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Chemicals and contaminants linked to cancer can be found in food, water and many other everyday products. However, no category of consumer products is subject to less government oversight than cosmetics and other personal care products. Although many of the chemicals and contaminants in cosmetics and personal care products likely pose little risk, exposure to some has been linked to serious health problems, including cancer.

Since 2009, 595 cosmetics manufacturers have reported using 88 chemicals, in more than 73,000 products, that have been linked to cancer, birth defects or reproductive harm.[1]

Many of these chemicals should be banned from cosmetics, as proposed in California Assembly Bill 2762, the Toxic-Free Cosmetics Act. Among the toxic chemicals[2] that should be banned are:

- Formaldehyde, a known carcinogen.
- Paraformaldehyde, a type of formaldehyde.
- Methylene glycol, a type of formaldehyde.
- Quaternium 15, which releases formaldehyde.
- Mercury, which can damage the kidneys and nervous system.
- Dibutyl and diethylhexyl phthalates, which disrupt hormones and damage the reproductive system.
- Isobutyl and isopropyl parabens (https://www.ewg.org/californiacosmetics/parabens), which disrupt hormones and harm the reproductive system.
- The long-chain per- and polyfluoroalkyl substances known as PFAS, which have been linked to cancer.
- M- and o-phenylenediamine, used in hair dyes, which irritate and sensitize the skin, damage DNA and can cause cancer.

All of these toxic chemicals have been banned by the European Union and many other nations, and many have been slated for removal from the store brands of major U.S. retailers, including Target, Rite Aid, Walgreens and CVS Health.[3] For example, as of the end of 2019, CVS Health prohibits the use of formaldehyde, many chemicals that release formaldehyde, many parabens, dibutyl phthalate and diethylhexyl phthalate. Some of these are already banned from products sold in Whole Foods.[4]

Some of the chemicals included in A.B. 2762 do not have to be disclosed on the package, because they are components of fragrance and so are exempt from federal labeling requirements. In particular, two phthalates included in A.B. 2762 – dibutyl phthalate and diethylhexyl phthalate – may be included in combinations of chemicals disclosed on the label as fragrance but do not have to be disclosed as individual chemicals.

Dibutyl phthalate is an endocrine disruptor and a developmental toxicant that harms male reproductive system development. It can cause early puberty in boys and other changes in the reproductive system. Diethylhexyl phthalate harms the reproductive system and can affect the developing fetus. It has also been classified by the International Agency for Research on Cancer as possibly carcinogenic.[5]

Many of these chemicals are rarely used in personal care products and will be easy to replace. For example, in Skin Deep®, EWG's database of cosmetics and other personal care products, EWG found isobutylparaben and isopropylparaben in just 96 and 12 products, respectively, offered for sale since January 2017. A 2018 analysis by EWG found fewer than 200 products contained one of 13 PFAS chemicals.[6]

The cosmetics industry has grown dramatically since 1938, when Congress last enacted cosmetics legislation, the Food, Drug, and Cosmetic Act. At that time, the cosmetics industry reported approximately $1 billion in sales.[7] In 2016, it reported more than $169 billion in sales.[8] Nevertheless, only two pages of the 829-page act governs cosmetics, and those provisions provide the Food and Drug Administration no financial resources and sharply limit its authority to regulate chemicals and contaminants that pose chronic risks.[9]

Although Congress has since then given the FDA the power to ensure that food additives,[10] color additives[11] and pesticides[12] pose "no harm" from

repeat exposures, Congress has not given the agency the same authority to regulate the chronic risks posed by chemicals and contaminants in cosmetics. Instead, the FDA largely relies on the personal care products industry to regulate itself as a way to address the risks its products pose.

Consumers use a wide variety of cosmetics and personal care products. Few consumer products contribute as many chemical exposures as cosmetics and other personal care products. Each day, American women use an average of 12 personal care products that contain 168 different chemicals. Men use an average of six personal care products that contain 85 different chemicals.[13] Many of these products are applied directly to the skin, the body's largest organ, where ingredients can be absorbed directly into the bloodstream.[14]

Consumer use of cosmetics continues to grow dramatically. Since 2010, the U.S. cosmetics market has grown an average of 4.1 percent annually, and internet sales have expanded to account for 8.4 percent of the total market share.[15]

Cosmetic imports are also on the rise. In fiscal year 2016, 2.9 million lines of cosmetics were imported into the U.S. from 181 different countries.[16] Lines of cosmetic imports doubled over the past decade, with a substantial increase after FY 2011.[17] Cosmetic imports from China increased by 79 percent between FY 2011 and FY 2016.

