

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave., N.W., Room CC-5610
Washington, D.C. 20580

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Homeopathic Medicine & Advertising)
Workshop (September 21, 2015))
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COMMENTS OF THE SENIOR CITIZENS LEAGUE
(November 20, 2015)

The Senior Citizens League (“TSCL”), through its undersigned counsel, submits the following comments pursuant to the FTC’s invitation for comments related to its September 21, 2015 workshop on homeopathic medicine and advertising.¹ These comments relate to the FTC’s consideration of “changes in the homeopathic market, its advertising, and what consumers know,” “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.”²

TSCL is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquartered in Alexandria, Virginia, is known as one of the largest U.S. organizations engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has nearly 1 million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens’ rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

¹ <https://ftcpublishcommentworks.com/ftc/homeopathyworkshop/>

² FTC June 1, 2015 Press Release, <https://www.ftc.gov/news-events/press-releases/2015/06/ftc-host-september-workshop-washington-dc-examine-advertising>

TSCL has advocated its views on various senior health issues to the U.S. Supreme Court and the FDA in the past, including the following submissions and matters:

- [Comments](#) on FDA Draft Guidance for Industry on Complementary and Alternative Medicine Products (May 29, 2007);
- [Comments](#) on FDA Draft Guidance for Industry on Evidence-Based Review System for the Scientific Evaluation of Health Claims (September 7, 2007);
- [Amicus Curiae Brief](#) to the Supreme Court in support of Petition for Certiorari in *Abigail Alliance v. VonEschenbach* (December 13, 2007);
- [Comments](#) on Report of the Subcommittee on Science and Technology, “FDA Science and Mission at Risk” (February 4, 2008);
- [Amicus Curiae Brief](#) to the Supreme Court in *Wyeth v. Levine* (August 14, 2008);
- TSCL Executive Director Shannon Benton statement at the [Transparency Public Meeting](#) on June 24, 2009;
- Comments to the FDA in its pending rulemaking on “Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century,” Docket No. FDA-2015-N-0540 (August 21, 2015); and
- Various Freedom of Information Act requests to the FDA.

TSCL’s members and supporters, as well as all Americans, have a vital interest in ensuring that the Food and Drug Administration’s current homeopathic product regulatory framework (Compliance Policy Guide 400.400) is not disturbed so as to make homeopathy less accessible, by impairing in any way continued public access to homeopathic remedies. Indeed, TSCL and its supporters are greatly concerned about the impact of all government policies and practices diminishing access to complementary and alternative medicine, including homeopathy, and they have special concern for the policies and procedures by which such products might become targets of expensive and unnecessary new regulation.

I. Seniors Use and Rely on Safe, Effective, and Affordable Over-the-Counter Homeopathic Remedies.

Homeopathic medicine is an important subset of the broader category of complementary and alternative medicine (“CAM”) products. Most studies show that about one-third of the adult population uses some form of CAM, while 29.4 percent of adults 65 and over use CAM. *See Trends in the Use of Complementary Health Approaches among Adults: United States, 2002-2012*, National Health Statistics Reports (February 10, 2015).³

Currently, homeopathic remedies are readily available and inexpensive, especially when compared to conventional, toxic, allopathic pharmaceuticals. Moreover, conventional drugs

³ <http://www.cdc.gov/nchs/data/nhsr/nhsr079.pdf>.

and treatments have considerable, often serious, and sometimes fatal, side effects, whereas homeopathic remedies are safe, and even minor side effects are uncommon.

The FTC’s press release announcing the September Workshop described the impetus for the FTC’s current review as “During the last few decades, the homeopathic drug⁴ industry in the United States has grown considerably from a multimillion-dollar to a multibillion-dollar market.” Thus, the FTC’s purported concern about the advertising of over-the-counter homeopathic products arises solely based on money — the growth in the sales of those products. Apparently, more and more people are finding homeopathy helpful for them. The FTC’s concern does not grow out of complaints or reports that such products are misleading or result in any harm — health or financial — to consumers. Although pharmaceutical companies may not appreciate Americans spending health care dollars on homeopathic products, the FTC has no business in taking the side of Big Pharma against the people.

