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HOMEOPATHY ON TRIAL: *ALLEN V. HYLAND'S, INC.* AND A FAILURE OF EVIDENTIARY GATEKEEPING

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ABSTRACT: This article explores how the law, through rules governing the admissibility of expert evidence, can—but sometimes fails to—safeguard consumers from misleading scientific and medical claims. Americans spend approximately three billion dollars annually on homeopathic health-care products. But do these products actually work, and, if they do not, are there are any legal consequences for those who make money by claiming that they do? This article addresses these questions. It first explains the responsibility of trial courts to act as evidentiary "gatekeepers," with the power to preclude the admission of unreliable evidence in support of purportedly scientific claims. It then discusses the nature, history, and evidentiary basis of homeopathy; describes a lawsuit tried to a southern California jury in 2015, in which consumers alleged that Hyland's, Inc. misrepresented the efficacy of its homeopathic products; and outlines how evidentiary gatekeeping failed in that case—resulting in a jury verdict in favor of Hyland's. This article concludes by considering the harms that can flow from such a failure and offers thoughts on the importance of ensuring that litigants and courts focus their efforts on precluding pseudoscience from distorting the civil justice system.

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> Every time the federal government [or anyone else] drags a quack into court, he has no trouble at all finding scores of people willing to testify about miraculous cures.
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> —Martin Gardner[1]

Americans spend over 30 billion dollars annually on "alternative" health care products.[2] By some estimates, approximately three billion of those dollars are spent by six million Americans on "homeopathic" remedies.[3] But do these products actually *work*? Perhaps surprisingly, although the Food and Drug Administration (FDA) regulates the labeling of homeopathic products, it does not regulate their *efficacy*. In other words, unlike the manufacturers of mainstream medicine, who must demonstrate to the FDA that their products actually do what they say they do, the makers of homeopathic remedies are under no such obligation.[4]

Given this regulatory vacuum, if homeopathic products do *not work*, are there any legal consequences for those who make money by claiming that they *do*? In some areas of the law, where government either cannot or does not fully occupy the field of regulation, litigation steps in. This happens, for example, in the area of consumer protection. In the case of homeopathy, absent regulation of its efficacy by the FDA, it may be up to consumers to bring private challenges—testing its claims in court.

But how, exactly, can the judicial system evaluate what many view as the extravagant claims of homeopathy? Can and should a jury be tasked with weighing the evidence for and against its efficacy? Is there even a reasonable debate to be weighed—and if not, do the courts have a mechanism for dealing with scientific and medical claims that arguably have no reasonable basis? This article explores these questions. Part I discusses the responsibility of federal courts to act as evidentiary *gatekeepers*, allowing only those propositions with sufficient scientific support to reach a jury. Part II discusses the nature of homeopathy and its principles. Part III outlines the history of homeopathy and its critics—and shows what appears to be a compelling absence of scientific and medical support for its claims.

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1. MARTIN GARDNER, FADS & FALLACIES IN THE NAME OF SCIENCE: THE CURIOUS THEORIES OF MODERN PSEUDOSCIENTISTS AND THE STRANGE, AMUSING AND ALARMING CULTS THAT SURROUND THEM 187 (1957).

2. *See* Maggie Fox, *Americans Spend $30 Billion a Year on Alternative Medicine*, NBC NEWS (June 22, 2016, 11:37 AM), http://www.nbcnews.com/health/health-news/americans-spend-30-billion-year-alternative-medicine-n596976.

3. *See, e.g.*, *Homeopathy*, NAT'L INSTS. HEALTH, https://nccih.nih.gov/health/homeopathy (last updated Apr. 2015).

4. *See id.* ("FDA does not evaluate the remedies for safety or effectiveness."); Harriet A. Hall, *An Intro to Homeopathy*, CSI (Apr. 30, 2014), http://www.csicop.org/specialarticles/show/an_intro_to_homeopathy ("In the United States, prescription drugs must be proved safe and effective before the FDA will approve them for marketing, but homeopathic remedies are not required to undergo any kind of testing."). This may soon change, as the FDA is currently reviewing its policy on homeopathy. *See infra* Section III.E.

Finally, Part IV describes a recent private challenge to those claims—a lawsuit tried to a southern California jury in the summer of 2015, in which consumers sued Hyland's, Inc., alleging that it misrepresented the efficacy of its homeopathic products. Disconcertingly, the jury in that case found in favor of Hyland's. This article proposes that this outcome was driven by a failure of the gatekeeping process by which courts decide whether purported "evidence" amounts to the kind of valid science that should be allowed into the jury room. It then concludes with a discussion of the harms that can flow from such a failure, and thoughts on the importance of ensuring that litigants and courts focus their efforts on precluding pseudoscience from distorting the civil justice system.

I. SCIENTIFIC EVIDENCE AND GATEKEEPING IN FEDERAL COURT

Scientific evidence plays a significant role in modern litigation. Indeed, it "is increasingly used in litigation as science and technology become more pervasive in all aspects of daily life."[5] In lawsuits that involve issues beyond the knowledge of the average juror, such as issues revolving around science and technology, expert witnesses often provide such evidence in the form of opinion testimony.

Expert testimony has great persuasive power. It thus has a corresponding power to mislead. As one commentator has cautioned: "Expert witnesses and attorneys should be aware of the studies that have been conducted regarding jurors' perception of expert witnesses. These studies have shown that jurors give great weight to expert testimony."[6] Accordingly, experts do not have free range to testify whenever, and on whatever subject, a litigant desires. Instead, courts place reasonable limits on their use. Thus, for example, the Federal Rules of Evidence state that a witness may offer expert opinion testimony only if all of the following are satisfied: "the expert's scientific, technical, or otherwise specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue"; "the testimony is based on sufficient facts or data"; "the testimony is the product of reliable principles and methods"; and "the expert has reliably applied the principles and methods to the facts of the case."[7]

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5. William W. Schwarzer & Joe S. Cecil, *Management of Expert Evidence*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 39, 42 (2d ed. 2000); *see also* DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 1-1.0 (2002) ("Science and technology will only grow in importance in the twenty-first century.")

6. Carol Henderson, *Expert Witness: Qualifications and Testimony*, *in* SCIENTIFIC EVIDENCE REVIEW: ADMISSIBILITY AND USE OF EXPERT EVIDENCE IN THE COURTROOM, MONOGRAPH NO. 6 1, 10 (2003); *see also id.* at 11 (citing Joan Cheever & Joanne Naiman, *The View from the Jury Box*, NAT'L L.J., Feb. 22, 1993, at s2, which "concluded that jurors were influenced by expert witnesses and accorded their opinions great weight. In the civil and criminal cases surveyed, eighty-nine percent of the jurors thought the experts were believable."); Carol Henderson Garcia, *Expert Witness Malpractice: A Solution to the Problem of the Negligent Expert Witness*, 12 MISS. C. L. REV. 39, 45 (1991) ("Jurors tend to give undue weight to expert opinions because we're all taught to believe science is infallible.").

7. FED. R. EVID. 702(a)–(d).

The U.S. Supreme Court has further elaborated on this standard. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[8] in the context of expert testimony based on "scientific knowledge," the Court explained that "'scientific' implies a grounding in the methods and procedures of science," and "'knowledge' connotes more than subjective belief or unsupported speculation"—it "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths *on good grounds*."[9] With this in mind, the Court explored the circumstances under which an expert may be allowed to testify on the basis of purported scientific knowledge.

The *Daubert* Court explained that "the Rules of Evidence . . . assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand."[10] This task involves determining, among other things, whether "the reasoning or methodology underlying the testimony is scientifically valid."[11] The Court noted that this is a "flexible" inquiry, and that its "overarching subject is the scientific validity and thus the evidentiary relevance and reliability . . . of the principles that underlie a proposed submission."[12] In subsequent decisions, the Court explained that federal trial courts have a "'gatekeeping' obligation" to admit only such expert testimony as is sufficiently relevant and scientifically reliable.[13]

A court's responsibility to screen expert evidence and scientific testimony for reliability can be a demanding task, and is necessarily accomplished on a case-by-case basis, considering the facts and opinions offered. The gatekeeping role of the courts "will sometimes ask judges to make subtle and sophisticated determinations about scientific methodology and its relation to the conclusions an expert witness seeks to offer."[14] Courts must, as one prominent commentator has argued, "develop sufficient mastery of science to exert control over the admission of scientific evidence; judges . . . sit to protect the integrity and fairness of the trial process."[15] This does not mean that judges must become "amateur scientists." Instead, it requires only that they be able to grasp the "basic logical principles" at the core of scientific theories and methodologies.[16]

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8. 509 U.S. 579 (1993).

9. *Id.* at 590 (emphasis added) (quoting WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1252 (1986)).

10. *Id.* at 597.

11. *Id.* at 592–93.

12. *Id.* at 594–95.

13. *See* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142 (1997). Many state courts have a similar obligation. *See, e.g.*, Sargon Enters., Inc. v. Univ. of S. Cal., 288 P.3d 1237, 1250 (2012) ("Under California law, trial courts have a substantial 'gatekeeping' responsibility."); *see also* Robert G. Knaier, *A Gatekeeper Embraced: Expert Opinion Testimony and the Long Road from* Daubert *to* Sargon, 26 CAL. LITIG., no. 3, 2013, at 37, 40.

14. *Joiner*, 522 U.S. at 147 (Breyer, J., concurring).

15. David L. Faigman, *Mapping the Labyrinth of Scientific Evidence*, 46 HASTINGS L. J. 555, 577 (1995).

16. *See* David L. Faigman, *The Tipping Point in the Law's Use of Science: The Epidemic of Scientific Sophistication that Began with DNA Profiling and Toxic Torts*, 67 BROOK. L. REV. 111, 124–25 (2001); *see also* Robert L. Park, *Science in the Courts*, 36 NEW ENG. L. REV. 575, 580

To assist trial court judges in evaluating the admission of scientific evidence, the Supreme Court has offered specific guidance. In *Daubert*, the Court explained that a number of nonexclusive factors are helpful in evaluating proposed scientific testimony: whether the theory or technique underlying it "can be (and has been) tested"; whether it "has been subjected to peer review and publication"; its "known or potential rate of error"; and whether it has gained "general acceptance" in the relevant scientific community.[17] Federal courts have subsequently explained that additional factors may be relevant under the circumstances of the particular case, such as "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying"—with the former serving as "important, objective proof that the research comports with the dictates of good science."[18] In addition, courts may consider whether the proposed "expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion," "has adequately accounted for obvious alternative explanations," and "is being as careful as he would be in his regular professional work outside his paid litigation consulting."[19]

Finally, in evaluating whether proposed expert testimony is sufficiently reliable to reach a jury, courts may consider whether "the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give."[20] Indeed, *Daubert*'s "general acceptance" test cannot be relied upon to "help show that an expert's testimony is reliable where the discipline itself lacks reliability, as, for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy."[21] Trial courts are thus not left without standards to apply in deciding whether to allow expert testimony to reach a jury. That does not, however, mean that they always apply those standards with the same level of rigor.

II. HOMEOPATHY AND ITS UNDERLYING PRINCIPLES

Homeopathy is a form of "alternative" health care. Its products are not, as many appear to believe, simply the sort of "natural" or "herbal" items one might

(2002) ("Basically, the Supreme Court ruled that federal judges have a responsibility to . . . make sure that juries do not hear scientific nonsense.").

17. 509 U.S. at 593–94.

18. Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (citing PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 206–09 (1991)).

19. FED. R. EVID. 702, advisory committee's note to 2000 amendment; *see also* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999) (explaining that one objective of the *Daubert* standard is to "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Joiner*, 522 U.S. at 146 (noting that a trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered"); Claar v. Burlington N.R.R., 29 F.3d 499 (9th Cir. 1994) (affirming the exclusion of expert testimony that failed to consider other obvious causes for the plaintiff's condition).

20. FED. R. EVID. 702, advisory committee's note to 2000 amendment.

21. *Carmichael*, 526 U.S. at 151.

find in any health food store.[22] They are, instead, remedies produced according to rather specific principles. According to the National Center for Complementary and Integrative Health (NCCIH), a division of the National Institutes of Health (within the U.S. Department of Health and Human Services), homeopathy is based on "two unconventional theories: 'like cures like'—the notion that a disease can be cured by a substance that produces similar symptoms in healthy people; and 'law of minimum dose'—the notion that the lower the dose of the medication, the greater its effectiveness."[23]

A. "Like Cures Like"

The principle of "like cures like"—referred to by advocates of homeopathy as *similia similibus currentur*—is a relatively simple concept. If something *causes* an *effect* in a *healthy* person, it also, at the right dose, can *relieve* a similar *symptom* in a *sick* person. For example: "Coffee can keep us awake. A typical homeopathic remedy for insomnia is therefore based on coffee."[24] Some have regarded this as "more an assumption than a principle," because it has little empirical support.[25]

Ingredients for homeopathic remedies are discovered "not by controlled studies but by 'provings.'"[26] During provings, healthy people ingest a substance and report "*everything* that happens" to them over the following hours and days.[27] A homeopathic practitioner then compiles these reports into "a *Repertory* where [other] homeopath[s] can look up a patient symptom or characteristic to see what remedies had been associated with it in provings."[28] However, because "[t]here is no attempt to separate the ordinary vicissitudes of everyday life from symptoms caused by the substance," these compilations can include a wildly broad array of effects that may or may not have been caused by the substance.[29]

Nevertheless, to identify an appropriate remedy for a given symptom, homeopaths consult the *Materia Medica*, which lists effects purportedly associated with each remedy.[30] Such effects can include "eyelids heavy, anemic headache

22. *See* JOSEPH SCHWARCZ, IS THAT A FACT? FRAUDS, QUACKS, AND THE REAL SCIENCE OF EVERYDAY LIFE 54 (2014) ("Let's begin by explaining what homeopathy is not. It is not an umbrella term for alternative or complementary practices."); SIMON SINGH & EDZARD ERNST, TRICK OR TREATMENT: THE UNDENIABLE FACTS ABOUT ALTERNATIVE MEDICINE 97 (2008) (noting that the founder of homeopathy "was adamant that homeopathy was distinct from herbal medicine, and modern homeopaths still maintain a separate identity and refuse to be labelled herbalists").

