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Modernization of Cosmetics Regulation Act of 2022 (MOCRA)
Section-by-Section Analysis

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Find it here: Pages 3576-3612 of the Omnibus Spending Bill
https://www.appropriations.senate.gov/imo/media/doc/JRQ121922.PDF

I. Mandatory Reporting of Serious Adverse Events (section 605)

New federal reporting requirements now exist for "serious adverse events" that occur following the use of a cosmetic product, defined as an adverse health-related event associated with the use of a cosmetic product that results in:

''(i) death; ''(ii) a life-threatening experience; ''(iii) inpatient hospitalization; ''(iv) a persistent or significant disability or incapacity; ''(v) a congenital anomaly or birth defect; ''(vi) an infection; or ''(vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or ''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A). Serious adverse event reports must be submitted to the FDA no more than fifteen business days after the company initially learns of the event and within 15 days for one year following the initial submission of the report to FDA, detailing any new information it receives regarding the serious adverse event. In addition, If the FDA has reasonable grounds to believe that a fragrance or flavor ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event, the agency may request in writing a list of such ingredients, and the company has 30 days to comply with the request. Records related to adverse events must be maintained for six years by companies and three years for small businesses.

POSITIVE CHANGE: We support the bill's broad definition of what constitutes a serious adverse event and its requirement that serious adverse events be reported to the FDA within 15 days after the report is received by the responsible party.

POSITIVE CHANGE: We also support the FDA's ability to get expedited access to a complete list of fragrance or flavor ingredients in the cosmetic product from the responsible person if the agency suspects the ingredients have caused a serious adverse event.

PROBLEMATIC: Despite the positive changes made by this section, we find it problematic that neither individual adverse event reports – nor a summary of adverse event reports are made available to the public in any manner. This lack of transparency will make it difficult for consumers to protect themselves from cosmetic products contributing to demonstrable harm.

II. Good Manufacturing Practice (Section 606)

Section 606 requires FDA to issue good manufacturing practice (GMP) regulations for cosmetics manufacturing and processing facilities with the intention of protecting public health and ensuring that cosmetic products distributed in the United States are not adulterated.

POSITIVE CHANGE: Previously, GMP were voluntary and inconsistent from facility to facility. The FDA is required to publish a notice of rulemaking for GMP regulations for cosmetic products two years after enactment and a final rule by three years after enactment.

III. Facility Registration and Product Listings (Section 607)

All existing facilities (domestic and foreign) that engage in the manufacturing or processing of a cosmetic product for distribution in the United States must register with the FDA no later than one year after MOCRA is enacted, which was December 29, 2022. MOCRA defines a facility as any establishment that manufactures or processes cosmetics that are distributed in the United States, but specifically excludes establishments that "solely perform" labeling, relabeling, packaging, repackaging, holding, and/or distributing cosmetic products. Retailers and beauty shops/salons are exempt from registration requirements, as are companies generating gross annual sales of less than $1 million. After the initial one-year deadline for registration, new businesses subject to these requirements will have 60 days to register with FDA after beginning their manufacturing operations. Cosmetic facility registrations must be renewed every two years, as is currently required for food facilities (by contrast, drug and device establishments must renew their respective registrations with FDA every year).

The Secretary may suspend the registration of a facility if they determine that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

The entity with its name on the label must submit a list of products and product ingredients, including the ingredients of any fragrances or flavors to the FDA no later than one year after the law's enactment and 120 days after introducing a new product into commerce.

POSITIVE CHANGE: We support the requirement – for the first time ever - that manufacturers be required to disclose fragrance and flavor ingredients to the FDA as a part of their cosmetic ingredient statements. This is critically important information for the FDA to receive because fragrance ingredients make up most of the ingredients in a cosmetic product, and the FDA cannot effectively regulate an industry if it does not have knowledge of and access to the full universe of ingredients being used to formulate cosmetic products.

POSITIVE CHANGE: We also support the other requirements for product and facility registration outlined in the new law.

PROBLEMATIC: We continue to find problematic, however, the allowance for "flexible listings," where companies "Provide a single listing submission for a cosmetic product (that) may include multiple cosmetic products with identical formulations or formulations that differ only with respect to colors, fragrances, flavors, or quantity of contents." This is extremely problematic because differences in both the constituent ingredients that make up fragrance and flavor formulations as well as the concentration of specific ingredients themselves can have major impacts on human health. This is especially true for vulnerable populations.

