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Examining Advertising for Over-the-Counter Homeopathic Products

Comments of the Center for Inquiry and Richard Dawkins Foundation for Reason and Science

Re: Homeopathic Medicine & Advertising Workshop (9/21/2015)

The Center for Inquiry (CFI) is an educational and advocacy organization that promotes reason and scientific integrity in public affairs. Our comments are submitted not only on behalf of our organization, its employees, and its members, but also on behalf of dozens of doctors and scientists associated with CFI and its affiliate program, the Committee for Skeptical Inquiry, with whom we work on these matters.

Our comments are being filed in conjunction with the Richard Dawkins Foundation for Reason and Science (RDF), a non-profit organization that promotes scientific literacy and a secular worldview. Neither CFI nor RDF has any financial interests relevant to this issue.

We applaud the Federal Trade Commission (FTC) for its decision to examine the issue of homeopathy and public safety. In particular, we applaud the FTC for its comments to the Food and Drug Administration (FDA) earlier this year, which expressed significant concerns about conflicts between the FDA's regulatory framework and the FTC's advertising substantiation policy. We agree that a conflict exists, and that this conflict results in confusion for, and harm to, the American public.

In these comments, we will briefly review the scientific evidence and analysis that show homeopathy is a pseudoscientific regimen ineffective at treating illnesses; illustrate the harm caused by a reliance on homeopathy instead of actual medicine; assess changes in the homeopathic market; analyze the relevance of class actions against homeopathic product companies; and propose actions the FTC should take to hold homeopathic products to the same standards as non-homeopathic drugs in order to fulfill its mandate to protect the American public.

Our comments will emphasize the importance of requiring that homeopathic products, like other over-the-counter products, justify health claims made in their advertising. Currently, the FDA allows homeopathic products to be marketed without requiring these products to undergo the same testing for effectiveness required of conventional drugs. Meanwhile, homeopathic products continue to claim in their advertising that they are safe and effective. We believe this situation must change, and that the FTC can play an important role in achieving change.

I. The Empirical Evidence and Homeopathy's Foundation

We could spend the entirety of our comments discussing the extensive, decades-long scientific examination of homeopathy, but suffice it to say the empirical evidence against homeopathy is

overwhelming: aside from a placebo effect, homeopathic products have no effect in treating illnesses.

Consider the most recent findings, which were released earlier this year by the Australian National Health and Medical Research Council (NHMRC). This group conducted a meta-study thoroughly assessing *more than 1,800 papers* on homeopathy, 225 of which met the criteria for inclusion. As the NHMRC stated upon release of its analysis:

> The review found no good quality, well-designed studies with enough participants to support the idea that homeopathy works better than a placebo, or causes health improvements equal to those of another treatment. Although some studies did report that homeopathy was effective, the quality of those studies was assessed as being small and/or of poor quality. These studies had either too few participants, poor design, poor conduct and or reporting to allow reliable conclusions to be drawn on the effectiveness of homeopathy.[1]

Proponents of homeopathy often suggest there are studies that show homeopathy is effective. As this analysis shows, one can find studies that suggest homeopathy has brought about a positive result. However, these studies have found only a *placebo* effect, and significantly do not, and cannot, explain *if* and *how* the particular methods of homeopathy have themselves treated the illness. Further, these studies must be seen within the broader context of hundreds of studies that have found homeopathy ineffective. The truth, as the NHMRC review states, is that "There are no health conditions for which there is reliable evidence that homeopathy is effective."

Importantly, these empirical findings on homeopathy have been recognized by the federal government. As the National Center for Complementary and Integrative Medicine states on its website:

> There is little evidence to support homeopathy as an effective treatment for any specific condition.[2]

Perhaps even more importantly, the FDA has also recognized that homeopathy is not effective, in part through its numerous warnings to consumers about the health risks of relying on homeopathic products to treat serious medical conditions. This includes, to cite a recent example, the FDA's March 19, 2015 warning against using homeopathic products that claim to treat asthma, an often life-threatening condition.[3] But it also includes the nearly 40 warning notices the FDA has sent to homeopathic manufacturers, as well as three recalls the FDA has overseen, since 2009.[4]

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[1] "NHMRC releases statement and advice on homeopathy." *NHMRC*. March 11, 2015. http://www.nhmrc.gov.au/media/releases/2015/nhmrc-releases-statement-and-advice-homeopathy

