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

Subject: Docket No. FDA-2015-N-0540
Homeopathic Product Regulation: Evaluating the FDA's Regulatory Framework After a Quarter-Century

Gentlemen:

Our firm represents the United States Justice Foundation,[1] on whose behalf we submit 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 (emphasis added).[2]]

FDA's Asserted Authority for Regulation of Homeopathy

The FDA states that it has permitted what it terms "homeopathic drugs" to be 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 "homeopathic drugs." The

[1] The United States Justice Foundation is located at 932 D Street Suite 3, Ramona, CA 92065-2355; www.usjf.net. It is a nonprofit legal defense and education foundation founded in 1979.

[2] The FDA held public hearings on April 20 and 21, 2015 on this topic and as to date, has received over 8,600 comments. *See* http://www.regulations.gov/#!docketDetail;D=FDA-2015-N-0540.

FDA notice asserts authority to control homeopathic remedies when it asserts that the "FDA has not reviewed this class of products for safety and efficacy." 80 *Fed. Reg*. 16328. The FDA's assertion that homeopathic remedies constitute "drugs" is essential for it to assert control over homeopathic remedies, but, as discussed below, that claim is specious.

The FDA is now seeking to exercise new, broader control over homeopathic remedies. 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? [Emphasis added.]

In this list of questions, the FDA ignores the threshold question: does the FDA have any statutory, or, indeed, constitutional authority to sit in judgment over the choice of Americans to use homeopathic remedies? It is our contention that the FDA has no such authority.

Nature and History of Homeopathy

The Homoeopathic Pharmacopoeia of the United States ("HPUS") website explains the nature of homeopathic remedies, as follows:

> Homeopathy is the art and the science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people.
>
> Any substance may be considered a **homeopathic medicine** if it has known "homeopathic provings" and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat.…
>
> Central to all homeopathy is the determination of the effect of substances on healthy volunteers and the use of the developed "drug picture" **by the consumer** and/or trained health care practitioners according to the homeopathic principle of similia similibus curentur - Let likes be cured by Likes.
>
> Historically, homeopathy has been practiced by medical doctors, and **has been used for self-care by the general public**. The issuance of The Homeopathic Domestic Physician by Constantine Hering, M.D., (1835) **opened this health care modality to the public. Homeopathy is an ideal therapeutic medium for self-medication of symptoms** usually associated with self-limiting conditions since the selection of the proper remedy for the case is dependent on the symptoms that the body exhibits in its reaction to the illness. In the use of homeopathy for conditions which are other than self-limiting, **the consumer** is advised to use the services of a health care provider. [What is Homeopathy? (emphasis added) http://www.hpus.com/what-is-homeopathy.php.]

The HPUS description above uses what is now an unusual term — "a homeopathic medicine." The FDA notice uses an even more unusual term — "homeopathic drug." Those familiar with homeopathy have rather used the term "homeopathic remedy" for many decades. Homeopathic remedies should certainly not be assumed to be drugs. They are natural substances, homeopathically prepared, which trigger the body's ability to heal itself.

However, the HPUS description above makes clear the historic truth that homeopathic remedies have a long and honorable tradition, since their development in the modern era by Dr. Samuel Hahnemann, around the time of the American Revolution. Interestingly, a prominent monument in Washington, D.C. is dedicated to Dr. Hahnemann that is listed on the National Register of Historic Places, and the National Registry states that Dr. Hahnemann, who was born in Meissen Saxony, was:

> the first foreigner not associated with America's independence to be represented in sculptural form in Washington, D.C. [and] the second doctor to gain sculptural recognition.[3]

The monument was approved by an Act of Congress on January 31, 1900 (31 Stat. 709) and was dedicated on June 21, 1900. Dr. Hahnemann's statue was dedicated by President William McKinley, a devotee of homeopathy.

