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The Food and Drug Administration Versus the Federal Trade Commission: Reconciling Their Interests in Regulating Homeopathic Products, 49 J. Marshall L. Rev. 1193 (2016)

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THE FOOD AND DRUG ADMINISTRATION VERSUS THE FEDERAL TRADE COMMISSION: RECONCILING THEIR INTERESTS IN REGULATING HOMEOPATHIC PRODUCTS

JORDANNAH BANGI*

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I. THE POPULARITY AND GROWING SAFETY CONCERNS FOR HOMEOPATHIC PRODUCTS SPUR FDA AND FTC SCRUTINY

In the battle for retail shelf space in pharmacies and drug store chains across the country, over-the-counter homeopathic products are edging out conventional medicines as more Americans continue to buy homeopathic products off the shelves.¹ The Centers for Disease Control and Prevention estimated that in 2007, Americans spent \$34 billion a year on alternative medicine and doctor visits.² Of that total, Americans spent \$2.9 billion on homeopathic medicines, and this figure is expected to increase.³ Consumers use homeopathic products just like conventional medicines to treat common ailments such as cough, cold and flu, muscle pain, and children's ailments.⁴ As its popularity increases because of its easy access, availability, and low cost, more individuals will seek natural and holistic approaches to personal health.⁵ However, recent notoriety in the health services market

1. See Press Release, Federal Trade Comm'n, FTC Posts Agenda for September 21 Workshop to Examine Advertising for Over-the-Counter Homeopathic Products (Sept. 11, 2015) (on file with author and www.ftc.gov/news-events/press-releases/2015/09/ftc-posts-agenda-september-21-workshop-examine-advertising-over) (noting the increase in the U.S. homeopathic drug industry has transformed "from one based primarily on formulations prescribed for individual users to mass-market formulations widely advertised and sold nationwide in major retail stores").

2. NAHIN, R. L. ET AL., NATIONAL HEALTH STATISTICS REPORTS COSTS OF COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) AND FREQUENCY VISITS TO CAM PRACTITIONERS: UNITED STATES, 2007, 1 (2009).

3. *Id.* at 3.

4. FTC Staff Comment Before the FDA Regarding the Current Use of Human Drug and Biological Products Labeled as Homeopathic and the FDA's Regulatory Framework for Such Products, 80 Fed. Reg. 16327 (Mar. 27, 2015), [hereinafter FTC STAFF COMMENT BEFORE THE FDA].

5. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 800 (Robert C. Clark et al. eds., 4th ed. 2014). Complementary and alternative medicines have gained widespread popularity. *Id.* This is evidenced by the "March 2002 publication of a final report by the White House Commission on Complementary and Alternative Medicine Policy [which] led to

has caught the interest of the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC).⁶

Both the FDA and FTC share responsibilities in regulating homeopathic products.⁷ Although there is some regulation overlap, generally the FDA oversees product labeling, while the FTC regulates the truth and falsity of advertising claims.⁸ However, homeopathy's recent rise in popularity and expanding product line has not only forced both agencies to review its current regulations, but has also revealed each agency's approach and differences to regulating homeopathic products.⁹

In April 2015, the FDA held a public hearing on homeopathic treatments in an effort to reevaluate its current regulatory framework.¹⁰ The FDA examined whether it should tighten its regulations given the growing popularity and concern for the safety and efficacy of homeopathic drugs.¹¹ In August 2015, the FTC, in response to the FDA's request for public input on this issue, submitted a comment to the FDA.¹² The FTC expressed its concern that the FDA's current regulations were inadequate and lacked "competent and reliable scientific evidence."¹³ In turn, the FTC sought its own public comment regarding homeopathic advertising in a workshop it held on September 21, 2015.¹⁴ Soon thereafter, the FDA reopened its request for comments for an additional 60 days, scheduled to end November 9, 2015.¹⁵ The future of the FDA's regulation of homeopathic products remains uncertain as it evaluates how to address the concerns of consumers, the FTC, health care professionals, the homeopathic drug industry, policy makers, and other stakeholders.

This Comment seeks to explore the rise of the homeopathic industry and the limitations associated with current regulations on homeopathic products. This Comment proposes that if the FDA

the establishment of an Office of Complementary and Alternative Medicine in the National Institutes of Health." *Id.*

6. Emily Field, *FDA Considers Heavier Regs for \$2.9B for Homeopathy Industry*, LAW360, (Apr. 21, 2015, 4:15 PM ET), www.law360.com/articles/645949/fda-considers-heavier-regs-for-2-9b-homeopathy-industry; see also FTC PUBLIC WORKSHOP, *supra* note 2. See *infra* Part II C for the lawsuits involving homeopathic products.

7. See *infra* Part II B.

8. *Id.*

9. *Id.*

10. U.S. FOOD & DRUG ADMIN, HOMEOPATHIC PRODUCT REGULATION: EVALUATING FDA'S REGULATORY FRAMEWORK AFTER A QUARTER-CENTURY (Sept. 10, 2015), www.fda.gov/Drugs/NewsEvents/ucm430539.htm [hereinafter FDA PUBLIC WORKSHOP].

11. *Id.* See *infra* Part II C.

12. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

13. *Id.*

14. *Id.*

15. Notice of Public Hearing; Reopening of Comment Period, 80 Fed. Reg. 54256 (Sept. 9, 2015).

mandates homeopathic products to undergo the same safety and effectiveness standards as conventional drugs, few will pass muster. This Comment suggests that the FDA should require homeopathic products to carry a disclaimer label similar to those used on prescription drugs or certain food or food products. Disclaimers would provide consumers with more adequate information to make informed decisions about homeopathic products and would help bridge the current divide between both agencies on the issue.¹⁶ This topic also sheds light on the challenges that federal agencies like the FDA and the FTC are facing in trying to balance their own individual interests over the regulation of homeopathy.¹⁷ This Comment also explores the unique position the FDA is in given its documented lack of oversight over homeopathic products in the past.¹⁸ The current regulatory landscape has made consumers confused about homeopathy and concerned about the safety and efficacy of homeopathic products and left the homeopathic industry richer than ever.

Part II of this Comment will provide a brief overview of homeopathy, its controversial reputation, and its explosion as a multi-billion dollar industry. It will also explore the history of each of the FDA and FTC's respective jurisdictions over the regulation of homeopathic products. This section will also discuss the limitations of the FDA's current regulations given the increase in lawsuits, consumer complaints, and warning letters in recent years. Furthermore, Part II will look at the FTC's recent criticisms

16. Jann Bellamy, *Battle of the Feds: FTC Tells FDA to do its Job Regulating Homeopathy*, SCIENCE-BASED MEDICINE (Sept. 3, 2015), www.sciencebasedmedicine.org/battle-of-the-feds-ftc-tells-fda-to-do-its-job-regulating-homeopathy/ (noting the conflict that exists between the FDA and the FTC in regulating homeopathic remedies).

The FTC's advertising substantiation policy *requires* that health-related efficacy claims be supported by competent and reliable scientific evidence. The FDA, despite federal law, *does not require* evidence of efficacy for homeopathic drugs prior to their being marketed. This creates a potential conflict between the two regulatory schemes, resulting in homeopathic over-the-counter (OTC) "drugs" on the market that both comply with FDA's policy and violate FTC's policy.

Id.

17. FTC Staff Comment Before the FDA, *supra* note 2 (noting the FTC's interest in revamping the FDA's existing regulatory framework which it sees creates harm for consumers and confusion for advertisers); see Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16327 (Mar. 27, 2015) (discussing the FDA's efforts to obtain public input on the current enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health).

18. *Id.* (noting that the FDA does not evaluate the safety and efficacy of OTC homeopathic drugs).

of the FDA's regulation of homeopathic products, specifically, the comment it sent to the FDA in August of 2015.

Part III of this Comment will evaluate the FTC's proposals and the FDA's position, and their likely impact on consumers and the homeopathic drug industry. Part IV of this Comment proposes that the FDA should require homeopathic products to carry a disclaimer label and to occupy a separate section on market shelves apart from other OTC drugs. This section will suggest why including ingredient and FDA regulatory information on store shelves and product packaging will enhance consumer safety. These recommendations will help the FDA adopt a regulatory policy that effectively caters to the growing homeopathic industry and the FTC's interest in improving the marketing and advertising of homeopathic products.

II. HOMEOPATHY AND THE CONFLICT BETWEEN THE FDA AND THE FTC'S POLICIES ON REGULATING HOMEOPATHIC PRODUCTS

A. The Principles and Practice of Homeopathy

1. Basic Principles of Homeopathy

The FDA defines homeopathy as “[t]he practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects.”¹⁹ Homeopathy has existed for thousands of years. The Greek physician Hippocrates (462-377 BC) is one of the first people to mention homeopathy.²⁰ He wrote, “By similar things a disease is produced and through the application of the like, it is cured.”²¹ Hippocrates “described the symptoms of disease as the expression of Nature’s healing powers – the view of modern homeopathy.”²² Galen, another Greek physician, also referred to the concept of “natural cure by the likes.”²³ In the 15th century, a Swiss physician who adopted the name Paracelsus, wrote that “likes must be cured by likes . . .”²⁴ In the 17th century physician

19. FDA Compliance Policy Guides, *CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed*, www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm.

20. WORLD HEALTH ORGANIZATION, LEGAL STATUS OF TRADITIONAL MEDICINE AND COMPLEMENTARY/ALTERNATIVE MEDICINE: A WORLDWIDE REV. 3 (2001).

21. TONI BARK, M.D. & DAVID DWYER, THE TEXTBOOK OF COMPLEMENTARY AND ALTERNATIVE MEDICINE 65-66 (Chun-Su Yuan & Eric J. Bieber eds., 2003).

22. *Id.* at 66.

