FTC Urges FDA to Reconsider Homeopathic Regulatory Framework

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In a comment filed last Friday, the Federal Trade Commission (FTC) responded to its sister-agency's request for comments by urging the Food and Drug Administration (FDA) to reconsider how homeopathic drugs are regulated. As we discussed here, both agencies recently signaled interest in the homeopathic area with the FDA hosting a two-day public hearing last April and the FTC announcing a workshop on September 21.

FTC workshops tend to be listening sessions in which FTC staff attorneys moderate panels of industry stakeholders to learn more about a particular topic in advance of announcing a specific position. In this instance, however, the FTC's comments to FDA make known their starting position and potentially offer valuable insights. FTC's main points were as follows:

- **Conflicting Regulatory Frameworks:** The FTC staff is concerned that FDA's existing homeopathic regulatory framework may conflict with the FTC's advertising substantiation policy, which requires competent and reliable scientific evidence for health benefit claims. The FTC points out that FDA's Compliance Policy Guide 400.400 (CPG), which allows for homeopathic marketing under certain conditions, requires manufacturers to list indications for use but that FDA has not reviewed homeopathic products for safety or efficacy. As a result, the FTC is concerned that some products or claims may not meet the "competent and reliable evidence" standard.

- **Industry and Consumer Confusion:** The FTC provides some evidence of industry and consumer confusion with regard to how homeopathic products are regulated. Regarding industry confusion, the FTC points to a National Advertising Division (NAD) matter in which one company argued – incorrectly in the FTC's view - that the NAD's requirement that the company have competent and reliable scientific evidence to support its ear pain relief claims was not required by either FDA or the FTC. Regarding consumer confusion, the FTC relies on a 16-person focus group of adults and parents performed in late 2010 as well as a larger online consumer copy test from 2012. Based on these exercises, the staff asserts that consumers do not understand the evidentiary or approval requirements for conventional versus homeopathic products and do not understand homeopathic principles.

- **Additional Points of Confusion:** The FTC also expresses concern that homeopathic products are shelved side-by-side with conventional medicines, which may lead consumers to believe that the products are subject to the same approval standards. In addition, the FTC noted that labeling terminology used to express concentration and dilution levels, e.g., 2X, is difficult for even sophisticated consumers to understand.

To address this confusion, the FTC calls on FDA to either withdraw the CPG, to eliminate the requirement that homeopathic products be labeled with a specific indication for use (which would violate FTC law if not properly substantiated), or require that any indication appearing on labeling be supported by competent and reliable scientific evidence.

The FTC's comment and supporting evidence are available here. Industry stakeholders will want to carefully consider it as they prepare for the September 21 workshop.