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Recent Developments Signal Headwinds for Homeopathic Drug Products

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Homeopathic drugs have an unusual status in the United States. On the one hand, they are incorporated into the Federal Food, Drug, and Cosmetic Act (FD&C Act) within the definition of "drug," which specifically includes articles recognized in the official Homoeopathic Pharmacopoeia of the United States (a historical perspective can be found in this *ScienceInsider* article from 2015, when government scrutiny was beginning to increase). But on the other hand, there is growing consensus that the effectiveness of such products is not supported by scientific evidence and that they are, in many cases, mere placebos that do not actually treat the patient's medical conditions; in the worst cases, they contain harmful ingredients that may cause serious injury.

This extraordinary dichotomy has led to both the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) in recent years issuing modernized enforcement policies related to homeopathic drugs. An FTC enforcement policy statement from late 2016 requires homeopathic products to be marketed with clear disclosures stating that, among other things, there is no scientific evidence that the products work (see our prior post on the FTC policy here). Then in 2019 FDA took action to withdraw a long-standing compliance policy guidance for homeopathic drugs and to simultaneously issue a significant number of Warning Letters to companies marketing such products in violation of the FD&C Act (our prior posts on those activities are here and here).

Most recently, FDA finalized its draft guidance on homeopathic drugs – first issued in draft form in 2017 and then revised in 2019 – to lay out for industry the agency's approach to "prioritizing regulatory actions for homeopathic products posing the greatest risk to patients." The final guidance document issued in December 2022 can be found here. FDA also appears to be moving aggressively on the enforcement priorities as five letters relating to violative homeopathic drug products have been posted to the agency's public Warning letter database since the beginning of calendar year 2023, as compared to four for the entire previous year. The FTC also included homeopathic drug manufacturers and distributors in the list of advertisers that received notices in April 2023 that their advertising claims need to be backed up with appropriate and reliable forms of scientific evidence (see here). Taken together, it's clear that the homeopathy industry remains under major scrutiny by federal regulators seeking to enforce their fundamental public safety mandates, whether they fall under the FD&C Act or the prohibition on deceptive advertising contained in the Federal Trade Commission Act.

Perhaps more noteworthy and concerning for the homeopathy industry, however, is a Fall 2022 decision by the District of Columbia Court of Appeals to allow civil cases to proceed against two retail pharmacies under a plaintiff's novel application of D.C.'s Consumer Protection Procedures Act. The plaintiff in both lawsuits is the Center for Inquiry (CFI), a nonprofit that states it is "dedicated to defending science and critical thinking in examining religion. CFI's vision is a world in which evidence, science, and compassion – rather than superstition, pseudoscience, or prejudice – guide public policy." As part of this mission, and among several other lawsuits it has initiated in the homeopathy space, CFI sued two retail pharmacies in the District of Columbia on the grounds that they were violating the local deceptive trade practice statute. The complaint alleged these violations arose through the pharmacies' indirect representations that homeopathic drug products labeled as cough, cold, and flu treatments have the same characteristics and benefits as over-the-counter drug products formulated with traditional active ingredients. In particular, although the pharmacies didn't make express promotional statements comparing the different product types, the plaintiff argued that they placed homeopathic products adjacent to their traditional counterparts on physical shelves and in online shopping results, thereby creating the misleading impression that the different products had comparable efficacy.

CFI's complaints were dismissed at the trial court level for failure to state a claim upon which relief could be granted. The two cases were then consolidated for purposes of the plaintiff's appeal to the D.C. Court of Appeals. On the question of whether a cognizable claim had been asserted (this post won't discuss the separate question that the appellate court reviewed, which was whether CFI had standing to sue the defendants), a three-judge panel ruled on September 29, 2022 that "whether the complained-of practices have a tendency to mislead reasonable consumers is a jury question" – thereby reinstating the complaints and remanding the cases for factual development. In reaching its decision, the court determined that a defendant did not need to make verbal statements in order for a "representation" to exist and that actions could also fall within the scope of the deceptive trade practices statute. Therefore the various factual allegations in CFI's complaints – for example that the pharmacies displayed homeopathic products next to "science-based" drug products and that signage in the stores indicated that the entire section contained products for "Cold, Cough & Flu Relief" – were sufficient at the pleading stage to survive a motion to dismiss. As of June 2023, the dockets for both of these CFI lawsuits are active and discovery appears to be ongoing, so they continue to bear watching for future resolution on the merits.

This recent ruling from the D.C. Court of Appeals foreshadows the possibility that retailers may opt to stop carrying homeopathic products in their stores (both physical and online) if the risk of liability to their own businesses becomes too great. Between the tightening of FDA's and FTC's rules for the industry and the increasingly creative use of existing consumer protection statutes by legal advocates, we could be witnessing a slow-motion demise of direct-to-consumer-based homeopathic product marketing. Only time will tell how the industry evolves in response to these numerous and formidable headwinds.

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