The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure, and a Proactive Approach

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The dilemma is that there have literally been thousands of new chemicals coming into the marketplace, and we have limited knowledge of their toxicity. Because many of these agents have not been screened, it is not known what health effect, if any, exposure to these chemicals will have....[Do] we assume that something is safe until it causes harm, or vice versa?[1]

Introduction

In summer 2016, Congress passed amendments to the Toxic Substances Control Act ("TSCA") more than forty years after it first passed the law,[2] and the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LSCA") became the law of the land on June 22, 2016.[3] The new law, the first major U.S. environmental law in decades,[4] was widely lauded by the American Chemistry Council and other industry groups,[5] but somewhat less warmly received by consumer and public advocacy groups.[6] This article will make the case that while the LSCA had the potential to move us toward a more health protective stance in our federal, chemical regulatory regime, stringent enforcement of the law in a health protective manner does not seem likely in the current political climate.[7] Indeed, the EPA's July 2017 implementation rules for review of new and existing chemicals vitiate many of the Act's intended protections.[8]

One might posit that it is difficult to make the case that our toxic chemical control laws are worthy of serious attention in the face of gun violence, terrorism and great strife across the

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[1] Dr. Jonathan Samet, Flora L. Thornton Chair of the Department of Preventive Medicine at the University of Southern California and former Co-Chair of The American Cancer Society Subcommittee on Cancer and the Environment. May 13, 2010. Found at: http://www.drbuttar.com/patientresources/cancer/Medscape-Presidents%20Cancer%20Panel%20Article.pdf).

[2] The Toxic Substances Control Act, Pub.L. 94-469 (1976); The Lautenberg Chemical Safety Act for the 21st Century, Pub.L. No: 114-182 (2016); codified at 15 U.S.C. 2601 et seq.

[3] The Lautenberg Chemical Safety Act for the 21st Century, P.L. No: 114-182 (2016). ; see also The Assessing and Managing of Chemicals under TSCA, United States Environmental Protection Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act (Last visited on March 21, 2018).

[4] Richard Denison, A Primer on the New Toxic Substances Control Act (TSCA) and What led to it, April 2017, found at: https://www.edf.org/sites/default/files/denison-primer-on-lautenberg-act.pdf

[5] Scott Jensen, ACC Lauds Passage of Senate Bill to Reform TSCA found at: https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Lauds-Passage-of-Senate-Bill-to-Reform-TSCA.html

[6] Chemical Safety Reform, Getting it Right, Center for Environmental Health, 2015 found at: http://www.ceh.org/wp-content/uploads/CEH_TSCA_Two-Pager_2015.pdf (discussing opposition to proposal for LSCA in Congress); Press Release, Coming Clean Inc., When It Comes to Protecting Public Health from Toxic Chemicals, TCSA Reform Leaves Much Unfinished Business (June 23, 2016),http://comingcleaninc.org/assets/media/documents/TSCA%20Statement%206%2023%2016.pdf. ; New TSCA Bill Falls Short of Protecting Americans From Toxic Chemicals, Melanie Benesh, Scott Faber, May 24, 2016, found at: https://www.ewg.org/enviroblog/2016/05/new-tsca-bill-falls-short-protecting-americans-toxic-chemicals#.WxgLMiMrIwc .

[7] Coral Davenport, Scott Pruitt, Trump's Rule-Cutting EPA Chief, Plots His Political Future, New York Times, March 17, 2018, https://www.nytimes.com/2018/03/17/climate/scott-pruitt-political-ambitions.html.

[8] *See infra* notes 166 to 189 and accompanying discussion;

globe, but in this paper, I will make just that case.[9] Regulating consumer chemicals and products to protect human health and the environment is an issue readily deserving of our attention, and this new law, embodied in the LSCA *and* accompanying regulation,[10] does not adequately advance the cause.

In Part I, I thus briefly review the literature that suggests that environmental causes account for many serious illnesses, including cancers, then explore existing and proposed mechanisms in our federal legal framework to regulate toxic substances to protect human health.[11] By way of example and to address some of the toxic substances to which consumers are regularly exposed and which are regulated under other federal law, the article will touch on mechanisms in the Federal Food, Drug, and Cosmetics Act of 1938,[12] the Food Quality Protection Act,[13] the Safe Drinking Water Act,[14] and the Clean Air Act.[15] In Part II, I provide an overview of the deficiencies in the "old" TSCA that the LSCA amendments sought to correct.[16] In Part III, I outline the basic provisions of the LSCA and critique its initial implementation and what I perceive to be accompanying deficiencies.[17] In Part IV, I envision a path forward with what I call a "proactive" stance to the regulation of toxic substances. Such a regulatory stance would couple existing law with greater information transparency, and market forces to encourage industry and regulators to better protect human health and the environment.[18] This paper is meant to spur a dialogue and move us in this proactive, and market assisted, direction.

I. Environmental Pollution and Existing U.S. Federal Law on Toxic Substances in the Environment

A. Environmental Pollution Contributes to Serious Illness and Cancer

In 2010, the President's Cancer Panel released a controversial report calling for more precautionary measures to prevent cancers in the U.S. and noting that many more cancers were environmentally related than were being recognized.[19] This was not some fringe group analysis with an extreme position, but a report by the very influential and mainstream, "President's Can-

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[9] *See infra* Sections I - III

[10] The Lautenberg Chemical Safety Act for the 21st Century, P.L. No: 114-182 (2016). ; see also The Assessing and Managing of Chemicals under TSCA, United States Environmental Protection Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act (Last visited on March 21, 2018); see infra notes 232 to 254 and accompanying discussion.

[11] *See* National Cancer Institute, About Cancer, Cancer-Causing Substances in the Environment, https://www.cancer.gov/about-cancer/causes-prevention/risk/substances (Last visit on March 21, 2018) ; infra notes 54 to 96 and accompanying discussion.

[12] 21 U.S.C. §§ 301-399f.

[13] Pub. L. 104-170 (1996), amending sections for FIFRA and the FFDCA; United States Environmental Protection Agency, Pesticides: Regulating Pesticides, Food Quality Protection Act (FQPA) of 1996, https://archive.epa.gov/pesticides/regulating/laws/fqpa/web/html/index.html (Last visited on March 21, 2018)(annotative information).

[14] Safe Drinking Water Act, 42 U.S.C. §300f et seq. (1974); see also Clean Water Act, 33 U.S.C. §1251 et seq. (1972); United States Environmental Protection Agency, Safe Drinking Water Act (SDWA), https://www.epa.gov/sdwa (Last visit on March 21, 2018).

[15] 42 U.S. Code § 7401 et. seq.

[16] *See infra* Part II and accompanying discussion.

[17] *See infra* Part III and accompanying discussion.

[18] *See infra* Part IV and accompanying discussion.

[19] President's Cancer Panel Annual Report 2012-2013, Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer, https://deainfo.nci.nih.gov/Advisory/pcp/annualReports/HPV/index.htm (last visited on March 21, 2018).

cer Panel." The American Cancer Society took issue with the report, claiming that many more cancers are due to lifestyle, than to environmental causes.[20] But medical experts, including the Panel, suggest that while lifestyle plays a part in cancer and disease development, environmental factors are significant and have been underestimated by the medical community.[21]

Cancer, for example, is one of the leading causes of death in the world.[22] Statistics show that at least one in three Americans will develop cancer in their lifetimes and based on past statistics, far more will die this year[23] from the disease than from gun violence or from terrorism combined.[24] The National Cancer Institute predicts that worldwide cancer incidence will increase over the next 12 years by more than 50%.[25] And childhood cancer rates have steadily increased by approximately .6% yearly since 1975.[26]

More so, cancer (as well as other diseases related to environmental causes) extracts a tremendous emotional and economic toll on affected families.[27] The American Cancer Society reported that medical costs for cancer care in the United States in 2015 amounted to $80.2 billion dollars.[28]

Even prior to the 2010 President's Cancer Panel Report, leading scientists and public policy experts, summarized their concerns about avoidable toxins in the environment and argued for a paradigm shift in our regulatory system to make it more precautionary (and proactive) in approach.[29] These experts urged[30] a regulatory approach more in line with initiatives in the European Union to evaluate chemicals before they are brought to market.[31] Jeanne Rizzo, CEO of The Breast Cancer Fund and RN stated, at the time of the Panel Report, the President's Cancer Panel "level[s] a hefty critique of failed regulation [of environmental contaminants], undue industry influence, and inadequate research and funding."[32]

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[20] Kate Sheridan, Americans Are Giving Themselves Cancer—Half Of Cases Caused By Lifestyle, Newsweek, http://www.newsweek.com/americans-are-giving-themselves-cancer-half-cases-caused-lifestyle-719512.

[21] Marla Cone, Doctors Underestimate Environment as Cause for Cancer, Scientific American, https://www.scientificamerican.com/article/environment-as-cause-for-cancer/

[22] World Health Organization, Cancer, February 2018, http://www.who.int/mediacentre/factsheets/fs297/en/ (site visited April 10, 2018); National Cancer Institute, Understanding Cancer, Cancer Statistics, https://www.cancer.gov/about-cancer/understanding/statistics (visited March 19, 2018).

[23] According to the National Cancer Institute, 595,690 people died from cancer in 2016. https://www.cancer.gov/about-cancer/understanding/statistics (visited March 18, 2018).

[24] *See* Cancer deaths in the U.S., in 2016 were 595,690. Deaths from gun violence in 2016 were 38,658 people https://everytownresearch.org/gun-violence-by-the-numbers/ (citing CDC statistics)(last visited July 5, 2018).

[25] https://www.cancer.gov/about-cancer/understanding/statistics (visited March 18, 2018). The World Health Organization has stated that cancer incidence over the next 20 years will increase by 70%. http://www.who.int/mediacentre/factsheets/fs297/en/ (last visited March 18, 2018).

[26] American Cancer Society, Cancer Facts & Figures, 2018, available at: //www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf at 12 (Last visit on March 21, 2018).

[27] The Experience of Caregivers Living with Cancer Patients: A Systematic Review and Meta-Synthesis, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4695863/. The World Health Organization estimates that in 2010 the economic worldwide cost of cancer was 1.16 trillion U.S. dollars. http://www.who.int/mediacentre/factsheets/fs297/en/ (last visited March 18, 2018).

[28] American Cancer Society, Cancer Facts & Figures, 2018, available at: www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf at 8 (last visited on March 21, 2018).

[29] Richard W. Clapp, Genevieve K. Howe and Molly Jacobs, Environmental and Occupational Causes of Cancer Revisited, Palgrave Macmillan Journals, 2006, available at: http://www.jstor.org/stable/3879066.

[30] *Id.*

[31] *See* EC No. 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (December 18, 2006) found at: http://ec.europa.eu/environment/chemicals/reach/reach_en.htm (last visited April 18, 2018).

[32] Jeanne Rizzo, It's Time for Breast Cancer Prevention Month, October 12, 2010,

In 2016, Nicole Bijilsma and Marc Cohen furthered the dialogue in their paper: Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room.[33] The article outlined the current state of chemical production in the world, noting that chemical sales volume by dollars had increased by a factor of 25 from U.S. $171 Billion in 1970 to greater than U.S. $4 trillion in 2010.[34] Experts Bijilsma and Cohen further noted that 50 percent of the working population is now afflicted with chronic disease that is not explained[35] and there has been a shift in recent decades from communicable disease to chronic diseases in developed countries.[36] The authors posited that a long list of diseases, including diabetes, hyospadias (male reproductive disorders),[37] infertility, Alzheimer's, autoimmune disease, obesity, and cancers, can all be associated or exacerbated by environmental exposures to man-made chemicals.[38]

In the U.S. alone, chemical manufacturers produce over 80,000 synthetic chemicals, with the vast majority of these untested for their effects on human health.[39] More so, toxic substances

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https://www.huffingtonpost.com/jeanne-rizzo/its-time-for-breast-cance_b_759556.html (site visited April 10, 2018); *see infra* notes _ to __ and accompanying discussion.

[33] Nicole Bijlsma and Marc M. Cohen, Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room, 8(4) Disable Health J. 535 (2016), found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772201/

[34] UNEP (United Nations Environment Programme). Global chemicals outlook: Towards Sound Management of Chemicals. Geneva: UNEP; 2013 https://sustainabledevelopment.un.org/index.php?page=view&type=400&nr=1966&menu=1515 (visited March 18, 2018).

[35] Nicole Bijlsma and Marc M. Cohen, Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room, 8(4) Disable Health J. 535 (2016), found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772201/ (citing Reichard A., Gulley S.P., Rasch E.K., Chan L. Diagnosis isn't Enough: Understanding the Connections Between High Health Care Utilization, Chronic Conditions and Disabilities Among U.S. Working Age Adults. 8(4) Disabil. Health J. 535 (2015) .

[36] Reichard A, Gulley SP, Rasch EK, Chan L Diagnosis Isn't enough: Understanding the Connections Between High Health Care Utilization, Chronic Conditions and Disabilities Among U.S. Working Age Adults, 8(4) Disabil. Health J. 535 (2015).

[37] *See* https://www.cdc.gov/ncbddd/birthdefects/hypospadias.html (last visited April 23, 2018). The CDC estimates that five of every male boy born in the U.S., will be born with some sort of hypospadia. https://www.cdc.gov/ncbddd/birthdefects/hypospadias.html (last visited April 23, 2018).

[38] Nicole Bijlsma and Marc M. Cohen, Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room, 8(4) Disable Health J. 535, 538 (2015), found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4772201/ ; *see also* CDC, Health Studies Branch -- Understanding Chemical Radiation and Exposures https://www.cdc.gov/nceh/hsb/chemicals/default.htm (site visited April 10, 2018). Paolo Boffetta, Fredrik Nyberg, Contribution of Environmental Factors to Cancer Risk, Volume 68(1) British Medical Bulletin 71, n. 163 (December 2003), found at: https://academic.oup.com/bmb/article/68/1/71/421220 ("It is noteworthy, however, that despite the relatively small relative risks of cancer following exposure to environmental carcinogens, the number of cases that might be caused, assuming a causal relationship, is relatively large, as a result of the high prevalence of exposure. This emphasizes the need for a better understanding of the actual risk of cancer posed by environmental factors, and of the effect of measurements aimed at controlling exposure to environmental carcinogens.").

[39] U.S. Gov't Accountability Office, GAO-13-249, Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals But Could Strengthen Its Approach, 10, n.12, 12-17 (2013); John Wargo, Pervasive Plastics: Why the U.S. Needs New and Tighter Controls, Yale Environment 360, https://e360.yale.edu/features/pervasive_plastics_why_the_us_needs_new_and_tighter_controls (Last visited on March 26, 2018).

are routinely found in breast milk and in human placenta.[40] Indeed, it is now commonly understood that we are all contaminated from the womb to the grave.[41]

Additionally, many of the more than 80,000 chemicals on the market are known to be Endocrine Disrupting Chemicals or "EDC's."[42] These chemicals interfere with the functioning of the human endocrine system and often mimic hormones.[43] EDC's affect our ability to regulate our bodies, our own ability to reproduce and have been linked at very low levels to nervous system disorders, cancers,[44] and our ability to reproduce.[45] This is especially concerning and relevant to the LSCA and the new regulatory scheme in that EDC's are found routinely in everyday products,[46] including household items, food and beverage containers, nonstick cooking surfaces, air fresheners, cleaning products, and many other chemical substances used by consumers.[47]

These suggestions about EDCs and the U.S. chemical regulatory approach are not hyperbole, not so far-fetched or even extreme a position. Consider the history under the TSCA. We thought at one time that Polychlorinated biphenols ("PCBs") were safe and useful chemicals, largely because of their ability to conduct electricity and improve the elasticity of caulking materials.[48] Congress and EPA allowed their continued production until 1979,[49] long after the manu-

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[40] WHO, Fourth WHO-Coordinated Survey of Human Milk for Persistent Organic Pollutants in Cooperation with UNEP. WHO; Geneva, Switzerland: 2007: Guidelines for Developing a National Protocol.