IV. Safety Substantiation (Section 608)

Section 608 of MOCRA requires manufacturers to maintain records "supporting that there is adequate substantiation of safety of such cometic product."

An adequate substantiation of safety is defined in Section 608(c)(1) as *"tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe."*

Section 608 (C) (2) defines 'safe' to mean that "the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual," with two caveats:

1) a cosmetic ingredient or cosmetic product is not considered injurious to users solely because it can cause minor and transient reactions skin irritations in some users; and

2) the Secretary "may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof."

PROBLEMATIC: The new law's weak safety standard does little to change the buyer-beware situation consumers currently face regarding the safety of cosmetic ingredients and is especially problematic because it codifies a weaker safety standard than *existing* FDA cosmetic safety regulation.

PROBLEMATIC: The law's codification of a definition of safe as "not injurious to users under the conditions of use prescribed in the labeling thereof," or "under such conditions of use as are customary or usual" is also concerning because it does not require manufacturers to consider real life – or foreseeable – uses or misuses of cosmetic products which is, ironically, the FDA's *current* regulatory condition of use standard for cosmetics (see 40 FR 8912 at 8916).

PROBLEMATIC: Current FDA regulation directs companies to rely on existing toxicological data to determine the safety of cosmetic ingredients and/or products and perform additional toxicological tests if none exist. Yet, the new law takes cosmetic safety a step backward by providing no clear direction that ingredients should be tested for long term, chronic health effects, as opposed to simply acute reactions like eye or skin irritation and by, even worse, codifying a weaker definition of what it means to substantiate ingredient or product for safety.

PROBLEMATIC: The new law's framework for its safety standard has historically - and primarily - been used to address pathogens, bacteria in food and cosmetic products or known toxins not chronic health effects (21 U.S. Code § 342) which tacitly gives companies permission to only test for acute reactions, not chronic health effects. This is less protective than existing cosmetic regulation laid out in (40 FR 8912 at 8916), where the FDA advised that "The safety of a cosmetic may be considered adequately substantiated if experts qualified by scientific training and experience can reasonably conclude from the available toxicological and other test data, chemical composition, and other pertinent information that the product is not injurious to consumers under conditions of customary use and reasonably foreseeable conditions of misuse."

Existing FDA cosmetic safety regulation further states: "The safety of a cosmetic can adequately be substantiated by a) Reliance on available toxicological test data on its ingredients and on similar products, and b) Performance of additional toxicological and other testing appropriate in the light of the existing data. Even if the safety of each ingredient has been substantiated, there usually still is at least some toxicological testing needed with the formulated product to assure adequate safety substantiation."

PROBLEMATIC: Finally, the new law permits – but does not direct – the Secretary to consider cumulative or other relevant exposures of cosmetic products and their ingredients but does not offer the same direction to manufacturers who are responsible for ensuring the safety of the lion's share of cosmetic ingredients.

608 (a) appears to maintain the exemption of coal tar ingredients from safety substantiation and states that manufacturers do NOT have to substantiate the safety of coal-tar hair dye that otherwise complies with the requirements of section 601(a). A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

PROBLEMATIC: It appears this section continues the 80-year exemption that prevents the FDA from taking action to protect the public from coal-tar hair dyes as long as the label includes a special caution statement, and the product comes with adequate directions for consumers to do a skin test before they dye their hair. This is not acceptable given these chemicals have been proven to be dangerous to the health of consumers and hair stylists. Currently, the FDA cannot take action against a coal-tar hair dye on the basis that it is or contains a poisonous or deleterious ingredient that may make it harmful to consumers, as long as the label includes a special caution statement, and the product comes with adequate directions for consumers to do a skin test before they dye their hair. Coal tar was specifically exempted from the 1938 passage of the Food, Drug and Cosmetic Act because of lobbying by the petroleum industry, even though even then, people understood the dangers of this family of hazardous compounds.

V. LABELING (SEC. 609)

‘‘(a) GENERAL REQUIREMENT. —Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.

‘‘(b) FRAGRANCE ALLERGENS. —

The new law directs the FDA to issue regulations identifying substances and threshold levels for cosmetic ingredients that are considered “fragrance allergens.” Proposed rulemaking implementing this requirement must be issued no later than 18 months after enactment and 180 days after the public comment period on the proposed rulemaking closes, the Secretary shall issue a final rulemaking. Manufacturers are then required to disclose any fragrance allergens contained in their cosmetic products on the product label. In promulgating those regulations, the agency must consider international, state, and local requirements regarding allergen disclosure, including the European Union’s substance and format for required disclosure of fragrance allergens.

