
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"—assertions that their product has the ability to cure diseases and ease symptoms.⁴ For example, Hyland's Homeopathic company advertises that certain products provide "Safe & Effective Relief of Runny Nose, Nasal Congestion, [and] Sore Throat"⁵ or "Relief of Occasional Sleeplessness, Fussiness, and Irritability" of babies.⁶ Unfortunately, none of the claims made by manufacturers of homeopathic medications need to be scientifically proven in order to be advertised.⁷

1. See generally 21 C.F.R. § 330 (2016) and accompanying subparts (outlining provisions and requirements for over-the-counter medication to be considered safe and effective).

2. Suzanne White Junod, *An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation*, 55 FOOD & DRUG L.J. 161, 162-63 (2000).

3. See FDA, *Compliance Policy Guides § 400.400, Conditions Under Which Homeopathic Drugs May Be Marketed*, FDA (May 1988, revised Mar. 1995), <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>.

4. See *id.*

5. *Hyland's DEFEND Severe Cold & Flu*, HYLANDS, <https://hylands.com/products/hylands-defend-severe-cold-flu> (last visited Sept. 9, 2016).

6. *Hyland's Baby Calming Tablets*, HYLANDS, <https://hylands.com/products/hylands-baby-calming-tablets> (last visited Sept. 9, 2016).

7. The only proof of effectiveness is governed by the homeopathic industry itself. The standards are not at the same level of scientific validity as traditional medications. See *infra* Part I.B.

The Food and Drug Administration (FDA) regulates all over the counter drugs to ensure that the medications are safe and effective for the uses indicated.⁸ Traditional medications can only advertise health claims if those claims are scientifically proven.⁹ However, the standards of proof of safety and efficacy of traditional medication are not applicable to drugs labeled as “homeopathic” as long as certain conditions are met.¹⁰ Whereas “traditional” medication efficacy is required to be proven through placebo-controlled studies with quantitative results,¹¹ “homeopathic” remedies require no such testing.¹² This leaves consumers vulnerable to products that falsely advertise the ability to alleviate symptoms with no requirement that those claims be scientifically verified.¹³

This creates friction between the FDA and the Federal Trade Commission (FTC). Each has differing standards as to what can and cannot be claimed on medication packaging. There is currently a tension between the FDA’s medication regulation and the FTC’s goal to protect consumers from false advertising.¹⁴ The FTC has authority to bring action against a company engaging in “unfair or deceptive acts or practices in or affecting commerce.”¹⁵ Since homeopathic medications can advertise that their product has an effect on the consumer that is not scientifically proven, the claims are not verifiably true. According to the FTC, companies cannot

8. 21 U.S.C. § 393 (2012); 27 MICHAEL K. STEENSON ET AL., MINN. PRAC. PROD. LIAB. LAW § 9.17 (2015 ed.).

9. See generally 21 C.F.R. § 330.10 (2016) (outlining the stringent standards for effectiveness for traditional medication).

10. STAFF OF FED. TRADE COMM’N, COMMENTS IN RESPONSE TO REQUEST at 3-4 (2015) https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf [hereinafter FTC Staff Comment].

11. 21 C.F.R. § 314.126(b) (2016); 21 C.F.R. § 330.10(a)(4)(ii) (2016).

12. Compare FDA, *supra* note 3 (requiring no proof of effectiveness for claims on homeopathic medication labels), with 21 C.F.R. § 211.165 (2016) (outlining requirements for proof of effectiveness of traditional allopathic drugs, including a requirement that the drug “will provide clinically significant relief of the type claimed”). See also WILLIAM BOERICKE, A COMPEND OF THE PRINCIPLES OF HOMEOPATHY AS TAUGHT BY HAHNEMANN AND VERIFIED BY A CENTURY OF CLINICAL APPLICATION 31-37 (B. Jain Publishers Pvt. Ltd. 1990) (1896) (outlining the “proving” process for homeopathic remedies, which requires no proof of the final effectiveness of the remedy).

13. A popular homeopathic remedy for colds advertises that the medication “temporarily relieves cold symptoms such as sneezing, runny nose, nasal congestion and minor sore throat.” *Coldcalm Tablets*, BOIRON USA, <http://www.boironusa.com/products/coldcalm-tablets/> (last visited Sept. 18, 2016). These claims have not been scientifically proven. FTC Staff Comment, *supra* note 10, at 4-5.

14. Michael Mezher, *FTC Asks FDA to Reevaluate Framework for Homeopathic Products*, RAPS (Aug. 24, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/08/24/23049/FTC-Asks-FDA-to-Reevaluate-Framework-for-Homeopathic-Products>.

15. 15 U.S.C. § 45(a) (2012).

disseminate “any false advertisement” for their products.¹⁶ To comply with the FTC requirements, drug manufacturers must be able to scientifically substantiate claims made on all over-the-counter medication.¹⁷ A clear conflict between FDA and FTC standards results: the FDA requires that a homeopathic medication simply has to follow the labeling requirements in Compliance Policy Guide 400.400, which does not require proof of effectiveness, but the FTC requires those same claims to be substantiated.¹⁸ This difference in treatment has come under recent scrutiny by the FTC, driven by the ignorance of consumers as to what “homeopathy” actually is.¹⁹

Homeopathic medication should be subject to the same requirements of scientific veracity and efficacy of all other drugs if such claims are made on packaging. There is no reason for an antique²⁰ and unscientific form of medicinal practice to be subject to less stringent demands of efficacy and safety. This comment is not suggesting that homeopathic medications be removed from the marketplace entirely, as homeopathic medicine may very well be effective for some consumers.²¹ However, if drug manufacturers are, for example, claiming that a medication will definitively reduce cold symptoms, such claims must be adequately and scientifically proven before those statements can be advertised.

Part I provides a background of homeopathy in general and examines the overall framework for labeling and advertising of over-the-counter medication. Part II argues that the best solution for consumer protection and resolving the discrepancy between the FDA and the FTC is to declassify

16. 15 U.S.C. § 52 (2012).

