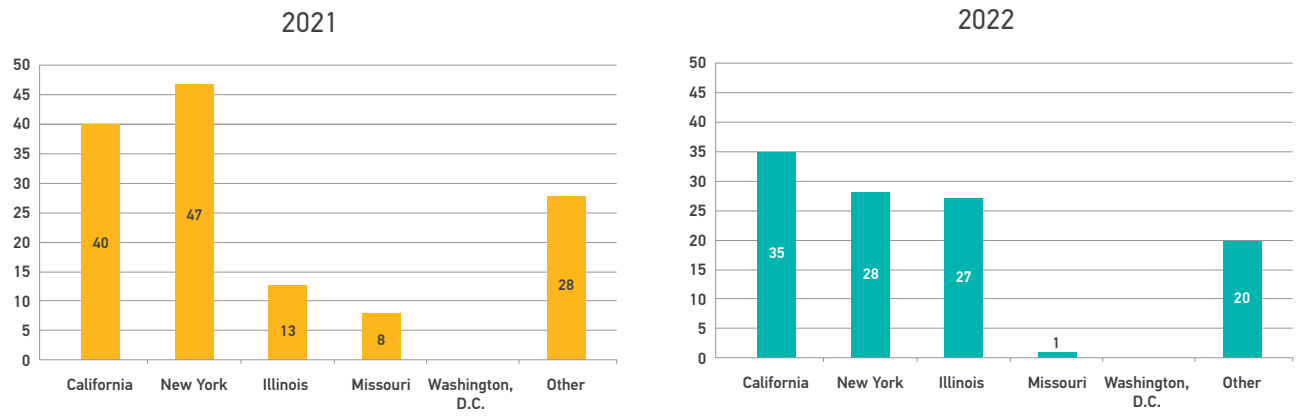
LEGAL TRENDS IN PERSONAL CARE PRODUCTS

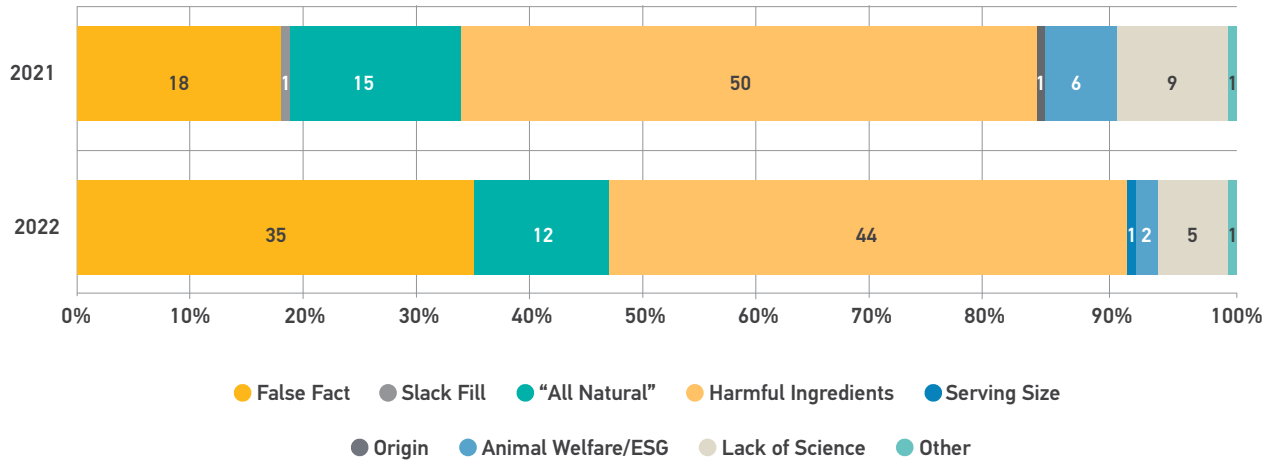
PERSONAL CARE CLASS ACTIONS: FILINGS BY JURISDICTION

FIGURE 8



INDUSTRY FILINGS AND TRENDS: CATEGORIES

FIGURE 9



Data compiled by Perkins Coie based on a review of dockets from courts nationwide.

