

Society for Science-Based Medicine

Comment to the Federal Trade Commission on Advertising for Over-the-Counter Homeopathic Products

November 20, 2015

The Society for Science-Based Medicine (“Society”) welcomes the opportunity to comment on the FTC’s regulation of OTC homeopathic drug advertising. We are grateful that the FTC submitted its own Comments to the FDA regarding homeopathic drug regulation and are hopeful that much-needed reform of homeopathic drug industry oversight will result from the two agencies’ combined efforts.

This Comment will focus on two areas of concern to the FTC:

- (1) What consumers know about homeopathic drugs; and
- (2) The level of substantiation that should be required for homeopathic advertising claims.

(1) What do consumers know about homeopathic drugs?

The FTC’s own research clearly demonstrates that consumers are confused. In its Comments to the FDA, the FTC reported that its staff

*“has conducted copy tests and focus groups concerning consumers’ understanding of homeopathy and homeopathic remedies. This research, combined with additional observations regarding how homeopathic remedies are marketed, exacerbates the concerns raised [elsewhere in the Comments], because our research suggests that **a significant percentage of consumers do not understand the nature of homeopathic products, how they are regulated, or the level of substantiation to support claims for those products.**”* [Emphasis added.]

Notably, the homeopathic drug industry has produced no credible evidence to rebut the FTC’s research.

In drafting its own Comment to the FDA, the Society reviewed a small fraction of the public comments regarding FDA regulation of homeopathic drugs posted online at regulations.gov. That review

dramatically reinforces the FTC's determination that consumers do not understand homeopathic drugs. As we said in our finalized Comment to the FDA:¹

"There could be no more compelling evidence that the current system is inadequate than the public comments posted online at regulations.gov. As of this writing, there are almost 8,000 comments, the majority of them consisting of positive anecdotes about homeopathic drug use. Considering the fact that there is no evidence of efficacy, it is clear the homeopathic industry has the public fooled.

"We see, over and over, comments that homeopathic remedies are 'safe and effective' or 'proven safe and effective' when the consensus of the scientific community is that they are not and, in fact, cannot be effective, and we know that safety remains largely unproven. One physician testified at the FDA's hearing that 'the majority of patients . . . that I encounter have no real understanding of what homeopathy is and often confuse it with herbal medicines.'

"Many commenters claim that homeopathic remedies are effective for a wide range of illnesses and conditions, not all of them self-limiting and some quite serious. Some use the word 'cure;' one claimed homeopathic drugs 'cured people of serious diseases.' Another claimed that a homeopathic drug brought a seven-year-old out of a coma. Yet another said homeopathy was effective for a 'vast range of ailments and conditions.' A random selection of about 350 of these comments included claims that homeopathic remedies are effective for [the following diseases and conditions]:

¹ Society for Science-Based Medicine. Comment: Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century, <http://sfsbm.org/images/FDAregulationhomeopathicdrugs.pdf>.

ADHD
allergic reactions
allergies
anxiety
asthma
autism
autoimmune condition
"balanced state"
bladder irritation
blood pressure
broken bones
bronchial issues
bruising
burns
cancer
car sickness
chest complaint
chills
chronic fatigue
cold sores
colds
cough
croup
depression
diarrhea
digestion
disability
dizziness
ear infections
"emotional balance"
eye infection
fatigue
fear
fever
flu prevention
food poisoning
growing pains
headaches
hives

hot flashes
indigestion
infertility
influenza
insect stings
insomnia
leg cramps
loss of range of motion
MRSA
nausea
"nerve calming"
overall health improvement
pain
pancreatitis (dog)
PMS
preventative care
psoriasis
puncture wounds
reflux
restlessness
rheumatoid arthritis symptoms
Rocky Mountain spotted fever
(dog)
runny nose
scalding
severe grief
shock
skin rashes
sore throats
stomach aches
stomach viruses
strengthening immune system
stroke (dog)
sunburns
swelling from spider venom
tooth pain
urinary tract complaint
vaginal discharge (dog)

“These consumers apparently have no understanding that the perceived ‘effectiveness’ of homeopathic products could well be due to such things as the natural course of disease, motivated reasoning, placebo responses, regression to the mean, confirmation bias, conditioning, the post hoc ergo propter hoc fallacy, or the effect of other treatments. In fact, from a scientific standpoint, these are the only plausible explanations for the putative effectiveness of homeopathic products.”