[41] *See* Colborn, T., Dumanoski, D., & Myers, J. P. , The U.S. National Health and Nutrition Examination Survey and human exposure to environmental chemicals. Calafat AM Int J Hyg. Environ. Health. 2012 Feb; 215(2):99-101 ; Nathaniel Rich, The Lawyer Who Became DuPont's Worst Nightmare, N.Y. Times Mag. (Jan. 6, 2016),https://www.nytimes.com/2016/01/10/magazine/the-lawyer-who-became-duponts-worst-nightmare.html (noting that PFOA, a fluorochemical part of a class of PFASs and used in Teflon, has been detected in American blood banks and that the average concentration of PFOA in the blood of an American adult by 2003 was four to five parts per billion when the manufacturer had originally called for a limit in drinking water of one part per billion);; Theo Colburn, Dianne Dumanoski, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?--A Scientific Detective Story (1997). Amanda Follett, Ignorance is Bliss? Balancing the Public's Right to Know and Industry's Claim to Confidential Business Information in TSCA Reform, 11 Rutgers J.L. & Pub. Pol'y 590, 601(2014).

[42] Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53(4) Utah Law Review, 1305, 1308-09 (2004).

[43] *Id.* at 1308.

[44] Sheldon Krimsky, Hormone Disruptors: A Clue to Understanding the Environmental Causes of Disease, 43 ENV'T 22, 27-29 (June 2001).

[45] Theo Colburn, Dianne Dumanoski, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?--A Scientific Detective Story (1997).

[46] *See* Kalyn Behnke, Comment, Toxic Preemption: Why the Lautenberg Chemical Safety Act's Erosion of State Authority Contaminates Environmental Law, 57 Juremetrics J. 459, 460 (2017).

[47] Scientists have said that PFOA's long used in Teflon coatings, for example, are suspected EDCs, and have a probable link to cancer. Rich, supra note __; Chemicals that are suspected of having adverse affects on the endocrine system are

ubiquitous. They include: tributylin, found in paint; flame retardants used in furniture; chemicals found in carpeting; electronic products; bisphenol-A, a chemical used in the lining of food and beverage containers; phthalates, found in plastics; pesticides; chemicals found in cosmetics; and alkylphenols, used in detergents. Additionally, hormone-disrupting chemicals are produced in paper manufacturing and in other combustion and industrial processes. These chemicals are found in our air and seep into our drinking water. Erin Gill, Cleaning Your Home Can Make You Ill, THE EVENING STANDARD, Nov. 25, 2003, at A26, available at 2003 WL 66596375 (noting that everyday items such as electrical goods, nonstick frying pans, and sofa and foam seating contain chemicals suspected of endocrine disruption)(adapted from Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53(4) Utah Law Review, 1305-1333, 1309 (2004)).

[48] *See* EPA on PCBs, supra note 1; Stockholm Convention on Persistent Organic Pollutants (POPs), PCBs Overview, http://chm.pops.int/Programmes/PCBs/Overview/tabid/273/language/enUS/Default.aspx (last visited Mar. 12, 2010) (including PCBs on list of chemicals that need to be eliminated); https://www.britannica.com/science/polychlorinated-biphenyl (sited visited April 18, 2018); Valerie Watnick, PCBs

facturers had evidence that PCBs presented an unreasonable risk to human health and the environment, including endocrine disruption.[50] In the years since their production has been mostly halted in this country, experts have deemed PCBs one of the most enduring and toxic substances[51] ever manufactured.[52]

Today, PCBs are still found in oceans, rivers, human blood, the tissues of animals and fish,[53] as well as widely embedded in school building materials across the country.[54] Indeed, even while PCBs are one of the few chemicals severely restricted in their use[55] under TSCA since 1979, they are not subject to an outright ban and still contribute to vast environmental pollution around the globe.[56]

B. Overview of Existing Federal Statutes Regulating Toxic Substances

The "proof is in the pudding" in the vast degree of contamination noted above,[57] and in that in the thirty plus years of the Toxic Substance Control Act's existence, federal regulation has only required testing of 200 chemicals and has banned or restricted less than ten of these chemicals.[58] The TSCA and accompanying regulation has not been effective at protecting humans

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in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company, 33(2) Environs, Environmental Law and Policy Journal, UCLA Davis 231, 238 (2010).

[49] 15 U.S.C. § 2605(e) et seq. (2010). The U.S. Environmental Protection Agency ("EPA") issued a final rule to implement section 6(e) of the Toxic Substances Control Act ("TSCA") on May 31, 1979. Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions, 40 C.F.R. pt. 761 (1982); see https://www.epa.gov/pcbs/polychlorinated-biphenyl-pcb-containing-fluorescent-light-ballasts-flbs-school-buildings#risks (visited April 4, 2018).

[50] *See* Monsanto sold banned chemicals for years despite known health risks, archives reveal, August 10, 2017, The Guardian, US Edition, found at: https://www.theguardian.com/environment/2017/aug/09/monsanto-continued-selling-pcbs-for-years-despite-knowing-health-risks-archives-reveal; Valerie Watnick, PCBs in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company, 33(2) Environs, Environmental Law and Policy Journal, UCLA Davis 231, 238 (2010); Transwestern Pipeline Co. v. Monsanto Company, 53 Cal.Rep.2d 887, 890 (Ct. App. 1996) (court finding that Monsanto learned that PCBs were persistent in the environment and that in 1970, it began placing warning labels on some of its products).

[51] Jan Alexander et al., Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from the Commission Related to the Presence of Non Dioxin-like Polychlorinated Biphenyls (PCB) in Feed and Food, 284 European Food Safety Auth. J. 1, 89 (2005), available at http://www.efsa.europa.eu/en/efsajoumal/doc/284.pdf.

[52] *See* Valerie Watnick, PCBs in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company, 33(2) Environs, Environmental Law and Policy Journal, UCLA Davis 231, 238 (2010).

[53] https://www.britannica.com/science/polychlorinated-biphenyl (site visited April 18, 2018).

[54] Valerie Watnick, PCBs in Schools and Corporate Responsibility for Remediation: Yorktown Central School District v. Monsanto Company, 33(2) Environs, Environmental Law and Policy Journal, UCLA Davis 231 (2010).

[55] *Id.* at 233, 238.

[56] Stockholm Convention on Persistent Organic Pollutants, May 23, 2001, 40 I.L.M. 532, available at https://www.cambridge.org/core/journals/american-journal-of-international-law/article/div-classtitlethe-stockholm-convention-on-persistent-organic-pollutantsdiv/47E6AE71CC66943C239D5383B2B935C0 (last visited April 18, 2018)

[57] *See supra* notes 36 to 52 and accompanying discussion.

[58] United States Environmental Protection Agency, Testimony of Steve Owens, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency before the Subcommittee on Commerce, Trade, and Consumer Protection Committee on Energy and Commerce, U.S. House of Representatives, 2010, Available at:
https://archive.epa.gov/ocir/hearings/testimony/111_2009_2010/web/pdf/2010_0729_so.pdf; see also Tracy Bach, Better Living Through Chemicals (Regulation)? The Chemical Safety Improvement Act of 2013 Through An Envi-

from the deluge of chemicals by industry.[59] Indeed, Congress recognized the need for a more proactive stance to toxics regulation as early as the 1970's, and originally designed TSCA to be a catch all, proactive statute, requiring testing of the burgeoning population of chemicals brought to market after World War II.[60] And while there are some 20 plus other laws that also regulate toxic substances (and their use in consumer products),[61] these laws do not generally require proactive testing and safety affirmation before a chemical goes to market.[62]

For example, cosmetics are regulated by the Food and Drug Administration, pursuant to the Federal Food, Drug, and Cosmetics Act of 1938.[63] The major provision regulating cosmetics prohibits both "adulterated" and "misbranded" cosmetics.[64] Misbranded cosmetics are those not properly labeled[65] and adulterated cosmetics are those that are made under "unsanitary," "putrid" or "filthy" conditions that "may be injurious or deleterious to users."[66] These statutory definitions of "misbranded" and "adulterated" remain in place today, although the Act was originally

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ronmental Public Health Law Lens , 15 Vermont Envtl.L. 490, 503 (spring 2014) (discussing the failure of TSCA over the past few decades).

[59] *See* U.S. General Accounting Office. Testimony before the Subcommittee on Toxic Substances, Research and Development. Committee on Environment and Public Works, U.S. Senate. Toxic Substances Control Act. Preliminary Observations on Legislative Changes to make TSCA more Effective. GAO/T-RCED-94-263. 1994 July 13. http://www.gao.gov/assets/110/105646.pdf ; Sheldon Krimsky, The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act, PLOS direction,. Dec. 15, 2017, found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5734679/ (last visited 7/4/18);

Noah Sachs, RESCUING THE STRONG PRECAUTIONARY PRINCIPLE FROM ITS CRITICS, 11 U. Ill. L. Rev. 1285, 1288, 1290(calling the existing regulatory structure moribund and noting that the Strong Precautionary Principle presumptively calls for regulatory action where a product or substance poses serious threats to human health or the environment, where there is no clear scientific certainty of the risk and that the burden of overcoming the presumption in favor of regulation rests with the manufacturer or producer); see U.S. Gov't Accountability Office, GAO-09-428T, Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act (2009); *See* Dep't of Health & Human Serv. et al., National Report on Human Exposure to Environmental Chemicals (2018) found at: https://www.cdc.gov/exposurereport/index.html ; Tracey J. Woodruff et al., Environmental Chemicals in Pregnant Women in the US: NHANES 2003-2004, Envtl. Health Persp. 878, 879 tbl.1 (2011); Nicole Bijlsma and Marc M. Cohen, Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room, Int J Environ Res Public Health, 2016 www.ncbi.nlm.nih.gov/pmc/articles/PMC4772201/; *see* Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53 Utah Law Review, No. 4, pp. 1305-1333 (2004).

[60] Council on Environmental Quality, Environmental Quality: The Eighth Annual Report of the Council on Environmental Quality 5 (1977).

[61] *See* Robert L. Glicksman, David L. Markell, William W. Buzbee, Daniel R. Mandelker & A. Dan Tarlock, Environmental Protection: Law and Policy 780, Table 8-2 (5th ed. 2007))(listing the more than 20 federal laws that regulate toxic substances).

[62] *See infra* notes 63 to 103 and accompanying discussion. There are some exceptions to the fact that U.S. toxics law is not proactive in nature. For example, the FDA's review process for drugs is proactive and requires the manufacturer to prove that the drug is safe before it goes to market. See 21 U.S.C. § 355(a)-(d). Some commentators have called FIFRA proactive in that it requires manufacturers to provide basic information before marketing and also requires mandatory federal labeling. See John S. Applegate, The Precautionary Preference: An American Perspective on the Precautionary Principle, 6 Hum. & Ecological Risk Assessment 413, 420 (2000).. However, FIFRA does not require major safety testing before a pesticide goes to market and it is primarily a marketing and labeling statute. *See* Valerie Watnick, FEDERAL PREEMPTION OF TORT CLAIMS UNDER FIFRA: THE EROSION OF A DEFENSE, 36 U. Mich. J.L. Reform 419 (2004).

[63] 21 U.S.C. §§ 301-399f.

[64] 21 U.S.C. § 331(a).

[65] *Id*.; 21 U.S.C § 362(a)-(c).

[66] 21 U.S.C. § 331(a); 21 U.S.C. § 361(a)-(d).

enacted in 1938,[67] and even as we have made vast strides in our scientific and technological knowledge in the last century.[68] Use of terms such as putrid and filthy focus on *acute* risks from cosmetics and evince a lack of understanding of current corporate production, and a total lack of concern about the long-term effects of a cosmetic product on the user.[69] By these standards, most cosmetic products are considered safe in the United States today, absent some meaningful proof of harm in the long-term, which is not regularly available."[70]

Federal cosmetics law, almost 40 years old, does not require premarket testing before sale, and thus, cannot possibly protect the public from long-term use of cosmetics that might contain toxic substances.[71] This is particularly troubling in that most consumers incorrectly assume that all chemicals, including those used in cosmetics in the U.S. market, are subject to rigorous testing and scrutiny.[72]

While food is more heavily regulated in the U.S. than cosmetics in theory, the Food Quality Protection Act (the "FQPA"), passed in 1996,[73] regulates the amount of residue or deleterious substances that may be found on fresh and processed food.[74] The 1996 FQPA amended the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA,) and the Federal Food, Drug and Cosmetic Act ("FFDCA"), both of which regulate the use of pesticides on food crops in the United States.[75] FIFRA requires that a pesticide must be registered for use,[76] but before a pesticide may be registered for a food use, the EPA must establish a legal limit on a pesticide residue, known as

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[67]The following discussion is adapted from: Valerie J. Watnick, The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment 31(3) Pace Environmental Law Review, 595, 602 (2014).

[68] *Id.*

[69] *Id.*

[70] *Id.* at 602 (2014); see also Mary O'Brien, Our Current Toxics Use Framework, Our Stolen Future, and Our Options, 11 J. ENVTL. L. & LITIG. 331, 346-51 (1996) (reviewing Theo Colburn et al, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? - A Scientific Detective Story (1996).

[71] Seven chemicals, such as: Dioxane, petrolatum, formaldehyde, synthetic fragrance, talc, parabens and phthalates found in cosmetic products are considered to be carcinogenic. N Parsa, Environmental Factors Inducing Human Cancers, Iran J Public Health, 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3521879/ at 6.; *see* Valerie J. Watnick, 31(3) The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment (2014), available at: https://digitalcommons.pace.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1749&context=pelr (last visit on March 26, 2018) ;Eric Lipton & Rachel Abrams, Their Hair Fell Out. Should the F.D.A. Have the Power to Act? N.Y. Times, Aug. 15, 2016; Testimony of Scott Faber Senior Vice President for Government Affairs Environmental Working Group on Exploring Current Practices in Cosmetics Development and Safety before the Senate Committee on Health, Education, Labor and Pensions September 22, 2016 (found at: http://www.nytimes.com/2016/08/16/us/politics/cosmetics-industry-congress-regulationwen.html?_r=0; https://www.help.senate.gov/imo/media/doc/Faber.pdf).

[72] Ian Urbina, Think Those Chemicals Have Been Tested? New York Times, 2013, http://www.nytimes.com/2013/04/14/sunday-review/think-those-chemicals-have-been-tested.html.

[73]Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (codified as amended in various sections of7 U.S.C. and 21 U.S.C.) [hereinafter FQPA). The FQPA amends the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (1994 & Supp. III 1997) [hereinafter FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136 et seq. (1994 & Supp. III 1997) [hereinafter FIFRA]. FIFRA regulates the registration of pesticides for all uses and FFDCA regulates their use on food.