[2] "Homeopathy: An Introduction." *NCCIH*. https://nccih.nih.gov/health/homeopathy

[3] "Over-the-Counter Asthma Products Labeled as Homeopathic: FDA Statement - Consumer Warning About Potential Health Risks." *FDA*. March 19, 2015. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439014.htm; also see: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm230764.htm

[4] "The FDA Might Finally Crack Down on Homeopathy." *Bloomberg*. April 20, 2015. http://www.bloomberg.com/news/articles/2015-04-20/the-fda-might-finally-crack-down-on-homeopathy

These empirical findings and subsequent warnings are not, and should not be, at all surprising: by its own definition, homeopathy *cannot* work. Developed in the late eighteenth century, long before the advent of modern medicine and science, and the understanding of the role of pathogens in causing disease, homeopathy is a wholly pre-scientific ideology based on several pseudoscientific assumptions:

- The "law of similars" or "let likes be cured by likes." This is the belief that a medical condition can in fact be treated by administering a diluted form of a substance known to cause it.

- The "law of infinitesimal doses." This is the belief that that the more one dilutes an ingredient, the more powerful it becomes. As a result, many homeopathic remedies are diluted beyond Avogadro's Number, the point at which the final product likely no longer contains a molecule of the supposed remedy.

- "Essence" and "water memory." The beliefs that substances added to water impart their "essence" onto the water molecules themselves, and that water retains a "memory" of things that have been in previous contact with it. This entirely unsubstantiated supposition is the creation of homeopaths who recognize the difficulty of reconciling the technique of extreme dilution with the laws of chemistry. So, although a finished homeopathic solution may no longer contain any molecules of the actual supposed remedy, homeopaths contend that the water maintains its power.

- "Miasm theory" and "vital force/vital principle theory." The hypotheses that all diseases are caused by one of three offending "miasms"—*psora*, *syphilis*, and *sycosis*—which disrupt the "vital force" at the core of a human being. As a system of vitalism, homeopathic remedies are meant to address these miasms.

- "The law of susceptibility." The hypothesis that negative thinking can attract said miasms and lead to illness.

These centuries-old pseudoscientific principles, among others at the core of homeopathy, are not just unsupported by evidence — they sit at complete odds with our modern understanding of biology, chemistry, and physics, the bodies of accepted scientific knowledge that form the basis of modern medicine.

II. The Harm Caused by Homeopathy

Despite overwhelming empirical evidence to the contrary, and a lack of reason in support of homeopathic claims, companies persist in marketing homeopathic products as drugs that can effectively treat illnesses, and consumers continue to spend billions of dollars each year mistakenly believing that these products will help them.

The harm caused to the American public is not solely economic — although the importance of this should not be dismissed given the scarce resources many consumers have for health care expenditures. Reliance on ineffective drugs can pose serious risks to a person's health. In short,

too many people often rely on homeopathic products to the exclusion of proven scientific remedies. As the NHMRC study states:

> People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness.

The website *What's the Harm* details many such cases.[5] We will highlight just a few key cases that illustrate our points.

> **Lucille Craven** of New Hampshire was diagnosed in 1997 with a small, pea-sized carcinomatous breast tumor. Although her doctor recommended mastectomy and lymphectomy, Lucille treated her cancer with homeopathy. She died less than 36 months later.[6]
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> **Diane Picha** of Wisconsin was diagnosed in late 1998 with lung cancer. After successful surgery to remove her tumor, her cancer grew back. Picha visited a homeopathic clinic, where she was advised to halt further medical treatments. She died in April 2000.[7]
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> **Katie Ross** of Nevada was diagnosed with ulcerative colitis; doctors recommended she have her colon removed. Her mother instead pursued homeopathic treatments. Katie dwindled from 90 to 50 pounds and nearly died when her colon perforated, but survived when her mother finally approved surgery at the doctor's pleading.[8]
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> **Isabella Denley** of Melbourne, Australia, was an epileptic toddler prescribed anti-convulsant medication by her neurologist. Her parents, however, treated her with exclusively homeopathic products. She died at just 13 months old.[9]

These examples exemplify the public's lack of knowledge regarding homeopathy, the danger of homeopathic products, and the crucial need for the federal government, and in particular the FTC, to take an active approach in ensuring the public is presented with accurate information about homeopathy.

