The evidence has been reviewed by several regulatory bodies in other countries, and the conclusions are relevant to the FDA’s deliberations:

The National Health and Medical Research Council (Australia)

*Effectiveness of Homeopathy for Clinical Conditions: Evaluation of the Evidence* (2015)
<https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02a_information_paper.pdf>

“There is a paucity of good-quality studies of sufficient size that examine the effectiveness of homeopathy as a treatment for any clinical condition in humans. The available evidence is not compelling and fails to demonstrate that homeopathy is an effective treatment for any of the reported clinical conditions in humans.”

*NHMRC Statement on Homeopathy* (2015)
<https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf>

“Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.

Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. 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. People who are considering whether to use homeopathy should first get advice from a registered health practitioner. Those who use homeopathy should tell their health practitioner and should keep taking any prescribed treatments.

The National Health and Medical Research Council expects that the Australian public will be offered treatments and therapies based on the best available evidence.”

UK House of Commons Science and Technology Committee

*Evidence Check 2: Homeopathy* (2010)
<http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf>

“In our view, the systematic reviews and meta-analyses conclusively demonstrate

that homeopathic products perform no better than placebos. We could find no

support from independent experts for the idea that there is good evidence for the

efficacy of homeopathy.”

“We conclude that placebos should not be routinely prescribed on the NHS[National Health Service]. The funding of homeopathic hospitals—hospitals that specialise in the administration of placebos—should not continue, and NHS doctors should not refer patients to

homeopaths.”

World Health Organization

A number of WHO representatives have cautioned against the use of homeopathy for serious illness due to its lack of efficacy.

**Dr Mario Raviglione, Director, Stop TB Department, WHO**: “Our evidence-based WHO TB treatment/management guidelines, as well as the International Standards of Tuberculosis Care (ISTC) do not recommend use of homeopathy.”

**Dr Mukund Uplekar: TB Strategy and Health Systems, WHO**: “WHO’s evidence-based guidelines on treatment of tuberculosis…have no place for homeopathic medicines.”
 **Dr Teguest Guerma, Director Ad Interim, HIV/AIDS Department, WHO:** “The WHO Dept. of HIV/AIDS invests considerable human and financial resources […] to ensure access to evidence-based medical information and to clinically proven, efficacious, and safe treatment for HIV… Let me end by congratulating the young clinicians and researchers of Sense About Science for their efforts to ensure evidence-based approaches to treating and caring for people living with HIV.”
 **Dr Sergio Spinaci, Associate Director, Global Malaria Programme, WHO:** “Thanks for the amazing documentation and for whistle blowing on this issue… The Global Malaria programme recommends that malaria is treated following the WHO Guidelines for the Treatment of Malaria”. (These guidelines do not include any use of homeopathy.)
 **Joe Martines, on behalf of Dr Elizabeth Mason, Director, Department of Child and Adolescent Health and Development, WHO:** “We have found no evidence to date that homeopathy would bring any benefit to the treatment of diarrhoea in children…Homeopathy does not focus on the treatment and prevention of dehydration – in total contradiction with the scientific basis and our recommendations for the management of diarrhoea.”

Evidence Concerning the Safety & Efficacy of Homeopathic Remedies

I. Plausibility and Pre-clinical Research Evidence

1. Law of Similars

The foundational principle of homeopathy is that a substance which causes a symptom in a healthy individual can, when properly processed (c.f. Potentization by Dilution and Succussion below), cure the underlying cause of that symptom in a diseased individual.

The Academy of Veterinary Homeopathy gives the following description of this principle:

“Homeopathic practitioners have found that substances that produce symptoms similar to the symptoms of disease can be used to cure that disease…. In homeopathy a medicine (remedy) is selected which would produce in a healthy body the same symptoms found in the sick animal (“like cures like”).

The way a particular substance is associated with a given symptom or set of symptoms is by referring to collections of what are called “pathogenetic trials” or “provings.” This is a method in which healthy individuals ingest or are otherwise exposed to a substance and keep a diary for days or weeks afterwards listing every physical and emotional experience they have. These diaries are then evaluated and patterns of similar symptoms are identified and then codified as symptoms that substance can cause.

