The dilution solution

As U.S. homeopathy claims get watered down, will the medicine carry on?

By Bill Giebler

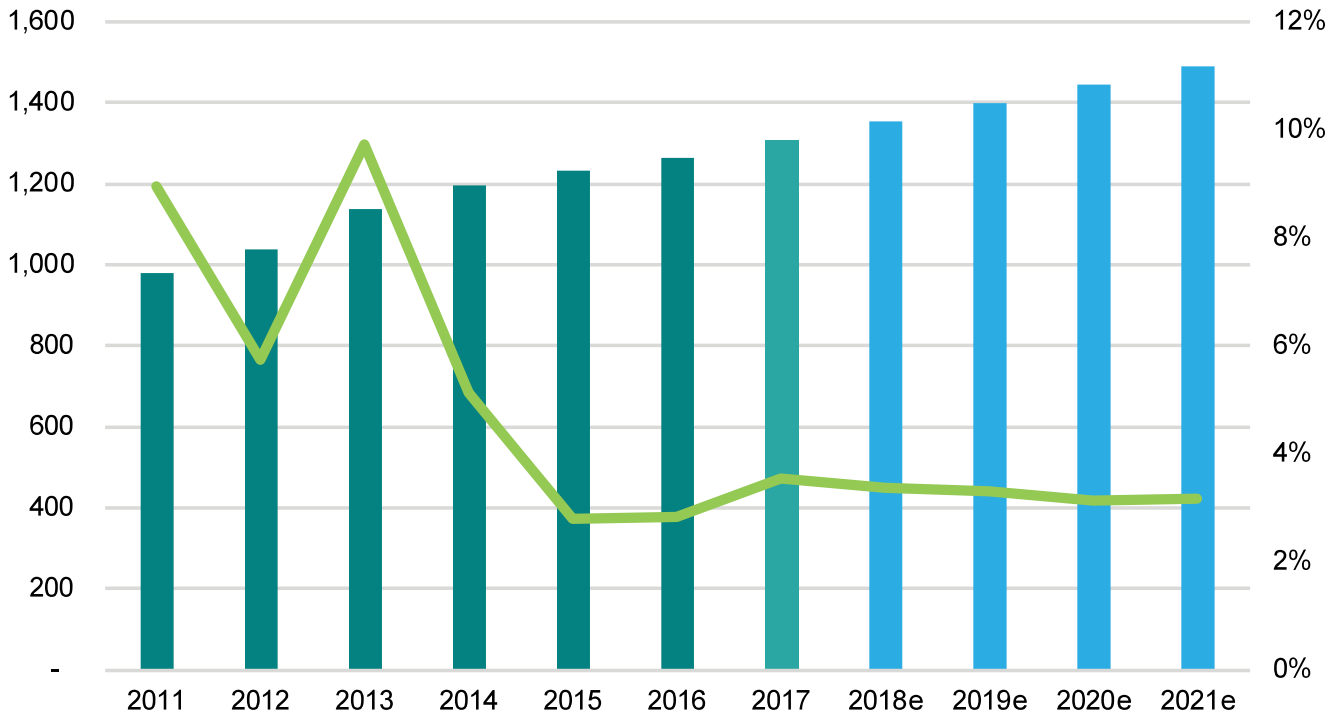
Homeopathic medicines exist in a world of mystery. If and how they work remains little understood, easily doubted and readily dismissed through a mechanistic lens. How they are regulated puts homeopathic drugs in a unique orbit, too. Even the term "drug"—legitimately used per regulatory agencies—comes with some consternation. The medicines, though made of natural substances in a 250-year-old practice and sold primarily in the natural and specialty channel, are regulated as OTC drugs and are, indeed, finding themselves on more conventional shelves across the U.S.

Across Europe, homeopathic products never left such shelves, and pharmacists around the union still pass individual dilutions across the counter daily. And while England faces a National Health Service plan to discontinue support of homeopathy, calling it "at best a placebo and a misuse of scarce NHS funds," the Swiss government has embraced it, giving it (and other complementary therapies, including herbal medicine and acupuncture) the same insurance status as conventional medicine. In France, leading homeopathic brand **Boiron** has

NBJ Takeaways

- Despite counter-intuitive therapeutic action and a lack of scientific evidence, sales of homeopathic products are growing across channels
- Regulatory actions have some fearing an end to the category
- Homeopathic products are seen as safe and effective by retailers and consumers

HOMEOPATHIC SUPPLEMENT SALES AND GROWTH, 2011-2021E



Source: Nutrition Business Journal estimates (consumer sales)

twice been named the #1 OTC brand.

