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Spotlight on PFAS and Other Substances in Cosmetics Likely to Grow in 2022

This year – 2022 – may finally be the year that the effort to modernize safety standards in the U.S. for cosmetics and other personal care products, which has been ongoing since 2013, comes to fruition. If so, the new cosmetics law will *further* focus a spotlight on the safety of perfluoroalkyl or polyfluoralkyl substances (PFAS) in cosmetics, and focus a spotlight on the safety of other substances in cosmetics, as well.

On December 14, 2021, during the Senate hearing to consider Dr. Califf's nomination to serve as the next FDA Commissioner, Senator Murray (D-WA), the Chair of the Senate Health, Education, Labor, and Pensions (HELP) Committee, hinted that cosmetics reform legislation may move this year with the Cures 2.0 legislation. The Cures 2.0 legislation contains FDA's user fee reauthorizations that must pass by September 2022.

Significantly, cosmetics reform could come in the form of S. 2100, the Personal Care Products Safety Act, which Senator Feinstein (D-CA) introduced in June 2021. If S. 2100 is enacted, *it would direct FDA to issue a proposed rule to ban the use of intentionally added PFAS in cosmetics, within 6 months of the passage of the Act*. (*See also* S. 2047 and H.R. 3990, both titled "No PFAS in Cosmetics Act" (containing similar provisions)). S. 2100, if enacted, would also modernize federal oversight of cosmetics by (1) requiring *cosmetics companies* to register with FDA, comply with good manufacturing practices, and report serious adverse events, among other things, and (2) requiring *FDA* to review the safety of five cosmetics ingredients or non-functional constituents, annually.

At this point, many in the cosmetics industry are very familiar with S. 2100, given that different iterations of the bill have been introduced in the last three Congresses – and they are very familiar with the public health and environmental concerns associated with PFAS, as well. PFAS have been associated with a number of health-related issues, including kidney cancer, and they have been referred to as "forever chemicals" because they do not break down easily. According to an FDA PFAS webpage, in

some instances PFAS are *intentionally added* to lotions, cleaners, nail polish, shaving cream, foundation, lipstick, eyeliner, eyeshadow, and mascara. But, in other instances, PFAS are unintentionally present in cosmetics as a result of raw material impurities or due to the breakdown of other ingredients that form PFAS.

PFAS in cosmetics have already had time in the spotlight. Last year, California, Maryland, and Maine all made headlines by enacting laws aimed at minimizing exposure to PFAS. California's law specifically bans the manufacture, sale, and distribution of *cosmetics* to which any one of 13 PFAS (and their salts) have been intentionally added, and it becomes effective in January 2025; Maryland's law is similar, and it becomes effective on the same date. Similar bills are pending in other states. Notably, Maine's law is even more sweeping. That law prohibits the sale of and distribution of *all* products to which PFAS has been intentionally added (subject to limited exceptions), and the prohibition becomes effective on January 2030. Maine's law also imposes certain reporting requirements, which will become effective in January 2023. Indeed, even more urgently California has another law, which became effective as of January 1, 2022, which imposes continuous reporting requirements for fragrances and flavors in cosmetics that are "identified as causing cancer or reproductive toxicity," and roughly 100 PFAS appear on the list of substances that trigger these reporting requirements.

In addition, in the European Union, several PFAS are already prohibited from cosmetics (through Annex III of the Cosmetics Regulation 1223/2009, although more generally, certain PFAS are regulated under REACH). And, more regulation is likely to come. For example, in the Chemical Strategy for Sustainability (Oct. 2020), the European Commission pledged to ban all uses of all PFAS unless the use is proven essential for society, and that objective seems to be shared by the Member States. In August 2021, five EU countries submitted a restriction proposal for all PFAS to the European Chemicals Agency, which, if adopted, could reduce the manufacture, distribution, and use of PFAS through REACH by 2025. Moreover, the ongoing revision of the EU Cosmetics Regulation will likely lead to more restrictions on (or even a ban of) PFAS in cosmetic products, and a related legislative proposal is expected by the end of 2022.