17. This includes claims that one drug is more effective than another competing drug. *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 557 (2d Cir. 1984) (stating that any representation concerning superior effectiveness of another product must be supported by “two or more adequate and well-controlled clinical investigations.”).

18. See FTC Staff Comment, *supra* note 10, at 4-5.

19. See FTC Staff Comment, *supra* note 10, at 9-12, 16.

20. Homeopathy was developed in the late 1700s. See SAMUEL HAHNEMANN, *THE HOMOEOPATHIC MEDICAL DOCTRINE*, at x (Charles H. Devrient trans., with notes by Samuel Stratten) (1833).

21. Homeopathic Product Regulation: Evaluating the Food And Drug Administration’s Regulatory Framework After a Quarter-Century Part 15 Public Hearing 289-91 (Apr. 20, 2015) (statement of Alyssa Wostrell), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM449164.pdf> [hereinafter FDA Transcript] (“A Stanford study of CAM use among the fastest growing segment of the population found that 5.8 percent of seniors surveyed use homeopathy and experienced greater symptom relief compared to other CAM options. A 2014 survey of homeopathic patients noted efficacy and safety as the top two, quote, “best liked attributes of homeopathy.”). See also *The Placebo Effect: What Is It?*, WEBMD, <http://www.webmd.com/pain-management/what-is-the-placebo-effect> (last visited Sept. 18, 2016); *The Placebo Effect Works Even When You Know You Are Taking a Placebo*, IFL SCIENCE, <http://www.iflscience.com/health-and-medicine/placebos-work-even-when-you-know-they-are-placebos> (last visited Sept. 18, 2016).

homeopathic products as drugs and to require proof of efficacy for health claims made by homeopathic manufacturers. Part III compares and contrasts this solution with other proposed solutions, arguing that keeping homeopathic products classified as “drugs” would result in over-regulation of the industry. Further, Part III argues that simply adding further disclosure to the packaging of the products would not provide enough information to consumers. Part IV summarizes and concludes.

PART I – THE DISCREPANCY OF LABELING REQUIREMENTS BETWEEN
HOMEOPATHIC REMEDIES AND TRADITIONAL OVER-THE-COUNTER
MEDICATION

A. *Homeopathy In General*

Homeopathic medicine is a distinct branch of alternative medicine developed by Samuel Hahnemann in the late 1700s.²² Homeopathy, contrary to common belief, is not the same as “natural” or “herbal.”²³ Rather, homeopathy is its own medical discipline based on principles developed independently by Hahnemann, and it has remained unchanged over its 200-plus years of existence.²⁴ The following discussion includes the true and accurate beliefs of homeopathic medicine practitioners with no hyperbole. These principles and beliefs underlie the theory of the effectiveness of the medication sold alongside traditional (and proven) medical remedies.

The two main principles of homeopathy are the “law of similars” and the “law of infinitesimals.”²⁵ The “law of similars” is based on the principle of “like cures like,” or that agents that produce a certain symptom can cure that same symptom.²⁶ In other words, “substances capable of causing disorder in healthy subjects are used as medicines to treat similar patterns of disorder experienced by ill people.”²⁷ It is from this principle that “homeopathy” gets

22. HAHNEMANN, *supra* note 20.

23. See SHUGOLL RESEARCH, HOMEOPATHY FOCUS GROUPS REPORT 2, 9-10 (2011), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitb.pdf.

24. W. STEVEN PRAY, A HISTORY OF NONPRESCRIPTION PRODUCT REGULATION 191 (Mickey Smith & Dennis Worthen eds., 2003).

25. See *id.* at 192, 195.

26. BOERICKE, *supra* note 12, at 9 (“We should imitate nature, which sometimes cures a chronic disease by superadding . . . medicine which is able to produce another very similar artificial disease, and the former will be cured—Similia Similibus.”); European Comm. for Homeopathy, *Homeopathy Definition*, HOMEOPATHY EUROPE, <http://www.homeopathyeurope.org/Practice> (last visited Sept. 18, 2016).

27. European Comm. for Homeopathy, *supra* note 26.

its name, literally meaning “similar disease.”²⁸ Hahnemann’s “generalization that, ergo, any disease may be cured by the administration of a medication that would actually cause similar symptoms . . . led practitioners to prescribe medications that cause diarrhea for diarrhea, crude coffee for sleeplessness, poison ivy for degenerative arthritis,” and so on.²⁹

The clear issue here is that prescribing medication that causes similar symptoms of an ailment could potentially be fatal for patients. Homeopathy protects itself from this expectation by implementing their second principle: “the law of infinitesimals.” This principle of homeopathy states that the smaller the dose of medication given to a patient, the stronger its effect.³⁰ Hahnemann chose to believe that “dilution of a substance actually increased its strength and efficacy.”³¹ The theory is that with ever increasing dilutions, the drug becomes more effective, as it leaves behind “a spiritlike essence or imprint that heals the body.”³²

All homeopathic medication that exists and is for sale contains substances that have been diluted to various potencies.³³ Hahnemann believed that it was impossible to separate “matter and force,” and that “the smallest conceivable part does not cease to be *some* of this substance and cannot possibly become nothing.”³⁴ Of course, modern molecular chemistry has indisputably refuted this claim. For instance, a popular dilution is 3C, which is one part drug to 1,000,000 parts water.³⁵ It is contended that the odds of even having one molecule of active ingredient after a common dilution of 30C (a 10⁶⁰ dilution) is “infinitesimal.”³⁶ In fact, stating that a

28. Hahnemann combined “the Greek words *homoios* (‘similar’) and *pathos* (‘disease’) to create this neologism.” PRAY, *supra* note 24, at 191.

29. PRAY, *supra* note 24, at 193.

30. SAMUEL HAHNEMANN, ORGANON OF MEDICINE 326-27 (R.E. Dudgeon trans., Gazelle Distribution Trade 5th ed. 2009) (1849).

31. PRAY, *supra* note 24, at 195.

32. *Id.*; BOERICKE, *supra* note 12, at 96 (“in order that the medicinal properties still latent within it may be yet farther awakened and developed, must first undergo a further attenuation, in order that the trituration or succession may enter still further into the very essence of the medicinal substance, and may thus also liberate and expose the more subtle part of the medicinal powers that lie hidden more deeply, which could not be effected by any amount of trituration and succession of the substances in their concentrated form”).