Although most chemicals in cosmetics pose little or no risk, some have been linked to serious health problems, including cancer, reproductive and neurological harm, and developmental delays. Cosmetic chemicals enter the body through the skin, inhalation, ingestion and internal use, and pose the same risks as food chemicals.[18] In addition to the risks posed by intentionally added ingredients, cosmetics can be contaminated with heavy metals, including arsenic, cadmium, lead, mercury and nickel.

Some chemicals used in personal care products pose risks at very low doses[22] and can interfere with the hormone system.[23] Research shows that "endocrine disrupting" chemicals such as parabens and phthalates may pose the greatest risk during prenatal and early postnatal development, when organ and neural systems form.[24] Exposure to these chemicals has been linked to endocrine diseases and some types of cancer.[25] For example, endocrine disruptors are known to affect how women's bodies use estrogen and thus have been linked to breast cancer.[26] Research has also shown that endocrine disruptors can harm the immune system – an effect that makes us more susceptible to disease and viruses.

Many cosmetics have also been linked to acute risks, including burns and infections. Formaldehyde-based hair-straightening procedures, referred to as "keratin treatments," have been linked to hair loss, rashes, blisters, nosebleeds, bleeding gums and loss of taste and smell.[27] Other cosmetics have caused hair loss.[28]

The FDA continues to find cosmetics contaminated with bacteria, including body wash, face powders, shadows and lotions, or containing banned colors chemicals, including shampoos, soaps, cleaners and temporary tattoos.[29]

Under the current law, the FDA has little authority to review chemicals in cosmetics and other personal care products. Personal care products companies do not have to register with the FDA, provide the FDA with ingredient statements, adopt Good Manufacturing Practices, or GMPs, report adverse events to the FDA, or provide the FDA with access to safety records.

The FDA does not have the power to suspend registration or order recalls when products pose a risk of serious adverse health consequences or death. By contrast, manufacturers of food, drugs and medical devices must register with the FDA, maintain and give the FDA access to records and

report adverse events. If food, drugs or devices are unsafe, the FDA can suspend production and product licenses. If unsafe food or devices reach the market, the FDA can order a recall and take legal action against drugmakers that do not recall their products.[30]

Of more than 10,000 chemicals used to formulate cosmetics, **just 11** ⟨https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics⟩ have ever been banned or restricted by the federal Food and Drug Administration. By contrast, the FDA, the Environmental Protection Agency and the Consumer Product Safety Commission have broad authority to ensure the safety of chemicals in other consumer products.

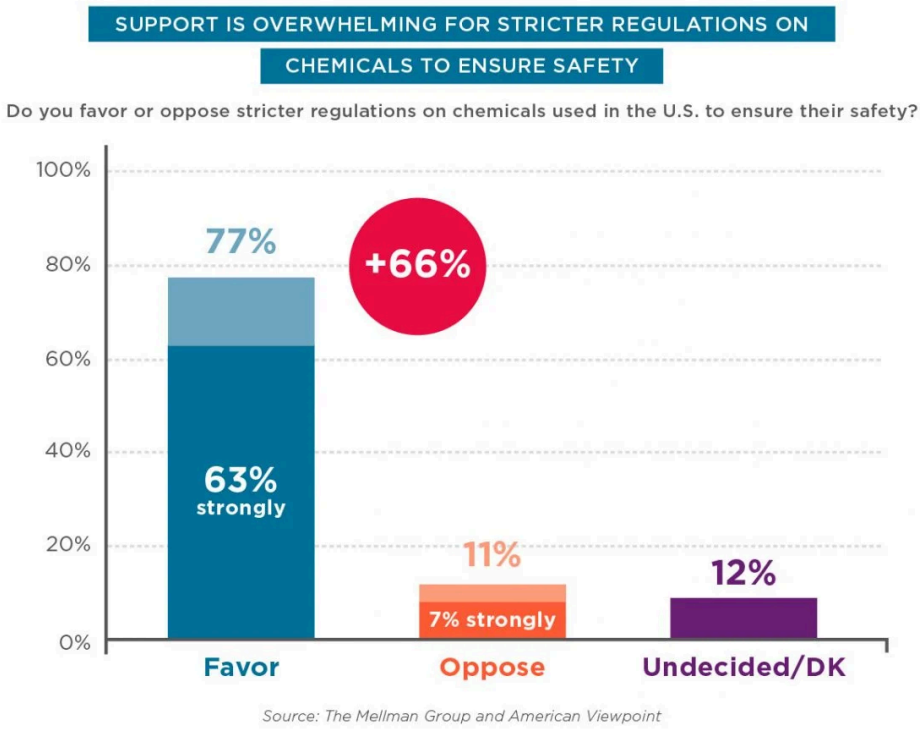
For example, the FDA has the authority to review chemicals in prescription[31] and over-the-counter drugs,[32] and chemicals found in food, [33] and the EPA has the authority to review chemicals in pesticides used in homes and on farms[34] and to set limits for pesticide residues on food.[35] In 2016, Congress expanded EPA authority to review chemicals in cleaners, paints, solvents and many other consumer products.[36]

