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Homeopathic Medicine & Advertising: An FTC Workshop

Comments of the

American Association of Homeopathic Pharmacists

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I. INTRODUCTION

In a June 1, 2015 press release, the Federal Trade Commission (FTC) announced that it would hold a public workshop on September 21, 2015 to examine various issues relating to the advertising of homeopathic drugs.¹ In the press release, the FTC stated that it:

invites the public to submit research, recommendations for topics of discussion, and requests to participate as panelists. The workshop will cover topics including:

A look at changes in the homeopathic market, its advertising, and what consumers know;

The science behind homeopathy and its effectiveness;

The effects of recent class actions against homeopathic product companies;

The application of Section 5 of the FTC Act to advertising claims for homeopathic products; and

Public policy concerns about the current regulation of homeopathic products.

The American Association of Homeopathic Pharmacists (AAHP) appreciates this opportunity to supplement and expand upon its oral presentations at the workshop. The AAHP is a trade association representing manufacturers and marketers of homeopathic drugs in the United States. Founded in 1923, many of its 35 member firms joined at that time. The AAHP estimates that its members produce more than 90 percent (based on sales volume) of the homeopathic products sold in the United States.

¹ <https://www.ftc.gov/news-events/press-releases/2015/06/ftc-host-september-workshop-washington-dc-examine-advertising> (accessed November 7, 2015).

The first operating principle in AAHP's mission statement is to encourage regulatory compliance among its members.² The AAHP has established a solid working relationship with the Food and Drug Administration (FDA), the Federal agency principally charged with regulating the manufacturing and marketing of homeopathic drugs. The association hopes that this forum will help initiate a similar relationship with the FTC.

The FTC is aware that FDA held a two-day hearing on the regulation of homeopathic drugs in April, 2015. That hearing was billed as a reexamination of Compliance Policy Guide 400.400, *Conditions Under Which Homeopathic Drugs May Be Marketed*³ (CPG), adopted in 1988. The AAHP submitted extensive comments to FDA in connection with that hearing. Those comments contain significant background data about homeopathy, its safe use by consumers, and consumer knowledge of and attitudes about homeopathy. The safety of homeopathic drugs is discussed at length in the association's comments to FDA. While the safety of homeopathic drugs is properly an issue for FDA, rather than the FTC, the AAHP believes that to the extent safety is considered here, the exemplary safety record of homeopathic drugs argues against the imposition of expensive and unnecessary research to substantiate product advertising claims. Rather than restate the data submitted to FDA, the AAHP refers the FTC to its FDA comments in response to the first two topics mentioned above.⁴ A copy of the AAHP FDA comments is attached to this submission as Exhibit 1 and incorporated herein.

The AAHP believes that new research discussed below shows that most consumers are aware that allopathic and homeopathic drugs are not the same and that the use of appropriate disclaimers in advertising can alleviate perceived consumer confusion. This research is discussed in detail in Section III, below.

II. BACKGROUND

Homeopathy is a 200-year-old school of medicine that today is categorized as an alternative or complementary form of medicine. It is founded on the observation of Dr. Samuel Hahnemann that a substance which causes certain symptoms in a healthy person when homeopathically prepared can alleviate those symptoms in a person who is not well. Despite an approach that is rejected by many today, homeopathy has remained a popular and useful therapeutic modality for hundreds of millions of consumers around the world.

Unlike other forms of complementary or alternative medicine, homeopathy occupies a unique status under the Federal Food, Drug, and Cosmetic Act (FD&C Act): the Homeopathic Pharmacopeia of the United States (HPUS) is recognized as an "official" compendium and

² See <http://www.aahp.info/about/strategic-priorities/> (accessed Oct. 25, 2015).

³ <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm> (accessed Nov. 7, 2015).

⁴ These comments will not address the third issue, above, the impact of class actions on the homeopathic industry. The AAHP does not see the relevance of this issue to the FTC's mission. To the extent that it is relevant, the AAHP endorses the comments made at the hearing by Christina Guerola Sarchio, Esq., who said that these lawsuits provided little or no benefit to consumers but provided significant fees to a certain class of lawyers.

ingredients contained therein are recognized as drugs.⁵ In 1988, FDA adopted a Compliance Policy Guide (CPG) to set forth the conditions under which homeopathic drugs could be marketed.⁶ The CPG outlines the various labeling requirements (and exemptions) applicable to homeopathic drugs and refers to several established homeopathic materia medica (*i.e.*, the homeopathic literature) as a “guide to the use of homeopathic drugs (including potencies, dosing, and other parameters). . . .” In essence, the CPG provides that if a recognized homeopathic drug was labeled in accordance with the Compliance Policy Guide, offered for an OTC use or uses documented in the homeopathic literature, and manufactured according to current Good Manufacturing Practices, FDA will not object to the marketing of that product.

The FTC did not participate in the FDA hearing in April, 2015, but the FTC staff did submit comments to the docket FDA established. The staff asserted in those comments that there was a “potential” conflict between the requirements of the CPG and the Federal Trade Commission Act advertising substantiation requirement: “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.” *Id.* at 6. To remedy this claimed conflict, the staff proposed three options:

1. “FDA could withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products.”
2. “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 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.”
3. “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.”

The AAHP believes that these options are not well-founded legally nor do they address the policy issues facing FDA.

⁵ 21 U.S.C. §§ 321(g)(1)(A) & (j).

⁶ Homeopathic drugs were, of course, available before 1988 but, beginning in the 1970s, FDA followed an inconsistent enforcement policy. The CPG was needed, in part, because FDA chose not to include homeopathic drugs in the OTC Drug Review. *See, infra*, at 4.

First, simply withdrawing the CPG does not in any way change the fundamental legal status of homeopathic drugs. FDA has been dealing with the issue of drug efficacy since 1962, when Congress adopted the Drug Amendments of 1962, which, for the first time, added the efficacy requirement to the new drug approval criteria. Faced with examining thousands of pre-1962 drugs, FDA first reviewed prescription drugs through a contract with the National Academy of Sciences-National Research Council. More than 50 years later that review is ongoing, if not moribund, with several thousand drugs never fully upgraded as safe and effective nor removed from the market. FDA turned to the efficacy of OTC drugs in 1972 and adopted a different approach. Rather than engage in the same time-consuming process used for the review of Rx drugs, FDA decided to examine OTC drug efficacy by category and create monographs that established which claims and which active ingredients were generally recognized as safe and effective, and thus not new drugs subject to premarket approval. The OTC Review produced a large number of final and tentative final monographs until FDA basically stopped supporting the review with adequate resources. Indeed, the agency held a hearing last year to examine potential new procedural approaches to OTC drug regulation.⁷

Homeopathic drugs were explicitly excluded from the OTC Review at its outset, FDA explaining that “[b]ecause of the uniqueness of homeopathic drugs,” they would be the subject of a separate review to follow the completion of the allopathic OTC Review.⁸ To revoke the CPG and declare, *ipse dixit*, that homeopathic drugs are illegal would present, at a minimum, an interesting court case. This is especially the case because the unfinished Drug Efficacy Study Implementation (DESI) Review and OTC Review leave homeopathic drugs in excellent company, including OTC and Rx standbys such as aspirin and phenobarbital, respectively. In fact, the agency estimates that there are several thousand unapproved prescription drugs on the market today. Indeed, the CPG essentially codifies what has been FDA’s position with regard to allopathic OTC drugs: absent a public health issue, products on the market when the Review began may remain on the market until a final monograph is adopted.⁹ As a matter of resource allocation, FDA has clearly decided that its time and attention is better spent in other areas. The FTC staff proposal to simply revoke the CPG ignores that decision.

The FTC staff’s second suggestion, that FDA remove the indication requirement from the CPG, likewise lacks a legal basis. In fact, during the discussions leading to the issuance of the CPG, one of FDA’s unwavering points was that the FD&C Act required that any drug label bear indications for use. (Prior to 1988, the labels of many homeopathic drugs simply stated: “Use according to standard homeopathic indications.”)

The FTC staff’s final suggestion, amending the CPG to require that indications be supported by “competent and reliable scientific evidence,” is essentially circular. FDA adopted

⁷ Food and Drug Administration, *Over-The-Counter Drug Monograph System—Past, Present, and Future*; Public Hearing, 79 FED. REG. 10,168 (Feb. 24, 2104).

⁸ 37 FED. REG. 946 (May 11, 1972).

⁹ See FDA Compliance Policy Guides 450.200 & 450.300, <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074388.htm> & <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074389.htm> (accessed Nov. 10, 2015).

the CPG to regulate homeopathic drugs until such time as the agency invested the time to review them. The FTC staff suggestion would ultimately require FDA to do what it has been unable to complete for allopathic drugs nor begin for homeopathic drugs.

Since FDA is the lead agency for regulating drugs, the reasonable approach is not, as the FTC staff has suggested, for FDA to change its enforcement policy, but rather for the FTC to harmonize its position with that of FDA. If the FTC adopts a significantly different position than FDA's (assuming FDA makes no substantial changes to the CPG), the FTC could prevent consumers from receiving information about lawfully marketed products. In addition, creating such a significant disharmony in the federal regulation of a product class would almost certainly lead to litigation that could put a court in the position of having to select which agency is correct. Litigation generally creates winners and losers and there is no good reason for either the FTC or FDA to risk such a decision.

The AAHP believes that the advertising of homeopathic drugs can readily comply with the FTC's advertising substantiation requirements, as discussed below.

III. THE USE OF APPROPRIATE DISCLAIMERS

Members of the AAHP are proud to market homeopathic drugs. Many of these companies are among the oldest pharmaceutical companies in the U.S. The AAHP recognizes that consumers who are not familiar with homeopathy might not realize that homeopathic drugs do not undergo the same regulatory review process as allopathic OTC drugs.¹⁰

In 2010, the AAHP began considering how to better inform consumers about the homeopathic nature of its products through the use of disclaimers.¹¹ In August, 2012, the AAHP adopted revisions to its long-standing advertising guideline¹² to provide that:

Advertising to consumers for an OTC homeopathic drug should include the following statement:

“These statements have not been reviewed by the Food and Drug Administration.”

Additional language which explains the homeopathic nature of the claim may also be included in conjunction with the statement above.

In addition to the advertising provision, the guideline also provides that, “If voluntarily applied to the label and labeling of homeopathic drugs, the principles set forth in this guideline should be followed.”

¹⁰ Both types of drugs are subject to essentially the same cGMP requirements, however, and FDA frequently acts against OTC homeopathic drugs which make prescription drug claims.

¹¹ This examination predated the disclaimers required by some settlements in class action litigation against certain homeopathic drug manufacturers.

¹² <http://www.aahp.info/position-statements/consumer-advertising-guideline-for-over-the-counter-homeopathic-medicines/> (accessed Nov. 10, 2015).

The language of the disclaimer was based on the disclaimer enacted by Congress as part of the Dietary Supplement Health and Education Act and should serve to appropriately inform consumers that the uses of homeopathic drugs have not been reviewed by FDA. The advertising and labeling disclaimer has been widely adopted by AAHP members and appears on an increasing number of ads and labels as existing packages sell through. Some companies use a slightly different disclaimer as a result of settlements of class actions alleging false advertising. Although worded slightly differently, these disclaimers provide consumers with essentially the same message as the AAHP disclaimer. In its comments to the FDA docket, the AAHP suggested that FDA amend the CPG to require that the AAHP voluntary disclaimer become a requirement for all homeopathic product labels.

Three years ago, the FTC commissioned a consumer perception study which examined consumer takeaway on a number of issues involving homeopathic drugs.¹³ Based on that survey, the FTC staff concluded that consumers were confused about the role of FDA in the regulation of homeopathic drugs, with between 10 and 29 percent of consumers believing that FDA approved the products for efficacy. The study also showed that label disclose could improve consumer comprehension.

As noted at the FTC workshop, the AAHP has sponsored new research which shows that the appropriate use of label and advertising disclaimers can present the consumer with truthful and non-misleading information about the status of homeopathic products. The research shows that many consumers are less confused about FDA's role in homeopathy than about many other regulated product categories.¹⁴ The research was conducted for the AAHP by Thomas J. Maronick, DBA, JD, Professor of Marketing at Towson University and the former Director of Impact Studies in the FTC's Bureau of Consumer Protection.¹⁵

Dr. Maronick conducted two studies. One studied consumer beliefs about FDA's role in approving the labels of a wide variety of FDA-regulated products. This study shows that 24 percent of consumers tested believed that FDA approved homeopathic drug claims, a number within the range found by the FTC study. While 24 percent is not an inconsequential number, it is very important to put it into context. The AAHP study shows that fewer consumers believe that FDA approves homeopathic product labels than believe that FDA approves cosmetic, pet food, and grocery product claims (39, 38 and 63 percent, respectively). In fact, fewer consumers believed that FDA approved homeopathic drug claims than any other product category tested. In short, this study proved a "control group" which puts the results of the FTC study in perspective. The study also suggested that most consumers can differentiate between allopathic OTC products and homeopathic OTC products: 76 percent of consumers understood that FDA

¹³ See Comments of the Staff of the Federal Trade Commission, Exhibit C (filed Aug. 21, 2015). Oddly, the FTC study examined OTC homeopathic product labels, not advertising.

¹⁴ The complete study appears in Exhibit 2. Because the FTC study examined labels instead of advertising, the AAHP study followed the same approach.

¹⁵ Dr. Maronick's curriculum vitae is attached to the study report.

reviewed claims for allopathic OTCs, while, as noted, only 24 percent thought the same about homeopathic drugs. The following table from Dr. Maronick’s report summarizes the results.

**Perception of FDA Approval of
 Claims Made for Products**

	Definitely/ Approved	Definitely/ Not Approved	Don’t know	Mean**
Prescription drug claims	136 (85.5%)	7 (4.4%)	16 (10.0%)	1.74
Dietary supplement claims	76 (47.8%)	55 (34.6%)	28 (17.6%)	2.28
Claims for cosmetics	63 (39.6%)	53 (33.3%)	43 (27.0%)	3.11
Claims for grocery foods	101 (63.5%)	29 (18.2%)	29 (18.2%)	2.45
Pet food claims	61 (38.7%)	44 (27.7%)	54 (34.0%)	3.23
Claims for homeopathic products	38 (23.9%)	71 (44.7%)	50 (31.4%)	3.47
Claims for over-the-counter medicines	121 (76.1%)	15 (9.4%)	23 (14.5%)	2.14
Claims for other products	20 (12.6%)	14 (8.8%)	125 (78.6%)	4.39

****Lower the mean value, the greater the number of “Definitely Approved/Approved”**

The FTC study found that disclaimers reduced consumer confusion. In a second study,¹⁷ Dr. Maronick studied consumer perception of product labels with one of three different disclaimers. The disclaimers that were tested are:

“These statements have not been reviewed by the Food and Drug Administration.”

“The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.”

“The uses of our products are based on traditional homeopathic practice. (see www.homeopathic.org)¹⁸ They have not been reviewed by the Food and Drug Administration.”

The key finding of this study is that, when a homeopathic drug bears one of the three label disclaimers above, only between 1 percent and 8 percent of consumers believed that homeopathic drug claims are approved by FDA. In fact, when controlling for yea-saying (using the same method as the FTC study), “*negative* values emerge for all three disclaimer groups for the percentage of respondents believing that FDA had approved [the test product] claims.”¹⁹ That is a dramatic decline from the 24 percent who believed that when not presented with a label disclaimer. Dr. Maronick concluded that, “the results strongly suggest that disclaimers can be effective for addressing any consumer misperception regarding the FDA approval status of claims made for homeopathic products.”²⁰

¹⁷ See Exhibit 2.

¹⁸ This is not a real website but, rather, a signal to consumers that additional information is available.

¹⁹ See Exhibit 2 at 13.

²⁰ *Id.*

This study also examined consumer beliefs about the amount of testing conducted by the manufacturer of the homeopathic product. Dr. Maronick concluded that this phase of the testing showed that

only between 8% and 14% of respondents across the three disclaimer groups believed that the “Tested on People” statement meant that the manufacturer had conducted scientifically controlled studies with humans....

The varied consumer interpretations of the Tested on People statement observed in Study 2 potentially call into question the FTC’s reliance on the Tested on People statement in the Hastak Study. As Table 6 demonstrates, a consumer’s affirmative response to the Tested on People statement does not necessarily mean the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. Rather, it shows that consumers believe the manufacturer conducted homeopathic studies on humans, with different views as to what type of testing on humans was conducted.²¹

These two studies, taken together, show both that consumers: (1) understand the limited role that FDA plays in reviewing homeopathic drug products, and (2) that disclaimers are an excellent way to inform consumers about the role of FDA in the marketing of homeopathic drugs. “An advertiser thus still may assert a health-related claim backed by medical evidence falling short of a [clinical trial] if it includes an effective disclaimer disclosing the limitations of the supporting research.”²²

III. Substantiation of Traditional Use

The FTC has recognized that product claims based on traditional use are appropriate when properly presented. In its guidance document, *Dietary Supplements; An Advertising Guide for Industry*,²³ the FTC explained that:

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, **or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose.**

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on

²¹ See Exhibit 2 at 15.

²² POM Wonderful, LLC, et al. v. Federal Trade Commission (No. 13-1060, D.C. Cir. Jan. 30, 2015)

²³ <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry#c> (accessed Nov. 9, 2015).

consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.

There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.²⁴

While the FTC guide is aimed at dietary supplement sellers, the principles it discusses are equally applicable to OTC homeopathic drugs. As discussed above, the AAHP's voluntary labeling and advertising disclaimer program provides consumers with information about the absence of FDA review of the product's claims and, depending on the disclaimer used, the fact that the claims are based on traditional homeopathic practice. As Dr. Maronick's research showed, most consumers do not believe that homeopathic and allopathic OTC drugs have the same level of scientific support.

It is also important to recognize that OTC medications, whether allopathic or homeopathic, should never be marketed so that they "could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision." Since OTC conditions are largely self-limiting by FDA definition, the use of OTC homeopathic drugs does not cause consumers to self-medicate for potentially serious conditions without medical supervision. All such conditions are considered by FDA to be prescription-only.

IV. A "Reasonable Basis" for Homeopathic Drugs

Beginning with its decision in the *Pfizer* case in 1972, the FTC developed the doctrine that an advertiser needed to have a "reasonable basis" for a product claim.²⁵ That doctrine was memorialized in the FTC's Advertising Substantiation Policy Statement in 1983.²⁶ According to this policy,

²⁴ *Id.* (emphasis added).

²⁵ *Pfizer, Inc.* 81 F.T.C.23 (1972).

²⁶ Available at <https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation> (accessed Nov. 10, 2015).

Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.

Until fairly recently, the FTC applied these factors in a flexible manner. Lately, however, commenters have noted that the FTC has adopted a more rigid and less flexible approach, especially with regard to health claims.²⁷ "In recent consent agreements . . . the Commission replaced that flexible standard with the same kinds of evidence that the FDA has traditionally required to approve new drugs. . . . If followed, these cases represent a significant ossification of a formerly flexible standard."²⁸ The two randomized controlled trials (RCTs) that the FTC now appears to believe are necessary for any health claim go well beyond the standard required by FDA in the OTC Review. The AAHP believes that a reasonable basis for homeopathic drug claims in advertising is the homeopathic literature, the same homeopathic literature relied on by FDA and regulatory authorities around the world, coupled with appropriate disclaimers that alert consumers to the regulatory status of homeopathic drug claims. This approach is fully consistent with the factors identified in the Advertising Substantiation Policy Statement.

a. The type of claim involved

While advertising for OTC homeopathic products clearly involves health claims, it is important to recognize the nature of those claims. OTC drugs, by definition, are not intended to treat life-threatening conditions.²⁹ Indeed, the homeopathy CPG states that, "Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC."³⁰ The AAHP believes that there is no sound basis to require RCTs -- the type of studies required by FDA for drugs to treat major illnesses such as high blood pressure, high cholesterol, and heart disease -- for drugs intended to treat conditions that will resolve on their own.

²⁷ See, e.g., Shaheen and Mudge, *Has the FTC Changed the Game On Advertising Substantiation*, 25 ANTITRUST 65 (2010); Abbott, *Time to Reform FTC Advertising Regulation* (The Heritage Foundation Legal Memorandum No. 140, Oct. 29, 2014).

²⁸ Beales, Muris and Pitofsky, *In Defense of the Pfizer Factors* 3-4 (George Mason Univ. Law and Economics Research Paper Series, 12-49, May, 2012) available at http://www.law.gmu.edu/assets/files/publications/working_papers/1249InDefenseofPfizer.pdf (accessed Nov. 10, 2015).

²⁹ See <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm093452.htm> (accessed Nov. 10, 2015).

³⁰ CPG 400.400, *supra* note 3.

b. The product

OTC homeopathic drugs have an unsurpassed safety profile.³¹ Virtually all have extremely low levels of active ingredients, and have essentially no side effects. Unlike some allopathic OTC drugs, there has never been a documented fatality from the use of a homeopathic drug.

c. The consequences of a false claim

As discussed above, most OTC products are intended to relieve symptoms that will resolve on their own if not treated. Accordingly, a false claim involving the efficacy of a homeopathic would have no adverse health consequences beyond minor discomfort. A consumer who received no relief from a product would, of course, have received no value for his or her money and the AAHP does not sanction fleecing consumers so long as they suffer no physical harm. Rather, the consequences of a false claim involving a homeopathic drug are minor. “The Commission should require relatively less evidence of the probable truth of a claim, however, if the benefits of relying on the claim if it is true greatly exceed the costs of relying on it if it is false.”³²

d. The benefits of a truthful claim

The benefits of a truthful claim involving a homeopathic drug include the relief of the condition for which the drug is intended and the avoidance of the possible side effects from another type of therapy. Additionally, homeopathic drugs are generally a very cost-effective choice.

e. The cost of developing substantiation for the claim

To comply with the FDA’s labeling requirements, homeopathic drug manufacturers examine the homeopathic literature to select appropriate active ingredients. This is essentially what homeopathic consumers have done for centuries. The FTC apparently believes that only RCTs provide appropriate support for OTC homeopathic claims. This approach creates two problems. First, the RCT was not designed to test the efficacy of homeopathic drugs. As explained by the American Institute of Homeopathy, the oldest extant national physicians’ organization in the U.S.,

Experts in homeopathic research and clinical practice have long espoused the position that RCTs are an excellent tool for determining efficacy of allopathic (conventional) medicines, but are not well suited to evaluate homeopathic drugs. The reasons for this position rest on several points, as follows:

³¹ See Exhibit 1 at 22-26.

³² See note 28, *supra*, at 16.

1. Homeopathic medicines are individualized for a specific constellation of symptoms and observed clinical findings, not to the conventional diagnosis per se.
2. Efficacy studies do not always predict effectiveness in clinical practice.
3. Most homeopathic medicines already have a wealth of valid clinical data published in the homeopathic scientific literature.
4. Homeopathic clinical data carries a high degree of reliability due to the outcome measures used.³³

Even were clinical trials a reasonable approach to evaluating homeopathic drugs, the cost involved would far exceed the resources of the industry and thus deprive consumers of products they want. One study reported that the cost of the Phase III clinical trials for four drugs for diabetes ranged from \$68.5 million to \$315.2 million, and averaged \$186.7 million per drug (the specific number of RCTs conducted was not discussed).³⁴

The complexity of conducting a clinical trial is demonstrated by the following Federal outline used to calculate the costs involved:³⁵

- Per-study costs is the sum of:
 - Data Collection, Management and Analysis Costs (per study);
 - Cost Per Institutional Review Board (IRB) Approval × Number of IRB Approvals (per study);
 - Cost Per IRB Amendment × Number of IRB Amendments (per study);
 - SDV Cost (per data field) × Number of SDV Fields (per study); and
 - The total of all per-site costs listed below, multiplied by Number of Sites (per study);
- Per-site costs is the sum of:
 - The total of all per-patient costs listed below, multiplied by Number of Planned Patients (per site);
 - Site Recruitment Costs (per site);
 - Site Retention Costs (per month) × Number of Site Management Months;
 - Administrative Staff Costs (per month) × Number of Project Management Months; and
 - Site Monitoring Costs (per day) × Number of Site Monitoring Days;
- Per-patient costs is the sum of:
 - Patient Recruitment Costs (per patient);

³³ See note 31, *supra*.

³⁴ Roy, *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials*, 5 (Manhattan Institute for Policy Research, 2012).

³⁵ Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, *Examination of Clinical Trial Costs and Barriers for Drug Development* (2014), available at <http://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development> (accessed Nov. 10, 2015).

- Patient Retention Costs (per patient);
- Registered Nurse (RN)/Clinical Research Associate (CRA) Costs (per patient);
- Physician Costs (per patient);
- Clinical Procedure Total (per patient); and
- Central Lab Costs (per patient);

One research study estimated the per-patient cost of a late stage Phase III trial at \$48,000.³⁶

The AAHP cites these figures because it brings into focus the reality of imposing Big Pharma standards in the form of RCTs on the generally small companies which populate the homeopathic industry. The entire homeopathic industry annually sells at retail about \$1 billion worth of drugs, or about the same amount as one Big Pharma blockbuster drug. Furthermore, there are about 1,500 homeopathic active ingredients in the Homeopathic Pharmacopeia of the United States. The resources that would be necessary to perform RCTs on those drugs is simply unavailable. Even were the industry to forgo advertising all but the 100 most popular homeopathic active ingredients, conducting two RCTs with 200 patients each³⁷ for each of those 100 active ingredients would total **\$1.94 trillion**.³⁸

As long as FDA permits the continued marketing of homeopathic drugs pursuant to the CPG, an FTC requirement that advertising claims be supported by RCTs is likely to lead to significantly fewer homeopathic drugs available to consumers. Full-line homeopathic companies earn the bulk of their revenues, and all of their profits, from a small percentage of the individual products they sell. Those high-volume products depend on advertising for market share. In the absence of advertising, the necessary consequence of an RCT requirement, it is unlikely that the top products would continue to generate the revenue necessary for full-line homeopathic companies to continue to subsidize the sale of hundreds of low-volume, low- or no-profit remedies, thus reducing consumer access and consumer choice.

The AAHP believes that the cost of conducting RCTs to substantiate homeopathic drugs claims is simply out of proportion to any potential benefit.³⁹ FDA and regulatory agencies throughout the world rely on the homeopathic literature to substantiate product claims. The FTC has not made a compelling case that a different standard is required.

³⁶ <http://medcitynews.com/2013/11/report-emphasis-drug-safety-health-economics-outcomes-data-driving-clinical-trial-costs/>.

³⁷ This is not an especially large trial for the kind of conditions homeopathic OTC drugs are intended to treat.

³⁸ 200 patients per trial x two trials per drug x \$48,500 cost per patient x 100 drugs.

³⁹ Kroger Co., 98 F.T.C. 639, 737 (1981) (“Where the demands of the purse require such compromises, the advertiser must generally limit the claims it makes for its data or make appropriate disclosures to insure proper consumer understanding of the survey’s results.”).

f. The amount of substantiation experts in the field believe is reasonable

There is no question that homeopathy is controversial and so, too, is the question of who qualifies as an expert to evaluate it. Adherents of “evidence-based medicine,” who believe that only RCTs can demonstrate drug effectiveness, would doubtless conclude that homeopathic drugs are not effective. Yet there are significant numbers of qualified physicians, both in the U.S. and abroad, who believe in the practice of homeopathy and believe the evidence that it works. The answer to this question thus depends upon whom one asks.

The AAHP believes that the FTC’s advertising substantiation factors, when applied in the flexible manner originally intended, support the conclusion that the traditional homeopathic literature provides adequate substantiation for appropriately qualified homeopathic advertising claims.

V. First Amendment Issues

Homeopathic medicine is “alternative” medicine in the sense that it is a complete theory of medicine based on a different view of how the body responds to disease. That a significant number of educated and licensed physicians believe in the practice of homeopathy is sufficient to prevent homeopathy from being classified as health fraud.

Worldwide, over 200 million people use homeopathy on a regular basis and homeopathy is included in the national health system in a number of countries, *e.g.*, Brazil, Chile, India, Mexico, Pakistan, Switzerland, and the United Kingdom.⁴⁰ One hundred million EU citizens, some 29 percent of the EU’s population, use homeopathic medicines in their day-to-day healthcare, often on the advice of their physician.