FEDERAL LEGISLATION

Enacted on December 29, 2022, the Modernization of Cosmetics Regulation Act (MoCRA) is the most significant statutory expansion to the U.S. Food and Drug Administration's (FDA) authority over cosmetics since 1938. MoCRA makes several important changes to federal oversight of cosmetics, including:

- **Mandatory recall authority over cosmetics.** For the first time, the FDA will have mandatory recall authority over cosmetic products when the agency determines with a reasonable probability that (1) the cosmetic product is adulterated or misbranded, (2) the use of or exposure to the cosmetic will cause serious adverse health consequences or death, and (3) the responsible entity has refused to voluntarily cease distribution and/or recall the violative cosmetic product.
- **Adverse event reporting and recordkeeping.** MoCRA requires the reporting of serious adverse events associated with the use of cosmetic products in the United States. A "serious adverse event" includes, among other things, inpatient

hospitalization or death. Responsible parties required to report adverse events include those who manufactured, packed, or distributed such products, and responsible parties are required to have their names appear on the product label. Responsible parties are required to keep records on adverse events associated with the use of the cosmetic for three years (for small businesses) to six years (for other businesses).

- **Good manufacturing practices for cosmetic facilities.** MoCRA provides the FDA the authority to promulgate good manufacturing practices (GMPs) regulations for facilities manufacturing or processing cosmetic products. GMPs are regulatory requirements regarding hygiene practices, process controls, and sanitation, among other matters. The FDA already has GMPs in place for many other product categories, such as drugs, food, and dietary supplements. The FDA last issued revised, nonbinding cosmetic GMP guidance in 2013, but the agency has not previously promulgated GMP regulations for cosmetics. Failure to meet these new cosmetic GMPs could result in a finding that the cosmetic is adulterated. The regulations may provide the FDA the authority to inspect records to demonstrate compliance with GMPs. The bill requires the FDA to also promulgate simplified GMPs for smaller businesses. Before promulgating the regulations to implement the GMPs, the bill requires the FDA to consult with cosmetics manufacturers and consumer organizations. The bill requires the FDA to promulgate these GMP regulations within two years of the bill's enactment and requires final regulations within three years of enactment.
- **Identification of fragrance allergens on product labels.** MoCRA requires cosmetic labels to identify each fragrance allergen in a product once the FDA issues its forthcoming fragrance allergen rule, which will consider European Union (EU) and other international requirements. If a cosmetic product label does not include required fragrance disclosures, it will be considered misbranded under section 602(b) of the Food, Drug, and Cosmetic Act (FDCA).
- **Asbestos and perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetics.** MoCRA requires the FDA to issue proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. In addition, MoCRA mandates that the FDA issue a report regarding the use of PFAS in cosmetic products and the scientific evidence regarding the safety and risks associated with the use of PFAS in cosmetics.
- **Preemption.** MoCRA expressly preempts state and local requirements that differ from MoCRA's standards related to registration and product listing, GMPs, records, recalls, adverse event reporting, or safety substantiation. MoCRA also contains a savings clause and certain limitations regarding the law's preemptive effect.

Notably, the cosmetics provisions will not require the FDA to review and, if warranted, ban or restrict chemicals, as originally proposed.

Many of MOCRA's provisions will go into effect over time, with some becoming effective a year after the bill's enactment and others awaiting finalized regulations. The cosmetic industry will have opportunities to provide notice and comment on proposed regulations.

STATE LEGISLATION

- We also saw increased state regulatory activities in the state legislatures, focusing on the regulation of micro-contaminants in cosmetics and personal care products, in particular addressing PFAS. PFAS are a broad class of manmade compounds added to cosmetics to make them smoother, more spreadable, and longer-lasting. In 2022 states passed the following legislation banning PFAS, among other contaminants:
- **California:** On September 29, 2022, Gov. Gavin Newsom signed the California PFAS-Free Cosmetic Act (AB 2771), which bans intentionally added PFAS (perfluoroalkyl or polyfluoroalkyl substances) known as "forever chemicals" from cosmetics sold in California as of January 1, 2025.
- **Colorado:** In 2022, Colorado enacted the PFAS Chemicals Consumer Protection Act, which seeks to limit sources of PFAS introduced into the state. The law also prohibits—or "phases out"—the sale and distribution of cosmetics after January 1, 2025, if they contain intentionally added PFAS chemicals.
- **New York:** Gov. Kathy Hochul signed S8291A into law, which prohibits the sale or offer for sale of any cosmetic product or personal care product containing mercury. The ban takes effect on June 1, 2023. Mercury has long been used in skin-

lightening or whitening creams marketed toward women of color—meant to remove blemishes, age spots, and wrinkles—as well as hair relaxers and treatments.

- **Washington:** On March 31, 2022, Gov. Jay Inslee signed HB 1694 into law, giving the Washington State Department of Ecology the authority to address PFAS in "priority products," including personal care products, cosmetics, and dental floss under the Safer Products for Washington Program. Washington state defines PFAS as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom," a broad definition that includes potentially thousands of substances. While the new law is not a complete ban on the use of PFAS, it does require Washington's Department of Ecology to determine an initial set of regulatory actions for PFAS in Chemical Action Plan (CAP)-identified products by June 1, 2024, and then adopt rules to implement the determinations by December 1, 2025.

