

Spread Too Thin: How the Preemption Provisions in the 2016 Amendments to TSCA Weakened the Federal Government's Regulation of Chemical Manufacturing

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I. Introduction

Every case has a story, and the case resulting in the largest fine in history under the Toxic Substances Control Act has a story well worth hearing. In the late 1990s, a West Virginia farm owner named Wilbur Tennant was shocked by the gruesome sight of one of his cows lying dead in the woods after having encountered the chemical drainage from a nearby chemical plant.¹ The drainage contained a dangerous substance called perfluorooctanoic acid, which was already known by the chemical manufacturer, DuPont, to be highly toxic.² As it turns out, the chemical that killed Mr. Tennant's livestock was manufactured for use in various household goods, including non-stick pans, and had already made its way into homes nationwide.³

The presence of toxic chemicals in everyday goods is a problem, but not one that has gone entirely unnoticed. In 2016, Congress amended the nation's toxic chemical legislation, the Toxic Substances Control Act ("TSCA"), through the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA").⁴ The amendments strengthened and refined the mechanism through which regulators can address the spread of toxic chemicals that put the health and safety of the public at risk. Unfortunately, no law is perfect, and the new amendments to TSCA are no exception. One significant new provision in the LCSA preempts all state laws regulating

chemicals that the U.S. Environmental Protection Agency ("EPA") has selected for review, which shifts the regulatory burden to federal regulators and prevents supplementary state regulation.⁵ As of February 2017, toxic chemical legislation was pending in over twenty states.⁶ With such active state legislative bodies, there is no denying that states are important supplemental regulators when it comes to toxic chemicals; unfortunately, the LCSA stifles much of the potential for state-federal cooperation.

Undoubtedly, the LCSA is an excellent start to improving the efficacy of toxic chemical regulation. However, EPA, through issuing guidelines and utilizing the rulemaking process, should implement a few finishing touches to ensure that the changes made under the amended TSCA increase the efficiency and effectiveness of chemical regulation in the United States. Part II of this Note discusses the facts and circumstances that have influenced the modern toxic chemical legislation. Part III examines TSCA amendments under the LCSA. Part IV of this Note evaluates the efficacy and implications of the new amendments, specifically examining how the preemption provisions of the LCSA will impact the relationship between state and federal toxic chemical regulation. Part V of this Note provides a solution to the problems identified in Part IV. Finally, Part VI provides a brief overview and summary of this Note.

II. Factual Background

According to EPA, there are currently over 85,000 chemicals in circulation.⁷ These substances are researched, manufactured, and sold by more than 10,000 chemical manufactur-

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1. 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>.
2. *Id.*
3. *Id.*
4. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified in scattered sections of 15 U.S.C.).

5. 15 U.S.C. § 2617(a)(1) (2012).
6. See Pat Rizzuto, *States Pursue Toxics Lawmaking Despite Federal Law Constraints*, 41 Chem. Reg. Rep. (BNA) 8, 41 CRR 8 (BL) (Feb. 14, 2017).
7. See *About the TSCA Chemical Substances Control Inventory*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory> [<https://perma.cc/2DC8-CDJY>] (last visited Jan. 4, 2018).

ing firms in charge of the \$800 billion industry, as of 2016.⁸ Surprisingly, this number does not include the roughly 2,000 additional chemicals that are introduced into consumer goods every year,⁹ including new chemicals created as substitutes for existing chemicals like Bisphenol A (“BPA”), a harmful substance found in some baby bottles, plastic spoons, and water bottles.¹⁰ This yearly flood of new and untested chemicals creates a significant barrier for health-conscious consumers seeking to obtain meaningful safety information on the chemicals found in everyday products. This informational disparity between chemical producers and consumers has rendered consumers virtually powerless when it comes to obtaining pertinent information about the safety of consumer goods. As a result, the Federal Government has become predominantly responsible for protecting the public from exposure to toxic chemicals.

To provide further context for the need for adequate chemical regulation, the following Sections examine why comprehensive chemical regulation has been and will continue to be critical to maintaining a healthy and safe population, and will offer examples of the devastation that has resulted from ineffective chemical regulation.

A. Toxic Chemicals Have Become Too Pervasive to Avoid

According to data obtained through EPA’s Toxics Release Inventory (“TRI”) Program, in 2015 alone, over 3.4 billion pounds of toxic chemicals were released into the environment or otherwise disposed.¹¹ The sheer quantity of toxic materials managed by the U.S. chemical industry demonstrates the magnitude of the risk posed by under-tested and under-regulated toxic substance manufacturing. Even members of the medical community, such as the International Federation of Gynecology and Obstetrics (“IFGO”), have raised serious concerns regarding the potential impact that the prevalence of toxic chemicals may have on reproductive health.¹² In a publication released in October of 2015, the IFGO urged reproductive health professionals to advocate for more stringent policies that will prevent toxic chemical exposure.¹³ Despite the growing consensus that toxic chemical exposure is a legitimate threat to public safety, consumers still struggle to identify dangerous products.

Plastics, like BPA,¹⁴ have become notorious for containing hazardous chemicals, in large part due to the discreet “BPA Free” labeling that has made its way onto most plastic water bottles on the market. Nonetheless, product labeling alone does not provide sufficient protection against hazardous chemical exposures. For example, the group of chemicals called polycyclic aromatic hydrocarbons (“PAHs”), many of which are considered carcinogens by the Department of Health and Human Services,¹⁵ can be found in tar-sealants used in parking lots and playgrounds.¹⁶ Studies by the U.S. Geological Survey have indicated that PAHs are consistently identified in the homes of residents near parking lots sealed with PAH-containing coal-tar-based sealcoat in concentrations twenty-five times higher than in homes not adjacent to lots using PAH-containing sealants.¹⁷

Even when toxic chemicals are ultimately recognized as dangerous, “safer” replacement chemicals are sometimes just as dangerous as the chemicals they replace. This is well-illustrated by the shift away from the use of BPAs. In recent scientific studies, multiple chemicals introduced into the market to address the need for a safe BPA replacement were linked to the very same endocrine-disrupting hazards posed by BPA.¹⁸

Another alarming example of a questionable chemical replacement is what came after the flame retardant often found in furniture and electronics,¹⁹ polybrominated diphenyl ethers (“PBDEs”), was phased out in the United States beginning in 2005, after studies showed that this chemical was linked to health problems.²⁰ To replace PBDEs, a new flame retardant, tris (1,3-dichloro-2-propyl) phosphate (“TDCIPP”), began making its way into household furniture.²¹ One study showed that a TDCIPP metabolite was found in humans at a rate fifteen times higher in samples from 2014–2015 than in data collected from 2002–2003.²² What is most alarming about the presence of TDCIPP in humans is that some research, like the 2016 study of TDCIPP in zebrafish, has indicated that TDCIPP can cause hepatotoxicity (i.e., chemically induced liver damage).²³