III. The Homeopathic Market and American Consumers

There has been tremendous growth in the sale of homeopathic products in recent years. One study found that Americans spent roughly $2.9 billion on homeopathic products and treatments in 2007,

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[5] What's the Harm. http://whatstheharm.net/homeopathy.html

[6] "My Wife's Death from Cancer." *Quackwatch*. February 27, 2002. http://www.quackwatch.org/01QuackeryRelatedTopics/Victims/craven.html

[7] "Woman files suit against homeopathic business." *Milwaukee Journal Sentinel*. June 15, 2001. https://news.google.com/newspapers?nid=1683&dat=20010615&id=GsAaAAAAIBAJ&sjid=XjAEAAAAIBAJ&pg=6844,4774757&hl=en

[8] "Doctors back Ohrenschall on treatment" *Las Vegas Sun*. Feb. 12, 1998. http://lasvegassun.com/news/1998/feb/12/doctors-back-ohrenschall-on-treatment/

[9] "Inquest told parents 'rejected advice'" *The Age*. November 26, 2003. http://www.theage.com.au/articles/2003/11/25/1069522605256.html

and an additional $170 million on visits to homeopathic practitioners.[10] More recent research estimates that retail sales of homeopathic and similar remedies in the United States had reached $6.4 billion in 2012, up nearly three percent from 2011. Overall, the homeopathic market grew 16 percent between 2008 and 2013. The group that conducted this research, Mintel, forecasted that demand would continue to increase over the next few years, and predicted that by 2017 sales would reach $7.5 billion, in part because the availability of such products would increase with the spread and growth of mass retailers.[11]

Despite this growth, it is clear that consumers on the whole lack basic knowledge on homeopathy. In late 2010, the FTC partnered with Shugoll Research with the objective to gauge consumer understanding of conventional and non-conventional medicines, including homeopathic products.[12] As detailed in the FTC's compelling comments to the FDA, while many adults and parents were able to differentiate conventional products from non-conventional products such as homeopathy, most were unable to differentiate between the federal regulatory and evidentiary requirements for these different kinds of products.[13] In fact, many adults and parents mistakenly believed that the FDA, or else manufacturers themselves, tested homeopathic products for efficacy, which is not the case.

To make matters worse, the focus group illustrated that many adults and parents do not understand the pseudoscientific principles behind homeopathic products. When the principles were first explained to adults and parents, they found these principles confusing. Further explanation led most adults and parents to question the nature and effectiveness of homeopathic products.

However, these results show that many adults and parents who choose to purchase homeopathic products are doing so based on incorrect or incomplete information. It also suggests that if the public were more aware of the principles underlying homeopathic products and their lack of meaningful regulation, they would look at such products more critically and possibly avoid them altogether.

IV. Class Actions Against Homeopathic Companies

The class action system plays an important role in the regulation of homeopathic labeling and advertising, just as it plays an important role in the system of regulating science-based medicine. Class action lawsuits, however, are a complementary remedy; they do not replace the need for government agencies to fulfill their mandate to protect consumers from false or misleading advertising and confusing labeling.

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[10] Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007. *National Health Statistics Report*. http://www.cdc.gov/nchs/data/nhsr/nhsr018.pdf

[11] "Homeopathic and Herbal Remedies - US - March 2013" *Mintel*. March 2013. http://store.mintel.com/homeopathic-and-herbal-remedies-us-march-2013

[12] Shugoll Research, Homeopathy Focus Groups Report (January 2011)

[13] "FTC Staff Comment Before the Food and Drug Administration Regarding the Current Use of Human Drug and Biological Products Labeled As Homeopathic, and the FDA's Regulatory Framework For Such Products." Federal Trade Commission. August 21, 2015. https://www.ftc.gov/policy/policy-actions/advocacy-filings/2015/08/ftc-staff-comment-food-drug-administration-regarding

