

WILLIAM J. OLSON, P.C.

ATTORNEYS AT LAW

370 MAPLE AVENUE WEST, SUITE 4

VIENNA, VIRGINIA 22180-5615

TELEPHONE (703) 356-5070

FAX (703) 356-5085

E-MAIL: [wjo@mindspring.com](mailto:wjo@mindspring.com)

<http://www.lawandfreedom.com>

114 CREEKSIDE LANE  
WINCHESTER, VA 22602-2429  
TELEPHONE (540) 450-8777  
FAX (540) 450-8771

WILLIAM J. OLSON  
(VA, D.C.)

HERBERT W. TITUS  
(VA OF COUNSEL)

JEREMIAH L. MORGAN  
(D.C., CA ONLY)

ROBERT J. OLSON  
(VA, D.C.)

May 23, 2020

By electronic submission

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: The Senior Citizens League and Center for Medical Freedom  
Response to FDA Request for Comment on Drug Products Labeled as  
Homeopathic, 84 Fed. Reg. 57441 (posted Oct. 25, 2019);  
FDA Docket No. 2017-D-6580-4828; Comment Deadline May 23, 2020

Gentlemen:

These comments are filed on behalf of The Senior Citizens League and the Center for Medical Freedom.

The Senior Citizens League (“TSCL”) ([www.seniorsleague.org](http://www.seniorsleague.org)) 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. nonprofit and nonpartisan 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.

The Center for Medical Freedom (“CMF”) ([www.centerformedicalfreedom.org](http://www.centerformedicalfreedom.org)) is a project of the Conservative Legal Defense and Education Fund (“CLDEF”), which was founded in 1985 as a nonprofit, non-partisan educational organization, incorporated under the laws of the District of Columbia. CLDEF is tax-exempt under Section 501(c)(3) of the Internal Revenue Code (“IRC”). CMF’s mission is to educate members of the public about

their right to make their own personal medical and healthcare choices, and their inherent right of self-defense to resist efforts by government at all levels to restrict and control those choices.

### Comments

These Comments address the FDA’s Draft Guidance entitled “Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry (Draft Guidance) (October 19, 2019).” Under this revised draft guidance, FDA’s “Enforcement and Regulatory Priorities” would be directed to six specific areas.

These commentators believe that the FDA is wholly without authority to impose regulations and direct enforcement efforts against homeopathic remedies, except with respect to the sixth proposed priority — “Products with significant quality issues.” If products are contaminated, that would trigger FDA’s jurisdiction over contaminated products. All of FDA’s efforts with respect to homeopathy should be in this one area, so that the FDA would do this one thing well. The FDA simply does not have authority to regulate homeopathic remedies manufactured in accordance with the Homeopathic Pharmacopeia of the United States (“HPUS”). Obviously, contaminated products are not being manufactured in accordance with HPUS.<sup>1</sup>

All five other Enforcement and Regulatory Priorities are not within the FDA, but stated in a way so as to give the false impression that there is a role for the FDA in this area.

Under the first priority, the fact that a person could report an injury, and attribute it to a homeopathic remedy, even if that remedy is incapable of producing that injury, should not give additional powers to the FDA. Homeopathic remedies simply do not have adverse side effects — as all pharmaceutical drugs do. If the simple unproven report of an alleged injury could enhance FDA jurisdiction over homeopathy, it would encourage those companies which make billions of dollars annually from a single pharmaceutical drug to arrange for such false reporting of incidents. Rather, the FDA should expend its energy on facilitating and encouraging the reporting of vaccine adverse reactions, which now are only rarely reported, no doubt because there are powerful interests that do not want those adverse vaccine reactions reported.

Under the second priority, homeopathic remedies are made from a wide variety of substances, but contain none of those substance. While a regulator seeking to assert authority

---

<sup>1</sup> The Draft Guidance makes numerous unsupported and unsupportable assertions, such as “A product that conforms to the HPUS dilution standards may still fall under the enforcement priorities...” (p. 1, n. 3). The only case in which this would be true for remedies manufactured in accordance with the HPUS, would be for those that are contaminated.

might look at the homeopathic remedy Opium, that remedy has given relief to many. As discussed below, the homeopathic remedy at most dilution levels likely contains zero molecules of Opium. For this Guidance to assert that the nature of the original substance used in the creation of the remedy is significant is an effort to bootstrap its jurisdiction into areas where it has none.

Under the third priority, homeopathic remedies can be used in other than oral and topical methods. It is interesting that the FDA would say that “contaminated injectable ... products can pose serious risks to the patient” because they “bypass some of the body’s natural defenses.” Of course, injection is the mechanism by which most vaccines are administered, where the manufactures have been completely absolved of all liability by federal law for injury or death arising from those vaccines which are injected to “bypass some of the body’s natural defenses.”