When chemicals are invisible to the eye and impossible to avoid, the general public’s lack of awareness of which chemicals are dangerous and how to prevent exposure has become

8. The Int’l Trade Admin., U.S. Dep’t of Commerce, *Chemical Spotlight, the Chemical Industry in the United States*, SELECTUSA, <https://www.selectusa.gov/chemical-industry-united-states> [https://perma.cc/R58W-2HC3] (last visited Jan. 4, 2018).
 9. See Nat’l Toxicology Program, U.S. Dep’t of Health and Human Servs., *About NTP*, NAT’L INSTS. OF HEALTH, <https://ntp.niehs.nih.gov/about/index.html> [https://perma.cc/VWU3-ZWEQ] (last visited Jan. 5, 2018) [hereinafter *About NTP*].
 10. See *Bisphenol A Action Plan*, U.S. ENVTL. PROT. AGENCY (Mar. 29, 2010), https://www.epa.gov/sites/production/files/2015-09/documents/bpa_action_plan.pdf.
 11. U.S. ENVTL. PROT. AGENCY, 2015 TOXICS RELEASE INVENTORY NATIONAL ANALYSIS: EXECUTIVE SUMMARY ii (2015), https://www.epa.gov/sites/production/files/2017-01/documents/tri_na_2015_executive_summary.pdf.
 12. See Gian Carlo Di Renzo et al., *International Federation of Gynecology and Obstetrics Opinion on Reproductive Health Impacts of Exposure to Toxic Environmental Chemicals*, 131 INT’L J. GYNECOLOGY & OBSTETRICS 219, 219–23 (2015).
 13. *Id.* at 219.

14. See *supra* Part II.
 15. See MOIZ MUMTAZ & JULIA GEORGE, U.S. DEP’T OF HEALTH AND HUMAN SERVS., TOXICOLOGICAL PROFILE FOR POLYCYCLIC AROMATIC HYDROCARBONS 15 (1995).
 16. Barbara J. Mahler & Peter C. Van Metre, *Coal-Tar-Based Pavement Sealants—A Potent Source of PAHs*, LAKE LINE MAG., Spring 2017, at 13.
 17. *Id.* at 17.
 18. See Johanna R. Rochester & Ashley L. Bolden, *Bisphenol S and F: A Systematic Review and Comparison of the Hormonal Activity of Bisphenol A Substitutes*, 123 ENVTL. HEALTH PERSP. 643, 648 (2015).
 19. Whitney J. Cowell et al., *Prevalence of Historical and Replacement Brominated Flame Retardant Chemicals in New York City Homes*, 3 EMERGING CONTAMINANTS 32, 32 (2017).
 20. Press Release, Am. Chemical Soc’y, Exposure to a Newer Flame Retardant Has Been on the Rise (Feb. 08, 2017) (<https://www.acs.org/content/acs/en/press-room/newsreleases/2017/february/exposure-to-a-newer-flame-retardant-has-been-on-the-rise.html>) [https://perma.cc/2MCT-T6T4].
 21. Chunsheng Liu et al., *Acute Exposure to Tris (1,3-dichloro-2-propyl) Phosphate (TDCIPP) Causes Hepatic Inflammation and Leads to Hepatotoxicity in Zebrafish*, Sci. Rep. 6:19045, (Jan. 8, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4705469/pdf/srep19045.pdf>.
 22. Kate Hoffman et al., *Temporal Trends in Exposure to Organophosphate Flame Retardants in the United States*, 4 ENVTL. SCI. & TECH. LETTERS 112, 112 (2017).
 23. Liu et al., *supra* note 21.

an increasingly pervasive public health issue. Unfortunately, the absence of accessible information about these harmful chemicals is sometimes by design.²⁴

B. *What You Don't Know Can Hurt You, as Told by Wilbur Tennant*

We like to think EPA can effectively respond to health hazards, but practical concerns sometimes provide for a different reality. Dangerous chemicals are present in more than just consumer goods; if a company decides to dispose of a substance improperly, the substance can also find its way into the water and surrounding environment, as was the case in the town of Parkersburg, West Virginia. In 1998, a Parkersburg farmer by the name of Wilbur Tennant began to notice his cows dying at an unusual rate. The nearby chemical plant, Washington Works, seemed to be the most likely source of the waste,²⁵ and Mr. Tennant believed the owner of the plant, the chemical company, DuPont, was responsible.²⁶

What caused Mr. Tennant to suspect DuPont as the culprit behind the mysterious deaths of his livestock was a videotape he made of an area on his property containing, as the *New York Times* described it, “a mound of soapy froth.”²⁷ Mr. Tennant repeatedly discovered his livestock dead on that same tract of land, and in many cases, with blood gushing from their noses and mouths.²⁸ After struggling to obtain information about the source of the frothy contaminant that may have killed his livestock, Mr. Tennant’s lawyer came across a letter from DuPont to EPA that briefly mentioned a chemical in one of DuPont’s landfills called “PFOA,” or perfluorooctanoic acid.²⁹ PFOA is a chemical often found in nonstick Teflon cookware³⁰ which laboratory tests have linked to “reproductive, developmental, and systemic effects.”³¹

As it turns out, DuPont not only knew PFOA was hazardous, but it also took significant steps to purge itself of the chemical.³² There were a few problems, however, with how DuPont chose to mitigate its PFOA problem. First, 3M, the creator of PFOA from which DuPont purchased production rights in 1951, had known since the 1960s that PFOA was

potentially dangerous.³³ In fact, 3M was producing another nearly identical chemical called PFOS (used in Scotchgard®), which was removed from the market after evidence linked it to “postnatal deaths and other adverse developmental effects in offspring.”³⁴ By the early 1990s, there was enough evidence in the hands of 3M and DuPont to concretely indicate a link between PFOA and a variety of health problems, including cancer.³⁵ Despite the blatant warning signs of danger to the public if PFOA production continued, DuPont delayed the removal of PFOA from the market, even after finding a “viable candidate” for replacing PFOA in 1993.³⁶ It should also be noted that \$1 billion of DuPont’s yearly profits came from its PFOA production.³⁷

Second, DuPont did not alert EPA to the risks associated with PFOA until 1982.³⁸ When DuPont finally came forward with health information on PFOAs, it did so by providing West Virginia regulators with the results of studies that questioned the link between PFOA and health problems,³⁹ a conclusion that undeniably failed to tell the whole story. Finally, beginning in the 1980s, DuPont’s concern over the health problems caused by PFOA forced the company to start finding ways to get rid of the chemical waste from PFOA production.⁴⁰ DuPont ultimately decided to dump the PFOA waste into Dry Run Creek near the Washington Works plant, despite DuPont’s awareness that utilizing this site for dumping created a high risk of contaminating the water sources of nearby residents.⁴¹

After evaluating the claim that PFOA had been killing Mr. Tennant’s cows, EPA ordered the testing of Parkersburg residents to determine the PFOA levels in the blood of residents living in proximity to the Washington Works plant⁴²; and the results were astounding. The normal PFOA level in humans is around five parts per billion (ppb), but the residents in the area near DuPont’s Washington Works plant had median PFOA levels between 298 and 369 ppb,⁴³ more than seventy times the healthy PFOA level. The PFOA

24. See Editorial, *Despite Clear Dangers, Dupont Kept Using a Toxic Chemical*, N.Y. TIMES (Jan. 12, 2016), <https://www.nytimes.com/2016/01/12/opinion/despote-clear-dangers-dupont-kept-using-a-toxic-chemical.html> [https://perma.cc/FK7M-V8NA].

