

Food and Drug Administration
Division of Dockets Management (HFM-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Homeopathic Product Regulation:)
Evaluating the Food and Drug Administration’s) Docket No. FDA-2015-N-0540
Regulatory Framework After a Quarter-Century)

COMMENTS OF THE SENIOR CITIZENS LEAGUE

(August 21, 2015)

The Senior Citizens League (“TSCL”), through its undersigned counsel, submits the following comments pursuant to 80 *Fed. Reg.* 16327 (March 27, 2015) and 80 *Fed. Reg.* 32868 (June 10, 2015). These comments relate to the FDA’s evaluation of “its current enforcement policies for drug products labeled as homeopathic from scientific, risk, and process perspectives” and “whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace.” 80 *Fed. Reg.* 16327. The FDA held public hearings on April 20 and 21, 2015 in this docket and currently has received over 8,500 comments.¹

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 one 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 See <http://www.regulations.gov/#!docketDetail;D=FDA-2015-N-0540>.

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- [Comments](#) on FDA Draft Guidance for Industry on Complementary and Alternative Medicine Products (May 29, 2007);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);
- Executive Director Shannon Benton statement at the [Transparency Public Meeting](#) on June 24, 2009; 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 is not disturbed, allowing continued public access to homeopathic remedies free of government interference. 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.

In this docket, the FDA asked for broad public input as well as responses to the following specific questions:

- What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?
- 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?
- 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.
- Are there areas of the current CPG that could benefit from **additional clarity**? If so, please explain.
- Is there information regarding the regulation of homeopathic products in other countries that could inform FDA’s thinking in this area?

- A large majority of human drug products labeled as homeopathic are marketed as OTC drugs. These products are 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?
- 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?
- 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? [80 *Fed. Reg.* 16328-29 (emphasis added).]

I. **American Seniors Use and Rely on Safe, Effective, and Affordable 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)* (<http://www.cdc.gov/nchs/data/nhsr/nhsr079.pdf>).

The FDA’s Notice states that in 2007 an estimated \$2.9 billion was spent on the purchase of homeopathic medicine in the United States. 80 *Fed. Reg.* 16328. Apparently, some see this growth in revenue from 1988 when it was only a “multimillion dollar industry” as a reason for expanding regulation of homeopathy.

Currently, homeopathic remedies are readily available and inexpensive, especially when compared to conventional, allopathic pharmaceuticals. Moreover, conventional drugs and treatments have considerable, often serious, and sometimes fatal, side effects, whereas any side effects of homeopathic remedies are extremely uncommon.

If the FDA were to regulate homeopathic remedies the way it regulates allopathic medicine, the cost of homeopathic remedies would be increased so significantly that many of these remedies would cease to be sold. Homeopathic remedies are fundamentally different from pharmaceutical drugs. They cannot be treated the same. Moreover, homeopathic products are selected for the individual and cannot be tested using testing modalities for toxic drugs.

The FDA request for comments appears to be questioning the continued over-the-counter (“OTC”) availability of homeopathic remedies in considering “an appropriate regulatory process for evaluating [the variety of] indications for OTC use” and “whether such products ... are appropriate for marketing as an OTC drug.” 80 *Fed. Reg.* 16329. Requiring prescriptions for homeopathic remedies, many of which have been used to good effect for two centuries, would do nothing but add another layer of cost and complexity and delay to obtain access to these remedies. In addition, most physicians who have received training only in allopathic medicine would be no more qualified to select appropriate remedies than the individual seeking relief — if not substantially less qualified. Moreover, such physicians would be more inclined to prescribe a familiar but more expensive pharmaceutical drug with serious side effects before prescribing an effective homeopathic remedy with no side effects with which they are less familiar.

Most seniors live on fixed incomes, with cost of living increases not keeping up with rising health care costs.² As 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.” *Id.*

Furthermore, many seniors experience gaps in their Medicare drug coverage, and these individuals can often be assisted by inexpensive alternative therapies, including homeopathy. Homeopathic remedies are virtually immune from toxicity, and are tailored to the individual’s symptom pattern without side effects. Senior citizens and others should have the freedom to buy them to address their own health care needs.