23. *Id.*

24. *Id.*

George Stahl wrote, “To treat with opposite acting remedies is the reverse of what it ought to be. I am convinced that disease will yield to, and be cured by, remedies that produce similar affections.”²⁵ And then in the 19th century, German physician Dr. Christian Friedrich Samuel Hahnemann further developed homeopathy as an alternative to the prevalent “violent and dangerous medical practices of his time.”²⁶ Dr. Hahnemann is credited with establishing two major principles of homeopathy,²⁷ including the “law of similars” (“let like cure like”) and the “law of infinitesimals.”²⁸ The first principle is the “law of similars,” which is premised on the idea that if a large dose of a medicinal substance can cause symptoms in a healthy person, that same substance, in a smaller dose, can treat those same symptoms in a person who is ill.²⁹ Employing the “law of similars,” a substance like ipecac, which causes nausea and vomiting in a healthy individual,³⁰ can be used, in “small concentrations for someone suffering from nausea and vomiting.”³¹ The second principle of homeopathy is the “law of infinitesimals.”³² The “law of infinitesimals” states that a medicinal substance that undergoes a process of successive dilutions (either by using water or alcohol or grinding the substance to a fine powder)³³ helps to lessen its toxicity and increase its potency and curative effects.³⁴

25. *Id.*

26. John Lunstroth, Voluntary Self-Regulation of Complementary and Alternative Medicine Practitioners, 70 ALB. L. REV. 209, 214 (2006) (discussing the development of homeopathy and its main tenets).

27. WORLD HEALTH ORGANIZATION, *supra* note 20, at 3.

28. Suzanne White Junod, *An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation*, 55 FOOD DRUG L.J. 161, 162 (2000) (examining the origins of homeopathy and the controversy surrounding the inclusion of the Homeopathic Pharmacopeia of the United States (HPUS) in the Federal Food, Drug, and Cosmetic Act (FDCA)).

29. Andrew B. Lustigman & John E. Villafranco, *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, 722 (2007) (discussing the FTC’s regulation of homeopathic advertising claims).

30. Ipecac, THE FREE DICTIONARY.COM, www.medical-dictionary.thefreedictionary.com/ipecac (last visited Sept. 27, 2015).

31. Kimberly Brown, Comment, *Federal Regulation of Homeopathy: A Pathway to Consumer Protection*, 29 TEMP. J. SCI. TECH & ENVTL. L. 337, 338 (2010) (noting the importance of the “law of similars” to Dr. Hahnemann’s development of homeopathic medicine).

32. Junod, *supra* note 28, at 162.

33. Max Sherman & Steven Strauss, *Homeopathic Drugs—Regulatory Concerns*, 45 FOOD DRUG COSMETIC L.J. 113, 115 (1990) (examining the process in homeopathy that uses extreme dilutions to lessen the toxic effects of a substance and to increase its potency).

34. Junod, *supra* note 28, at 162.

2. Types of Homeopathic Remedies and Where to Find Them

Homeopathic remedies use ingredients derived from plants, minerals, and other substances.³⁵ Examples include red onion, arnica (mountain herb), crushed whole bees, white arsenic, poison ivy, and stinging nettle.³⁶ Ingredients found in homeopathic products are diluted and formulated as sugar pills, tablets, ointments, gels, and creams.³⁷ These remedies aim to treat the “causes of the underlying disease as opposed to the symptoms” without the use of technology.³⁸

Homeopathic products occupy substantial retail shelf space alongside OTC pharmaceutical drugs.³⁹ Grocers like Whole Foods carry homeopathic remedies to treat allergies and heartburn.⁴⁰ The drug retailing chain Walgreens markets homeopathic remedies on its website including treatments for common ailments such as hemorrhoids, sleeping and snoring, and muscle pain and stiffness.⁴¹ Homeopathic remedies are also used to treat digestive issues, colds, influenza, allergies, and other maladies.⁴² Despite the popularity of homeopathic medicine, critics continue to doubt its effectiveness.⁴³

35. U.S. NAT'L CTR. FOR COMPLEMENTARY AND INTEGRATIVE HEALTH, HOMEOPATHY 1 (2009) at 1, https://nccih.nih.gov/sites/nccam.nih.gov/files/Homeopathy_08-03-2015.pdf.

36. *Id.*

37. *Id.*

38. Anna M. Richardson, *Informed Patients Go Homeo Happy: Applying the Doctrine of Informed Consent to Homeopathic Practitioners*, 34 OHIO N. U. L. REV., 593, 596-97 (2008) (discussing the history and development of homeopathy); see also Lunstroth, *supra* note 26, at 216 (noting that technology is not used to evaluate the patient or drugs. Instead, the patient “elucidates the symptoms under careful questioning of the homeopath and the signs of the disease are discerned by the patient, other observers, and the homeopath.”).

39. Brady Dennis, *FDA to Revisit its Policies on Homeopathic Products*, THE WASH. POST (Apr. 18, 2015), www.washingtonpost.com/national/health-science/for-first-time-in-decades-fda-to-revisit-how-it-regulates-homeopathic-products/2015/04/18/2753315c-e207-11e4-81ea-0649268f729e_story.html

40. *Id.*

41. WALGREENS, www.walgreens.com/store/c/homeopathic-remedies/ID=360535-tier2general (last visited Sept. 27, 2015).

42. Julie Deardorff, *Homeopathy Prospers Even as Controversy Rages*, CHI. TRIB. (Mar. 6, 2011), http://articles.chicagotribune.com/2011-03-06/news/ct-met-0306-homeopathy-20110306_1_homeopathy-oscillococcinum-products.

43. *Id.* See also Dennis Thompson, *FDA Weighs Tighter Regulation of Homeopathic Medicines*, HEALTHDAY REPORTER (Apr. 21, 2015), <http://consumer.healthday.com/alternative-medicine-information-3/mis-alternative-medicine-news-19/fda-weighs-tighter-regulation-of-homeopathic-medicines-698646.html> (noting that critics argue that that homeopathic products “should endure the same sort of regulation as the over-the-counter drugs with which they share shelf space.”). Critics also contend that “[there is] no evidence that homeopathic drugs actually work . . . there are concerns that the [homeopathic] medications may contain a mixture of ingredients that could prove dangerous to users.” *Id.*

3. Controversy Surrounding Homeopathy

Advocates of homeopathic products claim their “natural” properties effectively treat other health conditions without the side effects of conventional drugs.⁴⁴ Proponents of homeopathic products contend they are an effective alternative to conventional medicines.⁴⁵ Furthermore, they claim “the practice [of homeopathy] stimulates a patient’s ‘natural defense system, helps heal illness, and raises the general level of health.’”⁴⁶ Other advocates tout the products’ safeness and affordability.⁴⁷ When the FDA sought public comments on its current regulation of homeopathic drugs during an April 2015 hearing, Amy Rothenberg, board member of the American Association of Naturopathic Physicians (AANP), stated:

“Homeopathy is perceived favorably by physicians and patients, both for efficacy but especially for its safety profile. The low cost of the medicines, as well as the consistent quality of product, make them appealing to both physician and patient . . . Over decades of use, we have not found problems or variability with quality of the homeopathic product, and no toxicity has been reported.”⁴⁸

But homeopathy has also been subject to much criticism.⁴⁹

Some critics have dismissed homeopathy as mere “quackery,” “nonsense,” and “a sham.”⁵⁰ Others have blasted homeopathy as “pseudoscience,” claiming that it lacks any convincing evidence.⁵¹

44. *Id.*

45. Field, *supra* note 6.

46. Brown, *supra* note 31, at 346.

47. AMY ROTHENBERG, AMERICAN ASS’N OF NATUROPATHIC PHYSICIANS, HOMEOPATHIC PRODUCT REGULATION: EVALUATING FDA’S REGULATORY FRAMEWORK AFTER A QUARTER-CENTURY 3 (2015), www.fda.gov/downloads/Drugs/NewsEvents/UCM443222.pdf.

48. *Id.*

49. Deardorff, *supra* note 42 (noting homeopathy’s reputation as “one of the most polarizing forms of complementary and alternative medicine”).

50. See Chelsea Stanley, *Patient Protection and Affordable Act: The Latest Obstacle in the Path to Receiving Complementary and Alternative Health Care*, 90 IND. L.J., 879, 881 (2015) (discussing homeopathy as one of the most popular forms of complementary and alternative medicine, citing Bruce M. Hood, SUPERSENSE: WHY WE BELIEVE IN THE UNBELIEVABLE, 157 (2009); Nick Collins, *Homeopathy Is Nonsense, Says New Chief Scientist*, TELEGRAPH (Apr. 18, 2013, 2:48 PM), www.telegraph.co.uk/health/healthnews/10003680/Homeopathy-is-nonsense-says-new-chief-scientist.html; Timothy Caulfield & Christen Rachul, *Supported by Science?: What Canadian Naturopaths Advertise to the Public*, ALLERGY, ASTHMA, & CLINICAL IMMUNOLOGY, 2 (Sept. 15, 2011), <https://aacijournal.biomedcentral.com/articles/10.1186/1710-1492-7-14>.

51. Ronald A. Lindsay, Letter to the Editor, *The Pseudoscience of Homeopathy*, WASH. POST (May 9, 2014), www.washingtonpost.com/opinions/the-pseudoscience-of-homeopathy/2014/05/08/90e0de76-d55b-11e3-8f7d-7786660fff7c_story.html.

