Comments of the Staff of the Federal Trade Commission[1]

Submitted to the Food and Drug Administration
Department of Health and Human Services

In Response to a Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century

80 Fed. Reg. 16327 (Mar. 27, 2015)

Submitted on August 21, 2015

I. INTRODUCTION AND SUMMARY

The staff of the Federal Trade Commission's ("FTC" or "Commission") Bureau of Consumer Protection, Office of Policy Planning, and Bureau of Economics (collectively, "FTC staff") appreciates the opportunity to respond to the Food and Drug Administration's ("FDA") Notice of Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century.[2] The FDA has requested public comments regarding the current use of human drug and biological products labeled as homeopathic, as well as the agency's regulatory framework for such products.

In general, under the Food, Drug, and Cosmetic Act,[3] drug products must be approved by FDA or generally recognized as safe and effective. However, under the current regulatory

[1] These comments represent the views of the Division of Advertising Practices in the Federal Trade Commission's Bureau of Consumer Protection, the Federal Trade Commission's Bureau of Economics, and the Federal Trade Commission's Office of Policy Planning. These comments do not necessarily reflect the views of the Commission or any individual Commissioner. However, the Commission has voted to authorize the staff to submit these comments. Questions or comments concerning this document may be addressed to Gregory W. Fortsch, Bureau of Consumer Protection, Division of Advertising Practices, gfortsch@ftc.gov or (202) 326-3617.

[2] 80 Fed. Reg. 16327.

[3] 21 U.S.C. § 321(g)(1)(A)-(C).

framework for homeopathic drugs,[4] as set forth in its 1988 Compliance Policy Guide,[5] FDA does not require that OTC homeopathic drugs comply with these requirements if they satisfy certain conditions, including that the label of such products contain an indication for use.

For the reasons discussed below, the FTC staff recommends that the FDA reconsider its regulatory framework for homeopathic medicines. The FTC staff is concerned that the FDA's existing regulatory framework may conflict with the Commission's advertising substantiation policy in ways that may harm consumers and create confusion for advertisers.[6] These concerns are bolstered by the results of FTC staff research exploring consumers' understanding and perceptions of homeopathy and homeopathic drugs. As explained below, this evidence suggests that a significant percentage of consumers do not understand homeopathy, how the FDA regulates homeopathic drugs, or the level of scientific evidence supporting homeopathic claims.

II. INTEREST AND EXPERIENCE OF THE FTC

The FTC's authority over disease and other health-related claims comes from Sections 5 and 12 of the FTC Act. Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in or affecting commerce, such as the deceptive advertising or labeling of over-the-counter (OTC) drugs.[7] Section 12 prohibits the dissemination of false

[4] A homeopathic drug is any drug that is "labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements." Homeopathy is based on the view that disease symptoms can be cured by small doses of substances that produce similar symptoms when provided in large doses to healthy people. *See* FDA's Compliance Policy Guide (CPG) 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed," 53 FR 21728, June 9, 1988, *available at* www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm.

[5] *Id.*

[6] In addition to providing these comments, the FTC staff of the Division of Advertising Practices is holding a public workshop on September 21, 2015 to hear various points of view on the advertising of homeopathic medicine. *See* FTC to Host September Workshop in Washington, DC, to Examine Advertising for Over-the-Counter Homeopathic Products, *available at* https://www.ftc.gov/news-events/press-releases/2015/06/ftc-host-september-workshop-washington-dc-examine-advertising.

[7] Federal Trade Commission Act, 15 U.S.C. § 45(a)(2).

advertisements in or affecting commerce of food, drugs, devices, services, or cosmetics.[8] Under these provisions, companies must have a reasonable basis for making objective claims, including claims that a product can treat specific conditions, before those claims are made.[9] The FTC devotes significant enforcement and educational resources to protect consumers from unsubstantiated and misleading health claims in advertising for OTC products.

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. With regard to OTC drug products, pursuant to a 1971 Memorandum of Understanding between the two agencies, the FDA focuses on product labeling while the FTC focuses on product advertising.[10] With the exception of OTC homeopathic drugs discussed below, the regulatory approach of the two agencies has been remarkably consistent.