The U.S. saw the category grow 3.5 percent to $1.3B in 2017 by *NBJ* estimates. Much of this growth, and migration to mass, is via popular breakout condition-specific products and combination remedies. The individual remedies of classical homeopathy are often handled through practitioners, and via Boiron's display of blue tubes, ubiquitous in natural and specialty stores. That 3.5 percent growth puts the category under the overall growth for supplements, but even flat sales would indicate adoption by new users, a trend somewhat difficult to account for with a 250-year-old science based on counter-intuitive therapeutic action.

"It's an energetic medicine; people can't quite understand that," says Barbara Seideneck of Homeopathy School International in Loveland, Colorado, adding that people do understand treating with electronic stimulus and, to some degree, acupuncture. "These are all energetic medicines." Seideneck and others think consumers find it less important to understand how the medicines work and more important to experience that they do, and do so safely. "People are getting a little bit tired of the side effects of opiates and antidepressants and antibiotics, and they see that they have to take them over and over again and sometimes for the rest of their lives," says Seideneck. "I think people are looking for different answers."

Customer appreciation

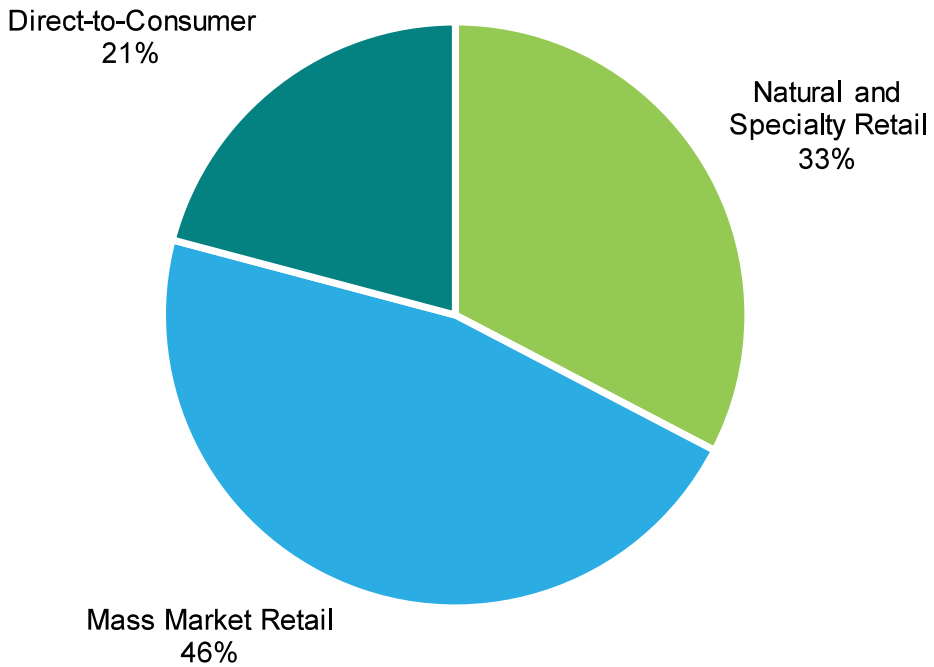
"I do think there is a greater level of awareness, anecdotally," says Karen Lewis, director of wellness for grocer **Earth Fare**. "It's driven by health condition needs," she continues, calling homeopathy a category with "fairly consistent" growth.

Lewis points to events like the 2018 cold and flu season, a season that wiped stores clean of popular homeopathics like Boiron's Oscillococcinum. "People seem to know that Oscillococcinum truly works for them. People know that homeopathy helps them. But I'm not sure they understand what it is."

Looking from a category management perspective, an assessment of the product category versus brand versus function is performed, Lewis says. "In this case, function probably is leading people to it first."

Don Summerfield, co-founder and vice president at **Pharmaca**, agrees. "Interest and trust in the safety and efficacy of these combination homeopathic products continue to gain traction," he says. "This is the first time since Pharmaca's inception that we actually ran out of homeopathic flu products," he adds, also citing a robust cold and flu season. "That's never happened before." (Boiron itself ran out of Oscillococcinum nationwide this season, selling 58 percent more than in the previous year.) For January and February, Oscillococcinum was the top-selling item in Pharmaca's nat-

HOMEOPATHIC SUPPLEMENT SALES BY CHANNEL, 2017



Source: Nutrition Business Journal estimates (consumer sales)

"It's remarkable that this medicine survives and thrives on word of mouth and is displacing conventional medicine with much heavier advertising."