Many of the provings used to guide homeopathic treatment today were conducted by Samual Hahneman himself, who invented homeopathy in the late 18th century. Subsequent efforts to demonstrate consistency or reproducibility of homeopathic provings have been unsuccessful. (1-6)

The concept of "like cures like" has an appealing logic and symmetry to it. It is essentially a variation of "sympathetic magic," the idea that things which resemble one another in some superficial way must be meaningfully related and that one can influence the other. Many cultures have magical practices in which one makes an effigy or figure resembling an individual, a "voodoo doll" for example, and then uses it to indirectly affect the health of that individual. Yellow plants are used to treat jaundice. Walnuts are eaten to treat problems in the brain because walnuts look a little like the human brain. Preparations of mandrake root are used to aid fertility because the root looks a little like a human penis. Examples of such sympathetic magic, which can be found in folk medicine traditions throughout the world. Scientific investigation has not, however, found the idea of sympathetic magic to be a reliable principle for deciding which substances in the natural world will be useful as medicines.

And despite the primacy of the Law of Similars in homeopathic theory, it is often difficult to relate this to the remedies actually used. It is possible, for example, to buy homeopathic products made from body parts such as hip joints and colons, animals such as iguana and dragonfly, and different kinds of sunlight. It is also possible to buy products derived from precious archaeological features such as the Great Wall of China and Stonehenge. It is difficult to understand what symptoms could be induced (and therefore be treated) by these products under the like-cures-like principle.

1. Potentization by Dilution and Succussion

The problem with giving a remedy that causes certain symptoms in order to treat those symptoms is that, obviously, doing so will almost certainly make the patient worse. In developing the theories of homeopathy, Hahneman solved this problem by progressively diluting the remedies until, in most cases, they no longer contain any active ingredients at all. Homeopaths believe that the more dilute a remedy is, the more potent it is, though only if it is vigorously shaken during the dilution process.

In testimony before the House of Commons Science and Technology Committee, Dr Peter Fisher, Director of the Royal London Homeopathic Hospital, described how homeopathic dilutions are made:

“[They] are prepared by a process of sequential dilution with vigorous shaking at each stage of dilution, known as succussion. Dilution is usually in steps of 1:10 or 1:100, referred to as x or d (decimal) or c (centesimal) respectively.

For example, a 30C dilution indicates that the solution has been diluted in the ratio of 1:100, thirty times successively; one drop of the original solution would be diluted with 100 drops of water and the resulting solution would be diluted again, and so on until 30 dilutions had taken place. According to the Prince's Foundation for Integrated Health, in some homeopathic products "not even a single molecule of the original substance remains in the diluted medicine prescribed to the patient."

Dr Fisher stated that the process of "shaking is important" but was unable to say how much shaking was required. He said "that has not been fully investigated” but did indicate that "You have to shake it vigorously…if you just stir it gently, it does not work."

The principle that a therapeutic substance becomes more potent the lower the dose, and that it can still be active even when it contains only the diluent (water), is inconsistent with the fundamental principles of chemistry and physiology underlying all of scientific medicine. A revolution in basic science would need to take place for this idea to have any possibility of being correct, and the inconsistent and low-quality studies that have attempted to validate homeopathic theory do not justify such a revolution.(7-9)

The Royal Pharmaceutical Society of Great Britain (RPSGB) offers the following comments on this issue:

“The philosophy of homeopathy that a substance becomes more potent as it is diluted goes against the conventional theory of the pharmacological action of compounds in the body…There is no robust scientific evidence to suggest that differences can be detected between ultradilute homeopathic remedies and the diluent used to prepare the remedy in terms of their physical properties and behaviour.”

“As a consequence of their extreme dilution, most high dilution/potency homeopathic remedies do not contain a single active molecule. The administration of a preparation containing substance at such large dilutions leads to a RPSGB view that such preparations will not produce clinical effects.”

There have been many attempts to demonstrate that ultradilute substances can have biological effects, *in vitro* or *in vivo*. Some studies in dedicated homeopathy or alternative medicine journals have reported positive findings, but a review of these studies found numerous methodological problems and ultimately concluded:

“There is a lack of independent replication of any pre-clinical research in homoeopathy. In the few instances where a research team has set out to replicate the work of another, either the results were negative or the methodology was questionable.”(9)

Other reviews have also found that replications of pre-clinical studies in homeopathy are often not successful, leading to an absence of consistent, repeatable evidence for the basic theoretical principles behind the practice.(10) Even the Prince's Foundation for Integrated Health, which is generally supportive of homeopathy, notes, "any specific mechanism of action based on extreme dilution is implausible and regarded as unsupportable by the majority of scientists working in this field."

