

# Safety Issues and Homeopathic Medicines

by Dana Ullman, MPH ©1992

*Natural Foods Merchandizer*, October, 1993

The word "safe," like the word "pure," means so much and yet so little. In their "purist" forms, very few things are totally pure or safe, and yet, we can "safely" say that certain things are at least relatively "pure" or "safe."

If we were to use these words only when their precise and absolute definitions were honored, we would rarely, if ever, use them. Instead, we usually use these words in a relative context.

One could, for instance, say that carrot juice is "pure" carrot juice, but there can be slight traces of certain pesticides or even dirt from the peel that can make this product not totally "pure." Similarly, pure chocolate is not always pure because there are often various contaminants which creep into chocolate vats (and I do literally mean "creep," for cockroaches like this sweet stuff so much that it is impossible to keep them out of it; because of this, the FDA allows a certain number of cockroach parts in chocolate, without having to mention it on the ingredient label).

These are but two of the many times in which the FDA occasionally fudges on its own definitions of pure and safe as well.

That said, let us talk about the safety of homeopathic medicines with the understanding that safety is a relative, not absolute, concept.

## History of Use in America

Before discussing the safety of homeopathic medicines, it is first useful to understand some history of homeopathy in America and how and why homeopathy maintains a unique legal status in this country.

The first national medical society in the United States was the American Institute of Homeopathy, founded in 1844. Three years later, a rival medical organization formed in part to quell the growth of the homeopaths; this organization called itself the American Medical Association.

Despite the antagonism against homeopathy from the AMA, homeopathy continued to grow and even gained strong acceptance and support from many of America's political, literary, artistic, and clerical elite. At the turn of the century, there were 22 homeopathic medical schools and over 100 homeopathic hospitals.

From 1918 to 1923, Dr. Royal Copeland, a homeopathic physician, served as Health Commissioner of New York City, and later was elected to the U.S. Senate. In 1938, he sponsored

the Federal Food, Drug and Cosmetic Act that incorporated homeopathic medicines into federal law.

Distinct from supplements and herbs, which are recognized as foods and cannot be marketed for the prevention or treatment of specific ailments, homeopathic medicines are drugs that can be marketed for specific conditions. A homeopathic medicine can be sold to the public as long as the ailment for which it is claimed to treat has an "OTC indication." An OTC indication is:

1. an ailment which is "self-limiting" (a condition which can resolve on its own);
2. does not require medical diagnosis or medical monitoring.

Because of these characteristics, it is illegal for homeopathic medicines or any other OTC drug to be marketed for serious medical conditions, such as heart disease, diabetes, multiple sclerosis, or similarly dangerous conditions. Whereas these conditions are not self-limiting, there are other conditions that are self-limiting but need a doctor's diagnosis. An OTC indication must have both of these characteristics.

An OTC product must not only fit these characteristics, it also must be in a dosage form that is non-toxic.

This discussion thus leads us to the most common questions that people ask about the manufacture and safety of homeopathic medicines.

## **I understand that some homeopathic medicines are toxic substances. How can they be safe?**

It is certainly true that the raw materials for many homeopathic medicines are known poisons. And yet, every toxicologist knows that a substance is poisonous only in a certain dose.

Actually, virtually everything is poisonous in certain doses. Too much oxygen can impede respiration, and too much calcium will lead to brittle bones.

Homeopathic medicines are manufactured through a specific pharmaceutical process called "potentization" in which the substance is serially diluted, that is, it is diluted in a 1:10 or 1:100 solution of distilled water, vigorously shaken, diluted again, shaken again, and this process is continued many times. Homeopathic medicines are commonly diluted so many times that there are very few, if any, of the molecules of the original substance. As a result of the small doses used, there is general consensus that homeopathic medicines that are presently available for OTC use are basically safe.

The small doses used in homeopathy make it nearly impossible to elicit a poisonous effect. As famed violinist and philanthropist Yehudi Menuhin once said, "Homeopathy is one of the few medical specialties which carries no penalties--only benefits."

Although skeptics assume that these medicines are simply placebos, 200 years of experience by hundreds of thousands of physicians and by tens of millions of patients confirm that these small, specially prepared doses do, in fact, have clinical effect. Further, a small but growing body of research also confirms this.

## **How do homeopaths determine what is a safe dose?**

The Homeopathic Pharmacopeia Convention of the United States (HPCUS) is a non-profit organization with board consisting of representatives from homeopathic pharmacists and homeopathic physicians. Drawing from research in conventional toxicology and clinical medicine, the HPCUS makes its determination on what dose is appropriate for consumer use (OTC), what dose is available via a doctor's prescription, and what doses cannot and should not be made available.

The manual for how to manufacture make homeopathic medicines is the Homeopathic Pharmacopeia of the United States (HPUS). It is presently being revised and is available on a subscription basis. Although it is very expensive to subscribe (it costs \$1,000+ for all past issues). A summary listing of the official homeopathic medicines is available as HPUS Abstracts. These Abstracts provide a listing of official homeopathic medicines, the precise dose in which a medicine is either an OTC or Rx drug, the criteria for inclusion in the HPUS, the guidelines for homeopathic combination medicines, and the legal requirements for labeling homeopathic medicines.