[74] Valerie Watnick, Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children, 31 Ariz. St. L.J. 1315, 1337 (1999).

[75] *See* Valerie Watnick, Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children, 31 Arizona state Law J. 1315, 1319 (1999);17 U.S.C. §§ 136a(a) (1994) 17. 21 U.S.C. §§ 321 et seq. (1994); 18.

[76] *See* 7 U.S.C. §§ 136a(a) (1994).

a tolerance, or an exemption from a tolerance, [77]pursuant to the FFDCA.[78] Tolerances are set for the food use on a single crop,[79] based on limited toxicity information, including available epidemiological studies, animal studies and exposure information.[80] Risk assessors, however, often lack basic information and must perform their assessments making multiple assumptions and judgments.[81]

Moreover, once the risk assessment is performed and the tolerance set, actual enforcement of these "tolerable" residue levels is inconsistent at best,[82] and potentially very misleading.[83] The USDA performs periodic residue testing, but on a per crop basis.[84] In USDA testing for the period ended 2016[85] and prior to 2015, the majority of crops contained pesticide residues and many contained residues from multiple pesticides.[86] Yet, one survey found that many Amer-

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[77] *See* 21 U.S.C. § 342 (1994 & Supp. III 1997) and 21 U.S.C.§ 346a(a)(1)(A) (1994 & Supp. III 1997); 7 C.F.R. § 205.670(e).

[78] *See* 21 U.S.C. § 346a(a)(1) (1994 & Supp. III 1997).

[79] *See* Valerie Watnick, Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children, 31 Arizona State Law J. 1315, 1319 (1999).

[80] EPA, Setting Tolerances for Pesticide Residues, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#food-safety (last visited April 23, 2018).

[81] EPA, About Risk Assessment found at; https://www.epa.gov/risk/about-risk-assessment ("risk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree")(last visited April 23, 2018); Watnick, Valerie, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 2004(4) Utah Law Review 1305, 1318-20 (2004) (Available at SSRN: https://ssrn.com/abstract=2284981 or http://dx.doi.org/10.2139/ssrn.2284981)

[82] Consumer Reports, Eat the Peach, Not the Pesticide, March 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food) (visited April 4, 2018); Valerie Watnick, The Organic Foods Production Act, the Process/Product Distinction, and a Case for More End Product Regulation in the Organic Foods Market 32:(1) Journal UCLA Journal of Environmental Law and Policy 40 (2014) (Permalink https://escholarship.org/uc/item/8h49r7k1).

[83] Consumer Reports, Eat the Peach, Not the Pesticide, March 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food) (visited April 4, 2018) (noting that more than half of crops tested by the USDA had pesticide residues on them, with the majority below tolerance levels).

[84] USDA Releases 2016 Annual Pesticide Date Program Summary, February 8, 2018)(press release on two year old testing noting that 78 % of crops tested contained pesticide residues); see Consumer Reports, Eat the Peach, Not the Pesticide, March 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food) (visited April 4, 2018)

[85] USDA Releases 2016 Annual Pesticide Date Program Summary, February 8, 2018)(press release on two year old testing noting that 78 % of crops tested contained pesticide residues).

[86] One industry group in 2016 maintained that crop residue testing proved crop safety in that only .36% of crops had pesticide residues exceeding allowable tolerance levels. CropLife America, USDA Pesticide Data Program Report Confirms Food Safety, January 13, 2016, http://www.croplifeamerica.org/news/2017/10/26/usda-pesticide-data-program-report-confirms-food-safety (last visited on: April 9, 2018); A U.S. government study of pesticide residues on organic foods in 2014 likewise found that residue levels on many crops exceeded even those allowable tolerances for conventional crops.[7] On November 8, 2012, the National Organic Program formally required organic certifiers to test products for prohibited substances and pesticide residues. The memorandum followed a 2010-11 pilot study by the NOP that tested 571 samples for pesticide residues. Memorandum from Miles McEvoy, Deputy Administrator, National Organic Program, to the National Organic Program Standards Board (Sept. 27, 2012), http://www.ams.usda.gov/AMSv1.0 /getfile?dDocName=STELPRDC5100672. Fifty seven percent of those samples tested had no residue at all and 96% complied with existing organic regulations. U.S.DEP'T OF AGRIC.,2010-2011 PILOT Study: Pesticide Resi-

icans believe that there is a legal limit to how many *different* residues may be found on a food product, when no such legal limit exists.[87] When the various pesticides are mixed together, the effect on human health is untested and unknown.[88] Indeed, the original tolerance, based on single chemical risk assessment, with some accounting for multiple pathways of exposure, and chemicals that act in similar manners,[89] does not adequately account for real life risk.[90] Pursuant to the FQPA, the risk assessor is to use "available" information on aggregate risk and common mechanisms of toxicity.[91] However, these factors do not account for the synergistic effects of the chemical or combined effects of multiple, daily chemical exposures to this and other chemicals (cumulative risk),[92] or fully account for individual human differences and reactions to chemical exposure (intra-species risk).[93]

Similar to the FQPA, the Safe Drinking Water Act[94] regulates the level of poisonous substances that may be found in public drinking water substance by substance. The Act speaks in terms of "not fewer than "5 contaminants per year" to be considered for regulation and then the setting of "maximum contaminant levels within 24 months" of the decision to regulate.[95] Just as in the results regarding crop testing, water testing has shown multiple different toxins in drinking water, and also, levels of toxins that exceed federal health limits and guidelines for individual toxic substances in drinking water.[96] Recent Environmental Working Group data, including data

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due Testing of Organic Produce (Nov. 2012), http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101234.

[87] Consumer Reports, Eat the Peach, Not the Pesticide, March 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food) (visited April 4, 2018)

[88] *See* Consumer Reports, Eat the Peach, Not the Pesticide, March 19, 2015, https://www.consumerreports.org/cro/health/natural-health/pesticides/index.htm (detailing and analyzing U.S. data on pesticide residues in food) (visited April 4, 2018).

[89] 21 U.S.C. § 346a(b)(2)(D)(iv)(v) (calling for consideration of aggregate exposures to a pesticide as well as consideration of chemicals that have a common mechanism of toxicity).

[90] Sanne H. Knudsen, Regulating Cumulative Risk, 101 Minn. L. Rev. 2313, 2324 (2017).

[91] 21 U.S.C. § 346a(b)(2)(D)(iv)(v).

[92]Knudsen, *supra* note 90, at 2315-17, 2322 , 2360-61 (making the important case that cumulative risk assessments must take "center stage" in regulation in that we are bombarded daily with synthetic chemicals and that individuals cannot control their personal chemical exposures); *see also* Adam Abelkop and John Graham, Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union, 32 Pace Envtl. L. Rev. 108, 120 (2015).

[93] "Such [risk] assessment rely heavily on data extrapolated from human epidemiology, animal testing and cell culture/in vitro laboratory studies that fail to account for multiple routes of exposure, mixture effects, transgenerational epigenetic effects or individual human risk factors such as age, gender, genetics, nutrition, psychosocial determinants and comorbidities." Nicole Bijlsma and Marc M. Cohen, Environmental Chemical Assessment in Clinical Practice: Unveiling the Elephant in the Room, Int J Environ Res Public Health, at 4, 2016 www.ncbi.nlm.nih.gov/pmc/articles/PMC4772201/(citing Pool R., Rusch E. Identifying and Reducing Environmental Health Risks of Chemicals in Our Society: Workshop Summary. National Academies Press; Washington, DC, USA: 2014; Darbre P.D. Chapter 16—An introduction to the challenges for risk assessment of endocrine disrupting chemicals. In: Darbre P.D., editor. Endocrine Disruption and Human Health. Academic Press; Boston, MA, USA: 2015. at 289–300l; Zeliger H. Human Toxicology of Chemical Mixtures. 2nd ed. William Andrew; Binghamton, NY, USA: 2011).

[94] Safe Drinking Water Act, 42 U.S. Code § 300f et. seq. The 1996 Amendments to the Act call for the EPA to use the "best available peer reviewed science" and to consider costs and benefits when making regulations. 42 U.S. Code § 300g–1.

[95] 42 U.S. Code § 300g–1 (b)(1)(B)(i)(III).

[96]EWG, New York City System, https://www.ewg.org/tapwater/system.php?pws=NY7003493#.WrKFcYjwbic (Last visit on March 21, 2018); Simone Wilson, Is NYC Tap Water Safe? 6 Cancer-Causing Chemicals Found At 'Unsafe' Levels: Report, New York City Patch, https://patch.com/new-york/new-york-city/nyc-tap-water-safe-6-cancer-causing-chemicals-detected-unsafe-levels-study (Last visited on March 26, 2018).

on one of the largest water systems in the country and touted to be one of the safest, found six toxic contaminants in the water of New York City above federal legal limits:[97] four of these substances considered carcinogens.[98] In the states of California and Texas, the Study found ten contaminants above federal health limits, in water serving over one million people.[99] Common sense dictates that the pace of regulation under the SDWA is too slow, too reactive, and too narrowly focused on one contaminant at a time to adequately protect human health.

Air pollution is similarly regulated under federal law by the Clean Air Act, which authorizes the EPA to issue air quality standards known as National Ambient Air Quality Standards and to enforce these standards.[100] Yet, the Clean Air Act only regulates a small subset of the pollutants (less than 200 out of thousands) that firms emit and firms are not required to completely eliminate emissions but to stay within limits and use the "maximum degree of reduction" possible, taking into account the cost of such reductions.[101] Despite early successes at improving ambient air quality,[102] one recent study found the air is still not clean enough in that "almost 95% of Americans continue to breathe unsafe levels of hazardous air pollutants" known to cause cancer or other health effects.[103]

II. The TSCA and its Legacy: Catch 22 and Grandfathering of Existing Chemicals

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[97] EWG, New York City System, https://www.ewg.org/tapwater/system.php?pws=NY7003493#.WrKFcYjwbic (Last visit on March 21, 2018); Simone Wilson, Is NYC Tap Water Safe? 6 Cancer-Causing Chemicals Found At 'Unsafe' Levels: Report, New York City Patch, https://patch.com/new-york/new-york-city/nyc-tap-water-safe-6-cancer-causing-chemicals-detected-unsafe-levels-study (Last visit on March 26, 2018).

[98] EWG, New York City System, https://www.ewg.org/tap water/system.php?pws=NY7003493#.WrKFcYjwbic (Last visit on March 21, 2018); Water pollution is caused by many factors, one of which is organic compounds that include, oil, plastics, detergents, chloroform, petroleum, PCBs, Fertilizer, sulfur oxide, pesticide and trichloroethylene, all of which are purportedly regulated by federal regulation. N Parsa, Environmental Factors Inducing Human Cancers, Iran J Public Health, 2012, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3521879/#b35-ijph-41-1; NEED Full cite of web above; Hogan CM. In: Water pollution Encyclopedia of Earth. McGinley Mark., editor. National Council on Science and the Environment; Washington, DC: 2010. pp. 70–190. Topic ed. ed in chief Cleveland.

[99] EWG Tap Water Database released July 26, 2017 found at: https://www.ewg.org/tapwater/#.WuNH-SMrJz_ (last visited April 27, 2018).

[100] The Clean Air Act, 42 U.S.C. 7401 et seq. The Act requires that private actors keep their emissions in check so that they do not violate the National Ambient Air Quality Standards except in cases of "major" sources. In cases where an entity will be a major source of air pollution, the actor must proactively seek a permit. See 42 U.S.C. § 7661a(a) (2006).

[101] 42 U.S.C. § 7412(a) and (d)(2); *See* Sachs, Strong Precautionary Principle, *supra* note _- at 1327, noting that only a small fraction of the thousands of air pollutants have been tested for their toxic properties.

[102] The Clean Air Act has in fact been called one of the great success stories of environmental regulation. Lisa Heinzerling, The Clean Air Act and the Constitution, 20 St. Louis U. Pub. L. Rev. 121, 121-23 (2001), found at: https://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?referer=https://search.yahoo.com/&httpsredir=1&article=1523&context=facpub .

[103] Michelle West, "Once In, Always In" Now Out: How the EPA is Reducing Regulations on Hazardous Air Pollutant Emitters," Georgetown Environmental Law Review online, March 3, 2018 (noting that "almost 95% of Americans breathe unsafe levels of hazardous air pollutants" known to cause cancer or other health effects.); see Envtl. Prot. Agency, Hazardous Air Pollutants, https://www.epa.gov/haps/what-are-hazardous-air-pollutants (last updated Feb. 9, 2017); *cf* Connor M. Callahan, Ransboundary Pollution and Cercla Liability: International Manufacturers' Ability To Exploit Aerial Depositions, 54 Idaho L. Rev. 145 (2018). The current administration is also currently rolling back air quality regulations. See Alexander Kaufman,EPA To Gut The Only Major Federal Rule To Cut Climate Pollution From Vehicles, Huffington Post, April 3, 2018, found at: https://www.huffingtonpost.com/entry/trump-epa-tailpipe-emissions_us_5abd595ae4b0f112dc9aefa5

In addition to federal law that regulates cosmetics, food, air and drinking water, as a catch all federal law, Congress designed the Toxic Substances Control Act in the 1970s, as a tool to regulate toxic substances not otherwise covered by regulation.[104] Under TSCA, however, EPA has had difficulty requiring manufacturers to provide adequate safety information on new chemicals and restricting production and marketing of new or existing chemicals.[105]

The TSCA has proven largely ineffective mainly due to a "catch 22" provision[106] embedded in the regulatory framework alongside the grandfathering of more than 60,000 existing chemicals at the time of its passage.[107] The TSCA did not allow EPA to require testing of a chemical if it did not have adequate data, but also did not allow the EPA to request such information from industry unless it *already* believed the chemical presented an unreasonable risk to public health or the environment, a claim difficult to make without data.[108] EPA could only request information if it already had some data to inform it that a chemical was a danger to human health or the environment: the "catch 22" nature of the old TSCA.[109] By putting the EPA in the bind of not having enough information to declare a chemical unsafe, the old TSCA also created a disincentive for the chemical industry to ever do any testing as they would not want to create any "negative," available information. Thus, not only did the TSCA prevent EPA from effectively regulating, but it also created disincentives for industry to test the safety of its own products. In the ensuing years since Congress passed TSCA, industry introduced new chemicals freely and also continued to produce and use most of the grandfathered chemicals.[110]

In addition to this ineffective process of existing chemical review, new chemicals, by way of a Pre-manufacture Notice by the manufacturer and then a determination by EPA, were also routinely approved without adequate testing data, sometimes based on similar compound structure.[111] For example, in September 2016, the EPA issued a Determination for Pre-

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[104] H.R. 114-176 (2015)("In 1971, the President's Council on Environmental Quality proposed comprehensive Federal legislation to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes."); 15 USC § 53: Toxic Substances Control, http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim (Last Visit on April 9, 2018).

[105] U.S. Gov't Accountability Office, GAO-09-428T, Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act 3 (2009); see supra notes _ to _ and accompanying discussion.

[106] Charles Schmidt, TSCA 2.0: A New Era in Chemical Risk Management, 124(10) Environmental Health Perspectives (October, 2016);
The EPA could not even ban asbestos under TSCA. See Corrosion Proof Fittings, et al. v. the Environmental Protection Agency and William K. Reilly. 947 F2d 1201 (5th Cir 1991). Available at: http://law.justia.com/cases/federal/appellate-courts/F2/947/1201/153685/(court stated that the EPA could have less restrictively handled asbestos by requiring less burdensome manner to do so such as labeling).

