of proof of effectiveness than other over-the-counter drugs. While traditional medications are required to adhere to statutory requirements defining "adequate and well-controlled studies,"[44] homeopathic remedies are required to only adhere to standards of proof found in a publication that they themselves created: the HPUS.[45] In fact, the FDA readily admits that "compliance with requirements of the HPUS . . . does not establish that [the medication] has been shown by appropriate means to be safe, effective, and not misbranded for use."[46] Effectively, the only institution qualified to comment on the product's effectiveness are the product's creators.

The methods of "provings" of homeopathic medications use the same principles developed by Hahnemann in the late 1700s.[47] Specifically, negative effects of the drug must be observed on a healthy individual in order to subsequently dilute the substance for treatment of those same symptoms.[48] The goal of the "proving" is to demonstrate that the substance to be potentially used for treatment causes positive symptoms.[49] Once those symptoms have been documented and proven on healthy individuals, the homeopathic practitioner can then dilute the substance to an appropriate dose.[50] The diluted medicine is not tested for efficacy.

Meanwhile, drugs which are not classified as homeopathic cannot be sold until recognized among qualified third-party experts to be safe and

40. Junod, *supra* note 2, at 164.

41. *Id*. at 176.

42. 21 U.S.C. § 321(g)(1)(A) (2012).

43. *Id*. The United States Pharmacopeia and National Formulary are now a single compendium.

44. 21 C.F.R. § 314.126 (2016).

45. FDA, supra note 3.

46. *Id*.

47. *Compare* BOERICKE,

for truthful advertising.[61] However, because a homeopathic drug manufacturer can violate FTC false advertising regulations while still conforming to FDA labeling requirements, the FTC has been reluctant to conduct enforcement action against those manufacturers.[62]

The conflict results because of the lack of scientific proof of the efficacy and safety of homeopathic drugs. Determining whether a product has violated FTC regulations is a three-step inquiry: what claims are conveyed in the ad; whether those claims are false, misleading, or unsubstantiated; and whether those claims are material to prospective consumers.[63] Currently, all claims made by a product, including products not classified as drugs, must be substantiated with scientific evidence.[64] This results in counterintuitive and surprising results in the marketplace. For instance, the FTC is comfortable bringing action against a pomegranate juice company because of claims unsubstantiated by scientific evidence,[65] but being classified as a "homeopathic drug" has meant, thus far, that no scientific validation was required.[66]

Especially troubling is the fact that the effectiveness of homeopathic

PART II. THE SOLUTION – HOMEOPATHIC MEDICATION CLAIMS MUST BE SCIENTIFICALLY PROVEN TO BE EFFECTIVE BEFORE SUCH CLAIMS CAN BE MADE

A. Homeopathic Products Should No Longer Be Classified As "Drugs"

The FTC has proposed three solutions to solve the conflict between the FDA and FTC.[74] However, none of the proposed solutions include the most important step: declassifying homeopathic products as "drugs" and reclassifying them as "dietary supplements."[75] Counterintuitively, the classification of homeopathic products as "drugs" has resulted in less regulation for safety and effectiveness. The method of proving effectiveness of homeopathic products is different than traditional allopathic[76] remedies.[77] While the United States Pharmacopeia evolved to prove effectiveness through "placebo-controlled, blinded drug trials," the Homeopathic Pharmacopeia remained stagnant, using methods of proof developed in the early 19th century.[78]

The oversight in the regulations is a result of the recognition of the Homeopathic Pharmacopeia as an official drug compendium.[79] Homeopathic products must be proven to be effective in order to be included in the Homeopathic Pharmacopeia; however, the methods of "provings" were developed by homeopaths themselves and depart from sound scientific principles.[80] Non-homeopathic drugs, meanwhile, must file an application with the FDA before conducting human tests.[81] The application must include such information as a section "describing the composition, manufacture, and control of the drug substance," a "description of the drug substance, including its physical, chemical, or biological characteristics," and "adequate

74. The three solutions are to either withdraw the CPG, eliminate the requirement that an

information about pharmacological and toxicological studies of the drug involving laboratory animals or in vitro."[82]

Homeopathic "provings" are something of a misnomer. The "proving" does not refer to proving the effectiveness of the remedy; rather, homeopaths prove that a potential remedy creates a negative effect among a healthy individual.[83] "Provings" and "treatments" are distinguished, where "provings induce states of ill-health."[84] Thus, by proving that a substance creates a negative effect, homeopathy teaches that the same substance can be diluted in order to heal that negative effect. According to the main principle of homeopathy, the "reaction provoked by that substance in subtoxic amounts can aid the patient's recovery."[85] Experiments were performed on the healthy because homeopaths taught that "a drug that produced specific effects in the provers would be efficacious in diseases with symptoms similar to the effects caused by the drug."[86] The completed, diluted medicine is never proven to be effective.

As long as a substance is "proven" to invoke negative reactions among a healthy individual, that substance can be included in the Homeopathic Pharmacopeia. Homeopathic products require double-blind testing among healthy individuals in which symptoms of a particular substance are observed by participants.[87] These observations are then submitted to a committee on standards of the American Institute of Homeopathy, which determines whether the drug will be included in the United States Homeopathic Pharmacopeia.[88] This procedure is a far cry from the rigorous standards applied to traditional medication. Yet, homeopathic medications are able to definitively state on their label that their product is effective for treatment of symptoms.[89] Even more surprising is that these products are being sold on shelves side-by-side with medications that were required to scientifically

82. 21 C.F.R. § 312.23(a) (2016).