25. Rich, *supra* note 1.

26. *Id.* at 1.

27. *Id.* at 3.

28. *Id.* at 3.

29. *Id.*

30. *Id.* See also Emily Hammond et al., *TSCA Reform: Preserving Tort and Regulatory Approaches*, CTR. FOR PROGRESSIVE REFORM ISSUE ALERT #1309 10 (2013), <http://ssrn.com/abstract=2733769>.

31. See *Assessing and Managing Chemicals Under TSCA: Per- and Polyfluoroalkyl Substances (PFASs) Under TSCA*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/and-polyfluoroalkyl-substances-pfass-under-tsca> [https://perma.cc/HN3L-9ZWV] (last visited Jan. 5, 2018).

32. See Rich, *supra* note 1 (“By the late 1980s, as DuPont became increasingly concerned about the health effects of PFOA waste, it decided it needed to find a landfill for the toxic sludge dumped on company property. . . . By 1990, DuPont had dumped 7,100 tons of PFOA sludge into Dry Run Landfill.”).

33. See *id.* (“In 1961, DuPont researchers found that the chemical could increase the size of the liver in rats and rabbits. A year later, they replicated these results in studies with dogs.”).

34. Thomas O. McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, 37 ENVTL. L. 1027, 1037 (2007).

35. See Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2356 (2017) (“As it turns out, the health risks from PFOA exposure are potentially significant; in 2011 government scientists released findings of a “probably link” [sic] between PFOA “kidney cancer, testicular cancer, thyroid disease, high cholesterol, pre-eclampsia and ulcerative colitis.”).

36. See Rich, *supra* note 1 (“An interoffice memo sent in 1993 announced that ‘for the first time, we have a viable candidate’ that appeared to be less toxic and stayed in the body for a much shorter duration of time. Discussions were held at DuPont’s corporate headquarters to discuss switching to the new compound. DuPont decided against it. The risk was too great: Products manufactured with PFOA were an important part of DuPont’s business, worth \$1 billion in annual profit.”).

37. See *id.*

38. *Id.*

39. *Id.*

40. See *supra* text accompanying note 32.

41. See *id.*

42. See U.S. ENVTL. PROTECTION AGENCY, *DUPONT AGREES TO LOWER LIMIT OF PFOA IN DRINKING WATER 3* (2009), <https://www.epa.gov/sites/production/files/2016-05/documents/dupont-fs0309.pdf>.

43. *Id.*

levels of the nearby residents were even higher than what DuPont's very own internal safety standards designated as safe.⁴⁴ Because of this discovery, the agency took two critical steps: (1) EPA obtained valuable data through litigation discovery, thereby allowing EPA to use its authority under TSCA to diminish the use of PFOA in household products, and (2) EPA awarded the largest fine ever issued for a violation of TSCA, in the amount of \$16.5 million.⁴⁵

Unfortunately, the outcome of the DuPont case was a rarity. It is highly improbable that a small-town farmer will know where to begin an arduous legal battle like the one fought by Mr. Tennant in Parkersburg, West Virginia, and even less likely that such a battle will be won. Unfortunately, the most important takeaway from the fight between Mr. Tennant and DuPont is not the optimistic sentiment that PFOAs finally experienced a damaging blow, and eventually, that PFOA manufacturing ceased. Instead, it was not until after hundreds of animals were dead and PFOA had contaminated an entire town that EPA had the opportunity to take effective regulatory action. This case revealed an unfortunate truth about the regulation of the toxic chemicals industry: there are too many chemicals that pass through the regulatory system without being thoroughly evaluated for safety. Had Mr. Tennant not been determined to get to the bottom of the issue, EPA might have never obtained necessary safety information on PFOAs, and consequently, may have never had the opportunity to address the tragic effects of the haphazard disposal of PFOA-laden waste.

The silver lining in this story is that situations like Mr. Tennant's gave momentum to some of the most important legislative changes in the history of toxic chemical regulation. The next Section of this Note will parse out the legal aspects of the recent toxic chemical legislation created to facilitate preventative and remedial measures for public exposure to hazardous chemicals.

III. Legal Background

Although the original passage of TSCA was a major victory for those seeking to improve the safety of toxic chemical manufacture, distribution, and management in the United States, many problems with the legislation were revealed in the years following its passage. Namely, EPA could not enact meaningful regulations without clearing the legislative hurdles present in TSCA. The deficiency in EPA's practical regulatory power under TSCA was widely recognized,⁴⁶ and curing this deficiency became a major objective for the drafters of TSCA amendments implemented under the Frank

R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA").^{47, 48}

The following portions of this Note discuss the history and development of the LCSA, specifically: Subpart A reviews the provisions of the new law and its underlying mechanics; Subpart B expands on the discussion of the preemption provisions of the LCSA, looking at the targets and timing of the preemption; and Subpart C discusses specific examples of state regulatory schemes affected by the preemption provision.

A. *How the Frank R. Lautenberg Chemical Safety for the 21st Century Act Finally Gave TSCA Some Teeth*

Until 1976, the initial date of passage of the Toxic Substances Control Act,⁴⁹ chemicals were researched and manufactured in what many referred to as "the Wild West" of toxic chemical regulation,⁵⁰ with scarce to nonexistent oversight by EPA concerning what could be released by manufacturers into consumer markets.⁵¹ During this time, EPA was powerless to require that chemical manufacturers test chemicals before assuming they were safe for human exposure,⁵² which left numerous chemicals inadequately reviewed. According to John R. Quarles, the Deputy Administrator of EPA at the time of TSCA's initial passage, the new regulatory scheme was "one of [the] most urgently needed environmental laws."⁵³ In reaching this conclusion, he pointed to the example of the use of vinyl chloride in plastics, a chemical linked to liver cancer that caused the deaths of fifteen people, as just one of many highly toxic chemicals found in various commercial goods.⁵⁴

Even after the passage of TSCA, toxic chemical regulation in the United States was inadequate. While intended to be effective chemical regulation, TSCA, as written, was a mere shell that ultimately kept EPA from getting anything done. For example, Section 6 of TSCA⁵⁵ mandated that EPA evaluate the risks posed by toxic chemicals and take regulatory action to limit these risks by conducting a balancing test and regulating these substances using the least burden-

44. Rich, *supra* note 1.

45. See Hammond et al., *supra* note 30; see also McGarity, *supra* note 34, at 1033-47.

46. *Frank R. Lautenberg Chemical Safety for the 21st Century Act: Hearing on S. 697 Before the S. Comm. on Env't and Pub. Works*, 114 Cong. 19-20 (2015) [hereinafter *2015 Hearing*] (statement of Hon. Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency).

47. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified at 15 U.S.C. § 2601 et seq. (2016)).

48. 161 Cong. Rec. S8877-78 (daily ed. Dec. 18, 2015) (statement of Sen. Merkley).

49. 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, 338 (2010).

50. See, e.g., Cory Gerlach, *New Toxic Substances Control Act: An End to the Wild West for Chemical Safety?*, HARV. U.: SCI. NEWS (Oct. 25, 2016), <http://sitn.hms.harvard.edu/flash/2016/new-toxic-substances-control-act-end-wild-west-chemical-safety/> [https://perma.cc/FT5K-WKB5].

51. Melissa Lee Phillips, *Obstructing Authority: Does the EPA Have the Power to Ensure Commercial Chemicals Are Safe?*, 114 ENVTL. HEALTH PERSP. 12 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1764141/> [https://perma.cc/7UAB-QTMY].

52. See *id.*

53. Press Release, U.S. Env'tl. Prot. Agency, Quarles Testifies on the Need for Toxic Substances Act (July 10, 1975), <https://archive.epa.gov/epa/aboutepa/quarles-testifies-need-toxic-substances-act.html> [https://perma.cc/3STU-ZY98].

54. *Id.*

55. Toxic Substances Control Act § 6, 15 U.S.C. § 2605 (2012).

some means.⁵⁶ When EPA sought to use its power to regulate asbestos under its Section 6 authority, the Fifth Circuit struck down its regulatory action by interpreting the words “least burdensome” in Section 6 as akin to “least costly.”⁵⁷

Even more indicative of TSCA’s ineffectiveness at regulating toxic chemicals is the testimony provided by Jim Jones, the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at EPA, at an LCSA hearing in 2015. When Oklahoma’s Senator Inhofe asked Mr. Jones how many chemicals have been regulated by EPA under its Section 6 authority since 1990, Mr. Jones provided a powerful answer: “Zero.”⁵⁸

As time went on, the problems with the initial TSCA became evident, particularly concerning EPA’s power—or lack thereof—to require chemical testing when a new substance was under its review.⁵⁹ In response to the gaps later revealed in the original TSCA and the growing need for more stringent controls on the chemicals in circulation, lawmakers started working to address the unsuccessful portions of the law. After forty years without meaningful reform to the nation’s toxic substance regulations, a few dedicated legislators’ desire to enact legislation providing “real momentum for meaningful reform” culminated in the Frank R. Lautenberg Chemical Safety for the 21st Century Act.⁶⁰ Among the areas of the law given much-needed updates were those that dealt with EPA’s ability to obtain information used to make thorough safety evaluations and place time limitations on the review period before chemicals were presumed safe.⁶¹ The new legislation also brought with it some profound changes, including a provision preempting concurrent state regulation of toxic substances.⁶² This proved to be one of the LCSA’s most complex and controversial additions.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law by President Obama on June 22, 2016, with significant bipartisan support.⁶³ Among those in favor of improving the outdated TSCA were consumers and environmental groups, and surprisingly, many large corporate entities.⁶⁴ Other notable groups in favor of the LCSA included animal rights groups, which were particularly pleased with the new restrictions placed

on testing potentially toxic chemicals on animals.⁶⁵ Ultimately, regulatory reform was welcomed by almost every industry participant.

However, a notable number of interest groups opposed the LCSA.⁶⁶ The opposition included over 450 organizations, including the Breast Cancer Fund, the Asbestos Disease Awareness Organization, and the American Nurses Association.⁶⁷ While the reasons provided by these groups varied, one common thread between the LCSA’s opposition was the strong disapproval of the amending legislation’s preemption provisions.⁶⁸ In fact, the preemption provision was arguably the most contentious portion of the new law and could have easily been the provision that prevented the final passage of the LCSA. The powerful chemical lobby was undoubtedly a significant player in the inclusion of this amendment,⁶⁹ especially given the industry’s claims that the patchwork regulation of toxic chemicals by state regulators was overly burdensome and costly.⁷⁰ Because such reform was long overdue, the LCSA brought numerous significant revisions to EPA’s power through toxic chemical legislation, which are discussed more specifically in the next Sections.

B. Chemical Review Process Under the Frank R. Lautenberg Chemical Safety for the 21st Century Act

The LCSA charges the EPA Administrator with determining which chemicals pose a substantial or unreasonable risk to human health, taking into account both the degree and likelihood of exposure to the chemical in question.⁷¹ The Administrator is not only responsible for making a risk determination upon the introduction of a new chemical into the market, but also for evaluating the risks posed by chemicals used for new purposes, and assessing chemicals already in use that the Administrator believes may be potentially harmful.⁷²

When a manufacturer wants to release a new chemical onto the market, it must file with EPA under Section 5 of the LCSA and submit a Pre-Manufacture Notice (“PMN”) at least ninety days before the start of the manufacturing.⁷³ After a receiving the PMN, the Administrator begins reviewing the chemical to determine whether the intended production and use are likely to pose an unreasonable risk to human

56. *Id.*

57. See generally *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991), *opinion clarified* (Nov. 15, 1991) (finding that EPA’s choice of regulatory action to prevent harmful asbestos exposure did not give sufficient weight to the financial costs of the chosen form of regulation).

58. 2015 Hearing, *supra* note 46, at 40 (statement of Hon. Jim Jones, Assistant Adm’r, Office of Chem. Safety and Pollution Prevention, Env’t Protection Agency).

59. Sarah E. Light, *Foreword: Regulating Toxic Chemicals Through Precautionary Federalism*, 3 PENN. UNDERGRADUATE L.J. 1, 5 (2016).

60. Pub. L. No. 114-182, 130 Stat. 448 (2016) (to be codified in scattered sections of 15 U.S.C.); 2015 Hearing, *supra* note 46, at 1 (opening statement of Sen. Inhofe, indicating that former Sen. Frank R. Lautenberg, whose mission toward the end of his career was to enact legislation providing “real momentum for meaningful reform,” had the intention of ensuring that all “stakeholders” in the potential reform were in agreement and sought wide bipartisan support for the changes).

61. 15 U.S.C. § 2603 (2012).

62. *Id.* § 2617.

63. 2015 Hearing, *supra* note 46, at 1 (opening statement of Sen. Inhofe).

64. *Id.* at 3–7 (letters of support from over 100 industry members of the American Allegiance for Innovation (“AAI”).

65. 15 U.S.C. § 2603(h); see also Lynn L. Bergeson, Lynn R. Goldman, James V. Aidala & Lawrence E. Cullen, *Toxic Substances Control Act Reform: What’s Happening, and What’s Next?*, 46 ELR 10357 (May 2016).

66. 2015 Hearing, *supra* note 46, at 10.