The National Registry further explains that Dr. Hahnemann "became disillusioned by the medical orthodoxy that relied on over drugging and bleeding [and that] homeopathy … revolutionized medicine during the nineteenth century … and some homeopathic practices became commonplace by the 1890s." *Id.* With this anti-establishment pedigree, it is no surprise that elements of the current medical orthodoxy historically have found homeopathy to be controversial, and some now would want the FDA to act on its behalf to suppress this health care option.

The HPUS description of homeopathy cited above explains that Americans have had the right to use homeopathic remedies without the need to seek the permission of the government, such as through the issuance of a prescription by a licensed physician and obtained from a licensed pharmacist. This system governing access to homeopathic remedies, which has worked wonderfully for the entire history of the nation, to the benefit of the public health of all Americans, is now threatened by the FDA — which appears to want to use ambiguous statutory language to deprive Americans of the free choice of homeopathic remedies at reasonable prices, leaving them to the tender mercies of the Pharmaceutical Industry, selling often highly toxic drugs at often exorbitant prices.

FDA's Asserted Authority for Regulation of Homeopathy

The FDA purports to exercise authority over homeopathy under the 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) (emphasis added).]

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") is published under

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[3] https://www.dropbox.com/s/d5w60cyxdj39qzn/Hahnemann%20Memorial.pdf?dl=0

the authority of the Homeopathic 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 Not Drugs

The basic statutory definition of a drug as including "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" employs language so broad that the definition could encompass virtually every substance that is consumed or comes in contact with the body.

For example, a bottle of water now sold at the corner 7-Eleven could be said to be "intended for use in the … cure of" thirst — which presumably has not yet been classified as a "disease" by modern medicine. However, if that same bottle of water was "intended for use in the … cure of" the medical conditions of Dehydration, or Polydipsia (excessive thirst), Dry Mouth disease — it would be a drug, by this definition.

Clearly, the "intent" of the person selling the substance cannot determine whether a substance is a drug. The statutory definition is overinclusive, as in the case of water, but it is also underinclusive, as it would exclude a pharmaceutical if it was not advertised to address a medical condition. This cannot be the way Congress intended to define a "drug."

The reference in the definition of a drug to "articles recognized in the official … Homoeopathic Pharmacopoeia of the United States…" does not demonstrate that homeopathic remedies were to be treated as other pharmaceuticals, but rather shows the opposite — that many in Congress treated homeopathic remedies over many decades differently than pharmaceutical drugs.[4]

One of the defining characteristics of a pharmaceutical drug is that it has serious toxicity — a key characteristic shared by all pharmaceutical drugs. Because of that toxicity, the federal government limits public access, to protect the public. That rationale does not apply to homeopathy.

Further, consider the following definition of a drug by a noted pharmacist:

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[4] *See, e.g.,* S.W. Junod, "An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation," FOOD AND DRUG LAW JOURNAL 55:161-183 (2001) (U.S. Senator "Copeland believed that it was in the realm of treatment that homeopaths excelled over regular physicians…. Homeopaths … could claim accurately that they created no drug addicts…. Adulteration of homeopathic drugs, delays in filling prescriptions, and carelessness in drug preparation were charges generally not leveled against homeopathic practitioners.").

> A chemical substance is a drug when it can induce observable changes in the physiopathology of a known disease by preventing, curing, arresting, or palliating.[5]

This definition does not apply to homeopathic remedies, which are neither chemicals nor taken or given for the physiopathology of disease. Additionally, while "[d]rug-related morbidity and mortality are built-in defects that are institutionalized in the social system of drug therapy" (*id.,* p. 126) that does not apply to homeopathic remedies. "Morbidity and mortality from the use of patent drugs was known to occur from acute or chronic poisoning." *Id.,* p. 131. Yet there is no morbidity/mortality associated with homeopathic remedies. Lastly, pharmaceutical drug tests attempt to determine what potency level is fatal to animals. There would be no reason for such testing of homeopathic remedies. One could not commit homicide or suicide with homeopathic remedies, no matter how hard one tried.