During the public forum, FTC speakers expressed the view that the only appropriate substantiation for homeopathic drug claims were RCTs, regardless of any disclaimer language associated with those claims. The AAHP believes that such a rigid approach not only offends the *Pfizer* factors, but also raises significant First Amendment issues.

The application of the First Amendment, and the values it promotes to commercial speech has undergone substantial evolution in recent years. While the FD&C Act was enacted in 1938, it is only recently that the courts have extended First Amendment protection to companies involved in off-label promotion of approved drugs.⁴¹ Indeed, a U.S. District Court recently enjoined FDA from bringing misbranding charges against a pharmaceutical manufacturer which sought to distribute information about the off-label use of one of its drugs. These decisions would have been unheard of 10 or 15 years ago. In *Amarin*,⁴² the court explained that FDA argued in its brief:

⁴⁰ <http://www.efhpa.eu/> (accessed Nov. 9, 2015).

⁴¹ *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2102).

⁴² *Amarin Pharma Inc. v. U.S. Food and Drug Administration* (S.D.N.Y. Aug. 7, 2015) *available at* <http://www.fdalawblog.net/Amarin%20Decision%208-2015%20Off-Label.pdf> (accessed Nov. 10, 2015).

that protecting speech aimed at promoting off-label drug use is “a frontal assault . . . on the framework for new drug approval that Congress created in 1962,” FDA Br. 1, because allowing a manufacturer to promote such use “has the potential to eviscerate [the] FDA drug approval regime.” Tr. 41. The short answer is that the FDCA’s drug-approval framework predates modern First Amendment law respecting commercial speech.

The AAHP believes that the FTC’s rigidity in interpreting the *Pfizer* factors is subject to the same criticism: it collides with “modern First Amendment law respecting commercial speech.” The use of appropriate disclaimers that qualify and explain the therapeutic claim made by the product cannot be rejected as a method of providing consumers with truthful and non-misleading information. “Linking the required level of substantiation to the claim made also comports with First Amendment protection for commercial speech. The courts have overturned FDA decisions to ban health claims not supported by “substantial scientific agreement” because disclosures of the limitations of the evidence could achieve the goal of preventing misleading claims.”⁴³ This is especially so here, where homeopathy has a 200-year history of safe use and significant support from the public, if not from the mainstream U.S. medical community.

Indeed, limiting the substantiation of homeopathic drug claims to RCTs, a form of evidence largely rejected by homeopathy, not only offends the First Amendment rights of those who sell homeopathic drugs, but also the First Amendment rights of those consumers who wish to learn about or purchase these products. The right to receive information is an important corollary to the right to distribute that information.⁴⁴

The emerging case law would clearly require careful scrutiny were the FTC to act against an advertiser of homeopathic drugs with an appropriate disclaimer. Even were such an FTC challenge to succeed, however, it would only apply to that advertiser and that disclaimer. Presumably, advertisers of homeopathic drugs would examine any FTC victory and adjust their disclaimers accordingly. The AAHP believes that all parties involved would benefit from reasonable guidance which permits the continued advertising of homeopathic drugs to consumers who clearly want such products.

VI. Conclusions

Homeopathy is a venerable and widely practiced form of medicine with a growing resurgence of interest in the U.S. The OTC use of homeopathic drugs is extremely safe, with few products capable of causing medically significant side effects. Numerous studies show that consumers want access to homeopathic and other forms of alternative medicine.

The AAHP believes that the research it sponsored demonstrates that, even in the absence of RCTs, advertising for homeopathic drugs based on the homeopathic literature and including

⁴³ See note 28, *supra*, at 14.

⁴⁴ *Martin v. Struthers*, 319 U.S. 141, 143 (1943).

Office of the Secretary
Federal Trade Commission
November 20, 2015

appropriate disclaimers satisfies the FTC's Advertising Substantiation Guidance. Applying the square peg of RCTs to the round hole of homeopathy would raise substantial First Amendment issues.

The AAHP welcomes the opportunity to work with the FTC to codify appropriate standards for advertising homeopathic drugs.

Respectfully submitted,

Mark Land

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President

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**Before the
U.S. Food and Drug Administration**

[DOCKET NO. FDA-2015-N-0540]

**HOMEOPATHIC PRODUCT REGULATION: EVALUATING
THE FOOD AND DRUG ADMINISTRATION'S REGULATORY
FRAMEWORK AFTER A QUARTER-CENTURY**

Comments of the

AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

November 9, 2015

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**Homeopathic Product Regulation: Evaluating the Food and Drug Administration's
Regulatory Framework after a Quarter-Century**

[DOCKET NO. FDA–2015–N–0540]

**Comments of the
American Association of Homeopathic Pharmacists**

I. INTRODUCTION AND SUMMARY OF COMMENTS

A. Introduction

In the FEDERAL REGISTER of March 27, 2015, 80 FED. REG. 16,327, the Food and Drug Administration (FDA or the Agency) announced that it would hold a public hearing “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.” That hearing took place on April 20-21, 2015 at FDA headquarters. In addition to permitting oral testimony, FDA also announced that it would receive written comments. The comment period was subsequently reopened until November 9, 2015. 80 FED. REG. 54,256 (Sept. 9, 2015).

In the March FEDERAL REGISTER notice, FDA explained that it

is evaluating its current enforcement policies for drug products labeled as homeopathic from scientific, risk, and process perspectives. The Agency is now soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last approximately 25 years.

The American Association of Homeopathic Pharmacists (AAHP) appreciates this opportunity to supplement and expand upon its oral presentation at the hearing. The AAHP is a trade association representing manufacturers and marketers of homeopathic drugs in the United States. The AAHP was founded in 1923 and many of its 35 member firms date to its founding. The AAHP estimates that its members produce more than 90 percent of the homeopathic products sold in the United States (based on sales volume). A market size simulation undertaken by the AAHP in April, 2015, showed a retail market for homeopathic drugs at \$834 million dollars.

The first operating principle in AAHP's mission statement is to encourage regulatory compliance among its members.¹ AAHP's dedication to regulatory compliance underscores its commitment and willingness to partner with FDA in its public health mission.

AAHP sponsors an education program entitled Compliance through Education. Delivered via webinars, white papers and technical articles, the program's goal is to inform members and the industry at large on GMP compliance and other scientific and regulatory developments. These educational efforts reach members and non-members alike and qualify AAHP as a capable and willing amplifier of FDA's message to regulated industry.

Historically, AAHP has worked cooperatively with FDA. The current FDA Compliance Policy Guide on the sale of homeopathic drugs, CONDITIONS UNDER WHICH HOMEOPATHIC MAY BE MARKETED, CPG 400.400 (the CPG), was developed after initial discussions in the 1980s between FDA officials and representatives of AAHP and the homeopathic community. Those discussions yielded a regulatory framework with an excellent record of protecting the public while minimizing the use of agency resources.

The AAHP believes that 25 years of experience shows that FDA made wise policy choices when it adopted the current CPG.² Consumers clearly want alternatives to established medicines and homeopathic drugs provide an extraordinarily safe alternative. The FEDERAL REGISTER notice seems posited on a supposed "tremendous growth" in the use of homeopathic medicines and claimed evidence that they are causing safety concerns. The AAHP believes that the evidence shows that neither of those concerns is well-founded.

The data the AAHP has reviewed shows that the market for homeopathic drugs is about one-third of the dollar volume cited by FDA (approximately \$1 billion in annual sales, rather than \$2.9 billion).³ The commercial reporting arm of Nutrition Business Journal estimates homeopathic drug product sales at approximately \$1 billion dollars.⁴ Other research, discussed below, suggests an even lower figure. Clearly, the \$2.9 billion figure is incorrect. In fact, rather than tremendous growth, the growth of the homeopathic category closely follows the growth of non-prescription drugs in general.

¹ See <http://www.aahp.info/about/strategic-priorities/> (accessed October 25, 2015).

² So does Daniel L. Michels, who was the Director of Compliance for CDER when the CPG was adopted. See Testimony of Daniel L. Michels at 261 (FDA Transcript of Hearing, Day 2, April 21, 2015).

³ The \$2.9 billion figure cited by FDA is apparently from the National Health Interview Survey conducted in 2007. However, as the NHIS explained in its report, the dollar volume of homeopathic drug sales has limitations: "The total costs per person for nonvitamin, nonmineral, natural products and homeopathy were calculated by multiplying the amount spent at the most recent purchase by the number of purchases per year. Because data were not available for the exact cost at each purchase, and the most recent purchase may not have been typical of the respondent's usual purchase of CAM products, the estimates may contain errors." Nahin, *et al.*, "Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007," NATIONAL HEALTH STATISTICS REPORTS (No. 18, July 30, 2009).

⁴ NUTRITION BUSINESS JOURNAL'S SUPPLEMENT BUSINESS REPORT 2015 at 118-119.

Similarly, the data do not support FDA's concerns about the safety of homeopathic drugs. A careful analysis of the poison control data and adverse event data cited by FDA shows that homeopathic drugs are extremely safe. Indeed, safety is a hallmark characteristic of homeopathic drugs. FDA's FEDERAL REGISTER meeting notice cites data from the American Association of Poison Control Centers (AAPCC) as if that data were evidence of serious safety issues. AAPCC data relates to exposures of consumers products in general. An exposure does not equal an adverse event; an exposure generally means that a consumer called a poison control center with an inquiry about an actual or suspected contact with a product or substance. Total exposure to homeopathic drugs in any given year is less than 1 percent of all reports. The rate of exposures is generally below the market share for homeopathic drugs. An analysis of the Rock Mountain Poison Control Center data was presented by Edward P. Krenzelok, Pharm.D., at the hearing and his significantly more detailed written analysis has been submitted to this docket.⁵ This analysis shows that most exposures were managed outside of a healthcare facility, with only one percent of all exposures resulting in admission. Related clinical effects were reported in five percent of all exposures, with vomiting the most common clinical effect reported (one percent of all exposures). Of exposures followed to a known medical outcome, 86 percent resulted in no effect or an effect deemed unrelated to the homeopathic product.

Furthermore, labelers of homeopathic drugs are required to report serious adverse events under the FDA's Medwatch program. The complexity of FDA's adverse event database prevents accurate analysis of that data nor has FDA cited any data from it. However, a quick survey of AAHP member firms showed very low rates of serious adverse event reports to FDA. [To be expanded; cannot locate copy of survey results right now].

For many years following adoption of the CPG in 1988, FDA's communications with industry facilitated proactive dialog and enforcement action. During that time, AAHP was a multiplier of FDA's field force, making FDA aware of potentially misbranded products. Industry and FDA were able to efficiently correspond and respond to questions.

More recently communications between FDA and industry have become less productive and proactive dialog has been replaced by warning letters and press releases. Strained communications between FDA and industry is likely the root cause of misinformation on both sides. The AAHP does not in any way mean to imply that FDA should not take regulatory action when necessary. Rather, the AAHP believes that effective dialog historically resulted in more effective use of FDA's resources. The AAHP is pleased to note that FDA-industry interaction is becoming more productive.

While any regulatory scheme can probably be improved, the AAHP believes that there is no factual predicate that demands significant change to a system that has worked well for 25 years.

⁵ Green, Krenzelok and Reynolds, *National Poison Data System (NPDS) Summary of Reported Homeopathic Exposures, 2005-2014* (Rocky Mountain Poison Control Center, 2015).

B. Summary of Comments

The market for homeopathic drugs is approximately \$1 billion annually and has shown steady, but unspectacular growth over the years. Most purchasers of homeopathic drugs are very satisfied with their purchase and a high percentage are repeat consumers. The single largest source of information about homeopathic drugs is the recommendation of satisfied users, not advertising or labeling.

Safety is the hallmark of the use of homeopathic therapy. Homeopathic drugs generally contain active ingredients at such low levels that adverse events, if any, are mild and transient. And since the overwhelming majority of homeopathic drugs are sold OTC, they are offered for essentially mild, self-limiting conditions. Accordingly, homeopathic drugs offer a very favorable risk-benefit ratio.

The CPG could benefit from several minor revisions, including a requirement that labels bear a disclaimer that the product claims have not been reviewed by FDA.

The evidence shows that FDA struck the right balance when it adopted the CPG in 1988 and there is no evidence that warrants expenditure of agency resources to change a policy that has protected the public for over 25 years.

Despite many national differences, the approach taken by FDA in the CPG is consistent with the approach taken in a number of other countries in which homeopathy is popular. To the extent that those countries have different approaches, changes to the FD&C Act would be required to adopt their positions.

The overwhelming majority of OTC homeopathic drugs are properly labeled for OTC conditions. Enhanced FDA compliance can address outlier products.

Homeopathic companies use a wide variety of resources to assure that their products are appropriate for OTC marketing; most follow the labeling of OTC allopathic drugs.

Consumers have a wide variety of sources of information about homeopathic drugs and have a better understanding of FDA's role in their marketing than many other categories of FDA-regulated products. The AAHP urges FDA to adopt the association's voluntary label disclaimer program as a requirement based on new survey data that shows disclaimers are an effective consumer information tool.

The staff of the Federal Trade Commission (FTC) submitted comments to this docket that made a number of assertions about the impact of the CPG and proposing that changes be made. Most of the FTC's assertions are founded on incorrect legal analyses or untested legal theories.

II. RESPONSES TO FDA FEDERAL REGISTER QUESTIONS

Eight published questions formed the basis of FDA's public hearing. In this section of its comments, the AAHP restates and expands upon its oral responses to those questions. For convenience, each FDA question is restated, followed by the AAHP's answer.

QUESTION 1. WHAT ARE CONSUMER AND HEALTH CARE PROVIDER ATTITUDES TOWARDS HUMAN DRUG AND BIOLOGICAL PRODUCTS LABELED AS HOMEOPATHIC?

Summary: The market for homeopathic drugs is approximately \$1 billion annually and has shown steady, but unspectacular growth over the years. Most purchasers of homeopathic drugs are very satisfied with their purchase and a high percentage are repeat consumers. The single largest source of information about homeopathic drugs is the recommendation of satisfied users, not advertising or labeling.

While the homeopathic drug industry is relatively small, there is a significant body of data on consumer views toward homeopathic products; that data is discussed below. The AAHP is not aware of comparable data on health care provider views.

A. Market Size

There is perhaps no better way to judge consumer attitudes toward homeopathic products than to review the sales of these products. While homeopathic drugs have enjoyed consistent growth, that growth is nowhere near the upward growth cited by FDA in the Federal Register notice (i.e., \$2.9 billion in sales annually). Because all market size data are estimates, there will always be differences of opinion on the size of the market. Nutrition Business Journal's research arm annually tracks growth for many industry segments. Their data shows the following:

Sales of Homeopathic Medicine⁶

	\$ million	% change
2005	\$649	n/a
2006	\$710	9.5%
2007	\$781	9.9%
2008	\$795	1.8%
2009	\$872	9.7%
2010	\$900	3.3%
2011	\$981	8.9%
2012	\$1,037	5.7%
2013	\$1,138	9.7%
2014	\$1,196	5.1%

⁶ See note 4, *infra*.

In April, 2015, the AAHP estimated that U.S. sales of homeopathic medicines range between \$800 million and \$1 billion annually at present. This figure was arrived at using the association’s dues categories, which are based on sales. That estimate was then extrapolated to retail sales. The AAHP believes that its 29 member companies sell about 90 percent of the products sold at retail in the U.S.

The chart below summarizes various data sources about the size of the homeopathic market.

Research Sources	Year Published	Information Gathering	U.S. Sales
<i>Nutrition Business Journal's</i> “Supplement Business Report”	Annually	Takes into account: <ul style="list-style-type: none"> • IRI (mainstream retailers) • SPINS (natural retailers) <ul style="list-style-type: none"> - <i>NBJ</i> survey addressing limitations • Survey of 200 practitioners • 3 sources for Internet sales 	2005 \$649m 2006 \$710m 2007 \$781m 2008 \$795m 2009 \$872m 2010 \$900m 2011 \$981m 2012 \$1,037b 2013 \$1,138b 2014 \$1,196b
	2014	IRI tracks sales based on barcodes in mass market, food and drug retailer.	\$297m
SPINs	2014	SPINsScan Natural channel tracks sales of barcoded products sold in natural product supermarkets as well as natural and organic products in conventional grocery stores, including private label items. SPINsScan information excludes sales through Whole Foods Market. <i>Nutrition Business Journal</i> phone survey to 400 small- to mid-size retailers (“10ks”) that are not included in SPINsScan.	\$53m (30% of this market) Add an est. 35% of this market Add an est. 35% of this market
AAHP	2015	29 manufacturers representing 90% of products Estimate from membership fees levels based on sales volume	\$800m to \$1b
National Institutes of Health	2009	“Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007” Estimates from 75,764 people 18+ from 29,266 households	\$2.9b

B. Consumer Data

Michelle Dossett, M.D., Ph.D., clinical researcher at Massachusetts General Hospital and an Instructor at Harvard Medical School, spoke to consumer perception of homeopathic drugs at the public hearing:

As the FDA is likely aware, every 5 years the National Center for Complimentary and Integrative Health at the NIH partners with the CDC and National Center for Health Statistics to include questions on the National Health Interview Survey about Americans' use of complementary medicine therapies. In February of this year, the National Center for Health Statistics and NIH published a report: *Trends in the Use of Complementary Health Approaches Among Adults: United States 2002-2012*. Their data shows that as of 2012, over 5 million American adults (or 2.2% of the U.S. population) had used homeopathy within the past year. This number represents an increase from 1.8% in 2007 and 1.7% in 2002. In collaboration with my colleagues at Harvard Medical School, I have been analyzing data from the 2012 survey on the use of homeopathic medicines among U.S. adults. This data has not yet been published. We found that the most common reasons people used homeopathy were for respiratory and ENT complaints such as head and chest colds, sore throats, and allergic rhinitis. This represented approximately 19% of homeopathy use. Another 12% used homeopathic medicines for musculoskeletal complaints such as sprains, muscle and joint pain, and arthritis. The vast majority of users, 81%, did not see a practitioner and presumably self-prescribed or prescribed based on the recommendations of friends or family.

Among those who used homeopathy or dietary supplements as one of their top 3 complementary therapies to address a health-related condition, those who used homeopathy were more likely to state that homeopathy helped their health-related condition a great deal. Moreover, homeopathy users who saw a practitioner, were more likely to rate this modality helpful than those who did not.

A number of studies have examined consumer satisfaction with and repeat purchases of homeopathic products.

Repeat Purchases - Emerson based on IRI⁷

- Homeopathic brands are increasing the number of repeat purchasers at a faster rate than allopathic brands (percent increase in repeat rate from April 2011-2012 to April 2014-2015).

<u>Homeopathic</u>	<u>Allopathic</u>
38% Hyland's	12% Vicks
20% Boiron	9% Robitussin

⁷ IRI compiled by Emerson

19%	Similasan	6%	Mucinex
11%	Zicam	3%	Alka Seltzer

National Center for Homeopathy

An online survey was distributed to 18,000-plus core users of homeopathic medicines.

- *How satisfied were you with the results from your most recent purchase of a homeopathic medicine on a scale of 1 to 10?*

The weighted average of answers was 9.24 toward 10 being “extremely satisfied.”

- *If you have used homeopathic medicines more than once, how satisfied have you been with the results overall on a scale of 1 to 10?*

The weighted average of answers was 9.21 toward 10 being “extremely satisfied.”

- *How likely are you to recommend homeopathic medicines to someone else?*

88% answered “very likely.”

- *How likely are you to repurchase this product or purchase other homeopathic medicines in the future?*

91% answered “very likely.”

Consumer Satisfaction - Mintel⁸

- *Overall, how would you rate your level of satisfaction with homeopathic remedies?*

34%	completely satisfied
57%	somewhat satisfied
8%	not very satisfied
2%	not at all satisfied

These high satisfaction rates (90% collectively positive) showed no significant differences among age, gender or household income. The audience was mainstream shoppers.

Mintel provided the following definition to survey participants to clarify and ensure more accurate answers: “*Homeopathic remedies are an alternative form of treatment that consist of diluted substances from plants, minerals, and animals to stimulate a person’s immune and defense system.*”

⁸ Mintel 2011 at 31, 32, 34 and 46.

37% reported having used homeopathic medicines.

- 33% would use homeopathic medicines again, demonstrating high satisfaction.
- 4% would not use homeopathic medicines again.

63% reported not having used homeopathic products.

- 36% would consider using homeopathic medicines, demonstrating a desire for such products. Among the reasons cited for not using homeopathic medicines were lack of awareness for this type of treatment and lack of availability.
- 27% would not consider using homeopathic medicines.

How Consumers Learn About Homeopathic Medicines

WLS Strategic Retail⁹

The WLS study found that awareness of homeopathic medicine has mostly come from word-of-mouth, not from direct outreach to consumers by manufacturers. (Question: *How did you first heard about term “homeopathic”?*)

36% Product recommendation, (demonstrating high satisfaction)

- 16% Read about it on the Internet
- 12% Heard about it in the media
- 4% In a health care newsletter
- 2% Information on the store shelf
- 2% Learned about at a fitness center
- 4% Other
- 24% Can't recall

Of the 36 percent of respondents who first heard about homeopathic medicine from a recommendation, the sources of the product recommendations came from:

- 18% Friends/relatives
- 10% Health care professionals
- 5% Pharmacist
- 3% Sales associate in store

Mintel asked consumers about their sources of information for a variety of health products.

Question: *When it comes to seeking health-related information, which of the following do you turn to for information on each of the listed topics?*

⁹ WSL Strategic Retail, 2013 Homeopathic Retail Survey, 16, 28-29 (Nov. 5, 2013).

	Homeopathic OTC	Herbal supplements	Other OTC	Rx
I do not seek out health info on this	44%	39%	21%	16%
An online site, such as WebMD or wrongdiagnosis.com	19	21	29	24
Books	17	19	12	9
My friends	17	20	23	12
My spouse or other family members	16	18	23	13
An alternative medicine practitioner	16	16	10	8
Articles in newspapers or magazines	14	15	14	10
A conventional/traditional doctor	13	18	38	71
Online blogs	11	12	10	6
A pharmacist	10	12	44	36
Colleagues	9	9	12	6
A nurse practitioner at my doctor's office	7	6	24	32
Television	7	8	15	8
TV commercials, or other advertisements, such as in magazines, newspapers, etc.	5	6	12	9
Radio	4	4	9	5
Other	4	3	6	3

This chart shows sources of information differ according to the type of treatment. Conclusions include:

- Traditional doctors are relied on more for information on Rx medications—which makes sense because these medications can only be received through a doctor.
- There may be a high percent of consumers not seeking information on homeopathic medicines because it is the least used treatment among these categories.
- Personal recommendations from friends and family are top ranked while advertising is nearly the lowest ranked. This demonstrates word-of-mouth and consumer satisfaction, not advertising, is a top means for sales expanding to new consumers.
- Patients may be reluctant to ask conventional health care professionals about homeopathy. Alternative medicine practitioners, who are less common, ranked above conventional doctors, pharmacists and nurses as a source of information for homeopathic users. Patients may feel conventional health care professionals are not knowledgeable about homeopathic medicines or may discourage their use.

Consumer Purchase Motivation¹⁰

A number of studies have examined why consumers purchase homeopathic drugs. An online survey distributed to 18,000-plus core users of homeopathic medicines by the National Center for Homeopathy elicited the following responses when asked the main reason for the most recent purchase of a homeopathic drug:

- 38% I've had a positive experience with other homeopathic products in the past.
- 24% I wanted something safe and effective.
- 11% I wanted a homeopathic product.
- 9% I wanted a natural product.
- 8% My doctor/health care provider recommended it.
- 3% A family member/friend recommended it.
- 6% Other

It is interesting to note that even among a group of acknowledged supporters of homeopathy, the most frequently cited reason for a buying a homeopathic drug was not that it was homeopathic, but rather that the purchaser had a positive experience with homeopathic drugs in the past.

Hartman¹¹

- The majority of shoppers are attempting to limit their overall usage of traditional OTC products. They believe in the efficacy of OTC products, but don't feel like the products are very "good" for them, especially when used frequently. 82% of shoppers agree with the statement: "I use OTC medicine but I try to minimize the amount I use." (*Source: Hartman, page 10*)
- At least one-quarter (and in some of the five categories studied, one-third or more) of shoppers are dissatisfied with some aspect (usually minor aspect) of their current traditional/conventional brands of OTC medications.

- 34% Disliked something about their most recent purchase of cough/cold/flu medications for adults
- 28% Disliked... internal pain relievers for adults
- 30% Disliked... external pain relievers for adults
- 34% Disliked... cough/cold/flu medications for children

¹⁰ National Center for Homeopathy, "Consumer Use of Over-the-Counter Homeopathic Medicines," Online survey (May 22-June 16, 2105) *available at* <http://www.nationalcenterforhomeopathy.org/news/consumers-very-happy-otc-homeopathic-medicines-nch-survey-results>.

¹¹ Hartman Group, *Identifying the Opportunities for Health and Wellness Within the OTC Category*, 11-12, 17 (April, 2010).

38% Disliked... teething medications

Complaint categories included bad taste, expense, doesn't always work well, difficult to open, difficult to read instructions, not widely available, difficult to take, ingredients are artificial/chemical.

- Hartman posed the question: *“When you buy OTC products, what are the top 3 most important factors other than price/value?”*

- 91% Effectiveness (i.e., works well)
- 52% Availability (I can find it easily where I shop)
- 42% Purity or healthiness of something that goes in/on the body
- 41% Ease of use
- 31% Lack of irritants/chemicals (on skin, eye, lung, etc.)
- 10% Supporting companies/brands that have good practices
- 7% Environmental impact of the product

- More than 4 in 5 (81% of) shoppers have either used natural/alternative OTC medicines or are interested in trying them. Most (55% of) shoppers are nonusers who are interested in trying natural/alternative OTC medicines.

Mintel¹²

Attitudes toward remedies

“When it comes to choosing remedies, which of the following statements, if any, do you agree with?”

	All	Over-the-counter remedy	Homeopathic remedy	Herbal remedy
Base: internet users aged 18+ who take remedies	1,530	1,447	285	353
I prefer all-natural remedies.	21%	19%	39%	44%
I seek out ‘organic’ on the label or in the ingredients.	8%	7%	19%	20%

Mintel asked non-users: *Which of the following describe your reasons for NOT using homeopathic products?*

¹² Mintel 2011 at 42, 140)

- 50% I don't know enough about them in general. (Skewed older & with household incomes >\$150k.)
- 35% Just haven't had a reason/need to try them. (Skewed younger.)
- 29% I don't know what ailments can be treated.
- 27% I don't believe they work/not effective. (Skewed with household incomes >\$75k.)
- 27% I don't know which brands to trust.
- 27% I don't know if they will interfere with other medicines I am taking. (Skewed older & with household incomes >\$75k.)
- 24% I don't think there's enough regulation. (Skewed older & with household incomes >\$75k.)
- 20% I think they are too expensive. (Skewed younger & with household incomes <\$25k.)
- 11% I don't think they are safe. (Skewed younger.)
- 8% They are not sold where I live. (Skewed younger & with household incomes <\$25k.)
- 2% Some other reason

Consumer Perception of Homeopathy

Almost all homeopathic medicine consumers agree products are natural, safe, effective and a good value.¹³

- 90% Know they are made of natural ingredients.
- 79% Feel they are safe for children.
- 78% Feel they are safer than other OTC medications.
- 77% Know that homeopathic medicines and other OTC medications work well together.
- 63% Feel homeopathic medicines are more effective than other OTC medications.
- 48% Feel homeopathic medicines can have unpleasant side effects.

The safety profile of homeopathic drugs helps buyers feel better knowing that the product is homeopathic:¹⁴

- 54% of homeopathic buyers feel better about their products when they learn they are homeopathic.
- The knowledge is especially positive among moms (63% verses non-moms at 45%).
- The positive impact increases with the number of conditions treated homeopathically (42% for those with 1 condition verses 74% for 4+ conditions)

¹³ WSL at 17.