III. FACTUAL AND REGULATORY BACKGROUND

A. FDA Authority

All articles that meet the definition of a "drug" under the Food, Drug, and Cosmetic Act ("FD&C Act")[11] – including homeopathic drugs – are subject to regulation under the FD&C Act. Specifically, the FD&C Act requires that drugs cannot be sold until they are recognized among qualified experts to be safe and effective. Despite this requirement, homeopathic drugs have never been regulated under the FD&C Act like other conventional drugs.

In an effort to bring all drugs into compliance with the FD&C Act, the FDA initiated a rulemaking in 1972 to determine which OTC drugs were generally recognized among qualified experts as safe and effective and not misbranded, under prescribed, recommended, or suggested

[8] Federal Trade Commission Act, 15 U.S.C. § 52.
[9] *See* Advertising Substantiation Policy Statement, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).
[10] *See* Working Agreement Between the FTC and FDA, 3 Trade Reg. Rep. ¶ 9851 (CCH) (1971).
[11] 21 U.S.C. § 321(g)(1)(A)-(C).

conditions of use. As part of that rulemaking, the FDA deferred review of drugs labeled as homeopathic "due to the uniqueness of homeopathic medicine" and stated that FDA would review them as a separate category at a later time.[12] To date, FDA has not reviewed this class of products for efficacy.[13]

Instead, in 1988, the FDA issued Compliance Policy Guide ("CPG") 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed," which permitted the manufacture and distribution of homeopathic products without FDA approval.[14] Under the CPG, which is still in effect, the FDA permits a company to sell OTC homeopathic products without demonstrating their efficacy and—unlike both non-homeopathic drugs and dietary supplements—to include claims in their packaging about treating specific conditions as long as the conditions are "self-limiting" and not chronic. The CPG also requires that the labeling of homeopathic drugs display an indication for use.

B. FTC Authority

The FTC's well-established position on advertising substantiation was first announced in 1972 and has been repeatedly reaffirmed.[15] For health, safety, or efficacy claims, the FTC has generally required that advertisers possess "competent and reliable scientific evidence,"[16] defined as "tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield

[12] 37 Fed. Reg. 9464, 9466 (May 11, 1972); *see also* 80 Fed. Reg. 16327, 16328 (Mar. 27, 2015).
[13] 80 Fed. Reg. at 16328.
[14] *See* FDA's Compliance Policy Guide (CPG) 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed," 53 FR 21728, June 9, 1988, *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm.
[15] *See Pfizer*, 81 F.T.C. 23 (1972); *POM Wonderful LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015).
[16] *See POM Wonderful*, 777 F.3d at 505 (the baseline requirement for health-related claims independently bars any representations unless supported by competent and reliable scientific evidence that is sufficient to substantiate that the representations are true).

accurate and reliable results."[17] Competent and reliable scientific evidence may take different forms depending on the type of claim being made. For some claims, the substantiation required may be one or more well-designed human clinical studies.[18] Neither the FTC Act, nor any FTC rule or policy statement, exempts advertising claims for homeopathic drugs from these standards.

IV. THE FDA REGULATORY FRAMEWORK MAY HARM CONSUMERS AND CAUSE CONFUSION FOR ADVERTISERS

A. Potential Conflict Between FDA's Regulatory Framework and FTC's Advertising Substantiation Policy

The FDA broadly defines labeling to include any article that accompanies a product. This can include websites and, under certain circumstances, advertising. Likewise, advertising is broadly interpreted under the FTC Act. Accordingly, the requirement that labeling for homeopathic drugs display an indication for use, even when the product has not been demonstrated to be efficacious for that indication, creates a potential conflict with the FTC's requirement that health claims be substantiated by competent and reliable scientific evidence. This potential conflict does not exist with respect to dietary supplements or non-homeopathic OTC drugs because both FTC and FDA law require that advertisers have substantiation to support efficacy claims for those products.

This potential conflict could be eliminated in one of three ways. First, the FDA could withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products. Second, the FDA could eliminate the requirement in the CPG that an indication appear on the labeling. Companies could still include an indication on the label, and

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[17] *See, e.g., Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998)

[18] *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989) (requiring "adequate and well-controlled clinical testing" to substantiate claims for hair removal product); *Thompson Medical Co.*, 104 F.T.C. at 826 (requiring two well-controlled clinical studies to substantiate certain analgesic drug claims); *see also, generally*, *POM Wonderful*, 777 F.3d at 498 (approving the imposition of a randomized controlled trial requirement for disease claims).

would likely do so, but it would not be a specific requirement of the FDA's discretionary non-enforcement policy. As it stands, when an advertiser follows the CPG requirement to provide an indication on its product label without competent and reliable scientific evidence to support it, the advertiser violates FTC law which, contrary to the CPG, requires such evidence for any health claims such as indications. Finally, given that the CPG is a discretionary enforcement policy, a third way to eliminate the potential conflict discussed above would be for the FDA to require that any indication appearing on the labeling be supported by competent and reliable scientific evidence.