23. *Homeopathy*, *supra* note 3; *see also* EDZARD ERNST, HOMEOPATHY: THE UNDILUTED FACTS 9–10 (2016).

24. ERNST, *supra* note 23, at 9.

25. *Id.*

26. Hall, *supra* note 4; *see also* SINGH & ERNST, *supra* note 22, at 96.

27. *See* Hall, *supra* note 4; *see also* GARDNER, *supra* note 1, at 188.

28. Hall, *supra* note 4.

29. *Id.*; *see also* BEN GOLDACRE, BAD SCIENCE: QUACKS, HACKS, AND BIG PHARMA FLACKS 33 (2010) ("There are obvious problems with this system. For a start, you can't be sure if the experiences the 'provers' are having are caused by the substance they're taking or by something entirely unrelated.").

30. *See* SINGH & ERNST, *supra* note 22, at 101; *see also* Hall, *supra* note 4.

of schoolgirls, constipation, diarrhea, sensation of coldness of heart, palms hot and perspiring, hangnails, dreams of robbers, oily skin, warts on palms of hands, chill between 9 and 11 am, etc."[31] One remedy listed for these particular symptoms: *natrum muriaticum*, that is, table salt.[32] Indeed, the list of homeopathic remedies ranges from the mundane to the extravagant: "[a]mong remedies listed in the homeopathic *Materia Medica* are Berlin wall, eclipsed moonlight, the south pole of a magnet, dog's earwax, tears from a weeping young girl, rattlesnake venom, and poison ivy."[33] According to homeopaths, these remedies and others form the bases of effective medicine.

B. "Law of Minimum Dose"

Homeopathic "medicine" is then administered according to the "law of minimum dose," also referred to as the "law of infinitesimals." The impulse behind this principle is that once a substance is identified that causes an effect in a healthy individual, it should then be diluted to the point that it no longer causes that effect.[34] Given that many homeopathic ingredients "start out with toxic intent (e.g. the active ingredient in poison oak or the protective discharge emanating from the cuttlefish),"[35] dilution might initially seem sensible. However, advocates of homeopathy further contend that dilution actually *increases* the potency of the resulting remedy, so long as the dilution is "accompanied by succussion (a carefully prescribed vigorous shaking of the mixture in a special manner)."[36] Thus, to create powerful remedies, dramatic dilution (with repeated succussion) is the norm.

Homeopathic products list the level to which they have been diluted, using the notations X and C.[37] The notation X refers to ten, and the notation C refers to one hundred; thus, a 10C dilution would be accomplished by diluting one part of a given substance in 100 parts of water, then diluting the resulting solution again in 100 parts of water, and ultimately repeating this process ten times.[38] This method can result in the initial substance being "administered in inconceiv-

31. Hall, *supra* note 4.
32. *Id.*
33. *Id.*
34. *Id.*
35. R. BARKER BAUSELL, SNAKE OIL SCIENCE 15 (2007).
36. *Id.* at 14–15; *see also* ERNST, *supra* note 23, at 10 (explaining that homeopathy's founder "became convinced that the process transfers some information or *vital energy* from the less to the more dilute remedy"); GOLDACRE, *supra* note 29, at 32–33 (describing "succussion" as providing a "sense of ritual and occasion," and noting that in its original form, it involved "ten firm strikes" against "a bespoke wooden striking board, covered in leather on one side and stuffed with horsehair"); SINGH & ERNST, *supra* note 22, at 96 (explaining that the founder first came to believe in the importance of succussion after "carrying his remedies on board a horse-drawn carriage," and concluding that the "vigorous shaking of the vehicle had further increased the so-called *potency* of his . . . remedies"); Hall, *supra* note 4 (describing "succussion" as remedies being "vigorously shaken (not stirred) by striking them against a leather surface at every step of dilution").
37. *See* SINGH & ERNST, *supra* note 22, at 97–98.
38. *Id.*

ably small doses" with "[c]ompounds [that] are frequently diluted to one *decillionth* (i.e., a millionth of a millionth of a millionth, etc., up to ten of these millionths) of a grain."[39]

In fact, homeopathic dilutions often result in products that contain "not a single molecule of the original substance."[40] Using Avogadro's number, it has been calculated that this is the case once a 13C dilution has been reached.[41] Many homeopathic products exceed this level of dilution. For example, the "most popular homeopathic cold and flu remedy," Oscillococcinum, "is sold as a *200C dilution*."[42] At these levels, what is likely left after the dilution process is nothing more than water, or, more accurately, sugar, as the resulting solution is often applied to a sugar pill for consumption (from which the water evaporates).[43]

Another way to conceptualize the absence of any purportedly active ingredients in homeopathic dilutions is to consider the volume of the final solution that would be required to be able to conclude that a single molecule of the original substance remains. At the common homeopathic dilution of 30C, "it would take a container 30 million times the size of the Earth to hold enough of the remedy to make it likely that it would contain a single molecule of the original substance."[44] And at "the declared homeopathic dose of 200C [for Oscillococcinum], the total mass of pills that would have to be consumed to encounter a single molecule of the original substance would be billions of times greater than the mass of the Earth."[45]

C. Defenses of Homeopathy

Given the facial implausibility of these core principles, one might wonder how advocates of homeopathy defend them. Regarding like cures like, the claim is often made that it is a principle on par with vaccination. However, unlike homeopathic remedies, which typically contain no active ingredients, vaccines

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39. GARDNER, *supra* note 1, at 188.

40. BAUSELL, *supra* note 35, at 15; *see also* ERNST, *supra* note 23, at 8; SINGH & ERNST, *supra* note 22, at 98–99.

41. Hall, *supra* note 4; *see also* ERNST, *supra* note 23, at 72–73 (explaining Avogadro's number and its relation to homeopathic dilutions).

42. Hall, *supra* note 4 (emphasis added); *see also* SCHWARCZ, *supra* note 22, at 56 ("[C]alculations readily show that homeopathic products such as Oscillococcinum 200C [a popular homeopathic flu remedy] do not contain a single molecule of the duck organs that serve as the raw materials for the production of the final 'remedy.'").

43. *See* SCHWARCZ, *supra* note 22, at 58 ("A drop of the diluted . . . solution is added to a pill made of sucrose and lactose, but the water soon evaporates."); *see also* SINGH & ERNST, *supra* note 22, at 99 ("[H]omeopathic remedies usually contain no active ingredient whatsoever.").

44. Hall, *supra* note 4; *see also* GOLDACRE, *supra* note 29, at 35 ("Imagine a sphere of water with a diameter of ninety million miles (the distance from the Earth to the sun) . . . with one molecule of a substance in it: that's a 30C dilution."). To further illustrate the concept of a 30C dilution, it amounts to a "dilution of 1 in 100^{30}," or "1 in 1,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000." *Id.*; *see also* ERNST, *supra* note 23, at 9, 81; SINGH & ERNST, *supra* note 22, at 98.

45. SCHWARCZ, *supra* note 22, at 57; *see also* GOLDACRE, *supra* note 29, at 35 ("At a homeopathic dilution of 200C . . . the treating substance is diluted more than the total number of atoms in the universe, and by an enormously huge margin.").

actually "contain measurable numbers of antigen molecules, . . . act by well-understood scientific mechanisms, and their results can be quantified by measuring antibody titers."[46] Regarding infinitesimal doses, advocates of homeopathy often point to a phenomenon called "hormesis," under which "a low dose of a chemical may trigger the opposite response to a high dose."[47] Hormesis, however, is not a well-established phenomenon across a broad category of substances, and, in any event, "describes a response to a *low* dose, not to *no* dose."[48] Homeopathy's core principles thus appear to have little conceptual support.

And what of the evidence that these products, at common dilutions, do not—and cannot—contain any active ingredients at all? Generally, advocates respond in ways that defy basic scientific principles. One answer is that the process of creating the final remedy leaves "some sort of imprint on the solution,"[49] or that the water used in the dilution process has a "memory" of the active ingredient.[50] A more specific way to make this claim is by contending that having been in contact with the original substance, "water clusters" form, store information in some way, and thus have an effect once the substance, itself, is gone. However, although such clusters do form, they "last for trillionths of a second and there's no way they could register or transmit information."[51] Moreover, past common levels of dilution, homeopathic solutions simply contain "no water molecules that have ever come into contact with the original substance!"[52]

Other answers include the hypothesis that homeopathic remedies contain "nanoparticles" that make them effective.[53] Still other explanations invoke a "vital force," "vibrations," the release of "energy" during the succussion process, and the effects of "quantum entanglement."[54] Even homeopathy's founder

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46. Hall, *supra* note 4; *see also* ERNST, *supra* note 23, at 10 ("Like might cure like in very special situations, but it is not a law that is applicable to all substances and all situations."); *id.* at 15 ("Contrary to most highly *diluted* remedies, *vaccines* do contain measurable amounts of active ingredients and they cause measurable responses of the immune system.").

47. Hall, *supra* note 4.

48. *Id.*

49. SCHWARCZ, *supra* note 22, at 57.

50. Hall, *supra* note 4; *see also* BAUSELL, *supra* note 35, at 15; ERNST, *supra* note 23, at 10; GOLDACRE, *supra* note 29, at 36; SINGH & ERNST, *supra* note 22, at 100.

51. Hall, *supra* note 4; *see also* GOLDACRE, *supra* note 29, at 36 ("[W]hile it is true that water molecules will form structures around a molecule dissolved in them at room temperature, the everyday random motion of water molecules means that these structures are very short-lived, with lifetimes measured in picoseconds, or even less."); SCHWARCZ, *supra* note 22, at 58 ("Water molecules do associate with each other momentarily through what any student of chemistry recognizes as hydrogen bonds. But these connections last only picoseconds before the molecules rearrange themselves.").

52. SCHWARCZ, *supra* note 22, at 58.

53. *See, e.g.*, Iris R. Bell & Mary Koithan, *A Model for Homeopathic Remedy Effects: Low Dose Nanoparticles, Allostatic Cross-Adaptation, and Time-Dependent Sensitization in a Complex Adaptive System*, 12 BMC COMPLEMENTARY & ALTERNATIVE MED., art. no. 191, 2012, at 1, 2.

54. *See* ERNST, *supra* note 23, at 25 (explaining that homeopathic remedies have been described as "vital force captured in a bottle"); Hall, *supra* note 4 (noting that these "ill-informed speculations" regarding quantum entanglement "would have a quantum physicist rolling on the floor"); Matthew Silverstone, *Scientific Proof that Homeopathy Works*, NAT. NEWS (Sept. 13, 2011), http://www.naturalnews.com/033558_homeopathy_science.html ("It is not the chemicals in

"came to believe that the healing power of his remedies did not depend on the substances contained in them, but that their 'action must be called spirit-like.'"[55] But none of these explanations has offered a plausible answer to the problem that, under the laws of biology and physics as we know them, homeopathic products appear to contain no active ingredients.[56]

The various ways in which homeopathy fails the test of basic scientific plausibility have not escaped the eyes of careful observers—or of governmental agencies charged with considering these issues. The NCCIH, mentioned at the outset, is "the Federal Government's lead agency for scientific research on the diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine."[57] Its "mission . . . is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care."[58] Having investigated the usefulness and safety of homeopathy, and its unconventional practices and products, the NCCIH has reached unambiguous conclusions.

First, "key concepts of homeopathy are not consistent with fundamental concepts of chemistry and physics."[59] As the NCCIH has recognized, "[m]any homeopathic remedies are so diluted that no molecules of the original substance remain," and it is "not possible to explain in scientific terms how a remedy containing little or no active ingredient can have any effect."[60] Further, and perhaps not surprisingly, given the inherent implausibility of homeopathic principles, the NCCIH has found that "[m]ost rigorous clinical trials and systematic analyses of the research on homeopathy have concluded that there is little evidence to support homeopathy as an effective treatment for any specific condition."[61]

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the solution that cause a biological change but the vibrations that emanated from the chemicals, which have an affect [sic].").