[107] 82 Fed. Reg. 4826, 4826 (January 17, 2017) found at: https://www.federalregister.gov/documents/2017/01/17/2017-00051/procedures-for-prioritization-of-chemicals-for-risk-evaluation-under-the-toxic-substances-control (discussing background on and need for recent 2016 amendments to the TSCA).

[108] Eve Gartner, Earthjustice Blog, Weak Laws and Weaker Governance Keep Toxic Chemicals on the Market, April 7, 2016. ((found at
https://earthjustice.org/blog/2016-april/weak-laws-and-weaker-governance-keep-toxic-chemicals-on-the-market).

[109] David Markell, New Directions in Environmental Law: An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation, 32 Wash. U. J.L. & Pol'y 333, 355, 359 (2010);
Charles Schmidt, TSCA 2.0: A New Era in Chemical Risk Management, 124(10) Environmental Health Perspectives (October, 2016);

[110] EPA Office of Inspector General, EPA Needs a Coordinated Plan to Oversee Its Toxic Substances
Control Act Responsibilities 4 (Feb. 17, 2010), found at: https://www.epa.gov/sites/production/files/2015-09/documents/20100217-10-p-0066.pdf

[111] EPA relies on structure activity relationships to determine if a new chemical will act like one structurally similar to it. See Richard Denison, EPA's New Chemicals Program: TSCA Dealt EPA a Very Poor Hand (April 16, 2009)

manufacture Notice (PMN) that polyester polyol polymer with aliphatic isocyanate and phenol was "not likely to present an unreasonable risk" under the new LSCA.[112] EPA estimated "the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard," which allowed it to conclude that "there is low concern for human health hazard for the chemical substance."[113]

These new chemical approvals based on similar chemical structures without complete toxicity data, additional approvals of new chemicals absent complete safety data,[114] the grandfathering of more than 60,000 existing chemicals,[115] alongside the widely exploited loophole in TSCA preventing the EPA from requesting additional health and safety data information on a substance, all allowed the development of a weak toxics substances regulatory scheme in the last 40 plus years. When EPA did try to regulate, it had to demonstrate that the benefits of regulating outweighed the costs and that it had regulated in the least burdensome manner.[116] Over the last half century, the EPA has largely had to assume chemicals safe unless proven otherwise, or "innocent until proven guilty."

In the more than forty years since the enactment of TSCA, the federal government has only called for testing of 200 chemicals and restricted the use of less than ten.[117] Essentially, TSCA placed the burden on EPA to show that a health or safety issue existed, rather than on the producer to show that its chemical is safe.[118] Asbestos, for example, while once thought to be safe, is now known to be toxic to man and the environment,[119] and a known human carcinogen.[120] Yet, asbestos, even after a protracted court battle,[121] is not banned for use under TSCA,

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found at: http://blogs.edf.org/health/2009/04/16/epas-new-chemicals-program-tsca-dealt-epa-a-very-poor-hand/ (last visited April 23, 2018).

[112] TSCA Section 5(a)(3)(C) Determination for Pre-manufacture Notice (PMN) P-16-0391) (Sept. 14, 2016), available at: https://www.epa.gov/sites/production/files/2016-09/documents/p-16-0391_determination_non-cbi_final.pdf .

[113] TSCA Section 5(a)(3)(C) Determination for Pre-manufacture Notice (PMN) P-16-0391) (Sept. 14, 2016), Available at: https://www.epa.gov/sites/production/files/2016-09/documents/p-16-0391_determination_non-cbi_final.pdf. Richard Denison, TSCA Dealt EPA a Very Poor Hand, Environmental Defense Fund Blog (April 16, 2009) found at: http://blogs.edf.org/health/2009/04/16/epas-new-chemicals-program-tsca-dealt-epa-a-very-poor-hand/ (last visited April 23, 2018).

[114] *See infra* notes 148 to 149 and accompanying discussion.

[115] Charles Schmidt, TSCA 2.0: A New Era in Chemical Risk Management, 124(10) Environmental Health Perspectives 182 (October, 2016).

[116] *Corrosion Proof Fittings, et al. v. the Environmental Protection Agency and William K. Reilly*. 947 F2d 1201, 1229 (5th Cir 1991)(requiring EPA to use the least burdensome option to regulate under TSCA); Wilson MP, Schwarzman MR. Towards a new U.S. chemicals policy: rebuilding the foundation to advance new science, green chemistry, and environmental health. become Health Persp. 2009. August;117(8):1202–1209. [PMC free article] [PubMed]

[117] Charles Schmidt, TSCA 2.0: A New Era in Chemical Risk Management, 124(10) Environmental Health Perspectives 182, 183 (October, 2016). The lack of a proactive mechanism is a common regulatory approach in the U.S. Under the FQPA, EPA can only ask for more information if it has information to determine that a chemical is harmful. Thus, pesticide manufacturers are dis-incentivized to ever test for ill effects and the EPA does not have the resources or the power to require testing absent most ill effects. While it is the case that the FQPA does call for some additional protections to be built into pesticide tolerances where data is absent and to protect children, the EPA has been reluctant to apply these added protections to vulnerable populations. *See* 21 U.S. Code § 346a (b)(2)(C).

[118] David Markell, An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation, 32 WASH. U. J.L. & POL'Y 333, 355 (2010)

[119] *See* Center for Disease Control Classifying Asbestos as Carcinogen, found at: https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=4 (classifying asbestos as a known human carcinogen) (visited April 4, 2018).

[120] *See e.g.*. Irving J. Selikoff, M.D.†, Jacob Churg, M.D.‡, and E. Cuyler Hammond, Relation between Exposure to Asbestos and Mesothelioma, New England Journal of Medicine, March 18, 1965 (noting the relationship between

but rather, certain asbestos containing product uses are merely restricted.[122] The EPA has thus banned *new* uses of asbestos, but has not affected an outright ban on the substance.[123]

In addition to the TSCA language limiting effective regulation, "chronic underfunding" of new research initiatives for premarket notification rulings and lack of staff have not allowed the EPA to effectively manage the sheer number of new chemical applications, or its review of existing chemicals.[124]

The TSCA regulatory scheme, alongside the rest of our reactive federal toxics law that does not require complete safety data before a chemical is brought to market or used in a consumer product, has resulted in a situation where manufacturers produce most synthetic chemicals in the U.S. without adequate safety testing and data. This reactive and fragmented aspect of our toxics regulation effectively makes Americans guinea pigs for myriad chemical bombardments daily.[125]

In some instances, states acted to fill the federal regulatory void to protect people and the environment from toxic substances. [126] California,[127] Maryland,[128] Massachusetts,[129] Vermont[130] and Oregon,[131] for example, all have more restrictive chemical regulations aimed at protecting

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asbestos exposure and cancers of the lung and gastrointestinal tract and studying the relationship of asbestos to Mesothelioma).

[121] *Corrosion Proof Fittings, et al. v. the Environmental Protection Agency and William K. Reilly*. 947 F2d 1201, 1229 (5th Cir 1991)(requiring EPA to use the least burdensome option to regulate under TSCA).

[122] https://www.epa.gov/asbestos/us-federal-bans-asbestos#notbanned ; Asbestos use is still permitted in myriad products, including, for example, disk brake pads, rood coatings, clothing and vinyl floor tile; see 16 C.F.R. § 1145.4 (banning certain new asbestos compounds); 15 U.S.C. § 2605 (2010) (allowing the EPA to ban any substance that presents an unreasonable risk to health or the environment).

[123] *See* Charles G. Garlow, Asbestos - the Long-Lived Mineral, 19 NAT. RES. & ENV'T 36, 36 (2005); See 16 C.F.R. § 1145.4 (banning certain new asbestos compounds); 15 U.S.C. § 2605 (2010) (allowing the EPA to ban any substance that presents an unreasonable risk to health or the environment); Asbestos Safety and Eradication Agency, about asbestos, https://www.asbestossafety.gov.au/about-asbestos/about-asbestos (Last visited on March 21, 2018). Recently and shockingly, consumers even found asbestos in some children's make up products in summer 2017, prompting Senator Diane Feinstein of California to propose a new law for cosmetics, at least partially aimed at keeping asbestos out of personal care products. Robert Coleman, EWG News Roundup (7/21): Trump's Troubling 6 Months, Asbestos in Children's Cosmetics and Chemical Industry Shill Tapped for Top EPA Slot, https://www.ewg.org/enviroblog/2017/07/ewg-news-roundup-721-trump-s-troubling-6-months-asbestos-children-s-cosmetics-and#.WqCIiyMrJz8 (Last visited on March 21, 2018); *see* Personal Care Products Safety Act 2017, https://www.congress.gov/bill/115th-congress/senate-bill/1113 (Last visited on March 21, 2018).

[124] Bach, *supra* note __, at 506. It is worth noting that since the enactment of the LSCA, the EPA has been eliminating the back log of new chemical applications quickly, approving most new chemicals for commercialization and has banned zero of the new chemicals submitted for review. ,https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last visited June 12, 2018).

[125] *See infra* notes 29 to 52 and accompanying discussion.

[126] Letter from Kamala D. Harris et al., California Attorney General, to Sen. Barbara Boxer, Chairwoman, Subcomm. on Env't & Pub. Works. (July 31, 2013) (on file with author), available chemical (Hereinafter, Multi-states Letter).

[127] *See* Cal. Code Regs. tit. 22, div. 4.5, ch. 55, §§ 69501–10 (2013); 27 Cal. Health and Safety Code section 25249.5. (1986)("Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986.)

[128] Md. Code Ann., Envir. § 6- 1202, 6-1303 and 6-1402.

[129] *See e.g.*. MA. General Laws ch. 21I.

[130] *See* Chemicals. 18 Vt. Stat. Ann. § 1511, 1512 (banning phthalates and bisphenol A).

[131] *E.g.,*ORS 453.055.

consumer health, particularly children's health,[132] and some of these regulatory efforts will be discussed in Part IV.

III. The LSCA

A. Compromise

In the years leading up to the LSCA, both public interest groups and industry pushed for reform. State coalitions sought legislation that would not preempt them from continuing to regulate to protect health.[133] Public interest groups urged that the existing law hamstrung the EPA by not allowing it to ask producers for more health and safety information.[134] Industry also sought reform to avoid a patchwork of state laws, build jobs and maintain innovation.[135] In summer 2016, Congress at last overhauled the TSCA with the enactment of the LSCA. The new Act, hailed as an improvement for public health,[136] was also lauded by the industry as a victory for the chemical companies.[137]

B. Reform

1. Summary

In passing the LSCA in summer 2016, Congress envisioned a more health protective toxics regulatory system.[138] The new Act attempted to correct parts of the "catch 22" nature of the TSCA, eliminating the need for a preliminary finding of risk before the EPA could require manufacturers to submit health and safety data.[139] Specifically with regard to new chemicals and sig-

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[132] Letter from Kamala D. Harris et al., California Attorney General, to Sen. Barbara Boxer, Chairwoman, Subcomm. on Env't & Pub. Works. (July 31, 2013) (Hereinafter, Multi-states Letter).

[133] Multi-states Kama Letter, *supra* note 126.

[134] *See supra* notes106 to 110 and accompanying discussion.

[135] *See* Press Release, Am. Chem. Council, ACC Committed to Working on Bipartisan TSCA Reform (July 25, 2012),available at http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Commits-to-Working-on-Bipartisan-TSCA-Reform.html; Amanda Follett, 11 Rutgers J.L. & Pol'y 590, 605 (2014)(citing Press Release, Adhesive and Sealant Council, ASC Urges Bipartisan TSCA Reform Legislation (Feb. 2, 2012)).

[136] The Toxic Substances Control Act, Pub.L. 94-469 (1976); The Lautenberg Chemical Safety Act for the 21st Century, Pub.L. No: 114-182 (2016) ; see H.R. 2576 (2015)(House Report on Toxic Substances Control Act Modernization Act of 2015) (noting that "[t]he increased testing authority in H.R. 2576 reflects the Committee consensus that EPA should have the information necessary to fill knowledge gaps before making regulatory decisions."); see also section of H.R. 114-176 (2015) (statement of general performance goals and objectives).

[137] American Chemistry Council, Lautenberg Chemical Safety Act (LCSA), https://www.americanchemistry.com/Policy/Chemical-Management/LCSA.html (last visited March 21, 2018).

[138] *See* H.R. 2576 (2015)(House Report on Toxic Substances Control Act Modernization Act of 2015) (noting that "[t]he increased testing authority in H.R. 2576 reflects the Committee consensus that EPA should have the information necessary to fill knowledge gaps before making regulatory decisions."); *see also* section of H.R. 114-176 (2015) (statement of general performance goals and objectives).

[139] Congressional Research Service, Bill summary H.R. 2576, Frank R. Lautenberg Chemical Safety for the 21st Century Act, found at: https://www.congress.gov/bill/114th-congress/house-bill/2576 (last visited April 18, 2018). Under the old TSCA, even if the EPA had concerns about a chemical's safety, it could not restrict the chemical's use without providing evidence about why such a restriction would be necessary. Congressional Research Service, Bill summary H.R. 2576, Frank R. Lautenberg Chemical Safety for the 21st Century Act, found at: https://www.congress.gov/bill/114th-congress/house-bill/2576 (last visited April 18, 2018).The new law attempts to correct what have been called "data gaps, safety gaps and technology gaps." *See* Michael P. Wilson & Megan R.

nificant new chemical uses, the LSCA requires manufacturers to submit safety information before the chemical goes to market. Additionally, the new law gives EPA the power to issue an order or consent decree to obtain information about a chemical.[140] It also calls for a prioritization of chemical review for existing chemicals, requiring the EPA to designate chemicals as "high" or "low priority."[141] However, the Act also preempts most state action when the EPA is acting to regulate a designated high priority chemical.[142] It also specifically calls for the EPA to administer the law in a manner that protects the health of vulnerable populations, such as children, pregnant women, and the elderly, as well as other populations, including the general public and workers.[143] Finally, the Act improves access to confidential business information for the public and other agencies.[144] The remainder of this essay will focus on the mechanisms in the Act to review existing and new chemicals.

2. Routes to Review

Under the Lautenberg Amendments, the law has two main routes by which new and existing chemicals are reviewed.[145] As under the old TSCA framework, when a new chemical or significant new use is proposed by the industry, the industry member submits a Pre-manufacture Notification or "PMN." New chemicals are reviewed at the EPA level and the revised law retains the EPA mandate to issue a pre-manufacture determination and notice under TSCA.[146] Thus, when a new chemical or significant new use is proposed by industry, the EPA makes a determination as to whether the chemical presents an unreasonable risk to health or the environment within 90 days or it may request more time if needed to lengthen this period to 180 days.[147] Under the old TSCA, prior to the Lautenberg Act, the 90-day notice existed for new chemicals, but many chemicals were presented to the EPA with little or no toxicity data.[148] After the 90-day period ended, the product was available to market simply because the notice period had ended, not because the EPA had conducted a thorough review of toxicity or overall health data.[149]

Schwarzman, Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health, 117 ENVTL. HEALTH PERSP. 1202, 1202 (2009). Data gaps refer to the inability of the EPA to request data, safety gaps refer to the TSCA's lack of reference to protect the public from possible health hazards, including vulnerable populations, and technology gaps refer to the inability of the EPA under TSCA to adjust to new technology and do research. *See id* and notes 106 to 110 and accompanying discussion.

