Takeaways:

- Recent detection of cosmetic products containing asbestos has led to voluntary recalls of five products so far this year.
- At present, the FDA does not have mandatory recall authority over cosmetic products.
- The FDA and Congress are contemplating proposals concerning the cosmetics industry that may lead to further enforcement activity in this sector.

The detection of asbestos in cosmetic products has led to several voluntary recalls so far this year. In March 2019, three products tested positive for asbestos, including eye shadow, compact powder, and contour powder. Weeks later, two more cosmetics were voluntarily pulled from shelves after asbestos was found in those

products. New proposals from the FDA and Congress may mean that additional enforcement activity concerning cosmetics becomes more common in the future. **FDA Regulation of Cosmetics** The FDA's regulatory authority over cosmetics largely draws from the Food, Drug, and Cosmetics Act ("FD&C Act"). Pursuant to this authority, the FDA prohibits the marketing of adulterated or misbranded cosmetic products. Other laws and regulations prohibit the marketing of certain ingredients for retail sale and require the use of warning statements on particular categories of cosmetics. Notably, the FDA does not have authority under the FD&C Act to pursue a recall. Instead, the agency may request that a company remove its cosmetics from the marketplace and coordinate with affected companies in their recall efforts. Even in the absence of recall authority, however, the FDA can issue public warnings about and launch investigations into cosmetic products. For example, the FDA issued a public statement in 2016 that it was investigating one manufacturer's hair products after receiving complaints that the products' use resulted in hair loss, balding, and rash. No subsequent recall of the product has occurred. In announcing the recall of the cosmetic products containing asbestos in March 2019, then-Commissioner Scott Gottlieb detailed that the agency had requested that a retailer remove three products from the marketplace that were found to contain asbestos during testing. As the FDA put it, that retailer "refused to comply with the FDA's request, and the agency does not have authority to mandate a recall. The FDA is therefore warning consumers not to use these products and will continue to communicate our safety concerns about them." In June 2019, the FDA updated its safety alert to include two additional cosmetics—including another product from the same retailer— that were found to contain asbestos. **Asbestos and Talc** As the FDA explained in its recent product safety alert describing the cosmetic product recall efforts, asbestos, a known carcinogen and naturally occurring mineral, is often found near talc. Talc is a common ingredient in numerous cosmetic products. When talc is mined, there is the potential for contamination between talc and asbestos. For this reason, the FDA notes that it is "important to select talc mining sites carefully and take steps to test the ore sufficiently." **On the Horizon** Manufacturers and distributors of cosmetic products, especially those containing talc, may see further enforcement activity as the FDA and Congress consider new proposals concerning the cosmetics industry. Then-Commissioner Gottlieb called the FDA's regulation of cosmetics "outdated" and outlined steps the agency would take to address the presence of asbestos in cosmetic products. In his March 2019 statement, Gottlieb noted that the agency would be working to improve traceability of talc products, investigating how many cosmetics currently contain talc, and requesting further information about how manufacturers test talc-containing products. He called on companies to voluntarily register the ingredients of their cosmetic products and proactively report adverse events to the FDA. As the FDA prepares to initiate these new steps under its existing authority, Congress is also considering the expansion of the FDA's enforcement authority over cosmetic products. Earlier this year, Senators Dianne Feinstein (D-CA) and Susan Collins (R-ME) introduced the Personal Care Products Safety Act of 2019. If this proposal becomes law, it will represent a sea change in how cosmetics are regulated and, among other things, will enable the FDA to issue product recalls of cosmetic products. The bill's other provisions call for the FDA to collect user fees for personal care products, mandate labeling for products not appropriate for children, and create further labeling and mandatory disclosure requirements. Several major cosmetic manufacturers have signaled their support for the proposed legislation.

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