"The most meticulous regulation of nonsense must still result in nonsense."

– Edzard Ernst, M.D., PhD., professor, Complementary Medicine, University of Exeter, UK

The FDA seems to be interested in testing Edzard's pithy quip. Homeopathy is pure, 100%, unadulterated nonsense. They are sugar pills, usually lacking in any active ingredient or any possible mechanism for a physiological effect, on which a magic ritual has been cast.

Further - they don't work. Whatever you might think about the ability of science to rule out a possible mechanism, homeopathic potions have been tested in clinical trials, and they don't work. Edzard Ernst himself completed a review of systematic reviews of homeopathy and (like many others who have reviewed the evidence) concluded:

"The findings of currently available Cochrane reviews of studies of homeopathy do not show that homeopathic medicines have effects beyond placebo."

The peer-reviewed literature is a bit dry, but the sentiment is the same. Homeopathy is bunk.

In a perfect world regulatory agencies charged with protecting the public from fraudulent claims and ineffective or harmful medical nostrums would see that homeopathy is quackery and simply not allow it to be sold as medicine, or with any health claims. At the very least, if you lean toward the libertarian view, homeopathic products should be sold with the full informed consent of the consumer - properly labeled as sugar pills without any medicinal effect.

In a perfect world pharmacies would not sell nonsense as medicine, even if the law allows it.

Of course, we don't live in a perfect world. In the US, homeopathic products are recognized and

regulated as if they were real drugs. This stems from the 1938 Federal Food, Drug, and Cosmetic Act , which established the FDA. The principle author of this act was Senator Royal S. Copeland from New York, who happened to be a practitioner of homeopathy. One man, therefore, managed to burden US regulations with this nonsense for the next 74 years and counting.

This regulation covers any homeopathic product listed in the Homeopathic Pharmacopeia of the United States and its supplements. This means that homeopaths simply need to write down a "remedy" in a supplement to their big book of nonsense and it's automatically approved by the FDA. No pesky need for science or evidence.

The FDA, apparently, is at least trying to regulate the nonsense that they have been charged with regulated. They recently concluded an investigation of a large UK manufacturer of homeopathic products, A Nelson & Co., Ltd. They found a few areas of concern, most of which are just bizarre when you think about the fact that homeopathy is pure nonsense all the way down anyway.

One area of concern has nothing to do with the pseudoscientific status of homeopathy - they found glass on the assembly line making it's way into product:

"a. During the inspection, the investigator observed glass fragments present during the manufacture of Kali Phos 30 c Clikpak, Batch #36659. Specifically, glass fragments were observed in the Clikpak Assembly (b)(4) enclosed area where open glass vials are inserted into the outer plastic Clikpak sheaths and move uncovered on the conveyance mechanism. Your firm failed to implement adequate measures to prevent glass contamination and had no documentation to demonstrate that appropriate line clearance and cleaning is conducted following occurrences of glass breakage, which has been a recurring problem."

There are standard manufacturing quality issues that potentially come up when medical products that are not adequately science-based are regulated - purity, accuracy of labeling, consistency of manufacturing and others. The problem with regulating these things in the context of a product that doesn't work is that, while it is helpful in protecting the public from contaminants, it created the false impression that the product is legitimate. In any case, keeping glass out of homeopathic sugar pills is a good thing.

The other areas of concern found by the FDA are where the whole "regulating nonsense" thing becomes comical:

"b. The investigator also observed for Batch #36659 that one out of every six bottles did not receive the dose of active homeopathic drug solution due to the wobbling and vibration of the bottle assembly during filling of the active ingredient. The active ingredient was instead seen dripping down the outside of the vial assembly. Your firm lacked controls to ensure that the active ingredient is delivered to every bottle."

That's right, one in every six bottles did not even receive the fake ingredient (it really is inaccurate for the FDA to call it "active ingredient", but I guess they have to keep up the charade). Apparently, no one in the homeopathic community noticed that 1/6 bottle of homeopathic product coming out of this company were just sugar pills. That's probably because the other 5/6 of the bottles are also just sugar pills.

It continues:

"c. The dosing process has not been validated appropriately. Specifically, your surrogate validation study, “Medication of un-medicated pillules with (b)(4),” visually demonstrates the variability of the amount of (b)(4) for the pillules in one vial. Your firm lacks control of the variation for the amount of the active ingredient in the pillules."

Oh no - there isn't the same amount of fairy dust in every pill. They go on to point out that their instruments (like their gas chromatograph) are not calibrated at sufficiently frequent intervals. That's right - the problem with the homeopathic manufacturing process is that their instruments are not calibrated properly.

The last concern has to do with labeling. Homeopathic products can be marketed for the treatment of actual diseases as if they are drugs, but then they have to be labeled as "Rx only." Some products indicated to treat diseases were not so labeled, and therefore in violation. Homeopathic products can also be marketed for self-limiting symptoms as over-the-counter (OTC) products, and these do not require the "Rx only" label.

Thank goodness we have the FDA to protect the public from fake homeopathic potions being labeled as OTC when they should be labeled and prescription only.

Conclusion

Sigh!

Note: Thanks to Tim Farley and Andy Lewis from The Quackometer for bringing this topic to my attention.

Steven Novella, M.D. is the JREF's Senior Fellow and Director of the JREF's Science-Based Medicine project.

Dr. Novella is an academic clinical neurologist at Yale University School of Medicine. He is the president and co-founder of the New England Skeptical Society and the host and producer of the popular weekly science show, The Skeptics' Guide to the Universe. He also authors the NeuroLogica Blog .