[140] Congressional Research Service, Bill summary H.R. 2576, Frank R. Lautenberg Chemical Safety for the 21st Century Act, found at: https://www.congress.gov/bill/114th-congress/house-bill/2576 (last visited April 18, 2018).

[141] 15 U.S.C. § 2605(b).

[142] 15 USC § 26

[143] Congressional Research Service, Bill summary H.R. 2576, Frank R. Lautenberg Chemical Safety for the 21st Century Act, found at: https://www.congress.gov/bill/114th-congress/house-bill/2576 (last visited April 18, 2018).

[144] 15 USC § 2613 (2016).

[145] In addition to creating routes of review for new and old chemicals, the LSCA also requires updates to the Toxics Substances Inventory to show active and non-active uses of chemicals. 15 U.S. Code § 2607 (2017);
40 CFR Part 710 (2017). This Inventory will then be subject to prioritization for review of existing chemicals. 82 FR 33753 (July 20, 2017), codified at 40 CFR 702 (2017). New chemicals will be added to the inventory as they are commercialized. 15 U.S. Code § 2607(b) (2016).

[146] 15 USC § 2604(a)(3).

[147] 15 USC § 2604(c).

[148] EWG Comments "On EPA's Framework for Decision-Making on New Chemicals," January 20, 2018, found at: https://www.ewg.org/testimony-official-correspondence/ewg-s-comments-epa-agency-s-new-chemical-assessment-system#.W1C7XCMrIwc (last visited July 19, 2018).

[149] EWG Comments "On EPA's Framework for Decision-Making on New Chemicals," January 20, 2018, found at: https://www.ewg.org/testimony-official-correspondence/ewg-s-comments-epa-agency-s-new-chemical-assessment-system#.W1C7XCMrIwc (last visited July 19, 2018); 15 USC sec. 2604 (c).

The new law, in contrast, creates a premarket review and notice for new chemicals and significant new uses of chemicals[150] and allows the EPA to require additional testing data,[151] removing the "catch 22" nature of the old law.[152] Under the Lautenberg amendments, if the Administrator determines that the information provided is insufficient to reasonably assess the health and environmental effects, such that the chemical may present an unreasonable risk of injury to health or the environment based on the submitted information, or that the substance will be produced in substantial quantities, the EPA is required to issue a section "5(e) order" restricting manufacture, distribution, disposal or use of the chemical.[153] The statute does not require the EPA to provide evidence to back up its 5(e) order restricting the chemical use and/or taking other action, such as requesting additional safety information.[154]

Thus, for the first time, EPA can affirmatively state that existing data is insufficient,[155] that the chemical will be produced in large volume, or that the chemical may present a risk to health or the environment and by order, restrict distribution in commerce of the new chemical to protect against the unreasonable risk of injury.[156] If the EPA does have enough information to determine that a new chemical or use presents an unreasonable risk to human health or the environment under the "conditions of use,"[157] it can issue an order or a rule to restrict the use and protect the public without consideration of cost or other non-risk factors.[158]

For existing chemicals, review is a longer, bifurcated process. EPA must similarly determine if the chemical poses an "unreasonable risk of injury to health or the environment" but it does this in a two-step process.[159] First, chemicals are initially designated as high or low priority substances without regard to cost or benefits.[160] Once the Administrator determines that a high priority chemical poses an unreasonable risk to health or the environment, the Administrator shall propose a rule not later than one year from the date of the final risk evaluation and publish a rule no longer than two years from the date of the risk evaluation, restricting the substance to the extent necessary so that the substance no longer presents a risk.[161] In this step of the regulation of an existing chemical to manage risk, the cost and benefits of the rule shall be considered, but must not be determinative.[162]

With over 80,000 chemicals on the market, limited resources, and so many untested for human health effects, a major issue in the new law is the prioritization of existing chemical as-

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[150] Significant new uses of chemicals are designated by the Administrator based on volume of production, the extent to which the new use changes the form or exposure to the substance, to which it increases the magnitude and duration of exposure and the reasonably anticipated manner and methods of commercialization. 15 U.S.C. § 2604 (a)(2).
[151] *See* 15 U.S.C. § 2604 (a); 15 U.S.C. § 2604 (e)
[152] See supra notes 106 to110 and accompanying discussion.
[153] 15 U.S.C. § 2604 (e) (this section corresponds to section 5(e) in the Public Law 114-182 (2016) and hence is known as a "5(e) order;" 15 U.S.C. § 2604 (a)(3).
[154] 15 U.S.C. § 2604 (e); *see* https://cdn.ewg.org/sites/default/files/testimony/EWG%20New%20Chemicals%20Framework%20Comments.pdf?_ga=2.210781661.956411359.1523896334-1903842848.1520470156 (EWG Comments "On EPA's Framework for Decision-Making on New Chemicals, at 8 (January 20, 2018).
[155] 15 U.S.C. § 2604(e).
[156] 15 U.S.C. § 2604(e).
[157] 15 U.S.C. § 2602(4)(defining "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.")
[158]15 U.S.C. § 2604(a)(3)(A); 15 U.S.C. § 2604(f).
[159] 15 U.S.C. § 2605(a).
[160] 15 U.S.C. § 2605(b)(4)(A).
[161] 15 U.S.C. § 2605(a); 15 U.S.C. § 2605(c)(1).
[162] 15 U.S.C. § 2605(c)(2)(A).

sessment,[163] and specifically what chemicals will be designated as high priority[164] and which ones low priority.[165] The LSCA thus instructs the EPA to designate a chemical high priority based on hazard and exposure potential,[166] the chemical's persistence and bioaccumulation, the potential exposure of susceptible sub-populations, such as chemical workers, children and pregnant women, the chemical's "conditions of use"[167] and the chemical's volume of production.[168] The LSCA allows the EPA to designate a chemical as low priority where there exists information sufficient to establish that the chemical would not meet the standard for a high priority chemical.[169] EPA is, however, only required to designate 20 chemicals high priority within three and a half years of July 2016 and then to continue to designate such chemicals at a pace that allows the Administrator to complete risk evaluations under the deadlines set in the Act.[170]

C. New Chemicals and Preemption in High Priority Evaluations: The Cornerstones of LSCA

The LSCA was a result of compromise,[171] in that TSCA reform was favored by both sides. Environmentalists and citizens groups did not feel that the more than 40 year old TSCA gave EPA enough power to regulate the over 87,000 chemicals on the market and the chemical industry was tired of being subjected to a patchwork of state laws regarding chemical safety and testing.[172] The cornerstone of the new law was thus its requirement, for the first time in almost half a century, during the period of major development of most man made chemicals, that a new chemical be reviewed for safety before it was brought to market,[173] and that states would be preempted from regulating an EPA designated "high priority" chemical substance once EPA stepped in to evaluate it.[174]

D. Initial Implementation

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[163] 15 U.S.C. § 2605(b)(1)(B). See Prioritizing Existing Chemicals for Risk Evaluation,https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation (visited June 12, 2018).

[164] 15 U.S.C. § 2605(b)(1)(B)(i) (high priority chemical is one that "may present unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the intended conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation").

[165] 15 U.S.C. § 2605(b)(1)(B)(ii)(low priority chemical is one that, based on sufficient information to establish, without regard to cost and benefit, the administrator does not believe is a high priority chemical).

[166] 15 U.S.C. § 2605(b)(1)(B)(i).

[167]15 U.S.C. § 2602(4).

[168] 15 U.S.C. § 2605(b)(1)(A).

[169] 15 U.S.C. § 2605(b)(2)(B) (the Administrator must designate 20 chemicals as "low priority" within three and a half years of the Act).

[170] 15 U.S. C. § 2605(b)(2)(C).

[171] S*ee* The Assessing and Managing of Chemicals under TSCA, United States Environmental Protection Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act (last visited on March 21, 2018); David Sheaffer, TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?, found at: http://www.law.msu.edu/king/2016-2017/Sheaffer.pdf

[172] Vance Merton, Congress poised to Pass Reform of Chemical Law, *The Washington Post*, NC Wilmington Edition, May 20, 2016.

[173] 15 U.S.C. § 2604(a)(3)(A); 15 U.S.C. § 2604(f) ; 15 U.S.C. § 2604(f).

[174] 15 U.S.C. § 2617. While states are prempted from regualting these high priority chemicals under review, they continuet to have the ability to regulate with public right to know laws (15 U.S.C.A. § 2617(d)(1)(A)(i)-(iv) (2017)) and to regulate in an manner designed to protect air and water consisente with the CWA and CAA. Additionally, California's and Massachssets state regulatory schemes remain intact after the LSCA.

1. Initial Rules

In January, 2017, just after President Obama completed his Presidency, the EPA proposed rules on the procedure for chemical risk evaluation and rules on prioritization[175] to apply to the over 80,000 chemicals on the market and potential new ones proposed by industry. Response to the proposed rules was generally favorable by environmental groups and those concerned with public health.[176] Public interest groups urged that the new law be implemented in the most health protective manner possible, suggesting that the default designation would make a chemical "high priority" and that certain chemicals always be high priority if, for example, they were listed as substances that cause cancer by the state of California[177] and/or if they were listed in the European Commission's list of endocrine-disrupting chemicals.[178] Environmental Working Group, for example, urged that the above considerations about high risk chemicals include aggregate exposures[179] from other sources regulated by the Safe Drinking Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act and/or the Food Quality Protection Act and regulated by the Food and Drug Administration, and cautioned the EPA *not* to use "sentinel exposure" in considering EDC's in particular, a measuring process that focuses on exposures of greatest significance, which might mean maximum exposures.[180] This approach, EWG urged,[181] would be problematic for multiple reasons, including that EDCs are known to have toxic effects at very low levels,[182] it can be difficult to identify the most exposed group, and that it would not account for differences in susceptible populations, including children, pregnant woman and the elderly.[183]

These originally proposed rules, in January 2017, made clear that the law requires EPA to prioritize an existing chemical substance as a whole, not by single use,[184] and this pronouncement was likewise received favorably by public interest groups. Additionally, the rules called for

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[175] Procedures for Chemical Risk Evaluation Under the Amended TSCA, 82 Fed. Reg. 7562, 7572 (proposed Jan. 19, 2017) (to be codified at 40 C.F.R. pt. 702); Procedures for Prioritization of Chemicals for Risk Evaluation Under the TSCA, 82 Fed. Reg. 4825, 4828 (proposed Jan. 17, 2017) (to be codified at 40 C.F.R. pt. 702).

[176] *See e.g.* https://www.ewg.org/enviroblog/2017/07/new-chemical-safety-rules-show-industry-influence-inside-epa#.WtZs902ouUl

[177] https://oehha.ca.gov/proposition-65 (site visited May 6, 2018).

[178] EWG Comments on Prioritizing Chemicals for Risk Evaluation Under New TSCA Re: Docket NUmber EPA-HQ-OPPT-2016-0399, August 24, 2016, found at:

FINAL EWG Comments Prioritization 8.24.16.pdf

(citing Gina Solomon, Deputy Sec'y for Health & Sci., Cal. Envtl. Prot. Agency, Oral Comment at EPA Public Meeting

on Section 6 Risk Evaluation (August 10, 2016)).

[179] Comments from the Environmental Working Group Proposed Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, Docket ID: EPA-HQ-OPPT-2016-0654-0001, at 12, March 20, 2017.

[180] 82 Fed. Reg. at 7576; see EPA responses to Public Comments Reviewed on the Scope Documents for the First Ten Chemicals For Risk Evaluation Under TSCA, at 4 -5, May 2018 (noting that EPA may use sentinel exposures in its risk assessments of the first ten chemicals to be evaluated).

[181]Comments from the Environmental Working Group Proposed Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, Docket ID: EPA-HQ-OPPT-2016-0654-0001, at 12, March 20, 2017.

[182] Valerie Watnick Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 2004(4) Utah Law Review 1305, 1318-20 (2004) (Available at SSRN: https://ssrn.com/abstract=2284981 or http://dx.doi.org/10.2139/ssrn.2284981)

[183] *See, e.g.,* Non-monotonic Dose Response Curves, Our Stolen Future, http://www.ourstolenfuture.org/NewScience/lowdose/nonmonotonic.htm (last visited April 30, 2018).

[184] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4826, 4829 (January 17, 2017).

the EPA to consider all reasonable intended uses in its risk characterizations, not just probable uses (a more limited subset of potential exposures).[185]

The American Chemical Council ("ACC") pushed back on most of these interpretations and protections embodied in the January 2017 rules and public comment,[186] seeking greater clarification of the criteria for designating a chemical as high priority and of the timeframes for the EPA to complete its work and for the industry to provide information.[187] The ACC also sought ample opportunity for it to provide information and comments to the EPA. [188]

The industry group went on to discuss the initial months of implementation, urging that the structural changes to the EPA review process were creating backlogs of new chemicals in need of review.[189] ACC also urged EPA to broaden its interpretation of "not likely to present an unreasonable risk" to include more existing chemicals, and that it should limit the phase "reasonably foreseen uses" under conditions of use for which a new chemical would be reviewed to only those *intended* by the applicant.[190] Finally, the industry group urged that the EPA should pursue other options rather than issuing a 5(e) order restricting use of a chemical, such as rule making.[191]

2. Final Rules

These comments by the ACC on the proposed initial regulations laid the groundwork for the massive revision of the proposed rules in line with industry demands.[192] In January 2017, a new presidential administration had entered the White house, one opposed to regulation in general.[193] And in July, 2017, the EPA released new rules that largely reflected industry comments.[194]

As to "conditions of use" for new chemicals to be considered under the Act, the new rules released in July 2017 limit the definition of the "conditions of use" for which industry must submit data for a new chemical or new chemical use. While the EPA originally said it would as-

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[185] 82 Fed. Reg. at 4828 ("EPA generally intends to ensure it has a more complete set of data upfront that would allow EPA to evaluate a chemical substance under all conditions of use [a broader scope] within the statutory deadlines.")

[186] *See infra* 187 to 191 and accompanying discussion.

[187] American Chemistry Council Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act Docket ID# EPA-HQ-OPPT-2016-0636 March 20, 2017 found at: https://www.americanchemistry.com/ACC-Comments-on-EPA-Proposed-Rule-for-Prioritization-under-Lautenberg-Act.pdf.

[188] American Chemistry Council Comments on EPA's Proposed Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act Docket ID# EPA-HQ-OPPT-2016-0636 March 20, 2017 found at: https://www.americanchemistry.com/ACC-Comments-on-EPA-Proposed-Rule-for-Prioritization-under-Lautenberg-Act.pdf

[189] Comments of the American Chemistry Council on the New Chemicals Review Program Under TSCA as Amended Docket No. EPA-HQ-OPPT-2016-0658, at 2-6, January 17, 2017, found at: https://www.americanchemistry.com/ACC-Comments-on-New-Chemicals-Review-Program-Under-TSCA-as-Amended-by-LCSA.pdf

[190] Id. at 12-18.

[191] Id. at 19-21

[192] See infra notes 164 to 165 and accompanying discussion.

[193] *See supra* note 7 and accompanying discussion.