Source: [Homeopathic Pharmacopoeia of the United States](#)

## **Are there any side effects to homeopathic medicines?**

From a strictly pharmacological perspective, there are no such things as "side effects," either of conventional drugs or of homeopathic medicines. Drugs simply have "effects," and we arbitrarily differentiate those effects that we like from those that we don't.

The symptoms that conventional drugs cause are not side effects but are the direct effect of a specific drug inhibiting the body's inherent reaction to a stress or infective agent. Although the effects of the drug may reduce the main complaint of the sick person, the new symptoms are sometimes more and sometimes less bothersome than the original. The consumer must decide which aggravation he or she prefers.

Homeopathic medicines, in contrast, are not known to create side effects.

## **I understand that it is possible to overdose using a homeopathic medicine. Is this true?**

The basic tenet of homeopathy, the principle of similars, assumes that a medicine is good for the specific pattern of symptoms that it is known to cause if given in large dose. In order to find out

what a medicine is effective in treating, homeopaths perform experiments called "provings" (derived from the German word *pruefung*, meaning test) in which healthy people are given continual doses of a potentized medicine. Although not everyone is sensitive to potentized doses of each substance, some people will develop symptoms of this particular substance. These symptoms can and will disappear if:

- after the person stops taking this medicine;
- if a higher potency of this medicine is given to them;
- if the person is prescribed a potentized remedy that causes the similar symptoms to those that the person is experiencing;
- if the person is prescribed a potentized remedy which is known to antedote the action of the first remedy; or
- if the person takes crude doses of a substance, such as coffee or camphor, which sometimes is known the antedote the effects of the remedy.

In summary, you can develop symptoms from taking a homeopathic medicine, though these symptoms rarely last very long and will usually go away shortly after the person stops taking the remedy.

Just as one can drink too much carrot juice and develop orange skin, one can take homeopathic medicines too frequently. And just as carrot juice should not be considered dangerous in its common dose, neither are homeopathic medicines.

It is, however, important for manufacturers to educate both consumers and retailers that homeopathic medicines are medicines; they are not supplements that people can and should be taking every day. They should be used for treating specific complaints and should not simply be taken unendingly.

Other information that consumers and retailers should know is that people should be taking a homeopathic medicine for a limited time and only when the person is experiencing a specific set of symptoms for which the medicine is indicated. If these symptoms disappear, it is not necessary to take the medicine any longer. If the symptoms change, it may be necessary to take a different remedy or formula that most accurately fits the new set of symptoms.

## **Are there certain potencies that are more dangerous?**

Homeopaths commonly use substances that are known poisons. However, the HPUS provides strict definitions of doses that are known to be dangerous. These more dangerous dose forms either require a physician's prescription or are simply not available.

At the other extreme, most homeopathic pharmacies do not encourage the retail sale of high potency homeopathic medicines (such as 200x, 1m, 10m, 50m, or CM; "M" stands for 1,000) unless the consumer has some knowledge of homeopathic medicines. Homeopathic manufacturers may sell these medicines to natural food stores, but they encourage retailers to have them behind the counter and to sell them only when a customer is knowledgeable or when a physician has prescribed that particular potency.

These high potency medicines are not dangerous in the traditional sense of toxicology. They are simply deeper-acting medicines which have the potential to create a healing crisis, that is, an increase in certain superficial symptoms (often skin symptoms) as the homeopathic medicine stimulates the deeper internal health of the person.

If a homeopathically uneducated person experiences a healing crisis, he or she may not realize that these new symptoms are actually benefiting their health, and this person may become anxious or even seek conventional medical treatment for these new symptoms. Such a medical intervention may significantly reduce the healing benefit of the homeopathic medicine that may not be easily re-established.

## **What is a healing crisis and can this be a problem?**

A healing crisis is an exacerbation of certain symptoms in the body's efforts to heal a deeper condition. It is, for instance, relatively common for people with chronic ailments to experience an externalization of symptoms in the process of cure, that is, a person with a recurrent respiratory condition may develop a skin rash in the healing process. The body always seeks to protect its deepest and most vital functions, and it always tries to externalize stress and discharge infective agents.

The basic assumption underlying homeopathy is that symptoms are defenses and that one should seek to aid the body's efforts in completing and externalizing them, rather than simply suppressing them. Homeopaths observe that there are three determinants that distinguish a healing crisis from a worsening of symptoms. Called Hering's laws of cure, homeopaths find that a true healing is occurring when:

1. symptoms are moving from the person's vital internal functions to more external, less vital functions;
2. symptoms are moving from the top of the body to the bottom of the body;
3. symptoms are moving in reverse order of experience, that is, a person may shortly re-experience old symptoms in the process of cure.

Although a person may experience some new or old symptoms after taking a homeopathic medicine, they are thought to be part of the healing process when they are following Hering's laws. When they are not, it is generally assumed that the homeopathic medicine is not working and the person's condition is getting worse.