Under the fourth priority, the FDA assumes that it has jurisdiction if a homeopathic remedy that could be used for serious health condition, because that could lead a patient to use that natural approach, rather than conventional medical treatments “that have been found safe and effective.” The FDA’s record of approving drugs that are safe and effective is coming under increasing scrutiny. “According to the U.S. Food and Drug Administration (FDA), 100,000 Americans die from reactions to prescription drugs each year, making this the fourth leading cause of death in the U.S.”<sup>2</sup> Particularly in view of the FDA’s record, Americans should have the ability to make decisions for themselves about efficacy. The FDA assumption that its scientists know better than Americans themselves should be rejected. As Blackstone explained in his *Commentaries*, each person owns, and has a property right to, his own body. The FDA has no property rights to our bodies.

Under the fifth priority, the FDA assumes that certain population groups, including the elderly, would be at greater risks “for adverse reactions associated with a drug product, even if it contains only small amounts of an ingredient...” This assertion again demonstrates a complete lack of understanding of homeopathy, which are not drugs and do not contain substances that the body must work hard to excrete. As applied to senior citizens, this assertion is patronizing. Homeopathic remedies trigger the body to heal itself, and their gentle action make them particularly useful with senior citizens.

Indeed, the very title of the Draft Guidance “Drug Products Labeled as Homeopathic,” demonstrates a lack of understanding of homeopathic remedies. Drugs are substances which have a level of toxicity. Homeopathic remedies do not. Homeopathic remedies are not drugs.

---

<sup>2</sup> Jacqui Deevoy, “[100,000 Deaths Per Year In The U.S. Caused By Prescription Drugs](#),” *Newspunch* (Feb. 6, 2015).

The lack of understanding of homeopathy evidenced in the FDA Draft Guidance indicates that the FDA would benefit from a short explanation of homeopathy, which follows. (Note that this layman's explanation is not intended to be a technically precise analysis, but merely an overview as initial introduction to this subject.)

### **Increasing Use of Homeopathy**

Great Britain's Royal Family, Mahatma Gandhi, John D. Rockefeller, Sr., Tina Turner, and Yehudi Menuhin do not have much in common, except for the fact that they all have been strong supporters of homeopathic remedies.<sup>3</sup>

In the past, homeopathic remedies were much more common in countries like Germany, the United Kingdom, parts of Latin America, Asia, and the British Commonwealth of Nations, particularly, India. However, today, homeopathic remedies are regularly used in the United States. Although many Americans are still unaware of their benefits, they certainly no longer a fringe treatment modality. Indeed, Americans — and senior citizens — use them with increasing regularity, especially as they learn more and more about their low cost and good results, without side effects. At the same time that homeopathic remedies have been becoming increasing popular, the pharmaceutical drug industry, perceiving an economic threat to their corporate profitability, have endeavored to urge its friends in government to impose unnecessary and burdensome regulations on the homeopathic sector.

It is not surprising that many Americans are still unfamiliar with homeopathy — as they grew up reliant on pharmaceutical drugs, never knowing that safe and effective alternatives exist. Physicians are trained in medical schools to first think of pharmaceuticals, rather than alternative approaches, such as removing toxins, improving nutrition, and holistic approaches. When one TSCL member recently asked his experience physician about use of a homeopathic remedy, the doctor said “Yes, I know about those – that's like herbs, right?” The senior citizen's response – “Well, no, its different.”

### **Homeopathic Remedies Are Not Drugs**

Homeopathic remedies are wholly unlike regulated prescription drugs. All pharmaceutical drugs have two characteristics. First, they are toxic to humans at some dosage levels. Second, even those drugs which have beneficial effects also have undesirable effects. To minimize attention of these undesirable effects, they are generally called “side effects” — even though in truth they are part of the “direct effect” of the drug.

---

<sup>3</sup> See <https://homeopathic.com/a-modern-understanding-of-homeopathic-medicine/>.

On the other hand, homeopathically prepared remedies are not toxic, but rather are a safe, gentle, and effective drug-free healing modality which has been used by hundreds of millions of persons for 200 years in scores of countries around the world.

Homeopathic remedies have a unique method of preparation in which the original ingredients used are so diluted that they do not contain actual medicinal ingredients or drugs. Therefore, calling them a “drug” is a misnomer. They are not a “drug” in any sense of the word.

Healing in homeopathy is totally unrelated to traditional allopathic medicine which is based on cause and effect via the direct action of the substance involved; *e.g.*, antibiotics kill bacteria, anti-virals eradicate viruses.

Homeopathy understands that each substance has a unique inherent energy which has power to activate the life force that our Creator built into human beings to react and overcome the negative symptoms they are experiencing. The mechanism to unleash this unseen energy, or life force, is through the process of dilution and succussion. This involves putting a tiny amount of any given substance into a large quantity of a neutral substance (*e.g.*, water or ethyl alcohol), shaking (“succussing”) it hundreds of times, then taking a small portion of that highly diluted liquid and diluting it again by placing it in another large quantity of water, rapidly shaking it many times, and then repeating the same process over and over again.

