Homeopathy: The Ultimate Fake (Stephen Barrett, M.D.)

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Homeopathic "remedies" enjoy a unique status in the health marketplace: They are the only category of quack products legally marketable as drugs. This situation is the result of two circumstances. First, the 1938 Federal Food, Drug, and Cosmetic Act, which was shepherded through Congress by a homeopathic physician who was a senator, recognizes as drugs all substances included in the *Homeopathic Pharmacopeia of the United States.* Second, the FDA has not held homeopathic products to the same standards as other drugs. Today they are marketed in health-food stores, in pharmacies, in practitioner offices, by multilevel distributors [A], through the mail, and on the Internet.

Basic Misbeliefs

Samuel Hahnemann (1755-1843), a German physician, began formulating homeopathy's basic principles in the late 1700s. Hahnemann was justifiably distressed about bloodletting, leeching, purging, and other medical procedures of his day that did far more harm than good. Thinking that these treatments were intended to "balance the body's 'humors' by opposite effects," he developed his "law of similars"—a notion that symptoms of disease can be cured by extremely small amounts of substances that produce similar symptoms in healthy people when administered in large amounts. The word "homeopathy" is derived from the Greek words *homoios* (similar) and *pathos* (suffering or disease).

Hahnemann and his early followers conducted "provings" in which they administered herbs, minerals, and other substances to healthy people, including themselves, and kept detailed records of what they observed. Later these records were compiled into lengthy reference books called *materia medica,* which are used to match a patient's symptoms with a "corresponding" drug.

Hahnemann declared that diseases represent a disturbance in the body's ability to heal itself and that only a small stimulus is needed to begin the healing process. He also claimed that chronic diseases were manifestations of a suppressed itch (*psora)*, a kind of miasma or evil spirit. At first he used small doses of accepted medications. But later he used enormous dilutions and theorized that the smaller the dose, the more powerful the effect—a notion commonly referred to as the "law of infinitesimals." That, of course, is just the opposite of the dose-response relationship

that pharmacologists have demonstrated.
The basis for inclusion in the Homeopathic Pharmacopeia is not modern scientific testing, but homeopathic "provings" conducted during the 1800s and early 1900s. The current (ninth) edition describes how more than a thousand substances are prepared for homeopathic use. It does not identify the symptoms or diseases for which homeopathic products should be used; that is decided by the practitioner (or manufacturer). The fact that substances listed in the *Homeopathic Pharmacopeia* are legally recognized as "drugs" does not mean that either the law or the FDA recognizes them as effective.
Because homeopathic remedies were actually less dangerous than those of nineteenth-century medical orthodoxy, many medical practitioners began using them. At the turn of the twentieth century, homeopathy had about 14,000 practitioners and 22 schools in the United States. But as medical science and medical education advanced, homeopathy declined sharply in America, where its schools either closed or converted to modern methods. The last pure homeopathic school in this country closed during the 1920s [1].
Many homeopaths maintain that certain people have a special affinity to a particular remedy (their "constitutional remedy") and will respond to it for a variety of ailments. Such remedies can be prescribed according to the person's "constitutional type"—named after the corresponding remedy in a manner resembling astrologic typing. The "Ignatia Type," for example, is said to be nervous and often tearful, and to dislike tobacco smoke. The typical "Pulsatilla" is a young woman, with blond or light-brown hair, blue eyes, and a delicate complexion, who is gentle, fearful, romantic, emotional, and friendly but shy. The "Nux Vomica Type" is said to be aggressive, bellicose, ambitious, and hyperactive. The "Sulfur Type" likes to be independent. And so on. Does this sound to you like a rational basis for diagnosis and treatment?

At Best, the "Remedies" Are Placebos

Homeopathic products are made from minerals, botanical substances, and several other sources. If the original substance is soluble, one part is diluted with either nine or ninety-nine parts of distilled water and/or alcohol and shaken vigorously (succussed); if insoluble, it is finely ground and pulverized in similar proportions with powdered lactose (milk sugar). One part of the diluted medicine is then further diluted, and the process is repeated until the desired concentration is reached. Dilutions of 1 to 10 are designated by the Roman numeral X (1X = 1/10, 3X = 1/1,000, 6X = 1/1,000,000). Similarly, dilutions of 1 to 100 are designated by the Roman numeral C (1C = 1/100, 3C = 1/1,000,000, and so on). Most remedies today range from 6X to 30X, but products of 30C or more are marketed.
A 30X dilution means that the original substance has been diluted 1,000,000,000,000,000,000,000,000,000,000 times. Assuming that a cubic centimeter