Additionally, animal welfare laws are gaining traction at the state level, with legislators increasingly considering restricting animal testing. In December 2022, New York state became the tenth state to ban the sale of cosmetics tested on animals when Gov. Kathy Hochul signed into law the New York Cruelty-Free Cosmetics Act. The law, which prohibits the sale and manufacturing of cosmetics that have been tested on animals, went into effect in January 2023. New York follows California, Hawaii, Illinois, Louisiana, Maine, Maryland, Nevada, New Jersey, and Virginia, which have all taken similar action.

REGULATORY ENFORCEMENT

Historically, the FDA has taken a fairly light approach to federal regulation of cosmetics and personal care products. This will change at the end of 2023 when certain provisions of MoCRA become effective, including the FDA's new Good Manufacturing Practices regulations and recall authority. In 2022, however, the FDA continued to issue warning letters to companies that made unapproved drug claims. On August 9, 2022, the FDA announced that it had issued three warning letters to companies for introducing mole and skin tag removal products into interstate commerce that are unapproved new drugs, in violation of the Federal Food Drug, and Cosmetic Act (FD&C Act). The FDA noted that the mole and skin tag removal products sold had not been evaluated by the FDA for safety, effectiveness, or quality and require FDA approval. There are no FDA-approved over-the-counter drug products for the removal of moles and skin tags.

The FDA also continued its focus on asbestos in cosmetics, including conducting ongoing sampling and testing to assess the presence of asbestos in talc-containing cosmetics. In January 2022, the FDA released a white paper developed by the Interagency Working Group on Asbestos in Consumer Products (IWGACP) that contains scientific opinions for the testing of talc-containing cosmetics, and talc intended for use in cosmetics, for the presence of asbestos. The white paper, "Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc (including Talc Intended for Use in Cosmetics)," outlines the scientific opinions of the IWGACP related to the detection and identification of asbestos fibers in talc-containing cosmetic products. The FDA will continue to monitor the safety of products on the market, including cosmetic products potentially contaminated with asbestos.

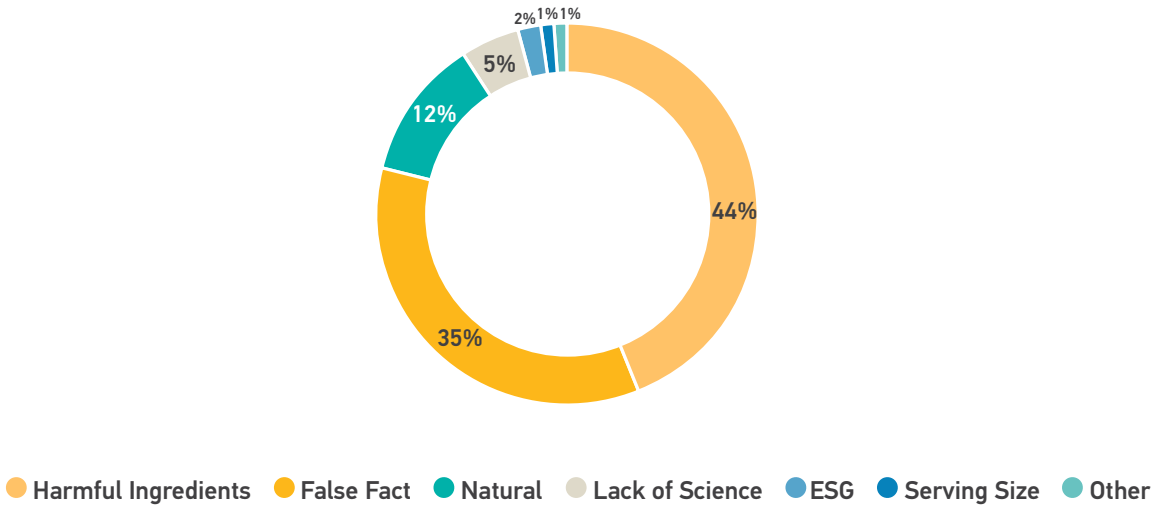
LITIGATION

Perkins Coie tracks all new lawsuits filed against personal care products and cosmetics companies across the country. By jurisdiction, in 2022 California saw the most filings nationwide, followed by New York and Illinois. Across the nation, 40% of filings allege that a harmful ingredient is present in the product. For example, consumers alleged that several cosmetics, including lipsticks, foundation, and mascaras contain PFAS, while other claims allege that certain sunscreens and dry shampoo products are contaminated with the carcinogen benzene. We also saw claims alleging certain hair straighteners and/or relaxers contain endocrine disrupting chemicals. Pure false advertising cases represented 36% of the filings in 2022. For example, we have seen filings challenging the effectiveness of cosmetic products with SPF for "Up to 24H Fresh Wear," when the products allegedly do not and cannot provide 24 hours of SPF without reapplication. "Natural" cases are still prevalent in the personal care space and we have seen challenges brought against "clean beauty" programs in 2022.