This process is called “potentization” and refers to a specific procedure of serial dilution, wherein one part of a given substance is diluted with 99 parts distilled water or ethyl alcohol which then is vigorously shaken. One part of this solution is diluted further with 99 parts distilled water or ethyl alcohol and then shaken again. This process of dilution with shaking may be continued to different strengths.<sup>4</sup>

When the medicines are potentized beyond a certain point, there probably is not even one molecule remaining. Homeopaths agree that solutions diluted beyond the 24x or 12c may not have any molecules of the original solution, but they assert that “something” remains: the essence of the substance, its resonance, its energy, its pattern. Avogadro’s law basically asserts that in all probability there should not be any molecules remaining after a substance is

---

<sup>4</sup> When a homeopathic medicine is labeled “C”, this means that the medicine was diluted 1:99. When a medicine is labeled “X” or “D”, it was diluted 1:9. When a medicine is described as a “30x,” this means it will diluted 1:9 and vigorously shaken; then diluted again 1:9 and shaken; this procedure is repeated 30 times. When a medicine is labeled “LM”, it was diluted approximately 1:50,000.

diluted beyond  $6.022 \times 10^{23}$ . The exact level of ultramolecularity depends on the concentration of the original substance.<sup>5</sup>

In simple terms, this means homeopathic remedies are not “drugs” in any sense of the term, as there is no active ingredient contained therein. Even at the lowest potencies, there is such extreme dilution as to render them completely nontoxic.

### **Homeopathy Uses Bio-Energy, Not Drugs**

In homeopathic medicines, substances are used in ultra-high dilutions that makes them non-toxic. These medicines are prepared by specialist pharmacies using a careful process of dilution and succussion (vigorous agitation). Thus far, Western science has not been able to explain the mechanisms that make the ultra-high dilution in homeopathy work, but there are many important facts about how our bodies work that Western science cannot explain — such as how the brain maintains a memory.

Homeopaths conceptualize a “life force” or “vital force” which they describe as the inherent, underlying, interconnective, self-healing process of the organism. This bio-energetic force is similar to what the Chinese call “chi,” Japanese call “ki,” yogis call “prana,” and Russian scientists call “bioplasm.” Homeopaths theorize that this bio-energetic process is sensitive to the sub-molecular homeopathic medicines. The resonance of the microdose is thought to affect the resonance of the person’s life force.<sup>6</sup>

Although the underlying philosophy of homeopathy may be subject to question by those who embrace all that modern Western pharmaceutical medicine has to offer, there are millions of adherents of homeopathy who maintain they are getting satisfactory if not remarkable results. The point is, since the homeopathic remedies do not contain any potentially harmful substances they need not be controlled and regulated.

As a practical example, let’s say you start with a grain of a commonly used homeopathic remedy called Natrum Muriaticum or common sea salt. You take a grain of that salt, put it in a gallon of water, shake (succuss) hundreds of times. You now have what is called a homeopathic potency of 1x. This lower dilution is rarely used, because adherents believe that low amount of shaking and dilution does not release enough life energy to stimulate a person’s own vital source energy to throw off negative symptoms. The usual minimum number of dilution/shaking processes a substance has to undergo to evoke its energy healing potential is thirty times, yielding an energy potency of 30c. It can be less, but the tiny

---

<sup>5</sup> See <https://homeopathic.com/a-modern-understanding-of-homeopathic-medicine/>.

<sup>6</sup> See <https://homeopathic.com/a-modern-understanding-of-homeopathic-medicine/>.

amount of the original substance is so extremely diluted as to render it, practically speaking, non-existent.

You take that one grain of salt, put it in a gallon of water, shake it hundreds of times, draw off a small quantity of the diluted, well agitated liquid, then put it in another gallon of water, shake it hundreds of times, then draw off a teaspoon of water, put it in another gallon of water agitate (succuss) it hundreds of times, then repeat the process again and again, for a usual minimum of 30 times over. By the time you are finished, you have the equivalent of grain of salt in a large swimming pool of water. If you were to draw off a teaspoon of that succussed liquid, put it under an electron microscope, you would not see the minutest particle of salt. Thus, homeopathic products are not in any sense like toxic drugs.

### **Conclusion**

In 200 years of use by hundreds of millions of people, it can be said that there is not a safer and more versatile health care modality than homeopathy. Homeopathic energy remedies do not contain any of the original ingredient — only what adherents believe is its unique life energy. Therefore, the FDA's authority over toxic drugs does not apply to homeopathy. Adding onerous regulations would only impinge on the personal and religious freedom of people who utilize this safe, low-cost, non-toxic, non-medicinal healing modality.

Sincerely yours,

*/s/ William J. Olson*

William J. Olson

WJO:ph