of water contains 15 drops, this number is greater than the number of drops of water that would fill a container more than 50 times the size of the Earth. Imagine placing a drop of red dye into such a container so that it disperses evenly. Homeopathy's "law of infinitesimals" is the equivalent of saying that any drop of water subsequently removed from that container will possess an essence of redness. Robert L. Park, Ph.D., a prominent physicist who is executive director of The American Physical Society, has noted that since the least amount of a substance in a solution is one molecule, a 30C solution would have to have at least one molecule of the original substance dissolved in a minimum of 1,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000 molecules of water. This would require a container more than 30,000,000,000 times the size of the Earth.

Oscillococcinum, a 200C product "for the relief of colds and flu-like symptoms," involves "dilutions" that are even more far-fetched. Its "active ingredient" is prepared by incubating small amounts of a freshly killed duck's liver and heart for 40 days. The resultant solution is then filtered, freeze-dried, rehydrated, repeatedly diluted, and impregnated into sugar granules. If a single molecule of the duck's heart or liver were to survive the dilution, its concentration would be 1 in 100^{200}. This huge number, which has 400 zeroes, is vastly greater than the estimated number of molecules in the universe (about one googol, which is a 1 followed by 100 zeroes). In its February 17, 1997, issue, *U.S. News & World Report* noted that only one duck per year is needed to manufacture the product, which had total sales of $20 million in 1996. The magazine dubbed that unlucky bird "the $20-million duck."

Actually, the laws of chemistry state that there is a limit to the dilution that can be made without losing the original substance altogether. This limit, which is related to Avogadro's number, corresponds to homeopathic potencies of 12C or 24X (1 part in 10^{24}). Hahnemann himself realized that there is virtually no chance that even one molecule of original substance would remain after extreme dilutions. But he believed that the vigorous shaking or pulverizing with each step of dilution leaves behind a "spirit-like" essence—"no longer perceptible to the senses"—which cures by reviving the body's "vital force." Modern proponents assert that even when the last molecule is gone, a "memory" of the substance is retained. This notion is unsubstantiated. Moreover, if it were true, every substance encountered by a molecule of water might imprint an "essence" that could exert powerful (and unpredictable) medicinal effects when ingested by a person.

Many proponents claim that homeopathic products resemble vaccines because both provide a small stimulus that triggers an immune response. This comparison is not valid. The amounts of active ingredients in vaccines are much greater and can be measured. Moreover, immunizations produce antibodies whose concentration in the blood can be measured, but high-dilution homeopathic products produce no measurable response. In addition, vaccines are used preventively, not for curing symptoms.

Stan Polanski, a physician assistant working in public health near Asheville, North

Carolina, has provided additional insights:

- Imagine how many compounds must be present, in quantities of a molecule or more, in every dose of a homeopathic drug. Even under the most scrupulously clean conditions, airborne dust in the manufacturing facility must carry thousands of different molecules of biological origin derived from local sources (bacteria, viruses, fungi, respiratory droplets, sloughed skin cells, insect feces) as well as distant ones (pollens, soil particles, products of combustion), along with mineral particles of terrestrial and even extraterrestrial origin (meteor dust). Similarly, the "inert" diluents used in the process must have their own library of microcontaminants.
- The dilution/potentiation process in homeopathy involves a stepwise dilution carried to fantastic extremes, with "succussion" between each dilution. Succussion involves shaking or rapping the container a certain way. During the step-by-step dilution process, how is the emerging drug preparation supposed to know which of the countless substances in the container is the One that means business? How is it that thousands (millions?) of chemical compounds know that they are required to lay low, to just stand around while the Potent One is anointed to the status of Healer? That this scenario could lead to distinct products uniquely suited to treat particular illnesses is beyond implausible.
- Thus, until homeopathy's apologists can supply a plausible (nonmagical) mechanism for the "potentiation"-through-dilution of precisely one of the many substances in each of their products, it is impossible to accept that they have correctly identified the active ingredients in their products. Any study claiming to demonstrate effectiveness of a homeopathic medication should be rejected out-of-hand unless it includes a list of all the substances present in concentrations equal to or greater than the purported active ingredient at every stage of the dilution process, along with a rationale for rejecting each of them as a suspect.
- The process of "proving" through which homeopaths decided which medicine matches which symptom is no more sensible. Provings involved taking various substances recording every twitch, sneeze, ache or itch that occurred afterward—often for several days. Homeopathy's followers take for granted that every sensation reported was caused by whatever substance was administered, and that extremely dilute doses of that substance would then be just the right thing to treat anyone with those specific symptoms.