55. ERNST, *supra* note 23, at 10.

56. *See* SCHWARCZ, *supra* note 22, at 59 ("[I]f you are willing to abandon or misuse the laws of chemistry, physics, and biology, you . . . can be satisfied by explanations that invoke 'vital force' or 'quantum entanglement.'"); *see also* SINGH & ERNST, *supra* note 22, at 100 ("From a scientific perspective, it is impossible to explain how a remedy that is devoid of any active ingredient can have any conceivable effect on any medical condition, apart from the obvious placebo effect."); Patrick L. Sheldon, *The Truth About Homeopathy: A Discussion of the Practice and the Dangers that Inhere*, 8 QUINNIPIAC HEALTH L.J. 289, 289 (2005) (warning of "the dangers associated with licensing the practice of homeopathy"). Sheldon notes further that the principles of homeopathy "are undermined by the laws of chemistry, scientific evaluations, and pure logic." *Id.* at 293. He concludes that "it is borderline unconscionable for a state to consider recognizing the practice of homeopathy." *Id.* at 308.

57. *About NCCIH*, NAT'L INSTS. OF HEALTH, https://nccih.nih.gov/about (last updated Nov. 18, 2015).

58. *NCCIH Facts-at-a-Glance and Mission*, NAT'L INSTS. OF HEALTH, https://nccih.nih.gov/about/ataglance (last modified June 3, 2016).

59. *Homeopathy*, *supra* note 3.

60. *Id.*; *see also* BAUSELL, *supra* note 35. Bausell describes homeopathy as a "therapy for which absolutely no scientifically defensible biochemical mechanism of action has been proposed." *Id.* at 247–48. He notes that absent any active ingredient, the "perfect homeopathic drug . . . could also serve as a very nice definition of a placebo." *Id.* at 261.

61. *Homeopathy*, *supra* note 3.

In other words, while "[s]cientific knowledge about chemistry, physics, and biology tells us [homeopathy] *should not work*," the NCCIH and others have noted that "careful testing has shown that it *does not work*."[62]

III. THE HISTORY OF HOMEOPATHY AND ITS EVIDENTIARY BASIS

A. Origins and Early Development

Homeopathy has a long and storied history. In the late 1700s and into the early 1800s, "conventional medicine was a disaster."[63] "Doctors weakened patients with bloodletting and purging; they poisoned them with mercury and other harmful substances; they killed more patients than they cured."[64] Given the state of medical science, many looked to alternative forms of health care for relief—even when that relief came from otherwise questionable sources.[65]

Samuel Hahnemann, a German physician born in 1755,[66] "was looking for safer, more effective ways to help his patients."[67] Indeed, even critics of home-

62. Hall, *supra* note 4.

63. *Id.*

64. *Id.*; *see also* ERNST, *supra* note 23, at 27 (explaining that medical treatments of the time "might have been well-intentioned, but they were neither safe nor effective," and conventional medicine "was often more dangerous than the diseases it was supposed to treat"); SINGH & ERNST, *supra* note 22, at 7–14 (describing the history of bloodletting—including the well-documented theory that U.S. President George Washington finally met his demise as a result of a radical bloodletting); Maxwell J. Mehlman, *Quackery*, 31 AM. J. L. & MED. 349, 350 (2005) ("[I]llness and injury were rampant. The germ theory of disease had not yet been discovered. Sanitation and good nutrition were virtually unknown. Hospitals were charnel houses.").

65. *See* Mehlman, *supra* note 64, at 350 ("[T]he 19th century quacks were not simply unscrupulous entrepreneurs who took advantage of gullible patients. They emerged in response to serious shortcomings of mainstream American medicine. . . . Faced with unresolved disease and horrific standard treatments, it is not surprising that many people sought relief by going to what might be considered quacks."); *see also* ERNST, *supra* note 23, at 17 ("Considering the atrocious risks of *heroic medicine* . . . it is easy to see why homeopathy quickly conquered the world."); GOLDACRE, *supra* note 29, at 31 ("At a time when mainstream medicine consisted of bloodletting, purging, and various other ineffective and dangerous evils, when new treatments were conjured up out of thin air by arbitrary authority figures who called themselves doctors, often with little evidence to support them, homeopathy would have seemed fairly reasonable."); SINGH & ERNST, *supra* note 22, at 108–09 (describing the sorry state of what has come to be known as the era of "heroic medicine," when "aggressive tactics" such as bloodletting, intestinal purging, and large doses of toxic substances were the norm).

66. Hahnemann was well educated, spoke several languages as a young man, and received his M.D. in 1779, at age 24. ERNST, *supra* note 23, at 21. He also was a "deeply religious and spiritual man." *Id.*

67. Hall, *supra* note 4; *see also* ERNST, *supra* note 23, at 22 ("As a young physician, Hahnemann began to realize that the health care of his time was neither *safe* nor *effective*."); SCHWARCZ, *supra* note 22, at 54–55 (explaining that "Hahnemann . . . became disillusioned with bloodletting, leeches, suction cups, purges, and arsenic powders, all standard treatments at the time," that it "seemed to Hahnemann that these did more harm than good," and that, in this regard, "[h]e was probably right"); SINGH & ERNST, *supra* note 22, at 94 ("[Hahnemann] gradually realized that his medical colleagues knew very little about how to diagnose their patients accurately, and worse still these doctors knew even less about the impact of their treatments, which meant that they probably did more harm than good.").

opathy recognize that "Hahnemann's arguably greatest achievement was to realise that patients were ill-served by [conventional] health care."[68] In its place, Hahnemann articulated the core principles of homeopathy. He noticed that after ingesting a dose of cinchona bark, he "developed symptoms similar to those of malaria, the disease cinchona was supposed to treat."[69] From this correlation, and from seeing it in his patients, Hahnemann derived the principle of "like cures like."[70] He further believed that by diluting the substances he identified as effective, so that they no longer caused symptoms in healthy individuals, he could somehow create powerful remedies for the sick.[71] Hanemann's "remedies" seemed a welcome alternative to conventional medicine, because they appeared to have no adverse side effects.[72] (Of course, it would later become increasingly clear that the reason for this is the absence of any active ingredients.)

Hahnemann first published on his "peculiar notions" in 1796,[73] in his *Law of Similars*.[74] In 1807, he "coined the word *Homöopathie*, from the Greek *hómoios* and *pathos*, meaning similar suffering."[75] In 1810, Hahnemann published *Organon of the Medical Art*, the definitive statement of his principles.[76] And in 1811, he published *Pure Materia Medica*.[77] Given the apparent safety of its remedies, and the increasing belief that they were effective, homeopathy then "spread rapidly through Europe during the first half of the nineteenth century."[78] It became "particularly fashionable in Paris in the 1830s," after Hahnemann married a young Parisian woman and moved there.[79] By the next decade, it reached England and America.[80] Indeed, homeopathy gained a strong foothold

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68. ERNST, *supra* note 23, at 27.

69. Hall, *supra* note 4; *see also* SCHWARCZ, *supra* note 22, at 55; SINGH & ERNST, *supra* note 22, at 95.

70. *See* ERNST, *supra* note 23, at 23.

71. Hall, *supra* note 4; *see also* SINGH & ERNST, *supra* note 22, at 95. Hahnemann may have been led to this principle out of a concern that some of the substances identified as effective were, in fact, poisonous. For example, he concluded that belladonna "could be used to treat sore throats, because it caused throat constriction in healthy subjects"—but because belladonna is a "classic poison," Hahnemann theorized that it should be administered in infinitesimal doses. SCHWARCZ, *supra* note 22, at 55; *see also* ERNST, *supra* note 23, at 23 ("Initially, Hahnemann [diluted his remedies] mainly because he needed to minimize the side-effects of the frequently toxic substances he employed as medicines.").

72. ERNST, *supra* note 23, at 25 ("Patients generally approved of Hahnemann's new method, and it is not difficult to see why: in sharp contrast to the *heroic treatments* of his conventional colleagues, his remedies were free of side-effects."); *see also* Mehlman, *supra* note 64, at 350–51 ("Homeopathy used tiny amounts of active substances that produced few ill effects.").

73. OLIVER WENDELL HOLMES, SR., *Homeopathy and Its Kindred Delusions*, *in* 9 THE COMPLETE WRITINGS OF OLIVER WENDELL HOLMES: MEDICAL ESSAYS 41 (Boston, Houghton Mifflin Co. 1892) (1842).

74. *See* SINGH & ERNST, *supra* note 22, at 95.

75. *Id.* at 96.

76. *Id.*; *see also* HOLMES, *supra* note 73, at 41 (referring to the Hahnemann work as *Organon of the Healing Art*).

77. HOLMES, *supra* note 73, at 41.

78. SINGH & ERNST, *supra* note 22, at 105; *see also* GARDNER, *supra* note 1, at 189.

79. SINGH & ERNST, *supra* note 22, at 106.

80. GARDNER, *supra* note 1, at 189.

in England, where it has long been "traditional for the Royal Family to maintain a homeopath as family physician."[81] And within "a few decades after [it] had arrived in America, the US had over 20 homeopathic colleges and around 60 homeopathic hospitals."[82]

B. A Century of Criticism

Hahnemann died in 1843. As early as 1842, however, his theories were suffering withering criticism. That year, Oliver Wendell Holmes, Sr.—physician, poet, humorist, and father of the future U.S. Supreme Court Justice, Oliver Wendell Holmes, Jr.—gave two lectures to the Boston Society for the Diffusion of Useful Knowledge, the second of which addressed homeopathy. Its claims, Holmes noted, "are considered by some as infinitely important, and by many as immeasurably ridiculous."[83] He had a "firm belief that [homeopathy's] pretensions and assertions cannot stand before a single hour of calm investigation,"[84] and he later published his lectures as a book entitled *Homeopathy and Its Kindred Delusions*.[85]

Holmes first described Hahnemann's ideas, including like cures like; the law of infinitesimal doses; and a third principle, one already largely abandoned by advocates of homeopathy: the belief that the overwhelming majority of chronic diseases are caused by an "infectious disorder"[86] called "Psora" or "Itch."[87] Holmes argued that the likelihood of one person discovering three such important, yet seemingly disconnected, laws of nature defies belief. As he put it,

> [W]hen one man claims to have established these three independent truths, which are about as remote from each other as the discovery of the law of gravitation, the invention of printing, and that of the mariner's compass, . . . the question naturally arises, Is not this man deceiving himself, or trying to deceive others?[88]

81. *Id.* at 190; *see also* ERNST, *supra* note 23, at 17 ("In the UK, homeopathy has enjoyed royal protection ever since it was first introduced in the 19th century."); Harriet A. Hall, *Homeopathy: Still Crazy After All These Years*, 15 SKEPTIC 8, 9 (2009) ("It's popular in Great Britain where Queen Elizabeth uses it, Prince Charles promotes it, five homeopathic hospitals are still operating, and the National Health Service is paying a good chunk of its budget for it.").

82. ERNST, *supra* note 23, at 29.

83. HOLMES, *supra* note 73, at 39; *see also* SINGH & ERNST, *supra* note 22, at 106–07 (discussing various arguments made by "ardent supporters and fervent critics" of homeopathy in America).

84. HOLMES, *supra* note 73, at 39.

85. OLIVER WENDELL HOLMES, SR., HOMEOPATHY AND ITS KINDRED DELUSIONS: TWO LECTURES DELIVERED BEFORE THE BOSTON SOCIETY FOR THE DIFFUSION OF USEFUL KNOWLEDGE (Boston, William D. Ticknor 1842).

86. HOLMES, *supra* note 73, at 45.

87. *Id.* at 45–46, 57.

88. *Id.* at 57.

Holmes also questioned not only Hahnemann's motives, but his scholarly integrity, noting that others had "proved many of Hahnemann's quotations from old authors to be adulterated and false."[89]

Holmes nevertheless inquired into the particulars of Hahnemann's claims. Regarding like cures like, he noted that while there is "no essential absurdity involved in the proposition that diseases yield to remedies capable of producing like symptoms,"[90] the belief that

> *every* cure ever performed by medicine should have been founded upon this principle, . . . that the Homœopathic axiom is, as Hahnemann asserts, 'the *sole* law of nature in therapeutics,' . . . is a dogma of such sweeping extent, and pregnant novelty, that it demands a corresponding breadth and depth of unquestionable facts to cover its vast pretensions.[91]

Just as David Hume explained in the mid-eighteenth century that a "wise man . . . proportions his belief to the evidence,"[92] Pierre Simon Laplace noted in the late-eighteenth century that "we ought to examine [phenomena] with an attention as much the more scrupulous as it appears the more difficult to admit them,"[93] and Carl Sagan argued in the late twentieth century that "extraordinary claims require extraordinary evidence,"[94] Holmes recognized that the burden of proof lay with Hahnemann and his followers, given their extravagant claims.

Regarding the law of infinitesimal doses, Holmes felt no need to grant even the barest plausibility. Whereas he found no "essential absurdity"[95] with the principle of "*Like* cures *Like*,"[96] he quickly noted that "[s]o much ridicule [had already] been thrown upon the pretended powers of the *minute doses*" that he needed only "touch upon this point for purposes of conveying, . . . some shadow of ideas far transcending the powers of the imagination to realize."[97] Although Holmes did not have the benefit at the time of Avogadro's number and its power to show that homeopathic dilutions left solutions without a trace of active ingredients, he recognized that by "simple arithmetical calculations, level to the capacity of any intelligent schoolboy,"[98] homeopathic dilutions were inherently absurd.

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89. *Id.* at 64.

90. *Id.* at 51.

91. *Id.* at 52.