The U.S. has also fallen far behind our international trading partners in the regulation of cosmetics. More than 40 nations have taken steps to ban or restrict, in combination, more than 1,400 chemicals or contaminants in cosmetics and personal care products, including chemicals linked to cancer, reproductive harm and neurological harm.[37]

All of the chemicals identified in A.B. 2762 have already been banned by the EU, including isopropylparaben and isobutylparaben, dibutyl phthalate and diethylhexyl phthalate,[38] mercury,[39] formaldehyde and many PFAS. Other nations have restricted the presence of chemicals such as formaldehyde[40] and perfluorooctanoic acid (PFOA).[41]

The cosmetics industry has long fought meaningful oversight. Since the early 1950s, it has defeated efforts by Congress to modernize cosmetics law.[42] Since 2015, some cosmetics companies have supported giving the FDA the authority and resources to review and regulate chemicals and contaminants of concern in cosmetics, and have supported requiring manufacturers to register, provide ingredient statements, adopt GMPs and report adverse events.

Some companies have also supported giving FDA the power to suspend production of dangerous products and order mandatory recalls.[43] However, other companies have not supported FDA review and oversight.



Consumers overwhelmingly support federal oversight of cosmetic chemicals. Two-thirds of consumers believe chemicals in cosmetics are already reviewed by the FDA, according to polling conducted by American Viewpoint and the Mellman Group in 2016.[44] Three-fourths of consumers – regardless of age, race or party affiliation – support stricter oversight of chemicals in cosmetics, and nearly nine in 10 consider stricter rules very important.

In addition, nine in 10 consumers believe cosmetic companies should have to notify the FDA if their products harm consumers; support giving the FDA mandatory recall authority; and support rules ensuring cosmetics are produced in clean environments.

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[1] Cal. Dep't of Pub. Health, Cal. Safe Cosmetics Program, Current Data Summary, https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/SummaryDa

(last accessed Mar. 8, 2019). The California Safe Cosmetics Act of 2005 requires cosmetic manufacturers to disclose to the California Department of Public Health all products containing ingredients known or suspected to cause cancer, birth defects or other reproductive toxicity as determined by certain authoritative scientific bodies, including the Environmental Protection Agency, the National Toxicology Program and the International Agency for Research on Cancer.

[2] Environmental Working Group, the Toxic Twenty Cosmetic Ingredients and Contaminants, accessed at http://cdn3.ewg.org/sites/default/files/u352/Toxic%2020%20List.pdf?_ga=2.36293026.364182527.1554126027-937396664.1520601435&_gac=1.259664632.1553597903.CjwKCAjwm-fkBRBBEiwA966fZF139RiUrtNyeYyElYAnOqpk3GtURCnrAjqAsTCXwDcJ10SIgOtY1E