One of the few studies published in the mainstream medical literature concerning ultradilute homeopathic remedies, published in *Nature* in 1988, purported to show that such a remedy could influence the degranulation of human basophils. (11) Because the findings were so revolutionary, the journal took the unprecedented step of arranging for an independent team of investigators to observe replications of the experiment.

This team found that the results had been generated by an unblinded technician, and when this individual was unaware of the treatment given to each sample, the positive findings disappeared.(12) Subsequently, multiple attempts by independent researchers to replicate the original experiment also failed to find an effect.(13-14) A review published in a homeopathy journal in 2009 concluded that after twenty years of research, it was still impossible to determine conclusively that purported effects of ultradilute solutions on human basophils were not due solely to artifact.(15)

Many theories have been proposed to explain how water containing no other substances could have potent and specific therapeutic effects. Homeopaths have claimed water has selective memory for the substances used to make homeopathic remedies or that in some way not yet understood quantum mechanics validates their claims. Attempts to validate claims that homeopathic remedies are measurably distinct from ordinary water have been methodologically weak and not reproducible.(16-18)

The proposed mechanisms of homeopathy are shown to be implausible when analyzed from a physical and chemical perspective, and thus it is of no surprise that the biological effects of homeopathy cannot be measured in large-scale clinical trials.

1. Clinical Trial Evidence
2. Human Studies

There have been an enormous number of clinical trials of homeopathy conducted in humans. These have been summarized in many systematic reviews over the last twenty years, and several clear patterns have emerged

1. Most studies are of poor quality, at high risk of bias, and published in journals dedicated to homeopathy and other alternative therapies. Despite this, a consistent clinical effect has not been identified.
2. Higher quality studies are much more likely to have negative findings. Studies with poor control for bias, confounding, and non-specific effects of participation in a clinical trial (placebo effect, Hawthorne effect, regression to the mean, spontaneous resolution, etc.) are more likely to have positive results.
3. Occasional positive findings cannot be replicated and disappear when methodological flaws are corrected.
4. The positive effects sometimes reported are far weaker than those for matched conventional therapies and unlikely to be clinically meaningful.
5. The balance of the evidence unquestionably indicates that the effects of homeopathic treatment are due to placebo effects, chance, bias, confounding, and other sources of error, *not* true therapeutic effects.

After an extensive review of the evidence and testimony from experts both supportive and critical of homeopathy, the House of Commons Science and Technology Committee concluded:

In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos. We could find no support from independent experts for the idea that there is good evidence for the efficacy of homeopathy.

Similarly, the Australian National Health and Medical Research Council (NHMRC) reviewed the evidence and concluded:

Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective.

Homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. 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. People who are considering whether to use homeopathy should first get advice from a registered health practitioner. Those who use homeopathy should tell their health practitioner and should keep taking any prescribed treatments.

The most recent review has specifically compared studies of homeopathic treatments with matched studies of conventional therapies to identify whether a clear effect beyond placebo could be seen for either. The conclusion was that while all clinical trials are imperfect, it is possible to distinguish a true therapeutic effect from placebo effects for conventional therapies but not for homeopathic treatment:

Biases are present in placebo-controlled trials of both homoeopathy and conventional medicine. When account was taken for these biases in the analysis, there was weak evidence for a specific effect of homoeopathic remedies, but strong evidence for specific effects of conventional interventions. This finding is compatible with the notion that the clinical effects of homoeopathy are placebo effects.(19)

Because there have been so many systematic reviews of clinical trials on homeopathic treatment, there is even a systematic review of those reviews. This review evaluated all prior systematic reviews and meta-analyses of homeopathy. According to the summary of this review:

 Electronic databases were searched for systematic reviews/meta-analysis on [homeopathy]. Seventeen articles fulfilled the inclusion/exclusion criteria. Six of them related to re-analyses of one landmark meta-analysis. Collectively they implied that the overall positive result of this meta-analysis is not supported by a critical analysis of the data.

Eleven independent systematic reviews were located. Collectively they failed to provide strong evidence in favour of homeopathy. In particular, there was no condition which responds convincingly better to homeopathic treatment than to placebo or other control interventions. Similarly, there was no homeopathic remedy that was demonstrated to yield clinical effects that are convincingly different from placebo.

