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Does CPSC or FDA Have Jurisdiction Over Your Consumer Product?

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As our readers know, we write about legal developments that affect companies involved in manufacturing, importing, distributing, and/or selling "consumer products." In many cases, these products fall squarely within the jurisdiction of the Consumer Product Safety Commission (CPSC).

But when is a so-called consumer product not regulated by the CPSC? Or, when does the CPSC have coterminous jurisdiction with another federal agency over a consumer product, or even jurisdiction over some aspect or a component of that consumer product?

The CPSC is charged with protecting consumers from potential hazards commonly associated with consumer products. Consumer products that fall under the CPSC's jurisdiction range from children's toys and child care articles to household products, as well as products such as fireworks and lawn mowers. Many commonly used consumer products, however, do not fall squarely within the CPSC's jurisdiction.

These include, for example, cars, trucks, motorcycles, and tires (regulated by the National Highway Traffic Safety Administration); firearms and ammunition (regulated by the Bureau of Alcohol, Tobacco, and Firearms); and pesticides and disinfectant products (regulated by the Environmental Protection Agency). A comprehensive list of non-CPSC regulated products can be found **here**.

In both of our practices, we are asked frequently product safety questions that concern consumer products within the jurisdiction of yet another federal agency, the Food and Drug Administration (FDA). In fact, the FDA is arguably the most well-known federal agency working in the consumer products space. The FDA has oversight authority over several non-prescription "consumer products" that are available to consumers from retail and online sellers, including:

- Over-the-counter (OTC) drugs like pain medications, allergy relief drugs, and cold/cough products;
- OTC medical devices like home pregnancy tests, glucose monitors, and even simple bandages;
- Cosmetics and personal care products like lipstick, shampoo, and lotions;
- Infant formula;
- Pet foods and livestock feeds;
- Certain electronic products that emit radiation like microwaves;
- Dietary supplements such as vitamins and herbal products; and
- Packaged human foods and beverages, as well as bottled water, produce, seafood, and whole shell eggs. (The U.S. Department of Agriculture oversees meat and poultry products, along with certain processed egg products.)

Occasionally, however, there is some jurisdictional overlap between the CPSC and FDA. For example, although FDA regulates the above-listed consumer products, the CPSC historically has maintained jurisdiction over one crucial aspect of many products that otherwise fall within the FDA's jurisdiction—child resistant packaging.

The Poison Prevention Packaging Act (PPPA) is administered by the CPSC, not the FDA. The PPPA requires the packaging of consumer products including chemical and cosmetic products, mouthwash, and over-the-counter drug and dietary supplements (otherwise regulated by FDA) to be designed or constructed to make those covered products difficult for children under 5 to open.

For other types of consumer-focused products, the primary factor determining whether FDA would claim regulatory authority is whether the manufacturer or distributor intends to market the product using medical or related claims. Specifically, when a product is marketed with claims that it can be used to diagnose, treat, cure, mitigate, or prevent a disease or condition or that it can alter any structure or function of the body, it crosses the line from being a simple consumer product to being a "medical device" or a "drug" as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

For example, a hearing aid that is a sound-amplifying device designed to help people who have hearing impairment is an FDA-regulated medical device; a personal-sound amplification product, or PSAP, is not regulated as a medical device because it is simply intended to amplify environmental sounds for non-hearing impaired consumers, such as hunters and bird watchers.

Other examples of products for which the manufacturer's specific marketing intent is critical to determining whether the CPSC or FDA has primary jurisdiction include infant sleep positioners and so-called "general wellness" products. An infant sleep positioner that does not make any sort of medical claim is subject to the CPSC's jurisdiction, whereas the same product that is sold as being effective to prevent Sudden Infant Death Syndrome (SIDS), to prevent plagiocephaly like flat head syndrome, or to relieve the symptoms of gastroesophageal reflux disease (GERD) has crossed the line to being regulated by FDA as a medical device.

Similarly, products such as exercise equipment or electronic devices that are intended solely to help consumers maintain a general state of health or develop a healthy lifestyle would not be regulated by the FDA as a medical device. For example, a product that helps users track their daily calorie intake would fall within the CPSC's jurisdiction, but if that same product claims that it will help treat users' anorexia, it becomes an FDA-regulated product.

In sum, depending on the particular class of "consumer product" at issue, companies may need to consider requirements imposed by one or more federal agencies—including the CPSC, the FDA, or both—along with potential risks arising from state or local law or from heightened scrutiny by consumer protection advocates in state attorney general offices or in the plaintiffs' bar. Education and information are key to minimizing those risks, and we encourage all companies active in this space to consider the possible impact a particular marketing strategy may have on the regulatory status of a new consumer product.

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Joanne S. Hawana counsels global Mintz clients on regulatory and distribution-related considerations for new FDA-regulated products. She also advises clients on the business impacts of new federal and state actions on food, drugs, cosmetics, electronic nicotine systems, and medical devices.