Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry

Comments of the Center for Inquiry

Re: FDA-2017-D-6580

The Center for Inquiry¹ (CFI) is an educational and advocacy organization that promotes reason and scientific integrity in public affairs. Our comments are submitted 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 with its affiliate program the Committee for Skeptical Inquiry² and its division, the Richard Dawkins Foundation for Reason and Science,³ with whom we work on these matters.

CFI initially applauds the U.S. Food and Drug Administration (FDA) for its draft document “Homeopathic Guidance for FDA Staff and Industry.”⁴ CFI agrees with the FDA that there is an important role for the government to play in ensuring the safety of products labeled as homeopathic in the United States as well as responsible marketing of such products. However, CFI believes that the suggested guidance does not adequately address the major issues posed by the marketing and sale of homeopathic products in the United States and leaves patients vulnerable to significant harm caused by the inappropriate use and sale of homeopathic products. CFI has significant concerns that the draft guidance issued by the FDA represents a step back from the FDA’s responsibility to ensure that American consumers are protected from the harms caused by ineffectively labeled and inadequately tested homeopathic products. While the FDA has a responsibility to protect consumers from the dangers referenced in the proposed guidance, this alone is insufficient. CFI therefore requests that the FDA broaden its proposed enforcement priorities to include regulation of the testing and labeling of all homeopathic products.

¹ http://www.centerforinquiry.net/
² https://www.csicop.org/
³ https://www.richarddawkins.net/
In these comments, we will briefly review the scientific evidence and analysis that show homeopathy is a pseudoscientific regimen ineffective at treating illnesses; illustrate the harm caused by a reliance on homeopathy instead of actual, science-based medicine; assess changes in the homeopathic market; review the proposed guidance by the FDA; and propose a broadening of the guidance involving actions the FDA should take in order to hold homeopathic products to the same standards as non-homeopathic drugs in order to fulfill its mandate to protect the American public.

These comments will emphasize that the harm caused by homeopathy to American consumers goes far beyond the enforcement priorities listed in the draft guidance. It will stress the importance of requiring that homeopathic products, like other products regulated by the FDA, justify the health claims that they make and undergo sufficient testing to ensure that they are both safe and efficacious for public use. Currently, the FDA allows homeopathic products to be marketed without requiring these products to undergo the same testing for effectiveness that is required of conventional drugs. Despite this, homeopathic products are presented to the public as safe and effective treatments for specific diseases. Consumers are therefore regularly and significantly harmed by homeopathic products in ways beyond the scope of the draft guidelines. This harm includes the problems targeted in the draft guidance but also encompasses the significant harm involved when consumers are misled into purchasing ineffective products and thereby eschew scientifically proven, tested, and regulated remedies. CFI believes that this situation must change and that the FDA, in conjunction with the Federal Trade Commission (FTC), must play an important role in achieving that change. Such a role for the FDA should not be restricted to the limited area focused on in the draft guidance.

I. The Empirical Evidence and Homeopathy’s Foundation

Decades of scientific examination of the empirical evidence regarding the efficacy of homeopathy has shown one key factor that must be placed front and center in any review of the regulation of homeopathic products. Other than a placebo effect, homeopathic products have no effect in treating illnesses. In research studies across the world, no credible evidence has shown them to have any other impact on disease. And no scientific theory has suggested any method by which a positive impact not related to the placebo effect could result from homeopathic products.

For example, in 2015, the Australian National Health and Medical Research Council (NHMRC) released its findings on homeopathic products. These findings were the result of a meta-study conducted by that group, thoroughly assessing more than 1,800 papers on homeopathy, of which 225 met the study’s criteria for inclusion. Upon release of the analysis, the NHMRC stated:

The review found no good quality, well-designed studies with enough participants to support the idea that homeopathy works better than a placebo, or causes health improvements equal to those of another treatment. Although some studies did report that homeopathy was effective, the quality of those studies was
assessed as being small and/or of poor quality. These studies had either too few participants, poor design, poor conduct and/or reporting to allow reliable conclusions to be drawn on the effectiveness of homeopathy.\(^5\) (Emphasis added).