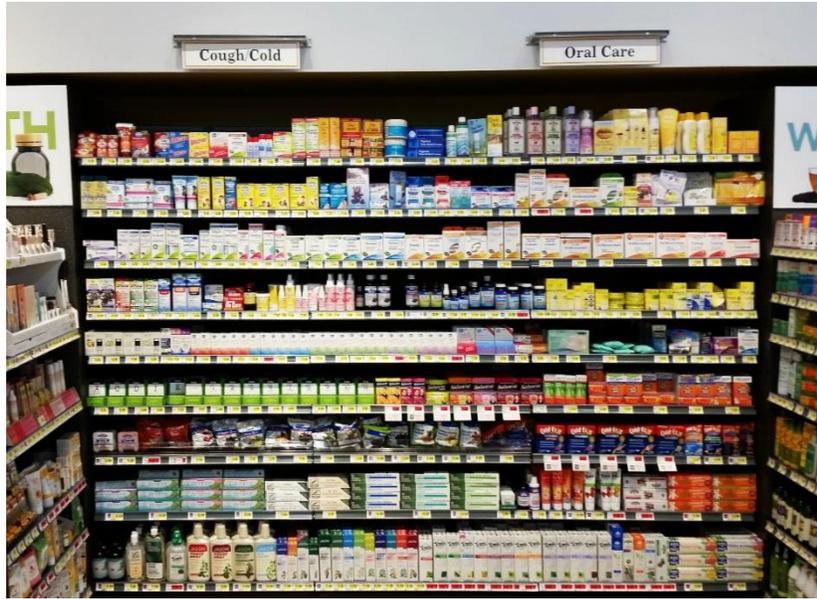
33. If a substance is not diluted, it is not homeopathic. This can be potentially dangerous to consumers if a homeopathic product is not truly diluted. See Amy Gaither, Comment, *Over the Counter, Under the Radar: How the Zicam Incident Came About Under FDA’s Historic Homeopathic Exception*, 62 ADMIN. L. REV. 487 (2010).

34. BOERICKE, *supra* note 12, at 96.

35. See Stephen Barrett, *Homeopathy’s “Law of Infinitesimals,”* HOMEOWATCH (Mar. 20, 2002), <http://www.homeowatch.org/basic/infinitesimals.html>.

36. David Gorski, *A Truly Homeopathic Defense of Homeopathy*, SCIENCE BASED MEDICINE (Dec. 17, 2012), <https://www.sciencebasedmedicine.org/homeopathy-as-nanoparticles>.

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 30X³⁷ 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.



39

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 10³⁰ 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 Boiron Homeopathy and Cold-Eeze. The traditional allopathic cures were found in a different aisle. Roy C. Manukyan, photograph of a display at Gelson's Markets, 635 Foothill Blvd, La Cañada Flintridge, CA 91011 (Feb. 6, 2016, 5:44 PM).

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, *supra* note 12, at 31, with Homeopathic Pharmacopoeia of the U.S., *Criteria for Eligibility*, HPUS, <http://www.hpus.com/eligibility.php> (last visited Sept.18, 2016).

48. BOERICKE, *supra* note 12, at 9; Junod, *supra* note 2, at 161.

49. BOERICKE, *supra* note 12, at 31-32.

50. *Id.* at 91.

effective.⁵¹ Effectiveness of a non-homeopathic drug is defined as a “reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed.”⁵² Further, such claims must be substantiated by “adequate and well-controlled studies” to determine whether “substantial evidence” supports “the claims of effectiveness for new drugs.”⁵³

Currently, homeopathic medication labeling is regulated under the same provisions as other over-the-counter drugs, but with key differences outlined in the Compliance Policy Guide 400.400 (CPG) for homeopathic medicine.⁵⁴ Under the CPG, homeopathic medications do not need to be tested for effectiveness in order for a health claim to be placed on the label.⁵⁵ Further, only homeopathic medications for “self-limiting” conditions may be marketed for over-the-counter use.⁵⁶ A self-limiting condition is one “which runs its course in a specific period of time limited by its own peculiarities and not by outside influences.”⁵⁷ Essentially, selling homeopathic medication over-the-counter is acceptable so long as the disease or condition would be relieved on its own without the aid of medication.⁵⁸

C. *Homeopathic Drugs Can Violate FTC False Advertising Laws While Staying In Conformity With FDA Guidelines*

One of the goals of the FTC is to protect consumers through preventing “fraud, deception, and unfair business practices in the marketplace,” including preventing untruthful advertising.⁵⁹ The FTC has the power to sue companies that make false claims in the marketplace.⁶⁰ Claims made by any drug, homeopathic or not, are supposed to meet the requirements of the FTC

51. 21 C.F.R. § 331.10 (2016).

52. 21 C.F.R. § 330.10(a)(4)(ii) (2016).

53. 21 C.F.R. § 314.126 (2016).

54. *See* FDA, *supra* note 3.

55. *See* Delarosa v. Boiron, Inc., 818 F. Supp. 2d 1177, 1183 (C.D. Cal. 2011) (“The Court is unaware of what standards, if any, exist to ensure that homeopathic OTC drugs are safe and effective. The FDA does not impose additional standards for strength, purity, quality, safety, or efficacy on homeopathic OTC remedies.”).

56. *See* FDA, *supra* note 3.

57. *Chevront v. File One Office Supplies*, 551 So. 2d 1221, 1223 (Fla. Dist. Ct. App. 1989).

58. *Id.* at 1222.

59. FTC, *About the FTC*, FTC, <https://www.ftc.gov/about-ftc> (last visited Sept. 18, 2016).

60. *See* FTC, *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, FTC, <https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority> (last visited Sept. 18, 2016).