In recent years, there have been a series of class action lawsuits brought against the manufacturers of homeopathic products. Most notably, the French homeopathic manufacturer Boiron was sued under California law challenging the labeling practices and overall efficacy of homeopathic treatments such as Oscillo (claimed to be a flu remedy). Boiron, a company with 2014 sales of nearly €610 million (approximately $670 million), agreed to settle the suit.[14] As part of the settlement, Boiron will pay users of its products $5 million, as well as make significant changes to its labeling practices, including a statement that "[t]hese Uses have not been evaluated by the Food and Drug Administration" and an explanation of homeopathic dilutions.[15] Current lawsuits include one against Hyland's Inc., makers of homeopathic treatments for cold and flu, such as Sniffles 'n Sneezes 4 Kids.[16] In January of 2015, the United States District Court for the Central District of California denied summary judgment to the defendants, allowing the case to proceed.[17]

But although such court cases have resulted in some changes in the way some homeopathic products are marketed, litigation does not negate the role of federal agencies in regulating homeopathic advertising and labeling. As the court system has made clear, the existence of regulation in one form does not prevent regulation in another. For example, Congress has given both the FDA and the FTC powers to regulate in similar areas, in order to address different interests. *See, e.g. POM Wonderful LLC v. Coca Cola Co.*, 134 S. Ct. 2228 (2014) (rejecting Coca Cola's argument that regulation of labeling under the Food, Drug, and Cosmetic Act precluded plaintiff filing a Lanham Act lawsuit alleging false advertising based on its labels).

Class action lawsuits serve a different function than regulation of advertising by the FTC, and therefore cannot replace such regulation. The purpose of a lawsuit is to remedy a harm that has already occurred, and the primary focus of the suit is to obtain compensation. In these cases, individuals who purchased homeopathic products are seeking to have their money returned to them. While plaintiffs may request an injunction against the manufacturer continuing with false advertising and misleading labeling, such a remedy may be unavailable. *See Allen v. Similasan Corp.*, 2013 U.S. Dist. LEXIS 69369 (S.D. Cal. May 14, 2013) (rejecting a claim for an injunction as plaintiffs were unlikely to buy a product again if they felt it was useless, and so were not susceptible to repeated harm).

The FTC on the other hand, is tasked with acting *before* harm is caused. The purpose of regulation by the FTC is to prevent false advertising, and thus to protect the consumer from harm, rather than the retrospective view of the court, which merely compensates those who have suffered harm.

Moreover, the interests of the FTC and those of class action plaintiffs necessarily differ. The plaintiffs in a lawsuit represent only themselves. Indeed, lawyers representing a class are bound by their ethics to secure the best possible result for the class of plaintiffs, whether through a ruling at trial or, more often, through a settlement. The FTC, on the other hand, is tasked by Congress

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[14] Boiron 2104 Financial Report, *available at* http://www.boironfinance.com/Shareholders-and-investors-area/Financial-information/Regulated-information/Financial-statements.

[15] http://www.gilardi.com/boironsettlement/pdf/BRGL_SettlementAgreement.pdf

[16] *Forcellati v. Hyland's Inc.*, Case no. 2:12-CV-01983 GHK, *available at* http://hylandslawsuit.com/pdf/complaint.pdf

[17] *Forcellati v. Hyland's Inc.*, 2015 U.S. Dist. LEXIS 3867 (C.D. Cal. January 12, 2105)

with the protection of the people. Its mission is "[t]o prevent business practices that are anticompetitive or deceptive or unfair to consumers."[18] In any enforcement action against a homeopathic manufacturer, or in the design of regulations to restrict the claims that may be made on homeopathic labels, the FTC is in a unique position to protect the interests of all consumers and potential consumers. By its nature, a class action lawsuit can consider only the interests of the plaintiffs involved.

Finally, FTC regulation, and enforcement actions against those who violate its regulations, are advantaged over private class actions as regards the burden of proof. A private plaintiff is required to demonstrate that the claims made by a homeopathic manufacturer are false; the FTC, on the other hand, may require that a manufacturer provides substantiation of its claims. This burden on a class plaintiff should not be underestimated, and the regulatory authority of the FTC places it in a much more favorable situation to ensure homeopathic advertising is fair and accurate. *National Council Against Health Care Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Ca;. App. 4th 1136 (Cal. App. 2003).

V. The Basis for the Regulation of Homeopathic Products

It is clear that class action lawsuits cannot serve as a substitute for sound government regulation of homeopathic products. Fortunately, the public has federal agencies such as the FDA and FTC tasked with protecting it from false advertising and harmful products and remedies.