67. *Id.*

68. *Id.* (“When considered in light of its aggressive preemption of state law that would actually remove existing protections in many states, the bill is actually worse than the existing statute from a consumer protection perspective.”)

69. See, e.g., *id.* at 90–91 (testimony of Kenneth Cook, President, Environmental Working Group).

70. *Id.* at 159 (statement of Richard A. Denison, Ph.D., Lead Senior Scientist, Environmental Defense Fund) (“Now, it needs to be noted that the current patchwork of state regulations and laws, which we have strongly supported, cover only a small number of chemicals and reach only a fraction of the American public.”).

71. 15 U.S.C. § 2605 (2016).

72. *Id.*

73. *Id.* § 2604.

health, paying particular attention to whether vulnerable populations, such as children and the elderly, will be particularly at risk of exposure.⁷⁴

After the Administrator makes a risk determination for a given chemical, it is placed on the TSCA inventory, which is the list of all chemicals EPA has reviewed and assigned risk-determinations.⁷⁵ Once on the inventory, chemicals are subject to Significant New Use Rules (“SNURs”) that apply if a manufacturer intends to use a substance for a substantially different purpose from the purpose initially indicated on the TSCA Inventory.⁷⁶ If the chemical is evaluated as a “significant new use” chemical, EPA must determine whether the substance will in fact be manufactured for a substantially new use.⁷⁷

In deciding whether the chemical substance will be manufactured for a significantly new use, the Administrator must consider (1) the projected amount of the substance that will be manufactured and produced, (2) the extent to which the chemical’s new use will change the type and form of exposure to the substance, (3) the extent to which the use will increase the magnitude and duration of exposure to the substance, and (4) the expected manner and methods of manufacturing, processing, distribution, and disposal of the substance.⁷⁸

In addition to undertaking review of new chemicals and chemicals designated as significant new use chemicals, the LCSA also provides the Administrator with broad authority to review any chemical reasonably believed to pose harm to human health or the environment, or any chemical for which sufficient data has not been developed to make such a determination.⁷⁹ This review authority gives the Administrator incredible power to review any chemical in existence, thus providing a mechanism for reevaluation of chemicals that were previously out of the Administrators review power under the initial TSCA legislation.

Once the Administrator begins review of a chemical, the Administrator must make a determination that either the chemical is “high-risk,” as it presents an unreasonable risk of injury to human health or the environment, or “low-risk,” as the chemical does not present an unreasonable risk to human health or the environment.⁸⁰ The Administrator may also find that additional information is required to make a determination regarding the chemical’s risk of injury to health or the environment, and that without this additional information, (1) the production, utilization or disposal of the substance may pose an unreasonable risk to the environment or vulnerable subpopulations, or (2) the substance will be produced in substantial quantities, and there will be either significant

human exposure to the substance or the chemical will enter the environment in large quantities.⁸¹

C. Time Limitations of the Review Process

Once the review process has begun, the LCSA imposes multiple limitations on the Administrator regarding the duration of the review process. First, chemicals reviewed pursuant to a PMN or under the SNURs cannot be manufactured for ninety days, unless the Administrator makes a risk determination before the ninety-day period has concluded.⁸² The Administrator may, for good cause, extend the initial review period by up to ninety days.⁸³ If the Administrator believes there could be significant exposure to the substance due to the volume of production, or that there is insufficient information to make an adequate determination, the Administrator must communicate this information to the manufacturer in writing within forty-five days of the end of the ninety-day initial review period.⁸⁴

The expiration of the ninety-day period does not relieve the Administrator of the duty to make a risk priority determination.⁸⁵ Such risk determination, irrespective of the ninety-day prohibition on manufacturing or production, must be made within the time frame the Administrator established during the rulemaking process.⁸⁶ However, the rule must set the deadline for risk prioritizations at no more than one year and no less than nine months after the initial risk evaluation is undertaken.⁸⁷ Additionally, manufacturer requested risk evaluations must be completed within three years of the date the request was granted.⁸⁸

Restrictions imposed on the manufacture of a certain chemical are dependent on the risk designation that is given to the substance. However, the Act makes clear that for chemicals subject to review, unless a “low-risk” determination is made, the manufacturer is prohibited from continuing the manufacture or production of the chemical under review, even if the Administrator fails to Act within the time frame allotted for completing the risk determination.⁸⁹

D. Testing Requirements and the Implications of High-Risk and Low-Risk Designations

As previously mentioned, once the EPA Administrator takes a chemical substance under review, a determination must be made concerning the priority designation of that chemical.⁹⁰ After beginning the risk evaluation of a chemical, the Administrator has six months to publish the scope of the review and indicate the types of uses and hazards that the Administra-

74. *Id.*

75. *Id.*; see also *Reviewing New Chemicals Under the Toxic Substances Control Act (TSCA): Is My Chemical Subject to a SNUR?*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tasca/regulatory-actions-under-tasca/> [<https://perma.cc/4K3V-AFRR>] (last visited Jan 23, 2017) [hereinafter *Reviewing New Chemicals*].

76. *Reviewing New Chemicals*, *supra* note 75.

77. 15 U.S.C. § 2604.

78. *Id.*

79. See *id.* § 2603.

80. *Id.* § 2605(b).

81. *Id.*

82. *Id.* § 2604(a)(1)(B).

83. *Id.* § 2604(c).

84. *Id.* § 2604(e)(1)(B).

85. *Id.* § 2604(a)(4)(A).

86. *Id.*

87. *Id.* § 2605(b)(1)(C).

88. *Id.* § 2605(b)(4)(G).

89. *Id.* § 2604(a)(4)(B)(iii).

90. *Id.* § 2604(a)(1)(B)(ii)(II).

tor's determination will encompass.⁹¹ There are three possible outcomes: (1) the chemical is determined to be a high-risk substance that "presents an unreasonable risk of injury to health or the environment"⁹²; (2) a risk determination cannot be made because of insufficient information with respect to the risk potential of the chemical or because of significant exposure potential⁹³; or (3) the chemical is determined to be a low-risk substance that "is not likely to present an unreasonable risk of injury to health or the environment."⁹⁴

Upon making a high-risk designation for a particular chemical, the Administrator must take one or more various types of actions, as needed, to protect against the risks posed by the chemical, including: (1) limiting the manufacture, processing, or distribution of the substance for particular uses; (2) requiring warning labels and other informational disclosures; (3) limiting the commercial uses for the chemical; (4) prohibiting the manufacture, processing, or distribution of the substance in commerce, as long as there is notice provided to the manufacturer within forty days of the expiration of the ninety-day review period; or (5) "consult[ing] with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance . . . to address workplace exposures."⁹⁵

If the Administrator is unable to designate a chemical as either high-risk or low-risk, the Administrator must issue an order that establishes any restrictions on the manufacture or production of the chemical until information sufficient to make a determination is produced.⁹⁶ The manufacturer may continue manufacturing or producing the chemical in any manner that is not inconsistent with the Administrator's order, even if additional tests of the chemical must be produced before a risk determination can be made.⁹⁷ Finally, if the administrator determines that a chemical is low-risk, the manufacture and production of the chemical may resume, and the Administrator must publish the risk determination in the *Federal Register*.⁹⁸