The Society went on to argue that these misattributions of efficacy are exactly the sort of confounding factors that the premarket approval process, which does not exist for homeopathic drugs, is designed to weed out.

While we cannot attribute all of the confusion evident in the public’s comments to advertising, neither can we say with certainty that none of it was. In fact, as noted, the FTC’s own research tells us otherwise. And while adequate FDA regulation would go a long way to curb the public’s misplaced confidence in homeopathic drugs, the FTC’s imposition of effective regulation of homeopathic drug advertising is a necessary bookend to FDA’s pre-market regulation, if and when it occurs. It is a *fortiori* necessary as long as the FDA maintains its unfortunate “hands off” posture.

(2) The level of substantiation required for homeopathic drug advertising claims.

That this is an issue at all is a tribute to the success of the homeopathic drug industry’s substantial efforts to convince the public that a parallel scientific universe exists solely for them. This unique universe, applicable only to homeopathy, denies basic laws of physics and chemistry and well-established principles of biology, so that we might be deceived into believing that: (1) “like cures like;” (2) the more a substance is diluted, the more potent it becomes; and (3) widely used and well-respected methods of determining the efficacy of other drugs, such as double-blind, randomized controlled trials, somehow fail when testing homeopathic drugs.

The truth is, homeopathy is highly implausible, unsupported by scientific evidence, ineffective in treating illness and, when relied upon instead of actual medicine, dangerous and even deadly.

The FTC is fortunate that the Australian National Health and Medical Research Council (NHMRC) recently completed a comprehensive evaluation of the evidence. The resulting analysis, "Effectiveness of Homeopathy for Clinical Conditions: Evaluation of the Evidence" (2015),² concluded:

"There is a paucity of good-quality studies of sufficient size that examine the effectiveness of homeopathy as a treatment for any clinical condition in humans. The available evidence is not compelling and fails to demonstrate that homeopathy is an effective treatment for any of the reported clinical conditions in humans."

This led to the NHMRC "Statement on Homeopathy:"

"Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there is no health condition for which there is reliable evidence that homeopathy is effective."

As well, the UK House of Commons Science and Technology Committee, in its "Evidence Check 2: Homeopathy,"³ after a review of the evidence, concluded:

"In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos. We could find no support from independent experts for the idea that there is good evidence for the efficacy of homeopathy."

If, and when, the homeopathic drug industry can produce substantiation based, as the FTC requires, "principles generally accepted in the scientific community"⁴ that homeopathic drugs actually "work" as advertised, the FTC will no doubt allow them to be advertised as such.

² Australian Government National Health and Medical Research Council, Statement on Homeopathy and Information Paper: "Evidence on the effectiveness of Homeopathy for treating health conditions." (2015) <https://www.nhmrc.gov.au/guidelines-publications/cam02>.

³ UK House of Commons, Science and Technology Committee, "Evidence Check 2: Homeopathy." (2010) <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2005/homeopathy-/>.

⁴ FTC, An Advertising Guide for Industry. <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>.

Until then, the Society hopes that the FTC will not be lured into watering down regulatory standards applied to other health care products, such as drugs and dietary supplements, in evaluating homeopathic drug advertising. As we argued to the FDA, we do not believe there is a way to create some hybrid regulatory system supported by one foot resting in science and the other in pseudoscience.

The Society for Science-Based Medicine is a 501(c)(3) tax-exempt charitable organization. Our mission includes advocacy on behalf of consumers to ensure that all government regulation affecting health care has a sound basis in science and the scientific method. For more information see www.sfsbm.org.