B. Related Conflicts and Problems Caused by the CPG

In addition to creating a potential conflict between FTC and FDA law, the CPG may lead to confusion for both advertisers and consumers, especially within the context of industry self-regulation of advertising. The CPG may also create a loophole by which manufacturers can take advantage of the less stringent requirements for homeopathic drugs, to the possible detriment of consumers.

The National Advertising Division ("NAD") of the Council of Better Business Bureaus is a self-regulatory body that attempts to resolve disputes between advertisers by providing voluntary recommendations on how to address misleading advertising. Pursuant to NAD procedures, one advertiser can file a claim against another advertiser to challenge advertising it believes to be false or deceptive. In addition, the NAD itself can raise advertising issues *sua sponte* as part of its routine monitoring program. To the extent that an advertiser declines to follow the NAD's recommendation, the NAD can refer the matter to the FTC.

In at least one prior instance, the potential conflict between the CPG and the FTC's substantiation requirement has complicated an NAD inquiry regarding advertising for a

homeopathic drug. In 2007, as part of its routine monitoring program, the NAD requested substantiation for several claims Similasan Corporation made in its advertising for its Earache Relief Ear Drops.[19] In its decision, the NAD recommended that the company discontinue its claim that the product "Relieves Pain, Soothes & Calms, [and is] Safe for Use with Antibiotics" because the advertiser could not provide competent and reliable evidence to support the claim.[20] Similasan responded in an "Advertiser's Statement" that it was not required to have such evidence because the CPG did not require it.[21] Of greater concern, however, was Similasan's comment that the NAD, in its decision, appeared to be "imposing a standard of proof which is imposed neither by the FDA ***nor the Federal Trade Commission***."[22]

As shown by Similasan's comment, the FDA's current regulatory framework could lead homeopathic drug advertisers to incorrectly assume, or at least to argue, that the FTC does not require competent and reliable scientific evidence to support the advertisers' efficacy claims. To the contrary, in several joint warning letters with FDA, the Commission staff has stated that the FTC Act requires competent and reliable scientific evidence to support claims made for products labeled as homeopathic.[23] Nevertheless, in the past, Commission staff has been reluctant to pursue cases against OTC homeopathic products because the Commission's traditional remedies, such as requiring that health claims be supported by competent and reliable scientific evidence, could create a potential conflict with FDA policy under the CPG.

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[19] *See* National Advertising Division Case Report #4650 (04/02/07), Similisan Corporation USA, Earache Relief Ear Drops, Exhibit (Ex.) A.
[20] *Id.* at 5.
[21] *Id.* at 6.
[22] *Id.* (emphasis added).
[23] *See, e.g.*, Nov. 28, 2011 letter to HCG Diet Direct, LLC, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm282052.htm; Nov. 28, 2011 letter to HCG Platinum, LLC, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm282062.htm; June 8, 2010 letter to Homeopathy for Health, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm215236.htm.

Overall, advertisers who mistakenly believe that compliance with the CPG exempts them from compliance with the FTC Act's substantiation requirement may unwittingly subject themselves to liability for injunctive and monetary remedies in an FTC enforcement proceeding. At the very least, the potential conflict between the FDA's homeopathic CPG and the FTC's substantiation requirement creates enforcement challenges for the FTC. This conflict also may create uncertainty for advertisers and consumers, which may substantially harm the interests of both.

Another concern is that the FDA's policy for homeopathic products may encourage some companies to attempt to skirt FDA regulations by marketing their dietary supplement products as homeopathic drugs. A manufacturer can label a product as "homeopathic" when it contains both homeopathic ingredients and other ingredients such as dietary supplements, if they designate the latter as inactive ingredients in the substance.[24] A manufacturer could easily take advantage of the protective umbrella created by the FDA's current regulatory framework, by simply labeling the product "homeopathic" and arguing that the product's efficacy claims need not be substantiated.