>[3] Target, Chemicals, https://corporate.target.com/corporate-responsibility/planet/chemicals (last visited Apr. 2, 2019); Rite Aid, Chemical Policy: Restricted Substances List, https://www.riteaid.com/documents/45609410/184110402/rite-aid-restricted-substances-list_1809.pdf/39450b19-0512-73c1-3afb-358987ea5ff6 (last visited Apr. 2, 2019); Walgreens Boots Alliance, Restricted Substances List, https://www.walgreens.com/images/adaptive/si/pdf/WalgreensBootsAllianceRestricte (last visited Apr. 2, 2019); CVS Health, Store Brand Restricted Substances List, https://cvshealth.com/sites/default/files/cvs-health-restricted-chemical-list-by-category.pdf (last visited Apr. 2, 2019).

[4] Whole Foods, Our Body Care Quality Standards, https://www.wholefoodsmarket.com/about-our-products/body-care-quality-standards (last visited Apr. 2, 2019); Whole Foods, Premium Body Care Unacceptable Ingredients, https://www.wholefoodsmarket.com/premium-body-care-unacceptable-ingredients (last visited Apr. 2, 2019).

[5] Poursafa, P., Ataei, E., & Kelishadi, R. (2015). A systematic review on the effects of environmental exposure to some organohalogens and phthalates on early puberty. *J Res Med Sci, 20*(6): 613-18, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4621657/; Mylchreest, E., Cattley, R.C., & Foster, P.M. (1998). Male reproductive tract malformations in rats following gestational and lactational exposure to Di(n-butyl) phthalate: an antiandrogenic mechanism? *Toxicol Sci, 43*(1): 47-60, https://www.ncbi.nlm.nih.gov/pubmed/9629619; Kay, V.R., Bloom, M.S., & Foster. W.G. (2014). Reproductive and developmental effects of phthalate diesters in males. *Crit Rev Toxicol, 44*(6): 467-98, https://www.ncbi.nlm.nih.gov/pubmed/24903855; Int'l Agency for Research on Cancer, Di(2-ethylhexyl) Phthalate (2013), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono101-006.pdf.

>[6] David Andrews and Carla Burns, *Is Teflon in Your Cosmetics?* Envtl. Working Grp. (Mar. 14, 2018), https://www.ewg.org/skindeep/2018/03/07/is-teflon-in-your-cosmetics/.

[7] Kerry A. Harnett, *Appearing Modern: Women's Bodies, Beauty, and Power in 1920s America* (Apr. 2009), https://dlib.bc.edu/islandora/object/bc-ir:102409/datastream/PDF/view.

[8] Personal Care Products Council, *Economic and Social Contributions Report* (2016), https://www.personalcarecouncil.org/wp-content/uploads/2018/10/PCPC_Economic_Social_Contributions_Report_Web.pdf; *se also* Statista, *Revenue of the Cosmetics Industry in the United States from 2002-2016,* https://www.statista.com/statistics/717673/cosmetics-personal-care-products-markets-revenue/https://www.statista.com/statistics/243742/revenue-of-the-cosmetic-industry-in-the-us/ (last visited Mar. 2019).

[9] Section 601(a) of the FDCA (21 U.S.C. § 361(a)) states that a cosmetic is deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual." A cosmetic is also adulterated under the 1938 FDCA if packed in unsanitary conditions that may render it "injurious to health" or its container is composed in whole or part of any poisonous or deleterious substance that may render it "injurious to health."

[10] Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

[11] Color Additives Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397.

[12] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489.

[13] Envtl. Working Grp., *Exposures Add Up- Survey Results* (2004), http://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results/.

[14] Marcy Laub, *Skin deep,* Harvard Univ. (2015), https://green.harvard.edu/news/skin-deep.

[15] Nilesh Rajput, *Cosmetics Market by Category, Global Opportunity Analysis and Industry Forecast, 2014 - 2022,* Allied Market Research (July 2016), https://www.alliedmarketresearch.com/cosmetics-market; *see also* Statista, *Cosmetics Industry – Statistics & Facts* (2016), https://www.statista.com/statistics/297070/growth-rate-of-the-global-cosmetics-market/; Euromonitor Intl., *Colour Cosmetics in the US* (May 2017) http://www.euromonitor.com/colour-cosmetics-in-the-us/report.