It is concluded that the best clinical evidence for homeopathy available to date does not warrant positive recommendations for its use in clinical practice.”(20)

The assessment of the eleven independent systematic reviews analyzed is summarized in Table 1.(21-31)

The “landmark meta-analysis” referred to in this review, and often cited by supporters of homeopathy, concluded homeopathy did have an effect greater than placebo:

The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo. However, we found insufficient evidence from these studies that homeopathy is clearly efficacious for any single clinical condition.(32)

Due to numerous criticisms of the methodology used, this study has been re-analyzed six times, including one re-analysis by the original authors. These subsequent analyses are summarized in Table 2.(33-38) All of the independent re-analyses concluded that the appearance of effects greater than placebo was related to the inclusion of poor-quality studies in the original analysis. The authors’ re-analysis of their own study concluded:

Studies that were explicitly randomized and were double-blind as well as studies scoring above the cut-points yielded significantly less positive results than studies not meeting the criteria. In the cumulative meta-analyses, there was a trend for increasing effect sizes when more studies with lower-quality scores were added…We conclude that in the study set investigated, there was clear evidence that studies with better methodological quality tended to yield less positive results.(35)

A comprehensive and critical look at the voluminous clinical trial evidence in humans concerning homeopathy demonstrates that despite centuries of use and study, no reliable or consistent evidence has been generated to show homeopathy is effective for a single indication, and it is impossible to demonstrate that the effects which are sometimes reported for homeopathic treatment are due to anything other than placebo effects and non-specific clinical trial effects inadequately controlled for in poor-quality trials. This contrasts starkly with the enormous advancement scientific medicine has made in the same time period, and illustrates clearly that homeopathy is an ineffective therapy.

1. Veterinary Studies

Not surprisingly, the clinical trial literature concerning homeopathy in veterinary medicine is considerably weaker in quantity and quality than the human clinical trial evidence. No systematic reviews or meta-analyses exist. The clinical trials that have been reported are generally small, not replicated, and have significant methodological limitations. Both positive and negative trials are reported, but despite claims of efficacy and decades of use and investigation, no clear pattern of evidence has emerged to support the efficacy of homeopathy for any indication.

A recent systematic review of the entire veterinary homeopathy literature was unable to find convincing evidence of a therapeutic effect.(36) This review was conducted by two advocates for homeopathy, clearly with an interest in supporting the practice: “Each of us is employed by a homeopathy charity to clarify and extend an evidence base in homeopathy.” Yet despite this obvious agenda, the authors attempt to follow the conventional standards for a systematic review, and the result is not very encouraging for homeopaths.

An extensive search found only 18 clinical trials that were eligible to be evaluated. Of these, one had a low risk of bias, six had an uncertain risk of bias, and eleven had a high risk of bias. Of the seven that had a low or uncertain risk of bias, three showed a statistically significant effect, three showed no effect, and one could not be evaluated. Of these seven trials, two were judged to provide “reliable evidence” based on an overall assessment. One showed a significant effect and the other did not. Both, the authors note, had some odd design features that made them different from the standard clinical trial format.

So the best that two committed supporters of homeopathy could find when attempting an objective evaluation of the veterinary homeopathy literature were two studies that were probably pretty reliably conducted, one of which found an effect and one of which didn’t. Once again, in the face of the inherent implausibility of the practice (despite the nonsense about “nanoparticles” which these authors themselves reference as if it solved the plausibility problem), and a century and a half of dedicated effort, such a glaring lack of positive evidence is far more consistent with homeopathy being a placebo than with it being the dramatically effective therapy its proponents claim.

Considering the clear pattern for small, poor quality human clinical trials to show positive results which cannot be replicated and which are contradicted by negative results in larger, better quality trials, the veterinary literature is not convincingly supportive of homeopathy. None of the few positive trials are methodologically adequate to rule out chance, bias, confounding, and other sources of falsely positive results.

The argument is sometimes made that the presence of some positive results in the published literature, even given limitations in the control for potential sources of error, justifies deferring judgment on the efficacy of homeopathy and pursuing additional research. While those interested in this therapy are, of course, free to continue trying to produce convincing evidence of efficacy for homeopathy, it is difficult to justify indefinitely withholding judgment on a medical therapy that has failed to conclusively demonstrate its value in over 200 years.