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 medication has never been proven. In fact, a recent study by the Australian National Health and Medical Research Council concluded that “there are no health conditions for which there is reliable evidence that homeopathy is effective.”⁶⁷ There are no scientific studies that prove otherwise.⁶⁸ The only

61. 15 U.S.C. §§ 45, 52 (2012).

62. FTC Staff Comment, *supra* note 10, at 8. The FTC has recently promulgated a policy statement stating that all over-the-counter homeopathic drugs must substantiate their health claims with competent and reliable scientific evidence. FTC, Enforcement Policy Statement on Marketing Claims of OTC Homeopathic Drugs (Nov. 15, 2016), https://www.ftc.gov/system/files/documents/public_statements/996984/p114505_otc_homeopathic_drug_enforcement_policy_statement.pdf. This does not resolve the conflict with the FDA.

63. *POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478, 490 (D.C. Cir. 2015), *cert. denied*, 136 S. Ct. 1839 (2016).

64. *Id.* at 488-91.

65. *Id.* at 483-84.

66. In fact, POM Wonderful did have scientific studies to validate their claims. Those studies, however, were not found to be sufficient to prove a causal relationship between the juice and the claims. The court stated that if the product wanted to advertise a causal relationship, “properly randomized and controlled human clinical trials” were needed. *POM Wonderful*, 777 F.3d at 493-94. Meanwhile, there are no scientific studies that suggest homeopathy is effective at all.

67. AUSTRALIAN GOVERNMENT NATIONAL HEALTH & MEDICAL RESEARCH COUNCIL, NHMRC STATEMENT: STATEMENT ON HOMEOPATHY (2015), https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf.

68. The chair of the NHMR study claimed that homeopathy is a “therapeutic dead-end.” Paul Glasziou, *Paul Glasziou: Still No Evidence for Homeopathy*, *BMJ* (Feb. 16, 2016), <http://blogs.bmj.com/bmj/2016/02/16/paul-glasziou-still-no-evidence-for-homeopathy>.

entity that determines whether the substances are effective is the HPUS.⁶⁹ To summarize, in the current framework, pomegranate juice advertising is more strictly controlled than products intended for medical use.

A further consequence of the current framework is that homeopathic products are sold alongside, and are claimed to have the same effects as, medications scientifically proven to be safe and effective.⁷⁰ Further, the labels are almost indistinguishable.

Drug Facts

Active ingredients**	Purpose*
Allium cepa 3C HPUS.....	Relieves sneezing and runny nose
Apis mellifica 6C HPUS.....	Relieves nasal congestion
Belladonna 6C HPUS.....	Relieves colds with a sudden onset (contains less than 10 ¹⁰ mg alkaloids per dose)
Eupatorium perfoliatum 3C HPUS.....	Relieves sinus pain
Gelsemium sempervirens 6C HPUS.....	Relieves headaches associated with colds
Kali bichromicum 6C HPUS.....	Relieves nasal discharge
Nuxvomica 3C HPUS.....	Relieves sneezing attacks (contains less than 10 ¹⁰ mg alkaloids per dose)
Phytolacca decandra 6C HPUS.....	Relieves sore throat associated with colds
Pulsatilla 6C HPUS.....	Relieves colds with a loss of taste and smell

The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.

Uses ■ temporarily relieves cold symptoms such as: ■ sneezing ■ runny nose ■ nasal congestion ■ minor sore throat

Warnings Ask a doctor before use in children under 3 years of age. Stop use and ask a doctor if symptoms persist for more than 3 days or worsen, or if sore throat persists for more than 2 days or occurs with a fever, headache, rash, nausea or vomiting. If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.**

Directions ■ Adults and children 3 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. Then, dissolve 2 tablets under the tongue every 2 hours until symptoms are relieved. ■ Children 3 to 5 years of age: Dissolve 2 tablets in 1 tablespoon of water for easier intake. Follow directions above.

Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■ store at 68-77°F (20-25°C)

Inactive ingredients croscarmellose sodium, lactose, magnesium stearate

*These "Uses" have not been evaluated by the Food and Drug Administration.
**C, K, CK, and X are homeopathic dilutions; see www.boironusa.com for details.

71

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.
KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

Drug Facts

Active ingredients (in each packet)	Purposes
Acetaminophen 650 mg.....	Pain relief/fever reducer
Dextromethorphan HCl 25 mg.....	Anticough/cough suppressant
Phenylephrine HCl 10 mg.....	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
 - minor aches and pains
 - minor sore throat pain
 - headache
 - nasal and sinus congestion
 - runny nose
 - sneezing
 - itchy nose or throat
 - itchy, watery eyes due to hay fever
 - cough due to minor throat and bronchial irritation
 - throat irritation

Warnings

Label warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours.

- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

See Read warning! If your throat is severe, persists for more than 3 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

Do not use:

- if a child under 4 years of age
- if you are allergic to acetaminophen
- with any other drug containing dextromethorphan (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing phenylephrine, even one used on the skin
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before using this product.

Ask a doctor before use if you have:

- liver disease
- kidney disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- breastfeeding problem such as engorgement, infection or chronic mastitis
- cough that occurs with the mucous phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are using:

- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product:

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- effectivity may occur, especially in children

Stop use and ask a doctor if:

- irritation, itching, or unpleasantness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- symptoms do not get better or worsen
- itchy, watery or itchy, watery eyes occur
- cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

72

The box of a traditional cold medication, with all its scientific warnings and indications for use, looks identical to the box of a homeopathic remedy. The only difference is in the listing of the active ingredients. To the untrained or unobservant eye, both products are equally effective in the treatment of cold symptoms.⁷³

69. See Homeopathic Pharmacopoeia of the U.S., *supra* note 47.

70. See *A 1,000,000,000,000-to-1-Shot*, CONSUMER REP., Apr. 2008, at 7.

71. Photograph of Boiron Homeopathic Medicine Coldcalm Tablets for Colds, 60-Count Boxes, http://ecx.images-amazon.com/images/I/819UA-mDO1L._SX425_.jpg.

