HAYNES BOONE

Cosmetics Law and Regulation

2023 YEAR IN REVIEW

2023 was an active year in cosmetics regulation, as Industry and FDA prepared for the implementation of various requirements under the federal Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which was signed into law just three days prior to the start of 2023 (on December 29, 2022). Additionally, the trend of state-issued ingredient bans continued with a number of additional states enacting restrictions on various ingredients in cosmetic products in 2023, along with continued class actions targeting cosmetic companies making various "clean" claims and/or marketing products containing PFAS.

MoCRA UPDATES

The most significant updates in cosmetic regulation during 2023 came from MoCRA, which significantly expands FDA oversight of the cosmetics industry. Once fully implemented, MoCRA will require:

(a) Facility registration (*enforcement delayed to July 2024*);

(b) Product listing (*enforcement delayed to July 2024*);

(c) Maintenance of records of adverse events (*effective and enforceable as of Dec. 2023*);

(d) Reporting of serious adverse event reports to FDA (*effective and enforceable as of Dec. 2023*);

(e) Adherence to current Good Manufacturing Practices ("CGMPs") (*likely to take effect within 2-4 years*);

(f) Records supporting substantiation of safety for each cosmetic product (*effective and enforceable as of Dec. 2023*);

(g) Minor label modifications to include contact information for adverse event reporting (*to take effect in December 2024*); and

(h) Labeling of fragrance allergens (*likely to take effect in late 2024 or early 2025*).

MoCRA's original compliance deadline for items (a)-(d) was December 29, 2023. Accordingly, FDA spent much of the year issuing guidances and constituent updates seeking to prepare the Agency, as well as the cosmetics industry, to comply with these new requirements, particularly the registration and listing requirements, which raised *many* practical/operational questions among affected companies.

- On March 27, 2023, FDA stopped accepting and processing both electronic and paper submissions to the voluntary registration program (VCRP) for cosmetics establishments and products.
- In August 2023, FDA issued draft guidance for the registration and listing of cosmetic product facilities and products under a new system.The draft guidance described MoCRA's requirements for registration and listing in greater detail and answered a number of basic interpretation questions.
- On November 1, 2023, FDA announced that it will provide more information on the launch date for electronic and paper registration/listing submissions and urged Industry to proactively prepare for MoCRA implementation by reviewing the documents and collecting the information required for submissions.
- On November 8, 2023, FDA issued an updated compliance policy for MoCRA's facility registration and product listing requirements under MoCRA.In the updated policy, the Agency stated that it would be ready to accept submissions by the original (December 29, 2023) deadline but would be delaying enforcement until July 1, 2024, effectively giving applicable companies and facilities an extra six months to comply.
- On December 28, 2023, FDA released its Final Guidance on Cosmetic Product Facility Registration and Listing. While the Final Guidance largely tracks the prior draft version, it contained a few notable updates:
  - FDA finally made the new electronic registration/listing portal, i.e., Cosmetics Direct, accessible to Industry.
  - Cosmetics Direct can be accessed here, and the corresponding User Guide is available here.
  - In response to comments and questions received after issuing the Draft Guidance, FDA attached a new appendix (Appendix B) to the Final Guidance containing answers to numerous Industry FAQs.

The Final Guidance also reiterated FDA's decision to decision to delay enforcement of MoCRA's registration and listing requirements until **July 1, 2024**.

In the meantime, Industry should continue refining adverse-event recording and reporting procedures, focusing on robust internal documentation, consistency, and reliability, while preparing to meet the upcoming registration and listing requirements.

