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Cosmetic Safety Legislation Introduced, Again

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In what is the latest in a line of Congressional proposals to beef up the federal government's authority to regulate cosmetics, Senator Dianne Feinstein (D-CA), has proposed a bill aimed at dramatically increasing ***Food and Drug Administration (FDA)*** oversight of the chemicals found in cosmetics and personal care products. The Personal Care Products Safety Act , S. 1014[1] mirrors past proposals considered by Congress,[2] albeit with a number of differences from past bills. The bill, which would make substantial revisions to the Federal Food, Drug, and Cosmetic Act (FFDCA)[3] chapter on cosmetics, was proposed on April 20, 2015, and referred to the Committee on Health, Education, Labor, and Pensions.

This bill comes more than one year after negotiations between FDA and the cosmetics industry over the development of legislation to expand federal authority over cosmetics broke down. Michael R. Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, penned a letter to two industry groups expressing his "profound disappointment in your proposed draft legislation on FDA oversight of cosmetic safety."[4] Among other things, this letter argued that the industry's most recent proposal could harm FDA efforts to act against dangerous cosmetics and would hamstring states' ability to protect their citizens from unsafe cosmetics. Not surprisingly, the industry groups involved took issue with the FDA letter's characterization of their positions and emphasized their commitment to creating a workable regulatory framework for cosmetics.[5] It remains to be seen whether Sen. Feinstein's proposal will lead to a thaw in the relationship between these two sides. FDA has not publicly commented on the bill.

Key Provisions

Facility Registration: Much like past proposals, under S. 1014, facilities that manufacture, process, pack, or hold cosmetics would be required to register with FDA. Manufacturing and processing facilities would have to be registered on an annual basis, while holding and packing facilities would be required to submit registrations every three years. Unlike past bills that required a registration to list individual cosmetics, registrants under this bill would be required to identify the categories of cosmetics that they manufacture, process, pack or hold. FDA would be required to make a list of registered facilities publicly available.

Fees: This bill, like those proposed in the past, would have owners and operators of processing and manufacturing facilities pay fees to FDA that will be dedicated to "cosmetic safety activities." An owner or operator with more than $500,000 in annual sales over a three-year period would be required to pay fees as part of its registration. The bill sets out a methodology by which FDA would develop a schedule of fees.

Ingredient Statements: Brand owners would be required to submit ingredient statements on an annual basis. The list of ingredients that would be part of this statement would include possible ranges of the amount of each ingredient found in the product. The statement would not have to list or identify nanomaterials. (Unlike in previous bills, nanomaterials are not addressed in this legislation.) These statements would remain subject to trade secret protections, and would only be made available to a state that requests them.

As part of these statements, brand owners would have to submit a certification that they have made a written determination "that the product is safe under the conditions of use recommended in the labeling" based on "adequate evidence that each ingredient in the finished product is safe for the use recommended or suggested." Brand owners would be required to maintain the documents or information supporting these safety determinations and would be required to produce them to FDA upon request.

Ingredient Listing and Safety Assessment: Much like previous bills, Sen. Feinstein's proposal would require FDA to assess the safety of cosmetic ingredients and "non-functional constituents," which are materials that are not intentionally added to a cosmetic as a separate substance and serve no function. As was the case with prior proposals, FDA would develop a list of substances to review, make a risk-based safety determination, and issue an order after notice and public comment finding that a substance is (a) safe under specified conditions for use, (b) safe with restrictions on use, or (c) not safe for use. This bill diverges from those we have seen before in (1) the standard FDA would use to assess risk and (2) the manner in which ingredients would be listed and suggested for review.

The proposals considered by Congress in the past used a standard of "reasonable certainty of no harm," taking into account the aggregate and cumulative effects of exposure to chemicals from a wide variety of sources.[6] This bill would set a more qualitative standard of "adequate evidence to support a reasonable certainty among competent scientists that the ingredient is not harmful" from the ingredient's customary or usual use. Furthermore, FDA would only consider a very limited set of cumulative effects: those from substances that are chemically related to and enter the body through similar routes of exposure as the ingredient under review.

The bill would also set more modest targets for listing and reviewing chemicals than its predecessors. In the past, bills would have required FDA to create a priority assessment list containing at least 300 chemicals and add 100 chemicals to that list each year after its creation.[7] Under the bill currently pending in the Senate, FDA would initially have to evaluate five ingredients: diazolidinyl urea, lead acetate, methylene glycol, propyl paraben, and quaternium-15. After this initial group of five, FDA would evaluate five ingredients or non-functional constituents each year based on the recommendation from a Cosmetics Safety Advisory Committee, which would include representatives from both industry and consumer groups.