83. BOERICKE, *supra* note 12, at 31; Sherman & Strauss, *supra* note 80, at 117.

Regulating homeopathic products as drugs would allow them to still be sold, but would have an effect on the types of claims being made. "Health claims" are differentiated from "structure/function" claims. A "health claim" is where a substance is claimed to be effective against a disease or health-related condition.[98] A dietary supplement may not make a "health claim"

free to enforce untruthful advertising claims without running into direct conflict with FDA regulations.[112]

While the regulatory framework under the DSHEA is perfect for homeopathic products, a carve-

PART III: THE SOLUTION SHOULD NOT OUTLAW THE SALE OF HOMEOPATHIC PRODUCTS COMPLETELY – WHY OTHER SOLUTIONS FAIL

A. Withdrawing the CPG While Still Classifying Homeopathic Products As "Drugs" – Homeopathy's Death Knell

The FTC has suggested that one of the solutions to solving the conflict would be to simply withdraw the CPG.[119] However, if this were the case, homeopathic drugs would never obtain approval by the FDA and would signal the end of homeopathic medication. The main issue is that homeopathic products would still be classified as "drugs." Drugs are able to "advertise a beneficial relationship to a disease or health-related condition."[120] If homeopathic products were classified as drugs, they must pass the same control trials as other drugs.

The drug approval process is "arduous."[121] The chances of approval of homeopathic products through rigorous scientific testing are slim to none.[122] Further, according to the true practice of homeopathy, "an appropriate

containing fifty-two substances, the costs would be overwhelming at best.[126] Further, one of the cornerstones of homeopathic practice is the individualization required for each patient; this level of individualization would add another layer of impossibility to the clinical trials typically used for traditional allopathic cures.[127]

Mandating the studies would be prohibitively expensive. However, if homeopathic manufacturers were given an incentive to perform those studies, it would result in a great benefit to the industry and medicine as a whole. If homeopathy was regulated under the DSHEA, only health claims with scientific backing could be made.[128] Thus, manufacturers would be incentivized to prove that their product was clinically effective.

B. Why Not Kill Homeopathy?

The argument begs to be made of whether homeopathy as an industry

However, prescribing homeopathic medication is not the same as obtaining the products over-the counter. Further, consumers report real benefit from homeopathic medications.[132] Alternative medicine is usually used in conjunction with traditional allopathic cures.[133] Consumers should have the option to purchase products that they believe help them. Further, the lack of marketing on the packaging of the products would not dissuade consumers from purchasing homeopathic remedies.[134] Finally, over the counter homeopathic medication is only allowed to be sold in the cases of self-limiting and non-serious medical conditions.[135] Thus, the option to purchase homeopathic remedies should be left available for consumers.

Requiring proof for homeopathic effectiveness would be beneficial for the scientific community as a whole. Some of the ideas behind homeopathy have inspired medicinal progress. The "provings" of Hahnemann in the 1800s resulted in, for example, the discovery of the use of nitroglycerin for the treatment of angina pectoris.[136] Although nitroglycerin was not used as a homeopathic remedy, the homeopathic community's observations resulted in the discovery of its use as a legitimate and proven treatment.[137] Further, scientific studies on homeopathic medication could result in breakthroughs. For instance, the botanical drugs Fulyzaq and Veregen were approved by the FDA in 2012 and 2006 respectively.[138]

The regulation of homeopathic medication as a dietary supplement offers adequate protection for consumers from false advertising. Any claim made by homeopathic products that would cause consumer confusion would have to be backed by adequate scientific research.[139]

C. Simply Adding An Asterisk To Homeopathic Products Is Not Sufficient

Another solution would be to modify certain aspects of the label of homeopathic products. At the recent FTC conference regarding homeopathic medication, Jay Borneman[141] gave his input as to how the regulations could be changed. His suggestion was threefold: first, to require that homeopathic products "be clearly labeled and advertised as homeopathic;" second, to require that the product has not been evaluated by the FDA; and third, to require that over the counter homeopathic ingredients "be subject to a final monograph in the HPUS" to "ensure that the drug has been reviewed for quality and safety."[142]

A similar proposal was approved by courts in multiple class action lawsuits against homeopathic manufacturers.[143] Recently, a settlement agreement was approved by a district court regarding homeopathic labeling.[144] The court approved an injunction requiring the drug manufacturer to include a disclaimer stating that the drugs' uses have not been evaluated by the FDA.[145] Further, the court approved the requirement that there must be language in close proximity to the drug facts on the package stating that "X is a homeopathic dilution" with a link to educational materials on the dilutions in language that an average member of the public can understand.[146]

A similar proposal was accepted by the California District Court against the homeopathic manufacturer Heel, Inc.[147] The settlement includes the mandate of a disclaimer regarding FDA evaluation and a link to the explanation of what homeopathic dilutions are.[148] Further, the settlement mandated that the company cannot use the words "Clinically Proven" on any product "for which it does not possess two, independent, randomized, double-blind, placebo-controlled human clinical trials."[149] Although this

141. John P. (Jay) Borneman is the Chairman and CEO of Standard Homeopathic Company and Hyland's and also serves on the board of the Homeopathic Pharmacopoeia of the United States. *Executive Profile: John P. Borneman*, BLOOMBERG (Sept. 18, 2016, 7:38 PM), http://www.bloomberg.com/Research/stocks/private/person.asp?personId=7128422&privcapId=4611385.

"homeopathic dilution" is, even if explained on the package.[158] The best way to remedy this confusion is to require scientific proof for health claims.[159]

Allowing a fine print disclaimer on homeopathic products would still allow homeopathic manufacturers to claim a false relationship between the product and the alleged effects of the product, which the FTC has the authority to enforce.[160] One court mentioned that disclaimers are