In rare instances it has been known for a person to experience an exacerbation of symptoms without subsequent relief on a deeper level. Homeopaths have found that people who experience this are thought to have a deep pathology that may not be curable with homeopathy or other known therapies.

## **Are there certain homeopathic medicines that are more dangerous?**

No homeopathic medicines are actually dangerous, but there are certain remedies which are known to be more "reactive" than others. By reactive, I mean, that people are known to experience healing crisis more frequently with this remedy than with others. Although this healing crisis is beneficial, it is recommended that people experiencing a healing crisis be supervised by someone with a professional level of understanding of homeopathy.

The most reactive homeopathic medicines are called "nosodes," which are a class of substances made from pathological tissue or organisms. Syphilinum (made from pus in a syphilis chancre), Medhorrinum (from gonorrhea), and Tuberculinum (taken from the sputum of a person with tuberculosis).

These medicines are prescription homeopathic medicines and are available only by prescription from a physician.

## **How do you know that the homeopathic medicine listed on the bottle or box is actually in there?**

There are various tests that homeopathic manufacturers or regulatory agencies can do to assure that the original crude doses of a substance are properly identified. However, the more a substance is potentized, one is less able to detect any of the original substance remaining. Although there is presently no known problem of fraudulent manufacture of homeopathic medicines, this may be a problem in the future.

The best way to assure reliability of homeopathic medicine is to purchase medicines from known homeopathic companies or companies who get them manufactured by them. Such companies are members of the American Homeopathic Pharmacists Pharmaceutical Association (AHPA)(<http://www.hpus.com>).

## **Can homeopathic medicines become contaminated?**

Several known "quackbusters" have made reference to a Lancet letter that noted that a homeopathic medicine was found to be contaminated with a steroid. However, true to the bias that they bring to their assessment of homeopathy, they always neglect to mention that this single incidence took place in Pakistan.

Intentional contamination of a homeopathic medicine is possible; however, except for this single incidence in Pakistan, it has never been known to happen anywhere else.

Modern botanical, biochemical, and pharmacological methods allow manufacturers to properly identify medicinal substances used, and the use of double- and triple-distilled water for the process of dilution assures a high level of purity to homeopathic products.

Contamination after manufacture of a homeopathic product is highly unlikely due to the various protective seals that manufacturers use on their bottles and boxes.

## **Are there any contraindications to taking homeopathic medicines?**

Although there are no known contraindications to taking homeopathic medicines, homeopathic practitioners and industry leaders recognize that consumers should not be encouraged to treat themselves or their families for any chronic or serious ailment. Such conditions require the assessment and treatment of a trained professional.

### **Conclusion**

In sum, homeopathic medicines are OTC drugs that are very safe. It is, however, important for consumers to know that homeopathic medicines are not vitamins or supplements that are taken daily. Homeopathic medicines are medicinal agents that can and should be used when there are proper indications for them.

At present, skeptics of homeopathy assert that the medicines are simply placebos. In the coming years when more research confirms that efficacy of homeopathic medicines, I predict that skeptics of homeopathy will take a new tact in their attack on the field. Instead of recognizing them as placebos, they will probably assert that they are indeed powerful medicines, but they are so powerful that consumers cannot and should not have access to them, except under the care of a physician. The skeptics' efforts to make homeopathic medicines prescription drugs will probably be aided by conventional medical organizations, by certain medical professors (most likely those who are funded by major drug companies), and even by small factions of homeopathic medical doctors.

I predict that there will be pressure for strong regulation on the sale and marketing of homeopathic medicines from conventional drug manufacturers. The drug companies will insist that homeopathic products are given preferential treatment and will demand greater proof of efficacy. Whether the FDA bows to such pressure or not will depend on the unity and organization of the homeopathic and natural products community.

Because homeopathic medicines are generic products that are not presently patentable, there is no incentive for any company to test the efficacy of its products. However, as homeopathy achieves more popularity and greater profitability, there will probably be significant pressure on the American Homeopathic Pharmaceutical Association to develop cooperative studies. It is also quite possible that homeopathic medicines will be patentable at some time in the near future. Such changes in the legal status of homeopathic medicines will provide significant incentive to homeopathic manufacturers to develop and test new homeopathic medicines.

Needless to say, it is essential that the homeopathic and natural products community do all that is possible to resist the movement of homeopathic medicines from OTC drugs to prescription drugs. It is likewise essential that the FDA recognize that homeopathic medicine cannot and should not be regulated in the same way as conventional drugs. At the same time, we must encourage the homeopathic industry to devote increasing monies to efforts to evaluate the safety

and efficacy of its products. With these tangible investments, homeopathy can and will become an integral part of the American medicine chest.

In the meantime, there has been and there will continue to be increasing efforts by homeopathic organizations and companies to teach people how to use homeopathic medicines for themselves and their families. We are empowering people to take care of themselves. Not only is such care effective, the empowering of individuals and families is healing in its own right.

Homeopathy is here to stay, and hopefully it will stay in the rightful hands: in everybody's hands, both doctors and patients.