[24] The CPG states that "drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products." However, a difficulty arises when companies include "non-homeopathic" active ingredients in the "inactive ingredient" list. In that case, it is up to FDA to show that these "inactive" ingredients are, in fact, active ingredients. An "active ingredient" is defined under 21 C.F.R. §§ 201.66(b)(2) and 210.3(b)(7)) as any component that is intended to furnish pharmacological activity or direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. There are a wide variety of inactive ingredients, and it is possible for companies to claim that their questionable "inactive" dietary supplements act as emulsifiers or preservatives. If the FDA cannot disprove this purpose, the product can be considered homeopathic.

V. FTC STAFF'S CONCERNS ARE BOLSTERED BY RESEARCH ON CONSUMER PERCEPTIONS ABOUT HOMEOPATHY AND HOMEOPATHIC MEDICINE

The FTC staff has conducted copy tests and focus groups concerning consumers' understanding of homeopathy and homeopathic remedies. This research, combined with additional observations regarding how homeopathic remedies are marketed, exacerbates the concerns raised above, because our research suggests that a significant percentage of consumers do not understand the nature of homeopathic products, how they are regulated, or the level of substantiation to support claims for those products.

A. Focus Group Results

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.[25] 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.[26] 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.[27]

Two focus groups were conducted in Baltimore, Maryland in late 2010.[28] One focus group included eight adults while the other included eight parents.[29] With input from the FTC staff, Shugoll developed two screening questionnaires to recruit these focus group respondents.

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[25] Shugoll Research, *Homeopathy Focus Groups Report* (January 2011), Ex. B at 2.
[26] *Id.*
[27] *Id.* The focus group report employed a qualitative research methodology rather than a quantitative one. *See id.* at 5. As stated in the report, qualitative research methodologies seek to develop directions rather than quantitatively precise or absolute measures, and the results are used to generate hypotheses for decision making and further testing rather than to provide a basis to make generalizations about the population under study. *Id.* Accordingly, the FTC employed the findings developed from this focus group to undertake the copy test discussed in Section V.B. below.
[28] Ex. B at 3.
[29] *Id*.

During the focus groups, the respondents were asked to discuss, among other things, the differences among conventional, herbal, and homeopathic products.[30]

Among focus group participants, adults and parents were likely to group or categorize products in a number of ways including conventional versus "natural" products, and awareness of non-prescription cold products was very high.[31] Adults tended to keep on hand several products designed to treat cold symptoms, and these products were primarily conventional. Additionally, parents were likely to have fever-reducing products in their medicine cabinets in addition to those designed to treat cold symptoms.[32] While adults and parents clearly differentiated conventional non-prescription products from non-conventional products, most struggled when asked to distinguish between herbal and homeopathic products.[33] Most parents and adults associated homeopathic products with natural or "non-chemical" products.[34]

Many adults and parents did not readily differentiate between evidentiary requirements and federal regulatory requirements for different types of products.[35] While they generally believed that manufacturers of conventional non-prescription products were required to support their claims with scientific evidence, they had varying opinions regarding the evidentiary requirements and federal oversight for herbal and homeopathic products, with some parents and adults indicating there were no requirements, others insisting there must be some governmental oversight, and still others who were unsure but hopeful that there were requirements.[36]

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[30] *Id.*
[31] *Id.* at 9.
[32] *Id.*
[33] *Id.* at 17.
[34] *Id.*
[35] *Id.* at 19.
[36] *Id.*

The focus group results also suggested that there is a poor understanding of the principles underlying homeopathic products.[37] Most adults and parents equated homeopathic products with natural and/or home remedies, and even those who had purchased homeopathic products were unfamiliar with the principles underlying homeopathy.[38] When those principles were explained to adults and parents in the group, they found them confusing; some parents were motivated by the relatively few side effects of homeopathic products, while the explanation of how homeopathy was supposed to work made other parents and adults question the effectiveness of the products.[39] Furthermore, most adults and parents were more likely to continue to use the conventional non-prescription products with which they were familiar and unlikely to purchase homeopathic products without an express recommendation from a trusted source due to their skepticism about the effectiveness of such products.[40]

As explained in the focus group report, while the parents and adults who participated in the focus group had a high degree of familiarity and understanding of conventional non-prescription products, they did not understand what "homeopathic" means or how homeopathy works.[41] In fact, the 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.[42] More importantly, upon learning more about the theory of homeopathy after Shugoll representatives explained the principles behind it to them, many participants became skeptical about its efficacy and more guarded about using it.[43] These results suggest that many consumers may choose homeopathic products based on incorrect and