STATE INGREDIENT BANS

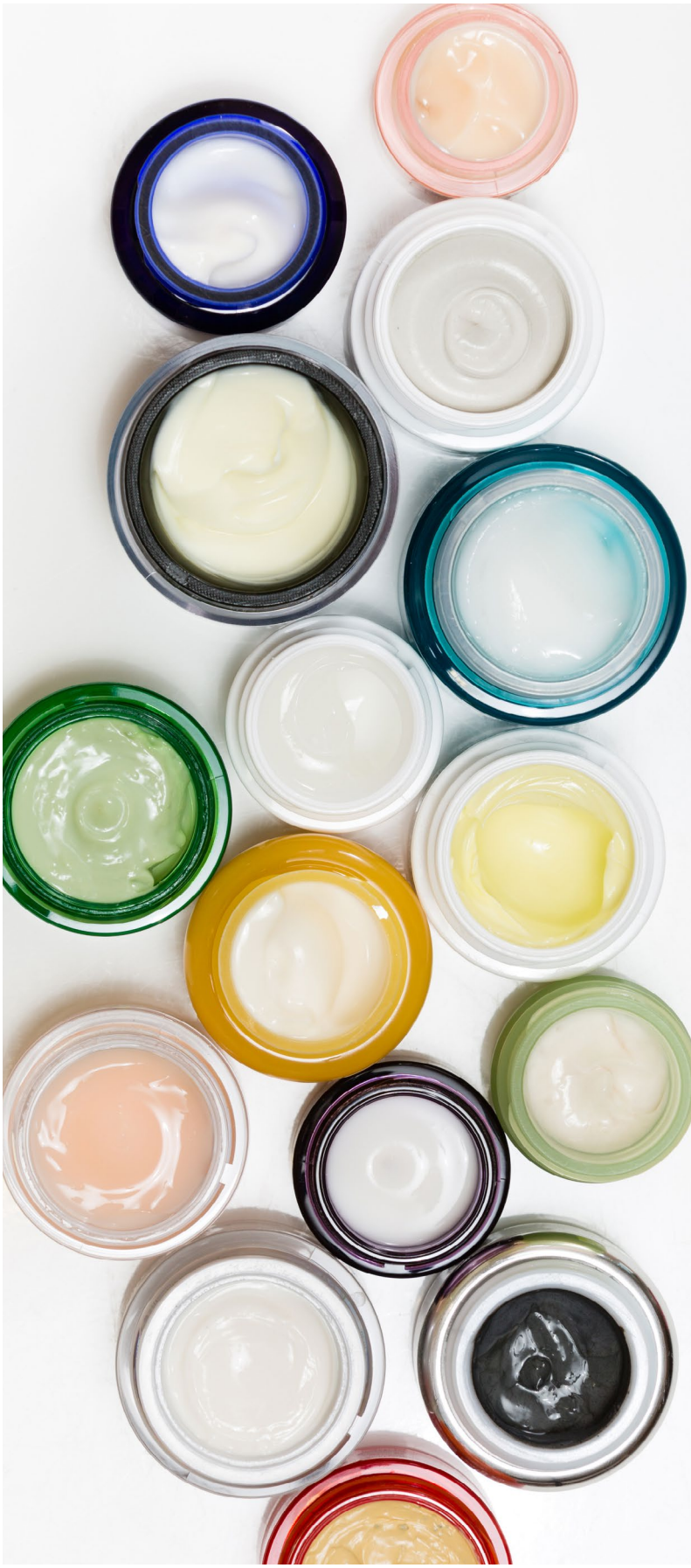
Prior to 2023, five states—California, Colorado, Maine, Maryland, and New York—had enacted legislation banning certain intentionally added ingredients in cosmetic products. During 2023, California expanded its law; Washington, Minnesota, and Oregon adopted new legislation, and eight other states proposed their own cosmetic ingredient bans, including Maine and New York which are looking to expand their respective lists of banned substances. Below is an overview of the state laws introduced in this area in 2023, as well as information about previously enacted laws with effective dates that recently passed or are upcoming in the relatively near future.

- ***California:*** Beginning **January 1, 2025**, it is prohibited to make, sell, or distribute in California cosmetic products containing any of the 13 enumerated PFAS substances, mercury, formaldehyde and its releasers, ortho-phthalates and esters, parabens, or phenylenediamines. Then, on January 1, 2027, the list of prohibited substances expands to include 26 additional ingredients. This act, like others, is limited to intentionally added ingredients. It does not include a notification requirement and does not grant rulemaking authority to a state agency. This act was an expansion of the law adopted in 2020 prohibiting some ingredients in cosmetic products.