E. No Double Dipping: The LCSA's New Preemption Provisions

Unlike prior toxic chemical legislation, the LCSA features a provision that preempts state laws from co-regulating any toxic chemical actively regulated under federal law.⁹⁹ The preemption provision invalidates state laws governing the production, manufacture, or use of chemicals in any manner when applied to chemicals that the Administrator has reviewed or is currently reviewing.¹⁰⁰ More specifically, a state law is preempted if it imposes restrictions, notifica-

tion requirements, or testing requirements for any chemical that is already the subject of EPA restrictions.¹⁰¹ Although the preemption provisions of the LCSA are extraordinarily broad, there are some exceptions to preemption, as well as an option for states to apply for a waiver of preemption if they choose to do so.¹⁰²

As previously mentioned, preemption was one of the most contentious issues facing the passage of the LCSA.¹⁰³ Some legislators viewed the preemption provision as destroying the potential for co-enforcement between state and federal authorities,¹⁰⁴ and the governors of various states with well-established chemical safety laws also fiercely opposed it.¹⁰⁵ Chemical manufacturers, however, saw the preemption provision as a victory. According to the chemical lobbying group, American Chemistry Council, the provision would "reduce the number of inconsistent state-based chemical initiatives that impede interstate commerce and send mixed messages to consumers."¹⁰⁶

The preemption of state regulation under the new amendments comes in the form of "ceiling preemption" that "prohibits lower levels of government from requiring anything more than or different from what the higher-level law requires . . . [and] can completely prohibit lower-level governments from passing any law regulating the topic or area in question."¹⁰⁷ The text of the LCSA calls for the preemption of state laws regulating a chemical for which a determination has been made by the Administrator, regardless of the actual outcome of the determination.¹⁰⁸ In other words, if the Administrator determines a chemical is low-risk, state regulation of that chemical is indefinitely prohibited.

Pause preemption refers to the preemption of new state laws regulating substances that the Administrator has begun to review, starting when the scope of review is established by the Administrator, and ending when a review determination has been made.¹⁰⁹ Pause preemption does not apply to the enforcement of already enacted laws regulating a chemical before the Administrator took the chemical under review.¹¹⁰ State laws requiring the production of information that "is

91. See *id.* § 2605(b)(4)(D).

92. *Id.* § 2604(a)(3)(A).

93. See *id.* § 2604(a)(3)(B).

94. *Id.* § 2604(a)(3)(C).

95. *Id.* § 2604(f)(5).

96. *Id.* § 2604(e).

97. *Id.*

98. *Id.* § 2604(g).

99. *Id.* § 2617.

100. *Id.*

101. *Id.*

102. *Id.*

103. See, e.g., 2015 Hearing, *supra* note 46, at 72–73 (statement of Sen. Cardin during questioning of Mr. Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency).

104. See, e.g., *id.* at 83 (questioning by Sen. Merkley of Mr. Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency).

105. *Id.* at 98 (Statement from Sen. Boxer indicating the opposition of governors from California, Massachusetts, New York, Iowa, Maine, Maryland, Oregon and Washington, as a result of the effects of the preemption provision of the TSCA amendment).

106. *Chemical Management: Lautenberg Chemical Safety Act*, AM. CHEMISTRY COUNCIL, <https://www.americanchemistry.com/Policy/Chemical-Management/LCSA.html> [https://perma.cc/R9LQ-6XE5] (last visited Apr 10, 2017).

107. 15 U.S.C. § 2617; *Fundamentals of Preemption*, PUB. HEALTH L. CTR., <http://www.publichealthlawcenter.org/sites/default/files/resources/nplan-fs-fundamentals-2010.pdf> (last visited Jan. 5, 2016).

108. 15 U.S.C. § 2617; TOXICS USE REDUCTION INST., UPDATES TO THE TOXIC SUBSTANCES CONTROL ACT (TSCA): CHANGES TO THE STATE-FEDERAL RELATIONSHIP: PREEMPTION PROVISIONS 1–2 (2016), <http://www.turi.org/content/download/10306/172638/file/Fact%20Sheet.%20TSCA%20Preemption%20Provisions.%20June%202016.pdf>.

109. 15 U.S.C. § 2617; TOXICS USE REDUCTION INST., *supra* note 108, at 1–2.

110. *Id.*

reasonably likely to produce the same information required” by the LCSA during the Administrator’s review process are pause preempted.¹¹¹ Essentially, pause preemption begins when the chemical is taken under review, and long-term preemption kicks in when a review determination is made. Pause preemption is merely intended to “fill the gap” while the Administrator is working to develop sufficient information to make a review determination.¹¹²

Although the scope of preemption in the LCSA is incredibly broad, a few state actions have been exempted from preemption. Most notably, states are not preempted from enforcing or creating any law that “implements a reporting, monitoring, or other information obligation for the chemical substance not otherwise required” by the LCSA or other federal law.¹¹³ Consequently, if a state regulation only requires informational disclosures and does not restrict the use or manufacture of the chemical as a result, preemption does not apply. Other additional exceptions to preemption include any state laws that are related to water quality, air quality, or waste treatment or disposal, unless the law would be inconsistent with action previously taken by the Administrator.¹¹⁴

In addition to determining the types of laws preempted, the LCSA establishes that any chemical-specific state laws enacted prior to April 22, 2016, and any state regulatory framework in place prior to August 31, 2003 are not preempted.¹¹⁵ Interestingly, the 2003 date was set to avoid preempting California’s Proposition 65,¹¹⁶ which played an integral role in setting the bar for the TSCA reform that came about in 2016. Despite the carve-out for the California toxics law, many other state regulatory laws are vulnerable to complete preemption if they are not directed at specific chemicals, as is required for any law passed after the 2003 cutoff date.

Another noteworthy aspect of preemption under the LCSA is that a state seeking to enforce a law subject to preemption, whether long-term or pause preemption, can apply for exemption from preemption.¹¹⁷ The LCSA differentiates between discretionary exemptions and required exemptions,¹¹⁸ both of which are subject to public notice and comment.¹¹⁹

The Administrator must grant required exemptions if the state requirements would not (1) unduly burden interstate commerce in creating or utilizing the substance; (2) cause a violation of any federal law, rule, or order; and (3) the state’s

concern for the specific chemical is based upon peer-reviewed science.¹²⁰ Alternatively, states with existing laws that restrict a chemical under review by the administrator will have as much as eighteen months after EPA begins the prioritization process, or until the risk evaluation is published—which ever is sooner—to continue enforcing the law.¹²¹ Once EPA makes a risk determination, however, the state law is again preempted, unless a discretionary exemption is granted.