This meta-study dramatically undermines the common claim from homeopathy's proponents that the evidence is divided and that there are studies that show that homeopathy is effective. As the analysis shows, while one can find studies that suggest that homeopathy has brought about a positive result, these studies either are of dubious quality or are reporting on the placebo effect of homeopathic products. Moreover, even those studies that have found a placebo effect, significantly, do not, and cannot, explain if and how the particular methods of homeopathy have themselves treated the illness.

This scientific consensus on the lack of efficacy of homeopathy has led the National Health Service in England to announce this past summer that it would no longer cover homeopathic treatments. Describing homeopathy as "at best a placebo and a misuse of scarce NHS funds," the public health service determined patients would be better served by eliminating its use. This determination was supported by the Royal College of Pharmacists, who explained that the decision to stop funding homeopathy "which has no scientific or pharmacological basis ... is long overdue."\(^7\)

These same empirical findings on homeopathy have been recognized by the federal government in the United States. The National Center for Complementary and Integrative Health (NCCIH) states on its website:

> There is little evidence to support homeopathy as an effective treatment for any specific condition.\(^8\)

The FDA itself, importantly, has also recognized that homeopathy is not effective. For example, the FDA has issued numerous warnings to consumers about the health risks of relying on homeopathic products to treat serious medical conditions. These include, for example, the FDA's March 2015 warning against using homeopathic products that claim to treat asthma, an often life-threatening condition.\(^9\) In the warning, the FDA states "The U.S. Food and Drug Administration is warning consumers not to rely on asthma products labeled as homeopathic that are sold over-the-counter (OTC). These products have not been evaluated by the FDA for safety and effectiveness."\(^10\) More recently, the FDA issued a warning to parents regarding the use of homeopathic baby teething products that contained belladonna, commonly known as Deadly

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\(^7\) Id.

\(^8\) "Homeopathy." NCCIH. https://nccih.nih.gov/health/homeopathy

\(^9\) "FDA warns consumers about the potential health risks of over-the-counter asthma products labeled as homeopathic." FDA. https://www.fda.gov/Drugs/DrugSafety/ucm438976.htm

\(^10\) Id.
Nightshade, describing them as "an unnecessary risk to infants and children," and "urg[ing] consumers not to use these products." These empirical findings and subsequent government warnings are not, and should not be, at all surprising; by its own definition, homeopathy cannot work. Homeopathy is based on a hypothesis developed in the late eighteenth century, long before the advent of modern medicine and science and the understanding of the role of pathogens in causing disease. It has remained largely unaltered since that time. Homeopathy is therefore a wholly pre-scientific ideology based upon a series of pseudoscientific assumptions:

- The "law of similar" or "let likes be cured by likes." This is the belief that a medical condition can be treated by administering a diluted substance observed to cause it or to cause similar symptoms. For this reason, homeopathic products often consist of diluted solutions of toxic substances (such as the use of Deadly Nightshade in baby teething products as noted supra).
- The "law of infinitesimal doses." This is a belief that the more one dilutes an ingredient, the more powerful it becomes. As a result, many homeopathic products are diluted beyond Avogadro's Number, the point at which the final product, however large the dose taken, likely no longer contains even a molecule of the supposed active ingredient.\(^\text{12}\)
- "Essence" and "water memory." The beliefs that substances added to water impart their "essence" onto the water molecules themselves and that water retains a "memory" of things that have been in previous contact with it. This entirely unsubstantiated supposition is the invention of homeopaths who recognize the impossibility of reconciling the technique of extreme dilution with the laws of chemistry. So, although a finished homeopathic solution may no longer contain any molecules of the actual supposed remedy, homeopaths contend that the water maintains its power.
- "Miasm theory" and "vital force/vital principle theory." The hypotheses that all diseases are caused by one of three offending "miasms"—psora, syphilis, and syphilis—that disrupt the "vital force" at the core of a human being. As a system of vitalism, homeopathic products are meant to address these miasms.
- "The law of susceptibility." The hypothesis that negative thinking can attract said miasms and lead to illness.