- ***Washington:*** Beginning **January 1, 2025**, it is prohibited to "manufacture, knowingly sell, distribute for sale, or distribute for use" in Washington, any cosmetic product that contains any of the nine prohibited intentionally added ingredients, including PFAS, mercury, formaldehyde and its releasers, ortho-phthalates and esters, and phenylenediamines. The Washington Department of Ecology is given authority to adopt and enforce associated rules. There is no requirement to notify the state of ingredient use. Under this law, *manufacturers* could face up to $5,000 for each initial violation and up to $10,000 for subsequent offenses.
- ***Minnesota:*** Beginning **January 1, 2025**, offer, sale, and distribution of cosmetics and other products containing intentionally added PFAS is prohibited. This law pertains to a variety of consumer goods, and there are additional notification requirements that go into effect January 1, 2026, for other products that are not yet required to otherwise comply. The law gives the state's Pollution Control Agency authority to promulgate and enforce rules under this statute.
- ***Oregon:*** Beginning **January 1, 2027**, cosmetic manufacturers may not knowingly make, sell, or distribute cosmetic products with intentionally added PFAS, mercury, formaldehyde and its releasers, ortho-phthalates, triclosan or phenylenediamines. The Oregon Health Authority is also required to build upon the statutory list of concerning chemicals and known carcinogens, the contents of which would trigger manufacturers to disclose this ingredient to consumers online. This law also provides penalty guidelines.

Recent/Upcoming Effective Dates for State Bans of Cosmetic Ingredients

- ***December 31, 2023:*** New York's threshold restriction of 1,4-dioxane drops from ten parts per million to only trace concentrations up to two parts per million. Mercury and its compounds are already banned from cosmetic products in New York.



- ***January 1, 2025:*** California, Colorado, Washington, Minnesota, and Maryland's enacted laws go into effect to ban some ingredients from cosmetic products in their state. Most of these laws' prohibited substances including PFAS, mercury, formaldehyde, ortho-phthalates, and phenylenediamines, while Colorado and Minnesota's statutes only bans PFAS. Also on January 1, 2025, Maine's notification requirement goes into effect requiring manufacturers of products for sale in the state with intentionally added PFAS to submit information about the product and the manufacturer to the Maine Department of Environmental Protection.
- ***January 1, 2027:*** Oregon's law goes into effect to ban classes of substances such as PFAS, mercury, formaldehyde, ortho-phthalates, and phenylenediamines. Additionally, the second set of substances banned on California takes effect including siloxanes, boron substances, some colors, and over twenty other substances.
- ***January 1, 2030:*** Maine's PFAS ban for cosmetics and other products takes effect.

Proposed State Bans of Cosmetic Ingredients

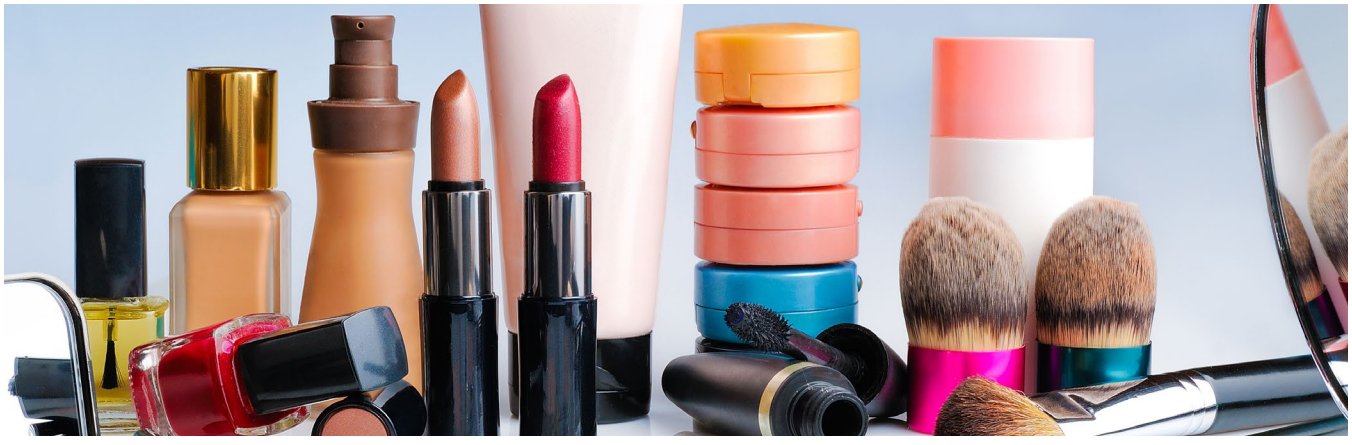
Eight states are currently considering proposed legislation to ban ingredients in cosmetics. Maine and New York are already have enacted some ingredient bans that apply to cosmetics and these additional laws would expand that list. New York is looking to ban PFAS in addition to its existing ban of Mercury and 1,4-dioxane. Maine is considering a bill that would ban a similar list of ingredients as seen in Maryland's, Washington's, and Oregon's laws, but it would go even further than any other enacted or proposed law to include heavy metals, benzophenones, and asbestos (including talc), among others.