Along these lines, it is humorous to analyze the arguments made by those who want government to regulate homeopathy out of existence. They argue that many homeopathic remedies are made from some dangerous and toxic substances which require regulation, and at the same time they assert that homeopathic remedies are so diluted in their manufacture that, "at best, the 'Remedies' are placebos."[6] Both statements cannot be true.

In their manufacture, substances are diluted to the point that, for remedies diluted beyond 12C or 24X, it is "statistically improbable that a single molecule of the original medicinal substance remains present" based on Avogadro's law.[7] This fact alone should force critics of homeopathy to admit the substances are not dangerous. However, critics then move to other arguments for banning access to homeopathic remedies. Some contend that homeopathic remedies are an unproven form of "energy" medicine, that they deter Americans from seeking timely care from licensed healthcare practitioners, and that they are not scientifically proven. However, those who use homeopathic remedies have already voted, with their pocketbook, that these remedies work, at least for them.

Given the individualized nature of homeopathic remedies, one need not assume that those who believe them to be ineffective are operating in bad faith, although given the billions of dollars at stake, it would not be beyond the realm of reason to believe that some in the

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[5] Richard Henry Parrish II, Defining Drugs: How Government Became the Arbiter of Pharmaceutical Fact (Transaction Publishers: 2003), p. xxii.

[6] http://www.quackwatch.com/01QuackeryRelatedTopics/homeo.html

[7] Harris L. Coulter, Divided Legacy: A History of the Schism in Medical Thought, Volume IV (North Atlantic Books, 1994), p. 254.

pharmaceutical industry might choose to ignore their efficacy to achieve greater profitability for their own competing products.

Critics of homeopathy refuse to admit that increasingly medicine is admitting that our Creator God designed the body to heal itself, and that which triggers this type of self-healing logically would be the best approach to ensuring good health. The critics fail to appreciate the extensive proving of homeopathic remedies over the past two centuries — which occurred while conventional medicine was mired down by orthodox theories such as blood letting, eugenics, and electro-shock therapies. And, these critics would deny to Americans the right to choose the medical care they receive from among competing schools of medicine.

Indeed, when one school of medicine attempts to use the government to quash another school of medicine, that can be a good indication that those demanding the protection of the public have been losing with the American people in marketplace. Those whose products are not preferred by consumers often cease to appreciate how the public benefits from competition among health care alternatives. It should come as no surprise that Americans are increasingly preferring homeopathic remedies, which millions have already found to be effective, are virtually side-effect free, inexpensive, and which can be self-prescribed without paying a physician and a pharmacist. However, what cannot be accomplished in the marketplace can be imposed by government. Pharmacy Professor Richard Henry Parrish II explains the historic pattern of certain health care providers turning to government to accomplish by compulsion what they could not do by persuasion:

> Government became the arbiter of pharmaceutical fact because the professions of pharmacy and medicine, as well as the pharmaceutical industry, could enforce their standards only through **police powers** reserved to government … at the expense of others' rights of association, speech, and property. [Richard Henry Parrish II, Defining Drugs: How Government Became the Arbiter of Pharmaceutical Fact, Transaction Publishers, (2003), p. 132 (emphasis added).]

The U.S. Constitution Vests No General Police Power in the Federal Government

As the FDA moves against alternative medicine, it will force a re-examination of whether the powers of the federal government include the power to ban certain schools of medicine and the physician products that they employ. The federal government's powers are limited to those enumerated in Article I, Section 8 of the U.S. Constitution. Even powers granted the federal government by the "necessary and proper clause," are limited to those powers which are "necessary and proper" to implement an enumerated power. Nowhere is the federal government given the power to control health care choices.

In fact, since the formation of the republic, police powers have been vested in the states — not the federal government. Laws which the FDA would purport to rely on were often justified based on a promiscuous reading of the Commerce Clause. The constitutionality of many federal "police power" style laws, enacted assuming on a virtually unlimited Commerce Clause power, have never been tested in court. Perhaps it is time for such challenges to be brought. They certainly are open to serious challenge based on recent scholarship and cases decided on the historic meaning of the Commerce Clause and its relationship to the Tenth Amendment, such as United States v. Lopez, 514 U.S. 549 (1995), and United States v. Morrison, 529 U.S. 598 (2000).