¹⁴ WSL at 15, 43 and 44

Hartman Research asked consumers about their familiarity with homeopathic drugs.¹⁵

Question: *How familiar would you say you are with homeopathy?*

- 13% Very familiar
- 37% Somewhat familiar with it
- 40% Have heard the name but don't know anything about it
- 11% Have never heard of this

- Mintel reported that about half of all respondents are either not aware of or not interested in homeopathic medicines. Among users and non-users alike, respondents are more likely to agree than disagree with the idea that doctors and pharmacists should increase the amount of support they lend to homeopathic medicines. Consumers are split on concerns about side effects and preference for alternative remedies over traditional.¹⁶

	Any degree of agreement	Neither agree nor disagree	Any degree of disagreement
Doctors/pharmacists should recommend more use of homeopathic remedies	40	47	14
Homeopathic remedies are better used for preventing ailments than they are for treating ailments	31	57	12
Homeopathic remedies only work for minor problems	29	54	17
Homeopathic remedies are safer than conventional / traditional medicines	29	54	17
I worry about the possible side effects from homeopathic remedies	29	44	27
I prefer homeopathic remedies over conventional/traditional medicines	26	47	27
Homeopathic medicine is all in the mind and only works if you believe in it.	21	46	32

Mintel asked about attitudes toward homeopathic medicines: *“Thinking about herbal, homeopathic and over-the-counter remedies, which of the following statements, if any, do you agree with?”*¹⁷

¹⁵ Hartman at 18.

¹⁶ Mintel at 48.

¹⁷ Mintel 2013 at 86.

	All	Homeopathic Med. Users
Base: internet users aged 18+ who suffer ailment	1,688	285
I trust that homeopathic remedies will adequately relieve my symptoms.	21%	48%
Homeopathic remedies are safer than traditional OTC remedies.	12%	28%

Where Consumers Purchase Homeopathic Medicines

Hartman¹⁸

- Shoppers most commonly expect to find homeopathic medicines in the OTC section of the store.

“Area of a local supermarket or pharmacy in which you would first look for homeopathic medicines?”

- 21% Mixed in with the traditional/conventional OTC products
- 20% In their own section, within the traditional/conventional OTC products
- 18% In their own section with other natural products
- 15% Mixed in with the vitamin/supplement products
- 8% I’d first ask a store employee
- 4% In their own section, not necessarily next to the traditional/conventional OTC products
- 1% In the checkout aisle
- 7% I don’t know where I’d look
- 6% None of the above

- Among mainstream shoppers (not core natural product shoppers), the following ranks the type of outlets where they purchased a natural/alternative OTC medication during the past 3 months (percent among retailer’s shoppers; top 10 choices plus key retailers):¹⁹

- 51% Local natural products/health food store
- 43% GNC
- 34% Whole Foods Market
- 32% Pharmaca Integrative Pharmacy
- 31% The Vitamin Shoppe
- 23% Raley’s
- 22% Duane Reade
- 22% Fred Meyer
- 20% Walmart
- 17% Trader Joe’s

¹⁸ Hartman at 29.

¹⁹ Hartman at 44.

- 13% CVS
- 13% Walgreens
- 7% Kroger Supermarket
- 7% Target

- Among mainstream shoppers (not core natural product shoppers), who are parents of a baby or toddler, half (51%) would like to see a greater assortment of teething treatments. Among mainstream shoppers who have a child age 2–12, half (51%) would like to see more cough/cold/flu treatments for children.²⁰

Shopper Psychographics

Mintel²¹

Consumers who report that they “trust” homeopathic medicine are more likely than those who are either ambivalent, or who do not trust such products, to report that they rarely get sick. These consumers appear to take a more active role in their healthcare management. They are more likely than their less-trusting counterparts to actively look for health information to be able to make choices when it comes to their health care.

- Attitudes/opinions about health & medicine, by trust level of homeopathic medicine, August 2011–August 2012

Those who trust homeopathic medicines are more likely to be proactive about their health care. They visit the doctor regularly and follow their directions and they also take vitamins to prevent illness. (Question: “*To what extent do you agree or disagree with the following statements?*”)

	All adults	I trust homeopathic medicine (any agree)	I trust homeopathic medicine (neither agree nor disagree)	I trust homeopathic medicine (any disagree)
Base: adults aged 18+	24,545	5,216	10,950	6,694
I rarely get sick.	65%	76%	62%	72%
I believe that vitamins and other nutrients really make a difference.	61%	81%	58%	60%
People need more vitamins as they get older.	57%	74%	54%	59%

²⁰ Hartman at 45.

²¹ Mintel/Experian Simmons NCS/NHCS Summer 2012 Adult Full Year—POP, pages 98–100.

Vitamins/minerals should be taken for long-term health benefits.	55%	75%	52%	54%
I rely primarily on my doctor to guide me on medical and health matters.	54%	58%	52%	64%
I always try to eat healthy foods and maintain a balanced diet.	53%	72%	50%	51%
I am willing to challenge my doctor’s recommendations on issues related to my health.	44%	65%	39%	43%
I often carefully examine the ingredient list on over-the-counter medicines.	43%	62%	41%	41%
I actively seek information about nutrition and healthy diet.	39%	64%	35%	34%
I look for health information so that I can choose from different healthcare treatments.	36%	63%	31%	29%
I frequently take preventative medicine.	29%	42%	27%	28%
I always look for the most advanced medicines available.	22%	43%	18%	17%
I prefer alternative medicine to standard medical practices.	19%	55%	13%	8%

Healthy Habits of Those Who Trust Homeopathic Medicines²²

- Exercise habits, by trust level of homeopathic medicine, August 2011–August 2012

36% of homeopathic trusters participated in a regular exercise program in the past year. This suggest they are more likely to lead a healthy lifestyle in terms of diet and exercise, and are invested in their health. (Question: “*Have you engaged in a regular exercise program in the last 12 months?*”)

	All adults	I trust homeopathic medicine (any agree)	I trust homeopathic medicine (neither agree nor disagree)	I trust homeopathic medicine (any disagree)
Base: adults aged 18+	24,545	5,216	10,950	6,694
Participated in regular exercise program	26%	36%	25%	21%

- Attitudes/opinions about diet and health, by trust level of homeopathic medicine, August 2011–August 2012

²² *Id.* at 97.

Those who trust homeopathic medications are more likely to eat a healthier diet. Additionally, they are more likely to eat natural and organic foods and are willing to invest in these products. (Question: “To what extent do you agree or disagree with the following statements?”)²³

	All adults	I trust homeopathic medicine (any agree)	I trust homeopathic medicine (neither agree nor disagree)	I trust homeopathic medicine (any disagree)
Base: adults aged 18+	24,545	5,216	10,950	6,694
I try to eat healthier foods these days.	62%	76%	59%	62%
I am working at eating a well-balanced diet.	53%	70%	49%	54%
I like to know as much as possible about ingredients before I buy food products.	38%	57%	34%	34%
I think fast food is all junk.	35%	48%	33%	33%
I'll pay just about anything when it concerns my health.	34%	44%	32%	32%
I'm usually the first to try a new health food.	15%	29%	12%	10%
When shopping for food, I especially look for organic or natural foods.	26%	49%	22%	18%
I prefer to eat foods without artificial additives.	46%	66%	42%	41%

Shopper Demographics

WSL Strategic Retail²⁴

- Of the women who purchase homeopathic medicines through the mass market channel, this group was typically age 18–34 (35%), Caucasian (64%), a mom with children under 18 years of age (56%), and live on the West Coast. Those with higher income (\$61,800) buy homeopathic medicines more than buyers of strictly other OTCs (\$57,200). Purchases of homeopathic medicines declines with age.
- Most new users of homeopathic medicines are Millennials (among women who purchase homeopathic medicines through mainstream retailers).

²³ *Id.* at 97-98.

²⁴ WSL at 10, 21, and 50.

National Center for Homeopathy

An online survey distributed to 18,000-plus core users of homeopathic medicines during April, 2015 showed that:

- 84% of the responders were female.
- The largest age category of responders (32%) were 55–64 years of age.
- States with the largest number of responders were California (11%), New York (6.6%), Florida (6.5%), Texas (6.3%) and Pennsylvania (5.1%).

Emerson based on IRI²⁵

- Young larger families with kids under the age of 13
- Does not skew in any one income or age bracket
- There is some appeal to English speaking Hispanics.

Mintel 2013²⁶

This study identified homeopathic drug users; it provided respondents with a definition of homeopathy to assist them in their responses.

“For those ailments that you have experienced in the past 12 months, which of the following have you used to treat them?”

Respondents most likely to have used a homeopathic medicine in the past year were:

- Female
- Between 25–34 years of age
- Have children under 18 years of age
- Have a household income of 75k-99.9k
- Hispanics are more likely than non-Hispanics to have used a homeopathic medicine.

(See chart on following page.)

²⁵ Emerson Marketing, IRI CSIA 104 week ending May 17, 2015.

²⁶ Mintel.

	All	Male	Female			
Base: internet users aged 18+ who suffer ailment	1,688	795	893			
Homeopathic users (page 62)	17%	15%	18%			
	All	No children under 18	Children under 18			
Base: internet users aged 18+ who suffer ailment	1,688	1,089	599			
Homeopathic users (page 63)	17%	14%	22%			
	All	Hispanic	Not Hispanic			
Base: internet users aged 18+ who suffer ailment	1,688	255	1,433			
Homeopathic users (page 103)	17%	22%	16%			
	All	18-24	25-34	35-54	55+	
Base: internet users aged 18+ who suffer ailment	1,688	229	328	666	465	
Homeopathic users (pages 62-63)	17%	19%	26%	17%	10%	
	All	Millennials (Generation Y)	Generation X	Baby Boomers	Swing Generation/ World War II	
Base: internet users aged 18+ who suffer ailment	1,688	590	366	553	179	
Homeopathic users (page 65)	17%	23%	19%	13%	6%	
	All	<\$25K	\$25K-49.9K	\$50K-74.9K	\$75K-99.9K	\$100K+
Base: internet users aged 18+ who suffer ailment	1,688	321	350	346	241	430
Homeopathic users (page 64)	17%	15%	14%	18%	23%	17%

Demographic profile by trust level of homeopathic medicine, August 2011–August 2012²⁷

According to Mintel’s analysis of Experian Simmons NCS/NHCS data, those who trust homeopathic medicine are more likely to be female, aged 25–54, and slightly more likely to be Hispanic.

“To what extent do you agree or disagree with the following statements?”

	All adults	I trust homeopathic medicine (any agree)	I trust homeopathic medicine (neither agree nor disagree)	I trust homeopathic medicine (any disagree)
Base: adults aged 18+	24,545	5,216	10,950	6,694
Gender:				
Male	48%	39%	50%	53%
Female	52%	61%	50%	47%
Age:				
18-24	12%	10%	15%	9%
25-34	18%	20%	18%	17%
35-44	18%	18%	18%	18%
45-54	19%	21%	18%	19%
55-64	16%	17%	16%	16%
65+	18%	15%	16%	20%
Hispanic origin:				
Hispanic	15%	17%	16%	10%
Not Hispanic	85%	83%	84%	90%

²⁷ Mintel/Experian Simmons NCS/NHCS Summer 2012 Adult Full Year—POP, page 95.

QUESTION 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?

Summary: Safety is the hallmark of the use of homeopathic therapy. Homeopathic drugs generally contain active ingredients at such low levels that adverse events, if any, are mild and transient. And since the overwhelming majority of homeopathic drugs are sold OTC, they are offered for essentially mild, self-limiting conditions. Accordingly, homeopathic drugs offer a very favorable risk-benefit ratio.

A. Dossett Testimony

There is considerable data to support the safety of homeopathic drugs. Michelle Dossett, M.D., Ph.D., clinical researcher at Massachusetts General Hospital and an Instructor at Harvard Medical School, addressed this issue at the public hearing. Speaking on behalf of the American Institute of Homeopathy (AIH), the professional organization of homeopathic physicians in the United States, Dr. Dossett said²⁸:

Good afternoon and thank you for the opportunity to speak today. My name is Michelle Dossett. I am an internist and clinical researcher at Massachusetts General Hospital and an Instructor at Harvard Medical School. I have a PhD in immunology and a masters in public health in clinical effectiveness. I became curious about homeopathy on seeing some of its clinical effects and reading the research literature. I will be speaking on behalf of the AIH on the safety of homeopathic medicines and public perceptions. My only financial disclosure is 2 hours of consulting for a homeopathic pharmaceutical company last year.

First, I will address the FDA's question regarding safety or risks of products labeled as homeopathic. I will not be discussing efficacy today due to time limitations. Dr. Jonas did an excellent job yesterday of discussing some of the challenges in interpreting the research in this field and the importance of critically analyzing the methodology used.

Physicians within the AIH report that while adverse events do occur with homeopathic treatment, such occurrences are magnitudes less in frequency than their experiences with conventional medicines, and these events tend to be mild and transient in nature. Many relate that the safety of homeopathic medicines is helpful in prescribing for complex patients, such as older patients who are on multiple conventional medications for chronic medical conditions. As the number of medications increases, the risk for interactions and adverse drug reactions increases as well. AIH members find that homeopathic medicines represent a much safer alternative for self-limited conditions in these patients. Rather than using an OTC drug like an NSAID which might be contraindicated, short term use of a homeopathic medicine can help alleviate symptoms

²⁸ See FDA Transcript of Hearing, Day 2 at 183.

while reducing concerns for adverse drug reactions. While such anecdotal information is informative, let's review research on the safety of homeopathic medicines.

In 2000 Dantas and Rampes published a systematic review of the literature from 1970-1995. They found 19 clinical trials with detailed information on adverse events and found a mean incidence of adverse events of 9.4 in the homeopathic groups and 6.17 in the placebo groups. The adverse events were mild and transient. The majority of case reports described aggravations of pre-existing symptoms rather than new symptoms and the overall level of causal association was low. Some reports described products that were mislabeled as homeopathic. For homeopathic pathogenetic trials, there was great heterogeneity. The mean incidence of effects was 54%, and overall they were similar to nocebo effects in phase I RCTs.

The health technology assessment commissioned by the Swiss government examined the safety of homeopathy and concluded that "the use of medium and high potencies is free from toxic and unexpected organ effects." I'll now review some of the data that has been published since.

In 2012, Jong and colleagues examined pharmacovigilance data from Germany on the use of homeopathic and anthroposophic solutions sold for injection. The practice of injecting homeopathic medicines is far more common in Germany than in the U.S. Of 303 million ampoules sold for injection, there were 486 case reports encompassing a total of 1180 adverse drug reactions. Only 46 of the reports were classified as serious and in nearly half of those cases, the homeopathic injection was deemed unlikely to be the cause of the event. Serious adverse drug reactions occurred significantly more frequently in those who received complex products and products diluted less than 1:10,000. The overall reporting rate of adverse drug reactions was less than 4 per 1 million ampoules sold.

Let's examine another report, a highly publicized paper by Posadzki and colleagues. The senior author, Professor Ernst, is a well-known critic of homeopathy. In this systematic review of the literature from 1978 – 2010 the authors found a total of 1159 case reports of adverse events from homeopathy published from 17 different countries. The adverse events ranged from mild to severe and included 4 fatalities. The most common adverse events were allergic reactions and intoxications. Upon examining the paper in further detail, one finds that 1070 of the reports are of "unspecified remedies" reported to a German poison control center, much like the reports from our own National Poison Data System. There is no validation that all of those 1070 reports are of actual homeopathic products and the vast majority of these cases represent accidental ingestions by young children with limited or no side effects.

On reviewing the remaining 89 cases, many are again of unspecified compounds. In other words, we don't know if they are really homeopathic medicines, and if they are, whether they are single or complex products, or have other non-homeopathic ingredients added to them. Some of the compounds ingested are reported by name and are clearly not traditional homeopathic medicines, and may contain non-homeopathic ingredients.

Nearly all of the reports lack documentation of concomitant conventional medical treatments. Several did use traditional homeopathic medicines but in very low dilutions (mother tinctures, or 1X potency, that is 10⁻¹) which would generally not be prescribed by a homeopathic providers. Finally, several of the adverse events are clearly misattributed. For example, Posadzki and colleagues attributed a case of bladder cancer that developed 7 years following homeopathic treatment to the homeopathic medicine that was received. In summary, it is rather remarkable that a review of 32 years' worth of literature across 17 countries, many in which homeopathy is used quite widely by the general population, found little evidence for serious toxicity from homeopathic treatment.

In the interest of time I will skip through the slides on the data from the National Poison Data System that was well explained by Dr. Krenzelok yesterday. I will only reiterate two points. First, that it is unclear what percentage of the product exposures in these cases are truly homeopathic medicines vs. other products that claim to be homeopathic on the label but also contain pharmaceutically active amounts of herbs, dietary supplements, or pharmaceuticals. Second, these homeopathic products appear to have a better safety profile than other pharmaceuticals in the database examined.

I will briefly share some information on perceptions of homeopathy users in the United States. According to the most recently published data from the National Center for Health Statistics and NIH published in February of this year, as of 2012, over 5 million American adults (or 2.2% of the U.S. population) had used homeopathy within the past year. This number represents an increase from 1.8% in 2007. In collaboration with my colleagues at Harvard Medical School, I have analyzed data from the 2012 National Health Interview Survey on the use of homeopathic medicines among U.S. adults. This data has not yet been published. Homeopathy was most commonly used for respiratory & ENT complaints such as head and chest colds, sore throats, and allergic rhinitis. This represented 19% of use. Another 12% used homeopathic medicines for musculoskeletal complaints such as sprains, and muscle & joint pain. 81% of users did not see a practitioner and presumably self-prescribed or prescribed based on the recommendations of friends or family.

Among those who used homeopathy or dietary supplements as one of their top 3 complementary therapies to address a health-related condition, 32% of those who used dietary supplements felt that it helped their health-related condition a great deal. In contrast 42% of those using homeopathy who did not see a practitioner, and 64% of those using homeopathy who did see a practitioner felt that it helped their health-related condition a great deal.

In summary, in reviewing the research data, homeopathic medicines are safe, especially compared to other OTC products. While adverse events are reported with homeopathic medicines, the vast majority are mild and self-limited. Use of homeopathic medicines in the U.S. is increasing and users frequently find them to be helpful.

Thank you for your time and attention.

B. Rocky Mountain Poison Control Center Report

In the Federal Register notice announcing the hearing, FDA gave the impression that the supposed increase in the use of homeopathic drugs was creating safety issues for consumers. FDA said, for example, that:

The 2012 American Association of Poison Control Center Annual Report indicated that there were 10,311 reported poison exposure cases related to “Homeopathic Agents,” with 8,788 of those reported cases attributed to children 5 years of age and younger. Of the 10,311 reported cases, 697 required treatment in a health care facility.²⁹

FDA’s use of the term “poison exposure cases” sounds serious, indeed. However, most of those “cases” were actually just a phone call to a poison control center. The overwhelming majority of these calls were the result of an accidental ingestion of a homeopathic product by a child, rather than an “adverse event” associated with the intentional use of the product. And the overwhelming majority of these accidental ingestions requires no medical intervention.

The report summarized its findings as follows:

Between 2005 and 2014, a total of 101,851 exposures to homeopathic agents were reported to the NPDS.

- Most exposures involved children <12 years of age (92%).
- Unintentional exposure represented 95% of all exposures, with pediatric (age <12 years) unintentional general exposures representing 86% of all exposures.
- Most exposures were managed outside of a healthcare facility (managed on site (non-healthcare facility (HCF)) (91%), with 1% of all exposures resulting in admission.
- Related clinical effects were reported in 5% of all exposures, with vomiting the most common clinical effect reported (1% of all exposures).
- Of exposures followed to a known medical outcome, 86% resulted in no effect or an unrelated effect.

These data confirm that the use of homeopathic drugs is extremely safe.

C. AAHP Serious Adverse Event Survey

The AAHP conducted a membership survey in April, 2015, to obtain information about the number of serious adverse event reports filed with FDA. Serious adverse event (SAE) reports are the only adverse event reports required to be filed with the agency.

²⁹ 80 FED. REG. at 16,328.

Twenty-five of the 29 members of the AAHP responded to the survey, including all of the largest members.³⁰ In calendar year 2013, a total of 82 SAEs were reported; in 2015, the number was 84. Approximately 75 percent of these SAEs were filed by one company and are believed to be due to the publicity that followed a product recall. These SAEs represent an extremely small percentage of the number of product units sold in those years (approximately 56 million in 2013 and 60 million in 2014). They represent an even smaller percentage of the number of dosage units contained in the products sold, approximately 1.8 billion in 2013 and 2 billion in 2014.

D. On-line Resources

The most useful resource for this purpose is the CORE-HOM database. This is a comprehensive, free database of clinical research in homeopathy maintained by the Carstens Foundation in Stuttgart, Germany (Karl Carstens was President of Germany in the 1970s) it is fully searchable by diagnosis, trial design, homeopathic medication used, etc. (www.carstens-stiftung.de/core-hom).

Among the most interesting research reports to be found in CORE-HOM are those on the comparative effectiveness of homeopathy. Comparative effectiveness research examines the effectiveness of treatments in the real world situations, as opposed to the artificial conditions often imposed in randomized controlled trials, comparing outcomes in groups of patients (often known as cohorts) receiving different treatments. There are several such studies of homeopathy, comparing outcomes in various groups of patients attending conventional family physicians and family physicians who integrate homeopathy in their practice.

A multinational comparative effectiveness study led by David Riley, M.D., involved 30 doctors, at six clinical sites in four countries, treating patients with acute respiratory problems. Response at 14 days was 82.6% for homeopathy compared to 68% for conventional treatment. The rate of adverse events for conventional treatment was 22.3%, versus 7.8% for homeopathy. A replication of this study included 1,577 patients, of whom 857 received homeopathic and 720 conventional treatment: improvement was significantly faster with homeopathy.

Trichard et al. compared ‘homeopathic strategy’ against ‘antibiotic strategy’ in routine medical practice in the management of recurrent acute rhino-pharyngitis in 499 children aged between 18 months and 4 years. Family physicians using homeopathy had significantly better results in terms of clinical effectiveness, complications, parents' quality of life and time lost from work, for lower cost.

Witt *et al.* at the Charité University Medical Center, Berlin compared homeopathic and conventional family physicians' outcomes in chronic diagnoses commonly treated in general practice (adults – headache, low back pain, depression, insomnia, sinusitis; children – atopic asthma, dermatitis, rhinitis). 493 patients were treated by 101 homeopathic and 59 conventional family physicians. The patients treated by the two groups of physicians were generally similar.

³⁰ See Exhibit 1.

The conclusion was that patients who sought homeopathic treatment had better outcomes for similar cost.

The largest comparative effectiveness study of homeopathy published to date is the EPI3 study. A nationwide study in France, coordinated by the Department of Pharmacoepidemiology at the University of Bordeaux, it included 6,379 patients from 804 medical practices. It compared treatment outcomes for patients who visited conventional, homeopathic, or mixed practice family physicians for musculoskeletal conditions, upper respiratory tract infection, sleep disorders, anxiety and depression. The study looked at clinical benefit, medical care and medication, adverse effects, and loss of therapeutic opportunity. The musculoskeletal cohort included 1,153 patients; patients who chose homeopathy had healthier lifestyles (lower mean BMI, less likely to smoke), higher levels of education, were more motivated to self-care but had more chronic disease compared to patients attending conventional physicians. The results over 12 months showed that in both acute and chronic episodes of musculoskeletal disease the outcomes were similar between groups, but the patients who attended homeopathic physicians took approximately half the amount of non-steroidal anti-inflammatory drugs compared to patients who attended family physicians who prescribed only conventional medications.

The upper respiratory tract infection cohort of EPI3 yielded an analogous result, showing that patients who consult family physicians certified in homeopathy used significantly less antibiotics and antipyretic/anti-inflammatory drugs for upper respiratory tract infections than those who attended family physicians who prescribe only conventional medications, with similar outcomes. This finding is of considerable public health importance since antibiotic resistance is now a major threat, with one of its main causes being overuse of antibiotics for conditions such as upper respiratory tract infections.

QUESTION 3. ARE THE CURRENT ENFORCEMENT POLICIES UNDER THE CPG APPROPRIATE TO PROTECT AND PROMOTE PUBLIC 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? IF SO, PLEASE EXPLAIN.

Summary: The evidence shows that FDA struck the right balance when it adopted the CPG in 1988 and there is no evidence that warrants expenditure of agency resources to change a policy that has protected the public for over 25 years.

The phrasing of the first part of this question contains a “fact” very much in dispute: whether there has been “tremendous growth” in the homeopathic drug market. As noted above, *supra* p. 3, the AAHP believes that the annual sales figure cited by FDA is about three times the figure available from several other sources.

Prior to the issuance of the CPG in 1988, FDA followed a different compliance policy guide, one which asserted that ALL homeopathic drugs were prescription only. That extreme position and incorrect position was substantially tempered by the fact that FDA didn't actually

enforce it very often and virtually never against domestic manufacturers. It did, however, episodically and inconsistently, enforce the Rx-only rule against imported products. An industry coalition met with the agency and noted that not only was the Rx-only rule incorrect, but that the agency's enforcement against importers only probably violated U.S. trade treaty obligations. At the same time, the agency, in language quite similar to that in the FEDERAL REGISTER notice announcing this hearing, said that homeopathy was growing and that it was time to reexamine how it was regulated. That meeting led to a series of discussions which resulted in the issuance of the current compliance policy guide. Today, the agency has cited what it called the substantial growth in the homeopathic market since 1988; a good part of that growth is actually due to FDA itself. Prior to 1988, the only indication on the label of most homeopathic drugs was, "Use accordingly to standard homeopathic indications." That indication fit well with the symptom-based approach that is at the core of homeopathy. FDA was unwilling to permit that approach to continue, insisting that the statute required a specific indication.

FDA's stated reasons for this hearing involved what it called the explosive growth in the market for homeopathic drugs and purported safety concerns. AAHP believes that the claimed safety issues are not real and have been adequately addressed by others. Similarly, the so-called explosive growth that seems to trouble the agency is based on numbers which the homeopathic manufacturers can only dream about. In fact, the market is about one-third of what FDA cites. So if things have not really changed that much, why should the agency expend the resources necessary to consider any substantial revision to the current CPG?

That FDA calls homeopathic drugs unapproved new drugs sounds scary, but actually puts them into excellent company, including such OTC standbys as aspirin and such Rx standbys as phenobarbital. In fact, the agency estimates that there are several thousand unapproved prescription drugs on the market today,³¹ perhaps accounting for two percent of all prescriptions written in the United States. The real issue is not whether homeopathic drugs are unapproved new drugs, which is a statutory term of art, but rather the process the agency must engage in for a binding determination of their status. That issue goes back to 1962, when Congress adopted the Drug Amendments of 1962, which, for the first time, added the efficacy requirement to the new drug approval criteria. Faced with examining thousands of pre-1962 drugs, FDA first reviewed prescription drugs through a contract with the National Academy of Sciences-National Research Council. Over sixty years later that review is still on-going, if not moribund, with several thousand drugs never fully upgraded as safe and effective nor removed from the market.

When FDA decided to examine OTC drugs in the aftermath of the 1962 Drug Amendments, it decided to take a different approach. Rather than review drugs individually, as it had done in the NAS-NRC Review, it decided to review them by therapeutic category. In announcing the OTC Review in 1972, FDA said that it was taking this approach for several reasons³²:

³¹ Lori Cantin, R.Ph., Pharm.D., CDER Marketed Unapproved Drugs Enforcement Team, *Marketed Unapproved Drugs* (June 21, 2012).

³² 37 FED. REG. 85, at 86 (Jan. 3, 1972).

1. The agency's limited resources would be overwhelmed by trying to review each OTC drug individually.
2. Litigation to remove violative drugs would have to be on a case-by-case basis, another enormously resource-intensive approach.
3. Litigation concerning the scope of the 1938 and 1962 grandfather clauses "would more than exhaust all present resources of the agency."

As noted by the agency in the FEDERAL REGISTER notice announcing this hearing, homeopathic OTC drugs were excluded from the OTC Review and were supposed to be the subject of a separate review to follow the completion of the OTC Review. The OTC Review is far from over and we have little reason to expect that an OTC review of homeopathic drugs is in the near future. Last year, FDA held a hearing at which it suggested that the OTC Review was broken and a new approach was necessary. Those familiar with the history of the OTC Review instead suggested that the only thing wrong with the OTC Review was that the agency had basically abandoned it.