These centuries-old, pseudoscientific principles, among others at the core of homeopathy, are not merely unsupported by evidence but also 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.

II. The Harm Caused by Homeopathy

\(^{11}\) "FDA warns consumers about homeopathic teething products." FDA. https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm523936.htm

\(^{12}\) For example, Oscilloxocinum, a homeopathic preparation that is claimed to treat influenza, consists of the liver and heart of a particular kind of duck diluted to a level of 200C, leaving one part duck offal to 10^400 parts water. By way of comparison, current estimates suggest that the known universe contains up to 10^{85} atoms.
Overwhelming empirical evidence and fundamental scientific principles indicate that homeopathy does not work as a treatment of illness, nor can it work. Despite this, companies persist in marketing homeopathic products as drugs that can effectively treat illnesses, and consumers continue to spend billions of dollars each year mistakenly believing that these products will help them.

A very significant harm of homeopathy is therefore economic—consumers are encouraged and misled into spending extremely large sums of money on products that do not and cannot treat the conditions from which they are suffering. The importance of this harm should not be dismissed, as consumers often have scarce resources for health care expenditures, and each dollar spent on homeopathic products is a dollar not available for real, science-based medicines. However, the harm caused by homeopathy is not solely economic. Reliance on ineffective treatments can pose serious risks to a person’s health. In short, too many people rely too often on homeopathic products to the exclusion of proven scientific remedies. As the 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.

In some cases, the consequences of this delay in seeking or complete rejection of science-based medicine may have tragic results. The website What’s the Harm details many such cases. We will highlight just a few key cases that illustrate our points.

**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 thirty-six months later.

**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.

**Katie 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.

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13. This economic harm to consumers is not addressed by the FDA’s new guidelines, an oversight that CFI believes must be addressed. See infra.


15. What’s the Harm? http://whatstheharm.net/homeopathy.html


when her colon perforated, but she survived when her mother finally approved surgery at the doctor’s pleading.\textsuperscript{18}

Isabella Denley of Kew, Victoria, Australia, was an epileptic toddler prescribed anti-convulstant medication by her neurologist. Her parents, however, treated her exclusively with homeopathic products. She died at just thirteen months old.\textsuperscript{19}

These examples exemplify the public’s lack of knowledge regarding homeopathy, the dangers of homeopathic products (above and beyond the dangers of toxic and tainted products), and the crucial need for the federal government, and in particular the FDA, to take an active role in ensuring the safety and efficacy of homeopathic products sold to the American population. In all too many cases the results can be tragic and either fatal or near fatal. In many more, however, the impact is less likely to make the newspapers. Those impacted by homeopathy often suffer longer than they need to from more minor ailments, such as the flu, teething issues for children, or ear infections. These ailments and their symptoms could often be treated simply and effectively with science-based remedies. Instead the patients suffer both the economic harm of being sold a pseudoscientific product that does not work and the physical harm of the continuation of their symptoms longer than needed because of their (or often their parents’) decision to utilize homeopathic products.

III. The Homeopathic Market and American Consumers

Recent years have seen a tremendous growth in the sale of homeopathic products, as well as all forms of “alternative medicine” in the United States. One study found that Americans spent roughly $2.9 billion on homeopathic products and treatments in 2007, along with an additional $170 million on visits to homeopathic practitioners.\textsuperscript{20} More recent research has indicated that U.S. sales of homeopathic and herbal remedies had risen to $5.4 billion in 2016. The homeopathic market was seen to have grown 16 percent between 2008 and 2013. The researchers here, market research firm Mintel, forecasted a steady continued increase in demand for homeopathic products.\textsuperscript{21}

Despite this rapid growth, it is clear that consumers on the whole lack basic and important knowledge on homeopathy. In late 2010, the FTC partnered with Shugoll Research to study consumer understanding of conventional and non-conventional medicines, including homeopathic products.\textsuperscript{22} As detailed in the FTC’s compelling comments to the FDA on