92. DAVID HUME, AN ENQUIRY CONCERNING HUMAN UNDERSTANDING 80 (Peter Millican ed., Oxford Univ. Press 2007) (1748).

93. PIERRE SIMON LAPLACE, A PHILOSOPHICAL ESSAY ON PROBABILITIES 105 (Frederick Wilson Truscott & Frederick Lincoln Emory trans., John Wiley & Sons 1902) (1812). This has sometimes been stated as follows: "The weight of evidence for an extraordinary claim must be proportioned to its strangeness." *See, e.g.*, *Pierre Simon Laplace*, TODAY SCI. HIST., https://todayinsci.com/L/Laplace_PierreSimon/LaPlacePierreSimon-Quotations.htm (last visited Apr. 19, 2017).

94. *See Cosmos: A Personal Voyage*; *Encyclopaedia Galactica*, at 1:32 (PBS television broadcast Dec. 14, 1980), http://www.dailymotion.com/video/x1h5p4k_carl-sagan-s-cosmos-e12-encyclopaedia-galactica_tv.

95. HOLMES, *supra* note 73, at 51.

96. *Id.* at 69.

97. *Id.* at 52.

98. *Id.*

Unlike other criticisms of homeopathy, which note the enormous amount of water that would have to be present in a final homeopathic solution to allow for the presence of a single molecule of the original substance, Holmes noted that the amount of fluid required to accomplish common homeopathic dilutions in the first place is staggeringly large. If 100 drops of fluid are required for the first stage of a dilution, and 10,000 drops are required for the second (thus diluting the first 100 again by 100), then, following that pattern, "[b]y the time the seventeenth degree of dilution should be reached, the alcohol [sometimes used as the dilution base] required would equal in quantity the waters of ten thousand Adriatic seas."[99] After further such thought experiments, Holmes posed the question, with no hint of sympathy: "Is there not in this as great an exception to all the hitherto received laws of nature as the miracle of loaves and fishes?"[100]

Ultimately, Holmes addressed "the most directly practical point connected with the subject, namely,—What is the state of the evidence as to the efficacy of the proper Homœopathic treatment in the cure of diseases."[101] He considered the opinions of the general public, to which he gave little credence, given popular beliefs in other dubious medical cures.[102] He considered the testimony of homeopathic practitioners, giving them little weight because of their inherent bias and the fact that their reports of success "are always, or almost always, written with the single object of showing the efficacy of the medicine used, or the skill of the practitioner, and it is recognized as a general rule that such cases deserve very little confidence."[103] Finally, Holmes looked to the "results of trials by competent and honest physicians, not pledged to the system [of homeopathy]."[104] There, he found evidence for "the entire nullity of the influence of all the Homœpathic remedies."[105]

Holmes concluded with a scathing critique of his subject: "Such is the pretended science of Homœopathy, to which you are asked to trust your lives and the lives of those dearest to you. A mingled mass of perverse ingenuity, of tinsel erudition, of imbecile credulity, and of artful misrepresentation . . . ."[106] Holmes did not expect homeopathy to last, and he presciently suggested that if it were to, the fault would lie in those who seek to benefit financially from its existence, at the expense of others: "If it should claim a longer existence [than previous sham medical cures], it can only be by falling into the hands of the sordid wretches who wring their bread from the cold grasp of disease and death in the hovels of ignorant poverty."[107]

Homeopathy nevertheless persisted. By 1900 an "immense literature" had grown up around the discipline.[108] But criticisms of homeopathy also persisted.

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99. *Id.* at 53.
100. *Id.* at 54.
101. *Id.* at 70.
102. *Id.* at 70–71.
103. *Id.* at 75.
104. *Id.* at 70.
105. *Id.* at 80 (citing French physician, Gabriel Andral (1797–1876)).
106. *Id.* at 101.
107. *Id.*
108. GARDNER, *supra* note 1, at 189.

In 1952, famed scientific skeptic Martin Gardner included it in his exhaustive exploration of pseudoscience, *Fads & Fallacies in the Name of Science*.[109] Echoing Holmes' devastating critique, Gardner began by noting that homeopathy was "[t]he first medical cult of any importance in America."[110] In referring to homeopathy as a cult, Gardner highlighted the ways in which its adherents clung to beliefs contrary to logic, evidence, and even the most basic scientific principles.

Gardner noted that dilutions common among homeopathic products were equivalent to "letting a drop of medicine fall into the Pacific, mixing thoroughly, then taking a spoonful."[111] He criticized Hahnemann's apparent belief that as a "drug became less 'material'" through the dilution process, "it gained 'spiritual' curative powers."[112] He noted common defenses of homeopathic principles—that like cures like is a principle on par with vaccination, and that at least some substances have been shown to be more effective at low doses—responding that "[t]he homeopathic error was to take both these limited truths, exaggerate them to the point of absurdity, and apply them universally to all medicines."[113]

As with many of his other critiques of pseudoscience, Gardner's focus on homeopathy was not necessarily that it posed a physical danger itself. He noted that homeopathic products, "in the diluted form in which they are given, are entirely harmless—producing neither symptoms nor cures (except, of course, psychosomatic ones)."[114] Indeed, in February 2007, James Randi, Gardner's long-time friend and fellow investigator of suspect claims, famously swallowed an entire bottle of homeopathic "sleeping pills" during a TED Talk on irrational beliefs.[115] Randi is still alive. His and Gardner's concern, however, was that the purveyors of homeopathic products are engaging in wrongful deception—amounting to fraud for economic gain—which also poses a risk of harm should purchasers of homeopathic products forgo effective medical treatments because of their belief that one "alternative" or another may provide relief.

Like Holmes, Martin Gardner had his doubts about whether homeopathy would last. He noted that at around the beginning of the twentieth century, "the movement declined," with schools of homeopathy closing their doors and fewer and fewer physicians practicing the craft.[116] And although there had been a "marked revival" in the middle of the century, particularly in Germany and France, homeopathy's popularity in the United States was waning.[117]

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109. *Id.* at 187–91.
110. *Id.* at 187.
111. *Id.* at 188.
112. *Id.*
113. *Id.* at 188–89.
114. *Id.* at 189.
115. *See* James Randi, *Homeopathy, Quackery and Fraud*, TED (Feb. 2007), http://www.ted.com/talks/james_randi?language=en.
116. GARDNER, *supra* note 1, at 190. Indeed, the popularity of homeopathy had been declining during the latter part of the nineteenth century, driven in part by the emergence of evidence-based medical breakthroughs, such as clinical trials, epidemiology, and effective vaccinations. *See* SINGH & ERNST, *supra* note 22, at 111–14.
117. GARDNER, *supra* note 1, at 190; *see also* SINGH & ERNST, *supra* note 22, at 114–15 (describing a resurgence in Germany, including among the Nazis).

C. Contemporary Skepticism

In recent years, however, unconventional medical treatments, including homeopathy, have made a comeback. Some commentators have noted that just as displeasure with eighteenth- and early nineteenth-century medicine drove the initial popularity and adoption of homeopathy, a similar displeasure with *modern* medicine has driven recent increases in the popularity of "complementary" or "alternative" medicine.[118] In the 1970s, in particular, a period in which some in the West were looking for alternative means of health care, many turned to homeopathy—which they saw as "an exotic, natural, holistic and individualized form of medicine."[119] Indeed, by the early twenty-first century, homeopathy had become "big business."[120] It is now widely used throughout the world, as "[m]illions of patients and consumers swear by homeopathy and employ its remedies on a daily basis."[121] Just one of its supposed flu remedies generates approximately $15 million per year in revenue in the United States alone.[122]

But again, as homeopathy persists, so do its critics—railing against its principles and against those who, as Holmes put it over 170 years ago, "wring their bread from the cold grasp of disease and death."[123] Dr. Harriet Hall, a retired family physician, former Air Force flight surgeon, and noted skeptic (she is a Fellow of the Center for Inquiry and writes the "SkepDoc" column in *Skeptic* magazine), has spent a great deal of energy highlighting the flaws in homeopathy. She has observed that homeopathy is "one of the longest running forms of pseudoscience in the modern world."[124] Hall attributes much of homeopathy's continued popularity to a broad misunderstanding of what it *is*—with some believing that it simply refers to a "mild natural herbal remedy."[125] Hall also points out, as many have, that compared to mainstream medicine, homeopathy is inexpensive and (because it contains no active ingredients) has no side effects.[126] It is, she explains, "the ideal placebo."[127] Further, homeopathic practitioners often

118. *See* BAUSELL, *supra* note 35, at 3 ("We have . . . entered an era of consumer dissatisfaction with conventional medicine's inability to treat, much less fix, chronic, sometimes disabling aches and pains. But, for better or worse, dissatisfaction tends to create demand, which in turn is met by supply. And in this case, what was being supplied was a truly bewildering variety of therapies, the vast majority of whose practitioners approached medical care from a holistic, nonbiological, nonpharmacological, noninvasive, non-evidence-based, nonscientific perspective."); ERNST, *supra* note 23, at 43 ("One important reason for today's popularity of homeopathy is clearly that many patients are not impressed with what modern medicine has to offer."). Additionally, Ernst notes that the "current boom in homeopathy can be seen as a poignant criticism of certain aspects of modern health care," including the lack of personalized attention, the ineffectiveness of many pharmaceuticals, and the presence of serious side effects. *Id.* at 44–46.

119. SINGH & ERNST, *supra* note 22, at 117; *see also* ERNST, *supra* note 23, at 17.

120. Hall, *supra* note 4.

121. ERNST, *supra* note 23, at 3.

122. *See* Hall, *supra* note 4.

123. HOLMES, *supra* note 73, at 101.

124. Hall, *supra* note 81, at 8.

125. *Id.*; *see also* Hall, *supra* note 4 ("Many consumers have no understanding of what homeopathy *is* . . . .").

126. Hall, *supra* note 4.

127. Hall, *supra* note 81, at 9.

spend significant time with their patients, offering solace and therefore magnifying the placebo effect.[128] What's wrong with that? Hall's response is that prescribing placebos is "unethical: we don't lie to patients; we can't tell them a remedy is effective if we know it is no more effective than a sugar pill."[129]

Dr. Hall is not alone in this assessment. Ben Goldacre, Senior Clinical Research Fellow at Oxford's Centre for Evidence Based Medicine, has made a career out of identifying misuses and misunderstandings of science—and explaining these issues in ways useful to the general public. In his best-selling book, *Bad Science: Quacks, Hacks, and Big Pharma Flacks*, Goldacre exhaustively discusses the failings of homeopathy.[130] He notes, among other things, that while homeopathy's "proponents are quite clear that the pills will make you better, . . . in fact they have been thoroughly researched, with innumerable trials, and have been found to perform no better than placebo."[131] Similarly, Dr. Joe Schwarcz, science popularizer and Director of McGill University's Office for Science and Society, included a chapter on homeopathy in his recent exploration of scientific misunderstanding, *Is That a Fact? Frauds, Quacks, and the Real Science of Everyday Life*. Known for his efforts to demystify science and expose pseudoscience, Dr. Schwarcz explains that homeopathy is "a practice that is based on principles that cannot be supported by the established laws of chemistry, biology, or physics."[132] For Schwarcz, "the results are clear. The effects of homeopathy are indistinguishable from the placebo effect."[133] Being misinformed about this "can have consequences ranging from a needless waste of money to an individual foregoing more effective treatments."[134]

Finally, famed magician, escape artist, and skeptic James Randi, has—like Houdini before him—spent much of his life investigating dubious claims and exposing those who would profit from them. He has long had homeopathy in his sights. In addition to having publicly swallowed bottles of homeopathic sleeping pills to demonstrate their impotence,[135] Randi has boldly challenged the homeopathy industry to prove that its products actually work. Through its Million Dollar Challenge, the James Randi Educational Foundation for many years offered to reward—with one million dollars—anyone who could provide evidence sufficient to demonstrate the truth of various paranormal claims. In 2011, Randi extended that offer to the manufacturers of homeopathic products: prove that they work in a double-blind study, and win the million dollars.[136] The

128. *Id.*; *see also* Hall, *supra* note 4 ("The initial consultation with a homeopath typically lasts an hour. He inquires about every conceivable aspect of the patient's life.")

129. Hall, *supra* note 81, at 9.

130. GOLDACRE, *supra* note 29, at 30–64.

131. *Id.* at 31.

132. SCHWARCZ, *supra* note 22, at 54.

133. *Id.* at 60.

134. *Id.* at 54.

135. *See* Randi, *supra* note 115.

136. Olivia Salon, *Sceptic Offers $1 Million for Proof That Homeopathy Works*, WIRED (Feb. 8, 2011), http://www.wired.co.uk/article/homeopathy-challenge [https://perma.cc/8PK9-MXHV].

reward has not been collected. Ultimately, given the extravagant claims of homeopathy, and the absence of evidence for its efficacy, Randi has cataloged homeopathy as nothing more than an attempt at "sympathetic magic."[137]

D. Broad Scientific and Medical Consensus

Criticisms of homeopathy are not limited to professional skeptics. The modern scientific and medical communities also see little value in it. Indeed, although "[a]lternative medicine," including homeopathy, "claims to be able to treat the same illnesses and diseases that conventional medicine tries to tackle, . . . we can test these claims by *evaluating the evidence*."[138] The results of that evaluation have been clear: a scientific consensus has formed that the evidence for homeopathy is lacking.