Are the enforcement priorities in the CPG appropriate? In view of the very low incidence of SAEs associated with homeopathic products, it is difficult to see how the public health would benefit from a significant investment of FDA resources in the creation and implementation of a new scheme. The risk-benefit calculus the agency adopted in 1988 is essentially unchanged today.

A. American Institute of Homeopathy

The current CPG has been criticized by some for relying on the homeopathic literature to support labeled indications. As discussed in response to Question 5, that is a common practice throughout the world. In addition, the uniqueness of homeopathy makes reliance on randomized controlled clinical trials both uncertain and unnecessary. The AAHP asked the American Institute of Homeopathy, the professional organization of homeopathic physicians in the United States,³³ to prepare a paper that discusses the evaluation of the effectiveness of homeopathic medicines. That document follows.

AMERICAN INSTITUTE OF HOMEOPATHY, EVALUATION OF EFFECTIVENESS OF HOMEOPATHIC MEDICINES

This position statement has been created to help provide guidance in the evaluation of homeopathic medicines using standard tools employed in conventional medicine. The American Institute of Homeopathy (AIH) is a national organization of physicians and other licensed health care providers with extensive training in both conventional and homeopathic medicine. This dual expertise makes the AIH unparalleled in its ability to provide guidance regarding the use of

³³ The American Institute of Homeopathy, the oldest extant national physicians' organization in the U.S., has promoted homeopathic medicine as a medical specialty since 1844. Its members are licensed physicians, dentists, veterinarians, nurse practitioners, physician assistants, pharmacologists and pharmacists. All members are trained in homeopathic medicine as well as the medical/dental training required for their respective license.

conventional evaluative approaches to the unique paradigm of homeopathic therapeutics. We have provided a brief overview of the current drug approval process for conventional therapeutics, reasoning for a different evaluative model that would be more appropriate to the homeopathic therapeutic system, and recommendations for future regulatory efforts.

Brief Overview of Current Drug Approval Mechanism in the United States

Currently, in the United States, the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA) evaluates new drugs prior to release into the market to ensure the new products are safe and effective.³⁴ In 1962, the requirement for the FDA to evaluate drugs marketed in the U.S. for effectiveness was added to the Federal Food, Drug, and Cosmetic Act by Congress. This amendment to the act defined substantial evidence of effectiveness as “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved...”³⁵ The FDA has generally interpreted this requirement to mean that at least two adequate and well-controlled trials are necessary to establish effectiveness. The primary tool for such evaluation is the Randomized Controlled Trial (RCT). A well-conducted RCT minimizes bias by controlling a number of variables in the subject population while approximating the expected treatment group in clinical practice. The RCT is a tool to demonstrate efficacy—the first step in demonstrating clinical effectiveness.

Clinicians rely on clinical practice guidelines derived from RCTs and systematic reviews to guide them in selecting the best therapy for an individual patient. Likewise, members of the public rely on FDA review as an assurance that a given over-the-counter (OTC) product will be effective for their particular health concern.

Homeopathic active ingredients are currently evaluated through a monograph process under the auspices of the Homeopathic Pharmacopoeia Convention of the United States (HPCUS). Active ingredients with approved monographs have both prescription and OTC dosage levels set by the HPCUS within the published monograph. The HPCUS evaluates products for safety using available toxicology and safety data obtained from a thorough evaluation of numerous databases including Toxnet, International Agency for Research for Cancer (IARC), FDA website, and SwissMedic HAS List. Homeopathic medicines have a well-established safety record in clinical

³⁴ Code of Federal Regulations; Title 21; Part 1316; Subchapter D (Drugs for Human Use);

³⁵ Federal Food, Drug & Cosmetic Act, Chapter V – Drugs and Devices, Subchapter A, Section 505 – New Drugs, paragraph (D), as amended by FDA Modernization Act of 1997.

trials, reports from clinical practice, and in cases of accidental or intentional overdose.^{36,37,38,39,40} This data applies to both single homeopathic medicines and combination homeopathic products.

The potential effectiveness of homeopathic medicines is evaluated through a specialized clinical trial called a “proving”, which is a clinical trial conducted on healthy subjects to determine the clinical utility of a new homeopathic drug. Once a set of clinical indications is demonstrated in a proving, clinicians will begin a long process of verifying that results from the proving are relative to clinical conditions when that medicine is used in practice. Numerous case reports and expert consensus build into a collective database called the *Repertory*. Some homeopathic medicines are *well verified medicines* with a substantial number of published clinical reports of symptoms that have responded to the drug. Such medicines are found in commonly used homeopathic *Materia Medica*s and *Repertories*. Other *less verified medicines* have less than 20 published reports which may be the result of a suboptimal clinical picture that was produced in the proving or because the particular medicine is less frequently needed in clinical practice.

Why Homeopathic Experts Opine that RCTs are Inappropriate for Homeopathic Medicines

Experts in homeopathic research and clinical practice have long espoused the position that RCTs are an excellent tool for determining efficacy of allopathic (conventional) medicines, but are not well suited to evaluate homeopathic drugs. The reasons for this position rest on several points, as follows:

1. Homeopathic medicines are individualized for a specific constellation of symptoms and observed clinical findings, not to the conventional diagnosis *per se*.
2. Efficacy studies do not always predict effectiveness in clinical practice.
3. Most homeopathic medicines already have a wealth of valid clinical data published in the homeopathic scientific literature.
4. Homeopathic clinical data carries a high degree of reliability due to the outcome measures used.

To better understand these statements, let us look first at how homeopathic medicines are used. Individualization of homeopathic medicine use will vary according to the particular form of access

³⁶ Dantas F, Rampes H. Do homeopathic medicines provoke adverse effects? A systematic review. *Br Homeopath J*. 2000 Jul;89 Suppl 1:S35-8.

³⁷ Bornhöft G, Matthiessen PF, editors. *Homeopathy in Healthcare – Effectiveness, Appropriateness, Safety, Costs* [Internet]. Berlin, Heidelberg: Springer Berlin Heidelberg; 2011 [cited 2015 Apr 28]. Available from <http://link.springer.com/10.1007/978-3-642-20638-2>

³⁸ Jong MC, Jong MU, Baars EW. Adverse drug reactions to anthroposophic and homeopathic solutions for injection: a systematic evaluation of German pharmacovigilance databases. *Pharmacoepidemiol Drug Saf*. 2012 Dec;21(12):1295-301.

³⁹ Posadzki P, Alotaibi A, Ernst E. Adverse effects of homeopathy: a systematic review of published case reports and case series. *Int J Clin Pract*. 2012 Dec;66(12):1178-88.

⁴⁰ Von Mach M-A, Habermehl P, Zepp F, Weilemann LS. [Drug poisonings in childhood at a regional poisons unit]. *Klin Pädiatr*. 2006 Feb;218(1):31-3.

to these medicines by the consumer. There are essentially three ways that consumers will access homeopathic medicines in the marketplace, as follows:

- a) Consumers who receive prescribed medicines from clinicians
- b) Consumers who have become well-informed about homeopathic medicine and partially individualize their own selection of OTC homeopathic products, and
- c) Consumers who have little or no knowledge of homeopathic medicine and use homeopathic products based upon a general indication.

These groupings are significant for how they use homeopathic medicines relative to the individualized nature of these drugs. Clinicians or prescribers treat both acute and chronic diseases. They often rely upon high degree of individualization of each treatment regimen. The specific constellation of symptoms corresponding to a homeopathic medicine is matched to the individual pathological state of the patient. Within any given diagnosis group of patients there may be multiple clinical patterns or constellations of symptoms that indicate different medicines. Sinusitis for example may have a number of medicines which show benefit for patients with different symptom patterns. The treatment course may consist of a single or multiple homeopathic medicines.

Consumers who are well-informed about homeopathic medicines will often use OTC products that have been formulated into combinations of homeopathic medicines targeted to one particular indication. Many of these consumers have accessed homeopathic information to help select more specific OTC products based upon the particular cluster or constellation of symptoms that they are experiencing for a self-limited problem. In this way, they may also select a single homeopathic medicine available OTC because they have a fair understanding of the specific use of that medicine.

In the third group, because these consumers are new to homeopathic medicine, they will tend to use combination products that are targeted to a particular indication. In this situation, individualized homeopathic medicines are combined according to their known usefulness for a specific indication.

While on the surface the approach to individualizing care and the use of a combination OTC product for more general indications may seem to be opposite approaches to care, the difference primarily reflects the nature of the conditions being treated. For chronic conditions, most clinicians prefer a single medicine or a combination of medicines that will treat a very specific array of symptoms as understood through clinical examination to best reflect the clinical state of the patient. When combination OTC products are designed, typically several medicines that have clinical evidence of being highly useful for a given condition are combined. These OTC products are marketed for acute and self-limited conditions. By combining multiple well-evaluated medicines for the condition, the likelihood of one or more of the medicines helping the condition is greatly increased. This approach is often used in conventional antibiotic therapy for severe infections prior to the identification of a precise organism.

Regarding the second point above, concerns arise for both consumers and prescribers when efficacy testing, for either homeopathic or allopathic drugs fail to translate into market safety or effectiveness. Products with RCTs that may have good internal validity, may fail to demonstrate external validity due to inaccurate translation to the population receiving treatment.

Most post-market drug failures and withdrawals are due to safety issues that arise in the larger population exposed to the product post-launch. However, some notable post-market failures have occurred due to lack of effectiveness including --- Drotrecogin alfa (Xigris) 2011⁴¹ and Gemtuzumab ozogamicin (Mylotarg) 2010⁴².

With respect to our third point, the homeopathic research process is primarily rooted in clinical data accumulation from pragmatic experiences of clinicians. Ultimate clinical effectiveness is best demonstrated in the clinical setting where medicines are used. Homeopathic clinical data has been collected over many years and then filtered for reliability and collated in the form of the *Repertory* and *Materia Medica* (texts that describe each medicine's usefulness according to clinically verified symptoms). This clinical data has been carefully collected and published in the homeopathic literature. Multiple experts have painstakingly reviewed this literature to systematically remove less reliable data to enhance the overall external validity of these resources in their application in clinical practice.

And finally as regards the fourth point, homeopathic clinical data is collected from those cases that produce clear effects in patients. While conventional medicine often uses endpoints related to palliation of a symptom, e.g. decreased pain or improved breathing, homeopathic medicine relies on the complete elimination of the symptoms, and overall improvement in health, as the outcome markers of preference. Homeopathic case data is reported when it has resulted in a well-documented, rapid, and dramatic cure of a symptomatic disorder of health. When data is drawn from treatment effects that demonstrate a rapid rate of improvement during treatment relative to the rate of improvement under non-treatment, the effect compared to background noise becomes very large.⁴³ Because homeopathic case data is typically drawn from cases related to a sudden and stable change, bias and background noise can be ruled out without the need for RCTs. Such clinical data has also been used in conventional therapeutics. For example, insulin in diabetes, propranolol for infantile hemangiomas or neostigmine for myasthenia gravis are therapies whose effects in the clinical setting suggest that background noise is unlikely to be of significance.

In addition, using a global evaluation of wellness enhances the validation of improvement in the disorder. If the evaluation of efficacy reduces the outcome assessment to a single marker (as in

⁴¹ FDA Medwatch Safety Alerts for Human Medical Products. Posted 10/25/2011. Available online at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm277143.htm> Last accessed August 24, 2015.

⁴² FDA Medwatch Safety Alerts for Human Medical Products. Posted 10/21/2010. Available online at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm216458.hth> Last accessed August 24, 2015.

⁴³ Glasziou P, Chalmers I, Rawlins M, McCulloch P. When are randomised trials unnecessary? Picking signal from noise. *BMJ*. 2007 Mar 3;334(7591):349-351.

many RCTs), the overall wellness of the individual may be lost as the primary objective which is of utmost importance to practitioners of homeopathic medicine.

The database of homeopathic literature is a large repository of patient-centered outcomes data. Case data filters in through various experts, becomes refined through inclusion in the *Materia Medica* under specific medicines, and ultimately gets collated, placed into a hierarchy, and standardized in the *Repertory*.

AIH Recommendations:

1. Although homeopathic medicines have an excellent safety record, HPCUS should continue to monitor new findings in relevant toxicology literature and update drug potency recommendations accordingly.
2. At this time, all active ingredients currently in the *HPUS* should be considered as *well verified* medicines. All ingredients within the *Homeopathic Pharmacopeia of the United States (HPUS)* should be approved for OTC and Rx use within the attenuation guidance listed in the *HPUS*.
3. *Specifically for prescription homeopathic drugs* – establish safe dosage for use based upon known toxicology. Because homeopathic medicines are historically very safe, allow all medicines for use as prescription drugs within attenuations set by HPCUS. Maximize availability of medicines to clinicians to encourage additional clinical verification (especially with regard to Less Verified medicines).
4. *Specifically for over-the-counter single ingredient homeopathic drugs* – continue to make OTC homeopathic products available according to current regulations; but, limit indications according to those recognized, and verified, within source material acceptable to the *HPCUS*.
5. *Specifically for over-the-counter combination homeopathic drugs* – any medicines currently OTC with combination products of *well verified* medicines that are being marketed for recognized self-limited indications from published homeopathic literature should be classified as Generally Recognized as Safe and Effective by the *HPCUS*.
6. OTC medicines using ingredients that include *less verified* medicines (as defined by those medicines with substandard provings or lacking sufficient clinical data per the standards established by the HPCUS) should be required to attain additional clinical verification of those ingredients to further establish the effectiveness for the selected indication.

* * * * *

B. Increase FDA Confidence by Requiring Compialty

The AAHP believes that one change in the current CPG that may increase FDA's confidence in marketed homeopathic products, and the risk-benefit decision inherent in the CPG, is a requirement that the active ingredients in all OTC homeopathic products intended for sale directly to consumers be the subject of a monograph in the *Homeopathic Pharmacopeia of the United States (HPUS)*. This issue was discussed prior to the adoption of the Compliance Policy Guide in 1988 and it is, perhaps, time to reevaluate the decision made then not to impose such a

requirement. While the existence of a “positive list” would have made enforcement simpler for FDA, the HPUS did not then contain monographs for all widely used homeopathic drugs. A monograph requirement, therefore, would have banished many legitimate homeopathic drugs. Instead, FDA adopted what is essentially a burden of proof concept: the “Labeling” section of the CPG contains this statement: “Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.”

Since homeopathic drugs are not reviewed by FDA prior to marketing, this provision provides no guidance as to whom or when “documentation must be provided” to establish that non-compendial products are “generally recognized as homeopathic products or ingredients.” To the best of the AAHP’s knowledge, the issue of whether a non-compendial product is “generally recognized as homeopathic” has arisen in a small number of cases, and then only when FDA has issued a Warning Letter.

Just as the common law developed in a case by case basis over many years, ultimately creating rules which were understood by lawyers and laymen alike, it is possible that FDA action in specific enforcement matters could have led to a “common law” definition of “generally recognized as homeopathic.” As that has not happened, the AAHP believes that now is the appropriate time to revisit the decision made in 1988 not to require the existence of an HPUS monograph to legally market to consumers an OTC homeopathic drug.

Since 1988, the HPUS has undergone substantial revision and the HPCUS has improved and strengthened its procedures for admitting new monographs. Since 1988, 172 monographs for existing products, many the subject of monographs in European homeopathic pharmacopeias, were added to the HPUS. Since 2010, the HPUS has adopted monographs for 13 new substances, an average of 2.6 monographs a year. While there are very few widely used homeopathic drugs which are not the subject of an HPUS monograph, that universe has shrunk dramatically. The AAHP now believes that the burden on the industry of a monograph requirement is outweighed by the greater certainty created by a monograph requirement. The AAHP thus supports amending the CPG to add that requirement for OTC drugs marketed directly to the public, with an appropriate phase-in period to allow HPUS review and consideration of monographs for some widely used products.⁴⁴

The Homoeopathic Pharmacopoeia of the United States has been in continuous publication since 1897. From 1897 to 1980, the HPUS was published in eight sequential editions (Editions 1-8) with the addition of the Compendium of Therapeutics (1974) under the auspices of the American Institute of Homeopathy, the professional society of homeopathic physicians, founded in 1844. In 1980, the Homoeopathic Pharmacopoeia Convention of the United States

⁴⁴ The AAHP does not believe that a monograph requirement is either necessary or appropriate for homeopathic drugs which are not marketed directly to the public. The market for homeopathic drug products marketed directly to professionals is small and the cost of developing and gaining HPUS monograph status is likely high in relation to the sales of any given product. Rather than deprive physicians and other homeopaths of the full complement of homeopathic drugs, the AAHP believes that no HPUS requirement should be imposed on products not marketed to the public.

was separately incorporated as a 501(c)(3) corporation, and it is this organization that has published the HPUS for the past 35 years. In 1982, a “Supplement A” was published and the priority of the Convention was to complete the monographs listed in the Compendium of Therapeutics. That task was ongoing for over a decade, culminating in the HPUS-RS, revision service published from 1992-2004. In 2004, the HPUS became an online publication exclusively with nearly continual updates and can be accessed via a subscription service.

The mission of the HPCUS is clearly articulated in Article III Section D of the HPCUS Articles of incorporation published in 1980:

To accumulate pertinent information and publish and to sell the Homoeopathic Pharmacopoeia of the United States and any additions or supplements thereto, to promote the art of healing according to the natural laws of cure from a strictly homoeopathic standpoint; to diffuse knowledge among the laity and professionals in the health care field concerning homoeopathic principles through means of publications; to research and obtain a thorough knowledge of the pathogenicity of each drug offered for inclusion in the Homoeopathic Pharmacopoeia of the United States as a homoeopathic drug; to develop criteria for eligibility of drugs for inclusion in the Homoeopathic Pharmacopoeia of the United States to serve as a repository for homoeopathic literature and drugs; and generally to do, perform, undertake, direct, encourage and investigate all aspects and functions of any nature directed to the furtherance of homoeopathic healing.

HPCUS therefore sets the standard for the production of high-quality homeopathic medicines to the consuming public with an emphasis on safety.

A seven-member board, plus an emeritus trustee, govern the HPCUS. Of the seven members, four are physicians and meet the criteria for independence. The work of the Convention falls into several key areas:

- a. Drug monograph evaluation
- b. Pharmaceutics and pharmaceutical methods, including GMPs
- c. Generation and evaluation of standards and controls parameters
- d. Continual safety and toxicology evaluation
- e. Continuous improvement to methods of data collection and evaluation

The HPUS has been an “official compendium” under the FFD&C Act since its passage in 1938 21 U.S.C. § 201(j). A drug, whether allopathic or homeopathic, is deemed to be adulterated under the act “If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.” 21 U.S.C. § 351(b). Similarly, it is deemed to be misbranded “If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein.” 21 U.S.C. § 352(g).

The role of official compendia was critical in 1938 in establishing standards for drugs. FDA has largely supplanted the USP in setting standards for allopathic drugs. The HPUS is still

critically important in the field of homeopathic medicine. The rigor of the HPUS and its procedures has been significantly enhanced in the past 20 years. In the FEDERAL REGISTER announcement of the hearing, FDA claimed that, “Since 2004, the HPCUS has added over 500 new ingredient monographs.” *Id.* At 16,328. The AAHP does not know how FDA calculated that number; perhaps it counted every monograph to which any editorial or typographical change was made. The fact is that only **nine** new active ingredient monographs have been added to the HPUS in the past 10 years.

The entire monograph review process underwent a systematic review and update beginning approximately five years ago. This review focused on ensuring that the current guidelines are harmonized with ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidance for cGMP, FDA guidance on human testing, and a number of other relevant documents within the homeopathic and conventional scientific literature. The updated guidance for monograph submission provides a higher degree of clarity and transparency for monograph sponsors.

All monographs are subject to the monograph review procedure outlined in the HPCUS Procedure Manual, and the Criteria for Eligibility outlined in the HPUS. New monograph submission to the HPCUS is facilitated by the editor of the HPUS. All new monograph submissions are delivered to the editor who reviews the submission for completeness and compliance with the general submission guidance. Once the editor has ascertained that the submission is complete and complies with the general guidance, the Monograph Review Committee (MRC) and the Pharmacopoeia Revision Committee (PRC) review the submission.

First, the technical requirements for a new homeopathic medicine must be evaluated by the Monograph Review Committee. This committee is composed of experts in homeopathic pharmacy, toxicology, and analytic methodology. The guidelines for monograph sponsors have been developed to conform to both ICH and FDA standards on cGMP and safety as they apply to homeopathic medicines.

The Monograph Review Committee specifically evaluates the submitted monograph for:

1. Identification and description of monographed substance
2. Quality standards and purity of starting material
3. Manufacturing process and process controls
4. Analytic procedures and reference standards for starting material
5. Storage and stability data
6. Toxicology including genotoxicity and carcinogenicity
7. First safe attenuation in humans for OTC and Rx use

The second committee conducting an independent review process is the Pharmacopoeia Review Committee. This expert panel is composed of physicians, methodologists, and epidemiologists with experience using and researching homeopathic medicines. The

Pharmacopeia Review Committee is responsible for a rigorous review of the Homeopathic proving and clinical evidence for the monograph submission. The Homeopathic Proving is the human experimental investigation into the clinical properties of a homeopathic drug.

The Pharmacopeia Review Committee specifically evaluates the submitted monograph for:

1. Qualifications of investigators
2. Prior information on investigational substance
3. Study design and methodology
4. Data collection and recordkeeping
5. Safety assurance
6. Informed consent process
7. Ethical and legal compliance
8. Analysis of study results

The primary objectives of these two reviews are to establish the identity of the new medicine under consideration, ensure quality standards are present for the manufacture of the new medicine, establish levels for safe use in humans, and establish that the new medicine has appropriate homeopathic utility. As with all classes of therapeutics, the HPCUS expects that a fuller understanding of the clinical utility of any new medicine will be generated over time through clinical experience and research. Similarly, manufacturers are expected to continue post-marketing surveillance of products to identify any unforeseen safety concerns. Like our counterparts at the USP, the monograph review process does not establish a labeling indication for any given homeopathic medicine. Such indications must be established by the manufacturer of a marketed product using the results of homeopathic provings, clinical reports, historical literature, and other investigational studies, all in accordance with the requirements of the CPG.

Upon completion of their reviews, the Monograph Review Committee and the Pharmacopeia Review Committee will submit their recommendations to the Board of Directors for final review of the monograph submission. Recommendations from the Monograph Review Committee will include their consensus on whether the safety, identification, and manufacturing practices are consistent with GMP and HPUS standards along with Rx and OTC potency level recommendations. Pharmacopeia Review Committee recommendations will primarily reflect the quality of methodology and outcomes of the proving or other clinical data. These committees will recommend approval of the monograph based upon the submitted data, or return to sponsor due to the need for additional evidence. Any safety concerns encountered during the gathering of supporting clinical data are handled with considerable scrutiny and are included with the report from this committee. Upon receipt of the final recommendations from the editor, Monograph Review Committee and Pharmacopeia Review Committee, the board of directors are charged with the final review and decision-making with regard to all new monographs submitted for inclusion in the HPUS.

C. Enforcement

While the AAHP believes that FDA made the correct policy choices when adopting the CPG, the AAHP believes that both the public and the industry would be better served by more vigorous enforcement of the current requirements.

Both in the FEDERAL REGISTER notice and during the hearing, FDA pointed to homeopathic drugs that were offered for apparently prescription-only indications. The AAHP fully endorses FDA efforts to banish from the market homeopathic OTC products illegally labeled for prescription indications. The AAHP recognizes that FDA enforcement resources are limited and would welcome an opportunity to discuss how the AAHP could partner with FDA to assure that OTC homeopathic drugs are offered solely for OTC indications.

QUESTION 4. ARE THERE AREAS OF THE CURRENT CPG THAT COULD BENEFIT FROM ADDITIONAL CLARITY? IF SO, PLEASE EXPLAIN.

Summary: The CPG could benefit from several minor revisions, including a requirement that labels bear a disclaimer that the product has not been reviewed by FDA.

FDA has asked whether there are areas of the current CPG that could benefit from additional clarity. The AAHP believes that there are several such areas.

A. Combinations of homeopathic active ingredients with other ingredients.

The apparent lack of clarity is not due to the language of the CPG, but rather to the agency's interpretation of that language. The CPG states that "Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products." In 1988, that sentence was clearly understood to prohibit mixing allopathic and homeopathic active ingredients in the same product, a position that the majority of the industry has always endorsed. At some point in the past, the agency began to interpret that sentence to also bar the combination of homeopathic active ingredients and diet supplement ingredients in the same product. The sentence bars only the mixture of "non-homeopathic active ingredients" with homeopathic actives. Only allopathic drugs can be "non-homeopathic active ingredients," not dietary supplements, which by definition are foods, not drugs. Foods cannot be "active ingredients." Furthermore, there is nothing in the statute which bars combination products, and the agency recognizes the appropriateness of cosmetic-drug combinations. The AAHP believes that if FDA opposes the combination of homeopathic active ingredients with other, non-drug substances, the language should be revised to accurately reflect the agency's position.

B. Latin identification of active ingredient names

When the CPG was issued in 1988, it contained a requirement that the names of homeopathic active ingredients be listed on product labels in English, rather than the traditional Latin. In response to industry comments that the use of Latin names for the many plant

ingredients used as homeopathic actives provided far greater accuracy, FDA informed the industry by letter that it had changed its mind and would permit the continued use of Latin names.⁴⁵ FDA said that it would make this change the next time the CPG was revised. While there has been one minor revision to the CPG since then, the English name requirement, while not enforced, lives on in the CPG. The agency should revise the CPG to state that Latin names for active homeopathic ingredients are acceptable, the agency's position since 1991.

C. PDP identification of product as homeopathic

While the AAHP does not believe that this has been an issue, the CPG nowhere explicitly requires that the label of a homeopathic drug disclose the fact that it is homeopathic. The AAHP believes that a requirement that the word "Homeopathic" prominently appear on the PDP of any product which is homeopathic. This disclosure is already part of the labeling guidelines of the HPCUS.

D. Include requirement for "Not Reviewed by FDA" disclaimer.

As discussed in detail in response to Question 10, *infra*, the AAHP has adopted a voluntary disclaimer program for homeopathic drug labeling and advertising, a guideline followed by the vast majority of AAHP members. The AAHP believes it would be appropriate and helpful to consumers to amend the CPG to require all homeopathic drugs to bear this disclaimer.

QUESTION 5. IS THERE INFORMATION REGARDING THE REGULATION OF HOMEOPATHIC PRODUCTS IN OTHER COUNTRIES THAT COULD INFORM FDA'S THINKING IN THIS AREA?

Summary: Despite many national differences, the approach taken by FDA in the CPG is consistent with the approach taken in a number of other countries in which homeopathy is popular. To the extent that those countries have different approaches, changes to the FD&C Act would be required to adopt their positions.

Homeopathy was originally developed in Germany and remains in wider use in Europe than in the U.S. to this day. In general, most countries outside of the U.S. have legislation that specifically addresses homeopathy (or complementary medicine in general) while still relying, to a great extent, on the homeopathic literature to support use and efficacy claims. Many countries have a dual system of regulation which depends upon whether or not the product label bears an indication for use, a distinction which is not legal under U.S. law. There is no dominant method of regulation of homeopathic drugs abroad, and any change to the U.S. system would inevitably require both legislative action and a significant investment in agency resources.

⁴⁵ Letter from Joel S. Davis, Chief, Compendial Operations Branch, Office of Compliance, CDER, to Alvin J. Lorman (July 26, 1991)

An AAHP member conducted a detailed survey of laws governing homeopathic drugs and has submitted that survey to this docket.

In addition, the AAHP has reviewed the requirements for the sale of homeopathic drugs in Australia.

Australia

Homeopathic medicines may be sold as “therapeutic goods” in Australia, and are governed in largely the same way as other complementary medicines.

A homeopathic preparation is defined as: “(a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and (b) prepared according to the practices of homoeopathic pharmacy using the methods of: (i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or (ii) serial trituration in lactose.” Therapeutic Goods Regulations of 1990 at Part 1(2) (definitions).

Some, but not the majority of, homeopathic preparations must be listed on the Australian Register of Therapeutic Goods (“ARTG”), maintained by the Therapeutic Goods Administration (“TGA”) under the Department of Health. Those that are listed are assessed by the TGA for quality and safety but not efficacy.