[16] *See* Letter from Anna K. Abram, Deputy Comm'r for Policy, Planning, Legislation and Analysis, Food & Drug Admin., to Representative Frank Pallone, Ranking Member, House Energy and Commerce Comm. (June 30,

2017), https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/docum

>[17] *Id.*

[18] *See generally* UNL Envtl. Health and Safety, *Toxicology And Exposure Guidelines* (Jan. 2003), https://ehs.unl.edu/documents/tox_exposure_guidelines.pdf.

[19] Geologically, talc and asbestos can be formed from the same parent rock. As a result, mined talc deposits in many parts of the world can be contaminated with asbestos fibers.

[20] Cosmetics companies are not required to register and provide ingredient statements to FDA, so FDA is unable to estimate the number products that contain talc.

[21] Envtl. Working Grp., EWG's Skin Deep® Cosmetics Database, https://www.ewg.org/skindeep/.

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[22] Laura N. Vandenberg *et al.*, *Hormones & Endocrine-Disrupting Chemicals: Low-Dose Effects & Nonmonotonic Dose Responses*, 33 Endocrine Rev. 378-455 (2012), http://www.ncbi.nlm.nih.gov/pubmed/22419778.

[23] Chemicals like phthalates and triphenyl phosphate can disrupt the hormone system by mimicking or blocking a natural hormone. When an endocrine-disrupting chemical mimics a hormone, the chemical tricks the hormone's receptor into thinking the chemical is the hormone. When the chemical blocks a hormone, the chemical can bind to a receptor and the hormone may not be activated. *See* Veldhoen N *et al.*, *The bactericidal agent triclosan modulates thyroid hormone-associated gene expression and disrupts*

postembryonic anuran development, Aquat Toxicol (June 2007), https://www.ncbi.nlm.nih.gov/pubmed/17011055.

[24] *See, e.g.,* Nat'l Inst. of Envtl. Health Sci., *Endocrine Disruptors*, https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm (last visited Apr. 2, 2019).

[25] *E.g.,* Andrea C. Gore *et al.*, *Executive Summary to EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals*, 36 Endocrine Rev. 593-602 (2015), http://press.endocrine.org/doi/10.1210/er.2015-1093.

[26] *Id.*

[27] *See, e.g.,* Envtl. Working Grp., *Brazilian-Style Blowouts: Still Poisonous, Still in Salons* (2015), http://www.ewg.org/enviroblog/2015/08/brazilian-style-blowouts-still-poisonous-still-salons.

[28] *See, e.g.,* Eric Lipton & Rachel Abrams, *Their Hair Fell Out. Should the F.D.A. Have the Power to Act?* N.Y. Times, (Aug. 2016), http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulation-wen.html?_r=0.

[29] Scott Faber, *Contaminated Cosmetics Pose Growing Risk to Consumers*, Envtl. Working Grp. (Feb. 2018), https://www.ewg.org/news-and-analysis/2018/02/contaminated-cosmetics-pose-growing-risk-consumers#.Wp65FpPwZ-V.

[30] *E.g.*, 21 U.S.C. § 350(d) (food); 21 C.F.R. § 807 (devices); 21 U.S.C. § 360 (drugs); 21 C.F.R. §§ 607.65, 1271 (biologics).

[31] 21 U.S.C. §§ 351-360fff.

[32] 21 C.F.R. § 330.

[33] 21 U.S.C. § 348.

[34] 7 U.S.C. §§ 136a-136d.

[35] 21 U.S.C. § 346a.

[36] 15 U.S.C. §§ 2604-05.

[37] Alyssa Katzenelson & Scott Faber, *On Cosmetics Safety, U.S. Trails More Than 40 Nations*, Envtl. Working Grp. (Mar. 20, 2019), https://www.ewg.org/news-and-analysis/2019/03/cosmetics-safety-us-trails-more-40-nations.

[38] Eur. Comm'n, Annex II: List of Substances Prohibited in Cosmetic Products (last update: 24/04/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf (last accessed Mar. 8, 2019).

[39] Gov't of Canada, *Cosmetic Ingredient Hotlist: Prohibited and Restricted Ingredients,*

https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients.html (last visited Mar. 2019); Eur. Comm'n, Annex II: List of Substances Prohibited in Cosmetic Products (last update: 24/04/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf (last visited Mar. 8, 2019).