The FDA stated that “[it] was not aware of scientific evidence to support homeopathy as being effective.”⁵² The NCCIH acknowledges that homeopathy conflicts with “fundamental concepts of chemistry and physics” and lacks support to establish its efficacy.⁵³ Other opponents claim that homeopathic products provide nothing more than a placebo effect.⁵⁴ Michael De Dora, director of public policy for the Center for Inquiry, testified to the FDA that, “[a]side from a placebo effect, homeopathic products have no effect in treating illnesses.”⁵⁵

Other critics have expressed concern that the homeopathy industry preys on the gullibility of consumers who do not understand homeopathy.⁵⁶ For example, during the FTC’s public comment period on the regulation of homeopathic drugs in June 2015, one critic submitted a comment expressing his skepticism of homeopathy, urging the FTC to hold manufacturers more accountable:

People spend time and money on homeopathy and receive no benefit. In empirical terms, homeopathy is a scam. Homeopathic remedies should not be on the market With respect to the FTC, the potential problem of homeopathy lies in their claims I think any claims of curing diseases made by companies which sell homeopathic remedies violate the truth-in-advertising principles. And the FTC should bar companies from making such claims.⁵⁷

In addition to soliciting public feedback, the FTC has also conducted focus groups that found that consumers did not understand the nature of homeopathic products and their regulation.⁵⁸ According to the FTC’s report, once members of the focus group were informed about what “homeopathic” means and

52. U.S. Food & Drug Admin., FDA Online Label Repository, <http://labels.fda.gov/>; see also U.S. Nat’l Ctr. for Complementary and Integrative Health, *supra* note 35 (noting that most rigorous clinical trials have concluded that there is little evidence to support the effectiveness of homeopathy; also citing research by the Australian government’s National Health and Medical Research Council which concluded that “there are no health conditions for which there is reliable evidence that homeopathy is effective.”).

53. U.S. Nat’l Ctr. for Complementary and Integrative Health, *supra* note 35.

54. Deardorff, *supra* note 42.

55. Homeopathic Product Regulation: Evaluating FDA’s Regulatory Framework After a Quarter-Century, Testimony of the Center for Inquiry to the Food and Drug Administration by Michael De Dora 1 (Apr. 20, 2015), www.fda.gov/downloads/Drugs/NewsEvents/UCM443495.pdf [hereinafter *De Dora Testimony*].

56. Field, *supra* note 6.

57. Michael Mientus, Public Comment, *FTC to Host September Workshop in Washington, D.C., To Examine Advertising for Over-the-Counter Homeopathic Products*, (June 16, 2015), www.ftc.gov/policy/public-comments/2015/06/16/comment-00016.

58. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

how it works, they became confused and more skeptical about its efficacy.⁵⁹ Despite this confusion, homeopathic products continue to appeal to consumers and constitute a large proportion of the retail drug industry.⁶⁰

4. Increase in the Popularity of Homeopathic Products

Homeopathy has undergone phenomenal growth and acceptance in the United States in recent years.⁶¹ A 2007 National Health Interview Study (NHIS) found that “out-of-pocket costs for adults were \$2.9 billion for homeopathic medicines and \$170 million for visits to homeopathic practitioners.”⁶²

According to a 2012 NHIS study, approximately “5 million adults and 1 million children used homeopathy in 2011.”⁶³ In fact, “alternative medicine industry revenue is expected to amount to around 14.3 billion U.S. dollars in the United States” by 2016.⁶⁴ Given homeopathy’s popularity over the years, the FDA and FTC have juggled the responsibility of regulating an industry that continues to pose significant challenges and issues for both agencies.

B. FDA and FTC Regulations over Homeopathic Products

Both the FDA and the FTC regulate homeopathic drugs.⁶⁵ Pursuant to a 1971 Memorandum of Understanding, the FDA and FTC share interagency responsibilities.⁶⁶ While the FDA oversees

59. *Id.* According to the FTC’s focus group report, “parents and adults tended to group all non-conventional products together, including homeopathic products, into a single category, using the terms “natural,” “herbal,” and homeopathic” interchangeably.”

60. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2 (providing background on homeopathic products and the Federal Food, Drug, and Cosmetic Act).

61. Brown, *supra* note 31, at 339.

62. U.S. Nat’l Ctr. for Complementary and Integrative Health, *supra* note 35. The study was conducted by the Centers for Disease Control and Prevention’s National Center for Health Statistics. *Id.*

63. *Id.*

64. Projected Alternative Medicine Industry Revenue Growth in the U.S. From 2011 to 2016 (In Million U.S. dollars), STATISTA.COM, www.statista.com/statistics/203972/alternative-medicine-revenue-growth/ (last visited Oct. 10, 2016).

65. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2, at 3 “There is considerable overlap between FDA’s and FTC’s jurisdiction. For over 40 years, the FTC and the FDA have worked together collaboratively to regulate the marketing of OTC products.”

66. See Working Agreement between the FTC and FDA, 3 Trade Reg. Rep. ¶ 9851 (CCH) (1971) (discussing the collaboration of the FTC and the FDA in regulating the promotion of food, beverage, and dietary supplement products).

product labeling for homeopathic products, the FTC regulates the truth and falsity of advertising claims.⁶⁷ It is common for both agencies to issue press releases or warning letters announcing simultaneous investigation of a particular company or product.⁶⁸ Despite some overlap in their responsibilities, each agency has differed in their respective regulatory approach to OTC homeopathic drugs.⁶⁹

The FDA regulates homeopathy under the Federal Food Drug and Cosmetic Act (FDCA).⁷⁰ The FDCA requires that all drugs, including homeopathic drugs, must be recognized among qualified experts as safe and effective before they can be sold.⁷¹ However, homeopathic drugs have *never* been regulated the same way as conventional drugs.⁷² In 1971, while officials recognized the appeal of homeopathic products among laypersons and “questioned the ‘usefulness’ of these products,” the FDA took a more hands-off approach in subjecting them to OTC review.⁷³ This decision was based in large part to the FDA’s preoccupation with reviewing between 100,000 and 500,000 other OTC drug ingredients and prioritizing the regulation of vitamins and minerals.⁷⁴ The FDA further justified its decision to exclude homeopathic products from OTC review until “a later time” because of their “uniqueness” and limited presence on the drug market.⁷⁵ Certainly, the FDA at this time did not anticipate that homeopathic products would eventually gain more popularity among consumers and require more stringent regulations.⁷⁶

67. *Id.*

68. See FDA, *FTC Act to Remove “Homeopathic” HCG Weight Loss Products from the Market*, FEDERAL DRUG ADMINISTRATION (Dec. 6, 2011), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm282334.htm (describing how the FDA and FTC issued seven warning letters to companies marketing OTC human chorionic gonadotropin (HCG) products labeled as “homeopathic” for weight loss). The cross-agency collaboration between the FDA and the FTC aim to “[keep] [sic] unproven and potentially unsafe products from being marketed . . .” *Id.*

69. FTC STAFF COMMENT BEFORE THE FDA *supra* note 2, at 3.

70. See 21 U.S.C. § 321(g)(1) (2006) (quoting “[d]rugs [are] articles recognized in the . . . official Homeopathic Pharmacopoeia of the United States . . . intended to be used for the cure, mitigation, or prevention of disease”); see also Food and Drug Administration Compliance Guide 7132.15, *Conditions Under Which Homeopathic Drugs May Be Marketed* (Mar. 1995), www.fda/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm (providing information on the labeling requirements and good manufacturing practices (GMPs) for homeopathic products).

71. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

72. *Id.*

73. Junod, *supra* note 28, at 178.

74. *Id.*

75. *Id.*

76. *Id.* at 179. In the early 1980s, changes in the homeopathic marketplace including the increase in imported homeopathic drugs and the American Institute of Homeopathy’s revised stance in support of marketing homeopathic

It was not until 1988 that the FDA considered new regulations governing homeopathic drugs.⁷⁷ The FDA released a Compliance Policy Guide (“CPG”) 400.400 entitled “Conditions under Which Homeopathic Drugs May be Marketed,” in response to a growing homeopathic drug market that “ha[d] grown to [be] a multimillion dollar industry in the United States.”⁷⁸ The CPG provided guidance on the regulation of OTC and prescription homeopathic and the conditions under which homeopathic drugs may ordinarily be marketed in the U.S.⁷⁹ In addition, the CPG allowed homeopathic products to be manufactured and distributed without FDA approval.⁸⁰ Under the CPG, homeopathic drugs, unlike conventional drugs or dietary supplements, may “include claims in their packaging about treating specific conditions as long as the conditions are ‘self limiting’⁸¹ and not chronic.”⁸² The current regulatory framework for homeopathic drugs, as set forth in the 1988 Compliance Policy Guide, does not require that OTC homeopathic products be evaluated for their safety and efficacy so long as “they satisfy certain conditions, including that the label of such products contain an indication for use.”⁸³

In contrast, the FTC’s regulatory responsibilities include overseeing advertisements about homeopathic drugs⁸⁴ and ensuring that claims about a product’s efficacy and safety are substantiated by competent and reliable evidence.⁸⁵ Section 5 of the FTC Act,⁸⁶ which applies to all OTC drugs including homeopathic drugs, “prohibits unfair or deceptive [sic] practice in or affecting commerce, such as [sic] deceptive advertising.”⁸⁷ The FTC requires that advertisers possess “competent and reliable scientific evidence,” based on “tests, analyses, research, or studies

drugs the same way as other OTC cold, cough, and headache medicines prompted the FDA to consider its previous regulations. *Id.*

77. *Id.*

78. FDA’s Compliance Policy Guide (CPG) 400.400 entitled “Conditions Under Which Homeopathic Drugs May be Marketed,” 53 FR 21728, June 9, 1988, www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm.

79. *Id.*

80. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

81. See John Tozzi, *FDA Faces Pressure to Regulate Homeopathic Products*, BLOOMBERG BNA, (Aug. 26, 2015, 1:50 PM), www.bloomberg.com/news/articles/2015-08-26/the-fda-is-under-more-pressure-to-regulate-homeopathic-products (referring to “self-limiting” conditions as those “that go away on their own”).

82. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

83. *Id.*

84. *Id.*

85. Sindhu Sundar, *FTC Says Lax FDA Rules on Homeopathic Drugs Pose Conflict*, LAW360 (Aug. 21, 2015), www.law360.com/articles/694053/ftc-says-lax-fda-rules-on-homeopathic-drugs-pose-conflict.