Dr. Park has noted that to expect to get even one molecule of the "medicinal" substance allegedly present in 30X pills, it would be necessary to take some two billion of them, which would total about a thousand tons of lactose plus whatever impurities the lactose contained.

Cell Salts

Some homeopathic manufacturers market twelve highly diluted mineral products called "cell salts" or "tissue salts." These are claimed to be effective against a wide variety of diseases, including appendicitis (ruptured or not), baldness, deafness, insomnia, and worms. Their use is based on the notion that mineral deficiency is the basic cause of disease. However, many are so diluted that they could not correct a mineral deficiency even if one were present. Development of this approach is attributed to a nineteenth-century physician named W.H. Schuessler.

"Electrodiagnosis"

Some physicians, dentists, and chiropractors use "electrodiagnostic" devices to help select the homeopathic remedies they prescribe. These practitioners claim they can determine the cause of any disease by detecting the "energy imbalance" causing the problem. Some also claim that the devices can detect whether someone is allergic or sensitive to foods, vitamins, and/or other substances. The procedure, called *electroacupuncture according to Voll* (EAV), *electrodiagnosis*, or *electrodermal screening*, was begun during the late 1950s by Reinhold Voll, M.D., a West German physician who developed the original device. Subsequent models include the *Vega, Dermatron, Accupath 1000,* and *Interro*.
Proponents claim these devices measure disturbances in the flow of "electro-magnetic energy" along the body's "acupuncture meridians." Actually, they are fancy galvanometers that measure electrical resistance of the patient's skin when touched by a probe. Each device contains a low-voltage source. One wire from the device goes to a brass cylinder covered by moist gauze, which the patient holds in one hand. A second wire is connected to a probe, which the operator touches to "acupuncture points" on the patient's foot or other hand. This completes a circuit, and the device registers the flow of current. The information is then relayed to a gauge that provides a numerical readout. The size of the number depends on how hard the probe is pressed against the patient's skin. Recent versions, such as the *Interro* make sounds and provide the readout on a computer screen. The treatment selected depends on the scope of the practitioner's practice and may include acupuncture, dietary change, and/or vitamin supplements, as well as homeopathic products. Regulatory agencies have seized several types of electroacupuncture devices but have not made a systematic effort to drive them from the marketplace.
For more information about these devices and pictures of some of them, click here. If you encounter such a device, please read this article and report the device to the

practitioner's state licensing board, the state attorney general, the Federal Trade Commission, the FBI, the National Fraud Information Center, and any insurance company to which the practitioner submits claims that involve use of the device. For the addresses of these agencies, click here.

Unimpressive "Research"

Since many homeopathic remedies contain no detectable amount of active ingredient, it is impossible to test whether they contain what their label says. Unlike most potent drugs, they have not been proven effective against disease by double-blind clinical testing. In fact, the vast majority of homeopathic products have never even been tested.

In 1990, an article in *Review of Epidemiology* analyzed 40 randomized trials that had compared homeopathic treatment with standard treatment, a placebo, or no treatment. The authors concluded that all but three of the trials had major flaws in their design and that only one of those three had reported a positive result. The authors concluded that there is no evidence that homeopathic treatment has any more value than a placebo [2].

In 1994, the journal *Pediatrics* published an article claiming that homeopathic treatment had been demonstrated to be effective against mild cases of diarrhea among Nicaraguan children [3]. The claim was based on findings that, on certain days, the "treated" group had fewer loose stools than the placebo group. However, Sampson and London noted: (1) the study used an unreliable and unproved diagnostic and therapeutic scheme, (2) there was no safeguard against product adulteration, (3) treatment selection was arbitrary, (4) the data were oddly grouped and contained errors and inconsistencies, (5) the results had questionable clinical significance, and (6) there was no public health significance because the only remedy needed for mild childhood diarrhea is adequate fluid intake to prevent or correct dehydration [4].