Labeling: The bill would impose labeling requirements less stringent than those in recent bills. Past bills would have required product labels to contain full lists of ingredients, and online vendors also would have had to display each product's ingredient list. Under this bill, most cosmetics would only be required to carry warnings if they contain chemicals for which FDA has determined a warning or

use limitation is necessary during its safety assessment. The legislation does not contain its own requirement for listing ingredients on product labels, which may suggest that the bill is not intended to disturb FDA's existing labeling requirements.[8]

Adverse Event Reporting and Recalls: The bill would require brand owners to report to FDA adverse health events and give FDA the authority to recall harmful products, a feature that has been part of the previous legislative efforts to expand federal cosmetics authority. Brand owners would be required to submit annual reports of all adverse events about which the owner received information during the previous year. Serious adverse events, such as those resulting in death or disfigurement, would have to be reported within 15 business days after a brand owner receives information regarding such an incident. The bill would also permit FDA to request voluntary recalls and order mandatory recalls when a brand owner will not voluntarily take its products off the market.

GMP: The bill would, like those taken up by Congress in the past, give FDA the authority to promulgate good manufacturing practices (GMP) regulations for cosmetics.

Animal Research: Like previous bills, this one would direct FDA to encourage the development of alternatives to using animals for cosmetics testing. The bill would have FDA promulgate guidance on such alternatives within three years of enactment.

Preemption: The bill would preempt new state laws that have the potential to duplicate some of the law's basic regulatory framework, and prohibit states from imposing safety restrictions on cosmetics ingredients in addition to those imposed by FDA after a safety review under this bill. States would be prohibited from enacting any new cosmetics registration, GMP, mandatory recall, or adverse event reporting requirements. Additionally, the bill would preempt all state laws that would impose more stringent requirements on ingredients or constituents for which FDA has already completed a safety review and issued an order. The bill would also preempt for one year any state law regulating the safety of a cosmetic constituent or ingredient under review by FDA.

Reception

The cosmetics and personal care products industry has been divided in its response to the bill. Larger companies have been supportive of the legislation; the Personal Care Products Council has come out in support of the proposed law.[9] These large cosmetics companies have unlikely allies in the form of multiple NGOs, which include the Environmental Working Group, the Society for Women's Health Research, and the National Alliance for Hispanic Health.[10] Small- and medium-sized cosmetics companies oppose the bill on the grounds that it would stifle innovation and impose substantial burdens on small businesses. [11]

Prospects for Passage

Past experience would suggest that Senator Feinstein's bill has little chance landing on President Obama's desk for his signature. Past efforts to expand FDA's cosmetics authority have all stalled out well before any possible floor action.

Despite this grim history, the bill does have one attribute that could allow it to escape the fate of its predecessors: at least some bipartisan support. Senator Susan Collins, a Republican from Maine, cosponsored the bill when Senator Feinstein, a Democrat, proposed it on the floor of the Senate. After the bill's initial proposal, two more Democrats signed on as cosponsors: Senators Barbara Boxer (D-CA) and Amy Klobuchar (D-MN). Whether the support of a single, moderate Republican is

sufficient to overcome partisan gridlock will be seen in the months to come.

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[1] S. 1014.

[2] See here.

[3] 21 U.S.C. § 301 *et seq.*

[4] Letter from Michael R. Taylor to Lezlee Westine (Personal Care Products Council) & Pamela Jo Busiek (Independent Cosmetics Manufacturers and Distributors) (Mar. 6, 2014).

[5] See PBA & ICMAD, Leading Beauty Industry Organizations Respond to FDA Letter on Proposed Cosmetic Industry Regulation Bill (Mar. 7, 2014); Personal Care Products Council, Statement by President & CEO Lezlee Westine On Negotiations with the U.S. Food & Drug Administration (FDA)

Regarding Cosmetics Legislation (Mar. 6, 2014).

[6] See (discussing the safety standard in the Safe Cosmetics and Personal Care Products Act of 2013).

[7] See, e.g. id., (discussing the listing process under the Safe Cosmetics and Personal Care Products Act of 2013);

[8] *See* 21 C.F.R. Part 701.

[9] Sen. Dianne Feinstein, Senators Introduce Bill to Strengthen Personal Care Product Oversight (Apr. 20, 2015).

[10] *Id.*

[11] ICMAD, Feinstein Bill Would Burden Small Business and Stifle Innovation (Apr. 20, 2015).

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