Homeopathic medicines that are considered to be low risk, and therefore exempt from the listing requirement include “homoeopathic preparations more dilute than a one thousand fold dilution of a mother tincture and which are not required to be sterile; and which do not include an ingredient of: (i) human origin; or (ii) animal origin,” i.e. certain parts of cattle, sheep, goats or mule deer,” “unless the indications proposed by the sponsor are in the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code.” Therapeutic Goods Regulations Schedule 5, Item 8 (emphasis added).

However, mother tinctures and 1X, 2X and 3X homoeopathic preparations must be included on the ARTG to be sold. “Mother tinctures” are defined in the Regulations as: “homoeopathic preparations that: (a) consist of, or contain a dilution of, mother tincture that: (i) is a 1,000 fold dilution, or a lesser dilution, of that mother tincture; and (ii) is not required to be sterile; and (iii) is not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard otherwise than because of a component that is more than a 1,000 fold dilution of a mother tincture; and do not consist of, or contain as a component, a preparation of a herb specified in Part 4 of this Schedule as a 1,000 fold dilution, or a lesser dilution, of a mother tincture.” Therapeutic Goods Regulations Schedule 4, Part 1, Items 4 and 4A. 1X, 2X and 3X homoeopathic preparations are defined as “homoeopathic preparations (where each dilution is more dilute than a one thousand fold dilution of a mother tincture), each of which: is not required to be sterile; and according to the indications proposed by the sponsor of the preparation, is for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to

the Therapeutic Goods Advertising Code.” Therapeutic Goods Regulations Schedule 4, Part 1, Item 5.

Whether or not they have to be listed on the ARTG, all commercially sold homeopathic medicines must: comply with advertising requirements set out in the Therapeutic Goods Regulations Schedule 2, and be labeled in compliance with the general requirements for labels for medicinal products codified at Therapeutic Goods Order (“TGO”) 69 and any other applicable official standards.

In addition to generally applicable labeling requirements, TGO 69 provides that labels for homeopathic medicines contain certain special language. For homeopathic preparations where all active ingredients are homeopathic, TGO 69(3)(15) requires that the label include: (a) “a statement indicating that the active ingredients in the goods are homeopathic preparations, such as, 'homeopathic product' or 'homeopathic preparation'; and (b) where the indications for use are of a kind permitted to be advertised only to [practitioners, and not the general public], . . . a statement that the therapeutic indications have not been approved, such as 'Homeopathic product without approved therapeutic indications'.

For homeopathic medicines containing both homeopathic and non-homeopathic ingredients, TGO 69(3)(16) requires that the label “must include . . . a statement that the goods include ingredients that are homeopathic preparations, such as 'Contains homeopathic ingredients’”. Where the indications for use are of a kind permitted to be advertised only to homeopathic practitioners, and not the general public, the same warning that the preparation “Contains homeopathic ingredients without approved therapeutic indications” must also be included.

Despite the required warnings that the therapeutic indications have not been approved, homeopathic medicines and preparations in Australia may include in their labels therapeutic indications—but only provided the medicine is not displayed or advertised to the general public, *i.e.*, it is only supplied to registered homeopathic practitioners.

Manufacturers of all homeopathic medicines that include indications and are listed on the ARTG must certify that they hold evidence to support any indications made about the medicine, and hold onto that evidence in the event of compliance review (which are conducted like audits, to a proportional number of alternative medicine manufacturers). The evidence required is governed by the “Evidence guidelines: Guidelines on the evidence required to support indications for listed complementary medicines.”⁴⁶

QUESTION 6. A LARGE MAJORITY OF HUMAN DRUG PRODUCTS LABELED AS HOMEOPATHIC ARE MARKETED AS OTC DRUGS. THESE PRODUCTS ARE

⁴⁶ Available at <https://www.tga.gov.au/publication/evidence-guidelines>.

AVAILABLE FOR A WIDE VARIETY OF INDICATIONS, AND MANY OF THESE INDICATIONS HAVE NEVER BEEN CONSIDERED FOR OTC USE UNDER A FORMAL REGULATORY PROCESS. WHAT WOULD BE AN APPROPRIATE REGULATORY PROCESS FOR EVALUATING SUCH INDICATIONS FOR OTC USE?

Summary: The overwhelming majority of OTC homeopathic drugs are properly labeled for OTC conditions. Enhanced FDA compliance can address outlier products.

The AAHP agrees with FDA's statement that a large majority of homeopathic drugs are sold as OTC products. FDA also asserts that many allegedly OTC homeopathic products have indications that have never been considered for OTC use and asks what an appropriate regulatory process for evaluating those claims might be.

The AAHP believes that the overwhelming majority by sales volume of homeopathic OTC products are, in fact, appropriately labeled as OTC for conditions that have a long history of OTC use. The supposed Rx claims masquerading as OTC fall into three categories. The first category consists of claims which FDA and most of the industry would agree are Rx. Most of these claims are made by companies with little experience in homeopathy, which do most of their marketing by the Internet, and which have little history in the homeopathic community. And most of these products disappear when the manufacturers receive a Warning Letter.

The second category consists of claims which the agency considers Rx but are claims upon which reasonable people could differ. Warning Letters citing these claims usually prompt a vigorous and documented response from the manufacturer. After receiving the response, FDA often does nothing for years, thus signaling that it is unwilling to enforce its assertions. To the best of the AAHP's knowledge, this category consists of a very small number of claims, certainly not a number large enough to justify creation of a new regulatory process.

The third category of claims the agency considers Rx are based more on the differences between allopathic and homeopathic medicine than on any actual need for physician intervention. Since homeopathy is traditionally a symptom-based approach, it uses words which are not generally used on allopathic labels. Prior to the adoption of the CPG in 1988, many homeopathic drug products simply did not bear indications for use. When the CPG reiterated the statutory requirement for an indication for use, many in the industry aimed to duplicate language found in the homeopathic materia medica, which often make use of medical terminology unfamiliar to consumers but which describe conditions amenable to self-diagnosis and treatment when brought up to date linguistically. That process is still taking place. Many of the terms to which FDA has objected in the past appear not as indication/uses, but in the Purposes section of the Drugs Facts panel or as symptom indications for single ingredients products, products which are typically purchased by very sophisticated consumers. These allegedly Rx claims include words such as "inflammation," "burning runny nose," "bleeding" and "gum disease." Of late, some FDA compliance personnel have taken the position that no indication which does not appear in the OTC Review can be used on homeopathic products. That is simply not the law.

The AAHP believes that vigorous FDA enforcement action against the clear outliers in this area would go a long way toward achieving the agency's goal.

QUESTION 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?

Summary: Homeopathic companies use a wide variety of resources to assure that their products are appropriate for OTC marketing; most follow the labeling of OTC allopathic drugs.

Legitimate homeopathic companies use a variety of methods to assure that the products which they label for the over-the-counter market are appropriately OTC. The AAHP conducted a survey of its members between March 30 and April 7, 2015, regarding the steps that member companies utilize to determine whether individual products are appropriate for marketing on an OTC basis. This survey was limited to the AAHP member companies.

A total of 28 companies responded to the survey representing (97 percent of the Voting Members of the AAHP). The AAHP believes that these 28 companies produce between 90 and 95 percent of the U.S. market for OTC homeopathic drugs. All but two responding companies market and label products as OTC homeopathic drug products. (The exceptions are contract manufacturers that market no homeopathic products under their own label, but do manufacture for other companies marketing OTC Homeopathic drug products.)

All respondents (100 percent) reported that the OTC products they manufacture or market meet the guidelines for minimum OTC attenuation levels found in the Homeopathic Pharmacopeia of the United States. Eighteen respondents (64 percent) use the wording in FDA allopathic OTC final or tentative final monographs as a guide when evaluating label indications for their OTC drug products; one company indicated the wording in the FDA OTC final or tentative final monographs is sometimes slightly simplified, without changing the meaning, in order to meet label space constraints.

The balance of the survey consisted of open ended questions to determine specific methods or processes used by the responding companies to determine whether claims were appropriate for marketing their products as OTC drugs. All respondents were asked what additional steps are undertaken in considering their marketing of OTC products. Respondents reported using an average of 4 different methods to arrive at their evaluations. The following processes were cited by the respondents:

- Comparison with non-homeopathic (allopathic) OTC products that are presently available in the US market (11 percent)
- Use of indications which meet the definition in the Agency's Compliance Policy Guide 400.400 for products that may be marketed OTC ("self-limiting disease conditions amenable to self-diagnosis"), as well as review of Warning Letters issued by the Agency to the wider industry (39 percent)

- Close adherence to indications listed in the homeopathic literature when evaluating their OTC label wording (43 percent)

This survey shows that AAHP members are conscientious and aware of the boundary between OTC and prescription-only drug products.

There is no question, however, that some companies market products to consumers with label claims that are clearly Rx. The majority of these companies appear to operate on the Internet only; their products do not amount to a significant percentage of homeopathic drug sales in the U.S. Nonetheless, the AAHP and its members share the agency's concern about Rx products which masquerade as OTC products. Such products not only endanger consumers, but they are also a black eye for any industry which is committed to the public health. The AAHP would be pleased to work with FDA to identify products suitable for regulatory action.

QUESTION 8. DO CONSUMERS AND HEALTH CARE PROVIDERS HAVE ADEQUATE INFORMATION TO MAKE INFORMED DECISIONS ABOUT DRUG PRODUCTS LABELED AS HOMEOPATHIC? IF NOT, WHAT INFORMATION, INCLUDING, FOR EXAMPLE, INFORMATION IN LABELING, WOULD ALLOW CONSUMERS AND HEALTH CARE PROVIDERS TO BE BETTER INFORMED ABOUT PRODUCTS LABELED AS HOMEOPATHIC?

Summary: Consumers have a wide variety of sources of information about homeopathic drugs and have a better understanding of FDA's role in their marketing than many other categories of FDA-regulated products. The AAHP urges FDA to adopt the association's voluntary label disclaimer program as a requirement based on new survey data that shows disclaimers are an effective consumer information tool.

The amount of information that can fit on the label of a typical drug product is finite and there will always be a tension between the dual goals of adding more information and preserving readability. FDA addressed this issue with considerable success when it adopted the Drug Facts panel requirement for OTC drugs in 1999. Although FDA said at the time that it would not require the manufacturers of homeopathic OTC drugs to include a Drug Facts panel, it appears that a significant majority of homeopathic products sold in mass market outlets do use the Drug Facts panel as a way to provide drug information to consumers.

After adoption of the Drug Facts panel, the AAHP began to consider how to better inform consumers about the homeopathic nature of homeopathic drug products through the use of disclaimers.⁴⁷

Initially thought to be an issue primarily for mass market products, where consumers might not be aware of homeopathy, the AAHP also considered purchasers in health food stores

⁴⁷ This examination predated the disclaimers required by some settlements in class action litigation against certain homeopathic drug manufacturers.

and on-line who are thought to be more sophisticated homeopathic users. Accordingly, initial focus was on advertising, not labeling.

In August, 2012, the AAHP adopted revisions to its long-standing advertising guideline that provided as follows:

Advertising to consumers for an OTC homeopathic drug should include the following statement:

“These statements have not been reviewed by the Food and Drug Administration.”

Additional language which explains the homeopathic nature of the claim may also be included in conjunction with the statement above.

In addition to the advertising provision, the guideline also stated the following:

“If voluntarily applied to the label and labeling of homeopathic drugs, the principles set forth in this guideline should be followed.”

The advertising and labeling disclaimer have been widely adopted by AAHP members and appear on an increasing number of ads and labels as existing packages sell through.⁴⁸ The disclaimer was based on the disclaimer enacted by Congress as part of the Dietary Supplement Health and Education Act and should serve to appropriately inform consumers that the uses of homeopathic drugs have not been reviewed by FDA. Some companies use a slightly different disclaimer as a result of settlements of class action alleging false advertising. Although worded slightly differently, these disclaimers provide consumers with essentially the same message as the AAHP disclaimer.

The AAHP has recently sponsored two consumer perception surveys which show that appropriate disclaimers can play an important role in furthering consumer choice. Three years ago, the Federal Trade Commission commissioned a consumer perception study which examined consumer takeaway on a number of issues involving homeopathic drugs.⁴⁹ Based on that survey, the FTC staff concluded that consumers were confused about the role of FDA in the regulation of homeopathic drugs, with between 10 and 29 percent of consumers believing that FDA approved the products for efficacy.

The new research sponsored by the AAHP shows that consumers are less confused about FDA's role in homeopathy than about many other regulated product categories⁵⁰. The new research was conducted for the AAHP by Thomas J. Maronick, DBA, JD, Professor of

⁴⁸ An AAHP survey conducted in October, 2015, elicited replies from 21 of 29 members. All but one member company already uses or plans to use the disclaimer in advertising and in labeling.

⁴⁹ That report was an exhibit to the written comments filed by the FTC staff in this docket.

⁵⁰ The complete study appears in Exhibit 2.

Marketing at Towson University and the former Director of Impact Studies in the FTC’s Bureau of Consumer Protection.⁵¹

Dr. Maronick conducted two studies. One studied consumer beliefs about FDA’s role in the approving the labels of a wide variety of FDA-regulated products. This study shows that 24 percent of consumers tested believed that FDA approved homeopathic drug claims, a number within the range found by the FTC study. While 24 percent is not an inconsequential number, it is very important to put it into context. The AAHP study shows that fewer consumers believe that FDA approves homeopathic product labels than believe that FDA approves cosmetic, pet food, and grocery product claims. (39, 38 and 63 percent, respectively). In fact, fewer consumers believed that FDA approved homeopathic drug claims than any other product category tested. The study also suggested that most consumers can differentiate between allopathic OTC products and homeopathic OTC products: 76 percent of consumers understood that FDA reviewed claims for allopathic OTCs, while, as noted, only 24 percent thought the same about homeopathic drugs. The following table from Dr. Maronick’s report summarizes the results.

Perception of FDA Approval of Claims Made for Products

	Definitely/ Approved	Definitely/ Not Approved	Don’t know	Mean**
Prescription drug claims	136 (85.5%)	7 (4.4%)	16 (10.0%)	1.74
Dietary supplement claims	76 (47.8%)	55 (34.6%)	28 (17.6%)	2.28
Claims for cosmetics	63 (39.6%)	53 (33.3%)	43 (27.0%)	3.11
Claims for grocery foods	101 (63.5%)	29 (18.2%)	29 (18.2%)	2.45
Pet food claims	61 (38.7%)	44 (27.7%)	54 (34.0%)	3.23
Claims for homeopathic products	38 (23.9%)	71 (44.7%)	50 (31.4%)	3.47
Claims for over-the-counter medicines	121 (76.1%)	15 (9.4%)	23 (14.5%)	2.14
Claims for other products	20 (12.6%)	14 (8.8%)	125 (78.6%)	4.39

****Lower the mean value, the greater the number of “Definitely Approved/Approved”**

In a second study,⁵³ Dr. Maronick studied consumer perception of product labels with one of three different disclaimers. The disclaimers we tested are:

“These statements have not been reviewed by the Food and Drug Administration.”

“The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.”

⁵¹ Dr. Maronick’s curriculum vitae is attached to the study report.

⁵³ See note 50, *supra*.

“The uses of our products are based on traditional homeopathic practice. (see www.homeopathic.org)⁵⁴ They have not been reviewed by the Food and Drug Administration.”

The key finding of this survey is that, when a homeopathic drug bears one of the three label disclaimers tested, only between 1 percent and 8 percent of consumers believed that homeopathic drug claims are approved by FDA. In fact, when controlling for yea-saying (as did the FTC Report), “*negative* values emerge for all three disclaimer groups for the percentage of respondents believing that FDA had approved [the test product] claims.” That is a dramatic decline from the 24 percent who believed that when not presented with a label disclaimer. Dr. Maronick concluded that, “the results strongly suggest that disclaimers can be effective for addressing any consumer misperception regarding the FDA approval status of claims made for homeopathic products.”

This study also examined consumer beliefs about the amount of testing conducted by the manufacturer of the homeopathic product. Dr. Maronick concluded that this phase of the testing showed that

only between 8% and 14% of respondents across the three disclaimer groups believed that the “Tested on People” statement meant that the manufacturer had conducted scientifically controlled studies with humans....

The varied consumer interpretations of the Tested on People statement observed in Study 2 potentially call into question the FTC’s reliance on the Tested on People statement in the Hastak Study. As Table 6 demonstrates, a consumer’s affirmative response to the Tested on People statement does not necessarily mean the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. Rather, it shows that consumers believe the manufacturer conducted homeopathic studies on humans, with different views as to what type of testing on humans was conducted.

These two studies, taken together, show both that consumers (1) understand the limited role that FDA plays in reviewing homeopathic drug products, and (2) that disclaimers are an excellent way to inform consumers about the role of FDA in the marketing of homeopathic drugs.

III. OTHER ISSUES

FTC COMMENTS TO FDA

⁵⁴ This is not a real website, but, rather, a signal to consumers that additional information is available.

Summary: The staff of the Federal Trade Commission (FTC) submitted comments to this docket which made a number of assertions about the impact of the CPG and proposing that changes be made. As will be discussed below, most of the FTC's assertions are founded on incorrect legal analyses or untested legal theories.

The FTC staff asserted that there was a “potential” conflict between the requirements of the CPG and the Federal Trade Commission Act advertising substantiation requirement: “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.” To remedy this claimed conflict, the staff proposed three options:

1. “FDA could withdraw the CPG, thereby subjecting homeopathic drugs to the same regulatory requirements as other drug products.”
2. “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 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.”
3. “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.”

The FTC staff’s suggestions lack legal support.

First, simply withdrawing the CPG does not in any way change the fundamental legal status of homeopathic drugs. Homeopathic drugs were widely marketed before the CPG was adopted in 1988. As noted above, FDA has been dealing with the issue of drug efficacy since 1962, when Congress adopted the Drug Amendments of 1962, which, for the first time, added the efficacy requirement to the new drug approval criteria. Faced with examining thousands of pre-1962 drugs, FDA first reviewed prescription drugs through a contract with the National Academy of Sciences-National Research Council. Over sixty years later, that review is on-going, if not moribund, with several thousand drugs never fully upgraded as safe and effective nor removed from the market. FDA turned to the efficacy of OTC drugs in 1972 and adopted a different approach. Rather than engage in the same time-consuming process used for the still-unfinished review of Rx drugs, FDA sought to examine OTC drug efficacy by category and create monographs which established which claims and which active ingredients were generally recognized as safe and effective, and thus not new drugs subject to premarket approval. The OTC Review produced a large number of final and tentative final monographs until FDA

basically stopped supporting the review with adequate resources. Indeed, the agency held a hearing last year to examine potential new procedural approaches to OTC drug regulation.⁵⁵

As noted above, homeopathic OTC drugs were excluded from the OTC Review and were supposed to be the subject of a separate review to follow the completion of the OTC Review. To revoke the CPG and declare, *ipse dixit*, that homeopathic drugs are illegal would present, at a minimum, an interesting court case. This is especially the case because the unfinished DESI Review and OTC Review leave homeopathic drugs in excellent company, including such OTC standbys as aspirin and such Rx standbys as phenobarbital. In fact, the agency estimates that there are several thousand unapproved prescription drugs on the market today. The real issue is not whether homeopathic drugs are unapproved new drugs, which is a statutory term of art, but rather the process the agency must engage in for a binding determination of their status. The CPG was adopted to deal, in part, with that issue. The FTC staff proposal to simply revoke the CPG is short-sighted.

The FTC staff's second suggestion, that FDA remove the indication requirement from the CPG, likewise lacks a legal basis. In fact, during the discussions leading to the issuance of the CPG, one of FDA's unwavering points was that the FFD&C Act **required** that any drug label bear indications for use. (Prior to 1988, the labels of many homeopathic drugs simply stated: "Use according to standard homeopathic indications.") The FTC staff seems to believe that it would assist them in enforcing their statute if FDA were to permit violating its statute.

The FTC staff's final suggestion, that the CPG require that indications be supported by "competent and reliable scientific evidence," is essentially circular. FDA adopted the CPG to regulate homeopathic drugs until such time as the agency invested the time to review them. The FTC staff suggestion would ultimately require FDA to do what it has been unable to begin for homeopathic drugs nor complete for allopathic drugs.

In short, the FTC staff's three proposals to FDA are all based on incorrect legal and policy choices.

V. CONCLUSIONS

For all of the reasons stated above, the AAHP believes that FDA struck the right balance when it adopted CPG 400.400 in 1988. And, despite modest growth in the market for homeopathic drugs, there is no compelling reason to make any significant changes to the CPG.

⁵⁵ Food and Drug Administration, *Over-The-Counter Drug Monograph System—Past, Present, and Future*; Public Hearing, 79 FED. REG. 10,168 (Feb. 24, 2104).

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The AAHP has made several suggestions which would clarify the CPG and assist FDA and the industry in complying with its requirements. The AAHP believes that these suggested changes would permit the CPG to continue serving the public, the agency and the industry in the years to come.

Respectfully submitted,

Mark Land

Mark Land
President

EXHIBIT 1

	SAE 2013	SAE 2014	Total Units 2013	Total Units 2014	Avg Doses/unit	Doses 2013	doses 2014
Company 1	0	0	6,976,500	6,609,000		139,530,000	132,180,000
Company 2	59	68	19,205,515	19,773,028		576,165,450	593,190,840
Company 3	0	1	100,417	99,819		502,085	499,095
Company 4	0	0	25,945	28,431	0	0	0
Company 5	0	0	inc in other	inc in other		inc in other	inc in other
Company 6	0	0	94,582	94,582		7,482,360	7,482,360
Company 7	0	0	1,233,388	1,298,303		74,100,000	78,000,000
Company 8	2	2	144,831	223,195	30	4,344,930	4,344,930
Company 9	0	0	60,000	110,000	16	960,000	1,760,000
Company 10	0	0	1,475,287	1,444,156		91,530,060	89,736,485
Company 11							
Company 12	0	0	277,155	291,742		8,402,165	8,844,384
Company 13	0	0	5,904	6,436		98,400	107,267
Company 14	0	1	13,008	12,900	90	1,170,720	1,161,000
Company 15	0	0	300,000	350,000	70	21,000,000	24,500,000
Company 16	0	0	Inc in other	inc in other		inc in other	inc in other
Company 17							
Company 18	1	0	4,412,916	3,445,741	60	264,774,960	206,744,460
Company 19							
Company 20	1	1	11,160,782	11,908,143		237,771,848	284,318,244
Company 21	1	2	2,136,724	1,947,916	30	64,101,720	58,437,480
Company 22	18	9	6,400,000	7,200,000	30	192,000,000	216,000,000
Company 23	0	0	225,322	245,129	118	26,587,996	28,925,222
Company 24	0	0	100,000	100,000	24	240,000	2,400,000
Company 25	0	0	69,300	432,000		18,000,000	11,000,000
Company 26	0	0	24,703	16,266		592,872	390,384
Company 27	0	0	793,272	3,573,417	50	39,663,600	178,670,850
Company 28							
Company 29	0	0	1,058,811	1,113,217	70	74,116,770	77,925,190
TOTAL	82	84	56,294,362	60,323,421		1,843,135,936	2,006,618,191

EXHIBIT 2

**AN EMPIRICAL ANALYSIS OF CONSUMERS' PERCEPTIONS
OF THE FDA APPROVAL STATUS OF LABELING CLAIMS
AND OF DISCLAIMER LANGUAGE ON A HOMEOPATHIC
REMEDY FOR HEARTBURN**

Prepared for:
American Association of Homeopathic Pharmacists

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October 13, 2015

**AN EMPIRICAL ANALYSIS OF CONSUMERS' PERCEPTIONS
OF THE FDA APPROVAL STATUS OF LABELING CLAIMS
AND OF DISCLAIMER LANGUAGE ON A HOMEOPATHIC
REMEDY FOR HEARTBURN**

-Report-

BACKGROUND

I am a Professor of Marketing in the College of Business and Economics at Towson University in Towson, Maryland. My educational background includes a BA in Philosophy from St. Thomas Seminary, an MSBA from the University of Denver, a Doctorate in Business Administration (“DBA”) from the University of Kentucky with a major in Marketing, and a JD from the University of Baltimore, School of Law. I am an inactive member of the Maryland Bar. At Towson University I teach undergraduate and graduate courses in strategic marketing and marketing research. I have also taught graduate and executive development courses at a number of universities in the Baltimore and Washington DC area.

My professional background includes Director of Impact Evaluation in the Bureau of Consumer Protection at the Federal Trade Commission (“FTC”) from 1980 – 1997. In that capacity I was the in-house marketing expert for all divisions of the Bureau, advising attorneys and senior management on marketing aspects of cases being considered or undertaken by Commission attorneys. I was also responsible for the evaluation of research submitted by firms being investigated by the Commission and for the design and implementation of all consumer research undertaken by the Bureau during that period. Since leaving the Commission in 1997, I have served as an expert-witness in marketing-related cases and have testified in Federal and State courts. A copy of my CV is included as **Exhibit 1**.

REGULATORY BACKGROUND

In recent years, the Food and Drug Administration (“FDA”) and the FTC have been evaluating a range of issues associated with the sale and marketing of homeopathic drugs in the United States. In April 2015, FDA held a public meeting to solicit comments on a variety of questions associated with the regulation of homeopathic drugs.¹ In response, FTC staff submitted comments to FDA in August 2015 that encouraged the FDA to reconsider its regulatory framework for homeopathic drugs.² Most recently, in September 2015, the FTC held a public workshop to discuss issues associated with the advertising of homeopathic drugs.³

Through its comments to FDA and its public workshop, the FTC questioned the consumer interpretation of homeopathic drug labeling and promotion. Specifically, the FTC indicated that “[m]any consumers may incorrectly believe these products are pre-approved by the FDA and tested on humans for efficacy.”⁴ The FTC based this proposition in part on the results of a copy test study performed by Dr. Manoj Hastak (“Hastak Study”) that was submitted to the FDA along with the FTC staff’s comments.⁵

The Hastak Study examined consumer perceptions after being exposed to three mock homeopathic labels. The study participants were asked, among other things, (i) whether they

¹ See FDA, *Homeopathic Product Regulation: Evaluating FDA’s Regulatory Framework After a Quarter-Century*, <http://www.fda.gov/Drugs/NewsEvents/ucm430539.htm> (last updated Sept. 10, 2015); Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century; Public Hearing, 80 Fed. Reg. 16327 (Mar. 27, 2015).

² See *Comments of the Staff of the FTC in Response to a Request for Comments by FDA Related to Its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century*, at 14, Docket No. FDA-2015-N-0540 (Aug. 21, 2015), available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf (hereinafter “FTC Comments to FDA”).

³ See FTC, *Homeopathic Medicine & Advertising*, <https://www.ftc.gov/news-events/events-calendar/2015/09/homeopathic-medicine-advertising> (last accessed Oct. 12, 2015).

⁴ FTC Comments to FDA, at 16.

⁵ See Manoj Hastak, *Effects of Exposure to Packages of Several Homeopathic Products on Consumer Take-Away and Beliefs* (Aug. 2012), available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitc.pdf (hereinafter “Hastak Study”).

believed that “a government agency like the Food and Drug Administration has approved [the homeopathic drug] as being effective” and (ii) whether “the manufacturer of [the homeopathic drug] has tested the product on people to show that it is effective.”⁶ Significantly, the Hastak Study did not ask participants whether they believed the FDA approved other types of FDA-regulated products, nor did the Hastak Study elicit from respondents what they believed was meant by the phrase “tested the product on people.”

The Hastak Study found, after controlling for “yea-saying,” that (i) 10.3% to 28.6% of participants exposed to the mock labels for the three homeopathic products indicated that they believed that a government agency like the FDA had approved the products for efficacy and (ii) 22.8% to 33.6% of participants exposed to the original product packaging for the three homeopathic products indicated that they believed the manufacturers had tested the products on people to show their effectiveness.⁷ The Hastak Study also found that disclaimers included on homeopathic product packaging could significantly reduce the misperception of FDA approval.⁸ In analyzing the Hastak Study results, the FTC acknowledged: “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.”⁹

STUDY OVERVIEW

I was retained by counsel for the American Association of Homeopathic Pharmacists (“AAHP”) to design and implement two online surveys (referred herein as “Study 1” and “Study 2”) to assess consumer perceptions about homeopathic products. In designing the studies, I relied on my educational background, my academic/teaching background, and my professional

⁶ *Id.* at 6.