86. The FTC Act addresses broadly “unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C.A. § 45 (West) (2012).

87. Federal Trade Commission Act, 15 U.S.C. § 45(a)(2) (2012).

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.”⁸⁸ The FTC has acknowledged that “advertising claims for homeopathic drugs” are not exempt from the requirement that they be substantiated by competent and reliable evidence.⁸⁹ Section 12 of the FTC Act prohibits false advertisements “in or affecting commerce of food, drugs, devices, services or cosmetics.”⁹⁰ The FTC mandates that “companies must have a reasonable basis for making objective claims, including that a product can treat specific conditions, before those claims are made.”⁹¹ While both agencies take different approaches in regulating homeopathic remedies, both agree that increased popularity and use of homeopathic medicine warrant renewed focus on improving current FDA and FTC regulatory frameworks.

C. Recent Problems and Legal Developments Over Homeopathic Products Giving Rise to the Need for the FDA to Overhaul its Current Regulations

The push to overhaul the FDA’s current regulations over homeopathic products is a response to growing litigation and complaints made to the FDA against homeopathic manufacturers.⁹² For example, a consumer filed a class action lawsuit against ProPhase Labs, Inc., a manufacturer of over-the-counter homeopathic cold remedies⁹³ alleging that the manufacturer engaged in false and misleading marketing and

88. *See, e.g.*, In re Brake Guard Prods., Inc., 125 F.T.C. 138 (1998) (finding certain claims made for the Brake Guard device in Brake Guard Products, Inc.’s advertisements, logos and promotional material were “false and misleading” and lacked “competent and reliable scientific data”); U.S. v. Jason Pharm., Inc., Case No. 112-cv-01476 (2012), at 6, www.ftc.gov/sites/default/files/documents/cases/2012/09/120910jasonpharmdecree.pdf (finding that manufacturer of a weight loss product made deceptive and misleading health claims without “competent and reliable scientific evidence.”). The consent decrees from both cases support the FTC’s attempt to employ and enforce a heightened level of substantiation for health related claims. *Id.*

89. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

90. Federal Trade Commission Act, 15 U.S.C. § 52 (2012).

91. Tozzi, *supra* note 81 (noting that homeopathic products are an estimated \$3 billion industry in the U.S.).

92. Audet & Partners LLP, *Class Action Against Whole Foods Challenges Homeopathic Claims*, CLASS ACTION BLOG (Aug. 25, 2014), <http://class-action-blog.com/class-action-whole-foods-challenges-homeopathic-claims-2/> (acknowledging the increase in the number of class action lawsuits that “have been brought against companies claiming that their [sic] products have homeopathic or medicinal qualities.”).

93. *See* Complaint at 2, Gibbs v. ProPhase Labs, Inc., No. 15-cv-865 (N.D. Cal. Feb. 2, 2015).

advertising of its homeopathic OTC cold remedy products.⁹⁴ In another lawsuit, consumers sued the manufacturer, Matrixx Initiatives, maker of various Zicam Cold Remedy products (collectively “Zicam”).⁹⁵ Consumers sued the drug manufacturer complaining they had lost their sense of smell after using Zicam.⁹⁶ Boiron, Inc., another maker of homeopathic products, was also scrutinized after consumers complained it had made false and misleading claims⁹⁷ by alleging its products “could relieve pain and treat symptoms of the cold and flu when, in reality, the products did not work as advertised.”⁹⁸ Consumers filed a similar lawsuit against supermarket chain Whole Foods Market Inc. (Whole Foods) for its line of homeopathic products.⁹⁹ The complaint claimed that the plaintiffs purchased Whole Foods’ homeopathic brand of drugs, “365 Be Well” but did not receive the advertised benefits.¹⁰⁰ The plaintiffs alleged that “they relied on [Whole Foods] deceptive and false labeling in purchasing” its line of homeopathic products.¹⁰¹ The lack of substantiation associated with certain homeopathic products is not only supported by such class action litigation, but also by warning letters issued by the FDA.

Consumer complaints have also raised concerns over the FDA’s current regulatory approach on homeopathic products. Since 2007, the FTC has received over 141 consumer complaints

94. *Id.*

95. Brown, *supra* note 31, at 340, 356 (discussing how hundreds of consumers have filed lawsuits against Matrixx Initiatives, the manufacturer of an OTC homeopathic cold remedy known as Zicam).

96. FDA: *Nasal Spray Can Cause Loss of Smell*, CBSNEWS (June 16, 2009), www.cbsnews.com/news/fda-nasal-spray-can-cause-loss-of-smell/.

97. See First Amended Complaint, Galluci et al. v. Boiron, Inc. et al. at 1-2, No. 11-cv-02039-JAH-NLS (S.D. Cal. Feb. 6, 2012) (involving a class action lawsuit in which consumer plaintiffs alleged defendant falsely advertised its homeopathic products, including Arnicare, Chestal, Coldcalm, Quietude, Camilia, and others, as effective treatments in [relieving] various ailments and symptoms). Plaintiffs relied on various representations defendant made about the effectiveness of their products in relieving symptoms associated with the cough, flu, “common cold,” muscle pain and stiffness, insomnia, teething, and other ailments. *Id.* Plaintiffs argued that defendant’s products, “[were] ineffective due to extremely high dilutions, the ineffectiveness of active ingredients in relieving such symptoms, or both.” *Id.*

98. Various Boiron Homeopathic Products: Oscillo, Arnicare, Chestal, Coldcalm, Camilia, and More, www.truthinadvertising.org/various-boiron-homeopathic-products-oscillo-arnicare-chestal-coldcalm-camilia-and-more/ (last visited Oct. 19, 2015).

99. Courtney Coren, *Whole Foods Hit with \$5M Homeopathy False Advertising Class Action*, TOP CLASS ACTIONS (Aug. 25, 2014), <http://topclassactions.com/lawsuit-settlements/lawsuit-news/38394-whole-foods-hit-5m-homeopathy-false-advertising-class-action/>.

100. *Id.*

101. Herazo v. Whole Foods Mkt., Inc., 2015 U.S. Dist. LEXIS 96811, *4 (S.D. Fla. July 23, 2015).

that mention homeopathy.¹⁰² Some complaints involved “alleged rip-offs and hard-sell tactics” while others involved deceptive advertising.¹⁰³ For example, “[a]n 80-year-old woman targeted by telemarketers paid \$469 for an oral weight-loss spray purporting to contain human growth hormone, sold as homeopathic.”¹⁰⁴

In addition to consumer complaints, the increase in the FDA’s issuance of “warning letters” about certain homeopathic remedies reflects the current limitations of the FDA regulations on homeopathic products.¹⁰⁵ Since 2009, the FDA has issued nearly 40 warning letters to various companies regarding the safety of various homeopathic products.¹⁰⁶ For example, after receiving over 130 reports of patients losing their sense of smell from using the product, Zicam, the FDA issued a warning letter to Matrixx Initiatives.¹⁰⁷ In the following year, the FDA sent a warning letter to Homeopathy for Health after determining that the company claimed on its website that its products were effective at “diagnos[ing], prevent[ing], treating[ing] or cur[ing] the H1N1 flu virus.”¹⁰⁸ In 2011, the FDA declared that HCG (Human Chorionic Gonadotropin), weight-loss drug products that were sold OTC and labeled as “homeopathic,” were “illegal and [made] unsubstantiated claims.”¹⁰⁹ The FDA claimed it did not approve

102. Tozzi, *supra* note 81.

103. *Id.*

104. *Id.*

105. Thompson, *supra* note 43.

106. *Id.*

107. Brown, *supra* note 31, at 357; *see also id.* (stating the FDA has received nearly 40 warning letters since 2009 regarding the safety of homeopathic products including complaints about Zicam); Public Health Advisory: Loss of Sense of Smell with Intranasal Cold Remedies Containing Zinc (June 16, 2009), www.fda.gov/drugs/drugsafety/postmarketdrugsafety/informationforpatientsandproviders/ucm166059.htm (discussing how the “FDA is alerting consumers that *Zicam Cold Remedy Nasal Gel*, *Zicam Cold Remedy Nasal Swabs*, and *Zicam Cold Remedy Swabs, Kids Size*, a discontinued product that consumers may still have in their homes, have all been associated with long lasting or permanent loss of smell . . . These products, marketed by Matrixx Initiatives, are zinc-containing, nasal cold remedies used to reduce the duration and severity of cold symptoms. However, these products have not been shown to be effective in the reduction of the duration and severity of cold symptoms.”).

108. Heidi Turner, *FDA Issues Warning about Certain Homeopathic Remedies*, LAWYERSANDSETTLEMENTS.COM (Jan. 17, 2012, 8:00 AM), www.lawyersandsettlements.com/articles/homeopathy-remedy-fraud/homeopathy-scam-lawsuits-fraud-lawsuit-2-17338.htm#Vg1_Xpcoeec.

109. *Id.*; *see also HCG Diet Produces Are Illegal*, FDA CONSUMER HEALTH INFORMATION (Dec. 2011), at 1, www.fda.gov/downloads/forconsumers/consumerupdates/ucm281457.pdf (noting the FDA’s warning against the use of “homeopathic” human chorionic gonadotropin (HCG) weight loss products, which are sold in the form of oral drops, pellets and sprays). The FDA further warned that certain companies were selling illegal homeopathic HCG weight-loss drugs, which had not been approved by the FDA for its safety and efficacy. *Id.*

HCG to treat weight-loss, but rather, to assist in female infertility.¹¹⁰ And in 2015, the FDA cautioned asthma sufferers to not use homeopathic products, stating that, “[these remedies] have not been evaluated by the FDA for safety and effectiveness.”¹¹¹ Most recently in September 2016, the FDA issued a warning letter to consumers recommending that they stop using all homeopathic teething products including tablets and gels and “dispose of any in their possession.”¹¹² The FDA previously issued a safety alert in 2010 for Hyland’s Teething Tablets, which contained the herb, belladonna, after babies showed symptoms of poisoning from the product.¹¹³ The FDA acknowledged in its recent warning that it had not evaluated or approved homeopathic teething products for their safety or efficacy and had not found them to have “any proven health benefits.”¹¹⁴ The warning stems from cases linked to ten children’s deaths and reports over the past six years of children who used these products and suffered from “fever, lethargy, vomiting, sleepiness, tremors, shortness of breath, irritability, and agitation.”¹¹⁵

D. The FTC’s Criticisms of the FDA’s Current Regulations

Given the recent increase in lawsuits, consumer complaints, and warning letters involving homeopathic products, the FTC has urged the FDA to reassess its homeopathy regulatory policies. The FTC asserts that current regulatory framework is inadequate in holding homeopathic manufacturers accountable and ensuring the safety of consumers.¹¹⁶ In response to the FDA’s request for public

110. *Id.*

111. *Id.*

112. Press Release, U.S. Food & Drug Adm’n, *FDA Warns Against the Use of Homeopathic Teething Tablets and Gels* (Sept. 30, 2016) (on file with author) www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm523468.htm.