Moreover, this growth in the use of homeopathic products which has occurred during a time of constantly growing health care costs nationally is telling. Even in months when the change in CPI is flat or declining, health care costs continue to rise.⁵ For example, in 2016, there will be no automatic Cost of Living Adjustment (“COLA”) for Social Security beneficiaries.⁶ And for seniors on a fixed incomes, this does **not** mean that medical expenses will magically remain static. As COLAs consistently remain below the rise in health care costs, seniors consistently lose the purchasing power of their retirement benefits, having lost 31 percent of their purchasing power since 2000.⁷

⁴ By its choice of language, the FTC evidences its misunderstanding of homeopathy. Homeopathic remedies are not drugs. They are not toxic. *See* discussion in TSCL’s August 2015 Comments to the FDA (referenced in footnote 8, *infra*).

⁵ *See* M. Patton, “U.S. Health Care Costs Rise Faster Than Inflation,” *Forbes* (June 29, 2015) <http://www.forbes.com/sites/mikepatton/2015/06/29/u-s-health-care-costs-rise-faster-than-inflation/>.

⁶ TSCL, “Why isn’t there any COLA next year when Medicare costs are spiking?” (Nov. 18, 2015) <http://seniorsleague.org/2015/why-isnt-there-any-cola-next-year-when-medicare-costs-are-spiking/>.

⁷ *See* <http://seniorsleague.org/issues/cola/>. Former TSCL Chairman Larry Hyland explained, “‘A major reason that senior costs rise more quickly than the COLA is healthcare costs’ ... Seniors and disabled adults spend a larger share of their income on healthcare costs, which tend to increase several times faster than overall inflation.” “89% of Seniors Say Expenses Rising More Than Current Cost-Of-Living Adjustment (COLA)” (Apr. 2013), <http://seniorsleague.org/2013/89-of-seniors-say-expenses-rising-more-than-current-cost-of-living-adjustment-cola/>.

If the FTC were to regulate the advertising of homeopathic remedies the way it regulates allopathic medicine, the cost of homeopathic remedies would be increased so significantly that most of these remedies would cease to be sold, and for those that would still be available, these increased — and unnecessary — costs would be borne by the consumer.

Homeopathic remedies are fundamentally different from pharmaceutical drugs. They cannot be treated the same. Moreover, homeopathic products are selected for the symptom pattern manifested by an individual and cannot reasonably be tested using expensive and time-consuming approaches employed for toxic drugs designed to address specific diseases.

Furthermore, many seniors experience gaps in their Medicare drug coverage, and these individuals often find benefit from inexpensive alternative therapies, including homeopathy. Homeopathic remedies are immune from toxicity, almost entirely without side effects. Senior citizens and others should have the freedom to buy them, making their own decisions to address their own health care needs. The government has no business effectively preventing senior citizens from purchasing homeopathic products.

II. There Is No Need for the FTC to Interfere with the FDA’s Regulation of Homeopathic Products.

Since 1988, homeopathic remedies have been marketed without prior FDA approval under FDA [Compliance Policy Guide 400.400](#) (June 9, 1988) (“CPG”). The CPG also sets forth the labeling requirements for what are called “homeopathic drugs.” It is undisputed that the “FDA has not reviewed this class of products for safety and efficacy” (80 *Fed. Reg.* 16328). However, the reason for this absence of review is not neglect, but rather that the law never envisioned review of homeopathic remedies. And there is not, nor has there ever been, a need or authority to conduct such a review. Clearly, there is no need for such a review now.

Earlier this year, the FDA issued a notice seeking comment on its current regulatory framework and held a hearing on April 20-21, 2015 on this topic. *See* “Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework after a Quarter-Century,” <http://www.regulations.gov/#!docketDetail;D=FDA-2015-N-0540>. In response, the FDA received nearly 10,000 comments, including comments by TSCL.⁸

Additionally, in response to the FDA’s notice, FTC staff submitted comments to the FDA.⁹ The FTC comments explain that the FDA’s CPG requires homeopathic product

⁸ <http://www.lawandfreedom.com/site/health/TSCL%20FDA%20Homeopathy%20Comments.pdf>.

⁹ <https://www.ftc.gov/news-events/press-releases/2015/08/ftc-staff-comment-fda-should-reevaluate-its-current-regulatory>.

manufacturers to include an indication for use on the label of such products. The FTC staff claims that the CPG’s requirement “creates a potential conflict with the FTC’s requirement that health claims be substantiated by competent and reliable scientific evidence.” *Id.* at 5.