[194] Melanie Benesh, New Chemical Safety Riles Show Industry Influence Inside EPA, found at: https://www.ewg.org/enviroblog/2017/07/new-chemical-safety-rules-show-industry-influence-inside-epa#.WzEv9CMrIwc(site visited June 25, 2018).

sess a new chemical or use considering the chemical substance as a whole,[195] it has reversed course and has said it will consider individually submitted conditions of use based on the fact specific application, and has also stated publicly in August 2017 that it will consider uses where the activity is "probable."[196] This change tracks ACC comments urging the EPA to limit its application of the statutory language requiring EPA to consider intended, known or reasonably foreseen" uses.[197]

This interpretation of the law, limiting the conditions of use the EPA will consider in a PMN for a new chemical or significant new chemical use, while not formalized beyond principles the EPA publicly released in August 2017, has also not been formally corrected by the agency.[198] What is surprising about this interpretation is that under the law, EPA must consider uses over the whole life of the chemical, from manufacture to disposal, and its current, limited "conditions of use" interpretation does not incorporate all of these uses.[199]

In so limiting the potential uses and corresponding exposures factored into the safety analysis, EPA also engages in a two-step process. It first looks at whether the intended use presents an unreasonable risk and then on its own, identifies and analyzes other reasonably foreseeable uses in a second step.[200] EPA's current view of "reasonably foreseeable" uses thus narrows its reviews, and potentially excludes threats posed by accidental discharges as well as discharges of chemicals when they are improperly used, all "reasonably foreseeable" events under the law.[201] The final rules additionally allow the EPA to exclude uses purportedly regulated by other agencies such as OSHA, further limiting the potential overall risk of a new chemical.[202]

With regard to prioritization of what chemicals EPA would evaluate first, while the originally proposed rules in January 2017 provided that the default classification of an existing chemical would be "high priority," the final rule's default classification deletes most references to high priority chemical designations and makes many more references to low priority or safe chemicals.[203] Additionally, the initially proposed rules contained a pre-prioritization information

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[195] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7565-66 (proposed Jan. 19, 2017).

[196] Press Release, Environmental Protection Agency, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epaeliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.

[197] 15 U.S.C. § 2602(4); Comments of the American Chemistry Council on the New Chemicals Review Program Under TSCA as Amended Docket No. EPA-HQ-OPPT-2016-0658, at 12-18, January 17, 2017, found at: https://www.americanchemistry.com/ACC-Comments-on-New-Chemicals-Review-Program-Under-TSCA-as-Amended-by-LCSA.pdf

[198] Comments from the Environmental Working Group On EPA's Framework for Decision-Making on New Chemicals Docket ID #: EPA-HQ-OPPT-2017-0585 (January 20, 2018), found at; https://cdn.ewg.org/sites/default/files/testimony/EWG%20New%20Chemicals%20Framework%20Comments.pdf?_

[199] 15 U.S.C. § 2602(4) (defining conditions of use).

[200] Press Release, Environmental Protection Agency, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), found at: https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.

[201] *See* 15 U.S.C. § 2602(4); Press Release, Environmental Protection Agency, EPA Eliminates New-Chemical Backlog, Announces Improvements to New Chemical Safety Reviews (Aug. 7, 2017), https://www.epa.gov/newsreleases/epaeliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.

[202] Melanie Benesh, New Chemical Safety Riles Show Industry Influence Inside EPA, found at: https://www.ewg.org/enviroblog/2017/07/new-chemical-safety-rules-show-industry-influence-inside-epa#.WzEv9CMrIwc(site visited June 25, 2018).

[203] 82 Fed. Reg. 33753 (July 20, 2017), codified at 40 CFR 702.5(d) and found at: https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act

gathering period important to meet the strict LSCA periods for review,[204] while the new rules remove this information gathering period.[205]

IV. The Way Forward: The Status Quo or A Proactive Stance

A. Deficiencies Recognized

1. SNURs replace Orders

Perhaps the most troubling aspect of the EPA's initial implementation of the law in these initial months, with regard to new chemicals and significant new uses has been to replace "consent orders" on significant new chemical uses, about which the EPA has concerns that the use presents an unreasonable risk, with new rule making in the form of an Significant New Use Rule ("SNUR").[206] This weakened implementation with regard to new chemicals is contrary to the statutory mandate in the LSCA that requires EPA to control a potential unreasonable risk to an exposed and susceptible subpopulation.[207] The statute is clear that if EPA lacks enough information to make a reasonable evaluation or if the chemical is manufactured in large quantities, the EPA *shall* issue an order aimed at preventing unreasonable risk to human health or the environment, especially to protect potentially exposed, susceptible populations.[208]

In contrast to the practice of using consent *orders*, the use of SNURs results in a protracted rule making process, and allows industry members to market their products during the years long process between initial proposed rule and final rule.[209] This type of process impedes the EPA's ability to protect public health from substances it has concerns present an unreasonable risk.[210]

SNUR's are simply too slow a mechanism to regulate a toxic substance in most instances. For example, in 2015, the EPA issued a proposed new rule on long-chain perfluoroalkyl carboxylate (LSPFACs), that would require those engaged in certain manufacture or processing activities to notify EPA 90 days prior to such activities as part of the ongoing effort to phase out these highly toxic and persistent substances. Almost three years since its proposal, this new rule has not yet been finalized, implemented or published.[211]

2. Agency as Consultant and Editor

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[204] 82 Fed. Reg. 4826, 4829 (January 17, 2017); 15 U.S.C. § 2604(i) (stating applicable review period).
[205] 40 C.F.R. 702.5(e).
[206] EPA Implementation Framework document, 2017, found at: https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf .
[207] 15 U.S.C. § 2604(a)(3)(A); ; 15 U.S.C. § 2604(e)(i)(II). 15 U.S.C. § 2604(f).
[208] 15 U.S.C. § 2604(a)(3)(B) (emphasis added); 2604(e)(i).
[209] Richard Denison, Too Little, Too Late: Why SNURs Alone are Not a Sufficient Alternative to Consent Orders for New Chemicals, Environmental Defense Fund (Nov. 30, 2017), http://blogs.edf.org/health/2017/11/30/too-little-too-late-why-snurs-alone-are-not-a-sufficient-alternative-to-consent-orders-for-new-chemicals/
[210] 15 U.S.C. § 2604(a)(3)(B) (emphasis added); 2604(e)(i) ; *see* Richard Denison, Too Little, Too Late: Why SNURs Alone are Not a Sufficient Alternative to Consent Orders for New Chemicals, Environmental Defense Fund (Nov. 30, 2017), http://blogs.edf.org/health/2017/11/30/too-little-too-late-why-snurs-alone-are-not-a-sufficient-alternativeto-consent-orders-for-new-chemicals/; 5 U.S.C. § 2604(a)(3)(A); 15 U.S.C. § 2604(f). 15 U.S.C. § 2604(a)(3)(B) (emphasis added).
[211] *See* 80 Fed. Reg. 2885 (January 21, 2015) (new rule on long-chain perfluoroalkyl carboxylate not implemented almost three years after its proposal).

Additionally, while the LSCA requires EPA to consider pre-manufacturing notices ("PMN") based on the information submitted, and if the information is not complete or sufficient to allow a favorable risk determination, to issue an order to protect public health and the environment,[212] the EPA is not doing so.[213] Rather, EPA is instead informing the submitter that it has concerns and giving the party a chance to amend its PMN.[214] This approach is problematic in that it wastes EPA's resources, slows down its reviews, and puts it in the position of being an industry consultant.[215] The approach, is however consistent with EPA statements on its implementation procedures. In November 2017, in a framework document released by EPA, the agency stated that it will issue an order for more information under the law so that it can reduce uncertainty associated with "may present an unreasonable risk" determinations, or to remedy an "insufficient information" determination.[216] In other words, it will seek more information, so that concerns can be allayed, and the chemical can be commercialized as soon as possible. In addition, this EPA framework document, while laying out the four possible determinations the EPA may make in a new chemical case, it does *not* lay out the resulting action in each determination.[217] In such manner, the EPA leaves the door open to issue a rule, even in the face of a lack of information to make a reasoned judgment, or in the face of a substantial production quantity.[218]

3. Failure to Adequately Account for Vulnerable and Exposed Populations

In reviewing new chemicals, in myriad ways, EPA is not adequately accounting for pregnant women, workers and children, and other vulnerable subpopulations as required by the statute.[219] In such reviews, EPA's standard response has been to impose a default safety factor to account for differences in population. The science, however, has moved away from such blanket impositions of default factors, as they are not sufficiently comprehensive to account for life stages, such as fetal, childhood, and other developmental periods.[220] EPA would act in a more health

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[212] 15 U.S.C. § 2604(a)(3)(B); 15 U.S.C. § 2604(e); 15 U.S.C. § 2604(f).

[213] Comments from the Environmental Working Group On EPA's Framework for Decision-Making on New Chemicals Docket ID #: EPA-HQ-OPPT-2017-0585 (January 20, 2018), found at; https://cdn.ewg.org/sites/default/files/testimony/EWG%20New%20Chemicals%20Framework%20Comments.pdf?_ga=2.207370134.443198503.1524666359-1903842848.1520470156

[214]Comments from the Environmental Working Group On EPA's Framework for Decision-Making on New Chemicals Docket ID #: EPA-HQ-OPPT-2017-0585 (January 20, 2018), found at; https://cdn.ewg.org/sites/default/files/testimony/EWG%20New%20Chemicals%20Framework%20Comments.pdf?_ga=2.207370134.443198503.1524666359-1903842848.1520470156

[215] Comments from the Environmental Working Group On EPA's Framework for Decision-Making on New Chemicals Docket ID #: EPA-HQ-OPPT-2017-0585 (January 20, 2018), found at; https://cdn.ewg.org/sites/default/files/testimony/EWG%20New%20Chemicals%20Framework%20Comments.pdf?_

[216] EPA Implementation Framework document, at 3, 2017, found at: https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf ; *see* 15 U.S.C. § 2604(a)(3)(B).

[217] EPA Implementation Framework document, at 3, 2017, found at: https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf.

[218] *Id.*

[219]15 U.S.C. § 2604(a)(3) (review and determination regarding significant new uses and new chemicals shall include consideration of vulnerable populations); *see* 15 U.S.C. § 2605(b)(1)(a)(prioritization shall include consideration of whether the chemical presents an unreasonable risk to a potentially exposed or susceptible subpopulation).

[220] Juleen Lam et al., Comment on the Proposed Rule on Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (March 20, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0088 (citing to Nat'l Acad. Sci., Science and Decisions: Advancing Risk Assessment (2009),

protective manner by using current up to date defaults that appropriately account for these vulnerable populations.[221]

4. EDC's Not Adequately Recognized

Under the new law, the EPA will also not significantly change its regulation of potential EDCs, although widespread exposure to EDCs has been touted as one of the most insidious problems in human history.[222] For example, the implementation plan with regard to new chemicals specifically calls for EPA to consider duration *and* magnitude of exposure, all but ignoring the body of evidence indicating that EDCs may be even more dangerous at low levels and may have inverse bell curves for toxicity.[223] EDCs challenge established assumptions about linear relationships between dose and harm. They complicate the development of toxicology methods and require new methods that do not rely on extrapolating from high dose testing to determine human risk at lower levels.[224] Instead, these substances may need testing at varying dosages, lengthening the time it will take to perform risk evaluations and further burdening and delaying agency action.[225]

5. Loopholes

While the Act gives EPA more authority to regulate certain suspect existing chemicals designated as "high priority," a major loophole allows the EPA to give a "favorable" determination that a *new* chemical will not pose an unreasonable risk to man or the environment based on chemical composition, intended uses, and information provided, or to designate an existing chemical as low priority,[226] and therefore effectively circumvent any future restrictions. This is particularly troubling with regard to new chemicals which are suspected of being unreasonably dangerous, for which further information is needed, and for which the EPA is allowing commercialization pending final rule-making.[227] In these cases, it will be easy for the applicant, years down the road, to say that the chemical is an "existing chemical" subject to prioritization and the protracted and backlogged review expected to be associated with existing chemical review. The LSCA's basic premise is that once an existing chemical is designated as low priority or a new

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_http://www.nap.edu/catalog/12209/scienceand-decisions-advancing-risk-assessment).

[221] *See* Cal. EPA, Office of Envtl. Health Hazard Assessment, Child-Specific Reference Doses Finalized to Date, http://oehha.ca.gov/risk-assessment/chrd/table-all-chrds (Jun. 22, 2010).

[222] *See generally* Laura N. Vandenberg et al., Hormones and EndocrineDisrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses, 33 Endocrine Rev. 378 (2012), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3365860/; Theo Colburn, Dianne Dumanoski, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?--A Scientific Detective Story (1997).

[223] New Chemicals Decision-Making Framework: Working Approach to Making Determinations Under Section 5 of TSCA, November 2017: found at: https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf; See Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53(4) Utah Law Review, 1305-1333, 1323 (2004)(citing multiple sources, including Chhanda Gupta, Reproductive Malformation of the Male Offspring Following Maternal
Exposure to Estrogenic Chemicals, 224 PROC. Soc'y FOR EXPERIMENTAL BIOLOGY & MED. 61- 68 (2000)).

[224] Sheldon Krimsky, The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act, PLOS Biol,. Dec. 15, 2017, at n. 11 and found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5734679/ (last visited 7/4/18)

[225] Krimsky, *supra* note224, at n.11.

[226] 15 U.S.C. § 2604(3)(C).

[227] 15 U.S.C. § 2604(f).

chemical or significant new chemical use has been newly approved for use under the Act, there will be no foreseeable further safety assessment required.[228]

Another loophole that appears poised to rear its head in this new regulatory structure is that the LSCA allows the EPA to make a 5(f) determination that a chemical or significant new use presents an unreasonable risk of injury to health or the environment.[229] While this may seem antithetical, such a finding gives the EPA authority to choose to issue a rule, order or otherwise impose "requirements."[230] In such cases, the EPA does not have to issue an order.[231] The requirement to issue an order is instead only triggered when the EPA affirmatively states that it does not have enough information to permit a reasoned evaluation of the health and environmental effect of a chemical, where the use may present such risk, or where the substance will be produced in substantial quantities, and is anticipated to enter the environment in significant quantity. [232] In section B below, I discuss a way around this potential loophole, which would make such a finding very unattractive to industry and potentially to the EPA. [233]

6. Bureaucratic and Resource Constraints Will Prevent Administration in an Efficient or Effective Manner Provisions Regarding Existing Chemicals

Additionally as to existing chemicals, while the Act was designed to be more health protective, calling for the first time, for some review of existing chemicals, the exceedingly slow process of review makes this portion of the Act a bureaucratic nightmare, with little potential to effect true change. With over 87,000 existing chemicals on the market today,[234] over 60,000 without safety data on file, and with the Act calling for EPA to review just 20 within three and a half years of the Act,[235] there could be no doubt from the start that the LSCA would not make great strides in terms of protecting human health with regard to existing chemicals. The Act simply does not call for the agency to move the work along fast enough to protect human health.

One report has suggested that as to existing chemicals, it will take the EPA "28 years to complete [initial] risk evaluations on the 90 high priority chemicals in its work plan, 30 years to finalize related regulations on those chemicals, and 35 years to implement the resulting rules." [236] Other reports are even less sanguine. One scientist reported that even if EPA were to meet the

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[228] *See* 15 U.S.C. § 2604(3)(C); 15 U.S.C. § 2605(b)(1)(B)(ii); 15 U.S.C. § 2605(b)(2)(within three years of June 22, 2016, the administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances).