Georgia, Illinois, and Vermont are each considering bills to ban the usual classes of substances—similar to laws enacted in in Maryland, Washington, and Oregon—which, if passed, would be the first laws on the books banning cosmetic ingredients in such states.

Nevada, Rhode Island, and Hawaii are also looking to join the ranks of states with cosmetic ingredient bans with PFAS bans that would apply to a variety of products, including cosmetics.

REGULATORY ENFORCEMENT FOR "GREENWASHING" OF COSMETICS

The FTC has not taken enforcement action this year against cosmetic producers regarding greenwashing claims (i.e., false or misleading claims about a product or company's sustainability or eco-friendliness), but the Commission is currently considering updates to the Green Guides, which could bring stricter regulations and greater risk for enforcement action. The Green Guides are not strictly enforceable, but they provide insight into what the Commission may consider misleading. In December 2022, the FTC requested public comments to a variety of questions posed to consider updating the Green Guides. The Commission has not responded to comments or published a proposed new rule, but it did hold a Public Workshop in May "to examine 'recyclable' advertising claims."



OTHER REGULATORY ENFORCEMENT AGAINST COSMETIC COMPANIES

There was virtually no FTC enforcement against cosmetics companies in 2023. However, with the implementation date of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) looming, all of the FDA warning letters issued to cosmetics companies in 2023 stemmed primarily from inspections of drug manufacturing facilities, which, in some cases, also involved the manufacture of branded cosmetics. In such letters, FDA warned of alleged violations of current good manufacturing practices (CGMPs) that could potentially render both the drug products and cosmetic products manufactured by the company to be adulterated.

Clean Cosmetics LLC

On January 30, 2023, FDA's Division of Pharmaceutical Quality Operations (DPQO) issued a warning letter to Clean Cosmetics LLC following an August 2022 inspection, during which FDA found alleged violations of CGMPs that FDA warned made the company's drug product adulterated. DPQO accused the company of failing to conduct adequate testing on incoming components for identity before using them to manufacture over-the-counter (OTC) products and alleged that the company's review of certificates of analysis (COA) was deficient (e.g., a lot of ethanol to be used in the company's hand sanitizer product allegedly contained methanol). In addition, after receiving the company's responses to the Form 483, FDA determined that the company did not include sufficient detail for its proposed corrective actions to bring the facility into compliance.

Cosmetic Science Laboratories LLC

On March 10, 2023, DPQO issued a warning letter to Cosmetic Science Laboratories LLC following a September 2022 facility inspection. The warning letter outlined alleged violations of CGMP regulations for the company's finished pharmaceuticals. DPQO flagged the company's purported failure to establish adequate written procedures for production and process control, including the failure to provide investigators with sufficient evidence that the company performed cleaning validation and equipment qualification. FDA

noted that the company allegedly manufactured its drug products using the same equipment that was used to manufacture its cosmetics and warned that the "microbiological residues on equipment from previous manufacturing activities [could] adversely impact the purity, quality, and safety of drug products also manufactured on that equipment."[1]

Accra-Pac, Inc. dba Voyant Beauty

On April 20, 2023, DPQO issued a warning letter to Accra-Pac, Inc. subsequent to an inspection of its drug manufacturing facility in August and September of 2022. DPQO cited the facility for, among other things, alleged nonconformance to CGMP regarding the manufacture of its products. DPQO noted that some of the practices the company used that potentially caused the company's over-the-counter (OTC) drug products to be contaminated with benzene could also cause the company's cosmetic products to be contaminated with benzene and, thus, adulterated.