\textsuperscript{22} Shugoll Research, Homeopathy Focus Groups Report (Jan. 2011).
homeopathic regulation in 2015, while many adults and parents were able to differentiate conventional products from non-conventional products such as homeopathy, most were unable to differentiate between the federal regulatory and evidentiary requirements for these different types of products.23

IV. The Basis for the Regulation of Homeopathic Products

Federal agencies such as the FDA and the FTC are tasked with protecting the public from false advertising, harmful products, and alleged but baseless “remedies.” Both agencies have a critical role to play in the regulation of homeopathic products in order to protect the public.

Under the Federal Food, Drug, and Cosmetic Act (FD&C), all drug products must be shown to be safe and effective. However, as explained in part by guidance it has released over the years, the FDA has chosen to exempt homeopathic products from certain of these requirements if they meet certain conditions, such as compliance with the Homeopathic Pharmacopeia and labeling products, which provides directions for their use.

In its prior comments to the FDA on homeopathy, CFI urged the Agency to reverse course on this matter:

To ensure the protection of the American public, we believe the FDA should rely on its well established regulatory system to require homeopathic products to meet the same safety and efficacy standards as conventional drugs. That said, we recognize there are practical and political barriers to mandating this requirement.

However, no such obstacles prevent the FDA from mandating that homeopathic products carry truthful, informative labeling. We propose that the FDA require homeopathic products to carry a prominent warning that they have not been evaluated by the FDA for safety or effectiveness. In addition, the product’s labeling should disclose the product’s active ingredients in plain English, using standard scientific measurements.”24

Despite the FDA’s comments process on homeopathy, no significant steps have been taken to improve the regulation of homeopathic products. CFI continues to believe that both of these options—mandatory, scientifically reliable testing and appropriate labels with prominent warnings—represent important steps that the FDA should undertake to protect American


consumers. CFI stresses that limiting enforcement priorities to those listed in the draft guidance abandons the FDA’s responsibility to regulate in these areas.

The FTC, however, with independent authority over the advertising of homeopathic products, issued an Enforcement Policy Statement Regarding Marketing Claims for Over-the-Counter Homeopathic Drugs in November 2016. Under this statement, the FTC announced it would hold “[e]fficacy and safety claims for homeopathic drugs … to the same standards as similar claims for non-homeopathic drugs.” The FTC noted that homeopathic manufactures are unable to cite “competent and reliable scientific evidence” to support “health, safety, or efficacy claims,” such evidence being in the form of “well-designed human clinical testing,” as “[f]or the vast majority of OTC homeopathic drugs, the case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the products’ efficacy.” According to the FTC, then, “marketing claims that such homeopathic products have a therapeutic effect lack a reasonable basis and are likely misleading.” The FTC noted such deception may be avoided:

[If] that promotion effectively communicates to consumers that: (1) There is no scientific evidence that the product works and (2) the product’s claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.

CFI therefore requests that the FDA work in conjunction with the FTC to regulate homeopathic products in this manner rather than limiting its enforcement priorities.

V. The FDA Proposed Guidelines

The FDA recommended guidelines suggest a “risk-based approach” to deal with the manufacture, distribution, and marketing of homeopathic products. While continuing the current position that “any product labeled as homeopathic that is being marketed illegally is subject to FDA enforcement action at any time,” the guidelines intend “to prioritize enforcement and regulatory actions involving drug products labeled as homeopathic and marketed without the required FDA approval” in six specific categories:

- Products with reported safety concerns;
- Products that contain or purport to contain ingredients associated with particularly significant safety concerns.

26 Id.
27 Id.
28 Id.
29 Id.
- Products for routes of administration other than oral and topical;
- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions;
- Products for vulnerable populations; and
- Products deemed adulterated under section 501 of the FD&C Act.