[229] 15 U.S.C. § 2604(f).

[230] 15 U.S.C. § 2604(f).

[231] 15 U.S.C. § 2604(f).

[232] 15 U.S.C. § 2604(e)(1).

[233] *See infra* notes 297 to306 and accompanying discussion.

[234] Amanda Follett, Ignorance is Bliss? Balancing the Public's Right to Know and Industry's Claim to Confidential Business Information in TSCA Reform, 11 Rutgers J.L. & Pub. Pol'y 590, 596 (2014)(noting that the TSCA chemical inventory, created in 1976, now totals over 80,000).

[235] 15 U.S.C. § 2605(b)(2)(within three years of June 22, 2016, the administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances). For a commentary on the pace of review of existing chemicals and the overall regulatory structure, see Coral Davenport, EnaMarie Huetteman, Lawmakers Reach Deal to Expand Regulation of Toxic Chemicals, May 19, 2016, found at; https://www.nytimes.com/2016/05/20/us/politics/toxic-substances-chemicals-environment.html (noting that public health advocates had hoped to see at least 300 chemicals reviewed per year); https://www.ewg.org/enviroblog/2016/05/new-tsca-bill-falls-short-protecting-americans-toxic-chemicals#.Wsew7SMrLJx (visited April 4 , 2018).

[236] Catherine Traywick, Jack Kaskey, Bloomberg Reporting, EPA Wins Clout to Fight Toxic Chemicals, But It May Take a While, June 8, 2016.

statutory mandate of 20 chemicals over 3.5 years, the maximum time allowed for review,[237] and it were to prioritize and evaluate just 8500 or 10% of the existing chemicals, the process would take 1500 years to complete.[238] If the list were reduced to just 500 chemicals and three years to evaluate and establish rules on these chemicals, the task would take 50 years.[239]

More so, it seems unlikely that the EPA can even meet these moribund deadlines without adequate resources. Given the anti-regulatory nature of the current administration and proposed budget cuts to the EPA,[240] the task seems impossible. As one legal expert has commented, agencies have been faced with an impossible task, in the face of tremendous uncertainty as to the effects of chemical substances on the development of disease such as cancer, and faced with concerted and well-funded opposition, the agencies must come up with solutions that are more policy based and political, rather than based on any true scientific or factual certainty.[241]

7. Failure to Account for Synergistic and Compounded Interactions Between Chemicals

Even at its best, the LSCA does not properly account for interactions between the myriad chemicals to which we are exposed every day, as chemicals are generally assessed one chemical substance at a time.[242] Additionally, it did not even begin, nor could it, to tackle the problems inherent in an industrial system so dependent on so many chemicals, the continued commercialization of new substances, and the potential and likelihood for combined or even synergistic reactions between these chemicals.[243] Finally, the LSCA does not give due weight to our mass exposure to EDC's and the problems described in relation to such exposure.[244]

8. Resulting Implementation Efforts

The unfortunate result for those concerned with the regulation of toxic chemicals to protect human health is that most new chemicals will continue to be approved for commercialization without full information about the conditions of use, subject to ongoing rule making while being commercialized, few of the more than 60,000 grandfathered existing chemicals will be reviewed fully or quickly,[245] with most default designated as "low priority," and we will largely maintain

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[237] 15 U.S. Code § 2605(b)(2).

[238] Sheldon Krimsky, The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act, PLOS Biol,. Dec. 15, 2017, at n. 28, found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5734679/ (last visited 7/4/18).

[239] Sheldon Krimsky, The Unsteady State and Inertia of Chemical Regulation Under the US Toxic Substances Control Act, PLOS Biol,. Dec. 15, 2017, at n. 28, found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5734679/ (last visited 7/4/18).

[240] Glenn Thrush, Coral Davenport, Donald Trump Budget Slashes Funds for E.P.A. and State Department, New York Times,15 March 2017, found at: https://www.nytimes.com/2017/03/15/us/politics/budget-epa-state-department-cuts.html?_r=0

[241] *See generally* John Applegate, Worst Things First: Risk, Information, and Regulatory Structure in Toxic Control. 9 Yale J. on Reg. 277, 280-81, 304 (1992).

[242] *See supra* notes 220 and accompanying discussion; Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53(4) Utah Law Review, 1305-1333 (2004); Abelkop and Graham, *supra* note __, at 120.

[243] *See* Valerie J. Watnick, Our Toxics Regulatory System and Why Risk Assessment Does Not Work: Endocrine Disrupting Chemicals as a Case in Point, 53(4) Utah Law Review, 1305-1333 (2004).

[244] Theo Colburn, Dianne Dumanoski, Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival?--A Scientific Detective Story (1997); *see supra* notes _- to __and accompanying discussion.

[245] 15 U.S.C. § 2605(b)(2)(B).

the status quo in our toxics regulatory system in terms of assessing new chemicals and reviewing existing ones.

The facts to date bear this out, almost two years after Congress passed the Act. EPA has reviewed 1498 new chemical cases since enactment of LSCA.[246] It has banned zero new chemicals, not allowed commercialization of just three uses and issued a 5(e) order, has allowed 124 of these cases to be commercialized without restrictions as not presenting an unreasonable risk, and it has permitted commercialization of 408 chemicals with restrictions pursuant to rule or order.[247] Based on published information, it is difficult to assess whether these approvals have been by rule or order or both, but they have all been allowed to commercialize, many likely pending a lengthy rule-making process.[248] The EPA has additionally exempted 618 of these submissions as low volume/low release and low exposure and denied 121 requests for such exemption.[249] The end result is that in the space of 24 months, manufacturers have filed 535 notices of "intent to commence manufacturing" these new substances, and 1339 new chemicals have been approved for use or given exemptions as low volume and will now enter our environment. [250]

The proactive approach that was so hoped for when Congress mandated prescreening of new chemicals and significant new uses of chemicals, with robust data, has not yet come to be and seems unlikely to result.[251] Such a proactive regulatory scheme would have been in line with the Precautionary Principle, which generally provides that a lack of data and certainty as to ill effects shall not preclude a government from taking cost effective measures to protect human health and the environment.[252] Although not without critics,[253] the Principle, with varying levels of precaution and burden shifting,[254] has become widely accepted around the world as a fundamental basis for environmental regulation.[255]

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[246] Statistics for the New Chemicals Review Program under TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last visited June 19, 2018).

[247] *Id.* Applicants have withdrawn 177 new cases and 38 low volume exemption requests.

[248] *Id.*

[249] *Id.*

[250] *Id*.

[251] *See supra* and infra notes 194 to 214, 217 to226 and accompanying discussion

[252]Robert Percival, Who's Afraid of the Precautionary Principle?, 23 (1) Pace Environmental L. Rev. 21, 21-22 (2001)("uncertainty should not be used as an excuse to eschew cost-effective preventive measures-is fundamental to modem environmental law's quest to transcend the limits of its common law legacy":); James Cameron, Juli Abouchar, The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment, 14(1) Boston College International and Comparative Law Review, 1, 2 (1991).

[253] *See* Cass Sunstein, Beyond the Precautionary Principle, 151 U.Pa. L.Rev. 1003, 1008-10 (2003) (urging that the precautionary principle is paralyzing and is appealing because of loss aversion, the myth that nature is benevolent, the availability of bad environmental results, probability neglect and what Sunstein calls system neglect, or a failure to see the other side of heavy handed environmental regulation);

[254] Professor Noah Sachs argues that the principle has many burdens and defends and advocates for the "Strong Precautionary Principle." Sachs, *supra* note __ at 1292-1300. Sachs urges that a strong precautionary principle puts regulators in the role of gatekeepers and puts the burden on private actors to prove their products are safe before they go to market. *Id.* at 1295-1299.

[255] Rio Declaration on Environment and Development, U.N. Conference on Environment and Development, Annex I, princ. 15, U.N. Doc. A/Conf. 151/5/Rev.1 (1992), reprinted in 31 I.L.M. 874, 879.; Treaty Establishing the European Community, Nov. 10, 1997, art. 174, O.J. (C340) 3 (1997); The Act Part 5: Controlling Toxic Substances, ENV'T CAN; Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, art. 1(3), 2006 O.J. (L 396) 1 (EC)("This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.").

A toxics chemical regulatory framework in line with a strong Precautionary Principle would be one that acknowledges that we cannot ever know the real-life risk associated with the combination of chemicals to which we are exposed or the manner in which such exposure may effect varying vulnerable and exposed populations at different life periods. Faced with this uncertainty, the strong precautionary principle would shift the burden to the private actors to show their products are safe before they go to market.[256]

The LSCA, while not specifically embodying the Precautionary Principle, had a moment to move us in a precautionary direction -- to at least begin a burden shifting process, and require robust screening of new chemicals.[257] In that review of existing chemicals is a more time consuming and unwieldy process and given the already 60,000 plus existing chemicals in need of review, this area of the law was always the least likely to result in real and immediate change.[258] The critical aspect of the LSCA is and was the review of new chemicals with robust data. This was the perceived manner to protect public health and the environment proactively from future new chemical uses.[259]

In its final rules implementation and framework documents, bowing to industry pressure, the EPA, however, has significantly weakened the protective provisions in LSCA.[260] This favorable stance toward industry is not surprising given that those at the EPA in positions of power often find themselves working for the very companies they regulate after leaving the EPA and that some at EPA were previously in positions of power in industry.[261]

The unfortunate result is that the LSCA, as originally envisioned, aimed to support innovation, build jobs and make industry subject to less "red tape" by eliminating an ongoing patchwork of state laws.[262] Instead, the law leaves the industry open to widespread continuing state regulation while the protracted process of federal regulation moves forward, as well as state ini-

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[256] *See* Sachs, *supra* note 253 at 1295-99.

[257] *See* 15 U.S.C. § 2604.

[258] As this article goes to press, the EPA has just released its Problem Formulations for the Risk Evaluations To Be Conducted Under the Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations; Notice of Availability Pages 26998 - 27000 [FR DOC # 2018-12520] for the first ten existing chemicals to be evaluated by EPA. June 11, 2018. Additionally, EPA sought white house approval of an information collection request to give submitters access to agency guidance which the EPA hopes will speed their review of new chemicals. Eyeing TSCA Backlog, EPA Seeks Expedited White House ICR Review, Risk Policy Report, June 19, 2018. Risk Policy Report is published by a pay per view publisher that provides policy information.

[259] S*ee supra* notes 153 to 154, 116 to 135, 217 and accompanying discussion.

[260] *See supra* notes 149 to 152, 164 to 165 and accompanying discussion.

[261]See The Ever-Revolving Door: Industry and the EPA, Beyond Pesticides, October 3, 2017, found at: https://beyondpesticides.org/dailynewsblog/2017/10/ever-revolving-door-industry-epa/ (visited June 13, 2018); Trump Picks Dow Chemical Lawyer for Key Role at EPA, U.S. News, March 2, 2018, found at: https://www.usnews.com/news/business/articles/2018-03-02/trump-picks-dow-chemical-lawyer-for-key-role-at-epa (last visited June 13, 2018). In at least one recent case, there are credible reports that industry and the EPA acted together to slow down EPA action that might have hurt the manufacturer of a widely used herbicide. See Collusion or Coincidence? Records Show EPA Efforts To Slow Herbicide Review Came In Coordination With Monsanto, Huffington Post, August 18, 2017, found at: https://www.huffingtonpost.com/entry/collusion-or-coincidence-records-show-epa-efforts_us_5994dad4e4b056a2b0ef02f1 (last visited June 12, 2018).

[262] *See supra* notes to 133 to 137 and accompanying discussion; National Conference of State Legislatures (NCSL), Toxic Substances Control Act Reform (May 19, 2014), http://www.ncsl.org/research/environment-and-natural-resources/state-chemical-statutes.aspx (opposing preemption of state rights to regulate).

tiated lawsuits designed to protect state citizens[263] where EPA is engaged in review of a high priority substance and the Act prevents state rule-making.[264]

TSCA had a moment when it looked like it would bring U.S. chemical regulation closer [265]to the European Union ("EU") model contained in the Registration, Evaluation, Authorization and Restriction of Chemicals, or REACH initiative[266] and Canada's Canadian Environmental Protection Act ("CEPA"),[267] and even in line with California's Proposition 65 and its Green Initiative.[268] In the next section, I suggest that the Act still holds some promise, especially with regard to the approval of new chemicals. The mechanisms in the law for review of new chemicals, for the first time, embody a forward-looking, proactive stance. This stance at least signals our collective intent to improve a heretofore woefully inadequate regulatory system for toxic substances, and is of value, if the public will is harnessed.

B. Proactive Approach: Premarket Review Coupled with Market Pressure

While models around the world, such as in Canada and Europe, are precautionary in nature, and require data before sale, and the LSCA attempts to move our regulatory structure in this direction, California has coupled this requirement with greater information transparency. It is this aspect of California's regulatory scheme, information transparency and potentially labeling, that I urge, will move U.S. regulation toward a more health protective stance. Information transparency has the power to drive industry to produce and sell safer products according to consumer demand.[269]

California was indeed the first state to enact a proactive chemical regulatory system, with later efforts by Maine and Connecticut in 2013.[270] California's law comes in two parts, a proac-

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[263] Nathan A. Cardon, Sheila A. Millar, and Anushka N. Rahman, Green Chemistry in 2017: The State of the States, National Law Rev. May 16, 2017.

[264] California and Massachusetts have well developed state regulatory systems that were exempted from preemption by the LSCA. 15 U.S.C.A §§ 2617(a), (b), (d)(2) (2017). California and other states have not been reticent about suing over environmental concerns. *See* Chris Mooney, Washington Post: California, 17 other states sue Trump administration to defend Obama-era Climate Rules for Vehicles, May 9, 2018, found at: https://www.washingtonpost.com/news/energy-environment/wp/2018/05/01/california-17-other-states-sue-trump-administration-to-defend-obama-era-vehicle-efficiency-rules/?noredirect=on&utm_term=.d8ca04af6484

[265] "The similarities between the amended TSCA and the EU REACH program are easily seen if one reviews prior scholarly work: Like [the pre-amended] TSCA, EU chemical legislation prior to REACH focused on testing of "new" chemicals (those introduced after 1981 in Europe), exempted most existing chemicals from testing, and placed the burden of proof on EU Member States to prove that chemicals were unsafe. The older European legislation led to the same informational logjams and data gaps that the United States has experienced under TSCA. Of the 30,000 existing chemicals with annual production volumes in Europe of over one ton, only 140 had been identified as priorities for testing under the prior legislation, and full risk assessments had been prepared for only about seventy of these chemicals. Chemicals introduced since 1981 had been subject to rigorous toxicity testing in Europe, but they represented less than 1 percent of all the chemicals marketed in Europe." (citing Noah M. Sachs, Jumping the Pond: Transnational Law and the Future of Chemical Regulation, 62 VAND. L. REV. 1817, 1833-35 (2009)).

[266] David Sheaffer, TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?, found at: http://www.law.msu.edu/king/2016-2017/Sheaffer.pdf

[267] *See* Canadian Environmental Protection Act, S.C. 1999, c. 33 (1999), available at http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=24374285-1.