In 1995, Prescrire International, a French journal that evaluates pharmaceutical products, published a literature review that concluded:

As homeopathic treatments are generally used in conditions with variable outcome or showing spontaneous recovery (hence their placebo-responsiveness), these treatments are widely considered to have an effect in some patients. However, despite the large number of comparative trials carried out to date there is no evidence that homeopathy is any more effective than placebo therapy given in identical conditions.

In December 1996, a lengthy report was published by the Homoeopathic Medicine Research Group (HMRG), an expert panel convened by the Commission of the European Communities. The HMRG included homeopathic physician-researchers and

experts in clinical research, clinical pharmacology, biostatistics, and clinical epidemiology. Its aim was to evaluate published and unpublished reports of controlled trials of homeopathic treatment. After examining 184 reports, the panelists concluded: (1) only 17 were designed and reported well enough to be worth considering; (2) in some of these trials, homeopathic approaches may have exerted a greater effect than a placebo or no treatment; and (3) the number of participants in these 17 trials was too small to draw any conclusions about the effectiveness of homeopathic treatment for any specific condition [5]. Simply put: Most homeopathic research is worthless, and no homeopathic product has been proven effective for any therapeutic purpose. The National Council Against Health Fraud has warned that "the sectarian nature of homeopathy raises serious questions about the trustworthiness of homeopathic researchers." [6]

In 1997, a London health authority decided to stop paying for homeopathic treatment after concluding that there was not enough evidence to support its use. The Lambeth, Southwark, and Lewisham Health Authority had been referring more than 500 patients per year to the Royal Homoeopathic Hospital in London. Public health doctors at the authority reviewed the published scientific literature as part of a general move toward purchasing only evidence-based treatments. The group concluded that many of the studies were methodologically flawed and that recent research produced by the Royal Homoeopathic Hospital contained no convincing evidence that homeopathy offered clinical benefit [7].

Proponents trumpet the few "positive" studies as proof that "homeopathy works." Even if their results can be consistently reproduced (which seems unlikely), the most that the study of a single remedy for a single disease could prove is that the remedy is effective against *that* disease. It would not validate homeopathy's basic theories or prove that homeopathic treatment is useful for other diseases.

Placebo effects can be powerful, of course, but the potential benefit of relieving symptoms with placebos should be weighed against the harm that can result from relying upon—and wasting money on—ineffective products. Spontaneous remission is also a factor in homeopathy's popularity. I believe that most people who credit a homeopathic product for their recovery would have fared equally well without it.

Homeopaths are working hard to have their services covered under national health insurance. They claim to provide care that is safer, gentler, "natural," and less expensive than conventional care—and more concerned with prevention. However, homeopathic treatments prevent nothing, and many homeopathic leaders preach against immunization. Equally bad, a report on the National Center for Homeopathy's 1997 Conference described how a homeopathic physician had suggested using homeopathic products to help prevent and treat coronary artery disease. According to the article, the speaker recommended various 30C and 200C products as alternatives to aspirin or cholesterol-lowering drugs, both of which are proven to reduce the incidence of heart attacks and strokes [8].

Illegal Marketing

In a survey conducted in 1982, the FDA found some over-the-counter products being marketed for serious illnesses, including heart disease, kidney disorders, and cancer. An extract of tarantula was being purveyed for multiple sclerosis; an extract of cobra venom for cancer.
During 1988, the FDA took action against companies marketing "diet patches" with false claims that they could suppress appetite. The largest such company, Meditrend International, of San Diego, instructed users to place 1 or 2 drops of a "homeopathic appetite control solution" on a patch and wear it all day affixed to an "acupuncture point" on the wrist to "bioelectrically" suppress the appetite control center of the brain.
America's most blatant homeopathic marketer appears to be Biological Homeopathic Industries (BHI) of Albuquerque, New Mexico, which, in 1983, sent a 123-page catalog to 200,000 physicians nationwide. Its products included BHI Anticancer Stimulating, BHI Antivirus, BHI Stroke, and 50 other types of tablets claimed to be effective against serious diseases. In 1984, the FDA forced BHI to stop distributing several of the products and to tone down its claims for others. However, BHI has continued to make illegal claims. Its 1991 Physicians' Reference ("for use only by health care professionals") inappropriately recommended products for heart failure, syphilis, kidney failure, blurred vision, and many other serious conditions. The company's publishing arm issues the quarterly Biological Therapy: Journal of Natural Medicine, which regularly contains articles whose authors make questionable claims. An article in the April 1992 issue, for example, listed "indications" for using BHI and Heel products (distributed by BHI) for more than fifty conditions—including cancer, angina pectoris, and paralysis. And the October 1993 issue, devoted to the homeopathic treatment of children, includes an article recommending products for acute bacterial infections of the ear and tonsils. The article is described as selections from Heel seminars given in several cities by a Nevada homeopath who also served as medical editor of Biological Therapy. In 1993, Heel published a 500-page hardcover book describing how to use its products to treat about 450 conditions [9]. Twelve pages of the book cover "Neoplasia and neoplastic phases of disease." (Neoplasm is a medical term for tumor.) In March 1998, during an osteopathic convention in Las Vegas, Nevada, a Heel exhibitor distributed copies of the book when asked for detailed information on how to use Heel products. A 2000 edition is larger but does not have the neoplasia section [10].
Between October 1993 and September 1994, the FDA issued warning letters to four homeopathic manufacturers:

- BHI was ordered to stop making claims that *BHI Cold,* which contained sulfur and pulsatilla, were effective against mumps, whooping cough, chronic

respiratory diseases, herpes zoster, all viral infections, and measles. In addition, when combined with other BHI remedies, it had been illegally claimed to be effective against otitis, pleurisy, bronchitis or pneumonia, conjunctivitis, and tracheitis.

- Botanical Laboratories, Inc., which distributed Natra-Bio products, was ordered to stop claiming that *BioAllers* was a homeopathic remedy for reliving symptoms of allergy due to pollen, animal hair, dander, mold, yeast, and dust. The products were promoted as homeopathic even though some ingredients were not in the *Homeopathic Pharmacopeia*.
- L.B.L.-Bot.Bio.Hom.Corp, of Roosevelt, New York, was ordered to stop making false claims that products could prevent AIDS, reduce cholesterol, cure diabetes and other pancreas disorders, and cancerous blood disorders.
- Nutrition Express, of Houston, Texas, was warned that products it was marketing for the temporary relief of infection, minor liver disorders, lymphatic disorders, and menstrual discomforts were misbranded because their labels or labeling included statements that represented that the products were intended to be used for curing or preventing disease.

Greater Regulation Is Needed

As far as I can tell, the FDA has never recognized any homeopathic remedy as safe and effective for any medical purpose. In 1995, I filed a Freedom of Information Act request that stated:

I am interested in learning whether the FDA has: (1) received evidence that any homeopathic remedy, now marketed in this country, is effective against any disease or health problem; (2) concluded that any homeopathic product now marketed in the United States is effective against any health problem or condition; (3) concluded that homeopathic remedies are generally effective; or (4) concluded that homeopathic remedies are generally not effective. Please send me copies of all documents in your possession that pertain to these questions [10].

An official from the FDA Center for Drug Evaluation and Research replied that several dozen homeopathic products were approved many years ago, but these approvals were withdrawn by 1970 [12]. In other words, after 1970, no homeopathic remedy had FDA as "safe and effective" for its intended purpose. As far as I can tell, that statement is still true today.

If the FDA required homeopathic remedies to be proven effective in order to remain marketable—the standard it applies to other categories of drugs—homeopathy would face extinction in the United States [13]. However, there is no indication that the agency is considering this. FDA officials regard homeopathy as relatively benign (compared, for example, to unsubstantiated products marketed for cancer and AIDS) and believe that other problems should get enforcement priority. If the FDA attacks

homeopathy too vigorously, its proponents might even persuade a lobby-susceptible Congress to rescue them. Regardless of this risk, the FDA should not permit worthless products to be marketed with claims that they are effective. Nor should it continue to tolerate the presence of quack "electrodiagnostic" devices in the marketplace.
In 1994, 42 prominent critics of quackery and pseudoscience asked the agency to curb the sale of homeopathic products. The petition urges the FDA to initiate a rulemaking procedure to require that all over-the-counter (OTC) homeopathic drugs meet the same standards of safety and effectiveness as nonhomeopathic OTC drugs. It also asks for a public warning that although the FDA has permitted homeopathic remedies to be sold, it does not recognize them as effective. The FDA has not yet responded to the petition. However, on March 3, 1998, at a symposium sponsored by *Good Housekeeping* magazine, former FDA Commissioner David A. Kessler, M.D., J.D., acknowledged that homeopathic remedies do not work but that he did not attempt to ban them because he felt that Congress would not support a ban [14].

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(SOURCE: QUACKWATCH)