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The 200-year-old practice of homeopathy is estimated to be a multibillion-dollar industry in the United States.

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FDA takes new look at homeopathy

Jagger says: Homeopathic "colchicum autumnale" could cause serious harm to FMF patients.

By Kelly ServickApr. 21, 2015 , 7:00 PM

This week, officials at the U.S. Food and Drug Administration (FDA) took a 15-hour foray far outside the scientific mainstream. In a **2-day hearing**, the agency invited public input on how it should regulate homeopathy—a traditional healing practice that has been called into question by **numerous scientific studies**. For now, homeopathic remedies, sold largely over the counter, are classified as drugs that can be marketed without FDA approval in the United States. But the agency may be ready to rethink its policy.

"We've had tremendous growth in the market and also some emerging safety and quality concerns," Cynthia Schnedar, director of the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland, told *Science*Insider. "In light of that, we thought it was time to take another look."

The 200-year-old practice of homeopathy—estimated to be a multibillion-dollar industry in the United States—is based on two controversial principles: First, a substance that causes a specific symptom in a healthy person can relieve the same symptom in a sick person if consumed at a very low dose. Second, repeatedly diluting a substance actually makes treatment more potent, even if no detectable molecules of the original substance remain.

The 37 speakers at the FDA hearing ran the gamut from true believers to militant skeptics—and the two camps seemed at times to be speaking different languages.

"By its own definition, homeopathy cannot work," Michael De Dora, director of public policy at the nonprofit Center for Inquiry's Washington, D.C., branch, told the panel in his Monday presentation. Several large metastudies, including a recent analysis by the National Health and Medical Research Council in Australia, have concluded that **homeopathic remedies are no more effective than placebos for treating any condition**. "We need not spend much time on this," De Dora said, "as the federal government is well aware of the scientific evidence against homeopathy."

But other speakers—physicians and industry representatives—did spend much of their time extolling the treatments' medical value. And during the 5-minute question period following each talk, FDA panelists delicately pressed some of the speakers on their evidence.

“You strike me as someone who uses a lot of tools,” Robert Nelson, deputy director of FDA’s Office of Pediatric Therapeutics in Silver Spring, Maryland, told naturopathic physician Amy Rothenberg, before asking how she could be sure her patients were benefiting from homeopathy alone. Rothenberg responded that she prescribes exclusively homeopathic treatments to about half of her patients, though some get other forms of treatment from other doctors.

Elaine Lippmann, regulatory counsel in CDER’s Office of Regulatory Policy, asked several speakers the same question: “What is it about the scientific method of demonstrating safety and efficacy though our approval process that is inconsistent with homeopathy?”

“It’s like comparing apples and eggs,” explained homeopathic physician Karl Robinson of Houston, Texas. “Homeopathy is very much of an observational science,” he said. Five patients with the same official diagnosis could receive five different treatments based on their complex mental, emotional, and physical qualities. “It’s a different paradigm, that’s all.”

The cautious tone of the questioning reflects the unusual status FDA has bestowed on homeopathy. Since 1938, the agency has defined homeopathic products as drugs, thanks in part to U.S. senator and homeopathic physician Royal Copeland, who co-authored the Federal Food, Drug, and Cosmetic Act. And since then, FDA has relied on a document known as the Homeopathic Pharmacopoeia of the United States to determine what counts as a homeopathic drug. That list of substances—now 1295 items long—is maintained by an independent industry organization, the *Homeopathic Pharmacopoeia Convention of the United States*. Substances can be added to the list after they have had a successful “proving” in front of trained homeopaths, who determine how they affect healthy subjects at various concentrations.

Under FDA guidelines issued in 1988, a company can sell homeopathic products over the counter without demonstrating their safety or efficacy, and—unlike dietary supplements—their packaging can include claims about treating specific conditions, as long as they are “self-limiting” and not chronic. Such conditions include sprains, colds, or allergies.

But FDA *does* oversee the quality and manufacturing of homeopathic products, and it has recently raised several red flags. In 2009, it issued a **warning letter** to Matrixx Initiatives when high levels of zinc in several of its Zicam cold remedies were linked to a loss of smell in users. In 2010, **it warned** that homeopathic teething tablets produced by Hyland’s Homeopathic contained potentially harmful levels of the toxic nightshade plant. And last month, it **advised consumers** not to rely on a variety of over-the-counter homeopathic asthma remedies to control their attacks. FDA has issued 40 warning letters to makers of homeopathic products since 2009—up from nine letters between 2002 and 2008.

At the hearing, the agency asked for data that would further assess the risks and benefits of products already on the market. Toxicologist Edward Krenzelok of the Rocky Mountain Poison and Drug Center in Denver said that of nearly 80,000 homeopathic-related calls to regional poison control centers from 2006 to 2013, 98% of callers reported no effect or minor effects from exposure. Most of the calls—92%—involved children under the age of 6.

That relatively clean safety record was a talking point for several proponents of homeopathy. Pediatrician Robert Dumont of the Raby Institute for Integrative Medicine in Chicago, Illinois,

who praised homeopathic remedies as “exceptionally versatile in many medical problems,” assured the panel that he wasn’t concerned about negative interactions with other drugs, because at the concentrations he typically recommends, “there would be nothing in there to interact.”

But others argued that the true public health risks emerge when uninformed consumers decide to use homeopathic products instead of proven drug treatments. Janine Jagger, a professor of medicine at the University of Virginia in Charlottesville and president of the Familial Mediterranean Fever Foundation, described over-the-counter homeopathic remedies that list the same active ingredient as a prescription treatment for a rare genetic inflammatory disease. Patients that believe this highly diluted substance is comparable to the prescription drug could suffer serious harm, she says. “I have to explain this over and over and over to patients … and there are cases that I’ll never have the chance to explain that to,” she said. “I would like to have help from the FDA.”

Just what kinds of changes FDA would consider, if any, aren’t yet clear. FDA’s Schnedar is careful not to suggest that it plans to tighten its regulations. “There are no preconceived options on the table,” she says.

Several speakers had suggestions. De Dora argued that FDA should subject homeopathic products to the same premarket approval process as other drugs—a costly proposition for both regulators and manufacturers. Others, including Adriane Fugh-Berman of Georgetown University in Washington, D.C., suggested that FDA could at least clarify product labels—for example, by listing the concentrations of ingredients in milligrams rather than the number of times they have been ritually diluted.

Fugh-Berman suspects that after decades of a mostly hands-off policy, the current popularity of homeopathic products may finally inspire FDA to draft new regulations. “There have been several points in history where people have just ignored homeopathy because they thought it was dying,” she says, “And it keeps coming back.