POSITIVE CHANGE: We like the new law’s requirement that fragrance allergens be disclosed on product labels, this is a critically important health protection that is already in place in the European Union. Fragrance allergens are responsible for half of all cases of contact dermatitis in the U.S. These substances pose a risk of harm to a significant proportion, 11-14%, of the U.S. population. Thus, it is reasonable that the presence of fragrance allergens be disclosed on product labels so that consumers who suffer from fragrance allergies have the information they need to avoid these unsafe and, in some cases, life threatening exposures.

PROBLEMATIC: However, it makes no sense and is completely illogical that the FDA would be tasked with re-inventing the wheel vis-à-vis the bill’s directive that the FDA determine via regulation 18 months after bill enactment the list of fragrance allergens – and thresholds - to be disclosed under this provision.

POSITIVE CHANGE: We support the new law’s requirement that the FDA consider international requirements regarding fragrance allergens and hope it will take seriously the EU’s existing list of fragrance allergens and the reporting thresholds it has established. In 2012, the European Commission Scientific Committee on Consumer Safety reviewed multiple peer-reviewed studies, through a meta-analysis, on the concentrations of fragrance chemicals that cause allergic responses and then used statistical analysis to come up with “safe limits” of 100ppm for rinse-off products and 10ppm for leave-on products. The EU’s current list of Fragrance allergens is made up of 26 chemicals and there are regulations in place to expand that list to 83 fragrance ingredients well known to be allergens. We feel strongly that the European

Union utilized a sound scientific methodology, and the FDA does not need to invest its limited resources in redoing this list of widely accepted fragrance allergens and thresholds for disclosure which is currently being followed by the world's largest multinationals.

(c) COSMETIC PRODUCTS FOR PROFESSIONAL USE. —

‘‘(1) Defines professional to mean individuals who are licensed in cosmetology, nail care, barbering or esthetics.

‘(2) PROFESSIONAL USE LABELING. —Requires any cosmetic product intended to be used by a professional shall bar a label that lists the ingredients in the product.

POSITIVE CHANGE: We fully support the discussion draft's requirement that the ingredients in professional salon products appear on the product label. Nail and hair salon professionals work with a multitude of cosmetic products daily made with chemicals known or suspected to cause cancer, respiratory, neurological, and reproductive harm. They need and deserve the same level of ingredient disclosure required by law for cosmetic products marketed to consumers, so they can make informed choices about the products they use and how to protect their health.

VI. Records Inspection (Section 610)

POSITIVE CHANGE: If the Secretary has a reasonable belief that cosmetic product – or an ingredient in the product – is likely to be adulterated or use of or exposure to the product would present a threat of serious adverse health effects or death, the manufacturer is required to provide access to and a copy of all records relating to the cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans including, most importantly, safety substantiation data for a cosmetic product and its ingredients.

VII. Mandatory Recall Authority (Section 611)

Section 611 creates much stronger recall authority than currently exists when the FDA identifies safety risks or harm associated with a cosmetic product. The provision authorizes FDA to request a voluntary recall of a cosmetic product if the agency determines that there is a reasonable probability that the product is adulterated or misbranded and that use or exposure to the cosmetic product will cause serious adverse health consequences or death. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary, the Secretary may, by order the responsible party to immediately cease distribution of such article.

New authority was also created permitting the agency to suspend a cosmetic facility's registration if it determines a recalled product might similarly affect other products made by the facility.

POSITIVE CHANGE: This is a strong and necessary provision within the new law. We especially appreciate the public notification provision that directs the FDA, in the case of either an FDA mandatory recall or a voluntary recall, to ensure that: 1) a press release is issued and posted on the FDA's website with an image of the recalled item; and 2) alerts and public notices are issued to provide notification of the recall to consumers and retailers to whom the cosmetic was or may have been distributed that includes, at minimum, the name of the cosmetic product, a description of the risks associated with use of the product and – to the extent practicable – information for consumers about similar cosmetics that are not affected by the recall.

VIII. Small Businesses (Section 612)

POSITIVE CHANGE: Section 612 establishes special considerations for small businesses, defined as companies making gross annual sales of less than $1 million over the previous three-year period. Small businesses are not subject to the requirements in Section 606 (Good Manufacturing Practices) or Section 607 (Registration or Product Listings).