72. *TheraFlu Night Time Severe Cold and Cough, Honey Lemon, 12 Count*, AMAZON, <https://www.amazon.com/TheraFlu-Night-Severe-Cough-Honey/dp/B00LSUK42A> (last visited Sept. 2, 2016).

73. See *supra* notes 71-72.

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 allopathic⁷⁶ 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 indication appear on the labeling, or require that any indication be supported by scientific evidence. FTC Staff Comment, *supra* note 10, at 5-6.

75. Such a reclassification would allow the products to still be sold as well as requiring scientific evidence for any claims made on the packaging.

76. “Allopathy” is the treatment method of using dislike medication to combat illnesses. *Allopathy*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/allopathy> (last visited Sept. 2, 2016). Contrast with homeopathy, which uses substances that cause similar symptoms for treatment. *Homeopathy*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/homeopathy> (last visited Sept. 2, 2016).

77. See Kimberly Brown, Comment, *Federal Regulation of Homeopathy: A Pathway to Consumer Protection*, 29 TEMP. J. SCI. TECH. & ENVTL. L. 337, 347 n.111 (2010).

78. Junod, *supra* note 2, at 161-64.

79. *Id.* at 162-63. See also *supra* Section I.B.

80. Max Sherman & Steven Strauss, *Homeopathic Drugs—Regulatory Concerns*, 45 FOOD DRUG COSM. L.J. 113, 117 (1990); see *supra* Section I.B.

81. Sherman & Strauss, *supra* note 80, at 116.

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.

84. European Comm. for Homeopathy, *Homeopathic Provings – A Fundamental Principle of Homeopathy*, HOMEOPATHY EUROPE, <http://homeopathyeurope.org/research/provings/> (last visited Sept. 2, 2016).

85. Sherman & Strauss, *supra* note 80, at 115.

86. Bruce Fye, *Nitroglycerin: A Homeopathic Remedy*, 73.1 CIRCULATION 21, 22 (1986).

87. Sherman & Strauss, *supra* note 80, at 117.

88. *Id.* For a detailed description of the homeopathic monograph approval process, see Brown, *supra* note 77, at 350-51.

89. The website of a major homeopathic manufacturer, Boiron, enthusiastically offers a “medicine finder” to help find the medication that best alleviates the consumer’s symptoms. BOIRON USA, [HTTP://www.boironusa.com](http://www.boironusa.com) (last visited Feb. 15, 2016).

prove that their product had an observable healing effect on an individual suffering from symptoms.⁹⁰

Once homeopathic products are no longer classified as “drugs,” the FTC’s proposed solution for any indication appearing on homeopathic packaging to “be supported by competent and reliable scientific evidence”⁹¹ would be incredibly effective. Classifying homeopathic products as dietary supplements would subject them to requirements of scientific validation of any “indication” claim.⁹² An “indication” tells the consumer what the drug should be used for. For example, the statement “temporarily relieves . . . symptoms due to hay fever or other respiratory allergies” is an indication for use.⁹³ As it stands, homeopathic products can make such claims without reliable and competent scientific evidence, resulting in consumer confusion as well as a current regulatory conflict between government agencies.

B. Regulating Homeopathic Products As Dietary Supplements Will Result In More Effective Regulation

The standards for proof of safety and efficacy are different for dietary supplements than for drugs.⁹⁴ Congress enacted the Dietary Supplement Health and Education Act in 1994 to clarify that dietary supplements would be regulated “similar to food products” as long as the products did not promote themselves as being drugs.⁹⁵ Consequently, dietary supplements do not require premarket evaluation of safety and efficacy before the product can be marketed.⁹⁶ They must, however, comply with the truth-in-advertising standards of the FTC.⁹⁷

90. Transcript of Fed. Trade Comm’n Workshop on Homeopathic Medicine & Advertising at 9 (Sept. 21, 2015) [hereinafter FTC Workshop Transcript], http://www.ftc.gov/system/files/documents/public_events/644921/homeopathic_medicine_workshop_transcript_9-21-15.pdf (FTC staff “noted that it’s its belief that consumers may be confused by retail store shelf placement of homeopathic products side by side with conventional medicine that, in fact, has been approved by the FDA for efficacy”).

91. FTC Staff Comment, *supra* note 10, at 6.

92. *Id.* at 4-6.

93. FDA, *OTC Drug Facts Label*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm> (last visited Sept. 2, 2016).

94. See Rahi Azizi, Comment, “Supplementing” the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act, 98 CALIF. L. REV. 439, 440-41 (2010).

95. See *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1038 (10th Cir. 2006).

96. Lars Noah & Barbara A. Noah, *A Drug by Any Other Name . . . ? : Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL’Y REV. 165, 169 (2006).

97. See FED. TRADE COMM’N BUREAU OF CONSUMER PROT., DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 1, 3 (2011), <https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf>.

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” unless that claim is proven through competent scientific evidence.⁹⁹ Dietary supplements can, however, make “structure/function” claims.¹⁰⁰ Those claims are as follows:

Finally, structure/function claims (1) describe a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States, (2) describe the role of a dietary ingredient intended to affect the structure or function in humans, (3) characterize the documented mechanism by which a dietary ingredient acts to maintain such structure or function, or (4) describe the general well-being from consumption of a nutrient or dietary ingredient.¹⁰¹

A structure/function claim requires a disclaimer stating that the claim has not been evaluated by the FDA and is not intended to diagnose, treat, cure or prevent any disease.¹⁰² Such a permissible claim, for example, would be that a particular homeopathic product “improves immune system function.” A homeopathic product would *not* be able to, for instance, claim that their product “cures common cold symptoms” without scientific proof.

There are concerns and issues with dietary supplement regulation in general.¹⁰³ For instance, issues have surfaced regarding the problematic definition of a “dietary supplement” and the claims made by the manufacturers.¹⁰⁴ However, the regulatory landscape of the DSHEA is perfect for homeopathic products. Homeopathic products are extremely safe

98. See 21 C.F.R. § 101.14 (2016); FDA, *Label Claims for Conventional Foods and Dietary Supplements*, FDA, <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm> (last visited Sept. 2, 2016).

