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## Federal Personal Care Products Safety Act (S.1113)

### Fact Sheet

#### A. What does the proposed policy do?

- Requires cosmetic companies to register their facilities, products and ingredients with FDA, and comply with good manufacturing practices
- Directs the US Food & Drug Administration (FDA) to assess a safety of at least five cosmetics chemicals a year
- Creates a Cosmetics Safety Advisory Committee to advise the FDA on ingredients to consider for future review
- Requires full ingredient disclosure for professional salon products and web-based sales of cosmetic products
- Grandfathers in existing cosmetic safety laws and programs, but preempts states from adopting legislation or regulation that addresses the safety of chemicals under FDA safety review
- Preempts states from enacting legislation addressing registration of cosmetic facilities, Good Manufacturing Practices (GMP), recalls and adverse event reporting of cosmetics
- Encourages a reduction in animal testing
- Creates a sliding scale fee structure capped at \$20.6 million a year to help pay for the program

#### B. What are BCPP's priority problems with the bill?

- 1) Fragrance and flavors are exempt from FDA ingredient disclosure, so the FDA will not receive the full information it needs to effectively regulate cosmetic ingredient safety.
- 2) The bill maintains a federal labeling loophole which allows fragrance houses to keep secret the chemicals that make up "fragrance" from manufacturers and consumers, making it impossible for manufacturers to fully substantiate the safety of all the ingredients in their products, despite the bill's mandate that they do so. Because 40% of personal care products include fragrance, this means almost ½ of all products on the market today will not be fully assessed for safety.
- 3) The bill's safety standard, used by the FDA to assess the safety of 5 cosmetic chemicals a year is too weak and narrow.
  - It only applies to the FDA, not the manufacturers who will be responsible for most safety substantiations.
  - The protection of vulnerable populations including workers is unclear.
  - It does not consider "real life use situations" but instead directs manufacturers to only consider "recommended or suggested conditions of use" when assessing the safety of an ingredient or cosmetic product.

- The bill lacks a definition of “safe” in relation to cosmetic chemicals, nor does it specify a minimum battery of safety tests required of cosmetic companies to assess acute reactions or chronic health effects like cancer, reproductive and developmental harm.
- 4) The bill directs manufacturers to make a safety determination based on “adequate evidence.” “Adequate” is defined as met if the safety of each ingredient in the finished cosmetic product can be referenced as safe “under the conditions of use recommended or suggested” on the product’s label by official statements made by one or more expert medical or scientific body. The bill does not, however, prohibit cosmetic companies from referencing the industry-funded Cosmetic Ingredient Review (CIR) or the Research Institute for Fragrance Materials (RIFM) as “expert bodies.” CIR and RIFM have a clear conflict-of-interest, so allowing cosmetic companies to reference their industry-funded science to certify product safety is essentially the same flawed system we have now.
  - 5) The bill does not facilitate industry data sharing. Not sharing industry safety study data will result in more animal testing and slow the FDA safety review of cosmetics chemicals to a crawl. Also problematic, cosmetic industry suppliers of cosmetic chemicals, fragrance and raw materials are not required to provide their safety studies to either manufacturers or the FDA.
  - 6) The definition of “serious adverse events” raises too high a bar to capture many of the harmful reactions consumers are experiencing today from their use of beauty and personal care products. Also, summaries of adverse event reporting are not made publicly available. Instead, they are only available through a Freedom of Information Act request, which will have a chilling effect on the ability of the public to access these reports.
  - 7) States are preempted from establishing legislation to address the registration, GMP, recalls and adverse event reporting of cosmetic products. They are also preempted from adopting legislation or regulation addressing the safety of chemicals under safety review by the FDA.