113. Thompson, *supra* note 43; *see also Hyland’s Teething Tablets: Recall – Risk of Harm to Children*, U.S. FOOD & DRUG ADMIN., www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm230764.htm; *see also FDA Issues Consumer Safety Alert*, Food and Drug Administration News Release, (Oct. 23, 2010), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm230761.htm (stating the FDA’s receipt of reports of “serious adverse effects in children taking [Hyland’s Teething Tablets].”). The FDA warned that children who took the product suffered from belladonna toxicity. *Id.* The FDA also “received reports of children who consumed more tablets than recommended, because the containers do not have child resistant caps.” *Id.*

114. *Id.*

115. Jen Christensen & Jamie Gumbrecht, *Teething Tablets May Be Linked to 10 Children’s Deaths, FDA Says*, CNN (Oct. 13, 2016), www.cnn.com/2016/10/12/health/hylands-teething-tablets-discontinued-fda-warning/.

116. *Id.*

input on its current regulation of homeopathic products, the FTC submitted an official comment on August 21, 2015.¹¹⁷ The FTC raised concern over the FDA's policy in requiring homeopathic drugs to display an indication for use "even when the product has not been demonstrated to be efficacious for that indication."¹¹⁸ The FTC noted that the FDA's current regulatory approach may harm consumers and confuse advertisers.¹¹⁹ The FTC's comment discussed that the FDA's current framework may lead companies to "skirt more stringent regulations for OTC drug products or dietary supplements simply by labeling them as homeopathic or combining homeopathic ingredients with dietary supplements or other non-homeopathic ingredients."¹²⁰ The FTC also described research commissioned by the FTC's Division of Advertising Practices.¹²¹ The research indicated that "most consumers do not understand homeopathy, how the FDA regulates homeopathic drugs, or the level of scientific evidence needed to support health claims for homeopathic products."¹²² Given these concerns, the FDA now must reevaluate its regulations, which are at odds with the FTC's goals.

III. COMPARING THE FDA AND FTC'S POSITIONS ON THE CURRENT REGULATORY STANDARDS FOR HOMEOPATHIC PRODUCTS

The conflict between the FDA and the FTC's respective policies on regulating OTC homeopathic drugs has complicated their relationship as federal agencies.¹²³ The FDA and FTC normally share overlapping responsibilities in regulating

117. *Id.*

118. *Id.*

119. Press Release, *U.S. Fed. Trade Comm'n, FTC Stops Elusive Business Opportunity Scheme* (Aug. 20, 2015) (on file with author) www.ftc.gov/news-events/press-releases/2015/08/ftc-staff-comment-fda-should-reevaluate-its-current-regulatory (noting how the "FDA's current framework may lead some companies to skirt more stringent regulations for OTC drug products or dietary supplements simply by labeling them as homeopathic or combining homeopathic ingredients with dietary supplements or other non-homeopathic ingredients.").

120. *Id.*

121. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

122. *Id.* "The FTC staff worked with Shugoll Research to set up focus groups in order to explore consumer understanding of various non-prescription products including conventional, herbal, and homeopathic products."

123. Sundar, *supra* note 85 (noting that the FDA's current policy on homeopathic products conflicts with the FTC's requirement that medical advertising claims be supported by evidence); *see also* Bellamy, *supra* note 16 (acknowledging that this conflict results in "homeopathic over-the-counter (OTC) 'drugs' on the market that both comply with the FDA's policy and violate FTC's policy.").

homeopathic products without much disagreement.¹²⁴ However, the FTC's recent comments to the FDA about its current regulations on homeopathy have created an interagency conflict.¹²⁵ Currently, the FDA does not evaluate the safety and efficacy of homeopathic products, and impedes upon the FTC's efforts in policing fraud and false advertising on product labels.¹²⁶

This section will discuss each of the FDA and the FTC's positions on remedying the situation. It will first look at the rationale behind the FDA's hands-off policy in allowing homeopathic products to be marketed without prior approval, as to their safety and efficacy.¹²⁷ It will then discuss the input the FDA has received in response to its request for public comments on its current regulation of homeopathic drugs.¹²⁸ Then, this section will evaluate the FTC's concerns with the FDA's current policies and consider the challenges associated with implementing its recommendations.¹²⁹ Discussion will include the feasibility for the FDA to adequately address the concerns of the FTC and other stakeholders including consumers, advertisers, and the homeopathic industry.

A. *The Rationale Behind the FDA's Exemption of OTC Homeopathic Products from the Same Standards as Conventional Drugs*

To date, the FDA has exempted OTC homeopathic products from the same pre-market approval requirements as other

124. Bellamy, *supra* note 16 (noting that the FDA and FTC have shared responsibilities in regulating OTC products). While the FDA's focus is on product labeling, the FTC's concern is on advertising. *Id.*

125. *Id.*

126. *Id.*

127. Junod, *supra* note 28.

128. See *Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century*, (Sept. 9, 2015), www.fda.gov/Drugs/NewsEvents/ucm430539.htm (detailing the FDA's announcement regarding its interest in obtaining public feedback on homeopathic products).

On April 20-21, 2015, the Food and Drug Administration (FDA) held a public hearing at its White Oak Campus to obtain information and comments from stakeholders about the current use of human drug and biological products labeled as homeopathic, as well as the Agency's regulatory framework for such products. These products include prescription drugs and biological products labeled as homeopathic and over-the-counter (OTC) drugs labeled as homeopathic. FDA [sought] written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, and industry.

Id.

129. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

conventional drugs.¹³⁰ Homeopathic products are not required to undergo the same rigorous tests and clinical trials as conventional drugs.¹³¹ Instead, OTC homeopathic products merely need to be recognized by the private nonprofit organization, Homeopathic Pharmacopeia of the United States (HPUS).¹³² The HPUS is a collection of homeopathic monographs that are produced and updated by the Homeopathic Pharmacopeia Convention of the United States (the Convention).¹³³ The Convention is responsible for determining whether a proposed homeopathic ingredient will be listed in the HPUS.¹³⁴ In addition to being listed in the HPUS, homeopathic products must also meet the FDA's labeling¹³⁵ and manufacturing¹³⁶ requirements.¹³⁷

One explanation behind the FDA's decision in 1972 to exclude homeopathic products from OTC review was the prevailing belief that homeopathic products did not pose a health risk to consumers.¹³⁸ At the time, the FDA identified only five homeopathic pharmacies in the country; there were no other drug stores selling homeopathic drugs.¹³⁹ Alternatively, the FDA's decision not to adopt tighter regulations for homeopathic drugs was based on its desire to avoid putting "an unnecessary strain on the agency's already limited resources."¹⁴⁰ However, given the

130. John P Borneman & Robert I. Field, *Regulation of Homeopathic Drug Products*, 63 AM. J. HEALTH-SYS. PHARM. 86, 89 (2006) (noting "[t]he principal distinction between homeopathic and allopathic drug regulation is in the manner of pre-market approval").

131. See Brown, *supra* note 31, at 347 (explaining how before conventional drugs are allowed to enter into interstate commerce, they must undergo review under the new drug application (NDA) and meet the requirements of the "OTC monograph.").

132. The Homeopathic Pharmacopoeia of the United States, Criteria for Eligibility, www.hpus.com/eligibility.php (last visited Oct. 18, 2015).

133. Brown, *supra* note 31, at 338. In 1981, Dr. Wyrth Post Baker, then president of the American Institute of Homeopathy, which initially published the HPUS, established the Convention. American Institute of Homeopathy, Written Comments to FDA (June 1, 2015), <http://homeopathyusa.org/about-aih-2/position-statements-letters-2/written-comments-to-fda.html>. The Convention's responsibilities, as described in its Bylaws, include disseminating information promoting homeopathy, and evaluating the eligibility of drugs for inclusion in the HPUS. Homeopathic Pharmacopoeia Convention of the United States (HPCUS) Procedure Manual (Rev. 5.2, Jan. 2016), www.hpus.com/HPCUSProcedureManual52A.pdf.

134. *Id.*

135. 21 C.F.R. §201 (2015).

136. 21 C.F.R. §210 (2015) and §211 (2015).

137. Brown, *supra* note 31, at 338.

138. Junod, *supra* note 28, at 178.

139. Hutt, *supra* note 5, at 800.

140. Brown, *supra* note 31, at 338. The FDA continues to face resource challenges in meeting its expanding set of responsibilities, especially with legislation passed in recent years including "the Family Smoking Prevention and Tobacco Control Act of 2009, the Patient Protection and Affordable Care Act of 2010, the FDA Food Safety Modernization Act of 2011 . . ." U.S. Food &

current popularity and the rise in safety concerns surrounding homeopathic products have forced the FDA to reevaluate its position.¹⁴¹

B. Public Input on the FDA's Current Homeopathic Regulatory Framework and its Reflection of the FDA's Lack of Combating the Public's Misconceptions about Homeopathic Products

In March 2015, the FDA announced that it was holding its first public hearing on the issue of homeopathic regulation.¹⁴² Recognizing the growth of the homeopathic industry¹⁴³ and safety concerns¹⁴⁴ of OTC homeopathic drugs, the FDA sought input from

Drug Admin., FDA Strategic Priorities: 2014-2018, Message from the Commissioner (Sept. 2014), www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf. While the FY 2016 budget for the FDA includes \$4.9 billion in total resources, there is no doubt that more funding is needed in order for the agency to meet its responsibilities not only to modernize the food safety system and address other pressing health concerns, but also to enhance the safety and quality of drugs, including homeopathic products. U.S. Dept. of Health & Human Serv., HHS FY2016 Budget in Brief, www.hhs.gov/about/budget/budget-in-brief/fda/index.html#programs.