IX. Federal preemption (Section 614)

Section 614 (a) preempts the states from legislating on cosmetic safety in seven ways by prohibiting states from establishing or continuing any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement in the new law having to do with registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

Section 614 (b) permits States to ban or restrict the use of an ingredient in a cosmetic product; and continue any law that is in effect at the time of enactment that requires reporting of cosmetic ingredients.

This provision allows states to continue to enforce existing bans or limits on ingredients in cosmetic products, enact new bans and limits on ingredients, and continue to enforce any existing ingredient reporting "requirements."

Section 614 (b) protects existing reporting laws while preempting any new reporting laws.

VERY PROBLEMATIC: The Campaign for Safe Cosmetics strenuously objected to the inclusion of any kind of federal preemption in MOCRA.

The states have been at the forefront of protecting their citizens from toxic chemical exposures, and enacting state-level protections that reflect current science in a nimbler and more health-protective manner than the federal government has been able to accomplish. We believe strongly that Congress should support federal cosmetic safety reform that builds on state leadership as it relates to cosmetic safety, not legislate to take it away. Attacking states'

rights is contrary to the belief of federal and state lawmakers on both sides of the aisle who support the right of the states to protect the health and safety of their citizens. The states have long served as learning laboratories for Congress, accomplishing important pioneering work, including the disclosure and stricter regulation of unsafe cosmetic chemical exposures. Federal preemption is especially dangerous when a weak federal standard has been adopted – as is the case with MOCRA's safety standard – and the states are prohibited from enacting stronger protections.

VIII. Miscellaneous Sections

SEC. 3505. RECORDS INSPECTION.

POSITIVE CHANGE: The new law authorizes the FDA to inspect all records and other information described in sections 605 (Adverse Events), section 606 (GMP) and section 610 (records). The inclusion of section 610 (records) allows the FDA inspection of safety substantiation data for a cosmetic product and its ingredients needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans.

SEC. 3505. TALC-CONTAINING COSMETICS.

POSITIVE CHANGE: Not later than one year after enactment, the Secretary shall promulgate proposed regulations to establish and require standardized testing methods for detecting asbestos in talc-containing products; and not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

SEC. 3506. PFAS IN COSMETICS.

(a) IN GENERAL. —The Secretary shall assess the use of perfluoroalkyl and polyfluoroalkyl substances in cosmetic products and the scientific evidence regarding the safety and risks associated with such use in cosmetic products

(b) REPORT. —Not later than three years after enactment, the Secretary shall publish on the FDA website a report summarizing the results of the assessment

VERY PROBLEMATIC: We find this section to be extremely problematic given it directs the FDA to study the problem, as opposed to defining cosmetic products with PFAS chemicals as adulterated, and banning them outright from beauty and personal care products sold in the U.S. In 2022, both Colorado and California banned intentionally added PFAS chemicals from cosmetic products sold in their states.

PFAS chemicals are used in firefighting foam and a wide variety of textiles, juvenile products, food packaging, fabrics, carpets, leather, outdoor gear, and beauty and personal care products. There is a vast and growing body of scientific evidence linking PFAS exposure to serious, adverse health effects including **breast and other cancers, birth defects, hormone disruption, kidney and liver damage, and thyroid disease**. This is a class of over 9,000 chemicals that all share the same carbon-fluorine bond, the strongest bond known in organic chemistry which means PFAS chemicals stay in the environment forever and never biodegrade.

The public's direct exposure to PFAS in cosmetic products is only part of the problem. Beauty and personal care products also get washed down the drain or thrown into landfills, where PFAS can then leach into soil and waterways. Their use today, in non-essential products like waterproof mascara, lipstick and anti-frizz products are threatening the health of the people across the country, contaminating their drinking water and ecosystems, and creating a legacy problem that future generations will have to deal with. We know enough about PFAS to know they do not belong in cosmetic products which is why we continue to support a ban on the entire class of PFAS chemicals, as opposed to further research into their safety.

SEC. 3508. FUNDING.

POSITIVE CHANGE: There is funding authorized to be appropriated: $14,200,000 for fiscal year 2023, $25,960,000 for fiscal year 2024, and $41,890,000 for each of fiscal years 2025 through 2027, for purposes of conducting the activities under this subtitle and hiring personnel required to carry out this subtitle.