99. 21 C.F.R. § 101.14 (2016).

100. 21 C.F.R. § 101.93(f) (2016).

101. John E. Villafranco & Andrew B. Lustigman, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration and National Advertising Division*, 62 FOOD & DRUG L.J. 709, 714 (2007); see also 21 U.S.C. § 343(r)(6) (2013); 21 C.F.R. § 101.93(f).

102. Villafranco & Lustigman, *supra* note 101, at 714. See also 21 U.S.C. § 343(r)(6) (2016); 21 C.F.R. § 101.93(f) (2016).

103. See, e.g., Noah & Noah, *supra* note 96, at 165-67; Cary Elizabeth Zuk, Note, *Herbal Remedies Are Not Dietary Supplements: A Proposal for Regulatory Reform*, 11 HASTINGS WOMEN'S L.J. 29 (2000).

104. Laura A.W. Khatchersian, *Regulation of Dietary Supplements: Five Years of DSHEA*, 54 FOOD & DRUG L.J. 623, 629 (1999).

and have little side effects if the dilution requirements are met.¹⁰⁵ In fact, one of the only instances of an unsafe homeopathic product was when Zicam manufactured a nasal spray with *too much* active ingredient in the product, thus running afoul of the principles of homeopathy.¹⁰⁶

Even with the issues inherent in the DSHEA, classifying homeopathic drugs as dietary supplements would provide multiple benefits. Mainly, the products would no longer be classified as drugs, and thus would allow them to be sold as long as the products did not make unsubstantiated health claims.¹⁰⁷ If homeopaths can scientifically demonstrate that their products do, in fact, cure or aid symptoms, then they can continue to make claims on their packaging. Dietary supplements are able to make such health claims only when the FDA “determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”¹⁰⁸ Consumers will further continue to be secure in the knowledge that the FDA regulates and confirms that products making claims can be scientifically backed.

Regulation of homeopathic medication as dietary supplements would further allow regulation of false and deceptive advertising by the FTC.¹⁰⁹ Homeopathic product manufacturers must still ensure that the advertising is “truthful, non-misleading and substantiated at the time of dissemination.”¹¹⁰ This advertising must be “based on competent and reliable scientific evidence.”¹¹¹ Contrary to the current regulatory scheme, homeopathic products would not be able to hide behind the CPG, and the FTC would be

105. “[A]pproximately 5.8% of all of the homeopathic exposure patients end up in an emergency department or seeking some type of healthcare outside of just a call to the Poison Center, versus about five times the number with all pharmaceuticals . . . Ninety-five percent were treated without a healthcare facility referral, and there’s overall very low morbidity and mortality associated with at least the calls that are retrieved and managed by poison centers.” Transcript, MICHAEL FARKAS, CAPITAL REPORTING CO., HOMEOPATHIC PRODUCT REGULATION: EVALUATING THE FOOD AND DRUG ADMINISTRATION’S REGULATORY FRAMEWORK AFTER A QUARTER-CENTURY PART 15 PUBLIC HEARING 26-27 (2015), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM449164.pdf> (reporting statement of Edward Krezelok). This is probably because the product being sold has very little active ingredient. See *supra* Part I.A.

106. Gaither, *supra* note 33.

107. Requiring homeopathic products to remain classified as “drugs” would subject them to a stringent regulatory environment that would be all but impossible for them to meet. See *infra* Part III.A.

108. 21 C.F.R. § 101.14(c) (2016).

109. Villafranco & Lustigman, *supra* note 101, at 711; F.T.C.; Act of 2006 §§ 5, 12; 15 U.S.C. §§ 45(a), 52 (2009).

110. Villafranco & Lustigman, *supra* note 101, at 712.

111. *Id.*

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-out may need to be enacted in order for homeopathic products to be considered a “supplement.” The underlying purpose of the DSHEA was “to ensure that the public has over-the-counter access to ‘dietary supplements,’ which includes vitamins, minerals, amino acids and herbs.”¹¹³ Strictly speaking, homeopathic medication does not supplement the body’s needs for vitamins and minerals. Further, if the FDA finds that the purpose and marketing materials of homeopathic products is meant for the treatment, mitigation, and cure of a disease, then homeopathic products would go back to being classified as “drugs.”¹¹⁴

Once a product’s claim goes “beyond risk reduction and purports to treat a disease,” the FDA can mandate that the product be classified as a drug.¹¹⁵ The FDA has discretion as to how to classify the claims.¹¹⁶ Further, regulation of homeopathic products as a dietary supplement could restrict the sale of homeopathic medication not ingested in the way of capsules or pills. Homeopathic medications used, for instance, as nasal sprays may be subject to greater scrutiny and regulation due to the delivery mechanism.¹¹⁷ Because nasal sprays and topical creams are more similar to drugs than simple nutritional supplements, such products may be restricted from sale at all regardless of the types of claims made.¹¹⁸ However, once homeopathic products are classified as dietary supplements, the regulatory landscape would provide benefits to the consumer, benefits to the manufacturers, and would allow the FTC to perform its duties and protect against false advertising.

112. “[T]he FDA’s current regulatory framework could lead homeopathic drug advertisers to incorrectly assume, or at least argue, that the FTC does not require competent and reliable scientific evidence to support the advertisers’ efficacy claims.” FTC Staff Comment, *supra* note 10, at 7 (2015).

113. *United States v. Ten Cartons*, 888 F. Supp. 381, 392 (E.D.N.Y. 1995); *see also* *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 46 (D.D.C. 2003) (stating that the DSHEA’s purpose was to protect consumers’ right of access to safe dietary supplements).

114. *See United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004).

115. *Whitaker*, 239 F. Supp. 2d at 50.

116. *See id.*

117. There was great discussion about Ener-B and the fact that it was not meant to be “ingested.” Rather, it was meant to be applied directly to the nasal cavity. *See Ten Cartons*, 888 F. Supp. at 392-95.