[268] Cal. Code Regs. tit. 22, div. 4.5, ch. 55, §§ 69501–10 (2013); 27 Cal. Health and Safety Code section 25249.5. (1986)("Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986.)

[269] *See infra* notes 270 to 305 and accompanying discussion.

[270] Bach, supra note __, at 511; Proposition 65, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, http://www.oehha.org/prop65.html (last visited Feb. 12, 2014).Proposition 65, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, http://www.oehha.org/prop65.html ; CAL. HEALTH & SAFETY CODE § 25249.8

tive Green Initiative requiring safety data before marketing of a chemical is approved[271] and a comprehensive labeling statute for any product known to cause cancer, birth defects, or reproductive harm.[272] The Green Initiative has similarities to LSCA, and will eventually prioritize the most concerning chemicals for review and require review of new chemical products for safety.[273] The state has released and since revised, after public comment, its priority product work plan, identifying a limited number of chemicals for consideration, in an effort to regulate high priority chemicals.[274] The priority work plan guide is easily accessible and can be downloaded for public view.[275]

California's comprehensive labeling regime embodied in Proposition 65 and enacted as a ballot initiative in 1986, was officially designed to protect drinking water from chemicals known to cause cancer, birth defects or reproductive harm.[276] The Proposition essentially provides that before a product can go to market in California containing a substance listed on the Proposition 65 list, it must contain legislatively mandated labeling indicating that it contains a chemical with serious health concerns.[277] The California Agency, known as OEHHA, and operated under the California Environmental Protection Agency ("OEHHA")[278] administers the list according to statute,[279] calling for it to rely on others, including outside experts, authoritative bodies, including the International Agency for Research on Cancer (the "IARC"), the EPA, and the World Health Organization, as well as on state level authoritative bodies to identify toxins.[280] The OEHHA displays these toxic substances of concern, with their reason for concern (cancer, birth defects or reproductive harm), for easy public view on its website.[281] Once listed, a chemical can become delisted if is meets the relevant statutory criteria.[282]

LSCA already contains the tools for this kind of very public "list" approach within the statute as written for new chemicals and significant new chemical uses.[283] Section 6 allows the Administrator by rule (subject to Administrative Procedure) to compile and keep current a "list" of chemical substances with "respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use or disposal, or any combination of such," presents or may present an unreasonable risk of injury to health or the environment, without consideration of cost

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(1986); see also OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY (2014), available at http://oehha.ca.gov/prop65/prop65_list/files/P65single01032014.pdf..

[271] *See* Cal. Code Regs. tit. 22, div. 4.5, ch. 55, §§ 69501–10 (2013). Cal. Code Regs. tit. 22, div. 4.5, ch. 55, §§ 69501–10 (2013).

[272] 27 Cal. Health and Safety Code section 25249.5. "Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The proposition protects the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals."

[273] *See* Cal. Code Regs. tit. 22, div. 4.5, ch. 55, §§ 69501–10 (2013).

[274] *See* Final 2018-20 Priority Product Work Plan (June 2017), available at https://www.dtsc.ca.gov/SCP/PriorityProductWorkPlan.cfm

[275] *Id.*

[276] 27 Cal. Health and Safety Code section 25249.5.

[277] 27 Cal. Health and Safety Code § 25249.5. The California Proposition 65 labeling is soon to be more explicit, labeling at least one of the exact substances contained in the consumer product that is of concern effective August 2018. 27 Cal. Health and Safety Code, § § 25600 et seq.

[278] *See* https://oehha.ca.gov/proposition-65/proposition-65-list (for an easy to use list of toxic chemicals).

[279] 7 Cal. Health and Safety Code, section sections 25600 et seq.

[280] 27 Cal. Health and Safety Code §§ 25904, 25249.8, 25305,25306.

[281] See https://oehha.ca.gov/proposition-65

[282] 27 Cal. Health and Safety Code §§ 25249.8(b), 25306, 25904.

[283] 15 U.S.C. § 2604(b)(4).

or non-risk factors."[284] This list of "new" chemicals would include those that may be approved and subject to rule-making or administrative order to restrict their use while they are commercialized. In the interim, while they are being brought to market, these chemicals could be prominently displayed on the public "list."[285] Market pressure would thus be brought to bear, causing manufacturers not to want to go to market with these chemicals of concern.

American industry is and has been particularly receptive to consumer demand and public interest.[286] In the nutrition area, the organic and health food business is booming in response to consumer demand and proper labeling of organic food under federal law. [287] Conventional food labeling law[288] has likewise been used effectively in the past twenty years to make consumers more aware of the food choices they are making and to drive demand for health food and lower fat and calorie food.[289] Clearly provided information to the public allows consumers to make better food choices and drive demand for more nutritionally rich products.[290] The labeling and information transparency approach has successfully created greater awareness, and consumer demand for improved food quality and healthfulness in the supermarket has pushed manufacturers and retailers to respond accordingly.[291]

In cosmetics law, consumer demand likewise created change. When The Breast Cancer Fund first charged Revlon with putting carcinogenic products in its make-up, particularly its mascara, Revlon at first denied the charges.[292] Later, the company, apparently bowing to consumer and NGO pressure by The Breast Cancer Fund, reformulated some of its products to take out suspected toxic substances, including chemicals of concern, parabens, DMDM Hyantoin, and Quaternium-15, which releases formaldehyde into the air and can potentially be breathed in by a

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[284] 15 U.S.C. § 2604(b)(4).

[285] 15 U.S.C. § 2604(b)(4).

[286] See, e.g, Bob Moritz, Fortune, America's New Healthcare Economy: 3 Trends to Watch, January 21, 2015 (discussing consumer demand effects healthcare industry); NRDC Press Release, The Home Depot to be third major U.S. retailer to ban deadly paint strippers, June 19, 2018 (announcing that it will pull all paint removal products products containing toxic methylene chloride and N-methylpyrrolidone ; Jan Lee, CVS Banishes Formaldehyde, Other Toxics From Cosmetics, TRIPLEPUNDIT, April 24, 2017, http://www.triplepundit.com/2017/04/cvs-will-ban-formaldehyde-toxic-substances-cosmetics-2019/ (reporting that CVS will not sell consumer products containing EDCs); Andy Szal, Target Aims to Remove 'Unwanted Chemicals' From Its Products, CHEMINFO, January 4, 2017, http://www.chem.info/news/2017/01/targetaims-remove-unwanted-chemicals-its-products?cmpid=horizontalcontent.

[287] Organic Market Overview, USDA, April 4. 2017; Valerie Watnick, The Organic Foods Production Act, the Process/Product Distinction, and a Case for More End Product Regulation in the Organic Foods Market 31(1) UCLA Journal of Environmental Law & Policy, Vol. 41, 42 (2013).

[288] Michael Marlow, DO THE BENEFITS OF CALIFORNIA'S PROPOSITION 65 LAW OUTWEIGH ITS COSTS? 1 Michael L. Marlow, Professor of Economics, Cal Poly - San Luis Obispo, Presentation at the IlSI Annual Meeting 2017.

[289]Tobias J. Gillett, Lessons from Nutritional Labeling on the 20th Anniversary of the Nlea: Applying the History of Food Labeling to the Future of Household Chemical Labeling, 37 Wash. U. J.L. & Pol'y 267, 267–72 (2011).

[290] Tobias J. Gillett, Lessons from Nutritional Labeling on the 20th Anniversary of the NLEA: Applying the History of Food Labeling to the Future of Household Chemical Labeling, 37 Wash U. J. L & Pol'y, 267,269, 335 (2011).

[291] Tobias J. Gillett, Lessons from Nutritional Labeling on the 20th Anniversary of the Nlea: Applying the History of Food Labeling to the Future of Household Chemical Labeling, 37 Wash. U. J.L. & Pol'y 267, 267–72 (2011).

[292] RevlonLetter to The Breast Cancer Fund to cease and desist, dated ____, *see* A toxic situation: Walmart and Target take on chemical safety, The Guardian, https://www.theguardian.com/sustainable-business/walmart-target-toxic-chemicals-soap-makeup-revlon

person wearing mascara containing the chemical or others.[293] At least one expert has concurred that California's labeling system, while controversial for various reasons,[294] including that labels do not *yet* specify any one chemical that causes the risk and precipitated the warning (this will change in August 2018), can inspire businesses to make more health protective choices. [295]

In a similar manner to these past influences, greater transparency and consumer demand can work to improve chemical safety alongside federal regulation. The passage of the LSCA clearly signals a collective intent to more thoroughly and proactively regulate toxic substances by the populace. This is an important first step. Americans, through their elected representatives, have made clear that they do care about chemicals in the environment and their legislators have acted in response with the new legislation embodied in LSCA.

An LSCA toxic "list" (the "List") is permissible and called for under the law,[296] allowing the Administrator to compile a list of chemicals that present or may present an unreasonable risk of injury to health or the environment.[297] Were such a List to be transparently publicized, and easily accessible like those on California's Proposition 65 list,[298] it could be feared by manufacturers. California's website is easy to use, full of information, and even contains citations to the law.[299] A new chemical can be determined to have been submitted with enough information to say it is not likely to present an unreasonable risk, or that it does present unreasonable risk based on enough information. In this latter case, the EPA can issue an order *or a rule,* but the product can still be marketed. It is this determination that manufacturers would be more likely to avoid if the chemical to go to market were then placed on the publicly accessible List. And if this toxic List were public and accessible.[300] In contrast, if EPA determines that it does not have enough information to reasonably determine if the chemical presents unreasonable risk, or may present an unreasonable risk but more information is needed, or that it will be produced in substantial quantities, EPA *must* issue an order -- and in such cases can restrict the commercialization of the chemical.[301] While this chemical might still be placed on the List, it would not be entering the market without restrictions imposed by EPA order.

Manufacturers would not want to have their products appear on an LSCA toxins List, and to avoid this List, manufacturers would not ever want to seek out the section 5(f)[302] loophole that allows rulemaking in place of an EPA order restricting the use of the chemical under section 5(e).[303] Instead, manufacturers would be incentivized to provide enough information so that their application can be approved with a finding of not likely to present unreasonable risk and thereby avoid the "List" altogether. An active and transparent LSCA list would inform the public about a chemical of concern, close at least one of the loopholes as to new chemicals in the LSCA going to market pending rule-making, exert market pressure, and put industry in a position of wanting

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[293] Marc Gunther, Under Pressure: Campaigns That Persuaded Companies to Change the World, Feb. 9, 2015, https://www.theguardian.com/sustainable-business/2015/feb/09/corporate-ngocampaign-environment-climate-change (reviewing consumer impact on businesses).

[294] Brendan Borrell, Are Proposition 65 Warnings Healthful or Hurtful?, Los Angeles Times, Nov. 2, 2009.

[295] Michael L. Marlow, Professor of Economics, Cal Poly - San Luis Obispo, Do The Benefits of California's Proposition 65 Law Outweigh its Costs?, ILSI Meeting, 2017.

[296] 15 U.S.C. § 2604(b)(4).

[297] 15 U.S.C. § 2604(b)(3).

[298] The Proposition 65 List, found at: https://oehha.ca.gov/proposition-65/proposition-65-list (the list is updated monthly and is accessible by a simple google search in easy to read formats including excel, pdf and a mac friendly chart).

[299] https://oehha.ca.gov/proposition-65 (for a link to the consumer friendly site on Proposition 65 and its List).

[300] 15 U.S.C. § 2604(a)(3)(A).

[301] 15 U.S.C. § 2604(e)

[302] 15 U.S.C. § 2604(f).

[303] 15 U.S.C. § 2604(e). *See* California Code, Health and Safety Code - HSC § 25249.6 (Proposition 65).

to both make their products safer and provide enough information to EPA to garner a "not likely to present unreasonable risk finding." [304] To further improve transparency and push industry to make safer products, the EPA can and should make its website concerning Pre Market Reviews for new chemicals more user friendly and more transparent by clearly identifying actions it is taking to protect against perceived risks, be they new rules, orders or other restrictions.[305]

Conclusion

The Lautenberg Chemical Safety for the 21st Century Act revised the Toxic Substances Control Act; more than forty years after Congress first passed the Act, and is the first major environmental legislation in decades. The TSCA, originally designed to regulate toxic substances found in everyday products and not regulated by other federal laws, has been largely ineffective. In the forty plus years since passage of the TSCA, the Act has been scarcely used to ban or restrict toxic substances due to a difficult enforcement mechanisms and the grandfathering of most existing chemicals. Our past ineffective toxics regulatory scheme leaves us unprotected from chemical substances and results in much pain and suffering, in the form of cancer and other disease, as well as grave economic loss in terms of lost wages and health care costs.

For the first time, the LSCA allows EPA to move proactively to restrict new chemicals and new chemical uses on a large scale: to act in a precautionary manner, rather than in a reactive one. Initial proposed rules called for the EPA to subject new chemicals to robust review and required industry groups to submit supporting health and safety data on all reasonably expected uses of the a proposed new chemical. Moreover, the original interpretation of the LSCA would have required that the default assumption for existing chemicals would have been high priority review rather than low priority. Implementation in this manner would have helped to remove the "innocent until proven guilty" nature of our toxic substances control laws with regard to the over 80,000 chemicals on the market.

Industry pushed back on these and other health protective mechanisms in the LSCA rules and the resulting rules, finalized in July 2017, significantly weakened protections in the Act, leaving it with little teeth to protect human health and the environment. The EPA limited its review of new chemicals and new chemical uses by constraining the uses it would consider when faced with a new chemical application. Existing chemicals will by and large be designated as low priority, and this, coupled with the exasperatingly slow process of reviewing the over 87,000 chemicals currently on the market in the U.S., at just 20 chemicals over three and a half year periods, makes the prospects for this to effect real change unlikely.

More so, chemicals do not act one by one or in a vacuum. Our toxics regulatory scheme still does not and cannot realistically account for existing interactions between the thousands of chemicals on the market, the endocrine disrupting properties of many chemicals, the effect of chemical exposure on vulnerable or exposed populations, or even synergistic reactions between chemicals. If we continue to release manmade chemicals into the environment in high quantities, some of these chemicals will wind up in our air, food and water, and will combine in toxic quantities to cause disease. The reality is we live in a closed system and there is no "away" to dispose of toxic chemicals created by man. When one considers that we are exposed to multiple avenues of these "safe" levels of pesticides and other toxic substances daily from food, air and water, the combination creates the potential for poisonous synergies and resulting toxicity on a large scale. The aggregate risk from our daily deluge of chemical exposure can no longer be ignored and calls for at least a better understanding of the actual risk associated with environmental expo-

[304] *See* 15 U.S.C. § 2604(a)(3)(C).
[305] *See* 15 U.S.C. § 2604(f).

sures to the newest manmade chemicals, and even more importantly, a generally more proactive approach to chemical regulation.

Going forward, regulators should act to protect vulnerable populations, consider all conditions of use for new chemicals and actively and transparently "List" those existing chemicals that present or may present an unreasonable risk to human health or the environment. The public can then bring market pressure to bear on manufacturers to improve their products and produce safer chemicals and products. All is not lost. The LSCA as written provides new tools for the EPA to proactively regulate new chemicals, and tools for such a public toxics List. Most importantly, it signals our collective intent to be serious about chemical safety, and this, alone, is a step in the right direction.