In many ways leading this charge is Edzard Ernst, M.D., Ph.D., emeritus professor at the University of Exeter. Notably, Ernst was raised in a family that believed in homeopathy, and he was "regularly treated" with homeopathic remedies as a child.[139] He later began his career practicing and researching homeopathy, publishing extensively on the subject.[140] Ernst ultimately became skeptical of homeopathy and other "alternative" medical treatments, which led to a critical examination of their principles. He has since spent the past few decades pointing out their flaws.[141] In 2008, he published *Trick or Treatment: The Undeniable Facts About Alternative Medicine* with science journalist and particle physicist Simon Singh, outlining the absence of credible evidence for alternative medicine.[142] And in 2016, Ernst published *Homeopathy: The Undiluted Facts*, an accessible guide to homeopathy in which he concludes, after evaluating hundreds of clinical trials and systematic reviews, that there is no plausible mechanism by which homeopathy *might* work—and no consistently reliable evidence showing that it *does* work.[143]

But Ernst is not merely an author. He is a researcher. In 2002, he conducted his own broad analysis of several scientific reviews of homeopathy.[144] Ernst located 17 systematic reviews and meta-analyses, and analyzed their results. He found that "considerable doubt" exists on the proposition that "homeopathic remedies retain biological activity even when diluted beyond Avogadro's number."[145] He found that "the hypothesis that any given homeopathic remedy"

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137. JAMES RANDI, AN ENCYCLOPEDIA OF CLAIMS, FRAUDS, AND HOAXES OF THE OCCULT AND SUPERNATURAL 121 (1995); *see also* Ben Goldacre, *A Kind of Magic?*, GUARDIAN (Nov. 16, 2007), https://www.theguardian.com/science/2007/nov/16/sciencenews.g2 [https://perma.cc/EL4F-JQPM.].

138. SINGH & ERNST, *supra* note 22, at 36 (emphasis added).

139. ERNST, *supra* note 23, at 4.

140. *Id.*

141. *See* Edzard Ernst, *I Used to Think Homeopathy Was Helpful. Now I'm a Critic. So What Happened?*, SPECTATOR HEALTH (May 3, 2016), https://health.spectator.co.uk/i-used-to-think-homeopathy-was-helpful-now-im-a-critic-so-what-happened/ [https://perma.cc/DV5U-X28K].

142. SINGH & ERNST, *supra* note 22.

143. ERNST, *supra* note 23, at 49–51.

144. E. Ernst, *A Systematic Review of Systematic Reviews of Homeopathy*, 54 BRIT. J. CLINICAL PHARMACOLOGY 577, 577 (2002).

145. *Id.* at 577.

performs better than a placebo "is not supported by the evidence from systematic reviews."[146] And he concluded that "homeopathy cannot be viewed as an evidence-based form of therapy."[147]

Further systematic analyses support Ernst's conclusions. In 2005, *The Lancet* published a study by Aijing Shang and colleagues, comparing 110 placebo-controlled trials of homeopathy with 110 matched placebo-controlled trials of conventional medicine.[148] The authors "examined the presence of bias [in both groups of studies] resulting from inadequate methods and selective publication, and estimated results in trials least affected by these biases."[149] When the authors focused on "large trials of higher quality," they found that "there was no convincing evidence that homoeopathy was superior to placebo."[150] They thus explained that their results "provide support for the hypothesis that the clinical effects of homeopathy, but not those of conventional medicine, are unspecified placebo or context effects."[151]

In the same issue, *The Lancet* published an editorial calling into question whether there is even an issue left to consider.[152] There, the editors of one of the oldest and most recognized medical journals in the world noted the curious fact that the "debate" regarding homeopathy "continues, despite 150 years of unfavourable findings."[153] They concluded: "Surely the time has passed for selective analyses, biased reports, or further investment in research to perpetuate the homoeopathy versus allopathy [conventional medicine] debate. Now doctors need to be bold and honest with their patients about homoeopathy's lack of benefit . . . ."[154]

Indeed, in 2012, Ernst noted that although "[a]bout 200 clinical studies of homeopathic remedies are available to date," systematic reviews of those studies "[a]lmost uniformly . . . come to the conclusion that homeopathic remedies are not different from placebo."[155] And in 2016, Ernst explained that an analysis

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146. *Id.* at 581.

147. *Id.*

148. Aijing Shang et al., *Are the Clinical Effects of Homoeopathy Placebo Effects? Comparative Study of Placebo-Controlled Trials of Homoeopathy and Allopathy*, 366 LANCET 726, 726–32 (2005).

149. *Id.* at 730.

150. *Id.* Of course, not *every* study to have examined homeopathy has resulted in unequivocally negative findings. But not all scientific studies are created equal; for example, some employ better methodology than others, and some include larger and more stable sample sizes. Hence the focus on "large trials of higher quality" in the Shang study. When higher quality studies are considered, the results consistently fail to support the thesis that homeopathy is efficacious. *See* GOLDACRE, *supra* note 29, at 59 (noting that advocates of homeopathy often rely on "poorer-quality trials," that the "most reliable figure . . . is for the restricted pool of the most 'fair tests,'" and "when you look at those, homeopathy performs no better than placebo").

151. Shang et al., *supra* note 148, at 730.

152. Editorial, *The End of Homoeopathy*, 366 LANCET 690, 690 (2005) [hereinafter LANCET], http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(05)67149-8.pdf.

153. *Id.*

154. *Id.*; *see also* GOLDACRE, *supra* note 29, at 59 ("There have been more than a hundred randomized placebo-controlled trials of homeopathy, and the time has come to stop. Homeopathy pills work no better than placebo pills; we know that much.").

155. Edzard Ernst, *Why I Changed My Mind About Homeopathy*, GUARDIAN (Apr. 3, 2012), https://www.theguardian.com/science/blog/2012/apr/03/homeopathy-why-i-changed-my-mind.

of approximately 300 clinical trials and 50 systematic reviews reached the same conclusion.[156] The conventional medical community has reached a consensus: homeopathy has neither a plausible mechanism of action nor a credible claim to effectiveness.

E. Growing Governmental Consensus

For sensible reasons, governmental policymakers often move slowly and conservatively, waiting for science to reach consensus before taking practical action.[157] In the case of homeopathy, the evidence against it has reached a level that even conservative policymakers can no longer ignore. Thus, for example, in 2010 the U.K. Science and Technology Committee of the House of Commons issued a report evaluating whether "scientific evidence supports government policies that allow the funding and provision of homeopathy . . . and the licensing of homeopathic products . . . ."[158] The Committee noted that homeopathy has been publicly funded in Britain since 1948, and that four homeopathic hospitals currently operate in the United Kingdom.[159] The Committee nevertheless found that homeopathy's "principle of like-cures-like . . . fails to provide a credible physiological mode of action for homeopathic products," and noted that "this is the settled view of medical science."[160] Regarding the principle of low doses, the Committee found "the notion that ultra-dilutions can maintain an imprint of substances previously dissolved in them to be scientifically implausible."[161]

After reviewing the body of scientific studies addressing homeopathy, the Committee concluded that "the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos."[162] Consistent with the opinion of the *Lancet* editorial board, the Committee further asserted: "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."[163] Ultimately, the Committee recommended that the government stop funding homeopathy, and

156. ERNST, *supra* note 23, at 51.

157. Judge Richard Posner once explained that "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996). The same might be said of other institutional decision makers. Governments and regulators must be cautious about deciding the practical effects of scientific issues, including *economic* effects, when those issues are not sufficiently settled. Otherwise, those affected by such issues, including market actors, may be subjected to inconsistent, unpredictable results.

158. SCIENCE AND TECHNOLOGY COMMITTEE, EVIDENCE CHECK 2: HOMEOPATHY, 2009–10, HC 45, at 3 (UK) [hereinafter EVIDENCE CHECK].

159. *Id.* at 5.

160. *Id.* at 16.

161. *Id.* at 17.

162. *Id.* at 19.

163. *Id.* at 21.

concluded that it is "unacceptable" for the government to continue licensing homeopathic products, "conferring upon them some of the status of real medicine."[164]

In 2015, the Australian government reached similar conclusions. The National Health and Medical Research Council (NHMRC) is "Australia's peak body for supporting health and medical research."[165] It "develops health advice for the Australian community, health professionals and governments" and "provides advice on ethical behaviour in health care and in the conduct of health and medical research."[166] In 2015, the NHMRC published a report assessing "the evidence of effectiveness of homeopathy."[167] The NHMRC analyzed 57 "systematic reviews which evaluated the effectiveness of homeopathy in treating health conditions in humans," covering a total of 176 individual studies.[168] It found that there was "no reliable evidence . . . that homeopathy was effective for treating the range of health conditions considered: no good-quality, well-designed studies . . . reported either that homeopathy caused greater health improvements than placebo, or caused health improvements equal to those of another treatment."[169] The NHMRC concluded that "there are no health conditions for which there is reliable evidence that homeopathy is effective."[170]

Consistent with these findings, the U.S. government is making progress toward recognizing this medical consensus and acting accordingly. As noted above, the NCCIH has concluded that "key concepts of homeopathy are not consistent with fundamental concepts of chemistry and physics."[171] Further, the Federal Trade Commission (FTC), which regulates the advertising of homeopathy, recently issued an Enforcement Policy Statement to address the standards to which it will hold over-the-counter homeopathic products.[172] In that statement, the FTC noted that "homeopathic product claims are not based on modern scientific methods and are not accepted by modern medical experts."[173]

The FTC further clarified that although it has, in the past, "rarely challenged misleading claims for products that were homeopathic or purportedly homeopathic," the "[e]fficacy and safety claims for homeopathic drugs are held to the

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164. *Id.* at 28, 41.

165. NAT'L HEALTH & MED. RESEARCH COUNCIL, NHMRC INFORMATION PAPER: EVIDENCE ON THE EFFECTIVENESS OF HOMEOPATHY FOR TREATING HEALTH CONDITIONS 4 (2015) [hereinafter NHMRC].

166. *Id.*

167. *Id.* at 6.

168. *Id.* at 5.

169. *Id.* at 6.

170. *Id.* In early 2016, the chair of the working group that produced the NHMRC report published a response to subsequent criticism, noting that members of the "homeopathic community were outraged," explaining the NHMRC's methodology, and reaffirming its conclusion that homeopathy is "a therapeutic dead-end." Paul Glasziou, *Still No Evidence for Homeopathy*, BMJ OPINION (Feb. 16, 2016), http://blogs.bmj.com/bmj/2016/02/16/paul-glasziou-still-no-evidence-for-homeopathy/.

171. *Homeopathy*, *supra* note 3.

172. *See* Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs, 81 Fed. Reg. 90122, 90122 (Dec. 13, 2016).

173. *Id.* at 1.

same standards as similar claims for non-homeopathic drugs."[174] Specifically, the FTC has "generally required that advertisers possess 'competent and reliable scientific evidence'" for their claims.[175] The FTC recognized, however, that "[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 product's efficacy."[176] Thus, to the extent that the manufacturers of homeopathic products market those products as having a "therapeutic effect," those claims "lack a reasonable basis and are likely misleading."[177] Therefore, absent credible scientific evidence of efficacy, the FTC has now indicated that to avoid unlawful deception in advertising, the manufacturer of a homeopathic product must henceforth "communicate 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."[178]

Finally, the FDA has stated that it "is not aware of scientific evidence to support homeopathy as effective."[179] Unfortunately, although the FDA has the power to regulate homeopathy, it does not currently require that homeopathic products pass tests for safety and effectiveness.[180] In 1972, the FDA began an effort to ensure that all over-the-counter drugs sold in the United States are safe and effective, but deferred its review of homeopathic drugs because of their "uniqueness," stating that it would review them at a later time.[181] Now, forty-five years later, the FDA has not yet performed that review. Instead, in 1988, it issued guidelines allowing homeopathic drugs to be marketed in the United

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174. *Id.* at 2.

175. *Id.* at 2–3 (quoting Pom Wonderful LLC, 155 F.T.C. 1, 4 (2013)).

176. *Id.* at 3.

177. *Id.*

178. *Id.* at 4; *see also* Press Release, Fed. Trade Comm'n, FTC Issues Enf't Policy Statement Regarding Mktg. Claims for Over-the-Counter Homeopathic Drugs (Nov. 15, 2016), https://www.ftc.gov/news-events/press-releases/2016/11/ftc-issues-enforcement-policy-statement-regarding-marketing; Steven Novella, *FTC Homeopathy Win*, SCIENCE-BASED MED. (Nov. 16, 2016), https://www.sciencebasedmedicine.org/ftc-homeopathy-win/ ("In essence, the net effect of the labeling on the product cannot be misleading to the consumer."). Notably, at least one commentator has argued that the FTC's action may lead to a perverse result because "[t]hose drawn to homeopathic medicine are more likely to be skeptical of mainstream medicine, . . . [thus, t]o read that most modern medical experts don't accept homeopathy highlights the anti-establishment allure of the product." Alan Levinovitz, *Homeopathic Medicines Will Carry Labels Saying They're Unscientific*, SLATE (Nov. 17, 2016), http://www.slate.com/articles/health_and_science/medical_examiner/2016/11/the_ftc_s_new_homeopathic_medicine_rules_will_backfire.html.