Avlon Industries, Inc.

On July 18, 2023, DPQO issued a warning to Avlon Industries, Inc., after allegedly finding a lack of

cleaning validation for equipment (e.g., mixing tanks, hoses, filling lines, and packaging lines) used to manufacture the company's OTC drug products after a January 2023 inspection. DPQO warned against the company allegedly manufacturing drug products using the same equipment used to manufacture cosmetics, leading to possible contamination with chemical and microbiological residues and having an adverse effect on the products' purity, quality, and safety.

Daxal Cosmetics Private Limited

On August 3, 2023, FDA's Center for Drug Evaluation and Research (CDER) issued a warning letter to Daxal Cosmetics Private Limited because the company allegedly failed to respond to multiple FDA requests for records regarding the import of the company's OTC products, including toothpaste, that contained diethylene glycol (DEG) and ethylene glycol (EG). In the warning letter, CDER indicated that the use of ingredients contaminated with DEG or EG could result in lethal poisonings and advised that the company consult FDA guidance for instructions on how to meet CGMP requirements. CDER noted that, in January 2023, FDA placed all of the company's drugs and drug products on Import Alert 66-79 and that, until FDA could confirm compliance with CGMP, FDA may withhold approval on any new applications or supplements listing the company as the manufacturer.

Seoul Cosmetics Co., Ltd.

On October 2, 2023, CDER issued a warning letter to Seoul Cosmetics Co., Ltd., following a January/February 2023 facility inspection where CDER allegedly saw significant violations of CGMP in the manufacture of the company's drug products. CDER warned that failure to address the alleged violations could result in FDA refusal of admission for the company's products into the United States.

Handock Cosmetics Co., Ltd.

On October 4, 2023, CDER issued a warning letter to Handock Cosmetics Co., Ltd., following a March 2023 inspection where CDER noted alleged CGMP violations. CDER deemed the company's brand of hand sanitizer to be an unapproved new drug introduced or delivered for introduction into interstate commerce in violation of the Section 505(a) of the Food, Drug, and Cosmetic Act (FD&C Act) and determined that two other hand sanitizer gel products manufactured by the company were misbranded.

CDER also warned the company to review and update its drug product listing information, as there were allegedly no active drug listings linked to the facility.

"CLEAN" CLASS ACTIONS

Class action lawsuits against cosmetics companies making "clean" claims in 2023 ran the gamut. Although most of these class actions were dismissed in the cosmetic companies' favor, some remain ongoing. Two of the most closely watched class actions in 2023 were brought against Sephora USA Inc. and Target Corporation.

Finster v. Sephora USA Inc.

Throughout 2023, class action litigation has been ongoing against Sephora USA Inc. ("Sephora") where the plaintiff accused Sephora's products marketed as "clean" under the "Clean At Sephora" advertising campaign of containing synthetic ingredients, such as polyglycerol esters (PGEs). In February 2023, Sephora filed a motion to dismiss the class action and disputed the allegations that its "Clean At Sephora" initiative was false and misleading. This case is ongoing.

Boyd v. Target Corp.

In August 2023, plaintiffs brought a class action lawsuit against Target Corporation ("Target") and its "Target Clean" labeling campaign, which designates products that are free from thirteen ingredients that are known to be harmful to health and/or the environment. Plaintiffs are alleging that the label is misleading because products still contained other harmful ingredients. Plaintiffs claim some of the "Target Clean" products contained parabens, formaldehyde, and per- and polyfluoroalkyl substances ("PFAS"), among others. This case is ongoing, as well.

Vences v. WaterWipes, Inc.

Another company, WaterWipes, Inc., was sued in February 2023 for marketing a variety of wipes, including Biodegradable Textured Clean Baby Wipes, as "100% biodegradable" claiming the wipe "biodegrades in 4 weeks" despite not biodegrading through "customary disposal" (i.e., in a landfill), which is required to make a biodegradable claim under the Green Guides (specifically, 16 C.F.R. § 260.8(c)). This case was settled out of court in April.