VI. Recommendations

CFI applauds the FDA for recognizing that homeopathic products bring with them dangers to consumers. The current approach of homeopathic manufactures and the retail outlets where their products are available to the public, including supermarkets and drug stores, is to present homeopathic products as effective and safe alternatives to science-based medicine. As indicated supra, these products are not effective, and, in many situations, they may not be safe. They may contain toxic substances, such as Deadly Nightshade. The levels of the alleged active ingredient may be inadequately controlled at the manufacturing level, resulting in levels significantly higher than what the consumer believes he or she is ingesting. The product may be adulterated, further placing consumers at risk. It is justifiable that the FDA pay special attention to products that may directly poison consumers, that are targeted at consumers such as the elderly or young children who are more likely to suffer side effects, or that purport to cure the most serious conditions, whose sufferers are likely to be at their most desperate.

CFI believes, however, that the FDA’s proposed guidelines fail to address the fundamental problems with the homeopathic industry in the United States and need to be extended to address the harm suffered by American consumers. While it is eminently sensible that the most extreme problems with homeopathy—where consumers suffer avoidable death or serious injury as a result of taking homeopathic products—be especially targeted for enforcement, this should not and must not signal to the homeopathic industry that it can continue to sell billions of dollars of product in America on an annual basis while failing to provide the most basic information needed for those customers to make an informed choice.

Proponents of homeopathy often argue that homeopathic products should be available because individuals have the right to freedom of choice. CFI fully supports the right to freedom of choice. However, we also believe that true freedom of choice is impossible unless one is fully informed about the choices. The FDA, in partnership with the FTC, has the responsibility to provide appropriate guidance to consumers to enable them to become fully informed. 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 because they are not in a position to evaluate drug effectiveness themselves without incurring unacceptable risks. This is not solely to ensure that the products they purchase do not kill or gravely sicken them but also to ensure that these products actually treat the symptoms and diseases that they claim to treat. Harm to consumers is not solely direct in the form of tainted or toxic products; the FDA must also consider the
opportunity cost imposed on consumers when they spend limited resources on products with no scientific evidence of efficacy or eschew treatments that have been proven to have beneficial effects, replacing them with products that are, at best, placebos.

Accordingly, we recommend that in addition to the suggested guidelines targeting the most egregious violations by the homeopathic industry, the FDA announce and implement guidelines that require all homeopathic products meet the same standards as non-homeopathic drugs.

i. Testing for homeopathic products

The FDA is tasked with one of the most important duties within the federal government: to protect the health of all American citizens—especially from products that are either unsafe or whose alleged efficacy is unsupported by evidence. This category includes homeopathic products.

As the FDA recognizes, the 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.

Accordingly, 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. If homeopathic products can truly address illnesses and are safe, then homeopathic practitioners should welcome these studies. Any opposition should be considered a sign that homeopathic products are neither safe nor effective by modern medical standards.

ii. Labeling for homeopathic products

Although requiring homeopathic products to be tested for safety and efficacy is certainly warranted, we recognize the agency has limited resources. Some might maintain that given these limited resources, the agency need not require standard effectiveness testing for homeopathic products. Because they are relatively inert, these products do not usually pose the same risk of side effects as drugs that actually work in treating disease and symptoms. (We note, however, that there have been a substantial number of poisoning incidents involving homeopathic products. Where concentration levels are inappropriately high, or manufacturing standards lax, such poisoning may occur.) Whatever the wisdom of that approach, this clearly does not provide an argument against the appropriate labeling of homeopathic products. To the contrary, appropriate, informative labeling is even more imperative if the FDA does not require homeopathic products to be tested for safety and efficacy, as those would allow these products to remain on the market without adequate warning, marketed to a public that is unaware homeopathic products are different in kind from non-homeopathic drugs and not subject to the same regulatory process as conventional drugs.
CFI maintains that far too many homeopathic manufacturers exploit consumer ignorance about the extent to which the FDA actually regulates them. The marketing websites for homeopathic manufacturers often contain assurances that these manufactures and their products are “regulated by the FDA.” The National Center for Homeopathy, in an “infographic,” informs consumers that homeopathic products are “FDA regulated” with this assertion followed immediately by the claim that homeopathic drugs have been “clinically shown to be effective.” To the average consumer, who has some awareness of the role of the FDA in protecting the public from harmful or useless products, these messages can have no effect but to imply that the FDA has required homeopathic products to be tested for effectiveness—which, of course, is not the case.