118. *See id.*

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 remedy is chosen only after detailed documentation of a patient’s symptoms and signs . . . is completed. This ‘individualization’ would make it extremely difficult to conduct a randomized clinical trial.”¹²³ Finally, there is dubious scientific evidence that homeopathic medication has any true effectiveness whatsoever.¹²⁴

The costs of clinical trials are staggering, and even if homeopathy were truly effective, the sheer cost of the tests would result in an almost insurmountable burden to the industry. A clinical trial can cost more than \$100 million.¹²⁵ With the list of commonly used homeopathic remedies

119. FTC Staff Comment, *supra* note 10, at 5.

120. *Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999).

121. *See id.*; 21 U.S.C. § 355 (2013 & Supp. 2016).

122. *See* Patrick L. Sheldon, Note, *The Truth About Homeopathy: A Discussion of the Practice and the Dangers That Inhere*, 8 QUINNIPIAC HEALTH L.J. 289, 314-17 (2005) (outlining a history of studies finding no effectiveness of homeopathy on treating a condition).

123. *Sherman & Strauss, supra* note 80, at 118.

124. A comprehensive study by the Australian Medical Association concluded that homeopathy is not effective. *Austl. Med. Ass’n, Evidence Is Clear That Homeopathy Is Not an Effective Treatment*, AMA (Apr. 18, 2010), <https://ama.com.au/media/evidence-clear-homeopathy-not-effective-treatment>.

125. *See* U.S. DEP’T OF HEALTH & HUMAN SERV.’S, EXAMINATION OF CLINICAL TRIAL COSTS AND BARRIERS FOR DRUG DEVELOPMENT (2014), https://aspe.hhs.gov/sites/default/files/pdf/77166/rpt_erg.pdf; Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012, 7:41 AM), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs>.

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 deserves to die. One of the main reasons is “the lack of scientific proof establishing its efficacy,” which, according to some, renders the entire practice as “quackery.”¹²⁹ According to Kathleen M. Boozang’s article *Western Medicine Opens the Door to Alternative Medicine*, to prescribe homeopathic medications would violate basic medical ethics; physicians must at the very least “utilize their skills and knowledge to offer patients treatment which they *reasonably believe* will actually treat the condition from which they suffer.”¹³⁰ Boozang further asserts that even acquiescing to a patient’s demand for alternative therapies is against “traditional ethical principles” because of a physician’s “affirmative obligation to refuse to provide medical treatment when medicine cannot cure the disease or improve the patient’s condition.”¹³¹

126. See *List of Homeopathic Preparations*, WIKIPEDIA, https://en.wikipedia.org/wiki/List_of_homeopathic_preparations (last updated Mar. 9, 2016, 11:16 AM).

127. See Sherman & Strauss, *supra* note 80, at 118.

128. 21 C.F.R. § 101.14 (2016); FDA, *supra* note 98.

129. Sheldon, *supra* note 122, at 314; Mary Forgione, *James Randi’s Challenge and the Search for Science in Homeopathy*, L.A. TIMES (Feb. 7, 2011), <http://articles.latimes.com/2011/feb/07/news/la-heb-james-randi-homeopathy-20110207>; see Lambert v. Shearer, 616 N.E.2d 965, 971-72 (1992) (stating that a doctor’s opinion that homeopathy is “pure quackery and witchcraft” was relevant to the issue at hand and was not simply “some irrelevant professional attack”).

130. Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 205 (1998) (emphasis added).

131. *Id.* at 208 n.146 (citing Eric M. Levine, *A New Predicament for Physicians: The Concept of Medical Futility, the Physician’s Obligation to Render Inappropriate Treatment, and the Interplay of the Medical Standard of Care*, 9 J.L. & HEALTH 69, 85 (1994)) (quoting James J. Murphy, *Beyond Autonomy: Judicial Restraint and the Legal Limits Necessary to Uphold the Hippocratic Tradition and Preserve the Ethical Integrity of the Medical Profession*, 9 J. CONTEMP. HEALTH L. & POL’Y 451, 466 (1993)).

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 As long as consumers are protected from misleading and false advertisements, they should not be restricted as to the choices of treatment available to them.¹⁴⁰

132. FTC Workshop Transcript, *supra* note 90, at 25 (statement of Candace Corlett). FDA Transcript, *supra* note 21, at 289-91 (statement of Alyssa Wostrell).

133. Ryan Abbott, *Treating the Health Care Crisis: Complementary and Alternative Medicine for PPACA*, 14 DEPAUL J. HEALTH CARE L. 35, 46 (2011).

134. Consumers, once fully informed and educated about homeopathy, might be more likely to use such remedies. See FDA Transcript, *supra* note 21, at 28-40 (statement of Karl Robinson).

135. FDA, *supra* note 3.

136. Fye, *supra* note 86, at 22.

137. *Id.* at 21.

138. FDA Approves First Anti-Diarrheal Drug For HIV/AIDS Patients, 2012 WL 6759395, at *1; see also Abbott, *supra* note 133, at 71-72.

139. Villafranco & Lustigman, *supra* note 101, at 711-12. 15 U.S.C.S § 45(a) (LexisNexis 2016).

140. Junod, *supra* note 2, at 182 (explaining that DSHEA was partly passed because “Congress wanted consumers to have broader rather than more restricted access to dietary supplements.”).

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 Borneman¹⁴¹ 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>.

142. FTC Workshop Transcript, *supra* note 90, at 22-23 (statement of Jay Borneman).

143. See *Mason v. Heel, Inc.*, No. 3:12-cv-03056-GPC-KSC, 2014 WL 1664271, at *5 (S.D. Cal. Mar. 13, 2014); *Nigh v. Humphreys Pharmacal, Inc.*, No. 12cv2714-MMA-DHB, 2013 WL 5995382 (S.D. Cal. Oct. 23, 2013).

144. *Nigh*, 2013 WL 5995382, at *1.

145. *Id.* at *2.

146. *Id.*

147. *Heel, Inc.*, 2014 WL 1664271, at *5-6.

148. *Id.* at *5.