⁷ *Id.* at 9, 11.

⁸ *Id.* at 8-9.

⁹ FTC Comments to FDA, at 14-15.

experiences designing consumer surveys for academic purposes, for the FTC, and for litigation, as described above and in my CV.

The purpose of Study 1 was to determine consumers' perceptions of the FDA approval status of labeling claims for a variety of FDA-regulated product categories, including, among others, homeopathic products. As noted above, the Hastak Study did not ask participants whether they believed the FDA approved other types of FDA-regulated products. Thus, the Hastak study effectively lacked a "control" for consumers' perceptions of FDA approval. Given the FTC's concern that certain consumers may mistakenly believe that homeopathic products are FDA-approved,¹⁰ the purpose of Study 1 was to evaluate how consumers perceived the FDA approval status of labeling claims for homeopathic products relative to other product categories and the extent to which any misperceptions varied, if at all, among product categories.

The purpose of Study 2 was to assess consumers' perceptions of one of three disclaimers included on the package of a fictional homeopathic product, Acidux, for the relief of heartburn, bloating, and upset stomach. The three versions of the disclaimer tested were:

- Disclaimer A: "These statements have not been reviewed by the Food and Drug Administration;"
- Disclaimer B: "The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration;" and
- Disclaimer C: "The uses of our products are based on traditional homeopathic practice. (see www.homeopathic.org). They have not been reviewed by the Food and Drug Administration."

Like the Hastak Study relied on by the FTC, Study 2 examined consumers' perceptions as to whether or not the product was FDA approved and whether or not the product had been tested on people. The questions from the Hastak Study were modified to address the fictitious product, Acidux, used in Study 2. Study 2 also assessed consumers' understanding of the

¹⁰ See FTC Comments to FDA, at 14.

meaning of “tested the product on people”—the specific language used by a question in the Hastak study. Finally, Study 2 assessed consumers’ understanding regarding the level of scientific support for claims for homeopathic products relative to non-homeopathic products.

STUDY METHODOLOGY

The data for both studies were collected using the Qualtrics.com internet survey platform, with the sample drawn from the Branded Research Internet panel of individuals who have agreed to participate in internet surveys on a periodic basis. The Branded Research panel is a well-known panel used in online survey research and satisfies industry standards established by the European Society for Opinion and Market Research (ESOMAR), a leading association of internet panel providers. Moreover, online surveys using Internet panels are a well-accepted approach in the field of advertising and consumer research.

Study 1

The survey population for Study 1 was a nationwide sample of individuals over age 18 who have purchased a product to relieve cold symptoms, pain, heartburn, or flu symptoms. Following Qualtrics.com’s standard practice, members of the Branded Research panel who met the initial age criteria were sent an email message inviting them to participate in an online survey by clicking on a link included with the email invitation. There was no mention of the topic of the survey in the email invitation. Respondents were screened to exclude those who had not purchased a product to relieve cold symptoms, pain, heartburn, or flu symptoms in the last 12 months. Respondents were also excluded if they (or anyone in their household) worked in marketing research, a grocery or drug store, or for a drug or pharmaceutical company. A copy of the Study 1 questionnaire is attached as **Exhibit 2**.

Respondents meeting the screening criteria were then asked to indicate their understanding of whether the FDA approves labeling claims related to: prescription drugs, dietary supplements, cosmetics, grocery food products, pet foods, homeopathic products, and over-the-counter medicines. The response options included:

- Definitely are approved by the FDA;
- Are approved by the FDA;
- Are not approved by the FDA;
- Definitely are not approved by the FDA; and
- Don't know/Not sure.

Study 2

The design of Study 2 was modeled in large part after the design of the Hastak Study. The survey population for Study 2 was a nationwide sample of individuals over age 18 who purchased a product to relieve heartburn for themselves or their families over the last 12 months. Following Qualtrics.com's standard practice, members of the Branded Research panel who met the initial age criteria were sent an email message inviting them to participate in an online survey by clicking on a link included with the email invitation. There was no mention of the topic of the survey in the email invitation. Respondents who clicked the link, i.e., agreed to participate in the online survey, were first screened to confirm that they had purchased a product to relieve heartburn in the last 12 months. Respondents were also excluded if they (or anyone in their household) worked in marketing research, a grocery or drug store, or for a drug or pharmaceutical company.

Respondents who met the screening criteria were then shown the front and back label of one of three packages of a fictitious homeopathic drug product (Acidux)—each with one of the three disclaimer options (Disclaimer A, B, or C) on the back panel. No respondent saw more

than one of the three packages. Respondents were not permitted to change an answer once given. A copy of the Study 2 questionnaire is attached as **Exhibit 3**.

After looking at the front and back panels of the package of Acidux, respondents were asked (i) “what, if anything, does the package say or suggest about uses of the product?” and (ii) “what, if anything, does the package say or suggest about testing done on/for this product?” Verbatim responses were recorded.

Respondents were then shown the label on the back panel of the package again and asked to note the disclaimer language that was highlighted on the bottom of the panel. Respondents were then shown three statements, which mirrored the statements used in the Hastak Study, and were asked whether they believed each statement was true or not. The statements were:

- A government agency like the Food and Drug Administration has approved Acidux as being effective in relieving heartburn (referred herein as the “FDA Approval statement”);
- The manufacturer of Acidux has tested this product on people to show that it is effective in relieving heartburn (referred herein as the “Tested On People statement”); and
- The American Medical Association (“AMA”) has certified that Acidux is more effective than other remedies in relieving heartburn (referred herein as the “AMA Certified statement”).¹¹

Respondents who answered affirmatively to the Tested On People statement were then asked their understanding of the type of testing done by the manufacturer. The response options to this question included:

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective;
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective;
- The manufacture provided the product to people and tracked its effectiveness but did not conduct any clinical studies;

¹¹ The AMA Certified statement both here and in the Hastak study, was used as a control for yea-saying. Affirmative responses to the FDA Approval statement and Tested On People statement were adjusted by subtracting the affirmative responses to the AMA Certified statement for each of the three disclaimer presentations.

- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product’s effectiveness;¹²
- Don’t know/Not sure how to interpret the statement; and
- Other (specify).

All respondents who reviewed Disclaimer B or C (*i.e.*, “The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration,” without or with the “see www.homeopathic.org” link), were then asked their perception of “the amount of scientific support the manufacturer of Acidux may have for the uses of the product.” Verbatim responses were recorded. Respondents were then asked a closed-end question regarding their perception of the level of scientific support the manufacturer has for the uses of the product, with the following response options:

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic product has for the uses of its product;
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of similar non-homeopathic product has for the uses of its product;
- Don’t know/Not sure; and
- Other/Specify

Those respondents who indicated that the uses are supported by a different level of support were then asked to qualify the support as “higher,” “the same,” or “lower” than for comparable non-homeopathic products.

RESULTS

Study 1

Demographic Profile. A total of 159 respondents completed Study 1. As noted in Table 1, the vast majority of respondents in Study 1 (87%) were female and three-fourths (77%) were between age 25 and 54, with 39% having completed at least two years of college. Also, as noted

¹² The order of the response options was randomized to avoid order bias.

in Table 1, over half of the respondents (58%) had purchased homeopathic products at least occasionally.

Table 1
Demographic Profile of Respondents – Study 1

Gender	Male	21 (13%)
	Female	138 (87%)
Age	18-24	25 (16%)
	25-34	76 (48%)
	35-44	28 (18%)
	45-54	17 (11%)
	55 or older	14 (9%)
Education	High School or less	45 (28%)
	Some College	52 (33%)
	2 Yr College	27 (17%)
	4 Yr College	26 (16%)
	Grad School/Degree	9 (6%)
Frequency of buying homeopathic products	Never	18 (11%)
	Seldom	31 (19%)
	Occasionally	53 (33%)
	Frequently	32 (20%)
	Always	8 (5%)
	Don't know/Not sure	17 (11%)
	TOTAL	159

Perception of FDA Approval of Claims. As noted in Table 2, the vast majority of consumers (85%) believe the FDA “definitely approved” or “approved” prescription drug claims, while 76% of respondents believe FDA approves claims for over-the-counter medicines. Less than a quarter of respondents (23.9%) believe the FDA “definitely approved” or “approved” claims made for homeopathic products, which is lower than the percentage of consumers who believe FDA approves claims for every other product category, including pet foods (38.7%), cosmetics (39.6%), dietary supplements (47.8%), and grocery foods (63.5%). These results reveal that consumers are more likely to believe that claims for these other product categories are FDA-approved than they are to believe the FDA has approved claims for homeopathic products.

This finding helps put the results of the Hastak Study, which did not examine consumer perceptions of the FDA approval status of other product categories, in context and thus suggests that the FTC’s concern that consumers mistakenly believe that homeopathic products are FDA-approved may be misplaced. The results of Study 1 actually indicate that consumers have a *better* understanding of the FDA approval status of claims made for homeopathic drugs than the FDA approval status of claims for other product categories that are not approved, such as grocery foods, dietary supplements, cosmetics, and pet foods.

Table 2
Perception of FDA Approval of
Claims Made for Products

	Definitely/ Approved	Definitely/ Not Approved	Don’t know	Mean**
Prescription drug claims	136 (85.5%)	7 (4.4%)	16 (10.0%)	1.74
Dietary supplement claims	76 (47.8%)	55 (34.6%)	28 (17.6%)	2.28
Claims for cosmetics	63 (39.6%)	53 (33.3%)	43 (27.0%)	3.11
Claims for grocery foods	101 (63.5%)	29 (18.2%)	29 (18.2%)	2.45
Pet food claims	61 (38.7%)	44 (27.7%)	54 (34.0%)	3.23
Claims for homeopathic products	38 (23.9%)	71 (44.7%)	50 (31.4%)	3.47
Claims for over-the-counter medicines	121 (76.1%)	15 (9.4%)	23 (14.5%)	2.14
Claims for other products	20 (12.6%)	14 (8.8%)	125 (78.6%)	4.39

**Lower the mean value, the greater the number of “Definitely Approved/Approved”

Study 2

Demographic Profile. Approximately 450 respondents completed Study 2, i.e., 150 respondents per disclaimer group. As noted in Table 1, 69% of respondents were women, and respondents were evenly split across all age groups. Also noteworthy is that respondents were relatively well-educated, with 56% of the respondents having at least some college and 40% having a 4-year college degree or more. Half of the respondents (50%) reported that they had purchased homeopathic products at least occasionally.

Table 3
Demographic Profile of Respondents – Study 2

Gender	Male	143 (31%)
	Female	311 (69%)
Age	18 -- 34	3 (1%)
	25-34	90 (19%)
	35-44	108 (23%)
	45-54	112 (24%)
	55 or older	161 (34%)
Education	High School or less	89 (20%)
	Some College	111 (24%)
	2 Yr College	71 (16%)
	4 Yr College	127 (28%)
	Grad School/Degree	56 (12%)
Frequency of buying homeopathic products	Never	91 (20%)
	Seldom	117 (26%)
	Occasionally	139 (31%)
	Frequently	69 (15%)
	Always	17 (4%)
	Don't know/Not sure	20 (4%)
	TOTAL	454

General Perception of Testing. As noted in the Methodology, respondents were first asked what the label they reviewed said or suggested about testing done for/on this product. As noted in Table 4, approximately two-thirds of respondents across the three disclaimer conditions did not know or did not see any claim about testing before the disclaimer was highlighted and, among those who noted information about testing, between 5.9% and 12.3% noted that the claims were not approved/tested by the FDA. Only six respondents across the disclaimer conditions (i.e., 1.3%) thought the FDA had approved the claims.

Table 4
Perceptions of Testing of Products
[Verbatim Responses]

	Disclaimer A	Disclaimer B	Disclaimer C
Not FDA Approved/Tested	9 (5.9%)	19 (12.3%)	12 (8.1%)
FDA tested/approved	1 (0.7%)	--	5 (3.4%)
Natural/Safe	3 (2.0%)	2 (1.3%)	2 (1.4%)
Homeopathic/Manufacturer tested	--	2 (1.3%)	8 (5.4%)
Not tested (general)	4 (5.9%)	1 (0.6%)	1 (0.7%)
Tested/Proven (general)	9 (5.9%)	6 (3.9%)	4 (2.7%)
Not tested on animals	5 (3.3%)	8 (5.2%)	--
Homeopathic (general)	7 (4.6%)	3 (1.9%)	5 (3.4%)
Don't know/Not sure/Not see	101 (66.4%)	97 (62.6%)	98 (66.2%)
Miscellaneous	13 (8.6%)	17 (11.0%)	13 (8.8%)
N	152	155	148

Perception of FDA Approval Statement. As noted in the Methodology section, respondents were asked whether they believed each of three statements—the FDA Approval statement, the Tested On People statement, and the AMA Certified statement—were true or not. As noted in Table 5, the raw results indicate that between 16% and 29% of the respondents across the three disclaimer groups believed FDA had approved the fictitious homeopathic product (Acidux) as effective. However, after the responses to the AMA Certified statement have been netted out to control for yea-saying, *negative* values emerge for all three disclaimer groups for the percentage of respondents believing that FDA had approved Acidux claims. These results indicate that regardless of the disclaimer viewed, the number of respondents believing that FDA had approved Acidux claims was even less than the number that would be expected from yea-saying. Thus, the results strongly suggest that disclaimers can be effective for addressing any consumer misperception regarding the FDA approval status of claims made for homeopathic products.

Table 5
Consumer Perceptions and Take-Away from
Disclaimer Language on Acidux Packaging

	Disclaimer A		Disclaimer B		Disclaimer C	
	n (%)	Net %*	n (%)	Net %*	n (%)	Net %*
FDA APPROVAL						
Yes, believe	25 (16%)	-8%	31 (20%)	-2%	45 (29%)	-1%
No, don't believe	112 (74%)		110 (71%)		100 (65%)	
Don't know	15 (10%)		14 (9%)		9 (6%)	
	152		155		154	
TESTED ON PEOPLE						
Yes, believe	74 (49%)	25%	80 (52%)	30%	83 (54%)	24%
No, don't believe	31 (20%)		29 (19%)		30 (19%)	
Don't know	47 (31%)		46 (30%)		45 (27%)	
	152		155		154	
AMA CERTIFIED						
Yes, believe	36 (24%)		34 (22%)		46 (30%)	
No, don't believe	76 (50%)		77 (50%)		72 (47%)	
Don't know	40 (26%)		44 (28%)		36 (23%)	
	152		155		154	

*Net = percent less "yes" responses to AMA Certified statement

Perception of Tested On People Statement. As noted in Table 5 above, the raw results indicate that between 49% and 54% of the respondents across the three disclaimer groups believed the manufacturer of Acidux had tested the product on people to show that it is effective. After the responses to the AMA Certified statement have been netted out to control for year-saying, only 24% to 30% of respondents across the three disclaimer groups believed Acidux had been tested on people. These results also indicate that consumer perceptions regarding the truth of the Tested on People statement did not vary substantially across the disclaimer groups.

Perception of Meaning of Tested on People Statement. Respondents who believed the Tested on People statement was true were then asked a closed-ended question regarding the meaning of the Tested on People statement. As noted in Table 6, there is no consumer consensus regarding the meaning of the Tested on People statement regardless of the disclaimer viewed. For respondents who reviewed Disclaimer A, the most common response was "Don't know/Not sure" (31.5%), whereas for Disclaimers B and C, the most common response was that the

manufacturer conducted homeopathic studies with humans (39% and 51%, respectively). The fact that Disclaimers B and C included the statement “The uses of our products are based on traditional homeopathic practice” likely contributed to this result. In other words, the reference to “traditional homeopathic practice” may have signaled to consumers that the efficacy of homeopathic products is established through alternative types of testing besides scientifically controlled clinical studies. Nonetheless, only between 8% and 14% of respondents across the three disclaimer groups believed that the “Tested on People” statement meant that the manufacturer had conducted scientifically controlled studies with humans.

Table 6
Meaning of Tested On People Statement

	Disclaimer A	Disclaimer B	Disclaimer C
Manufacturer conducted scientifically controlled studies with humans	6 (8%)	11 (14%)	8 (10%)
Manufacturer conducted at least one study (not necessarily scientifically controlled) with humans	12 (16%)	10 (13%)	7 (8%)
Manufacturer provided product to people and tracked its effectiveness	15 (20.5%)	12 (15%)	11 (13%)
Manufacturer conducted homeopathic studies with humans	15 (20.5%)	31 (39%)	42 (51%)
Don't know/Not sure	23 (31.5%)	15 (19%)	15 (18%)
Other	2 (1%)		
	74*	79*	83*

*Limited to those who said “Yes, Believe” to Tested On People statement

The varied consumer interpretations of the Tested on People statement observed in Study 2 potentially call into question the FTC’s reliance on the Tested on People statement in the Hastak Study. As Table 6 demonstrates, a consumer’s affirmative response to the Tested on People statement does not necessarily mean the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. Rather, it shows that consumers believe the manufacturer conducted homeopathic studies on humans, with different views as to what type of testing on humans was conducted.

Perception of Scientific Support for Product Claims. Respondents who reviewed Disclaimers B or C were asked their understanding of the level of scientific support the manufacturer had for claims made for Acidux, both as an open-ended question and with closed-end responses. As noted in Table 7, approximately one-quarter of respondents seeing Disclaimers B and C indicated they did not interpret the disclaimer as saying or suggesting that the FDA had tested the claims. Rather, they believed either the manufacturer had conducted the tests (in general) or the manufacturer had used “homeopathic practices” (undefined) as the tests.

Table 7
Perception of Level of Scientific Support
Disclaimers B and C
[Verbatim Responses]

	Disclaimer B	Disclaimer C
FDA/Government not test	33 (22.0%)	30 (19.7%)
Manufacturer (not government) test	7 (4.7%)	6 (3.9%)
	} 40 (26.7%)	} 36 (23.6%)
Homeopathic practices/tests	11 (7.3%)	19 (12.5%)
Natural/Homeopathic/Safe	9 (6.0%)	14 (9.2%)
Unsafe/May not be safe	6 (4.0%)	8 (5.3%)
No scientific support	34 (22.7%)	21 (13.8%)
No tests (general)	3 (2.0%)	10 (6.6%)
Don't know/Not sure/No answer	34 (22.7%)	22 (14.5%)
Miscellaneous	13 (8.7%)	22 (14.5%)
TOTAL	150	152

Additionally, as noted in Table 8, when asked for specifics about the level of scientific support for homeopathic products compared to similar non-homeopathic products, 41% of respondents who reviewed Disclaimer B and 50% of respondents who reviewed Disclaimer C believed that the level of scientific support for Acidux claims was different than the level of scientific support for claims for similar non-homeopathic products. The majority of these respondents (54-57%) then indicated that the level of scientific support is lower than the level for similar non-homeopathic products.

Table 8
Amount of Scientific Support for Product Claims
Disclaimers B & C

Amount of Scientific Support	Disclaimer B	Disclaimer C
Same Level as non-homeopathic products	21 (14%)	24 (16%)
Different Level than non-homeopathic products	63 (41%)	75 (50%)
Higher than non-homeopathic products	--	5 (7%)
Same as non-homeopathic products	21 (33%)	15 (20%)
Lower than non-homeopathic products	34 (54%)	43 (57%)
Don't know/Not sure	8 (13%)	10 (13%)
Other	--	2 (3%)
Don't know/Not sure	59 (39%)	46 (30%)
Other	9 (6%)	6 (4%)
	152	151

Significantly, only 14-16% of respondents believed that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers such as Disclaimers B and C may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.

CONCLUSIONS

The results of Study 1 and Study 2 produce several notable findings that should help inform further research involving the use of disclaimers in the labeling and advertising of homeopathic products. The key takeaways include:

- Less than a quarter of respondents (23.9%) believed that FDA approved claims for homeopathic products, which was the lowest percentage of all product categories tested. More respondents believed that FDA approved claims for other product categories that are not FDA-approved, such as pet foods (38.7%), cosmetics (39.6%), dietary supplements (47.8%), and grocery foods (63.5%). These results call into question the FTC's concern about consumer confusion regarding the FDA approval status of homeopathic products, given that the results show that consumers have a better understanding of the FDA approval status of homeopathic drugs than other product categories.
- After controlling for yea-saying, effectively zero respondents believed that FDA had approved the homeopathic product examined in Study 2, regardless of the disclaimer viewed. This result strongly suggests that disclaimers can be effective for addressing any

potential consumer confusion regarding the FDA approval status of homeopathic products.

- After controlling for yea-saying, 24% to 30% of respondents across the three disclaimer groups believed the homeopathic product examined in Study 2 had been tested on people to show that it is effective. However, there was no consensus among respondents regarding the meaning of the phrase “tested on people.” As Study 2 demonstrates, a consumer’s affirmative response to the Tested On People statement does not mean that the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. In fact, the most common substantive response was the response that claims were supported by homeopathic studies conducted on humans.
- Significantly, only 14-16% of respondents believed when initially asked that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.


Thomas J. Maronick, DBA, JD

Professor of Marketing/Consultant

EXHIBIT 1

CURRICULUM VITAE
THOMAS JOSEPH MARONICK

PERSONAL INFORMATION

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EDUCATION

Juris Doctor

University of Baltimore School of Law, Baltimore, Maryland
-Emphasis on Corporate/Business and Consumer Law
-Admitted to the Bar, State of Maryland

Doctor of Business Administration

University of Kentucky, Lexington, Kentucky
-Major in Marketing; Minor in Management and Org. Behavior
-Dissertation: "A Multivariate Analysis of Organizational Climate
in the Channel of Distribution"

Master of Science in Business Administration

University of Denver, Denver, Colorado
-Major in Marketing

Bachelor of Arts

St. Thomas Seminary, Kenmore/Seattle, Washington
-Major in Philosophy

ACADEMIC APPOINTMENTS

Professor of Marketing

Towson University College of Business and Economics, Towson, MD, 1987-- Present
-Responsible for teaching courses in Marketing Management,
Marketing Strategy, Marketing Research, Marketing Seminar, Ethics/Public Policy

Associate Professor of Marketing

University of Baltimore School of Business, Baltimore, MD
-Responsible for teaching undergraduate and graduate courses
in Marketing, Marketing Management, Marketing Research,
Consumer Behavior, Business Policy & Strategy, Small Business Strategy

Instructor of Business Administration

Virginia Commonwealth University, Richmond, VA
-Responsible for teaching undergraduate and graduate course in Management

NON-ACADEMIC EMPLOYMENT

Director--Office of Impact Evaluation, Federal Trade Commission 1980 -- 1997

Bureau of Consumer Protection, 1980 -- 87 [Full-time]; 1987 -- 97 [Part-time]
-Served as the FTC's in-house expert on marketing and survey matters.
-Responsible for design and implementation of over 300 marketing and consumer surveys
undertaken by Commission as part of policy-making and litigation activities.
-Provided expert advice/testimony to staff on marketing & consumer behavior issues

potential consumer confusion regarding the FDA approval status of homeopathic products.

- After controlling for yea-saying, 24% to 30% of respondents across the three disclaimer groups believed the homeopathic product examined in Study 2 had been tested on people to show that it is effective. However, there was no consensus among respondents regarding the meaning of the phrase “tested on people.” As Study 2 demonstrates, a consumer’s affirmative response to the Tested On People statement does not mean that the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. In fact, the most common substantive response was the response that claims were supported by homeopathic studies conducted on humans.
- Significantly, only 14-16% of respondents believed when initially asked that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.


Thomas J. Maronick, DBA, JD

Professor of Marketing/Consultant

Marketing Consultant, 1997 -- present

- Provide expert advice/guidance on marketing strategy and consumer research issues as part of litigation support teams for plaintiff and defendant clients
- Serve as testifying expert witness (deposition, hearing, trial) in consumer-related litigation, class-action certification, deceptive advertising, Lanham Act issues cases, consumer survey research
- Have undertaken over 60 survey research projects for clients in litigation-related matters, including advertising and trademark/trade-dress issues

FIELDS OF SPECIAL INTEREST

Marketing Mgt./Strategic Planning
Marketing/Advertising Research
Expert Witness/Lanham Act Matters

Consumer Protection/Public Policy
Executive Development
Class Action Litigation

EXPERT WITNESS/LITIGATION SUPPORT

AREAS:

Class Action Litigation
Marketing/Marketing Practices
Advertising/Deceptive Advertising
Trademark/Trade Dress/Consumer Confusion
Consumer Behavior
Survey Research/Advertising Research/Copy Testing

MATTERS:

Advertising: Made-in-USA
 Automobile claims
Retailing: Pricing
 Advertising
 Warranties
Telecommunications:
 Advertising/Deception
 Marketing/Promotional Materials
 Target Markets
Software/Internet:
 Internet ISP Software Claims
 Internet Domain Name Issues
Package Goods:
 Deceptive Claims in Advertising
 Deceptive Labeling
Direct Marketing:
 Advertising/Promotion
 Target Markets
Trademark/Trade Dress:
 Consumer Confusion
Consumer Surveys:
 Design/Implementation
 Analysis/Critique

WEBSITE: adexpert.net

PAPERS AND PUBLICATIONS

(previous 10 years)

“A Review of Direct-to-Consumer (DTC) Advertising and Sales of Prescription Drugs: Does DTC Advertising Increase Sales and Market Share?” (with Riva Kahn) Journal of Pharmaceutical Marketing & Management, Vol. 13 (4) (Nov.) 2001.

“Extended Warranties: Consumer Misperceptions of Retailer Claims” Proceedings, European Institute of Retailing and Services Studies, Prague, Czech Republic (July, 2004)

“Celebrity v. Company President as Endorsers of High Risk Products for Elderly Consumers” Journal of Promotion Management Vol. 11, (4), (Nov.) 2005.

“Impact of a Festival Market on Downtown Shopping Behavior” Proceedings, AMS/Korean AMS CPM Conference, Seoul, Korea (July, 2006)

“Consumer Perceptions of Extended Warranties” Journal of Retail and Consumer Services, Vol. 14 (2) (May) 2007.

“Specialty Retail Center’s Impact on Downtown Shopping, Dining, and Entertainment: A Longitudinal Analysis” International Journal of Retail and Distribution Management, Vol. 35 (7) (November) 2007.

“The Role of the Internet in Survey Research: Guidelines for Researchers and Experts” Proceedings, Global Business and Technology Association Conference, Madrid, Spain (July, 2008).

“Country of Origin – Does It Matter Anymore?” Proceedings, Academy of Marketing Science 2009 World Marketing Congress, Oslo, Norway (July, 2009)

“The Role of the Internet in Survey Research: Guidelines for Researchers and Experts” Journal of Global Business and Technology, Vol. 5 (1), (Spring, 2009).

“Pitting the Mall and the Internet in Advertising-Research Competition” Journal of Advertising Research. Vol. 51 (1) (March, 2011).

“Do Consumers Read Terms of Service Agreements When Installing Software – An Empirical Analysis” Proceedings, Athens Institute for Educational Research, Athens, Greece (July, 2011)

“Do Consumers Read Terms of Service Agreements When Installing Software – A Two-Study Empirical Analysis” International Journal of Business and Social Research Vol. 4 (4) (June, 2014)

EXHIBIT 2

AAHP-2
(3)

▼ Screener Block Block Options ▼

Q1
▼

Thank you for responding to this very short survey. If you are not sure of an answer, please indicate "Don't know/Not sure." Please do not guess.

< _____ >

Page Break

Q2
▼

Which of the following products, if any, have you purchased for yourself or a member of your family in the last 12 months? [CHECK ALL THAT APPLY]

- A product to relieve cold symptoms for a child aged 2 - 12
- A product to relieve pain
- A product to relieve flu symptoms
- A product to relieve heartburn
- None of the above

< _____ >

If None of the above is Selected, Then Skip To End of Survey

Page Break

Q3
▼

Do you or does anyone in your household work...[CHECK ALL THAT APPLY]

- In marketing research
- In advertising or public relations
- For a grocery store or drug store
- For a drug or pharmaceutical company
- None of the above

< _____ >

If None of the above is Not Selected, Then Skip To End of Survey

Page Break

Q4

Are you...