To resolve this supposed potential conflict, the FTC staff — as well as Commissioner Ohlhausen (*see* opening remarks at September 21 workshop¹⁰) — recommends the drastic alternative measures of either withdrawing the CPG or modifying it to eliminate the requirement that an indication appear on the label. Thus, under the FTC’s proposal, a manufacturer could provide an indication on the label if it wanted to, but it would then fall under the FTC’s requirement for substantiation of health claims, based on standards that are ill-suited to test homeopathic remedies (which are tailored not to diseases, but to particularized symptom patterns). Obviously, this would create a Hobson’s choice for many manufacturers, who already comply with appropriate homeopathic remedy preparation requirements.

Despite the FDA’s well-functioning system, the FDA’s rulemaking seeks to exercise new, broader control over homeopathic remedies. The FDA’s *Federal Register* notice cites “10,311 reported poison exposure cases related to ‘Homeopathic Agents,’ [of which] 697 required treatment in a health care facility.” 80 *Fed. Reg.* 16328. The 2012 annual report relied on by the FDA reports only one death possibly resulting from these reported cases, with no clear indication of the nexus of even that one death to homeopathy.

By contrast, traditional pharmaceuticals frequently have harsh side effects that can require additional medication to treat those side effects. Some drugs, like the anti-coagulant drug Warfarin, which is approved by the FDA, require close monitoring to determine whether they are working properly, and adverse events from Warfarin still number in the tens of thousands annually.¹¹ Indeed, some research has shown that certain guidelines for the use of beta-blockers, which are approved by the FDA, may have resulted in as many as 800,000 deaths in Europe before that guideline was rescinded.¹² **It is estimated that adverse drug**

¹⁰ https://www.ftc.gov/system/files/documents/public_events/644921/homeopathic_medicine_workshop_transcript_9-21-15.pdf.

¹¹ *See* C. Ornstein, “Popular blood thinner causing deaths, injuries in nursing homes,” *Washington Post* (July 12, 2015), http://www.washingtonpost.com/national/health-science/popular-blood-thinner-causing-deaths-injuries-in-nursing-homes/2015/07/12/be34f580-1469-11e5-89f3-61410da94eb1_story.html.

¹² *See* L. Husten, “Medicine or Mass Murder? Guidelines Based on Discredited Research May Have Caused 800,000 Deaths in Europe Over the Last 5 Years,” *Forbes* (Jan. 15, 2014), <http://www.forbes.com/sites/larryhusten/2014/01/15/medicine-or-mass-murder-guideline-based-on-discredited-research-may-have-caused-800000-deaths-in-europe-over-the-last-5-years/>.

reactions to traditional pharmaceuticals result in over 100,000 iatrogenic deaths each year.¹³

Homeopathy presents no such problem whatsoever. Even exercising is an enormously more dangerous behavior than taking homeopathic remedies. Like the FDA, the FTC has no reason to devote its limited resources to homeopathic remedies. Homeopathy may be the safest health care modality ever devised! Surely, the American people would be better off if the FDA and FTC focused their attention on toxic drugs, not safe homeopathic remedies.

Returning to the FTC's impetus for initiating this docket, who stands to gain from increased regulation of homeopathic remedies? If prescriptions were required to buy homeopathic remedies, doctors might gain some from additional visits from patients requesting homeopathic remedies which are currently available OTC, but such products may not continue to be available if the FDA repeals or modifies the CPG. Moreover, most physicians are unfamiliar with homeopathy. Pharmaceutical manufacturers and pharmacists who make and dispense regulated drugs would gain from the forced use of toxic and expensive pharmaceuticals as alternatives to safe and inexpensive homeopathic remedies. Clearly, consumers would pay more, without deriving any corresponding benefit, and they would be compelled to try toxic drugs such as beta-blockers (described above) which the FDA and regulators in other countries found were safe before they killed 800,000 people. Certainly, there has been no evidence to date that consumers would benefit from change in the regulation of homeopathy.

The people who helped build this great nation, the senior citizens represented by TSCL, have the right to decide on their own health care. Neither they nor any Americans should be treated as ignorant, simple-minded consumers, incapable of weighing the risks and benefits of different health care choices. The FTC should immediately cease all efforts to increase wholly unnecessary additional regulation of homeopathic remedies.

Respectfully submitted,
/s/

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¹³ See G. Null, PhD, *et al.*, *Death by Medicine*, 27 (Praktikos Books 2010).