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Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century

Testimony of the Center for Inquiry to the Food and Drug Administration

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Thank you. I speak today as director of public policy for the Center for Inquiry (CFI), an educational and advocacy organization that promotes reason and scientific integrity in public affairs. My testimony, however, is 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.

We applaud the Food and Drug Administration (FDA) for holding this important hearing. Given the tremendous growth in the sale of homeopathic products in recent decades, a reassessment of the FDA's regulation of these products is clearly warranted. Our goal is to briefly review the scientific evidence that shows homeopathy is an ineffective method to treat illnesses; illustrate the harm caused by reliance on homeopathy instead of actual medicine; and propose actions the FDA 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.

I. The Empirical Evidence

We could spend hours discussing the extensive, decades-long scientific examination of homeopathy, but suffice 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, released last month 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. It concluded that:

“There are no health conditions for which there is reliable evidence that homeopathy is effective.”ⁱ

Proponents of homeopathy will suggest that there are studies which show homeopathy is effective. It is true you can find studies that suggest homeopathy has brought about a positive result. Yet these studies have found only a *placebo* effect, and significantly do not and cannot explain *if* and *how* homeopathy has treated the illness. Further, these studies must be seen within the broader context of hundreds of studies that have found homeopathy ineffective.

Of course, this all makes sense: by its own definition, homeopathy *cannot* work. Its centuries-old pseudoscientific principles 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.

Again, we need not spend much time on this, as the federal government is well aware of the scientific evidence against homeopathy. 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.”ⁱⁱ

Further, *the FDA itself* has recognized that homeopathy is not effective through its various consumer warnings about the health risks of relying on homeopathic products to treat medical conditions. This includes the FDA’s March 19, 2015 warning against using homeopathic products that claim to treat asthma, an often life-threatening condition.ⁱⁱⁱ

II. The Harm Caused by Homeopathy

Despite substantial empirical evidence to the contrary, companies persist in marketing ineffective homeopathic products as drugs that can effectively

treat illnesses, and consumers continue to spend upwards of billions of dollars each year believing that they will be helped — and worse, that even if these products might not be not effective, they are at least not harmful. This should deeply concern organizations charged with protecting public health, especially as the problem is in part caused by said organizations' failure to regulate homeopathic products.

Despite what many consumers believe, homeopathic products *can* directly cause harm. Sadly, children often bear the brunt of this harm. For instance, in its 2012 report, the American Association of Poison Control Center noted that there were a whopping 10,311 reported cases of poison exposure related to “homeopathic agents,” with 8,788 of those reported cases attributed to children *5 years of age or younger*. Of the 10,311 reported cases, 697 required treatment in a health care facility.^{iv}

Still, perhaps the greatest harm caused by homeopathy is not necessarily caused by the products themselves — which, when properly prepared, rarely contain anything other than water and inactive ingredients such as sugars and binding agents — but by the fact that people often rely on homeopathic products to the exclusion of proven scientific remedies. As the Australian 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.^v I will highlight just a few.

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.^{vi}

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.^{vii}

Kate 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.^{viii}

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.^{ix}

These examples clearly illustrate the public's lack of knowledge regarding homeopathy, the danger of homeopathic products, and thus the need for the FDA to take an active approach in promoting accurate knowledge on homeopathy.

III. Proposed Regulations

Proponents of homeopathy often argue that homeopathic products should be available because individuals have the right to freedom of choice. We fully support the right to freedom of choice. However, we also believe that *true* freedom of choice is impossible unless one is *fully informed* on the choices. In fact, this is one of the fundamental principles justifying FDA regulation: the public needs the guidance of an expert agency when it comes to buying drugs.

Accordingly, we propose the FDA announce and implement strict guidelines that require all homeopathic products meet the same standards as non-homeopathic drugs. In particular, we suggest the FDA take three steps:

Testing for homeopathic products. As the FDA recognizes, the federal Food, Drug and Cosmetic Act *does not* exempt homeopathic products from meeting the same standards of safety and efficacy as non-homeopathic drugs. Nor does this Act prevent the FDA from enforcing these standards. In order to protect public health, we urge

the FDA to mandate that all homeopathic products on the market pass safety and efficacy tests equivalent to those required of non-homeopathic drugs on the market.

Labeling for homeopathic products. Labeling on homeopathic products needs to improve; this is especially true if the FDA does not require they be tested for safety and efficacy, as this would allow dangerous homeopathic products to remain on the market without warning, marketed to a public that is unaware homeopathic products are different in kind from non-homeopathic drugs. Currently many homeopathic products boast that they are regulated by the FDA without explaining they are not subject to testing. This is seriously misleading. We therefore urge the FDA to ensure that all homeopathic products prominently state two things:

- 1) The product's claimed active ingredients in plain English, and;
- 2) That the product has not been evaluated by the FDA for either safety or effectiveness.

Regular consumer warnings. We have been encouraged by the FDA's recent announcements warning consumers that homeopathic products will not treat their illnesses. Given the lack of public knowledge on homeopathy, we urge the FDA to make such announcements on a regular basis, especially, but not only, during times of illness outbreaks and public health crises.

In summary, homeopathy is unsupported by scientific evidence, ineffective in treating illness and, when relied upon instead of actual medicine, dangerous and even deadly. To ensure the protection of the American public, the FDA should rely on its well-established regulatory system to require homeopathic products to meet the same standards as non-homeopathic drugs, or *at the least* mandate labeling for homeopathic products which states: the product's claimed active ingredients in plain English; and that the product has not been evaluated by the FDA for safety or effectiveness. The American public deserves as much from the agency tasked with protecting them. Thank you.

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- i "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>
- ii "Homeopathy: An Introduction." NCCIH. <https://nccih.nih.gov/health/homeopathy>
- iii "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>
- iv "2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System." AAPCC. https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2012_NPDS_Annual_Report.pdf
- v What's the Harm. <http://whatstheharm.net/homeopathy.html>
- vi "My Wife's Death from Cancer." Quackwatch. February 27, 2002. <http://www.quackwatch.org/01QuackeryRelatedTopics/Victims/craven.html>
- vii "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>
- viii "Doctors back Ohrenschall on treatment" *Las Vegas Sun*. Feb. 12, 1998. <http://lasvegassun.com/news/1998/feb/12/doctors-back-ohrenschall-on-treatment/>
- ix "Inquest told parents 'rejected advice'" *The Age*. November 26, 2003. <http://www.theage.com.au/articles/2003/11/25/1069522605256.html>