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55 or older



Page Break

Q5

Which of the following claims, if any, have to be approved by the Food and Drug Administration (FDA)?

	Definitely are approved by the FDA	Are Approved by the FDA	Are not approved by the FDA	Definitely are not approved by the FDA	Don't know/Not sure
Labeling claims made for prescription drugs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for dietary supplements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for cosmetics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for grocery food products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for pet foods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for homeopathic products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims for over-the-counter medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims for other products (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Page Break

Q6

Gender?

- Male
- Female



Page Break

Q7

Education?

- High school or less
- Some college/technical school
- 2-Yr College degree
- 4-Yr College degree
- Graduate school/degree



Page Break

Q8

How often, if at all, do you buy homeopathic products for yourself or members of your family?

- Never
- Seldom
- Occasionally
- Frequently
- Always
- Don't know/Not sure



EXHIBIT 3

AAHP-1
(D)

▼ Screener Block

Block Options ▼

Q1

Thank you for responding to this very short survey. There are no "right answers." If you're not sure of an answer, please indicate "Don't know/Not sure." Please do not guess.



Page Break

Q2

Which of the following products, if any, have you purchased for yourself or a member of your family in the last 12 months? [CHECK ALL THAT APPLY]

- A product to relieve cold symptoms for a child aged 2 - 12
- A product to relieve pain
- A product to relieve flu symptoms
- A product to relieve heartburn
- None of the above



If A product to relieve heartburn Is Not Selected, Then Skip To End of Survey

Page Break

Q3

Do you or does anyone in your household work...[CHECK ALL THAT APPLY]

- In marketing research
- In advertising or public relations
- For a grocery store or drug store
- For a drug or pharmaceutical company
- None of the above



If None of the above Is Not Selected, Then Skip To End of Survey

Page Break

Q4

Are you...

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55 or older

Page Break

Block 1

Block Options

Q5

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.

Page Break

Q6

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nuxvomica 4C HPUS	Relieves heartburn due to excessive eating and drinking
<small>The letters HPUS indicate that this ingredient is officially recognized in the Homeopathic Pharmacopoeia of the United States.</small>	
Uses* temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.	
Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist temporarily for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
Directions • Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. • Children under 12 years of age: Ask a doctor.	
Other information • do not use if glued caps and flaps are open or if the blister seal is broken •	
Inactive ingredients	

Acidux

Drug Facts
(continued)

Questions or comments?
1-800-666-0000
Company
20 Central Avenue
Any Town, USA
10999-9999

INDIGESTION
Heartburn • Bloating
Upset Stomach
Acid Indigestion*

Acidux
HOMEOPATHIC MEDICINE

*These statements have not been reviewed by the Food and Drug Administration.

Page Break

Q7

What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]

Empty text input field for user response.

Page Break

Q8

What, if anything, does the package say or suggest about testing done for/on this product? (PLEASE SPECIFY)

Empty text input field for Q8 response.



Page Break

Q9

Here is the back panel of the package. Note the highlighted statement at the bottom of the panel

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nux vomica 4C HPUS	Relieves heartburn due to excessive eating and drinking
<small>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small>	
Uses* ■ temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach	
Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. ■ Children under 12 years of age: Ask a doctor.	
Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■	
Inactive ingredients ▶	

* These statements have not been reviewed by the Food and Drug Administration.



Page Break

Q10

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.



Page Break

Q11

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [Select one answer]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q12

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q13

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q14

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** Is Selected

What, if anything, does the statement that "These statements have not been reviewed by the Food and Drug Administration say or suggest about the type of testing the manufacturer of this product may have done? [PLEASE SPECIFY]



Page Break

Q15

Which of the following statements, if any, is reflective of your understanding of what "These statements have not been reviewed by the Food and Drug Administration" say or suggest about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)

Block 2

Block Options

Q16

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.

Page Break

Q17

<p>Drug Facts</p> <p>Active ingredients* Purpose* Carbo vegetabilis 4G HPLUS Relieves stomach bloating with gas Nuxvomica 6C HPLUS Relieves heartburn due to excessive eating and drinking (contains less than 10 mg alkaloids per dose)</p> <p><small>The letters HPLUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small></p> <p>Uses* Temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.</p> <p>Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 3 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>Directions Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. *Children under 12 years of age: Ask a doctor.</p> <p>Other information do not use if glued carton end flaps are open or if the blister seal is broken.</p> <p>Inactive ingredients</p>	<p>Acidux</p> <p>INDIGESTION</p> <p>Heartburn • Bloating Upset Stomach Acid Indigestion*</p> <p>Acidux</p> <p>HOMEOPATHIC MEDICINE</p> <p>Drug Facts (continued) Questions or comments? 1-800-600-0000 Company 37 Central Avenue Any Town, USA 10000-0000</p>
--	--

*The uses for our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Page Break

Q18

What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]

Page Break

Q19

What, if anything, does the package say or suggest about the testing done for/on this product? [PLEASE SPECIFY]

Empty text input field for Q19 response.

< >

Page Break

Q20

Here is the back panel of the package again. Note the highlighted statement at the bottom of the panel.

Drug Facts

Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nux vomica 4C HPUS (contains less than 1.0 mg alkaloids per dose)	Relieves heartburn due to excessive eating and drinking

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

Uses* ■ temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach

Warnings
 Ask a doctor before use in children under 12 years of age.
 Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children.

Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.
 ■ Children under 12 years of age: Ask a doctor.

Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■

Inactive ingredients ▶

*The uses for our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

< >

Page Break

Q21

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.

< >

Page Break

Q22

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q23

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q24

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q25

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** is Selected

Which of the following statements, if any, is reflective of your understanding of what "The uses of this product are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration" says or suggests about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)



Page Break

Q26

What, if anything, does a statement that says "The uses of this product are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration" say or suggest about the scientific support the manufacturer of this product may have for the uses of the product? [PLEASE SPECIFY]



Page Break

Q27

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify



If The uses of this homeopathi... Is Not Selected, Then Skip To End of Block

Page Break

Q28

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The manufacturer of this homeopathic product has a HIGHER LEVEL of scientific support for the uses of the product as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The manufacturer of this homeopathic product has the SAME LEVEL of scientific support for the uses of the product as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- The manufacturer of this homeopathic product has a LOWER LEVEL of scientific support for the uses of the product than a manufacturer of s similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify



Page Break

Block 3

Block Options

Q29

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.



Page Break

Q30



Drug Facts

Active ingredients*	Purpose†
Carno vegetabilis AC HPUS	Relieves stomach bloating with gas
Nux vomica AC HPUS	Relieves heartburn due to excessive eating and drinking

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

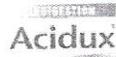
Uses* •temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.

Warnings
 Ask a doctor before use in children under 12 years of age.
Stop use and ask a doctor if symptoms persist more than 14 days in children or 14 days in women. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children.

Directions • Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.
 • Children under 12 years of age: Ask a doctor.

Other information •do not use if glued carton and tabs are open or if the blister seal is broken.

Inactive ingredients



Drug Facts
(continued)

Questions or comments?
1-800-860-0089

Company
15 Central Avenue
Apt 1100m, USA
1000-0000



NDC 0800

INDIGESTION*

**Heartburn • Bloating
Upset Stomach
Acid Indigestion***

Acidux®

HOMEOPATHIC MEDICINE

*The uses for our products are based on traditional homeopathic practice. (See www.Homeopathy.org.) They have not been reviewed by the Food and Drug Administration.



Page Break

Q31



What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]



Page Break

Q32



What, if anything, does the package say or suggest about testing done for/on this product? [PLEASE SPECIFY]



Page Break

Q33

Here's the back panel of the package again. Note the highlighted statement at the bottom of the panel.

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nuxvomica 4C HPUS	Relieves heartburn due to excessive eating and drinking (contains less than 10 ¹ mg alkaloids per dose)
<i>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</i>	
Uses* temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach	
Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. ■ Children under 12 years of age: Ask a doctor.	
Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■	
Inactive ingredients	

*The uses for our products are based on traditional homeopathic practice. (See www.Homeopathy.org.) They have not been reviewed by the Food and Drug Administration.

< Page Break >

Q34

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.

< Page Break >

Q35

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [Select one answer]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure

< Page Break >

Q36

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q37

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q38

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** is Selected

Which of the following statements, if any, is reflective of your understanding of what "The uses of this product are based on traditional homeopathic practice. (See www.homeopathy.org). They have not been reviewed by the Food and Drug Administration, says or suggests about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)



Page Break

Q39

What, if anything, does a statement that says "The uses of this product are based on traditional homeopathic practice. (see www.homeopathy.org). They have not been reviewed by the Food and Drug Administration," say or suggest about the scientific support the manufacturer of this product may have for the uses of this product? [PLEASE SPECIFY]



Page Break

Q40

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify

If The uses of this homeopathi... Is Not Selected, Then Skip To End of Block

Page Break

Q41

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The manufacturer of this homeopathic product has a HIGHER LEVEL of scientific support for the uses of the product than a manufacturer of similar non-homeopathic products has for the uses of its product.
- The manufacturer of this homeopathic product has the SAME LEVEL of scientific support for the uses of the product as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- The manufacturer of this homeopathic product has a LOWER LEVEL of scientific support for the uses of the product than a manufacturer of s similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify

Page Break

Demographics

Block Options

Q42

Gender?

- Male
- Female

Page Break

Q43

Education?

- High school or less
- Some college/technical school
- 2-Yr college degree
- 4-Yr college degree
- Graduate school/degree

< _____ >

Page Break

Q44

In what state do you currently reside?

Alabama

< _____ >

Page Break

Q45

How often, if at all, do you buy homeopathic products for yourself or members of your family?

- Never
- Seldom
- Occasionally
- Frequently
- Always
- Don't know/Not sure

< _____ >

EXHIBIT 2

**AN EMPIRICAL ANALYSIS OF CONSUMERS' PERCEPTIONS
OF THE FDA APPROVAL STATUS OF LABELING CLAIMS
AND OF DISCLAIMER LANGUAGE ON A HOMEOPATHIC
REMEDY FOR HEARTBURN**

Prepared for:
American Association of Homeopathic Pharmacists

BY:
Thomas J. Maronick, DBA, JD
Professor of Marketing
Towson University
Towson, Maryland

October 13, 2015

**AN EMPIRICAL ANALYSIS OF CONSUMERS' PERCEPTIONS
OF THE FDA APPROVAL STATUS OF LABELING CLAIMS
AND OF DISCLAIMER LANGUAGE ON A HOMEOPATHIC
REMEDY FOR HEARTBURN**

-Report-

BACKGROUND

I am a Professor of Marketing in the College of Business and Economics at Towson University in Towson, Maryland. My educational background includes a BA in Philosophy from St. Thomas Seminary, an MSBA from the University of Denver, a Doctorate in Business Administration (“DBA”) from the University of Kentucky with a major in Marketing, and a JD from the University of Baltimore, School of Law. I am an inactive member of the Maryland Bar. At Towson University I teach undergraduate and graduate courses in strategic marketing and marketing research. I have also taught graduate and executive development courses at a number of universities in the Baltimore and Washington DC area.

My professional background includes Director of Impact Evaluation in the Bureau of Consumer Protection at the Federal Trade Commission (“FTC”) from 1980 – 1997. In that capacity I was the in-house marketing expert for all divisions of the Bureau, advising attorneys and senior management on marketing aspects of cases being considered or undertaken by Commission attorneys. I was also responsible for the evaluation of research submitted by firms being investigated by the Commission and for the design and implementation of all consumer research undertaken by the Bureau during that period. Since leaving the Commission in 1997, I have served as an expert-witness in marketing-related cases and have testified in Federal and State courts. A copy of my CV is included as **Exhibit 1**.

REGULATORY BACKGROUND

In recent years, the Food and Drug Administration (“FDA”) and the FTC have been evaluating a range of issues associated with the sale and marketing of homeopathic drugs in the United States. In April 2015, FDA held a public meeting to solicit comments on a variety of questions associated with the regulation of homeopathic drugs.¹ In response, FTC staff submitted comments to FDA in August 2015 that encouraged the FDA to reconsider its regulatory framework for homeopathic drugs.² Most recently, in September 2015, the FTC held a public workshop to discuss issues associated with the advertising of homeopathic drugs.³

Through its comments to FDA and its public workshop, the FTC questioned the consumer interpretation of homeopathic drug labeling and promotion. Specifically, the FTC indicated that “[m]any consumers may incorrectly believe these products are pre-approved by the FDA and tested on humans for efficacy.”⁴ The FTC based this proposition in part on the results of a copy test study performed by Dr. Manoj Hastak (“Hastak Study”) that was submitted to the FDA along with the FTC staff’s comments.⁵

The Hastak Study examined consumer perceptions after being exposed to three mock homeopathic labels. The study participants were asked, among other things, (i) whether they

¹ See FDA, *Homeopathic Product Regulation: Evaluating FDA’s Regulatory Framework After a Quarter-Century*, <http://www.fda.gov/Drugs/NewsEvents/ucm430539.htm> (last updated Sept. 10, 2015); Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century; Public Hearing, 80 Fed. Reg. 16327 (Mar. 27, 2015).

² See *Comments of the Staff of the FTC in Response to a Request for Comments by FDA Related to Its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century*, at 14, Docket No. FDA-2015-N-0540 (Aug. 21, 2015), available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf (hereinafter “FTC Comments to FDA”).

³ See FTC, *Homeopathic Medicine & Advertising*, <https://www.ftc.gov/news-events/events-calendar/2015/09/homeopathic-medicine-advertising> (last accessed Oct. 12, 2015).

⁴ FTC Comments to FDA, at 16.

⁵ See Manoj Hastak, *Effects of Exposure to Packages of Several Homeopathic Products on Consumer Take-Away and Beliefs* (Aug. 2012), available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/exhibitc.pdf (hereinafter “Hastak Study”).

believed that “a government agency like the Food and Drug Administration has approved [the homeopathic drug] as being effective” and (ii) whether “the manufacturer of [the homeopathic drug] has tested the product on people to show that it is effective.”⁶ Significantly, the Hastak Study did not ask participants whether they believed the FDA approved other types of FDA-regulated products, nor did the Hastak Study elicit from respondents what they believed was meant by the phrase “tested the product on people.”

The Hastak Study found, after controlling for “yea-saying,” that (i) 10.3% to 28.6% of participants exposed to the mock labels for the three homeopathic products indicated that they believed that a government agency like the FDA had approved the products for efficacy and (ii) 22.8% to 33.6% of participants exposed to the original product packaging for the three homeopathic products indicated that they believed the manufacturers had tested the products on people to show their effectiveness.⁷ The Hastak Study also found that disclaimers included on homeopathic product packaging could significantly reduce the misperception of FDA approval.⁸ In analyzing the Hastak Study results, the FTC acknowledged: “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.”⁹

STUDY OVERVIEW

I was retained by counsel for the American Association of Homeopathic Pharmacists (“AAHP”) to design and implement two online surveys (referred herein as “Study 1” and “Study 2”) to assess consumer perceptions about homeopathic products. In designing the studies, I relied on my educational background, my academic/teaching background, and my professional

⁶ *Id.* at 6.

⁷ *Id.* at 9, 11.

⁸ *Id.* at 8-9.

⁹ FTC Comments to FDA, at 14-15.

experiences designing consumer surveys for academic purposes, for the FTC, and for litigation, as described above and in my CV.

The purpose of Study 1 was to determine consumers' perceptions of the FDA approval status of labeling claims for a variety of FDA-regulated product categories, including, among others, homeopathic products. As noted above, the Hastak Study did not ask participants whether they believed the FDA approved other types of FDA-regulated products. Thus, the Hastak study effectively lacked a "control" for consumers' perceptions of FDA approval. Given the FTC's concern that certain consumers may mistakenly believe that homeopathic products are FDA-approved,¹⁰ the purpose of Study 1 was to evaluate how consumers perceived the FDA approval status of labeling claims for homeopathic products relative to other product categories and the extent to which any misperceptions varied, if at all, among product categories.

The purpose of Study 2 was to assess consumers' perceptions of one of three disclaimers included on the package of a fictional homeopathic product, Acidux, for the relief of heartburn, bloating, and upset stomach. The three versions of the disclaimer tested were:

- Disclaimer A: "These statements have not been reviewed by the Food and Drug Administration;"
- Disclaimer B: "The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration;" and
- Disclaimer C: "The uses of our products are based on traditional homeopathic practice. (see www.homeopathic.org). They have not been reviewed by the Food and Drug Administration."

Like the Hastak Study relied on by the FTC, Study 2 examined consumers' perceptions as to whether or not the product was FDA approved and whether or not the product had been tested on people. The questions from the Hastak Study were modified to address the fictitious product, Acidux, used in Study 2. Study 2 also assessed consumers' understanding of the

¹⁰ See FTC Comments to FDA, at 14.

meaning of “tested the product on people”—the specific language used by a question in the Hastak study. Finally, Study 2 assessed consumers’ understanding regarding the level of scientific support for claims for homeopathic products relative to non-homeopathic products.

STUDY METHODOLOGY

The data for both studies were collected using the Qualtrics.com internet survey platform, with the sample drawn from the Branded Research Internet panel of individuals who have agreed to participate in internet surveys on a periodic basis. The Branded Research panel is a well-known panel used in online survey research and satisfies industry standards established by the European Society for Opinion and Market Research (ESOMAR), a leading association of internet panel providers. Moreover, online surveys using Internet panels are a well-accepted approach in the field of advertising and consumer research.

Study 1

The survey population for Study 1 was a nationwide sample of individuals over age 18 who have purchased a product to relieve cold symptoms, pain, heartburn, or flu symptoms. Following Qualtrics.com’s standard practice, members of the Branded Research panel who met the initial age criteria were sent an email message inviting them to participate in an online survey by clicking on a link included with the email invitation. There was no mention of the topic of the survey in the email invitation. Respondents were screened to exclude those who had not purchased a product to relieve cold symptoms, pain, heartburn, or flu symptoms in the last 12 months. Respondents were also excluded if they (or anyone in their household) worked in marketing research, a grocery or drug store, or for a drug or pharmaceutical company. A copy of the Study 1 questionnaire is attached as **Exhibit 2**.

Respondents meeting the screening criteria were then asked to indicate their understanding of whether the FDA approves labeling claims related to: prescription drugs, dietary supplements, cosmetics, grocery food products, pet foods, homeopathic products, and over-the-counter medicines. The response options included:

- Definitely are approved by the FDA;
- Are approved by the FDA;
- Are not approved by the FDA;
- Definitely are not approved by the FDA; and
- Don't know/Not sure.

Study 2

The design of Study 2 was modeled in large part after the design of the Hastak Study. The survey population for Study 2 was a nationwide sample of individuals over age 18 who purchased a product to relieve heartburn for themselves or their families over the last 12 months. Following Qualtrics.com's standard practice, members of the Branded Research panel who met the initial age criteria were sent an email message inviting them to participate in an online survey by clicking on a link included with the email invitation. There was no mention of the topic of the survey in the email invitation. Respondents who clicked the link, i.e., agreed to participate in the online survey, were first screened to confirm that they had purchased a product to relieve heartburn in the last 12 months. Respondents were also excluded if they (or anyone in their household) worked in marketing research, a grocery or drug store, or for a drug or pharmaceutical company.

Respondents who met the screening criteria were then shown the front and back label of one of three packages of a fictitious homeopathic drug product (Acidux)—each with one of the three disclaimer options (Disclaimer A, B, or C) on the back panel. No respondent saw more

than one of the three packages. Respondents were not permitted to change an answer once given. A copy of the Study 2 questionnaire is attached as **Exhibit 3**.

After looking at the front and back panels of the package of Acidux, respondents were asked (i) “what, if anything, does the package say or suggest about uses of the product?” and (ii) “what, if anything, does the package say or suggest about testing done on/for this product?” Verbatim responses were recorded.

Respondents were then shown the label on the back panel of the package again and asked to note the disclaimer language that was highlighted on the bottom of the panel. Respondents were then shown three statements, which mirrored the statements used in the Hastak Study, and were asked whether they believed each statement was true or not. The statements were:

- A government agency like the Food and Drug Administration has approved Acidux as being effective in relieving heartburn (referred herein as the “FDA Approval statement”);
- The manufacturer of Acidux has tested this product on people to show that it is effective in relieving heartburn (referred herein as the “Tested On People statement”); and
- The American Medical Association (“AMA”) has certified that Acidux is more effective than other remedies in relieving heartburn (referred herein as the “AMA Certified statement”).¹¹

Respondents who answered affirmatively to the Tested On People statement were then asked their understanding of the type of testing done by the manufacturer. The response options to this question included:

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective;
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective;
- The manufacture provided the product to people and tracked its effectiveness but did not conduct any clinical studies;

¹¹ The AMA Certified statement both here and in the Hastak study, was used as a control for yea-saying. Affirmative responses to the FDA Approval statement and Tested On People statement were adjusted by subtracting the affirmative responses to the AMA Certified statement for each of the three disclaimer presentations.

- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product’s effectiveness;¹²
- Don’t know/Not sure how to interpret the statement; and
- Other (specify).

All respondents who reviewed Disclaimer B or C (*i.e.*, “The uses of our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration,” without or with the “see www.homeopathic.org” link), were then asked their perception of “the amount of scientific support the manufacturer of Acidux may have for the uses of the product.” Verbatim responses were recorded. Respondents were then asked a closed-end question regarding their perception of the level of scientific support the manufacturer has for the uses of the product, with the following response options:

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic product has for the uses of its product;
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of similar non-homeopathic product has for the uses of its product;
- Don’t know/Not sure; and
- Other/Specify

Those respondents who indicated that the uses are supported by a different level of support were then asked to qualify the support as “higher,” “the same,” or “lower” than for comparable non-homeopathic products.

RESULTS

Study 1

Demographic Profile. A total of 159 respondents completed Study 1. As noted in Table 1, the vast majority of respondents in Study 1 (87%) were female and three-fourths (77%) were between age 25 and 54, with 39% having completed at least two years of college. Also, as noted

¹² The order of the response options was randomized to avoid order bias.

in Table 1, over half of the respondents (58%) had purchased homeopathic products at least occasionally.

**Table 1
Demographic Profile of Respondents – Study 1**

Gender	Male	21 (13%)
	Female	138 (87%)
Age	18-24	25 (16%)
	25-34	76 (48%)
	35-44	28 (18%)
	45-54	17 (11%)
	55 or older	14 (9%)
Education	High School or less	45 (28%)
	Some College	52 (33%)
	2 Yr College	27 (17%)
	4 Yr College	26 (16%)
	Grad School/Degree	9 (6%)
Frequency of buying homeopathic products	Never	18 (11%)
	Seldom	31 (19%)
	Occasionally	53 (33%)
	Frequently	32 (20%)
	Always	8 (5%)
	Don't know/Not sure	17 (11%)
	TOTAL	159

Perception of FDA Approval of Claims. As noted in Table 2, the vast majority of consumers (85%) believe the FDA “definitely approved” or “approved” prescription drug claims, while 76% of respondents believe FDA approves claims for over-the-counter medicines. Less than a quarter of respondents (23.9%) believe the FDA “definitely approved” or “approved” claims made for homeopathic products, which is lower than the percentage of consumers who believe FDA approves claims for every other product category, including pet foods (38.7%), cosmetics (39.6%), dietary supplements (47.8%), and grocery foods (63.5%). These results reveal that consumers are more likely to believe that claims for these other product categories are FDA-approved than they are to believe the FDA has approved claims for homeopathic products.

This finding helps put the results of the Hastak Study, which did not examine consumer perceptions of the FDA approval status of other product categories, in context and thus suggests that the FTC’s concern that consumers mistakenly believe that homeopathic products are FDA-approved may be misplaced. The results of Study 1 actually indicate that consumers have a *better* understanding of the FDA approval status of claims made for homeopathic drugs than the FDA approval status of claims for other product categories that are not approved, such as grocery foods, dietary supplements, cosmetics, and pet foods.

Table 2
Perception of FDA Approval of
Claims Made for Products

	Definitely/ Approved	Definitely/ Not Approved	Don’t know	Mean**
Prescription drug claims	136 (85.5%)	7 (4.4%)	16 (10.0%)	1.74
Dietary supplement claims	76 (47.8%)	55 (34.6%)	28 (17.6%)	2.28
Claims for cosmetics	63 (39.6%)	53 (33.3%)	43 (27.0%)	3.11
Claims for grocery foods	101 (63.5%)	29 (18.2%)	29 (18.2%)	2.45
Pet food claims	61 (38.7%)	44 (27.7%)	54 (34.0%)	3.23
Claims for homeopathic products	38 (23.9%)	71 (44.7%)	50 (31.4%)	3.47
Claims for over-the-counter medicines	121 (76.1%)	15 (9.4%)	23 (14.5%)	2.14
Claims for other products	20 (12.6%)	14 (8.8%)	125 (78.6%)	4.39

**Lower the mean value, the greater the number of “Definitely Approved/Approved”

Study 2

Demographic Profile. Approximately 450 respondents completed Study 2, i.e., 150 respondents per disclaimer group. As noted in Table 1, 69% of respondents were women, and respondents were evenly split across all age groups. Also noteworthy is that respondents were relatively well-educated, with 56% of the respondents having at least some college and 40% having a 4-year college degree or more. Half of the respondents (50%) reported that they had purchased homeopathic products at least occasionally.

**Table 3
Demographic Profile of Respondents – Study 2**

Gender	Male	143 (31%)
	Female	311 (69%)
Age	18 -- 34	3 (1%)
	25-34	90 (19%)
	35-44	108 (23%)
	45-54	112 (24%)
	55 or older	161 (34%)
Education	High School or less	89 (20%)
	Some College	111 (24%)
	2 Yr College	71 (16%)
	4 Yr College	127 (28%)
	Grad School/Degree	56 (12%)
Frequency of buying homeopathic products	Never	91 (20%)
	Seldom	117 (26%)
	Occasionally	139 (31%)
	Frequently	69 (15%)
	Always	17 (4%)
	Don't know/Not sure	20 (4%)
	TOTAL	454

General Perception of Testing. As noted in the Methodology, respondents were first asked what the label they reviewed said or suggested about testing done for/on this product. As noted in Table 4, approximately two-thirds of respondents across the three disclaimer conditions did not know or did not see any claim about testing before the disclaimer was highlighted and, among those who noted information about testing, between 5.9% and 12.3% noted that the claims were not approved/tested by the FDA. Only six respondents across the disclaimer conditions (i.e., 1.3%) thought the FDA had approved the claims.

Table 4
Perceptions of Testing of Products
[Verbatim Responses]

	Disclaimer A	Disclaimer B	Disclaimer C
Not FDA Approved/Tested	9 (5.9%)	19 (12.3%)	12 (8.1%)
FDA tested/approved	1 (0.7%)	--	5 (3.4%)
Natural/Safe	3 (2.0%)	2 (1.3%)	2 (1.4%)
Homeopathic/Manufacturer tested	--	2 (1.3%)	8 (5.4%)
Not tested (general)	4 (5.9%)	1 (0.6%)	1 (0.7%)
Tested/Proven (general)	9 (5.9%)	6 (3.9%)	4 (2.7%)
Not tested on animals	5 (3.3%)	8 (5.2%)	--
Homeopathic (general)	7 (4.6%)	3 (1.9%)	5 (3.4%)
Don't know/Not sure/Not see	101 (66.4%)	97 (62.6%)	98 (66.2%)
Miscellaneous	13 (8.6%)	17 (11.0%)	13 (8.8%)
N	152	155	148

Perception of FDA Approval Statement. As noted in the Methodology section, respondents were asked whether they believed each of three statements—the FDA Approval statement, the Tested On People statement, and the AMA Certified statement—were true or not. As noted in Table 5, the raw results indicate that between 16% and 29% of the respondents across the three disclaimer groups believed FDA had approved the fictitious homeopathic product (Acidux) as effective. However, after the responses to the AMA Certified statement have been netted out to control for yea-saying, *negative* values emerge for all three disclaimer groups for the percentage of respondents believing that FDA had approved Acidux claims. These results indicate that regardless of the disclaimer viewed, the number of respondents believing that FDA had approved Acidux claims was even less than the number that would be expected from yea-saying. Thus, the results strongly suggest that disclaimers can be effective for addressing any consumer misperception regarding the FDA approval status of claims made for homeopathic products.