THE PFAS TREND

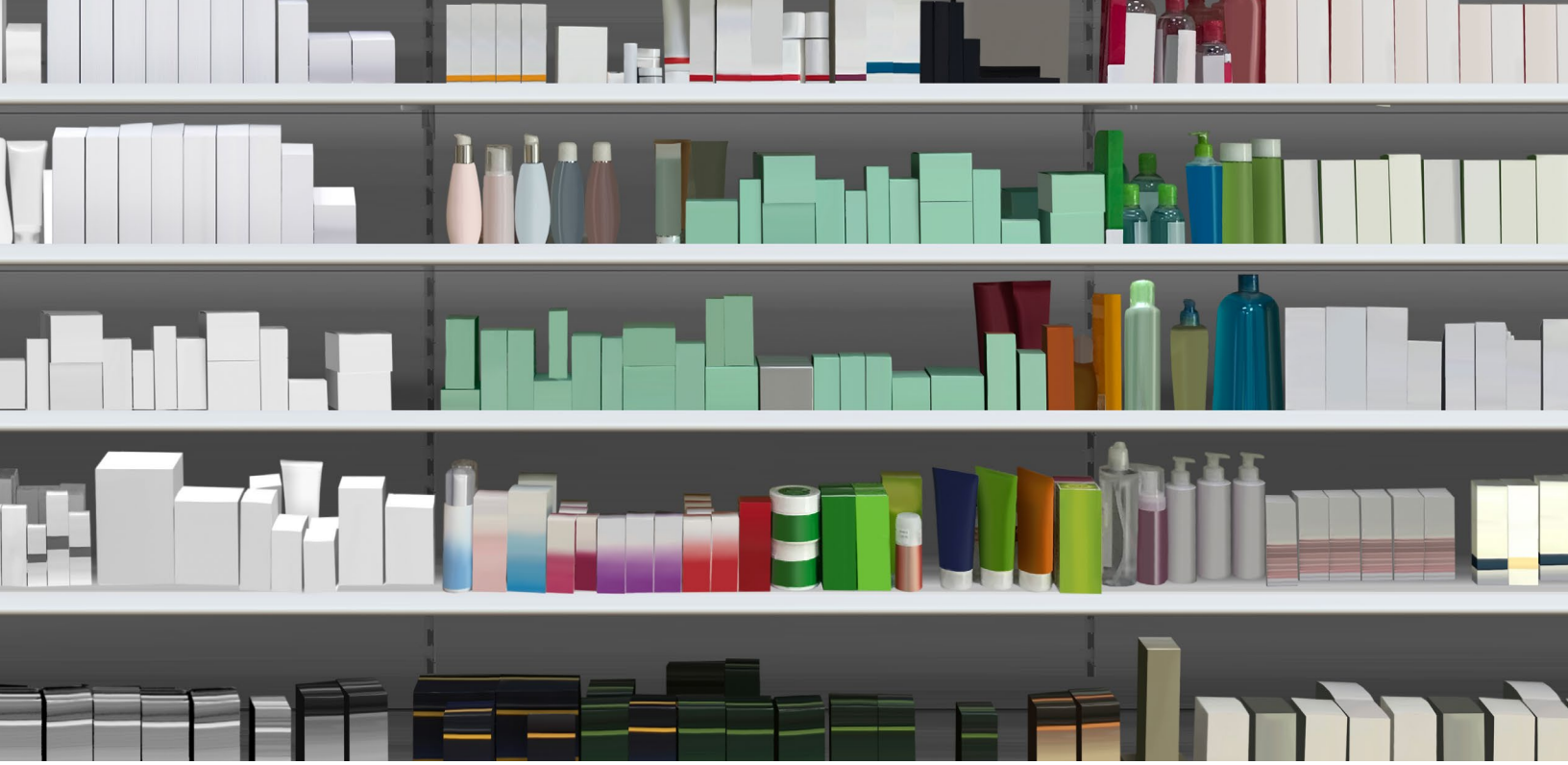
The presence of PFAS was another prominent complaint in 2023 class actions challenging "clean" claims involving cosmetic products.