II. There Is No Need for Additional Regulation of Homeopathic Products.

The FDA’s authority is established by Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301, *et seq.* The FDCA defines a “drug” as, *inter alia*, “articles recognized in the ... official Homoeopathic Pharmacopoeia of the United States ... and ... articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals....” 21 U.S.C. § 321(g)(1)(A)-(B).

Furthermore, the FDCA’s definition of “official compendium” includes “the ... official **Homoeopathic Pharmacopoeia of the United States** ... or any supplement....” 21 U.S.C. § 321(j). The Homoeopathic Pharmacopoeia of the United States (“HPUS”) has been continuously published since 1897 and currently is published by the Homeopathic

² “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/>.

Pharmacopoeia Convention of the United States. See <http://www.hpus.com/>. “The standards set forth in the HPUS ... affect the naming, quality, and labeling of drug products.” 80 *Fed. Reg.* 16328.

Homeopathic remedies are 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 that there is not nor has ever been a need to conduct such a review, and there is no need for such a review now.

Despite this well functioning system, the FDA is now seeking to exercise new, broader control over homeopathic remedies. The FDA 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 its nexus to homeopathy. Moreover, the 2013 annual report of the American Association of Poison Control Center lists 9,833 case mentions related to “homeopathic agents,” 622 of which required treatment in a health care facility, and no deaths. There is every reason to believe that these instances also involved treatments other than homeopathy. Far more people die each year from exercising or dieting than homeopathic remedies. Homeopathy may be the safest health care modality ever devised!

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, require close monitoring to determine whether they are working properly, and adverse events from warfarin number still in the tens of thousands annually.³ **It is estimated that adverse drug reactions to traditional pharmaceuticals result in over 100,000 iatrogenic deaths each year.**⁴ Homeopathy presents no such problem whatsoever. Surely, the American people would be better off if the FDA focused its attention on toxic drugs, not homeopathic remedies.

As an example of the FDA working with the homeopathic product industry to ensure safety of those products, in 2010, the FDA consulted with Standard Homeopathic Company, which voluntarily agreed to recall one of its products, Hyland’s Teething Tablets, from the

³ 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.

⁴ See G. Null, PhD, *et al.*, “Death by Medicine,” 27 (Praktikos Books 2010).

market. The product reportedly had a “inconsistent amounts” of belladonna, with some anecdotal reports of adverse events.⁵ Standard Homeopathic Company revised its formula for this product, and reintroduced it to the market in 2011.⁶ This is an example of the voluntary homeopathic industry cooperation that now exists, and will continue to exist, without unnecessary government regulation.

The FDA has no reason to devote additional resources to homeopathic remedies. As recently reported, “Janet Woodcock, director of FDA’s Center for Drug Evaluation and Research, said inadequate funding might force the FDA to cut back on its ... responsibilities.” J. Reid, “Is the FDA Ready for 21st Century Cures?” (May 29, 2015) (<http://morningconsult.com/2015/05/is-the-fda-ready-for-21st-century-cures/>). Its resources should not be unnecessarily expended on further study and regulation of safe homeopathic remedies.

This brings into question the FDA’s impetus for initiating this docket. Who stands to gain if the FDA increases regulation of homeopathic remedies? Doctors would gain some from additional visits from patients requesting homeopathic remedies which are currently available OTC. However, 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. Certainly, there has been no evidence to date that consumers would benefit from additional regulation of homeopathy.

The people who helped build this great nation, the seniors represented by TSCL, have the right to decide on their own health care. The FDA should refrain from engaging in wholly unnecessary regulation of homeopathic remedies, and should focus its efforts elsewhere.

Respectfully submitted,
/s/

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⁵ See FDA News Release (Oct. 23, 2010) <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm230761.htm>.

⁶ <http://www.hylands.com/news/hylands-teething-recall.php>.