Under the Food, Drug, and Cosmetic Act (FD&C), all drug products must be shown to be safe and effective. However, as explained in part by guidance it has released over the years, the FDA has chosen to exempt homeopathic products from these requirements if they meet certain conditions, such as compliance with the Homeopathic Pharmacopeia and labeling products, which provides directions for their use.

In its comments to the FDA, CFI urged the Agency to reverse course:

> To ensure the protection of the American public, we believe the FDA should rely on its well established regulatory system to require homeopathic products to meet the same safety and efficacy standards as conventional drugs. That said, we recognize there are practical and political barriers to mandating this requirement.
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> However, no such obstacles prevent the FDA from mandating that homeopathic products carry truthful, informative labeling. We propose that the FDA require homeopathic products to carry a prominent warning that they have not been evaluated by the FDA for safety or effectiveness. In addition, the product's labeling should disclose the product's active ingredients in plain English, using standard scientific measurements.[19]

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[18] https://www.ftc.gov/about-ftc

[19] "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century" Center for Inquiry. August 21, 2015. http://www.centerforinquiry.net/docs/opp/CFI_FDA_HomeopathyComments_AUG2015.pdf

So far, there has been no indication that the FDA will choose either of these options (mandatory, scientifically reliable testing or appropriate labels with prominent warnings). In any event, the FTC has independent authority over advertising of homeopathic products, and we urge the FTC to exercise its authority to protect consumers from false and misleading claims relating to homeopathic products.

As the Agency is aware, Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce — including in the advertising of over-the-counter drugs.[20] Relatedly, Section 12 prohibits the dissemination of false advertisements in or affecting commerce of food, drugs, devices, services, or cosmetics.[21]

Homeopathic products clearly fall within these parameters. Homeopathic products are consistently advertised as both effective and safe in addressing a range of health conditions. Yet, as empirical study has illustrated decisively and repeatedly, these claims are false. As the NHMRC studied concluded, "There are no health conditions for which there is reliable evidence that homeopathy is effective." And while some homeopathic products may not pose an inherent danger, their use puts the American public at risk, insofar as they rely on homeopathic products instead of seeking proven, scientific remedies. Accordingly, there can be no meaningful dispute that the health claims made for homeopathic products are not substantiated by competent and reliable scientific evidence, as required by FTC regulations.

VI. Recommendations

Homeopathy is unsupported by scientific evidence, proven to be ineffective at treating illness and, when relied upon instead of actual medicine, dangerous and even deadly. Likewise, the promotion of homeopathic products as safe and effective is clearly false and deceptive. Moreover, claims regarding the indicated use of homeopathic products are unsubstantiated as they are not supported by competent and reliable scientific evidence.

The only real question for the FTC is not whether advertising for homeopathic products violates Sections 5 and 12 of the FTC Act, but whether the FTC needs to refrain from exercising its enforcement authority to prevent a possible conflict with FDA's regulations. We submit such restraint is neither necessary nor appropriate. It is not appropriate because the FTC has an independent mandate to protect the American public from false advertising claims. It is not necessary because although FTC enforcement of its standards for substantiation of health claims may well prevent homeopathic manufacturers and retailers from relying on current advertising strategies, it would not directly interfere with FDA jurisdiction over the actual sale of such products to the public.

Granted, the FDA currently requires homeopathic manufacturers to provide an indication for use on their labeling if they want to benefit from the FDA's policy of discretionary non-enforcement of regulations requiring a showing of safety and effectiveness. But the FDA can eliminate this labeling requirement as a part of its discretionary non-enforcement policy—or better still, the

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

[21] Federal Trade Commission Act, 15 U.S.C. § 52

FDA could require homeopathic manufacturers to substantiate their claims of indicated use by competent and reliable evidence. Such a position could have an adverse effect on the sales of homeopathic products, but the mandate of both the FDA and the FTC is to protect the American public, not to safeguard the sales of relics from the cabinets of eighteenth century medicine.

For the foregoing reasons, we recommend that the FTC use its power, as outlined in Sections 5 and 12 of the FTC Act, to ensure that homeopathic products on the market do not make advertising claims of safety or effectiveness in treating any health conditions unless the manufacturers of those products can support those claims with sound scientific evidence.

Respectfully submitted,

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