Discretionary exemptions, in contrast to required exemptions, are granted upon the Administrator’s determination that the following four factors are satisfied: (1) compelling conditions make the exemption necessary to protect human health or the environment; (2) compliance with the proposed state requirement would not unduly burden interstate commerce; (3) compliance with the proposed state requirement would not cause a violation of any applicable Federal law, rule, or order; and (4) the proposed requirement addresses a risk posed by a chemical substance in a way that is consistent with the best available science, based upon studies utilizing sound and objective scientific practices, and based on the weight of the scientific evidence.¹²² The statute does not provide any guidance on how the Administrator should interpret each of these requirements when granting a discretionary exemption.

After a state applies for a waiver of preemption, the Administrator must make a risk determination within 110 days of receiving a required exemption application, and within 180 days of receiving a discretionary exemption application.¹²³ If an application for required exemption is not reviewed within the 110-day time frame, the exemption is automatically approved.¹²⁴ A required waiver is only valid until the Administrator publishes the final risk determination.¹²⁵ All decisions concerning whether state exemption applications are granted or denied are judicially reviewable and subject to various time and venue limitations.¹²⁶

F. State Toxic Chemical Laws: What Now?

State preemption was particularly contentious because it subjected many existing state laws to potential preemption,¹²⁷ but despite this, many states have continued to push ahead with new chemical reform legislation.¹²⁸ As of February of 2017, chemical reform legislation had been introduced in sixteen states, with another five states anticipating the eventual introduction of similar legislation, as of 2017.¹²⁹ Among the pieces of legislation passed since the enactment of the LCSA is a bill in California that would impose ingredient label-

111. 15 U.S.C. § 2617; TOXICS USE REDUCTION INST., *supra* note 108, at 1–2.

112. Daniel E Uyesato, *TSCA Amendments: Highlights and Implications for Downstream Users of Chemicals*, 48 A.B.A. SEC. ENV’T, ENERGY, RESOURCES 1, 2–4 (2016).

113. 15 U.S.C. § 2617(d)(1)(A)(ii) (2016).

114. *Id.*

115. *Id.* § 2617(e)(1).

116. *See, e.g.*, S. REP. NO. 114-67, at 26 (2015) (“[Section 17] adopts similar language to section 231(b) of the Consumer Product Safety Improvement Act (CPSIA), which was intended to exclude California’s “Proposition 65” requirements from federal preemption under that Act. It is the Committee’s intent that adopting this provision in S. 697 would effectively achieve the same result.”); *see also* Dennis E. Raglin, *The New Toxic Substances Control Act: How We Got Here, the Highlights of the New Law, and How It Impacts Companies and Their Products*, 34 WESTLAW J. TOXIC TORTS 1, 3 (2016).

117. *See* 15 U.S.C. § 2617(f).

118. *Id.* § 2617(f)(1)–(2).

119. *Id.* § 2617(f)(5).

120. *Id.* § 2617(f)(2)(A).

121. *Id.* § 2617(f)(2)(B).

122. *Id.* § 2617(f)(1).

123. *Id.* § 2617(f)(3).

124. *Id.* § 2617(f)(4).

125. *Id.* § 2617(f)(7).

126. *Id.* § 2617(f)(8).

127. *See, e.g.*, 2015 Hearing, *supra* note 46, at 79 (statement of Sen. Cardin during questioning of Mr. Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency).

128. Rizzuto, *supra* note 6.

129. *Id.*

ing requirements in household cleaning products, including fragrances,¹³⁰ and a Maine law restricting the sale of couches containing certain levels of flame retardants.¹³¹

Although some states seem undeterred by the new chemical reform laws, many critics of the preemption provision are concerned with the implications of taking states out of the picture when it comes to regulating the chemicals taken under review.¹³² Some commentators believe that pushing the states out and shifting the final say to EPA is arbitrary.¹³³ While there can only be speculation as to the implications of this power-shift, giving the Administrator the sole power to regulate chemicals may undermine the possibility of thorough toxic chemical review.¹³⁴ By diminishing state regulatory power, there is no safety net to mitigate the consequences of a mistaken risk determination issued by the Administrator.

For instance, in 2015, the U.S. Court of Appeals for the Ninth Circuit held that EPA approval of a chemical called sulfoxaflor, produced by Dow AgroSciences, was based on “flawed and limited data,” striking down the approval until further data was presented to show the chemical was safe.¹³⁵ After reviewing sulfoxaflor, EPA determined that additional testing was required before granting unconditional approval of the chemical as a pesticide, but EPA unexpectedly granted the chemical unconditional approval before the additional testing had been completed.¹³⁶ Sulfoxaflor was controversial because of its potentially devastating impact on local honey-bee populations.¹³⁷

This story is illustrative in evaluating the LCSA’s preemption provisions because California’s Department of Pesticide Regulation indicated that it has “long had concerns about sulfoxaflor’s impact on bees and has never allowed unconditional registration in that key farming state.”¹³⁸ In other words, EPA approved a potentially bee-harming chemical for use as a pesticide on crops that attract bees, whether by mistake or negligence, and the state of California was ready to pick up the pieces.¹³⁹ Although pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide

Act (“FIFRA”),¹⁴⁰ not under TSCA,¹⁴¹ the facts of the situation show the respective roles state and federal regulators can play when new chemicals are poised to enter the market.

During a hearing on the LCSA, Sen. Barbara Boxer (D-Cal.) stated: “I absolutely don’t believe in allowing the perfect to be the enemy of the good.”¹⁴² Unfortunately, the LCSA in its current form is not good enough. There is too much at stake when the EPA Administrator is given the sole authority to regulate toxic chemicals that could cause severe medical problems for millions of Americans. To combat this, the states and EPA must work together to create a symbiotic state-federal relationship and ensure the goal of the nation’s toxic chemical regulatory system is to effectively, accurately, and efficiently regulate toxic substances.

IV. Legal Analysis

The preemption of the state regulations of chemicals under review, or already reviewed, by EPA may be the pitfall of the entire LCSA. The most basic issue posed by the preemption provision is the under-utilization of the state regulatory systems, which are the best entities to address the issues most seriously affecting the states’ unique geography because of their proximity to and vested interest in the outcome of local issues. Preemption fails to recognize that the states have the most effective means for determining which chemicals have the potential to cause the most harm to their populations.

The priorities and perspectives on chemical regulation for state and federal regulators are vastly different. This may be a result of the differences in the geographical area for which they are responsible. However, when both regulatory bodies work in tandem to keep toxic chemicals from making their way into the homes of unsuspecting families, the likelihood that toxic chemicals slip through the regulatory cracks is much lower. By tying the hands of state regulatory bodies, which begins the moment EPA takes an interest in reviewing a given chemical, too much power is placed in the hands of the federal regulators. Furthermore, if the EPA Administrator gets it wrong, states have few choices other than to engage in costly and time-consuming litigation or to just sit back and watch the potential hazards of dangerous chemicals go unchecked.