The theoretical foundations of the practice are implausible and incompatible with established science. The enormous pre-clinical and clinical trial literature in humans has failed to validate the practice. And the limited research in veterinary species is more compatible with homeopathy being a placebo than with having a clinically meaningful therapeutic effect. As the House of Commons Science and Technology Committee concluded:

There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious. Competition for research funding is fierce and we cannot see how further research on the efficacy of homeopathy is justified in the face of competing priorities.

1. The Dangers of Homeopathy
2. Direct Harm

It is generally assumed that because homeopathic preparations frequently do not contain any active ingredients or any trace of the substance from which they were originally made, that they are intrinsically safe. For the most part, direct harm from ingestion of homeopathic remedies is very uncommon. However, there is evidence that direct harm from such remedies does occur.

The World Health Organization (WHO) supports, as a matter of policy, traditional or folk systems of medicine as an expression of cultural identity. Without taking a position on the scientific evidence for efficacy, the WHO has provided guidelines for countries wishing to permit the sale and use of homeopathic remedies. In these guidelines, the WHO acknowledges:

there are a few aspects of the production of homeopathic medicines that could constitute potential safety hazards. Firstly, not all homeopathic medicines are administered at a high dilution. Sometimes, a homeopathic medicine made from source material, such as a mother tincture, is administered in the most concentrated form.

Secondly, homeopathic medicines are made from a wide range of natural or synthetic sources: minerals and chemicals, but also plant materials, including roots, stems, leaves, flowers, bark, pollen, lichen, moss, ferns and algae; microorganisms, including fungi, bacteria, viruses and plant parasites; animal organs, tissues, secretions and cell lines. Human materials may include tissues, secretions, hormones, and cell lines. Some of these source materials constitute potential safety hazards, even at high dilutions.

However, safety assessment should also consider possible impurities of the source material or contamination and failures of good manufacturing practice.

There have been some reports of detectable heavy metal contamination of homeopathic remedies.(37) Given the absence of evidence for efficacy, even such small risks seem difficult to justify.

1. A much more significant risk is the substitution of an ineffective therapy for truly beneficial care. Homeopaths frequently recommend their patients avoid conventional medicine. For example, the Academy of Veterinary Homeopathy (AVH) Standards of Practice state:

Only the remedy that is homeopathic to the patient is to be used.

Drugs and methods of treatment which are not homeopathic to the case are to be avoided because of the possibility of interference with the progress of cure. [the footnote reads," Organon of Medicine, 6th edition, paragraphs 23, 25-45, 69, and 291. Here discussion of the curative effect of similar medicines and the harmful effects of non-similar medicines is made clear. Drugs, herbs and other forms of treatment prevent cure and cause ultimate harm to the patient. Hahnemann states that only the medicine homeopathic to the patient's condition is to be used in treatment."]

Exceptions are made for life-threatening illnesses and situations in which there is a clear reason a patient cannot stop taking a conventional medicine, but this only emphasizes that homeopathy is self-evidently not effective in such cases. The danger lies in selecting homeopathic treatment over scientific medicine in cases where the threat to health and life is not immediately apparent.

The AVH also takes a position well beyond that justified by science concerning the use of vaccines:

During homeopathic treatment, vaccination is usually contraindicated. If health problems have arisen or are exacerbated by vaccination, homeopathy is one of the few medical specialties that recognizes these problems and has the potential to address them curatively. Some veterinary homeopaths recommend no vaccines of any kind. Some will tailor a limited vaccination protocol for you and your pet. Whatever your options and your decision, your veterinary homeopath can provide guidance and an important perspective.

While not all homeopaths discourage conventional therapy, the practice is fundamentally based on the premise that conventional, scientific medicine is in error in its basic approach and that homeopathy is an entirely different, and superior, way to truly cure disease. There have been a number of well-documented cases of people following this line of reasoning strictly and suffering severe injury or death as a result.(38)

Given that all medicine involves balancing risks against benefits, the case against homeopathy seems clear. There is a conspicuous absence of evidence of benefits despite centuries of use and investigation. And there are real risks, not to mention ethical concerns, associated with substituting an ineffective therapy for truly beneficial medical care. The balance seems unquestionably weighted against treating homeopathy as a legitimate veterinary therapy.

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