Some homeopathic products do state on their packages that their proposed uses have not been evaluated by the FDA (for example, Boiron’s Coldcalm)—but these notices are set forth in miniscule font at the bottom of the packaging and are in no way highlighted. They are barely noticeable to the average consumer.

Many homeopathic OTC products are marketed to consumers, whether on retailers’ websites or in the local drugstore, alongside conventional drugs. Often they will be displayed under signs directed at consumers, marking the location as, for example “Cold and Flu” or “Pain Relief.” The average consumer has no reason to suspect that these products have not been evaluated for safety and efficacy by the FDA, like conventional drugs. Under these circumstances, informative labeling that is calculated to catch the attention of the customer is required.

The FDA is no stranger to labeling requirements, of course. To the contrary, requiring appropriate informative labeling is a core part of the FDA’s mission. See, e.g., Wyeth v. Levine, 555 U.S. 555, 566-67 (2009). Some labeling is intended for healthcare professionals, but, especially with over-the-counter products, the FDA’s emphasis is on informing the consumer. The FDA maintains that labeling that enables consumers to use “OTC drug products safely and effectively” is essential.

There is significant scientific evidence to support the effectiveness of labeling in improving public awareness and, by consequence, public health. One of the most comprehensive studies on

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31 See, for example, the website for Natural Care, http://enaturalcare.com/about-us/ (“Today, homeopathy is regulated by the FDA (Food and Drug Administration), and has been since 1938.” However, hidden at the bottom of the page, the company adds the disclaimer “These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease.”); the website for Zicam, http://www.zicam.com/faqs/about-zicam-products.php (“Is Zicam® Regulated by the FDA? The active ingredients in all Zicam® Cold Remedy products are listed as drugs in the Homeopathic Pharmacopoeia of the United States (HPUS) which is a compendium recognized in the Federal Food, Drug, Cosmetic Act [FD&C Act]); as such, these products are classified by the FDA as OTC homeopathic drugs. All Zicam® products are sold over-the-counter in accord with FDA’s laws, regulations and guidelines.”); and the website for Similasan, https://www.similasanusa.com/faqs (“Are Homeopathic Products regulated by the U.S. Food and Drug Administration? Yes...”) 32 “What is Homeopathy?” National Center for Homeopathy, http://www.homeopathycenter.org/what-homeopathy

this issue, which included five meta-analyses on various dimensions of warning label effectiveness, concluded "that warnings influence behavior." In particular, these meta-analyses found that certain warning labels can be effective in attracting consumers' attention and positively influencing consumer behavior. These conclusions are supported by other studies, such as one on the effectiveness of nutrition-labeling. Similarly, other studies on public health issues, such as cigarettes, have found that warning labels inform smokers about the health hazards of smoking, encourage smokers to quit, and prevent non-smokers from starting to smoke.

Significantly, these studies have stressed that it matters what kind of labels are used. For instance, very small print labels, such as the ones currently used on some homeopathic products, are far less effective—that is, in catching consumers' attention and influencing consumers' behavior—than labels that feature prominent text, colors, and/or graphics.

Accordingly, we urge the FDA to ensure that all OTC homeopathic products carry a prominent statement similar in wording to the following:

This product has not been evaluated by the FDA for either safety or effectiveness and, therefore, it has not been determined to be safe or effective in preventing or treating any condition or disease.

This statement should be included on the front of homeopathic products, in a design featuring noticeable text, colors, and/or symbolism.

