

## The Safety of Homeopathy

Two of the most important questions that must be asked of any form of medicine are: “Is it safe?” and “do the benefits outweigh its risks?”

When it comes to homeopathy, the answer to both these questions is “yes.”

Homeopathy has been in worldwide use for more than two centuries. It is currently being utilized by more than 500 million people and several hundred thousand physicians. It is the second most commonly used form of medicine in the world. There have been billions of exposures to homeopathic medicines, thousands of case reports, and numerous articles published in peer-reviewed scientific journals on this topic.

There are no documented cases confirming that homeopathic medicines are responsible for hospitalization, life-threatening reactions, persistent or significant disability/incapacity or congenital anomaly/birth defects, allergic reactions, serious adverse events, or deaths. Homeopathic treatment is only rarely associated with side effects of any sort, and these consistently tend to be both “mild and transient.” Homeopathy is probably the safest form of medicine ever developed by man.

### Adverse Effects of Homeopathy

According to testimony provided to the Food and Drug Administration (FDA) regarding the National Poison Data System (NPDS) and The American Association of Poison Control Centers (AAPCC), exposure reports to “homeopathic” products account for 1% (or less) of all calls to Poison Control Centers. The AAPCC does not verify the identity of the “homeopathic” products (and identity confusion abounds between herbal and dietary supplements), which can lead to an *overestimation* of reports being attributed to “homeopathic” products. Nevertheless, the overwhelming majority (98%) of reports regarding “homeopathic” products are categorized as either *minor or no* adverse effects, and these are typically managed without the need for a medical referral. Compared with conventional pharmaceutical drugs, “homeopathic” medicines demonstrate greater safety and fewer adverse events, by several orders of magnitude.<sup>1</sup>

Both consumer and operator confusion at groups like Poison Control Centers frequently leads to mis-characterization of non-homeopathic products (i.e., herbal or nutritional) as homeopathic. Reports provided by these centers often lump together groups of diverse products into the single category of “homeopathic” (thereby misrepresenting and inaccurately reporting adverse effects to homeopathic products which are not homeopathic).<sup>2</sup> Similar confusion takes place among both authors and editors of some of the world’s leading medical journals when they mistakenly identify adverse effects due to nonhomeopathic products and categorize them as resulting from homeopathy (when they are not).<sup>3,4</sup>

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<sup>1</sup> <https://www.regulations.gov/document?D=FDA-2015-N-0540-4429>. Presentation from Edward P. Krenzelok, Rocky Mountain Poison and Drug Center.

<sup>2</sup> Ullman D. The FDA and Regulation of Homeopathic Medicines. Huffington Post 2015. [https://www.huffingtonpost.com/dana-ullman/the-fda-and-regulation-of\\_b\\_8125722.html](https://www.huffingtonpost.com/dana-ullman/the-fda-and-regulation-of_b_8125722.html)

<sup>3</sup> Posadzki P, Alotaibi A, Ernst E. Adverse effects of homeopathy: a systematic review of published case reports and case series. *Int J Clin Pract* 2012;66(12):1178-88. <https://www.ncbi.nlm.nih.gov/pubmed/23163497>

<sup>4</sup> Saine, A. (2013, March 28). Homeopathy: Great Medicine or Dangerous Pseudoscience? Retrieved from <https://www.homeopathy.ca/debates/>

An extensive search performed by physicians at the Royal London Homeopathic Hospital included a systematic review of information regarding adverse effects of homeopathic medicines identified using electronic databases, hand searching, searching reference lists, reviewing trial and article bibliographies, contacting homeopathic manufacturers and drug regulatory agencies in both the UK and USA, and by communicating directly with experts in homeopathy. The group concluded that the mean incidence of adverse effects of homeopathic medicines was slightly greater than placebo in controlled clinical trials (9.4 vs 6.1) but their impacts were minor, transient and consistent, mostly involving headaches, tiredness, skin eruptions, dizziness, bowel dysfunction such as diarrhea or loose stools, and, more frequently, aggravations of patients' pre-existing symptoms (see Homeopathic Aggravations, below). These authors were unable to identify any serious adverse events (SAE) related to homeopathic products concluding that:

"Homeopathic medicines in high dilutions... are probably safe and unlikely to provoke severe adverse reactions."<sup>5</sup>

The safety of homeopathic products was independently reviewed in 11 trials published between 1986 and 1995 and the authors concluded that:

- Homeopathic medicines may provoke AEs, but these are generally mild and transient
- There is under-reporting
- There are cases of 'mistaken identity', where herbal and other medicines were [mistakenly] described as homeopathic
- The main risks associated with homeopathy are indirect, relating to the prescriber rather than the medicine.<sup>6</sup>

A study performed at the Glasgow Homeopathic Hospital acute care facility tracked 1,000 consecutive patients with acute medical issues treated homeopathically. They found that adverse reactions took place in less than 2% of cases and that these reactions were consistently mild and transient.<sup>7</sup>

The European Council for Classical Homeopathy (ECCH) performed an extensive in-depth analysis of the safety of homeopathic medical products using literature reviews, surveys of treatment provided by practitioners, overviews from regulatory bodies and self-regulation of the medical profession, and determined that harm can result from several sources: product contamination, product toxicity, and incorrect utilization.

These authors determined that due to the specific nature of homeopathic products (their dilution through the potentization process) and the application of Good Manufacturing Practices (GMP) both in the EU and the USA, coupled with appropriate use, they are safe to use beyond the 1:10,000 ( $10^{-5}$  or 5c) dilution. They determined that:

"homeopathic treatment has a very high level of safety, particularly in comparison with conventional medicinal products."<sup>8</sup>

<sup>5</sup> Dantes F, Rampes H, Do homeopathic medicines provoke adverse effects? A systematic review. *Br Homeopathic J* 2000;89(Supl 1):S35-8. <https://www.ncbi.nlm.nih.gov/pubmed/10939781>

<sup>6</sup> Fisher P, Dantas F, Rampes H. The safety of homeopathic products. *J R Soc Med* 2002;95(9):474-476. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280007/>

<sup>7</sup> Reilly D Homeopathy: Increasing Scientific Validation. *Altern Ther Health Med* 2005;11(2):28-31. <https://www.ncbi.nlm.nih.gov/pubmed/15819447>

<sup>8</sup> The Safety of Homeopathy. An ECCH Report. January 2009. [https://www.omeopatia.org/upload/Image/my\\_news/safety%20homeo.pdf](https://www.omeopatia.org/upload/Image/my_news/safety%20homeo.pdf)

A systematic review of 24 placebo controlled trials of homeopathic treatment published between 1966 to 2002 included a total of 3,437 patients and determined that three times as many adverse events were found in those taking homeopathic medicines when compared with placebos. These events were always mild and transient, but they concluded that while homeopathic remedies are not totally devoid of adverse effects, they are clearly distinguishable from placebos.<sup>9</sup>

A health technology assessment authorized by the Swiss government concluded that extensive reviews of clinical studies demonstrate that homeopathy is both safe and effective.<sup>10</sup>

Homeopathic drug interactions with conventional medications have also been studied through worldwide literature searches and found to be extremely unlikely “due to the enormous dilutions usually involved and the lack of classical pharmacological or toxicological effects” of homeopathic medicines, unless improperly or carelessly prepared.<sup>11</sup>

A systematic review of observational studies, including 7,275 subjects, published after 1995 revealed that adverse events reported from homeopathic treatment occur in 0 – 11% of subjects, depending on the study. These events tend to be mild and transient, and include headaches, localized pain, dryness of skin, rashes, eye irritation, digestive problems (upset stomach, vomiting), feelings of heat, agitation, and psychological symptoms such as increased irritability and feelings of depression.<sup>12</sup>

Some studies have compared the incidence of adverse events between conventional and homeopathic treatment and conclude that (a) adverse events from conventional medicines are at least twice as likely, and (b) adverse events from conventional medicines tend to be more severe. No serious adverse events (SAE) have ever been reported from homeopathic treatment.<sup>13</sup>

### Homeopathic Aggravations

Homeopathic “aggravations” are not side effects per se, because they are generally defined as a transient worsening of a patient’s *already existing* symptoms. They are typically considered to be a *favorable* response, indicating that a curative reaction to the homeopathic treatment is taking place. Many studies note that these aggravations exist, although their incidence is not known.<sup>14</sup>

An example of a homeopathic aggravation might be a mild and transient elevation in temperature following the administration of a homeopathic medicine to a patient who *already*

<sup>9</sup> Grabia S, Ernst E. Homeopathic aggravations: a systematic review of randomized, placebo controlled clinical trials. *Homeopathy* 2003; 92: 92-98. <https://www.ncbi.nlm.nih.gov/pubmed/12725251>

<sup>10</sup> Bornhöft G, Wolf U, von Ammon K, et al. Effectiveness, safety and cost-effectiveness of homeopathy in general practice – summarized health technology assessment. *Forsch Komplementärmed* 2006;13(suppl 2):19- 29. <https://www.ncbi.nlm.nih.gov/pubmed/16883077>

<sup>11</sup> Woodward KN. The potential impact of the use of homeopathic and herbal remedies on monitoring the safety of prescription products. *Human and Experimental Toxicology* 2005; 24: 219-233. <https://www.ncbi.nlm.nih.gov/pubmed/16004184>

<sup>12</sup> Op cit, ECCH Report.