179. *FDA Online Label Repository*, U.S. FOOD & DRUG ADMIN., https:// www.labels.fda.gov [perma.cc/R2XK-L9NG] (last visited Mar. 29, 2017).

180. The Food, Drug and Cosmetic Act of 1938 generally requires that any "drug" sold in the United States must be safe and effective. *See* 21 U.S.C. §§ 301–399 (2012). Homeopathic remedies are included in the Act's definition of "drug." *Id.* § 321(g)(1)(A)–(C). However, due in part to the influence of Royal Copeland (1868–1938)—a homeopath and United States Senator—the Act largely protected homeopathy by stating that its remedies must merely comply with standards set forth in the *homeopathic* literature, specifically, the Homeopathic Pharmacopeia of the United States. *See* ERNST, *supra* note 23, at 31.

181. Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464, 9466 (May 11, 1972).

States without approval of safety and effectiveness, so long as they meet certain labeling requirements, such as including "at least one major . . . indication for use, stated in terms likely to be understood by lay persons."[182]

Nevertheless, progress is being made. The FDA is currently reviewing its position regarding the regulation of homeopathy. In 2011, leading advocates of science and skepticism, including the Center for Inquiry (CFI) and the Committee for Skeptical Inquiry (CSI), petitioned the FDA to "initiate rulemaking that would require all over-the-counter homeopathic drugs to meet the same standards of effectiveness as non-homeopathic drugs," and to "place warning labels on homeopathic drugs until such time as they are shown to be effective."[183] In April 2015, "[a]fter three-and-a-half years of pressure," the FDA "finally announced public hearings on its handling of homeopathy," and invited CFI to provide testimony.[184] The FDA subsequently held hearings at which experts and others were able to help it "decide how it should regulate these products."[185]

In August 2015, the FTC weighed in on these hearings, "recommend[ing] that the FDA reconsider its regulatory framework for homeopathic medicines."[186] The FTC noted that "a significant percentage of consumers do not understand homeopathy, how the FDA regulates homeopathic drugs, or the level of scientific evidence supporting homeopathic claims."[187] Moreover, the FTC contended that the FDA's current position is in conflict with the FTC's own mission. The Federal Trade Commission Act "prohibits the dissemination of false advertisements" in, among other things, the OTC drug industry.[188] Accordingly, as noted above, the FTC is charged with ensuring that "companies . . . have a reasonable basis for making objective claims, including claims that a product can treat specific conditions, before those claims are made."[189]

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182. CPG Sec. 400.400, Conditions Under Which Homeopathic Drugs May Be Marketed, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm (last updated Mar. 20, 2015).

183. *CFI and CSI Petition FDA to Take Action on Homeopathic Drugs*, CTR. FOR INQUIRY (Aug. 30, 2011), http://www.centerforinquiry.net/news/cfi_and_csi_petition_fda_to_take_action_on_homeopathic_drugs/.

184. Press Release, Ctr. for Inquiry, *Ctr. for Inquiry Invited to Testify Against Homeopathy at FDA Public Hearings* (Apr. 16, 2015), http://www.centerforinquiry.net/newsroom/center_for_inquiry_invited_ to_testify_against_homeopathy_at_fda_public_hear/.

185. Jen Christensen, *Homeopathic Medicine Under FDA Scrutiny*, CNN (Apr. 21, 2015, 12:26 PM), http://www.cnn.com/2015/04/20/health/homeopathic-medicine-fda; *see also* Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing, 80 Fed. Reg. 16327 (Mar. 27, 2015).

186. Federal Trade Commission, Comments of the Staff of the Federal Trade Commission Submitted to the Food and Drug Administration Department of Health and Human Services in Response to a Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century 2 (Aug. 21, 2015) [hereinafter FTC Comments], https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf.

187. *Id.* at 2.

188. *Id.* at 2–3; *see also* 15 U.S.C. § 52 (2012).

189. FTC Comments, *supra* note 186, at 3.

Thus, the FDA's requirement that homeopathic product labels include an "indication for use, even when the product has not been demonstrated to be efficacious for that indication, creates a potential conflict with the FTC's requirement that health claims be substantiated by competent and reliable scientific evidence."[190] The FTC went on to note that at least one way the FDA could eliminate this conflict is to require that "any indication appearing on the labeling [of homeopathic products] be supported by competent and reliable evidence."[191] This route would bring the FDA into alignment with the FTC's own requirements, and, indeed, likely would result in conclusions similar to those reached by the NCCIH, the U.K. Science and Technology Committee, Australia's NHMRC, and the near universal consensus of the scientific and medical communities.

IV. *ALLEN V. HYLAND'S, INC., ET AL.*: A GATEKEEPING FAILURE

Given the dubious history and basis of homeopathy, and the absence of evidence in its favor, are there any legal consequences for those who nevertheless maintain that it works? More specifically, are there consequences for those who make *money* by convincing consumers that homeopathic products are safe and effective means of health care? After all, misleading another for financial gain is unlawful, whether characterized as deceit, intentional or negligent misrepresentation, or fraud.[192]

Absent robust regulatory oversight in the United States—the FDA has yet to decide whether it will modify its stance—litigation has begun to fill the void, with consumers filing lawsuits alleging that the manufacturers and distributors of homeopathic remedies are engaged in various forms of unlawful deceit. For example, in 2012, in federal court in Los Angeles, plaintiff Kim Allen and other purchasers of homeopathic products brought a class action lawsuit against Hyland's, Inc. and its parent, the Standard Homeopathic Company (collectively,

190. *Id.* at 5.

191. *Id.* at 6. Other ways the FDA could eliminate the conflict would be to withdraw the 1988 guidelines altogether, or withdraw only the requirement that homeopathic product labels include an indication for use. *Id.* at 5–6.

192. *See, e.g.*, CAL. CIV. CODE § 1709 (West, Westlaw through 2016 Sess.) ("One who willfully deceives another with intent to induce him to alter his position to his injury or risk, is liable for any damage which he thereby suffers."); *id.* § 1711 (West, Westlaw through 2016 Sess.) ("One who practices a deceit with intent to defraud the public, or a particular class of persons, is deemed to have intended to defraud every individual in that class, who is actually misled by the deceit."); RESTATEMENT (SECOND) OF TORTS § 525 (AM. LAW. INST. 1977) ("One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused to him by his justifiable reliance upon the misrepresentation."); *id.* § 552(1) ("One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.").

"Hyland's"), alleging that Hyland's had engaged in false and deceptive advertising in the way it marketed its homeopathic products.[193]

A. Plaintiffs' Allegations

In *Allen v. Hyland's, et al.*, the plaintiffs contended that Hyland's deceptively marketed its various products—including remedies meant to address sleeplessness, teething problems, migraines, leg cramps, colds and coughs, and allergies—as "natural, safe, and effective alternatives to prescription and non-homeopathic OTC drugs."[194] They noted that the FDA does not evaluate the efficacy of homeopathic products; alleged that Hyland's has known for years "that consumers . . . do not understand what homeopathy is, how it supposedly works, or the nature of the Products"; and contended that Hyland's pursued its "false and deceptive marketing campaign with the fore knowledge that consumers are confused about the true nature of their Products."[195] The plaintiffs further impugned the efficacy of Hyland's' products, contending that its sleeping pill, Calms Forte, "can have no effect of any kind in humans," because it is highly unlikely "that even a single molecule derived from the original 'extract' of the 'active ingredients' could be present in the . . . product sold to consumers"[196]—and making similar claims about the other products at issue.[197]

B. Defendants' Proposed Expert Opinions

Faced with these allegations, Hyland's' defense consisted, in part, of attempting to present evidence that its products can and do *work*. But how does a defendant like Hyland's do this? Typically, this is accomplished through the testimony of expert witnesses, whose "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue."[198]

Hyland's thus proposed to have several experts testify. To show that homeopathic products *can* work, these experts included, among others, Edward Calabrese, Ph.D., a toxicologist at the University of Massachusetts, Amherst, School of Public Health;[199] Iris Bell, M.D., PhD, a researcher in areas related to complementary and alternative medicine;[200] and Dr. Peter A.G. Fisher, Clinical Director and Director of Research at the Royal London Hospital for Integrated

193. *See* Third Amended Complaint at ¶¶ 1–2, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. May 3, 2013) (ECF No. 203). The author retrieved the Complaint, trial transcript, and other documents in the *Allen* case from the website for Public Access to Court Electronic Records (PACER), at www.pacer.gov.

194. *Id.* at ¶ 25.

195. *Id.* at ¶¶ 25, 27, 29, 32.

196. *Id.* at ¶ 52.

197. *Id.* at ¶¶ 63, 75, 86, 95, 104, 111, 131.

198. FED. R. EVID. 702(a).

199. *See Edward J. Calabrese*, UNIV. MASS. SCH. PUB. HEALTH & SCI., https://www.umass.edu/sphhs/person/faculty/edward-j-calabrese (last visited Mar. 22, 2017).

200. *See Meet Dr. Bell*, IRIS BELL, http://irisbell.com/about/ (last visited Mar. 22, 2017).

Medicine (and Physician to Her Majesty the Queen).[201] These experts proposed to testify that there is a theoretical basis for, and competent evidence supporting, homeopathy. To show that homeopathic products *do* work, Hyland's primarily offered Bernardo A. Merizalde, M.D., Assistant Clinical Professor at Thomas Jefferson University,[202] to testify that his patients experienced positive results when using homeopathic remedies.

Thus, it is here that the *Allen* case collided with the law of expert evidence—and expert exclusion—described above. Given the apparent absence of any credible scientific evidence in favor of homeopathy, the plaintiffs in *Allen* filed motions asking the court to preclude several of the defendants' experts from testifying at trial, arguing, among other things, that their opinions were not based on reliable principles and methods, as required by the Rules of Evidence.[203] Regrettably, the court denied these motions, and allowed defendants' experts to testify at trial, thus providing them with a platform on which to cloak the principles of homeopathy with the authority of academic and professional credentials.

C. The Trial

Trial commenced in September 2015. The *Allen* plaintiffs first offered their own expert testimony, to preemptively blunt and refute the defendants' experts. The plaintiffs primarily offered Noel Rose, M.D., Ph.D., Emeritus Professor in the Department of Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health,[204] to testify that "there is no scientific evidence to demonstrate Hyland's products are effective for relieving symptoms as represented," and that "the underlying principles of homeopathy are biologically implausible."[205]

At trial, Dr. Rose expressly agreed with the conclusion of the NCCIH that several key principles of homeopathy are inconsistent with fundamental concepts of chemistry and physics;[206] noted the conclusions of the U.K. Science and Technology Committee that there is no credible evidence supporting homeopathy, and that homeopathic products perform no better than placebos;[207] and

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201. *See Dr. Peter Fisher*, UNIV. COLLEGE LONDON HOSPITALS, http://www.uclh.nhs.uk/OurServices/Consultants/Pages/DrPeterFisher.aspx (last visited Mar. 22, 2017).

202. *See* Bernardo A. Merizalde, *Holistic, Integrative, Homeopathic Treatment Philosophy*, HEALTH HORIZONS, http://www.pahomeopathy.com/ (last visited Mar 22. 2017).

203. *See* Plaintiffs' Motion to Exclude Testimony of Defense Expert Dr. Peter A.G. Fisher at 2–3, Allen et al. v. Hyland's, Inc. et al., No. 2: 12-cv-01150 (C.D. Cal. July 14, 2015) (ECF No. 348); Plaintiffs' Motion to Exclude Testimony of Defense Expert Bernardo A. Merizalde, M.D., at 3, Allen et al. v. Hyland's, Inc. et al., No. 2: 12-cv-01150 (C.D. Cal. July 14, 2015) (ECF No. 349); *see also* Plaintiffs' Motion to Exclude Testimony of Defense Expert Edward J. Calabrese, Ph.D. at 3, Allen et al. v. Hyland's, Inc. et al., No. 2: 12-cv-01150 (C.D. Cal. July 14, 2015) (ECF No. 346).

204. *See Noel Rose*, JOHNS HOPKINS BLOOMBERG SCH. PUB. HEALTH http://www.jhsph.edu/faculty/directory/profile/588/noel-rose (last visited Mar. 24, 2017).

205. Plaintiffs' Trial Brief at 8, Allen et al. v. Hyland's, Inc. et al., No. 2: 12-cv-01150 (C.D. Cal. Aug. 25, 2015) (ECF No. 383).

206. Trial Transcript for Sept. 4, 2015 at 61:12–17, Allen et al. v. Hyland's, Inc. et al., No. 2: 12-cv-01150 (C.D. Cal. Jan. 8, 2016) (ECF No. 446).