[37] *Id.* at 23.
[38] *Id.*
[39] *Id.* at 24.
[40] *Id.* at 25-26.
[41] *Id.* at 28.
[42] *Id.*
[43] *Id.*

incomplete information about them. When given additional information, however, they looked more critically at homeopathic treatments and had a better basis on which to evaluate them in comparison to other remedies.[44]

B. Copy Test Results

Dr. Manoj Hastak, a professor of marketing at the Kogod School of Business at American University and a consultant for the FTC, designed a research study to investigate what was communicated to consumers upon exposure to a package of one of three homeopathic drug products.[45] The study was designed to address several targeted questions and was conducted online via an online panel.[46] Respondents were invited to complete a screening questionnaire and were offered an incentive of $3 if they were eligible for and participated in the study.[47] Depending on their eligibility, respondents were first assigned to one of ten conditions. These ten conditions consisted of three different versions of a Similasan product claimed to relieve cold-related symptoms in children aged 2-12, three different versions of a Boiron product called Oscillococcinum claimed to relieve flu symptoms, and four different versions of a Hylands product called Arnica claimed to relieve pain.[48]

The three versions of the Similasan product consisted of the original product available in the market at the time, a version that was identical to the original product available in the market except that the word "HOMEOPATHIC" at the top of the package front panel was made larger and more prominent, and a third version that was identical to the original product except that the words "This product has not been shown to relieve cold symptoms" was introduced in red

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[44] *Id.*.
[45] *See* Manoj Hastak, *Effects of Exposure to Packages of Several Homeopathic Products on Consumer Takeaway and Beliefs*, Report Submitted to the Federal Trade Commission (August 2012), Ex. C.
[46] *Id.* at 2.
[47] *Id.*
[48] *Id.*

lettering in a black box at the bottom of the back panel of the package.[49] The three versions of the Boiron product Oscillococcinum consisted of the original product available in the market at the time, a version that was identical to the product available in the market except that a more prominent "homeopathic" disclosure was added just above the brand name on the front panel, and a third version that was identical to the original version on the market except that the statement "This product has not been shown to relieve flu-like symptoms" in red lettering replaced the contact information for the manufacturer at the bottom of the back panel of the package.[50]

The four versions of the Hylands Arnica product consisted of an original version of the actual product available in the market at the time, except that any mention of the symptoms ostensibly treated by the product and company contact information were removed from the back panel, and a version that was identical to the original version except that the word "HOMEOPATHIC" was made larger and more prominent on the front panel and the company name was made smaller to make room for the larger "homeopathic" disclosure. A third version was identical to the original version except that the statement "Notice: This product has not been shown to relieve pain symptoms" in red lettering was added at the bottom of the back panel, and a fourth version was identical to the original version except that the statement "Notice: The ingredients in this product have not been tested for effectiveness" in red lettering was added at the bottom of the back panel.[51] After viewing a 3-D image of the product assigned to them, respondents answered a short questionnaire comprising closed-ended questions.[52]

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[49] *Id.* at 2-3.
[50] *Id.* at 3.
[51] *Id.* at 3-4. Screening questions were used to ensure that the respondents were in the target market for at least one of the three products. Ex. B at 4. To participate in the survey, respondents had to have purchased for themselves or for a family member one of the three product categories of interest (i.e., a product to relieve (a) cold symptoms for children aged 2-12, (b) pain, or (c) flu-like symptoms) within the past 12 months. In addition, respondents were

The copy test results reveal that many consumers mistakenly believed that the FDA has approved homeopathic products for efficacy.[53] After controlling for "yea saying,"[54] the copy test showed that between 10% and 30% (10.3% to 28.6%) of respondents exposed to the original product packaging for the three products indicated that they believed that a government agency like the FDA had approved the products for efficacy.[55] Although making the word "homeopathic" more prominent on the Similasan label significantly reduced the belief that the product was FDA approved, it did not have a similar effect for either the Oscillococcinum or Arnica products.[56] Likewise, at least one of the two disclosures utilized in this study significantly reduced the misperception of FDA approval for each product.[57] However, after controlling for "yea saying," the copy test showed that 18.9% of respondents exposed to the Similasan product packaging still indicated that they believed that a government agency like the FDA had approved the product for efficacy, as did 7.4% to 8.0% of respondents exposed to the packaging of the other two tested products. 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. Whether other disclosures could effectively and

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excluded if they were under 18 or if they or anyone in their household worked in marketing research, a grocery or a drug store, or for a drug or pharmaceutical company. *Id.*

[52] *Id.*

[53] *Id.* at 14.