Table 5
Consumer Perceptions and Take-Away from
Disclaimer Language on Acidux Packaging

	Disclaimer A		Disclaimer B		Disclaimer C	
	n (%)	Net %*	n (%)	Net %*	n (%)	Net %*
FDA APPROVAL						
Yes, believe	25 (16%)	-8%	31 (20%)	-2%	45 (29%)	-1%
No, don't believe	112 (74%)		110 (71%)		100 (65%)	
Don't know	15 (10%)		14 (9%)		9 (6%)	
	152		155		154	
TESTED ON PEOPLE						
Yes, believe	74 (49%)	25%	80 (52%)	30%	83 (54%)	24%
No, don't believe	31 (20%)		29 (19%)		30 (19%)	
Don't know	47 (31%)		46 (30%)		45 (27%)	
	152		155		154	
AMA CERTIFIED						
Yes, believe	36 (24%)		34 (22%)		46 (30%)	
No, don't believe	76 (50%)		77 (50%)		72 (47%)	
Don't know	40 (26%)		44 (28%)		36 (23%)	
	152		155		154	

*Net = percent less "yes" responses to AMA Certified statement

Perception of Tested On People Statement. As noted in Table 5 above, the raw results indicate that between 49% and 54% of the respondents across the three disclaimer groups believed the manufacturer of Acidux had tested the product on people to show that it is effective. After the responses to the AMA Certified statement have been netted out to control for year-saying, only 24% to 30% of respondents across the three disclaimer groups believed Acidux had been tested on people. These results also indicate that consumer perceptions regarding the truth of the Tested on People statement did not vary substantially across the disclaimer groups.

Perception of Meaning of Tested on People Statement. Respondents who believed the Tested on People statement was true were then asked a closed-ended question regarding the meaning of the Tested on People statement. As noted in Table 6, there is no consumer consensus regarding the meaning of the Tested on People statement regardless of the disclaimer viewed. For respondents who reviewed Disclaimer A, the most common response was "Don't know/Not sure" (31.5%), whereas for Disclaimers B and C, the most common response was that the

manufacturer conducted homeopathic studies with humans (39% and 51%, respectively). The fact that Disclaimers B and C included the statement “The uses of our products are based on traditional homeopathic practice” likely contributed to this result. In other words, the reference to “traditional homeopathic practice” may have signaled to consumers that the efficacy of homeopathic products is established through alternative types of testing besides scientifically controlled clinical studies. Nonetheless, only between 8% and 14% of respondents across the three disclaimer groups believed that the “Tested on People” statement meant that the manufacturer had conducted scientifically controlled studies with humans.

Table 6
Meaning of Tested On People Statement

	Disclaimer A	Disclaimer B	Disclaimer C
Manufacturer conducted scientifically controlled studies with humans	6 (8%)	11 (14%)	8 (10%)
Manufacturer conducted at least one study (not necessarily scientifically controlled) with humans	12 (16%)	10 (13%)	7 (8%)
Manufacturer provided product to people and tracked its effectiveness	15 (20.5%)	12 (15%)	11 (13%)
Manufacturer conducted homeopathic studies with humans	15 (20.5%)	31 (39%)	42 (51%)
Don't know/Not sure	23 (31.5%)	15 (19%)	15 (18%)
Other	2 (1%)		
	74*	79*	83*

*Limited to those who said “Yes, Believe” to Tested On People statement

The varied consumer interpretations of the Tested on People statement observed in Study 2 potentially call into question the FTC’s reliance on the Tested on People statement in the Hastak Study. As Table 6 demonstrates, a consumer’s affirmative response to the Tested on People statement does not necessarily mean the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. Rather, it shows that consumers believe the manufacturer conducted homeopathic studies on humans, with different views as to what type of testing on humans was conducted.

Perception of Scientific Support for Product Claims. Respondents who reviewed Disclaimers B or C were asked their understanding of the level of scientific support the manufacturer had for claims made for Acidux, both as an open-ended question and with closed-end responses. As noted in Table 7, approximately one-quarter of respondents seeing Disclaimers B and C indicated they did not interpret the disclaimer as saying or suggesting that the FDA had tested the claims. Rather, they believed either the manufacturer had conducted the tests (in general) or the manufacturer had used “homeopathic practices” (undefined) as the tests.

Table 7
Perception of Level of Scientific Support
Disclaimers B and C
[Verbatim Responses]

	Disclaimer B	Disclaimer C
FDA/Government not test	33 (22.0%)	30 (19.7%)
Manufacturer (not government) test	7 (4.7%)	6 (3.9%)
Homeopathic practices/tests	11 (7.3%)	19 (12.5%)
Natural/Homeopathic/Safe	9 (6.0%)	14 (9.2%)
Unsafe/May not be safe	6 (4.0%)	8 (5.3%)
No scientific support	34 (22.7%)	21 (13.8%)
No tests (general)	3 (2.0%)	10 (6.6%)
Don't know/Not sure/No answer	34 (22.7%)	22 (14.5%)
Miscellaneous	13 (8.7%)	22 (14.5%)
TOTAL	150	152

Additionally, as noted in Table 8, when asked for specifics about the level of scientific support for homeopathic products compared to similar non-homeopathic products, 41% of respondents who reviewed Disclaimer B and 50% of respondents who reviewed Disclaimer C believed that the level of scientific support for Acidux claims was different than the level of scientific support for claims for similar non-homeopathic products. The majority of these respondents (54-57%) then indicated that the level of scientific support is lower than the level for similar non-homeopathic products.

Table 8
Amount of Scientific Support for Product Claims
Disclaimers B & C

Amount of Scientific Support	Disclaimer B	Disclaimer C
Same Level as non-homeopathic products	21 (14%)	24 (16%)
Different Level than non-homeopathic products	63 (41%)	75 (50%)
Higher than non-homeopathic products	--	5 (7%)
Same as non-homeopathic products	21 (33%)	15 (20%)
Lower than non-homeopathic products	34 (54%)	43 (57%)
Don't know/Not sure	8 (13%)	10 (13%)
Other	--	2 (3%)
Don't know/Not sure	59 (39%)	46 (30%)
Other	9 (6%)	6 (4%)
	152	151

Significantly, only 14-16% of respondents believed that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers such as Disclaimers B and C may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.

CONCLUSIONS

The results of Study 1 and Study 2 produce several notable findings that should help inform further research involving the use of disclaimers in the labeling and advertising of homeopathic products. The key takeaways include:

- Less than a quarter of respondents (23.9%) believed that FDA approved claims for homeopathic products, which was the lowest percentage of all product categories tested. More respondents believed that FDA approved claims for other product categories that are not FDA-approved, such as pet foods (38.7%), cosmetics (39.6%), dietary supplements (47.8%), and grocery foods (63.5%). These results call into question the FTC's concern about consumer confusion regarding the FDA approval status of homeopathic products, given that the results show that consumers have a better understanding of the FDA approval status of homeopathic drugs than other product categories.
- After controlling for yea-saying, effectively zero respondents believed that FDA had approved the homeopathic product examined in Study 2, regardless of the disclaimer viewed. This result strongly suggests that disclaimers can be effective for addressing any

potential consumer confusion regarding the FDA approval status of homeopathic products.

- After controlling for yea-saying, 24% to 30% of respondents across the three disclaimer groups believed the homeopathic product examined in Study 2 had been tested on people to show that it is effective. However, there was no consensus among respondents regarding the meaning of the phrase “tested on people.” As Study 2 demonstrates, a consumer’s affirmative response to the Tested On People statement does not mean that the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. In fact, the most common substantive response was the response that claims were supported by homeopathic studies conducted on humans.
- Significantly, only 14-16% of respondents believed when initially asked that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.


Thomas J. Maronick, DBA, JD

Professor of Marketing/Consultant

EXHIBIT 1

**CURRICULUM VITAE
THOMAS JOSEPH MARONICK**

PERSONAL INFORMATION

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FAX (410) 532-2904
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Towson University
Towson, Maryland 21252
(410) 704-4077
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e-mail tmaronick@towson.edu

EDUCATION

Juris Doctor

University of Baltimore School of Law, Baltimore, Maryland
-Emphasis on Corporate/Business and Consumer Law
-Admitted to the Bar, State of Maryland

Doctor of Business Administration

University of Kentucky, Lexington, Kentucky
-Major in Marketing; Minor in Management and Org. Behavior
-Dissertation: "A Multivariate Analysis of Organizational Climate
in the Channel of Distribution"

Master of Science in Business Administration

University of Denver, Denver, Colorado
-Major in Marketing

Bachelor of Arts

St. Thomas Seminary, Kenmore/Seattle, Washington
-Major in Philosophy

ACADEMIC APPOINTMENTS

Professor of Marketing

Towson University College of Business and Economics, Towson, MD, 1987-- Present
-Responsible for teaching courses in Marketing Management,
Marketing Strategy, Marketing Research, Marketing Seminar, Ethics/Public Policy

Associate Professor of Marketing

University of Baltimore School of Business, Baltimore, MD
-Responsible for teaching undergraduate and graduate courses
in Marketing, Marketing Management, Marketing Research,
Consumer Behavior, Business Policy & Strategy, Small Business Strategy

Instructor of Business Administration

Virginia Commonwealth University, Richmond, VA
-Responsible for teaching undergraduate and graduate course in Management

NON-ACADEMIC EMPLOYMENT

Director--Office of Impact Evaluation, Federal Trade Commission 1980 -- 1997

Bureau of Consumer Protection, 1980 -- 87 [Full-time]; 1987 -- 97 [Part-time]
-Served as the FTC's in-house expert on marketing and survey matters.
-Responsible for design and implementation of over 300 marketing and consumer surveys
undertaken by Commission as part of policy-making and litigation activities.
-Provided expert advice/testimony to staff on marketing & consumer behavior issues

potential consumer confusion regarding the FDA approval status of homeopathic products.

- After controlling for yea-saying, 24% to 30% of respondents across the three disclaimer groups believed the homeopathic product examined in Study 2 had been tested on people to show that it is effective. However, there was no consensus among respondents regarding the meaning of the phrase “tested on people.” As Study 2 demonstrates, a consumer’s affirmative response to the Tested On People statement does not mean that the consumer believes scientifically controlled clinical studies with the homeopathic product (or even any clinical studies) have been performed. In fact, the most common substantive response was the response that claims were supported by homeopathic studies conducted on humans.
- Significantly, only 14-16% of respondents believed when initially asked that Acidux was supported by the same level of scientific support as non-homeopathic products. These results suggest that disclaimers may be an effective means to signal to consumers that claims for homeopathic products are not substantiated in the same manner as claims for non-homeopathic products.


Thomas J. Maronick, DBA, JD

Professor of Marketing/Consultant

Marketing Consultant, 1997 -- present

- Provide expert advice/guidance on marketing strategy and consumer research issues as part of litigation support teams for plaintiff and defendant clients
- Serve as testifying expert witness (deposition, hearing, trial) in consumer-related litigation, class-action certification, deceptive advertising, Lanham Act issues cases, consumer survey research
- Have undertaken over 60 survey research projects for clients in litigation-related matters, including advertising and trademark/trade-dress issues

FIELDS OF SPECIAL INTEREST

Marketing Mgt./Strategic Planning
Marketing/Advertising Research
Expert Witness/Lanham Act Matters

Consumer Protection/Public Policy
Executive Development
Class Action Litigation

EXPERT WITNESS/LITIGATION SUPPORT

AREAS:

Class Action Litigation
Marketing/Marketing Practices
Advertising/Deceptive Advertising
Trademark/Trade Dress/Consumer Confusion
Consumer Behavior
Survey Research/Advertising Research/Copy Testing

MATTERS:

Advertising: Made-in-USA
 Automobile claims
Retailing: Pricing
 Advertising
 Warranties
Telecommunications:
 Advertising/Deception
 Marketing/Promotional Materials
 Target Markets
Software/Internet:
 Internet ISP Software Claims
 Internet Domain Name Issues
Package Goods:
 Deceptive Claims in Advertising
 Deceptive Labeling
Direct Marketing:
 Advertising/Promotion
 Target Markets
Trademark/Trade Dress:
 Consumer Confusion
Consumer Surveys:
 Design/Implementation
 Analysis/Critique

WEBSITE: adexpert.net

PAPERS AND PUBLICATIONS

(previous 10 years)

“A Review of Direct-to-Consumer (DTC) Advertising and Sales of Prescription Drugs: Does DTC Advertising Increase Sales and Market Share?@ (with Riva Kahn) Journal of Pharmaceutical Marketing & Management, Vol. 13 (4) (Nov.) 2001.

“Extended Warranties: Consumer Misperceptions of Retailer Claims” Proceedings, European Institute of Retailing and Services Studies, Prague, Czech Republic (July, 2004)

“Celebrity v. Company President as Endorsers of High Risk Products for Elderly Consumers@ Journal of Promotion Management Vol. 11, (4), (Nov.) 2005.

“Impact of a Festival Market on Downtown Shopping Behavior” Proceedings, AMS/Korean AMS CPM Conference, Seoul, Korea (July, 2006)

“Consumer Perceptions of Extended Warranties” Journal of Retail and Consumer Services, Vol. 14 (2) (May) 2007.

“Specialty Retail Center’s Impact on Downtown Shopping, Dining, and Entertainment: A Longitudinal Analysis” International Journal of Retail and Distribution Management, Vol. 35 (7) (November) 2007.

“The Role of the Internet in Survey Research: Guidelines for Researchers and Experts” Proceedings, Global Business and Technology Association Conference, Madrid, Spain (July, 2008).

“Country of Origin – Does It Matter Anymore?” Proceedings, Academy of Marketing Science 2009 World Marketing Congress, Oslo, Norway (July, 2009)

“The Role of the Internet in Survey Research: Guidelines for Researchers and Experts” Journal of Global Business and Technology, Vol. 5 (1), (Spring, 2009).

“Pitting the Mall and the Internet in Advertising-Research Competition” Journal of Advertising Research. Vol. 51 (1) (March, 2011).

“Do Consumers Read Terms of Service Agreements When Installing Software – An Empirical Analysis” Proceedings, Athens Institute for Educational Research, Athens, Greece (July, 2011)

“Do Consumers Read Terms of Service Agreements When Installing Software – A Two-Study Empirical Analysis” International Journal of Business and Social Research Vol. 4 (4) (June, 2014)

EXHIBIT 2

AAHP-2
(3)

▼ Screener Block Block Options ▼

Q1
▼

Thank you for responding to this very short survey. If you are not sure of an answer, please indicate "Don't know/Not sure." Please do not guess.

< _____ >

Page Break

Q2
▼

Which of the following products, if any, have you purchased for yourself or a member of your family in the last 12 months? [CHECK ALL THAT APPLY]

- A product to relieve cold symptoms for a child aged 2 - 12
- A product to relieve pain
- A product to relieve flu symptoms
- A product to relieve heartburn
- None of the above

< _____ >

If None of the above is Selected, Then Skip To End of Survey

Page Break

Q3
▼

Do you or does anyone in your household work...[CHECK ALL THAT APPLY]

- In marketing research
- In advertising or public relations
- For a grocery store or drug store
- For a drug or pharmaceutical company
- None of the above

< _____ >

If None of the above is Not Selected, Then Skip To End of Survey

Page Break

Q4

Are you...

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55 or older



Page Break

Q5

Which of the following claims, if any, have to be approved by the Food and Drug Administration (FDA)?

	Definitely are approved by the FDA	Are Approved by the FDA	Are not approved by the FDA	Definitely are not approved by the FDA	Don't know/Not sure
Labeling claims made for prescription drugs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for dietary supplements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for cosmetics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for grocery food products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for pet foods	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims made for homeopathic products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims for over-the-counter medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Labeling claims for other products (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Page Break

Q6

Gender?

- Male
- Female



Page Break

Q7

Education?

- High school or less
- Some college/technical school
- 2-Yr College degree
- 4-Yr College degree
- Graduate school/degree



Page Break

Q8

How often, if at all, do you buy homeopathic products for yourself or members of your family?

- Never
- Seldom
- Occasionally
- Frequently
- Always
- Don't know/Not sure



EXHIBIT 3

AAHP-1
(D)

▼ Screener Block

Block Options ▼

Q1

Thank you for responding to this very short survey. There are no "right answers." If you're not sure of an answer, please indicate "Don't know/Not sure." Please do not guess.



Page Break

Q2

Which of the following products, if any, have you purchased for yourself or a member of your family in the last 12 months?
[CHECK ALL THAT APPLY]

- A product to relieve cold symptoms for a child aged 2 - 12
- A product to relieve pain
- A product to relieve flu symptoms
- A product to relieve heartburn
- None of the above



If A product to relieve heartburn Is Not Selected, Then Skip To End of Survey

Page Break

Q3

Do you or does anyone in your household work...[CHECK ALL THAT APPLY]

- In marketing research
- In advertising or public relations
- For a grocery store or drug store
- For a drug or pharmaceutical company
- None of the above



If None of the above Is Not Selected, Then Skip To End of Survey

Page Break

Q4

Are you...

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55 or older

Page Break

Block 1

Block Options

Q5

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.

Page Break

Q6

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nuxvomica 4C HPUS	Relieves heartburn due to excessive eating and drinking
<small>The letters HPUS indicate that this ingredient is officially recognized in the Homeopathic Pharmacopoeia of the United States.</small>	
Uses* temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.	
Warnings	
Ask a doctor before use in children under 12 years of age.	
Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly.	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children.	
Directions * Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.	
* Children under 12 years of age: Ask a doctor.	
Other information * do not use if glued caps and flaps are open or if the blister seal is broken *	
Inactive ingredients	

Acidux

Drug Facts (continued)

Questions or comments?

1-800-666-0000

Company
20 Central Avenue
Any Town, USA
10999-9999

INDIGESTION
Heartburn • Bloating
Upset Stomach
Acid Indigestion*

Acidux

HOMEOPATHIC MEDICINE

*These statements have not been reviewed by the Food and Drug Administration.

Page Break

Q7

What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]

Text input field for user response.

Page Break

Q8

What, if anything, does the package say or suggest about testing done for/on this product? (PLEASE SPECIFY)

Empty text input field for Q8 response.



Page Break

Q9

Here is the back panel of the package. Note the highlighted statement at the bottom of the panel

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nux vomica 4C HPUS	Relieves heartburn due to excessive eating and drinking
<small>(contains less than 10* mg alkaloids per dose)</small>	
<small>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small>	
Uses* ■ temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach	
Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. ■ Children under 12 years of age: Ask a doctor.	
Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■	
Inactive ingredients ▶	

* These statements have not been reviewed by the Food and Drug Administration.



Page Break

Q10

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.

Empty text input field for Q10 response.



Page Break

Q11

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [Select one answer]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure

< _____ >

Page Break

Q12

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure

< _____ >

Page Break

Q13

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure

< _____ >

Page Break

Q14

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** Is Selected

What, if anything, does the statement that "These statements have not been reviewed by the Food and Drug Administration say or suggest about the type of testing the manufacturer of this product may have done? [PLEASE SPECIFY]

< _____ >

Page Break

Q15

Which of the following statements, if any, is reflective of your understanding of what "These statements have not been reviewed by the Food and Drug Administration" say or suggest about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)

Block 2

Block Options

Q16

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.

Page Break

Q17

<p>Drug Facts</p> <p>Active ingredients* Purpose* Carbo vegetabilis 4G HPLUS Relieves stomach bloating with gas Nuxvomica 1G HPLUS Relieves heartburn due to excessive eating and drinking (contains less than 10 mg alkaloids per dose)</p> <p><small>The letters HPLUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small></p> <p>Uses* Temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.</p> <p>Warnings Ask a doctor before use in children under 12 years of age. Stop use and ask a doctor if symptoms persist continuously for more than 3 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>Directions* Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved. *Children under 12 years of age: Ask a doctor.</p> <p>Other information* do not use if glued carton end flaps are open or if the blister seal is broken.</p> <p>Inactive ingredients</p>	<p>Acidux</p> <p>INDIGESTION</p> <p>Heartburn • Bloating Upset Stomach Acid Indigestion*</p> <p>Acidux</p> <p>HOMEOPATHIC MEDICINE</p> <p>Drug Facts (continued) Questions or comments? 1-800-600-0000 Company 37 Central Avenue Any Town, USA 10000-0000</p>
--	--

*The uses for our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Page Break

Q18

What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]

Page Break

Q19

What, if anything, does the package say or suggest about the testing done for/on this product? [PLEASE SPECIFY]

Empty text input field for Q19 response.

< >

Page Break

Q20

Here is the back panel of the package again. Note the highlighted statement at the bottom of the panel.

Drug Facts

Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nux vomica 4C HPUS (contains less than 1.0 mg alkaloids per dose)	Relieves heartburn due to excessive eating and drinking

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

Uses* ■ temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach

Warnings
 Ask a doctor before use in children under 12 years of age.
 Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children.

Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.
 ■ Children under 12 years of age: Ask a doctor.

Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■

Inactive ingredients ▶

*The uses for our products are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

< >

Page Break

Q21

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.

< >

Page Break

Q22

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q23

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q24

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q25

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** is **Selected**

Which of the following statements, if any, is reflective of your understanding of what "The uses of this product are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration" says or suggests about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)



Page Break

Q26

What, if anything, does a statement that says "The uses of this product are based on traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration" say or suggest about the scientific support the manufacturer of this product may have for the uses of the product? [PLEASE SPECIFY]



Page Break

Q27

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify



If The uses of this homeopathi... Is Not Selected, Then Skip To End of Block

Page Break

Q28

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The manufacturer of this homeopathic product has a HIGHER LEVEL of scientific support for the uses of the product as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The manufacturer of this homeopathic product has the SAME LEVEL of scientific support for the uses of the product as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- The manufacturer of this homeopathic product has a LOWER LEVEL of scientific support for the uses of the product than a manufacturer of s similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify



Page Break

Block 3

Block Options

Q29

Assume that you are in your local drugstore or grocery store to purchase a product for yourself or a member of your family who is not feeling well. One of the products that you see on the shelf is the product on the screen that follows. Please look at it as you normally would.



Page Break

Q30



Drug Facts

Active ingredients*	Purpose†
Carno vegetabilis AC HPUS	Relieves stomach bloating with gas
Nux vomica AC HPUS	Relieves heartburn due to excessive eating and drinking

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

Uses* •temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach.

Warnings
 Ask a doctor before use in children under 12 years of age.
Stop use and ask a doctor if symptoms persist more than 14 days or more than 7 days in women if you have trouble swallowing or persistent abdominal pain. See your doctor promptly.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children.

Directions • Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.
 • Children under 12 years of age: Ask a doctor.

Other information •do not use if glued carton and tabs are open or if the blister seal is broken.

Inactive ingredients

INDIGESTION
Acidux

Drug Facts
(continued)
Questions or comments?
1-800-860-0089

Company
15 Central Avenue
Apt 1100m, USA
1000-0000



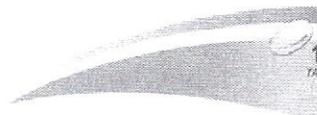
NDC 0800

INDIGESTION

Heartburn • Bloating
Upset Stomach
Acid Indigestion*

Acidux®

HOMEOPATHIC MEDICINE



*The uses for our products are based on traditional homeopathic practice. (See www.Homeopathy.org.) They have not been reviewed by the Food and Drug Administration.



Page Break

Q31



What, if anything, does the package say or suggest about the uses of this product? [PLEASE SPECIFY]



Page Break

Q32



What, if anything, does the package say or suggest about testing done for/on this product? [PLEASE SPECIFY]



Page Break

Q33

Here's the back panel of the package again. Note the highlighted statement at the bottom of the panel.

Drug Facts	
Active ingredients**	Purpose*
Carbo vegetabilis 4C HPUS	Relieves stomach bloating with gas
Nuxvomica 4C HPUS	Relieves heartburn due to excessive eating and drinking (contains less than 10 ¹ mg alkaloids per dose)
<i>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</i>	
Uses* temporarily relieves occasional heartburn, acid indigestion, bloating or upset stomach	
Warnings	
Ask a doctor before use in children under 12 years of age.	
Stop use and ask a doctor if symptoms persist continuously for more than 7 days or worsen. If you have trouble swallowing or persistent abdominal pain, see your doctor promptly.	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children.	
Directions ■ Adults and children 12 years of age and older: At the onset of symptoms, dissolve 2 tablets under the tongue every 15 minutes for 1 hour. If necessary, dissolve 2 tablets under the tongue 15 minutes before meals until symptoms are relieved.	
■ Children under 12 years of age: Ask a doctor.	
Other information ■ do not use if glued carton end flaps are open or if the blister seal is broken ■	
Inactive ingredients	

*The uses for our products are based on traditional homeopathic practice. (See www.Homeopathy.org.) They have not been reviewed by the Food and Drug Administration.

< Page Break >

Q34

Below are three statements about Acidux. All, some, or none of these statements may be true. Please look at each statement and indicate if you believe the statement is true, you believe it is not true, or you don't know or are not sure.

< Page Break >

Q35

A government agency like the Food and Drug Administration (FDA) has approved Acidux as being effective for relieving symptoms associated with heartburn, bloating, or upset stomach? [Select one answer]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure

< Page Break >

Q36

The manufacturer of Acidux has tested this product on people to show that it's effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q37

The American Medical Association (AMA) has certified that Acidux is effective in relieving the symptoms associated with heartburn, bloating, upset stomach? [SELECT ONE ANSWER]

- Yes, I believe this statement is true
- No, I don't believe this statement is true
- I don't know/am not sure



Page Break

Q38

Display This Question:

If The manufacturer of Acidux has tested this product on people to show that it's effective in relie... **Yes, I believe this statement is true** is Selected

Which of the following statements, if any, is reflective of your understanding of what "The uses of this product are based on traditional homeopathic practice. (See www.homeopathy.org). They have not been reviewed by the Food and Drug Administration, says or suggests about the testing the manufacturer of this product may have done? [SELECT ONE ANSWER]

- The manufacturer conducted scientifically controlled studies with human subjects to determine the product is effective
- The manufacturer conducted at least one study (not necessarily a scientifically controlled study) with human subjects to determine the product is effective
- The manufacturer provided the product to people and tracked its effectiveness but did not conduct any clinical studies
- The manufacturer conducted homeopathic studies on the product with human subjects to determine the product's effectiveness
- Don't know/Not sure how to interpret the statement
- Other (Specify)



Page Break

Q39

What, if anything, does a statement that says "The uses of this product are based on traditional homeopathic practice. (see www.homeopathy.org). They have not been reviewed by the Food and Drug Administration," say or suggest about the scientific support the manufacturer of this product may have for the uses of this product? [PLEASE SPECIFY]



Page Break

Q40

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The uses of this homeopathic product are supported by the SAME level of scientific support as a manufacturer of similar non-homeopathic products have for the uses of its product.
- The uses of this homeopathic product are supported by a DIFFERENT level of scientific support as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify

If The uses of this homeopathi... Is Not Selected, Then Skip To End of Block

Page Break

Q41

Which of the following, if any, reflects your understanding of what "The uses of this product are based on traditional homeopathic practice" says or suggests about the amount of scientific support the manufacturer has for the uses of this product?

- The manufacturer of this homeopathic product has a HIGHER LEVEL of scientific support for the uses of the product than a manufacturer of similar non-homeopathic products has for the uses of its product.
- The manufacturer of this homeopathic product has the SAME LEVEL of scientific support for the uses of the product as a manufacturer of a similar non-homeopathic product has for the uses of its product.
- The manufacturer of this homeopathic product has a LOWER LEVEL of scientific support for the uses of the product than a manufacturer of s similar non-homeopathic product has for the uses of its product.
- Don't know/Not sure
- Other/Specify

Page Break

Demographics

Block Options

Q42

Gender?

- Male
- Female

Page Break

Q43

Education?

- High school or less
- Some college/technical school
- 2-Yr college degree
- 4-Yr college degree
- Graduate school/degree



Page Break

Q44

In what state do you currently reside?

Alabama



Page Break

Q45

How often, if at all, do you buy homeopathic products for yourself or members of your family?

- Never
- Seldom
- Occasionally
- Frequently
- Always
- Don't know/Not sure