Given the concerns about PFAS, many cosmetics companies long ago publicly committed to eliminating PFAS from its products, and many others are working on reformulation. In addition, many in industry have been working with the Environmental Working Group to support the prohibition of certain PFAS from use in cosmetics.

Nonetheless, as discussed further below, if S. 2100 were enacted, the focus on PFAS, and other potentially concerning ingredients and non-functional constituents in cosmetics is likely to intensify. Section I, below, provides an overview of S. 2100, and Section II recommends best practices for industry.

I. Overview of S. 2100, the Personal Care Products Act

FDA began working with industry and public interest groups in 2013 on a proposed legislative framework that would modernize cosmetics oversight. From the beginning, the effort was targeted at requiring companies manufacturing cosmetics to register with FDA, comply with good manufacturing practices, and report serious adverse events, among other things. In addition, the initial framework contemplated providing FDA with authority to mandate recalls of cosmetics products, and requiring FDA to review the safety of certain cosmetics substances. The negotiations between FDA and industry, however, stalled due to controversial elements in the framework, including preemption, and the triggers for adverse event reporting.

In 2015, Senator Feinstein introduced the first iteration of the Personal Care Products Safety Act, S. 1014, which contained many of the same provisions contemplated in FDA's negotiation with industry. Although S. 1014 was never enacted, Senator Feinstein has reintroduced similar bills in each successive Congress (e.g., S. 1113, Personal

Care Products Safety Act, 115th Congress, May 11, 2017; S. 726, Personal Care Products Safety Act, 116th Congress, March 7, 2019). Senator Feinstein introduced the most recent iteration, S. 2100, on June 17, 2021, and that bill is still pending. Notably, according to a June 17, 2021, press release from Senator Feinstein the bill has broad support from industry, physician associations, and watchdog groups, such as the Environmental Working Group.

The most recent version of the Personal Care Products Safety Act, S. 2100, if enacted, would among other things (1) give FDA new, but basic regulatory tools to enhance cosmetics oversight, (2) require FDA to review the safety of five ingredients/non-functional constituents annually, (3) require FDA to issue a proposed rule, no later than six months after the date the legislation is enacted, that would ban the use of intentionally added PFAS in cosmetics, and (4) contain a limited preemption provision. Each of these four elements are discussed in more detail below.

(1) New/Basic Regulatory Tools

- *Registration/Fees/Ingredient Listing* – If S. 2100, is enacted, it would require cosmetics companies (e.g., brand owners that are manufacturers, entities whose names appear on cosmetics labels, and contract manufacturers) to register all of their facilities with FDA annually and to pay a registration fee. Each registration would contain the following information, among other things: (1) an ingredient list for all cosmetics products manufactured or processed in the registered facility; and (2) written assurance that each cosmetic product manufactured or processed in the registered facility has been substantiated for safety or carries a requisite warning.
- *Good Manufacturing Practices* – If enacted, the bill would require compliance with good manufacturing practices. Currently, in the U.S., compliance with good manufacturing practices is voluntary.
- *Adverse Event Reporting* – If S. 2100 is enacted, it would require adverse event reporting. Specifically, it would require adverse event reporting to FDA (1) for "serious adverse events" not later than 15 days after information concerning the "serious adverse event" has been received, and (2) for other "adverse events" in an annual report. A "serious adverse event," as defined in the legislation, is one that results in (1) death, (2) a life-threatening experience, (3) inpatient hospitalization, (4) a persistent or significant disability or incapacity, (5) a congenital anomaly or birth defect, or (6) significant disfigurement (e.g., serious and persistent rashes or infections and significant hair loss), or (7) the need for a medical or surgical intervention to prevent one of the aforementioned outcomes, based on appropriate medical judgment.
- *Mandatory Recall* – If S. 2100 is enacted, it would also give FDA mandatory recall authority over cosmetics. Currently, all cosmetics recalls are voluntary (although FDA can ask cosmetics companies to conduct them).