Furthermore, as even educated consumers who carefully look at packaging may be mystified by the unconventional way in which the ingredients of homeopathic products are listed—Anas barbara2 200CK (the listed active ingredient in Boiron's Oscilloccinum) seems more like an incantation than a disclosure of ingredients—the FDA should require the ingredients in homeopathic products to be listed in English. With Oscilloccinum, this would require the ingredient to be listed as duck liver and heart. This would inform customers what the active ingredient actually was, assisting them in making an informed choice as to the use of the product. As regards the dilution level, the labeling 200CK again provides little of real use to the public. A dilution level of 200CK leaves a concentration level of one part of the original substance (here the liver and heart of a duck) to 10^{400} parts of water. In order to properly inform consumers as to the quantities of active ingredient in the product they are purchasing, the FDA should require

homeopathic manufacturers to list the amount of that ingredient using the standard accepted scientific format and units, for example, milligrams or grams per tablet. Alternatively, homeopathic manufacturers could list the active ingredient in terms of the percentage of the product. Such labeling requirements will inform consumers accurately and in an understandable fashion what and how much is in the product which they are purchasing.

An example of the confusing and misleading nature of the system of labeling quantities of active ingredients on homeopathic products can be seen by examining Arnicare Cream. This topical ointment, which claims to temporarily relieve muscle pain and stiffness, lists its active ingredient as *Arnica montana* 1X HPUS 7%. This translates as a product with 0.7% of the active ingredient (1X referring to a single dilution, meaning the original substance comprises one part in ten of the final product). The lay customer picking up the packaging on the shelf will likely understand the product to contain 7% of the active ingredient, if indeed the notation makes any sense at all. Consumers are not experts in homeopathy, and it is appears highly unlikely that they will have any real understanding of what any dilution levels such as 1X or 100C mean. This situation is particularly severe with over-the-counter and consumer homeopathic products, as there is no homeopath writing a prescription who it is to be hoped has an actual understanding of this notation.

Section 502(c) of the Federal Food, Drug, and Cosmetic Act and its implementing regulation, 21 C.F.R. § 201.15(c)(1), together already require that under normal circumstances, all words, statements, and other information required to appear on product labeling shall appear in the English language.

Section 502(c) of the Act requires that information required to appear on product labels must be displayed in such a manner “as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” The Section’s implementing regulation, 21 C.F.R. § 201.15(c)(1), explicitly forbids the use of non-English language labeling, except under certain circumstances that do not pertain to this instance. Specifically, it provides that required information on product labels “shall appear thereon in the English language” (provided, however that “articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.”). 21 C.F.R. § 201.15(c)(1).

In addition, the FDA’s Compliance Policy Guide Sec. 400.400, “Conditions Under Which Homeopathic Drugs May Be Marked,” states explicitly that pursuant to Section 502(c) of the Act and 21 C.F.R. § 210.15(c)(1), “the industry is required to translate these names [of homeopathic ingredients] from Latin to their common English names as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first.”

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37 http://www.arnicare.com/about/arnicare-topicals/arnicare-cream/
A review of the shelves at drugstores and supermarkets makes clear this has not occurred. For example, Boiron’s package labeling for its homeopathic flu remedy, Boiron Oscillococcinum, continues to list the product’s alleged active ingredient in Latin, “Anas barbariae” rather than the English translation of the full Latin name: “extract of Muscovy Duck liver and heart.” Indeed, since CFI filed its petition to require Boiron to use English language labeling in 2011, Oscillococcinum labels have become less informative. The ingredient as noted supra is now listed as Anas barbariae, while previously it was listed as Anas barbariae hepatis et cordis extractum. At least, previously, Latin speakers were informed which of the organs of the duck were in the product. Even that information is no longer present.

CFI believes that requiring labeling in plain English is of fundamental importance to ensuring that consumers have the information necessary to enable them to make an informed choice as to their purchases. The proposed draft guidance states that the FDA “will withdraw Compliance Policy Guide (CPG) 400.400.” 38 CFI believes that not only should this CPG 400.400 not be withdrawn, but that the FDA should rigorously enforce its guidelines interpreting homeopathic manufacturers’ responsibilities under Section 502(c) of the FD&C Act, as implemented by the regulation 21 C.F.R. § 201.15(c)(1), and require these manufacturers to clearly label their products in plain English.