Both Lopez and Morrison have affirmed that the federal government has no general "police power." That is, among the enumerated powers of the federal government, one does not find any authority over public health, safety, and welfare. All of those matters belong either to the States or to the People. Through the usurpation of power by the passing of the law creating the Food and Drug Administration, the politicians and bureaucrats in Washington have robbed America of rich diversity and freedom in matters of health, safety, and welfare. The FDA proposal to consider adding to the burden of regulation on homeopathy is a step in the wrong direction, inimical to individual and public health.

The Free Exercise of Religion Protects the Freedom to Make Personal Healthcare Choices

Moreover, the matter of healthcare is a personal choice, involving the Free Exercise of Religion protected by the First Amendment. The Bible speaks to matters of health throughout both testaments. Many world-class scientists, such as James A. Duke, Ph.D., have studied Scripture for guidance on matters of health. *See* J.A. Duke, Herbs of the Bible: 2000 Years of Plant Medicine (Whitman Publications: 2007) (quoting the Holy Bible in its Preface: "On the banks, on both sides of the river, there will grow all kinds of trees for food. Their leaves will not wither nor their rich fruit fail, but they will bear fresh fruit every month, because the water for them flows from the sanctuary. Their fruit will be for food, and their leaves for healing." *Ezekiel* 47:12.)

Homeopathic remedies are widely used on the mission field, because they are safe, gentle, effective, inexpensive, store well, and can be prescribed based on symptoms manifested — rather than expensive and unavailable medical testing. FDA regulation of homeopathy would do grave injury to American Christian missionaries operating worldwide. Indeed, missionaries have brought homeopathy to parts of the world where it has become so well regarded that it is now a well-established and well-accepted component of local health care.

One medical doctor, who is a popular author and critic of modern orthodox medicine, Robert S. Mendelsohn, M.D., explained that "the doctor-patient relationship is based on something other than knowledge. *It's based on faith*. We don't say we *know* our doctors are good; we say we have *faith* in them. We *trust* them.... Modern Medicine can't survive

without our faith, because Modern Medicine is neither an art nor a science. It's a religion." R.S. Mendlesohn, Confessions of a Medical Heretic (McGraw-Hill: 1979), pp. xii-xiii.

Religion, as that word is used in the First Amendment, is a jurisdictional term demarcating those matters of life that are outside the authority of the government, belonging exclusively to God. Health care has always been assumed to be governed solely by reason, not by force, and thus is well within the scope of the Free Exercise Clause. Traditionally in America, the government has no power to force any person to eat wisely, sleep regularly, or undergo or abstain from any medical treatment. Indeed, the U.S. Supreme Court had ruled that "abstaining from certain foods" is a classic example of free exercise of religion. *See* Employment Div. v. Smith, 494 U.S. 872, 877 (1990). Both the Old and New Testaments have established an unbreakable connection between health and morality. Historically, homeopathy fits within that religious tradition, and hence has long been outside the jurisdiction of the civil authorities.

Conclusion

Although American pharmaceutical manufacturers might prefer to suppress homeopathy so that they may be able to market their drugs domestically and internationally, such would be a profoundly corrupt motive for the FDA to sanction. For many decades, the FDA has thus far understood that homeopathic remedies are virtually devoid of side effects, inexpensive, and found by millions to be effective for them. Thus, such remedies are completely different from toxic pharmaceuticals, and for these reasons, the FDA has allowed diversity in health care choices.

Applying the system for government-mandated pharmaceutical drug regulation to homeopathy would have a major ramification on the rights of citizens in a free society: It would stop citizens from acting in their own best interest, and would shift consequent responsibility to professionals and to government. The federal government has neither jurisdiction nor warrant to change direction now and interfere with the right of citizens to have unfettered access to homeopathic remedies.

Respectfully submitted,

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