141. FDA PUBLIC WORKSHOP, *supra* note 10.

142. *See id.* (recognizing the FDA's interest in obtaining public input on seven questions). "1) What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic? 2) What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic? 3) Are the current enforcement policies under the CPG appropriate to protect and promote health in light of the tremendous growth in the homeopathic drug market? Are there alternatives to the current enforcement policies of the CPG that would inform FDA's regulatory oversight of drugs labeled as homeopathic? 4) Are there areas of the current CPG that could benefit from additional clarity? 5) Is there information regarding the regulation of homeopathic products in other countries that could inform FDA's thinking in this area? 6) What would be an appropriate regulatory process for evaluating such indications for OTC use? 7) Given the wide range of indications on drug products labeled as homeopathic and available OTC, what processes do companies currently use to evaluate whether such products, including their indications for use, are appropriate for marketing as an OTC drug? 8) Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic?" *Id.*

143. *Id.*; *see also* Nahin, *supra* note 3 (referring to a survey by the Centers for Disease Control and Prevention's National Center for Health Statistics, which found that Americans spent about \$2.9 billion on homeopathic medicine in 2007).

144. *See* FDA PUBLIC WORKSHOP, *supra* note 10 (noting the negative health effects from homeopathic drug products); *see also* James B. Mowry, et al., "2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 30th Annual Report," 51 CLINICAL TOXICOLOGY, 949, 1188 (2013) (recognizing that according to a 2012 report conducted by the American Association of Poison Control, there were

various stakeholders.¹⁴⁵ Participants included consumers, patients, health care providers, lawyers, industry representatives, and others.¹⁴⁶ The FDA requested input on issues relating to consumer and healthcare provider attitudes, the agency's enforcement policies and evaluation procedures for OTC products, and product labeling.¹⁴⁷ The agency received testimony and written comments from both advocates and critics alike who expressed their views on how the FDA should address the limitations of its policies.¹⁴⁸ The FDA received responses from some who defended its current regulations and the benefits of homeopathy to others who highlighted consumer misconceptions about homeopathic products compared to proven drug treatments.¹⁴⁹ The FDA extended the comment period¹⁵⁰ twice to allow others to weigh in on the agency's regulation of homeopathic remedies, in June 2015,¹⁵¹ in September 2015,¹⁵² and again in November 2015.¹⁵³

Some advocates favored the status quo. Amy Rothenberg from the AANP stated that the current FDA regulations were adequate.¹⁵⁴ Rothenberg testified that, "The low cost of these medicines as well as the consistent quality of product, make them appealing to both physician and patient."¹⁵⁵ She further stated

10,311 reported cases of poisoning due to "Homeopathic Agents.").

145. Barbara Herman, FDA Reconsiders Regulating Homeopathic Remedies, INT'L BUS. TIMES (Apr. 19, 2015), www.ibtimes.com/fda-reconsiders-regulating-homeopathic-remedies-schedules-hearing-1887881.

146. *Id.*

147. FDA PUBLIC WORKSHOP, *supra* note 10.

148. *Id.*

149. Kelly Servick, *FDA Takes New Look at Homeopathy*, SCIENCE (Apr. 21, 2015, 7:00 PM), www.sciencemag.org/news/2015/04/fda-takes-new-look-homeopathy.

150. The FDA explains that the "comment period" allows for public input as it considers whether "to issue a new regulation or revise an existing one." U.S. Food & Drug Admin., *Comment on Proposed Regulations and Submit Petitioners*, (Oct. 2014), www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm%3Futm_source%3Drss%26utm_medium%3Drss%26utm_campaign%3Dcomment-on-proposed-regulations-and-submit-petitions. The FDA's decision to extend the comment period on three separate occasions reflects the agency's recognition of the complexity associated homeopathic product regulation and the importance of the public's input to help improve it.

151. Homeopathic Product Regulation: Evaluating the Food & Drug Admin.'s Regulatory Framework After a Quarter-Century; Extension of Comment Period, 80 Fed. Reg. 32868 (June 10, 2015).

152. Homeopathic Product Regulation: Evaluating the Food & Drug Admin.'s Regulatory Framework After a Quarter-Century; Extension of Comment Period, 80 Fed. Reg. 32868 (Sept. 9, 2015).

153. FDA PUBLIC WORKSHOP, *supra* note 10 (noting the FDA's move to reopen the comment period for an additional 60 days until November 9, 2015).

154. *See* Thompson, *supra* note 43 (quoting Amy Rothenberg of the American Association of Naturopathic Physicians who testified that "[the] FDA's current regulatory approach to homeopathic products is working well.").

155. *Id.*

that “[o]ver decades of use, we have not found problems or variability with quality of the homeopathic product, and no toxicity has been reported.”¹⁵⁶ Another advocate, Mark Land, vice president for Boiron USA, stated, “[t]he potential risk [of greater FDA regulation] to consumers is if any change in regulation were to limit access to these products.¹⁵⁷ Land, who is also affiliated with the AANP, touted the effectiveness of the FDA’s regulation in providing consumers with “safe, high quality, and cost effective drugs.”¹⁵⁸

Other critics expressed concern that the FDA should regulate homeopathy more aggressively. The FDA’s policy in not requiring homeopathic products to meet the same standards as other drugs has negatively impacted the health and safety of consumers.¹⁵⁹ The FTC, for instance, has argued that current FDA standards allow the possibility for manufacturers to “take advantage of the less stringent requirements for homeopathic drugs, to the possible detriment of consumers.”¹⁶⁰ This is evidenced most strikingly by the recent events involving homeopathic teething products and the possible links to seizures and other adverse effects¹⁶¹ in infants and children which led the FDA to issue a warning letter against their use.¹⁶² While Hyland’s Teething Tablets were the subject of an FDA safety alert in 2010¹⁶³, the FDA’s regulations in place back then still remain insufficient to protect consumer safety.

In her testimony to the FDA, Adriane Fugh-Berman, MD, Associate Professor in the Department of Pharmacology and Physiology at Georgetown University Medical Center, expressed her concern over the marketing of homeopathic products.¹⁶⁴ In particular, she was critical of homeopathic products next to conventional OTC drugs in pharmacies or supermarket shelves.¹⁶⁵

156. *Id.*

157. Rob Stein, *FDA Ponders Putting Homeopathy to a Tougher Test*, NPR (Apr. 20, 2015), www.npr.org/sections/health-shots/2015/04/20/398806514/fda-ponders-whether-homeopathy-is-medicine.

158. FDA PUBLIC WORKSHOP, *supra* note 10.

159. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

160. *Id.*

161. Press Release, U.S. Food & Drug Adm’n, *FDA Warns Against the Use of Homeopathic Teething Tablets and Gels* (Sept. 30, 2016).

162. *Id.* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm523468.htm.

163. *Hyland’s Teething Tablets: Recall – Risk of Harm to Children*, FOOD AND DRUG ADMIN., www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm230764.htm; *see also* FDA Issues Consumer Safety Alert, Food and Drug Administration News Release, (Oct. 23, 2010), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm230761.htm.

164. Homeopathic Product Regulation: Evaluating FDA’s Regulatory Framework After a Quarter-Century, Testimony of Adriane Fugh-Berman 2 (Apr. 20, 2015) [hereinafter *Fugh-Berman Testimony*].

165. *Id.*

Allowing homeopathic products to be placed alongside conventional drugs misleads consumers, testified Dr. Fugh-Berman.¹⁶⁶ Janine Jagger with the Familial Mediterranean Fever Foundation also asserted that the FDA should adopt stricter standards¹⁶⁷ and expressed confusion as to why people would choose “homeopathic options over pharmaceuticals that have been proven to work.”¹⁶⁸

In addition to criticisms of the FDA’s current policies, experts and members of the public provided feedback on how the FDA should revamp its regulatory framework. One proposal would be for the FDA to implement tighter regulations requiring all homeopathic products to meet the same standards as other FDA regulated pharmaceutical drugs.¹⁶⁹ Michael De Dora, with the Center for Inquiry, urged the FDA to conduct safety and efficacy tests on all homeopathic products.¹⁷⁰ This, however, may be difficult to implement on a practical level. Pharmaceutical drugs undergo a long and formal approval process. If homeopathic products were subject to similar or even more stringent standards before they could obtain the FDA’s stamp of approval, it is certain a whole different regulatory scheme would have to be created. Given the FDA’s already strapped budget and long list of priorities on its plate, subjecting homeopathic products to tighter regulations may be challenging to accomplish.

Another recommendation would be to require stricter labeling requirements for all homeopathic products.¹⁷¹ De Dora and Dr. Fugh-Berman shared the same view that current labeling of homeopathic products fails to adequately educate consumers.¹⁷² In addition to recommending that homeopathic products be shelved apart from other OTC drugs, Dr. Fugh-Berman suggested that labels should disclose both active and inactive ingredients using “modern nomenclature and standard dosing terms.”¹⁷³ She also recommended that if the FDA continues with its current regulatory framework, it should mandate that all homeopathic products bear a disclaimer indicating that the FDA has not evaluated their safety or effectiveness.¹⁷⁴ De Dora also called on the FDA to make regular consumer warnings to inform the public

166. *Id.*

167. Jen Christensen, *Homeopathic Medicine Under FDA Scrutiny*, CNN (Apr. 21, 2015), www.cnn.com/2015/04/20/health/homeopathic-medicine-fda/index.html.