(2) Annual Ingredient/Non-Functional Constituent Safety Reviews

S. 2100, if enacted, would require FDA to review five ingredients/non-functional constituents for safety each year. Typically, FDA would select ingredients/non-functional constituents from a list determined in consultation with the cosmetics industry and consumer and health groups. But, the Agency could also review any other ingredient or non-functional constituent, not on that list, on its own initiative. As part of each review, FDA would open a docket to solicit data and public comments. After FDA has reviewed the relevant information – assuming there is adequate evidence to make a safety finding – FDA would issue a proposed administrative order deeming the ingredient/non-functional constituent to be (1) safe in cosmetic products under specified conditions of use or tolerances, (2) safe in cosmetic products without the need for specified conditions of use or tolerances, or (3) not safe in cosmetic products.

FDA would then open up a docket for public comment on the proposed administrative order, review the comments, and then issue a final administrative order.

Notably, in the event that there is inadequate evidence upon which FDA can make a safety determination, the bill would allow FDA to solicit additional data from interested persons (1) for an additional 30-day period, and then again, if necessary (2) for an additional time period not to exceed 18 months. If there is still insufficient information upon which FDA can make a safety determination, FDA would then issue an order making a determination that the ingredient or non-functional constituent has not been shown to be safe in cosmetics.

(3) Ban on PFAS

As mentioned, S. 2100, if enacted, would require FDA to issue a proposed rule, not later than six months after the legislation is enacted, banning the use of intentionally added PFAS in cosmetics.

(4) Preemption

The preemption provision in S. 2100 is very detailed. Among other things, S. 2100 provides that "[n]o State or political subdivision of a State may establish or continue in effect any requirement for cosmetics other than a requirement that is in full effect and implemented on the date of enactment [of S. 2100]" with respect to "registration, good manufacturing practices, mandatory recalls, or adverse event reporting," or "the safety of a cosmetic ingredient or non-functional constituent that is the subject of a final order [unless the State/local requirement is more restrictive than the final order]."

In addition, S. 2100 provides that, if enacted, nothing in the Personal Care Products Safety Act, nor any "standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such [Act], shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State or Federal law creating a remedy for civil relief or criminal cause of action, whether statutory or based in common law."

II. Take-Aways/Best Practices

If the "past is prologue" and cosmetics reform legislation does not pass this year, FDA, States, public interest groups, and the media are likely to continue to focus on the safety of PFAS and other substances in cosmetics. And if S. 2100 or similar legislation is enacted this year, scrutiny regarding the safety of substances in cosmetics, including PFAS, will intensify. The enactment of cosmetics reform legislation, associated rulemaking related to PFAS, and the review of the safety of other cosmetics substances (as well as related regulatory dockets) will inevitably attract more attention.

In this new paradigm, cosmetics companies will want to:

1. Carefully monitor federal and state legislation in this space;
2. Accurately identify (a) all of their cosmetics products that contain PFAS that are intentionally added, (b) all of their cosmetics products that contain PFAS that are unintentionally present (should, for example, such products become subject to new federal or state requirements), and (c) all cosmetics products that contain reportable or other

potentially controversial substances. (King & Spalding works closely with certified labs that have this type of testing capability);

3. Ensure that they are aware of state and federal reporting requirements related to PFAS and other potentially controversial cosmetics substances;
4. Identify alternatives for any of the PFAS substances identified in (2) above;
5. Consider how manufacturing and waste disposal practices may be affected by the increased scrutiny on cosmetic substances;
6. Consider whether contractual provisions related to controversial substances, in contracts with contract manufacturers or suppliers, could better protect the company; and
7. Consider voluntary compliance with good manufacturing practices.