Onaka et al. v. Shiseido Americas Corp.

In March 2023, the Southern District of New York granted Shiseido Americas Corporation's ("Shiseido") motion to dismiss in a class action lawsuit alleging that Shiseido's products marketed as "clean" and "natural" actually contained PFAS. Plaintiffs sued under theories of breach of implied warranty, breach of express warranty, negligent misrepresentation, fraud, and violations of state consumer protection laws.

The plaintiffs argued that the advertising campaign for Shiseido cosmetic products, including bareMinerals, touting the products as "clean" and "natural," gave consumers the expectation that the products were "free from potentially harmful chemicals."[2] Plaintiffs presented the Court with independent tests allegedly revealing that the products contained PFAS, which have been linked to adverse effects, including "increased cholesterol, liver inflammation, increased blood pressure in pregnancy, decreased birth rate of children, decreased vaccine response in children, and increased risk of kidney or testicular cancer."[3]

However, the Court reasoned that the plaintiffs' single allegation of independent testing was inadequate because the plaintiffs did not state that they tested any of their *own* purchases and did not plausibly plead that the presence of PFAS in the products was so widespread as to render the products mislabeled. The Court also found it improbable that the plaintiffs overpaid for the products because they did not show that they purchased the products with regularity. Therefore, the Court granted Shiseido's motion to dismiss with prejudice.



Brown v. Coty, Inc.

Similarly, in March 2023, the Southern District of New York granted Coty, Inc.'s ("Coty") motion to dismiss in a class action where the plaintiff alleged that several Covergirl waterproof mascara products advertised as "clean" contained PFAS. The plaintiff argued that she relied on "packaging, labeling, and [the] ingredient list" to purchase "one or more" tubes of CoverGirl Lash Blast Volume Waterproof Mascara ("Lash Blast") within the past three years.[4] And, after conducting independent, third-party laboratory testing on several of the products, including Lash Blast and Covergirl Clump Crusher Waterproof Mascara ("Clump Crusher"), the plaintiff alleged that Lash Blast and Clump Crusher both contained "detectable levels of PFAS" that were not disclosed on the packaging.[5] The plaintiff also argued that Coty's statements on its website and press releases were misleading.

The Court reasoned that the plaintiff could not state a claim for breach of express warranty because she did not identify which of Coty's statements she relied on to make her purchase. The Court also determined that the statements at issue on Coty's website and press releases were nonactionable puffery because they did not describe any particular product, at all. The Court further found the plaintiff's claims that Coty added PFAS as an ingredient and that the PFAS could have been the result of product degradation to be unconvincing since the plaintiff did not plead that the products she purchased contained PFAS and, thus, could not allege an injury. The Court granted Coty's motion to dismiss but also granted the plaintiff's request for leave to amend her complaint.

CONCLUSION

The enactment of, and continued implementation of various requirements under, MoCRA will likely lead not only to additional regulatory enforcement against cosmetic companies, but it may also result in greater avenues for consumer litigation. Affected cosmetic companies should continue monitoring FDA's announcements, guidance documents, and enforcement actions in this space and should take time establish robust compliance frameworks and/or tighten up existing compliance measures.

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[1] U.S. Food and Drug Admin., Warning Letter: Cosmetic Science Laboratories LLC, No. MARCS-CMS 645558 (March 10, 2023).
[2] *Onaka et al. v. Shiseido Americas Corp.*, No. 21-CV-10665-PAC, 2023 WL 2663877, at 1, 6 (S.D.N.Y. March 28, 2023).
[3] ***Id.***
[4] *Brown v. Coty, Inc.*, No. 22-CIV-2696 (AT), 2023 WL 2691581 (S.D.N.Y. March 29, 2023).
[5] ***Id.***