207. *Id.* at 62:6–25, 64:4–7.

discussed the Australian NHMRC's conclusion that homeopathy is not an effective treatment for any illness.[208] Dr. Rose ultimately testified that homeopathic principles are "biologically implausible,"[209] and that "there is no sound scientific or medical evidence" that the Hyland's products at issue, or homeopathic products generally, "provide any benefit to patients . . . beyond the placebo effect."[210]

The plaintiffs further offered testimony from Robert Lee, Ph.D., a professor of pharmaceutics and pharmaceutical chemistry in the College of Pharmacy at Ohio State University.[211] Professor Lee has extensive experience researching nanoparticles and their role in drug delivery systems.[212] Dr. Lee testified that nanoparticles exist, and that they are generally much smaller than a single human cell.[213] Dr. Lee further testified that to the extent that nanoparticles can be engineered to aid in drug delivery systems, they follow a familiar dose-response pattern; that is, "the amount of nanoparticles [is] usually correlated to the amount of drugs that needs to be delivered."[214] He then addressed the topic of hormesis—the phenomenon by which a low dose of a substance may have a greater effect than a higher dose—explaining that it is "sometimes observed," but that it is "very dangerous to extrapolate the hormetic principles to all substances, which is basically what [defendants' experts are] trying to do."[215] Dr. Lee ultimately confirmed that there is no competent evidence that "hormesis plays any role in the effectiveness of medicines that are being transmitted through nanoparticles,"[216] that "trace amount[s] of nanoparticles that are generated during homeopathic manufacturing" would have "no impact" on the efficacy of homeopathic products,[217] and that "this whole theory of nanoparticles playing a role in homeopathic medicine is not scientifically based."[218]

In response, the defendants' experts nevertheless testified that there is a basis for believing that homeopathic products can and do work. Dr. Calabrese testified that he has studied hormesis for much of his career; that, in principle, "homeopathy can be studied in a legitimate way within a biomedical framework"; and that "[h]ormesis phenomenon supports [the] theory that homeopathic ingredients can have an effect at low doses and that it's contrary to their

208. *Id.* at 67:23–68:3.
209. *Id.* at 68:12–15.
210. *Id.* at 30:6–9, 21–23; 68:16–20.
211. *See* Trial Transcript for Sept. 9, 2015 at 43, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. June 20, 2016) (ECF No. 459); *Robert J. Lee*, OHIO STATE UNIV. C. PHARMACY, http://www.pharmacy.ohio-state.edu/faculty-staff/users/lee1339 (last visited Mar. 24, 2017).
212. *Robert J. Lee*, *supra* note 211. *See also* Trial Transcript for Sept. 9, 2015, *supra* note 211, at 49, 54.
213. *See* Trial Transcript for Sept. 9, 2015, *supra* note 211, at 56:25–58:3.
214. *Id.* at 65:2-10.
215. *Id.* at 78:16–79:10.
216. *Id.* at 79:6-10.
217. *Id.* at 83:15-23.
218. *Id.* at 85:13-19.

effect at high doses."[219] Dr. Bell testified that "the presence of nanoparticles" in homeopathic solutions answers the objection that, after dilution, there simply is no active ingredient left in a typical remedy.[220] She further testified that under the principle of hormesis, ultralow doses of nanoparticles can have a measurable effect—at one point analogizing homeopathy to vaccines.[221] Relying, in part, on "herbal literature," Dr. Bell then testified that the ingredients used in homeopathy are effective for treating various illnesses.[222] On cross-examination, however, Dr. Bell could not identify a single clinical trial demonstrating that the products at issue "actually work on human beings."[223] She also admitted that she had worked for Hyland's—the defendant for which she was testifying—for approximately nine years and had served as the medical director since 2011.[224]

Further, Dr. Peter Fisher testified at length regarding how homeopathic products might work. He addressed the apparent absence of active ingredients, stating that "very high energies are generated" during their preparation, and that this may explain the "mechanism of action."[225] Dr. Fisher further suggested that homeopathic remedies retain "information" gained through the dilution process, similar to data contained on a floppy disc or flash drive; and that there may be a "structure imposed on the water" that accounts for effects outlasting the existence of any molecules of the original active ingredients.[226] Ultimately, Dr. Fisher opined that homeopathy is "supported by a spectrum, a mosaic, if you like, of evidence."[227]

Finally, both Dr. Fisher and Dr. Bernardo Merizalde testified that they believe homeopathic medicine not only *can* work, but *does* work. Dr. Fisher testified that he believes homeopathic products are "effective in treating [his] patients."[228] Additionally, Dr. Merizalde testified that he recommends homeopathic remedies to his patients. Despite the absence of randomized control studies showing their effectiveness, Dr. Merizalde trusts homeopathic remedies because they "have been used for about 200 years," and he *believes* they are effective.[229]

The jury was thus placed in the difficult position of having to choose between seemingly well-credentialed experts on both sides. Moreover, the specific questions presented to the jury arguably compounded any confusion created by

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219. Trial Transcript for Sept. 15, 2015 at 108:10-23, 146:19–147:4, 149:2-14, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. June 20, 2016) (ECF No. 463).

220. *See* Trial Transcript for Sept. 10, 2015 at 13:4-13, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Jan. 8, 2016) (ECF No. 448).

221. *See id.* at 17:4-8, 17:24–18:5.

222. *Id.* at 51:16-23.

223. *Id.* at 62:20–63:10.

224. *Id.* at 60:8-13.

225. Trial Transcript for Sept. 14, 2015 at 10:18–11:2, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Jan. 8, 2016) (ECF No. 450).

226. *Id.* at 51:18–52:8, 52:25–53:6; *see also* Trial Transcript for Sept. 14, 2015 at 35:8–22, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. June 20, 2016) (ECF No. 462).

227. Trial Transcript for Sept. 14, 2015, *supra* note 226, at 86:7–21.

228. *Id.* at 18:21–24; *see also id.* at 35:8-10.

229. Trial Transcript for Sept. 11, 2015 at 4:15–18, 5:11–22, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Jan. 8, 2016) (ECF No. 449).

the defense experts' quasi-scientific testimony. The plaintiffs were essentially claiming that Hyland's falsely represented that its products work when, in fact, they "do not" work.[230] The court, however, instructed the jury that to find in favor of the plaintiffs, it would have to conclude that Hyland's products "cannot" work.[231] This is a meaningful difference. As Dr. Rose testified on cross-examination, proving a "negative" is, strictly speaking, impossible; thus although the likelihood of an improbable event may be "very low," one generally cannot say that it is "zero."[232]

Given conflicting testimony on the *possibility* that homeopathic products *might* work in some way, and the court's restrictive instructions on the elements of liability, the jury made their choice. They chose Hyland's. The jury found in favor of Hyland's on the plaintiffs' claims, absolving them of liability. The court ultimately entered judgment in favor of Hyland's on all counts.[233]

D. What Went Wrong?

How did this happen? How did a jury decide that Hyland's did not misrepresent the efficacy of its products? Surely, the court's instruction that Hyland's would be liable only if the plaintiffs proved homeopathy "cannot work" contributed to the result. So long as defense experts were able to propose ways that homeopathy *might* work, the jury was left with the difficult decision—for laypersons, in any event—of rejecting that testimony.

But should the jury ever have been put in the position of having to make that choice? Should the defense experts ever have been allowed to testify? Had the court in *Allen* granted the plaintiffs' motions to exclude those experts, the case likely would have ended with a settlement. Without the ability to put on evidence supporting its products, Hyland's may very well have recognized that it had no realistic chance of prevailing at trial. But the court denied those motions. In this respect, the court erred.

There can be little doubt that expert testimony in support of the efficacy of homeopathy fails tests of admissibility. Consider the Federal Rules of Evidence and the factors that courts should evaluate under *Daubert* and its progeny. Is testimony that homeopathy is effective "the product of reliable principles and methods"?[234] In other words, does it have a "reliable foundation"?[235] Is "the

230. Jury Instructions at 5:8-11, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Sept. 18, 2015) (ECF No. 425).

231. *Id.* at 31, 35.

232. Trial Transcript for Sept. 4, 2015, *supra* note 206 at 84. Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Jan. 8, 2016) (ECF No. 446).

233. Judgment at 7, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Aug. 16, 2016) (ECF No. 472). The court entered judgment after ruling that Hyland's prevailed on all claims, including those not decided by the jury, but rather decided by the court. Findings of Fact and Conclusions of Law at 7, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Aug. 16, 2016) (ECF No. 471).

234. FED. R. EVID. 702(c).

235. Daubert v. Merell Dow Pharm., Inc., 509 U.S. 579, 597 (1993).

reasoning or methodology underlying [it] . . . scientifically valid"?[236] As explained above, homeopathy's core principles—provings, like cures like, and the law of minimum dose—are based on little more than Samuel Hahnemann's late-eighteenth-century speculations. They were not developed through, nor have they been validated by, controlled scientific studies. Indeed, that the *Materia Medica* includes *tears from a weeping girl* among the catalog of active homeopathic ingredients, and that homeopathic dilutions regularly leave solutions without a single molecule of *any* active ingredient, should leave little doubt that the principles of homeopathy are "not consistent with fundamental concepts of chemistry and physics"[237]—and are not "scientifically plausible."[238] Simply put, they have no reliable scientific foundation. As Oliver Wendell Holmes, Sr. remarked while Hahnemann was still alive, these principles "cannot stand before a single hour of calm investigation."[239]

Nor is testimony purporting to support the efficacy of homeopathy "based on sufficient facts or data."[240] To be sure, the principles and efficacy of homeopathy have been "tested" and "subjected to peer review and publication" [241]—but they have consistently *failed* those tests and the scrutiny of that review process. As early as 1842, Holmes noted that "the results of trials by competent and honest physicians" showed no evidence of homeopathy's efficacy.[242] More recently, hundreds of clinical studies of homeopathy, and numerous systematic reviews of those studies, have shown that its remedies provide relief "not different than placebo,"[243] that there is in fact "plenty of evidence showing that it is not efficacious,"[244] and that "there is no reliable evidence that homeopathy is effective."[245] Indeed, the FDA has stated that it simply is "not aware of scientific evidence to support homeopathy as effective."[246] Thus, homeopathy's "rate of error" is known, and far from gaining "general acceptance" in the scientific and medical community,[247] it has gained near-universal condemnation.

The defense of homeopathy, in some respects, presents a classic example of "unjustifiably extrapolat[ing] from an accepted premise to an unfounded conclusion."[248] Advocates extrapolate from the efficacy of vaccines that *similia similibus currentur* has a sound scientific basis, and from the concept of hormesis that providing ultralow doses is well-founded methodology. But as

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236. *Id.* at 592–93.

237. *Homeopathy*, *supra* note 3; *see also* SCHWARCZ, *supra* note 22, at 54.

238. EVIDENCE CHECK, *supra* note 158, at 17.

239. *See* HOLMES, *supra* note 73, at 39.

240. FED. R. EVID. 702(b).

241. Daubert, 509 U.S. at 594–95.

242. *See* HOLMES, *supra* note 73, at 70, 80; *see also* Mehlman, *supra* note 64, at 349–50 (explaining that the term "quackery" became "widely used in the United States during the 19th century," that it "described hucksters, charlatans, and snake oil salesmen," and that homeopaths were counted among them).

243. Ernst, *supra* note 155.

244. EVIDENCE CHECK, *supra* note 158, at 21.

245. NHMRC, *supra* note 165, at 27.

246. *FDA Online Label Repository*, *supra* note 179.

247. Daubert v. Merell Dow Pharm., Inc., 509 U.S. 579, 594–95 (1993).

248. FED. R. EVID. 702, advisory committee's note to 2000 amendment.

one contemporary skeptic has explained, unlike homeopathic remedies, vaccines actually "contain measurable numbers of antigen molecules," and "act by well-understood scientific mechanisms";[249] and hormesis, even in the limited circumstances in which it appears to operate, "describes a response to a *low* dose, not to *no* dose."[250] As Martin Gardner noted many decades ago, the defense of homeopathy thus begins with plausible-sounding principles, and then "exaggerate[s] them to the point of absurdity."[251] In other words, it impermissibly extrapolates to "unfounded conclusion[s]."[252]

Finally, the defense of homeopathy glaringly fails to "account[] for obvious alternative explanations."[253] Do people who take homeopathic remedies sometimes feel better? Of course they do. But studies of homeopathy have overwhelmingly concluded that the reason for this is not that homeopathy is actually efficacious, but rather because it is "the ideal placebo."[254] It is cheap. It has no side effects (unless, as discussed below, it is adulterated). And practitioners spend substantial time with their "patients," thus encouraging psychosomatic effects.

In the end, advocates of homeopathy may have little to stand on other than that many people—including some "experts" who would gladly be paid to testify—inexplicably seem to *believe* that it works. But this will not do. That homeopathy has many believers does not validate it as a scientifically sound "field of expertise," or color it, against nearly 200 years of evidence to the contrary, as one "known to reach reliable results for the type of opinion the expert would give."[255] As our Supreme Court perhaps most saliently observed, "general acceptance" of a principle cannot "help show that an expert's testimony is reliable where the *discipline itself lacks reliability*."[256] As the Court explained, general acceptance of "principles of astrology or necromancy," for example, would not transform those subjects into appropriately reliable subjects of expert testimony.[257] The Court could easily have added homeopathy to that list.

Thus, in allowing the jury to receive testimony about the principles of homeopathy—not as a matter of historic curiosity, but as a matter of scientific validity—the *Allen* court arguably abdicated its gatekeeping responsibility to screen out unreliable expert testimony.[258] By permitting "experts" to testify in favor of a field the bases of which defy basic principles of biology, chemistry,

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249. Hall, *supra* note 4.