[40] Eur. Comm'n, Annex III: List of Substances Which Cosmetic Products Must Not Contain Except Subject to the Restrictions Laid Down (last update:

24/10/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20III_v2.pdf (last accessed Mar. 8, 2019); Eur. Comm'n, Annex V: List of Preservatives Allowed in Cosmetic Products (last update: 23/11/2018), http://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20V_v2.pdf (last accessed Mar. 8, 2019).

[41] Eur. Chemicals Agency, Annex XVII to REACH – Conditions of Restriction: Entry 68 Perfluorooctanoic Acid (PFOA), https://www.echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c (last accessed Mar. 8, 2019). The restriction comes into effect in July 2020.

[42] In October 1951, the House of Representatives authorized a Select Committee, led by then-Rep. James Delaney (D-N.Y.) to investigate the use of chemicals, compounds and synthetics in the production of cosmetics and related health effects. *See* H.R. Rep. No. 82-2182. More than a dozen bills to reform cosmetics have been introduced since then. *See*, *e.g.*, the Cosmetics Safety Act, S. 683, 93rd Cong. (1st Sess. 1973); H.R. 1527, 93rd Cong. (1st Sess. 1973) (requiring that cosmetics containing mercury or any of its compounds bear labeling stating that fact); H.R. 14805, 93rd Cong. (1st Sess. 1974) (authorizing FDA to halt the sales and distribution of food, drugs, and cosmetics adulterated or misbranded in a manner that presents an imminent hazard to the public health); H.R. 6249, 94th Cong. (1st Sess. 1975) (applying the provisions of the FDCA to hair dyes); the Cosmetics Safety Amendments of 1975, S. 1681, 94th Cong. (2nd Sess. 1976); Cosmetics Act, H.R. 1993, 95th Cong. (1st Sess. 1977); Cosmetics Safety Amendments, S. 2365, 95th Cong. (1st Sess. 1977); Food, Drug, and Cosmetics Amendments of 1980, H.R. 2554, 91st Cong. (1st Sess. 1980) (permitting the inspection of a consulting laboratory in which food, drugs, devices, or cosmetics are being processed,

packed, or held); the Safe Cosmetics Act of 2010, H.R. 5786, 111th Cong. (2nd Sess. 2010); the Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. (1st Sess. 2011); Cosmetics Safety Enhancement Act of 2012, H.R. 4262, 112th Cong. (2nd Sess. 2012); Cosmetics Safety Amendments of 2012, H.R. 4395, 112th Cong. (2nd Sess. 2012); Safe Cosmetics and Personal Care Products Act of 2013, H.R. 1385, 113th Cong. (1st Sess. 2013); Personal Care Products Safety Act, S. 1014, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2015, H.R. 4075, 114th Cong. (1st Sess. 2015); Cosmetics Modernization Amendments of 2017, Personal Care Products Safety Act, S. 1113, 115th Cong. (1st Sess. 2017); Personal Care Products Safety Act, S. 726, 116th Cong. (1st Sess. 2019).

[43] The following companies support bipartisan cosmetics reform legislation: Amyris (Biossance), Au Naturale, Babo Botanicals, Beautycounter, California Baby, Coalition of Handcrafted Entrepreneurs, Cote, Earth Mama Organics, Éclair Naturals, Estee Lauder Companies, EO Products, Goddess Garden Organics, Handcrafted Soap & Cosmetic Guild, Handmade Cosmetic Alliance, Herban Lifestyle, the Honest Company, Johnson & Johnson, Juice Beauty, L'Oreal, Made Of, Makes 3 Organics, Milk + Honey, MyChelle Dermaceuticals, OSEA, Peet Rivko, Procter & Gamble, Rahua, Revlon, Seventh Generation, Silk Therapeutics, SkinOwl, S.W. Basics, Tenoverten, Unilever, Vapour Organic Beauty.

[44] Mark Mellman & Linda DiVall, *Findings From a National Survey of Likely 2016 General Election Voters* (Feb. 2016), https://cdn.ewg.org/sites/default/files/u381/cosmetics.pdf?_ga=1.55566627.92668946.1470953450.