- Alissa Gould, Boiron

ural medicine category, the store's biggest retail department, which also includes dietary supplements.

But it's not just the flu. Summerfield suggests growth is also coming from mothers looking for safe and effective products for their children. Homeopathic pet care, too, is growing. "That's an easy, safe and effective way to treat some pretty common ailments that pets have."

Dilute beginnings

Homeopathy's unique position within the labeling and claims world reaches back to 1938 when the Federal Food, Drug and Cosmetic Act included the medicines as drugs. Senator Royal Copeland, instrumental in the decision, was himself a homeopathic physician. The practice of homeopathy itself dates to mid-1700s Germany when Pharmacist Samuel Hahnemann began experimenting with dilutions of common medicines, poisons and other substances. The remedies are prepared in systematic dilutions and vigorous shaking, or succussion, and prescribed per the "law of similars," wherein medicines in low dosage treat the symptoms they might cause at full dose.

Substances are typically diluted at 10 percent or 1 percent, known respectively as 1X or 1C dilutions. Such preparations are usually diluted again in the same ratio six, 15, 30 or even 200 times. Thus, a 30C "potency" often found on retail shelves was diluted 1 part per 100, 30 times. The higher numbers, counter-intuitively, are known as *higher* potencies, many of which are handled only by certified practitioners.

Such extreme dilutions render the medicines free of any chemical action. Anything diluted beyond a 12C, a point known as Avogadro's number, removes any molecular trace of the original substance. While the chemical action is reduced—if done according to Hahnemann's precise procedure—the energetic action is concentrated, says the homeopathic literature.

A 1988 FDA Compliance Policy Guide (CPG) further cemented homeopathy's status as drugs, while specifying safety guidelines. The terms of the CPG, as well as homeopathic marketing claims, are now under review by the **FDA** and **FTC**, respectively, which has some stakeholders concerned about the future of homeopathy in the U.S.

View from the Hill

Two items are under review in Washington. First is the FDA's draft guidance, which reconsiders the 1988 CPG, proposing to replace it with what the industry sees as a less comprehensive risk assessment. Second is a November 2016 FTC enforcement guidance that would require companies marketing homeopathic products to state that the product claims are not based on modern science.

As Boiron accepted an interview for this article, Director of Corporate Communications & Public Affairs Alissa Gould, who also acts as communications chair for the **American Association of Homeopathic Pharmacists** (AAHP), was headed to Capitol Hill to present the homeopathic industry's comments on FDA's proposed guidance before the May 21 close of the comment period.

Much of what the homeopathy industry is asking is that the FDA maintain the terms of the 1988 CPG. "It's a really simple list," Gould says. "For labeling on the box, we want to make sure it has directions for use, to state what the active ingredients are in homeopathic terms and to state the indications for use."

Central to the sanctity of homeopathic products is concern about homeopathic ingredients being added to other products. While possibly legitimate formulations, such products may also be dietary supplements piggy-backing on the ability to make homeopathic drug claims.

"As a definition of what constitutes a homeopathic product, [the guidance] should say that a homeopathic product contains an active ingredient that is listed in the HPUS [Homeopathic Pharmacopeia of the United States] and that the product is supported by references," Gould says. If a product's active ingredient is not recognized in the HPUS, industry organizations are asking the FDA to require proper documentation to support that active ingredient, or that the product be considered under a category other than homeopathy.

That would block some misleading labeling, says Ivan Wasserman, partner at Amin Talati Upadhye. "I think some less scrupulous marketers may have seen a homeopathic loophole, if you will, at FDA as a way of making a disease treatment claim which you couldn't make for a dietary supplement," he says.

A potential example of this is Vamousse, an OTC medicated foam that carried a homeopathic label for a salt product that eliminated head lice through a chemical action known as lysis. The makers of Vamousse were challenged on a variety of claims in a 2015 National Advertising Division case. While safe for people and effective against lice, the product did not fit the standard of homeopathy (a practice founded on the principle of treating the patient, not the disease) and has since dropped the homeopathic claim from its label and marketing.

Switching the discussion to the FTC, Wasserman calls that agency's enforcement guidance a reiteration of something the commission has always held. "While the FTC's policy statement is new, the ideas expressed therein are not," he says. "There's no exception [allowing] for treating over-the-counter homeopathic products differently than any

> *"People know that homeopathy helps them, but I'm not sure they understand what it is."*
>
> *- Karen Lewis, Earth Fare*

other class of over-the-counter product."