Additionally, "lack of science" suits allege that science does not support claims of effectiveness of a particular product. The year of 2022 also brought additional product origin cases, including one lawsuit filed against L'Oreal alleging that American shoppers are overpaying for its beauty products because they have been misled into believing the products are actually made

PERSONAL CARE CLASS ACTIONS: FILINGS BY TYPE

FIGURE 10



Data compiled by Perkins Coie based on a review of dockets from courts nationwide.

in France. In this lawsuit, the plaintiff alleges that L'Oreal's labeling of its products "L'Oreal Paris" and use of French words such as "sans huile" (oil-free) and "fini mat" (matte finish) lead consumers to believe that its products are French.

PFAS

Not surprisingly, given the attention to PFAS in the regulatory space, plaintiffs' lawyers increasingly turned their attention to PFAS in 2022. In fact, in December 2021, both Shiseido and CoverGirl were hit with putative class-action lawsuits related to alleged PFAS in their cosmetics products. First, on December 14, 2021, a putative class-action lawsuit was filed in the Southern District of New York against Shiseido, on behalf of all consumers who purchased bareMinerals products, which are marketed as clean and natural beauty products for normal, everyday use, but which allegedly contain PFAS. In this case, the plaintiffs allege that they tested bareMinerals products and discovered that they contained PFAS, which is supported by the June 15, 2021, scientific study in the *Journal of Environmental Science and Technology Letters*, which disclosed results of testing of bareMinerals products.

Shortly thereafter, on December 29, GMO Free USA d/b/a/ Toxin Free USA, a nonprofit, filed a lawsuit in the District of Columbia Superior Court against COVERGIRL cosmetics and Coty, Inc. regarding the marketing and sale of COVERGIRL brand TruBlend Pressed Powder, alleging that despite environmental and product safety representations, the product contains PFAS. In this lawsuit, plaintiff took aim at Coty's sustainability report, which touts its environmental initiatives along with its "Product Safety" strategy.

These lawsuits were quickly followed by several additional lawsuits filed in 2022 against personal care products and cosmetics companies, in which plaintiffs allege that various products, including mascaras, liquid foundations, concealers, and lipsticks, which are marketed as clean, environmentally friendly, and natural products for normal, everyday use, contain harmful PFAS. Many of these lawsuits are still pending.

BENZENE

Another wave of litigation filed in 2022 against personal care and cosmetics companies involved allegations of dry shampoos containing the chemical benzene. On October 31, 2022, laboratory and testing company Valisure LLC submitted a citizen petition to the FDA requesting the FDA's Commissioner of Food and Drugs issue a regulation, request recalls, and revise industry guidance among other actions in response Valisure's test results which allegedly detected high levels of benzene in specific batches of certain dry shampoo products. This citizen petition—like Valisure's other petitions—led plaintiffs' firms to

file a new wave of class-action and product liability lawsuits against several hair care companies.
In December 2022, class-action lawsuits were filed against Johnson & Johnson and Wella, in which plaintiff alleges that the companies sold dry shampoo products containing benzene, and failed to disclose its presence on the labeling of the products. In both lawsuits, the plaintiff claims Valisure tested for benzene in various dry shampoos, finding levels of benzene that exceed the minimum allowed by the FDA. Plaintiff alleges that the presence of benzene and the failure to disclose its presence on the packaging renders both companies' dry shampoo products adulterated and misbranded.

TITANIUM DIOXIDE

The FDA has approved the use of titanium dioxide (TiO2) as a color additive in food, drugs, and cosmetics, including drugs and cosmetics intended for use around the eyes. (See 21 C.F.R. §§ 73.575, 73.1575, 73.2575.) Nevertheless, consumers have begun bringing putative class actions challenging the presence of TiO2 in consumer products, alleging that the presence of TiO2 makes the products unsafe. Several lawsuits were filed against personal care companies, including one against This is L. Inc., in which the plaintiff alleged that the company's "100% Organic Core Tampons" misleads consumers to believe that the tampons were made entirely from cotton and/or organic ingredients when the product contains TiO2, as well as polyester and paraffin.