168. *Id.*

169. De Dora Testimony, *supra* note 55, at 4.

170. *Id.*

171. Fugh-Berman Testimony, *supra* note 164, at 6.

172. *FDA Evaluating Regulations for Homeopathic Drugs*, DRUG INDUSTRY DAILY, Apr. 22, 2015, www.fda.gov/oc/2015/04/22/fda-evaluating-regulations-for-homeopathic-drugs?v=preview.

173. Fugh-Berman Testimony, *supra* note 164, at 6.

174. *Id.*

that homeopathic products will not treat their illnesses.¹⁷⁵ These consumer warnings could provide consumers with a better understanding of the extent of the FDA's oversight of homeopathy and the risks associated with the use of homeopathic products. These recommendations aim to address the FTC's similar concerns about homeopathic products and consumer safety.¹⁷⁶

*C. The Feasibility of Implementing the FTC's
Recommendations to Improve the FDA's Regulatory
Policy over Homeopathic Products*

The FTC urged the FDA to regulate OTC homeopathic drugs more aggressively when it submitted an official comment to the FDA in August 2015.¹⁷⁷ The FTC argued that the current FDA regulatory framework makes it impossible for the agency to do its job in properly policing fraud and false advertising involving homeopathic products.¹⁷⁸ The FTC discussed research it previously conducted on consumer perceptions on homeopathy that supports the need for more stringent FDA regulations.¹⁷⁹ Based on its research, the FTC found that consumers do not understand

175. De Dora Testimony, *supra* note 55, at 5.

176. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

177. *Id.*

178. Tom Meyer, *FTC to FDA: Do Your Job So We Can Do Ours*, RICHOCHET (Aug. 31, 2015), <https://ricochet.com/ftc-fda-job-can/>.

179. John Rackson & Matthew Shultz, *FTC Calls for Greater Scrutiny of Homeopathic Products*, SELLER BEWARE BLOG (Sept. 15, 2015), www.consumeradvertisinglawblog.com/dietary-supplements/; *see also* FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

The FTC staff worked with Shugoll Research to set up focus groups in order to explore consumer understanding of various non-prescription products including conventional, herbal, and homeopathic products. Market research was conducted to explore the understanding and knowledge of non-prescription products among two key consumer segments –general adults (including parents and non-parents) and parents. The overall objective of the focus groups was to determine the extent to which consumers understand the differences among conventional, herbal, and homeopathic non-prescription products.” Based on its research, the FTC concluded “that consumers have an incomplete and incorrect understanding of what homeopathic products are and how they are regulated. Many consumers may incorrectly believe these products are pre-approved by the FDA and tested on humans for efficacy. To add to this confusion, homeopathic products are placed side -by-side in retail stores throughout the United States next to products that are actually pre-approved by the FDA and tested on humans for efficacy.” The FTC also concluded that “homeopathic product labels are confusing and do not conform with conventional product labeling.

Id.

homeopathy.¹⁸⁰ The FTC argued that “existing labeling requirements leads them to conclude erroneously that the FDA has approved homeopathic products for efficacy.”¹⁸¹ Based on these concerns, the FTC proposed three possible ways to resolve the conflicting FDA and FTC’s regulatory schemes governing homeopathic products.¹⁸² The first recommendation was for the FDA to withdraw the CPG and subject homeopathic drugs to the same regulatory standards as other conventional drugs.¹⁸³ The second proposal was for the FDA to eliminate the requirement that an indication for use appear on the label.¹⁸⁴ The FDA mandates that labels for homeopathic products must contain an indication for use, but does not require that it be truthful, which violates current FTC law.¹⁸⁵ A third recommendation was for the FDA to require that any indication appearing on the label be supported by competent and reliable scientific evidence.¹⁸⁶

It will be a challenge having the FDA mandate that manufacturers support its claims about their homeopathic products with scientific evidence. Requiring clinical data to support product claims could be at a detriment to the homeopathic industry because many manufacturers would have trouble establishing their claims with robust scientific evidence given the uniqueness¹⁸⁷ of homeopathic remedies and the way they are prepared and are used.¹⁸⁸ Many homeopathic remedies claim to

180. *Id.*

181. *Id.*

182. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2.

183. *Id.*

184. *Id.*

185. *Id.*

186. Kristi Wolff, *FTC Urges FDA to Reconsider Homeopathic Regulatory Framework*, AD LAW ACCESS, (Aug. 24, 2015), www.adlawaccess.com/2015/08/articles/ftc-urges-fda-to-reconsider-homeopathic-regulatory-framework/.

The FTC staff is concerned that FDA’s existing homeopathic regulatory framework may conflict with the FTC’s advertising substantiation policy, which requires competent and reliable scientific evidence for health benefit claims. The FTC points out that FDA’s Compliance Policy Guide 400.400 (CPG), which allows for homeopathic marketing under certain conditions, requires manufacturers to list indications for use but that FDA has not reviewed homeopathic products for safety or efficacy. As a result, the FTC is concerned that some products or claims may not meet the “competent and reliable evidence” standard.

Id.

187. U.S. Nat’l Ctr. for Complementary and Integrative Health, *supra*, note 35 (describing how “homeopathic treatments are highly individualized, and there is no uniform prescribing standard for homeopathic practitioners. There are hundreds of different homeopathic remedies, which can be prescribed in a variety of different dilutions for thousands of symptoms”).

188. Joe Williams, *FTC Takes on Homeopathic Industry as FDA Likewise Weighs Reg Path*, INSIDE HEALTH REFORM, July 1, 2015.

contain very little active ingredients and to be diluted in form.¹⁸⁹ Given the nature of homeopathy as an alternative form of medicine,¹⁹⁰ it would be difficult for the FDA to hold homeopathic products to the same rigorous standards as other conventional drugs.¹⁹¹ Thus, if manufacturers are unable to do clinical studies to establish efficacy, there won't be many homeopathic products that will pass muster through the approval process used for other drugs.¹⁹² Consequently, this would significantly limit the number of homeopathic drugs that are available on the market and would likely infringe upon the freedom of manufacturers to market their products. In addition, given continuing rising costs in healthcare¹⁹³ this may detrimentally impact consumers who rely on the low cost of alternative forms to medicine like homeopathy. Thus, requiring the FDA to impose more stringent regulations that mandate proof of scientific evidence for homeopathic drugs would restrict

189. Max Sherman & Steven Strauss, *supra* note 33 (examining the process in homeopathy that uses extreme dilutions to lessen the toxic effects of a substance and to increase its potency); *see also* WebMD, Topic Overview (Nov. 14, 2014), www.webmd.com/balance/guide/homeopathy-topic-overview (noting the form of homeopathic remedies include "pills or liquid mixtures (solutions) containing only a little of an active ingredient (usually a plant or mineral). These are known as highly diluted or "potentiated" substances.")

190. *See* *\$34 Billion Spent Yearly on Alternative Medicines*, NBCNEWS (July 30, 2009), www.nbcnews.com/id/32219873/ns/health-alternative_medicine/t/billion-spent-yearly-alternative-medicine/#.Vi2DDysoeec (noting that "Americans spend about \$34 billion annually on alternative medicine, according to the first national estimate of such out-of-pocket spending in more than a decade.")

191. *See U.S. Food & Drug Admin., The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (noting that the FDA's rigorous evaluation process involves looking at a drug's clinical trials, side effects, and manufacturing practices). Prior to the FDA's evaluation and approval, a sponsor of a new drug (i.e., companies, research institutions, and other organizations) must provide the FDA with the results of its preclinical (animal) testing. *Id.* Both the FDA and a local institutional review board (IRB), review a sponsor's Investigational New Drug Application (IND) and evaluate whether to conduct clinical trials of the drug on humans. *Id.* If they are approved to conduct clinical trials, a drug sponsor will have to conduct three separate tests, each involving an increased number of human subjects. *Id.* Once the tests are completed, a drug sponsor then submits a New Drug Application (NDA) to the FDA, requesting approval to market its drug. *Id.* If the FDA decides to file the NDA, it will then evaluate the drug's safety and effectiveness based on the sponsor's research and decide whether to fully approve the application or issue a complete response letter. *Id.*; *see also* 21 U.S.C. § 314.110 (2012), www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.110 (explaining that the FDA issues a complete response letter when it does not approve a sponsor's NDA).

192. *Id.*

193. *See* Mike Patton, *U.S. Health Care Costs Rise Faster than Inflation*, FORBES, (June. 29, 2015) www.forbes.com/sites/mikepatton/2015/06/29/u-s-health-care-costs-rise-faster-than-inflation/ (acknowledging that U.S. *health care costs* continue to *rise*, despite the advent of the Affordable Care Act).

consumers' freedom of choice. Furthermore, it is likely that if the FDA mandates homeopathic drug manufacturers to provide evidence to support their claims, manufacturers will surely resist the accompanied costs associated with these changes and disputes over the quality of research and testing may end up being resolved in court.¹⁹⁴ The FDA, rather than the court, should decide whether research provides substantial evidence or not.

On the contrary, adopting more stringent labeling standards as some stakeholders have recommended would likely improve consumer awareness of the risks associated with homeopathic products. But placing even more rigorous labeling requirements on products does not guarantee consumers would be better informed of the risks of these products. Despite the differences in opinion among experts and members of the public, it is obvious that the FDA's decision to defer regulatory oversight on homeopathic drugs has benefited the homeopathic industry at the expense of consumers, advertisers, and the FTC. How the FDA responds to addressing these various concerns will require a solution that strikes a balance between the need for more oversight without the threat of being too overly aggressive.