Wasserman compares the FTC's concern about antiquated science to its traditional use guidance for dietary supplements. "As long as you're clear that you're basing your claim on traditional uses of an herb, and that herb is used sort of in the same way as it was historically," he says, "you don't have to have modern substantiation." Wasserman believes the FTC's position is similar when it comes to homeopathic products.

In response to the FTC guidance, the AAHP drafted the following disclaimer and is encouraging manufacturers to display it prominently and immediately: *Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.*

"It's up to every individual company what they want to do," says Gould, "but this is what the association is recommending for the industry."

Critical conundrum

Critics of homeopathy often fall into a conundrum when questioning the safety and efficacy of homeopathy. There is the temptation to call the medicines both ineffective, because they lack any measurable chemistry, and dangerous, because some are produced from toxic ingredients. A recent *Washington Post* article, for instance, profiled the controversial use of a preparation from rabid dog saliva, administered to a child in Canada, though no harm was incurred on the patient.

Two high-profile cases of harm have come across the desks at FDA. One was against Hyland's teething tablets, which FDA cited in hundreds of consumer claims and 10 deaths, assumed to be due to the presence of Belladonna, a highly poisonous plant at full strength. Not a single citation was verified, however, and many were implausible (including a 40-year-old man who died of a drug overdose while also, inexplicably, taking Hyland's teething tablets).

The other harm case was against Zicam nasal swabs, in which a 1X dilution of zinc caused anosmia, loss of sense of smell, in some users. While meeting the guidelines of a homeopathic preparation, at only 1X, or 10 percent, Zicam contained measurable amounts of zinc, a known anosmia risk. Furthermore, nasal swabbing is not a recognized application in homeopathic practice.

"By providing full-strength zinc applied directly to the nose," defends Burke Lennihan, RN, CCH, in the February 2018 issue of *Alternative and Complementary Therapies*, "the alleged benefits of Zicam as well as its infrequent side effect were both based on its action as a supplement, not its action as a homeopathic medicine."

Indeed, after 200 years of safe use around the world, and with often immeasurable chemistry in the substances, efficacy is the more pertinent question surrounding homeopathy. Yet, providing scientific evidence of the thousands of remedies—or even the 83 found in a standard Boiron retail set—strikes many as prohibitive.

This is not to say there isn't any modern science. Boiron refers to two peer-reviewed studies, in 1989 and 1998, that substantiate the claim that Oscillococcinum reduces both the severity and duration of flu-like symptoms. And a recent review performed by researchers at Rutgers New Jersey Medical School and Robert Wood Johnson Medical School, and published in *Pharmacology & Pharmacy* in May of this year, supports the effectiveness of Traumeel, a combination homeopathic topical.

"Many of the articles that were used in creating this comprehensive review demonstrated that Traumeel decreases the incidence and even severity of certain diseases associated with inflammation," says Burton Tabaac, M.D. a lead clinical researcher on the review. The review also showed benefit to musculoskeletal injuries when compared to glucocorticoids and NSAIDS and, says Tabaac, "with a very low side effect profile."

Would scientifically substantiated products be exempt from the FTC disclaimer? Wasserman says yes. "FTC is saying, 'if you don't have modern science, then you have to tell people you don't,'" he says. "If you do have modern science, you don't have to say any of this."

No worries

As long as the medicines remain available, the experts contacted for this story agree, consumers will likely be undeterred by doubts and disclaimers.

"You have core users that know that the products are safe and effective, so they're going to continue to support the category regardless of a contrary position on that," says Pharmaca's Summerfield.

Furthermore, the FTC guidance pertains to advertising. "We do very little advertising," Gould says. "We survive on word of mouth." Oscillococcinum, for instance, holds 4.5 stars on Amazon with over 1,500 reviews. "It's remarkable that this medicine survives and thrives on word of mouth and is displacing conventional medicine with much heavier advertising," says Gould. "It's certainly earning its real estate on the shelves of the Walmarts and Targets and CVSs."

There may be nothing to be afraid of, it seems, in neither consumer safety nor in the marketing of homeopathic products in the U.S.—if marketers continue to play by the rules.

Wasserman's advice is straight-forward: make permitted claims and educate the consumer as much as possible. "Ironically," he says, "for efficacy claims for homeopathic products, less is *not* more."