250. *Id.*

251. GARDNER, *supra* note 1, at 188–89.

252. FED. R. EVID. 702, advisory committee's note to 2000 amendment.

253. *Id.*

254. Hall, *supra* note 81, at 8–9; *see also* EVIDENCE CHECK, *supra* note 158, at 19; NHMRC, *supra* note 165, at 6; SCHWARCZ, *supra* note 22, at 60; Ernst, *supra* note 144, at 581.

255. FED. R. EVID. 702, advisory committee's note to 2000 amendment.

256. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 151 (1999) (emphasis added); *see also* ERNST, *supra* note 23, at 15 ("Currently, there are several *theories* about the mode of action, but none of them has [sic] been generally accepted outside the realm of homeopathy.").

257. Carmichael, 526 U.S. at 151.

258. *See id.* at 141; *see also* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142 (1997).

and physics—indeed, in some respects "basic logical principles"[259]—the "integrity and fairness of the trial process" was compromised.[260]

E. Why Should We Care?

The result in *Allen* is, unfortunately, not an isolated event. Homeopathy manufacturers recently won yet another significant victory. In June 2016, in a lawsuit filed against Boiron, Inc., a federal jury found in favor of Boiron on plaintiffs' claims that it engaged in false advertising. The jury specifically concluded that Boiron's representations that one of its products "relieves flu-like symptoms" were *not false*.[261] For those who care about the efficiency and efficacy of the civil justice system, deterring fraudulent behavior, and consumer safety, this is cause for concern.

The civil justice system is a public good. The court system is a publicly funded institution through which litigants can vindicate their rights. But like any public institution, it has limited resources. Thus, it must use those resources—time and its share of public funds—wisely. Every matter before a court poses questions in this regard. Should trials last indefinitely? Should litigants be allowed to have unlimited witnesses testify on their behalf? Should the time and energy of the courts, parties, and jurors be wasted on frivolous claims—or on unfounded, speculative positions taken in support of those claims? The Federal Rules of Evidence expressly state that the answer is *no*. Under those rules, courts are empowered to exclude from consideration even "relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[262] This basic principle is the foundation for similar rules, discussed above, related to screening out irrelevant or unreliable expert testimony. Such testimony not only risks confusing and misleading juries; it also is a waste of time and resources.

In addition, allowing courts and litigants to be burdened with unsupported, unreliable expert testimony can impose more concrete harms. In the case of homeopathy, to the extent that such testimony is the driving force behind absolving manufacturers of liability, it facilitates a fraud on the public.[263] So long as manufacturers of homeopathic products continue to be allowed to engage in "artful

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259. *See* Faigman, *supra* note 16, at 124–25.

260. Faigman, *supra* note 15, at 577. In September 2016, the plaintiffs in *Hyland's* filed a motion asking for a new trial, arguing that the trial court erroneously instructed the jury that for the plaintiffs to prevail, they must prove the products at issue "cannot work"; and that, in any event, the verdict was contrary to the clear weight of the evidence. Plaintiff's Memorandum in Support of Motion for New Trial at 1, Allen et al. v. Hyland's, Inc. et al., No. 2:12-cv-01150 (C.D. Cal. Sept. 13, 2016) (ECF No. 476). The court has not yet decided that motion.

261. *See* Special Verdict Form at 1, Lewert v. Boiron, Inc., No. 11-CV-10803-AB (JPRx), 2017 WL 25457 (C.D. Cal. Jan. 3, 2017); *see also* Bonnie Eslinger, *Calif. Jury Finds For Flu Remedy Maker In False Ad Trial*, LAW360 (June 16, 2016, 6:44 PM), http://www.law360.com/articles/807733/calif-jury-finds-for-flu-remedy-maker-in-false-ad-trial.

262. FED. R. EVID. 403.

263. *See* Mehlman, *supra* note 64, at 357 (discussing court decisions addressing questionable medical practices, and noting that "[o]ne theme . . . is the idea that quacks fleece people, which suggests that a sine qua non of quackery is its commercial motive"); *see also* Park, *supra* note 16,

misrepresentation" in the claims they make[264]—and defend doing so through the vehicle of testifying experts—courts become complicit in an industry that earns billions through outright deceit.

And finally, allowing speculative expert testimony to prop up homeopathy, permitting it to thrive in an unregulated environment, also poses a real danger to public health. Homeopathy includes among its products remedies meant to address serious medical issues. People often put themselves and others at risk by *substituting* these remedies for more conventional medical care.[265] For example, people may forgo vaccinations, instead relying on homeopathic products—thus being "deluded into believing they are protected from vaccine-preventable diseases," and placing "themselves at risk and putting others in their community at risk."[266] Some homeopaths go so far as to claim to be able to treat serious illnesses such as diabetes, AIDS, and cancer, "with the most outrageous ones urging their victims to give up conventional treatment."[267] But as Australia's NHMRC report explained, 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."[268]

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at 585 ("[W]e all have to be concerned that the public is being misled by false scientific claims."); Daniel C. Rislove, *A Case Study of Inoperable Inventions: Why Is the USPTO Patenting Pseudoscience?*, 2006 WIS. L. REV. 1275, 1279 (2006) (arguing that "both consumers and investors have suffered due to the granting of patent protection to clearly pseudoscientific, inoperable inventions," and noting, as an example, that although homeopathy has "proven to be both inefficacious and scientifically implausible," several homeopathic treatments have been patented).

264. *See* HOLMES, *supra* note 73, at 101.

265. *See, e.g.*, Metzler v. N.Y. State Bd. for Prof'l Med. Conduct, 203 A.D.2d 617, 618 (N.Y. App. Div. 1994) (affirming the revocation of a homeopath's license to practice medicine, where his "treatment of one of his patients, who died from pneumocystic pneumonia and was suffering from AIDS, did not meet minimum standards of acceptable medical practice and was so egregious as to constitute gross negligence").

266. Hall, *supra* note 4; *see also* SCHWARCZ, *supra* note 22, at 61 ("[S]ome homeopaths offer pills for protection against malaria or radiation exposure."); SINGH & ERNST, *supra* note 22, at 184 ("[M]any homeopaths have a negative attitude towards immunization, so parents who are in regular contact with a homeopath may be less likely to immunize their child.").

267. SCHWARCZ, *supra* note 22, at 61. Schwarcz notes that an organization called "Homeopaths Without Borders" claims that homeopathic remedies can treat diseases such as "dengue, malaria, cholera, and other tropical diseases"—a claim that, in Schwarcz's view, is "criminal." *Id.*; *see also* SINGH & ERNST, *supra* note 22, at 186 ("There are numerous reports of patients with serious conditions (e.g., diabetes, cancer, AIDS) suffering harm after following irresponsible advice from alternative practitioners instead of following the advice of a doctor.").

268. NHMRC, *supra* note 165, at 6; *see also* ERNST, *supra* note 23, at 13 ("[I]f people use homeopathy instead of a conventional therapy for serious conditions, they may put their health at *risk*."); SINGH & ERNST, *supra* note 22, at 188 ("[E]ven the most benign alternative medicine can become dangerous if the therapist who administers it advises a patient not to follow an effective conventional treatment."); Ernst, *supra* note 141 ("[H]omeopathy carries a real and significant risk: whenever it is used to replace an effective intervention for a serious condition, it can become a risk to life."); Park, *supra* note 16, at 580 ("People who take these homeopathic medicines think they are curing themselves. It is a wonder that a few of the purveyors of homeopathy have not been successfully prosecuted.").

In addition, some homeopathic products fail to be what they claim to be. In some cases, they *do* contain active ingredients, and thus can have "actual physiological effects, harmful ones."[269] For example, in 2010, the FDA issued a Safety Alert regarding a homeopathic teething remedy manufactured by Hyland's, noting that it contained "inconsistent amounts of belladonna" and posed a risk of seizures and other adverse outcomes, and recommending that "consumers not use this product and dispose of any in their possession."[270] Similarly, in 2014 the FDA issued a Safety Alert for a number of homeopathic products, noting that they had "the potential to contain penicillin or derivatives of penicillin" and posed risks (among the allergic) including "life-threatening anaphylactic reactions, recommending that consumers "stop using the products and return them to the point of purchase."[271] In late 2016, Raritan Pharmaceuticals, Inc. issued a voluntary nationwide recall of homeopathic teething tablets and "ear relief" medication, "due to the potential for variation in the content of belladonna extract in the products."[272]

Most recently, in January 2017, the FDA again found "inconsistent amounts of belladonna, a toxic substance," in Hyland's homeopathic teething tablets, "sometimes far exceeding the amount claimed on the label."[273] The FDA thus warned that this is "an unnecessary risk to infants and children and urge[d] consumers not to use these products."[274] In February 2017, *Scientific American* published an article explaining that "[o]ver a 10-year period, from 2006 to 2016, the FDA collected reports of 'adverse events' in more than 370 children who had used Hyland's homeopathic teething tablets or gel."[275] And in April 2017, Hyland's finally recalled the product.[276]

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269. Hall, *supra* note 4.

270. *See* Press Release, U.S. FOOD & DRUG ADMIN., Hyland's Teething Tablets May Pose a Risk to Children (Oct. 23, 2010), http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm230764.htm [http://wayback.archiveit.org/7993/20161022000733/ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm230761.htm].

271. *See Pleo Homeopathic Drug Products by Terra-Medica: Recall—Potential for Undeclared Penicillin*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2014), http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm390002.htm.

272. *See Raritan Pharmaceuticals Inc. Issues a Voluntary Nationwide Recall of Products Containing Belladonna Extract Due to the Possibility of the Presence of Belladonna Alkaloids*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2016), http://www.fda.gov/Safety/Recalls/ucm530618.htm; *see also* Hailey Middlebrook, *Homeopathic Kids' Products Recalled Due to Belladonna*, CNN (Nov. 29, 2016, 9:02 AM), http://www.cnn.com/2016/11/28/health/raritan-homeopathic-kids-product-recall/.

273. *See* Press Release, U.S. Food & Drug Admin., FDA Confirms Elevated Levels of Belladonna in Certain Homeopathic Teething Products, (Jan. 27, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm538684.htm.

274. *Id.*

275. Sheila Kaplan, *Hundreds of Babies Harmed by Homeopathic Remedies, Families Say*, SCI. AM. (Feb. 21, 2017), https://www.scientificamerican.com/article/hundreds-of-babies-harmed-by-homeopathic-remedies-families-say/?WT.mc_id=SA_TW_HLTH_NEWS.

276. *See Standard Homeopathic Company Issues Nationwide Recall of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets Due to Mislabeling*, U.S. FOOD & DRUG ADMIN. (Apr. 13, 2017), https://www.fda.gov/Safety/Recalls/ucm552934.htm. Hyland's also recalled the tablets in Australia. *See* Rania Spooner & Chloe Booker, *Hyland's Homeopathic Baby Tablets Recalled in Australia over Safety Fears*, SYDNEY MORNING HERALD (Apr. 30, 2017), http://

Thus, there are significant consequences to allowing manufacturers and distributors of homeopathic products to defend themselves through the mouths of so-called experts. Doing so contributes to social, financial, and physical harm. To avoid these harms, courts must begin to take seriously their "obligation" to exclude irrelevant and unreliable expert testimony.[277]

Expert testimony is appropriate where there is a genuine debate—where it "will help the trier of fact to understand the evidence or to determine a fact *in issue*."[278] In the case of homeopathy, there simply is no genuine disputed issue. On one side sits *evidence*—based on over 170 years of commentary and criticism; hundreds of scientific studies; dozens of systematic analyses; and a broad scientific, medical, and regulatory consensus—that homeopathy has no plausible scientific basis, cannot work, and does not work. On the other side sits "unsupported speculation" about possible mechanisms of action.[279] As the editorial board of *The Lancet* explained over ten years ago, "the time has passed" for pretending that there is a live "debate" in the scientific community on this issue.[280] Similarly, the time has passed for allowing experts to make it appear, through their testimony to a jury, that such a debate exists. Indeed, there is significant danger in doing so. As Martin Gardner long ago noted, advocates of unfounded medical claims can present an "impressive façade";[281] and when "drag[ged] into court," they have "no trouble at all finding scores of people"—so-called experts included—"willing to testify about miraculous cures."[282]

But there is a way to combat this distortion of the civil justice system. Trial courts have robust power and clear responsibility to preclude litigants from introducing irrelevant and unreliable evidence in support of purportedly scientific claims. As explained above, homeopathy is precisely the sort of subject matter about which supporting "expert" testimony should be given no quarter. In *Allen v. Hyland's*, such testimony was unfortunately given free rein, with regrettable results. To the extent that courts continue abdicating their evidentiary gatekeeping role in this way, they may contribute to a waste of time and resources, financial harm to consumers, and risks to public health. But to the extent that litigants and courts strengthen their spines in this regard, take seriously the dangers of unfounded expert testimony, and make genuine efforts to *seek* and *grant* its exclusion, they might contribute to the health and well-being of both the courts and those who turn to them for help.

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www.smh.com.au/national/hylands-homeopathic-baby-tablets-recalled-in-australia-over-safety-fears-20170429-gvvfgx.html.

277. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

278. FED. R. EVID. 702(a) (emphasis added).

279. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 590 (1993).

280. LANCET, *supra* note 152, at 690.

281. GARDNER, *supra* note 1, at 186.

282. *Id.* at 187.