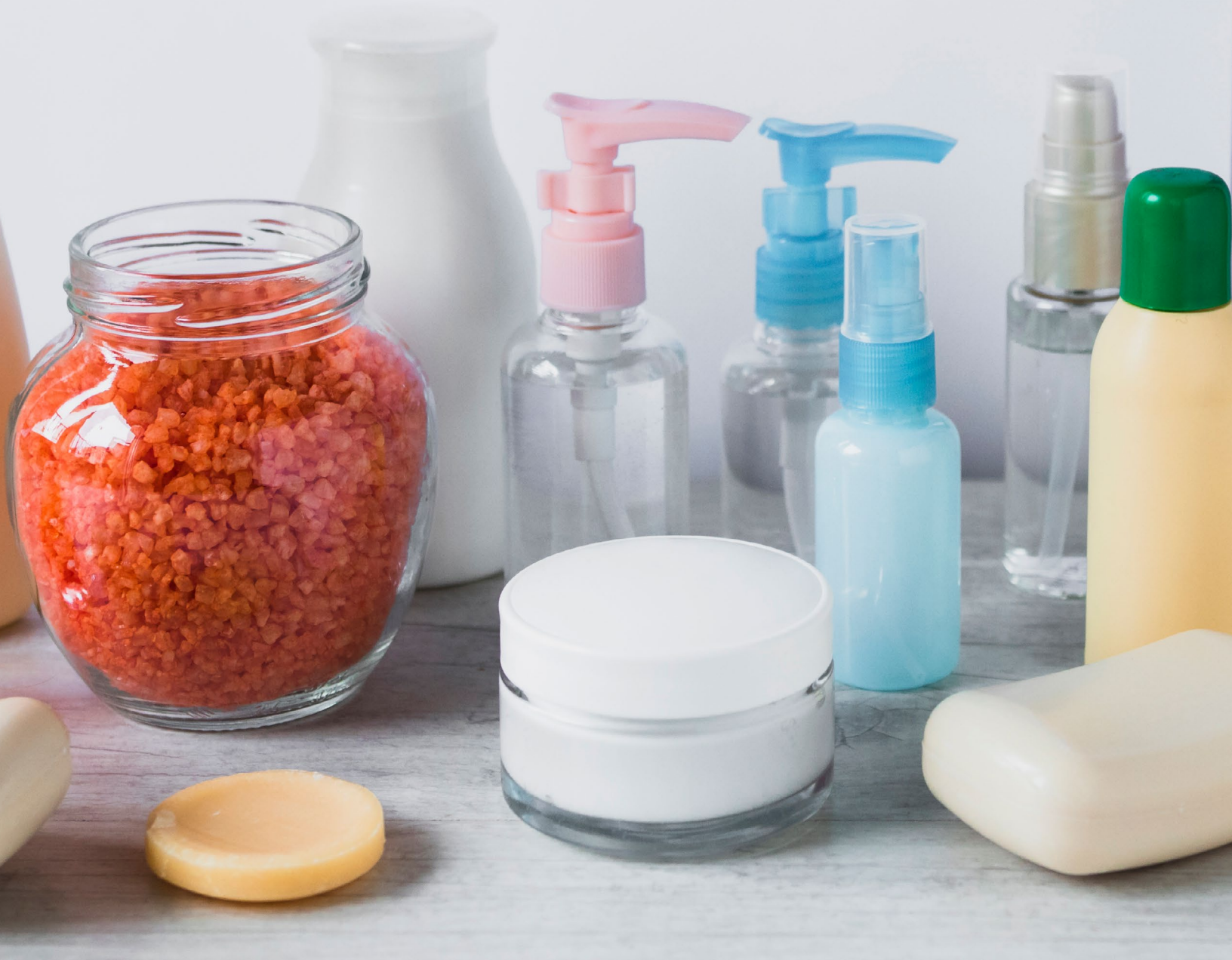
KEY CONTACTS

SUZIE TRIGG
PARTNER | CO-CHAIR - FOOD, BEVERAGE AND RESTAURANT PRACTICE GROUP | DALLAS / AUSTIN
suzie.trigg@haynesboone.com
+1 214.651.5098

CARLEIGH LENZ
ASSOCIATE | DALLAS
carleigh.lenz@haynesboone.com
+1 214.651.5493

KAYLA J. CRISTALES
ASSOCIATE | DALLAS
kayla.cristales@haynesboone.com
+1 214.651.5827

KRISTI WEISNER, PharmD
ATTORNEY | DALLAS
kristi.weisner@haynesboone.com
+1 214.651.5993



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