[54] "Yea saying" is the tendency to agree with questions asked regardless of content. As the survey report notes, affirmative responses to the FDA statement were adjusted by subtracting affirmative responses to a control statement designed to capture "yea saying." The control question asked consumers if they believed that that American Medical Association certified that the product was more effective than other remedies in relieving the symptoms the product claimed to relieve. Control questions are used to control for measurement error, including yea-saying bias, inattention, and other noise factors that may result from the provision of a closed-ended question format. *See* J. Craig Andrews & Thomas J. Maronick, *Advertising Research Issues from FTC versus Stouffer Foods Corporation*, 14 J. PUB. POL. & MARKETING 305 (1995).

[55] *Id.* at 9. Before controlling for "yea saying," responses ranged from 30% to 56% (32.6% to 56.0%). Approximately 175 consumers looked at each of the 10 conditions used in this survey.

[56] *Id.*

[57] *Id.* at 9-10.

consistently eliminate such misperceptions is an open question; however, this research shows the persistence of mistaken consumer beliefs about government approval for homeopathic products.

The copy test results also showed that consumers mistakenly believed that the manufacturers of homeopathic products tested their products on people in order to show their effectiveness.[58] After controlling for "yea saying," the copy test results showed that about 20% to 30% (22.8% to 33.6%) of respondents exposed to the original product packaging for the three products indicated that they believed the manufacturers had tested the products on people to show their effectiveness.[59] These results support the conclusion that consumers have incorrect perceptions about human efficacy testing for homeopathic products.[60]

C. Additional Observations

In addition to what we found in our copy test and focus group research, the FTC staff has observed other potential causes of consumer confusion in the marketing of homeopathic remedies. We believe that consumer confusion likely is created by the retail store shelf placement of homeopathic products side-by-side with conventional medicine that, in fact, has been approved by the FDA and tested on humans for efficacy. Confusion is likely created, as well, by the terminology used in homeopathy product labeling. In current labeling for homeopathic products, a manufacturer normally states that a product contains a particular substance in an amount that is expressed as a number followed by an "X," such as "2X." For

[58] *Id.* at 14.
[59] *Id.* at 11; *see supra* note 13. Before controlling for "yea saying," responses ranged from approximately 45% to 57%.
[60] Few homeopathic remedies have been subjected to human clinical trials under controlled conditions, and the vast majority of those that have been have not shown positive results. *See, e.g.*, Evidence on the effectiveness of homeopathy for treating health conditions, Australian Government National Health and Medical Research Council (NHMRC) (Mar. 2015), *available at* http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02a_information_paper.pdf (last visited June 2, 2015).

instance, 2X represents a dilution of 1 to 100 (1:100), or, in other words, a 1% concentration. For the average consumer or even a sophisticated one, it is difficult to understand what 2X means.

The FTC staff is concerned that consumers may choose homeopathic products over proven medicine based on any or all of the misperceptions and incomplete or incorrect information described above. As our research has indicated, once consumers were given access to basic information about homeopathy, they were more skeptical of the homeopathic treatment than when they incorrectly believed that homeopathic was simply a synonym for "natural" and had no knowledge of the principles behind homeopathy.

D. FTC Staff's Evaluation of Likely Consumer Confusion

Overall, the FTC staff's copy test and focus group research, combined with other research and market observations, suggest 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. Finally, homeopathic product labels are confusing and do not conform with conventional product labeling. A consumer's choice to use homeopathic medicine based on the above factors could cause harm. The FTC staff believes that the FDA should take these factors into consideration in its review of the regulatory framework for homeopathic products.

VI. CONCLUSION

The FTC staff believes that FDA's regulatory framework, which potentially conflicts with the Commission's advertising substantiation policy requiring that health-related efficacy

claims be supported by competent and reliable scientific evidence, may be harmful to consumers. In addition, the available evidence suggests that consumers have incomplete and sometimes incorrect information about homeopathy and homeopathic medicines. Accordingly, the FTC staff recommends that the FDA reconsider its regulatory framework for homeopathic medicines to address the concerns discussed in these comments.