IV. RECONCILING THE CONFLICT BETWEEN THE FDA AND THE FTC'S RESPECTIVE POLICIES ON THE REGULATION OF HOMEOPATHIC PRODUCTS

Ideally, the solution to the criticisms surrounding the regulation of homeopathic products will provide the public with a clearer understanding of how homeopathic drugs are regulated and to what extent homeopathic claims are backed by scientific evidence. Any true and attainable solution must include an approach that raises general public awareness of what homeopathy is and the risks associated with using homeopathic products. This section will look at how including disclaimers on labels and placing homeopathic products apart from other OTC drugs accommodates each of these concerns better than any suggested solution to the homeopathic regulation problem. This section will propose that information as to what a homeopathic product is, what ingredients it contains, and whether there is scientific evidence to support a product's efficacy should be included on both store shelves and in the product packaging itself. Combining each of these approaches provides the best means of helping consumers make more informed decisions about purchasing these products. It will ensure that drug manufacturers are held accountable for homeopathic claims they make.

194. Joe Williams, *supra* note 188 (acknowledging that the scientific evidence which the FTC insists the FDA should demand from drug manufacturers may end up being challenged in the courts).

A. Providing Consumer Warnings and Disclaimers on Homeopathic Products

To address the FTC's concern that existing regulations foster consumer confusion over the safety and effectiveness of homeopathic products,¹⁹⁵ the FDA should consider the use of disclaimers and warning labels. Dr. Fugh-Berman embraced this idea as an effective way to better educate consumers.¹⁹⁶ A disclaimer on homeopathic products would alert consumers that the FDA has not evaluated a homeopathic product for its safety and effectiveness. The FTC has acknowledged the common misconception among consumers that "[homeopathic] products are pre-approved by the FDA and tested on humans for efficacy."¹⁹⁷ Including disclaimers would help abrogate this misconception by allowing consumers to make more informed decisions before purchasing a homeopathic product.

Disclaimers and warning labels currently found on the packaging of dietary supplements provide useful guidance for the FDA.¹⁹⁸ Dietary supplements, like homeopathic products, contain certain claims made by manufacturers.¹⁹⁹ These claims may pertain to information about health, nutrients, or the impact a dietary supplement product may have on the body's organs.²⁰⁰ The FDA does not evaluate dietary supplements for their safety or effectiveness.²⁰¹ The manufacturer has the responsibility of

195. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2, at 16 (recognizing the lack of consumer understanding regarding homeopathic products and how they are regulated).

196. *See* De Dora Testimony, *supra* note 55, at 5 (urging the FDA to ensure that all homeopathic products state that they "[have] not been evaluated by the FDA for either safety or effectiveness"); *see also* Fugh-Berman Testimony, *supra* note 164, at 6 (recommending that the FDA add a disclaimer to the label of OTC homeopathic products). Fugh-Berman proposed the following disclaimer: "This product is a homeopathic remedy. As such it has not undergone review or approval by the FDA and, therefore, has not been documented to be safe or effective to diagnose, treat, prevent, mitigate, or cure any condition or disease." *Id.*

197. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2 (referring to consumer misconceptions on the FDA's role in evaluating the safety and effectiveness of homeopathic products).

198. Consumer Information: Dietary Supplements, FED. TRADE COMM'N (Nov. 2011), www.consumer.ftc.gov/articles/0261-dietary-supplements (noting the FDA's rules for health claims). Dietary supplements must include the disclaimer: "This statement has not been evaluate by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease." *Id.*

199. National Institutes of Health Office of Dietary Supplements, *Strengthening Knowledge and Understanding of Dietary Supplements*, <https://ods.od.nih.gov/factsheets/DietarySupplements-HealthProfessional/>.

200. *Id.*

201. *Id.*

ensuring the truth and accuracy of the claims included on a dietary supplement label.²⁰² To protect consumers from misleading claims that describe the drug's impact on the structure or function of the body, the Dietary Supplement Health and Education Act (DSHEA) requires products to carry a disclaimer.²⁰³ The disclaimer must state that the product "has not been evaluated by the FDA" and that it is not "intended to diagnose, treat, cure, or prevent any disease."²⁰⁴

Similarly, consumer warnings on food and food products provide additional examples as to why the FDA should mandate disclaimers for homeopathic products. For example, the FDA's 2009 Food Code (the Food Code) provides that food establishments must inform consumers about the risks associated with consuming raw or undercooked "animal food" (e.g., beef, eggs, fish, poultry, or shellfish).²⁰⁵ The Food Code provides that consumers must be informed of the risks of consuming such foods through written disclosures and reminders placed in brochures, menus and store shelves.²⁰⁶ Such warnings help to ensure consumer awareness and safety. Based on these considerations, the FDA should require homeopathic products to carry a disclaimer that warns consumers of the FDA's lack of oversight in evaluating the product's safety and efficacy. The disclaimer should caution consumers that claims about the ability of a homeopathic product to diagnose, treat, cure, or prevent a disease have not been substantiated by tests, studies or other research conducted by the FDA. Such a disclaimer would not only hold manufactures more accountable for their actions, but would also alert consumers of the risks associated in purchasing these products.

B. Placing Homeopathic Products Apart from other OTC Drugs on Store Shelves

Along with disclaimers, the FDA should separate homeopathic products from other OTC conventional drugs on store shelves. This would increase consumer awareness that there are significant differences between conventional OTC drugs and homeopathic products.²⁰⁷ As Dr. Fugh-Berman testified to the

202. U.S. Food & Drug Admin., *Questions and Answers on Dietary Supplements*, www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.htm#what_info.

203. 21 U.S.C.S. § 343(r)(6)(C) (2012).

204. FTC STAFF COMMENT BEFORE THE FDA, *supra* note 2 (acknowledging the requirement of dietary supplements to carry a disclaimer that the FDA has not evaluated them for their safety and effectiveness).

205. U.S. Food & Drug Admin, *FDA Food Code 2009: Chapter 3 – Food*, www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm186451.htm.

206. *Id.*

207. Lauren Cooper, *What You Should Know About Homeopathy* (Nov. 3,

FDA, permitting homeopathic products to sit side-by-side with OTC conventional drugs is misleading.²⁰⁸ Dr. Fugh-Berman stated that:

Many consumers have no idea what homeopathy is, and may assume that homeopathic products are phytomedicines or dietary supplements. Not only do homeopathic remedies undergo none of the FDA review that conventional drugs are subject to, but they are not regulated even to the degree that dietary supplements are. Disease claims are disallowed for dietary supplements, but homeopathic remedies can make the same disease treatment claims as conventional drugs!²⁰⁹

Consumers often have no way of distinguishing OTC drugs and homeopathic products, as they are currently marketed and sold. Consequently, consumers are led to believe that homeopathic drugs are subject to the same FDA oversight as other conventional drugs.²¹⁰ Separating homeopathic products on store shelves combined with a clear consumer notice identifying a homeopathic product section would help to clear up consumers' misunderstanding and confusion.

C. Including Ingredient and FDA Regulatory Information on Store Shelves and in Product Packaging

Another recommendation to address the homeopathic regulation problem would be for the FDA to include ingredient and FDA regulatory information on store shelves and product packaging. Including this information would assist the consumer in making an educated decision about the product they are purchasing. An insert or brochure should accompany all homeopathic products and provide information regarding what homeopathy is and the active ingredients that are included in the product. Moreover, the insert or brochure should include a warning that the FDA has not evaluated the product for either its safety or effectiveness. A similar warning label should also be visible on store shelves that stock homeopathic products. This would help ensure that consumers are fully informed of the homeopathic product's risks. More importantly, it would give consumers a more accurate picture as to the level of FDA scrutiny

2015), www.consumerreports.org/vitamins-supplements/the-truth-about-homeopathy (noting that "OTC drugs contain active ingredients that the Food and Drug Administration has reviewed for safety and effectiveness. Homeopathic meds are sold without those reviews.").

208. Fugh-Berman Testimony, *supra* note 164, at 4.

209. *Id.*

210. *Id.*

these products have undergone prior to their arrival on store shelves.

V. CONCLUSION

The conflict between the FDA and the FTC in regulating homeopathic products represents a unique moment in their relationship as sister agencies.²¹¹ The FDA has found itself in an unlikely situation wherein its current regulatory policies are inadequate. There is no question that the FDA's current regulatory framework fails to do an adequate job of keeping up with the rapidly growing industry of homeopathic products. The FDA has repeatedly failed to exercise the authority it has to protect consumers from homeopathic products that masquerade as similar OTC drugs and potentially cause harm. Based on the concerns of consumers, health care professionals, the homeopathic drug industry, the FTC, and other stakeholders, the FDA should put in place an improved regulatory framework that will demand more accountability and transparency from drug manufacturers.

In a culture where consumers demand quick fixes in treating certain ailments and other health maladies, it is no wonder why the homeopathic industry has enjoyed tremendous growth. With the promise of acting as an effective, alternative form of treatment, homeopathic products, thanks in part to relaxed FDA standards, have fueled a consumer culture that is willing to sacrifice knowledge about a product's safety in exchange for instant gratification. To remedy this situation, better oversight can be achieved by placing homeopathic products apart from other OTC drugs on store shelves and providing disclaimer labels on store shelves and in packaging. These recommendations will help raise the general public's awareness of homeopathy and its understanding as to the extent of the FDA's involvement in regulating homeopathic products. In addition, these suggestions will help the FTC better monitor advertising claims found on homeopathic products thereby ensuring the public's safety. Combining these recommendations will minimize harm for consumers and confusion for advertisers, and provide greater collaboration between the FDA and the FTC in regulating homeopathic products moving forward.

211. *Advertising FAQ's: A Guide for Small Business*, FTC, www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business (last visited Jan. 2, 2016). "The FTC and the FDA have a long-standing liaison agreement to allocate their efforts efficiently." *Id.* The FTC regulates advertising for foods, over-the-counter drugs, dietary supplements, medical devices, and cosmetics. *Id.* The FDA is responsible for regulating the labeling of these products. *Id.* The FDA is primarily in charge of handling prescription drug advertising and labeling. *Id.*