<sup>13</sup> Haidvogel M, Riley DS, Heger M, et al. Homeopathic and conventional treatment for acute respiratory and ear complaints: A comparative study on outcome in the primary care setting. *BMC Complementary and Alternative Medicine* 2007; 7:7. <https://www.ncbi.nlm.nih.gov/pubmed/17335565>

<sup>14</sup> Taylor MA, Reilly D, Llewellyn-Jones RH, et al. Randomised controlled trial of homoeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *Br Med J* 2000;321(7259):471-76. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC27460/>

has a fever. The mild and transient elevation in temperature is typically followed by a swift therapeutic decline in temperature back to the normal range along with generalized improvement in all other symptoms.

Homeopathic aggravations are thought to be the result of inherent homeostatic mechanisms built into the immune system that accelerate physiologic pathways augmenting the innate immune response leading to reestablishment of health. Most homeopathic physicians consider homeopathic aggravations of pre-existing symptoms to be common, and many believe that that they are a necessary stage in the curative recovery process.<sup>15,16,17,18,19</sup>

## Conclusion

Many investigations into homeopathic treatment including randomized controlled trials, observational studies, experimental studies, case reports, systematic reviews, worldwide literature searches, consultation with regulating authorities, and conversations with homeopathic practitioners reveal that homeopathy is an extremely safe and effective form of medicine.

Adverse events from homeopathic treatment are uniformly only “mild and transient” and no serious adverse events from homeopathic treatment have ever been verified. Careful review of the available scientific data does indicate that homeopathy is not only safe, but effective; its benefits clearly outweigh its risks.

Homeopathy, like any other medical specialty, does require a regulatory framework and a means of ensuring that products are produced according to Good Manufacturing Practices, free of contamination, toxic levels of ingredients, and that their use is widely understood and correctly administered.

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<sup>15</sup> Cook TM. Homeopathic Medicine Today. New Canaan, US 1989: Keats Publishing:33.

<sup>16</sup> Endrizzi C, Rossi E, Crudeli L, et al. Harm in homeopathy: Aggravations, adverse drug events or medication errors? *Homeopathy* 2005;94(4): 233-240. <https://www.ncbi.nlm.nih.gov/pubmed/16226201>

<sup>17</sup> Pschyrembel W. Pschyrembel Wörterbuch Naturheilkunde und alternative Heilverfahren, (2. überarbeitete Auflage). Berlin 2000: de Gruyter: 107.

<sup>18</sup> Swayne J. International Dictionary of Homeopathy. Edinburgh 2002: Churchill Livingstone:212.

<sup>19</sup> Thompson E, Barron S, Spence D. A preliminary audit investigating remedy reactions including adverse events in routine homeopathic practice. *Homeopathy* 2004; 93: 203-209. <https://www.ncbi.nlm.nih.gov/pubmed/15532700>



### Conclusion from Americans for Homeopathy Choice

When properly manufactured and applied, homeopathic medicine plays an important role in the treatment of patients with major health problems across the globe. Homeopathy is inexpensive, effective, and inherently safe. When properly utilized, homeopathy makes it possible to make what already exists currently in the conventional health care system, more effective. For example, homeopathy makes it possible to avoid overuse of antibiotics, reserving antibiotics for when they are actually needed. Homeopathy also reduces the need to rely on dangerous and addictive painkillers in various situations including postoperatively, and after injury. Among many other benefits, homeopathy also helps reduce the incidence of polypharmacy.

Positive results such as these are achieved because homeopathy is a well-developed system of individualized medicine. Those who use homeopathy consider it a “designer” medicine, customized to their specific needs.

We are concerned that the proposed Draft Guidance on homeopathy will undermine the right of individuals to choose homeopathy, and also undermine the very important role homeopathy has to play in addressing these health problems. This paper gives an example of how homeopathy can benefit our current healthcare system - **specifically because it is an inherently safe form medicine**. It is important that FDA actions strengthen rather than undermine homeopathy so that it can meaningfully contribute to and support the American healthcare system.