It is important to note that despite the claims of homeopaths, such requirements would be neither novel nor draconian. In 2013, Health Canada announced new regulations requiring so-called homeopathic vaccines, which are falsely promoted as safer and more effective than traditional vaccines, to contain the following warning: “This product is not intended to be an alternative to vaccination.” Health Canada’s reasoning behind this requirement was that it had heard from health care professionals who were concerned the products were “being used and promoted off-label as a substitution for vaccination.” 39 The FDA’s current situation with homeopathy is no different. There are products on the market that are being advertised and promoted as safe and effective methods to treat illnesses that have not undergone scientific review. The FDA clearly has an obligation to the public to ensure these products are appropriately labeled.

iii. **Regular Consumer Warnings**

As indicated, there are significant gaps in the public’s knowledge regarding homeopathy. We have therefore been encouraged by announcements from the FDA warning customers that homeopathic products will not treat their illnesses 40 and may be harmful. 41 Such statements have

40 “FDA warns consumers about the potential health risks of over-the-counter asthma products labeled as homeopathic,” FDA. https://www.fda.gov/Drugs/DrugSafety/ucm438976.htm
helped fill gaps in the public's knowledge, and the FDA should continue to issue them. In particular, in light of the FDA's proposed guidance and focus on particular enforcement priorities, the FDA must ensure that it continues to warn consumers of the ineffectiveness of homeopathic products, in particular for dangerous and potentially fatal conditions such as asthma, which can be well treated using conventional, science-based medicine.

Conclusion

In summary, homeopathy is unsupported by scientific evidence, ineffective in treating illness, and, when relied upon instead of science-based medicine, dangerous and even potentially deadly. In order to ensure the protection of the American public, we believe the FDA needs to look significantly beyond its proposed guidelines and enforcement priorities. Indeed, regulating the priority targets as laid out in the guidelines is already the core mission of the FDA regarding homeopathy. CFI fears, therefore, that the implementation of such guidelines represents a retreat by the FDA from its responsibility to fully regulate the homeopathic industry, and to ensure on behalf of American consumers that not only are the products sold by the homeopathic industry not toxic, they also are adequately tested and labeled to ensure that consumers who choose to use them are making a truly informed choice.

CFI therefore requests that the FDA broaden its guidelines proposed here to protect consumers from harm from homeopathic remedies, both directly from poorly manufactured, tainted, or toxic products and, more indirectly, from spending limited resources on products that have been mislabeled and inappropriately marketed to create the impression contrary to scientific research that they have been tested and approved by the FDA and therefore are warranted by that agency to be safe and effective. CFI requests that the FDA:

- Require homeopathic products to meet the same safety and efficacy standards as conventional drugs; and
- Require homeopathic products to carry truthful, informative labels, including a prominent warning that they are not supported by a scientific theory of medicine and they have not been evaluated by the FDA for safety or effectiveness. In addition, the product's labeling should disclose the product's active ingredients in plain English, using standard scientific measurements.

The FDA was founded in part to help protect Americans from snake oil salesmen. Today's snake oil potions include duck liver pills (marketed in Latin as *Anas barbara* in Oscillococcinum). The American people still need protection from those who sell products that have not been shown to be either safe or effective. Homeopathic quackery is as much a threat today as snake oil was a century ago. CFI asks the FDA to take action to ensure that Americans are not wasting

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41 FDA warns consumers about homeopathic teething products.” *FDA.*
https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm323936.htm
money and delaying medical recovery because homeopathy has not be subject to the same standards as science-based medicine.

The FDA has a proud tradition of protecting the American public and of enabling it to make informed choices. CFI notes that while it is understandable that the FDA should look first to products that are directly toxic; target children, the elderly, and pregnant women; are tainted; or purport to cure terminal diseases thus encouraging desperate individuals to eschew proven, science-based medical treatments, this should not cause them to back away from their responsibility regarding other homeopathic products. The FDA should, through testing and labeling requirements, ensure that American consumers are fully informed regarding the products that they purchase to treat their illnesses.

Respectfully submitted,

The Center for Inquiry

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