149. *Id.* at *6.

proposal is progressive, it still does not address the issue of why homeopathic manufacturers are able to make non-clinically proven claims as long as they do not explicitly use the words “clinically proven.” Heel, Inc. subsequently ceased operations in North America as a result of the lawsuit.¹⁵⁰

Unfortunately, neither proposal solves the main issues of homeopathic labeling. One of the reasons of the FTC’s call to the FDA to revise the regulations governing homeopathic medication is because of confusion among consumers as to what homeopathy is.¹⁵¹ Many consumers cannot “distinguish between herbal and homeopathic products.”¹⁵² Adults and parents also cannot “readily differentiate between evidentiary requirements and federal regulatory requirements for different types of products.”¹⁵³ Homeopathy was not fully understood by focus group participants, and “homeopathy” was used interchangeably with terms such as “natural” and “herbal.”¹⁵⁴ In focus group tests, even adding prominent FDA disclaimers on packaging resulted in a percentage of respondents believing that the products were FDA approved and were tested for safety and efficacy.¹⁵⁵ Aggressive disclosures did reduce the risk of confusion.¹⁵⁶ Further, the question still remains as to why the claims should continue to be allowed in the first place, remedied only with a disclosure.

The disclosure remedy also does not solve the discrepancy between the FDA and FTC. The solution adopted by the courts results in homeopathic products continuing to make unsubstantiated health claims. If the labeling imposed by the injunction was implemented, homeopathic medications would still be the only product that would be able to make health claims without scientific evidence and would thus still be misleading.¹⁵⁷ Further, the average consumer would have difficulty understanding what a

150. *Heel To Focus on Core Markets*, HEEL (May 23, 2014), <http://www.heel.com/en/heel-to-focus-on-core-markets.html>.

151. See FTC Staff Comment, *supra* note 10, at 6.

152. FTC Staff Comment, *supra* note 10, at 10.

153. *Id.*

154. *Id.* at 11.

155. MANOJ HASTAK, EFFECTS OF EXPOSURE TO PACKAGES OF SEVERAL HOMEOPATHIC PRODUCTS ON CONSUMER TAKEAWAY AND BELIEFS, REPORT SUBMITTED TO THE FEDERAL TRADE COMMISSION (2012), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitc.pdf.

156. See FTC Staff Comment, *supra* note 10, at 14 (“It is possible that different or more prominent disclosures could further reduce the percentage of consumers with the misperception that homeopathic products are FDA approved.”).

157. See FTC Staff Comment, *supra* note 10, at 5.

“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 “constitutionally preferable to outright suppression.”¹⁶¹ However, this is only true “so long as [the] advertising is not inherently misleading.”¹⁶²

Unfortunately, even if the product is labeled as not having been evaluated by the FDA, the issue still remains that the product claims that it will treat symptoms with no real proof of efficacy.¹⁶³ Homeopathic products are currently making claims that their products can treat diseases with no scientific proof.¹⁶⁴ Further, because the indications and claims are made on the label at the point of sale, there are limitations for civil remedies under the Lanham Act.¹⁶⁵

PART IV: CONCLUSION

Homeopathic products have been under intensive scrutiny by the public and by regulatory bodies.¹⁶⁶ FDA regulations had provided a disincentive for the FTC to perform its main function of enforcing false advertising claims against homeopathic drug manufacturers.¹⁶⁷ James Randi, a skeptic and self-described “investigator and demystifier of paranormal and pseudoscientific claims,”¹⁶⁸ began a lecture about irrational beliefs by taking what should be

158. *Id.* at 15-16.

159. *See supra* Part II.A.

160. 15 U.S.C. §§ 45, 55 (2015).

161. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

162. *Id.*

163. *See supra* Part II.A.

164. *See* AUSTL. GOV'T NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 67.

165. *See* Villafranco & Lustigman, *supra* note 101, at 712 (“In general, in order to comply with the FTC Act, dietary supplement advertisers must ensure that advertising is truthful, non-misleading and substantiated at the time of dissemination.”).

166. The FDA solicited opinions in a public hearing to better understand “consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic.” Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century; Public Hearing, 80 Fed. Reg. 16327-01 (Mar. 27, 2017).

167. *See* FTC Staff Comment, *supra* note 10, at 7.

168. James Randi Educ. Found., *About James Randi*, RANDI, <http://web.randi.org/about-james-randi.html> (last visited Sept. 9, 2016).

2016]

CLOSE THE HOMEOPATHIC LOOPHOLE

145

a fatal dose¹⁶⁹ of homeopathic sleeping pills.¹⁷⁰ Yet, homeopathy is a growing industry; in 2014, consumers spent \$1.2 billion on homeopathic drugs,¹⁷¹ in part due to the confusing and misleading labels on homeopathic packaging.

The solution to the discrepancy between the FTC and FDA is to reclassify homeopathic products as dietary supplements, thus requiring any health claim made on the package to be substantiated with scientific evidence. This would reduce the confusion among consumers as to the efficacy of the products being sold. Further, it would allow homeopathic products to remain on the shelves by not subjecting them to the rigorous drug approval process. Also, should companies selling homeopathic products wish to include health claims on their packaging, they are welcome to do so as long as such claims are backed with scientific proof and evidence.

*Roy C. Manukyan**

169. Mr. Randi does not get so much as drowsy from the product. TED, *Homeopathy, Quackery, and Fraud*, TED (Feb. 2007), https://www.ted.com/talks/james_randi?language=en.

170. *Id.*

171. Consumer Reports, *Homeopathic Drugs: No Better Than Placebos?*, WASHINGTON POST (Dec. 21, 2015), https://www.washingtonpost.com/national/health-science/homeopathic-drugs-no-better-than-placebos/2015/12/18/037b3976-7750-11e5-a958-d889faf561dc_story.html.

* J.D. Candidate 2017, Southwestern Law School. I would like to thank all those who have been patient with my chronic irritability throughout my law school education. Thank you to Alexandra Wright, whose support allowed me to overachieve beyond what I thought was possible. Thank you to my family, my mother Chareta Manukyan, my sister Becky Manukyan, and to my late father Ruben Manukyan, who I try to make proud each and every day.