The Sections below examine the unique benefits of state toxic chemical regulation and the practical limitations on federal toxic chemical regulation. They will examine where the justifications for preemption of state law fall short, specifically concerning the Administrator’s final say on reviewed chemicals. Finally, the next sections will discuss why exceptions and waivers do not adequately mitigate the problems with LCSA’s preemption provisions.

130. California Cleaning Product Right to Know Act of 2017, Cal. Health & Safety Code § 108950–108960.

131. Me. Rev. Stat. tit. 38, § 1609 (2010).

132. See Light, *supra* note 59, at 9.

133. *Id.* at 1.

134. *Id.* at 5.

135. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 522 (9th Cir. 2015) (“Because the EPA’s decision to unconditionally register sulfoxaflor was based on flawed and limited data, we conclude that the unconditional approval was not supported by substantial evidence.”).

136. Carey Gillam, *U.S. Court Finds EPA Was Wrong to Approve Dow Pesticide Harmful to Bees*, REUTERS: ENV’T (Sept. 10, 2015), <http://www.reuters.com/article/us-epa-agriculture-honeybees-idUSKCN0RA2CQ20150910> [<https://perma.cc/JN3Q-JT8G>].

137. *Id.*

138. *Id.*

139. To the credit of EPA, it did respond to the Ninth Circuit’s decision by “reevaluat[ing] the data supporting the use of sulfoxaflor and is approving a registration that meets all requirements of the court.” *Decision to Register the Insecticide Sulfoxaflor With Limited Uses and Pollinator Protective Requirements*, U.S. ENVTL. PROTECTION AGENCY, <https://www.epa.gov/ingredients-used-pesticide-products/decision-register-insecticide-sulfoxaflor-limited-uses-and> [<https://perma.cc/24XM-SFJF>] (last visited Jan. 5, 2018).

140. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136 (2012).

141. 15 U.S.C. §§ 2602 (2)(B)(ii).

142. 2015 Hearing, *supra* note 46, at 41.

A. States Are in the Best Position to Tackle Toxic Chemical Issues

Every state has its own unique industries. An important industry in Texas may be small potatoes to Idaho. States with region-specific industries, such as natural gas exploration, may be better equipped to handle the local impacts of drilling, specifically when it comes to controversial issues like hydraulic fracturing.¹⁴³ States are the most effective enforcers of regulatory laws because state agencies are closest to the problems. As concerns arise, state regulators may be more informed about the problem and have narrower responsibilities than federal regulators, which allows them to focus resources to more effectively eradicate exposure risks than the federal regulators. Effective resolution of toxic chemical concerns can also serve to keep a local problem from evolving into a bigger, national problem. Because EPA is in charge of all chemical issues arising on a national level and is consequently required to evaluate the need for chemical regulations from a national viewpoint, local problems will likely receive fewer resources than if these same issues are resolved by state legislators.

As previously discussed,¹⁴⁴ the case involving EPA's approval of the pesticide sulfoxaflo was based upon "flawed and limited data,"¹⁴⁵ which stood in contrast to the partial ban on the chemical already in place under California law. This example provides support for the assertion that in some cases, state laws will simply do a better job than federal laws at regulating potentially harmful chemicals. While it is certainly possible that EPA made an innocent mistake when it approved the use of a sulfoxaflo, it is also possible that EPA did not have information of a high enough quality to make an adequate determination. But while states are required to make determinations based on objective, peer-reviewed scientific studies, EPA is no longer subject to additional review by state legislators and regulators. This allows for the possibility that EPA will get it wrong if it continues to operate without a safety net—i.e., the states—which is both reckless and unnecessary.

If responsibility for the most potent chemicals is kept at the federal level, it puts remarkable pressure on the Administrator to get it right. In addition to the concentration of power and responsibility that the LCSA has created, the imposition of restrictions on state laws that impose more stringent safety standards for toxic chemicals is counterproductive to the fundamental purpose of the LCSA.

B. Practical Limitations on Strong Federal Toxic Chemical Regulations

Setting aside all other problems with preemption in the context of the LCSA, EPA is not equipped to take on the entire chemical industry alone. Because EPA requires that every new chemical is submitted for review, EPA has become solely responsible for all new chemicals that cause even the slightest safety or environmental concerns. If EPA reviewed all 2,000 new chemicals that enter the market each year to make a risk determination,¹⁴⁶ the EPA Administrator would be tasked with evaluating over thirty-eight chemicals every week. The quantity of empirical data that must be reviewed during each chemical evaluation will certainly make thirty-eight chemicals each week almost impossible to thoroughly evaluate; moreover, this number does not account for the review of any existing chemicals. While it is unlikely that this will actually be the workload of the Administrator under the LCSA, since chemicals are exempt from submission in certain circumstances,¹⁴⁷ it provides an illustration of how much EPA has been tasked with in order to keep state regulators out of the process.

Additionally, because EPA is subject to Congress's yearly budgetary decisions, the size of the staff and financial resources of EPA can vary significantly from year-to-year, meaning that the heavy workload placed on EPA by the new provisions of the LCSA could be difficult to manage in the face of potential budget cuts.¹⁴⁸ The steady flow of new chemicals into the market, however, is unlikely to be hampered merely because EPA is overloaded with pending risk-determinations. If anything, manufacturers have a win-win situation on their hands: states cannot regulate any chemical EPA reviews, and for the chemicals that are reviewed, EPA may not always have the necessary resources to review these chemicals thoroughly. When faced with the reality of the sheer volume of new chemicals that enter the market each year, EPA will likely need the added support and flexibility that state chemical regulators can provide.

The fact that EPA may be asked to bite off more than it can chew with respect to chemical evaluations only adds credibility to the concern that the Administrator may make a genuine mistake and cause significant harm to those exposed to what was thought to be a safe chemical. Ultimately, EPA needs the state regulators far more than the state regulators need federal regulations in their home states.

C. Shortcomings of Arguments in Favor of State Chemical Law Preemption

As the American Chemistry Council readily pointed out, chemical manufacturers do not appreciate duplicative regu-

143. *Should the Federal Government Regulate Fracking?*, WALL ST. J. (Apr. 14, 2013), <https://www.wsj.com/articles/SB10001424127887323495104578314302738867078> [<https://perma.cc/YT84-UT3K>] ("But others say states are well equipped to regulate fracking. They say the risks of fracking are overstated, and the impacts of fracking—both positive and negative—are mostly local, and different people balance them differently. So regulation should be left to the people who feel them most directly.")

144. See *supra* Part III.C.

145. See Gillam, *supra* note 136.

146. See *About NTP*, *supra* note 9.

147. See, e.g., 15 U.S.C. § 2604(h).

148. Kaly Behnke, Comment, *Toxic Preemption: Why the Lautenberg Chemical Safety Act's Erosion of State Authority Contaminates Environmental Law*, 57 JURIMETRICS J. 459, 477 (2017).

latory costs.¹⁴⁹ Weighing the benefits of uniformity of laws (and therefore, less duplicative regulation) against the benefits of having state regulators as a vigilant support system is central to the preemption debate.¹⁵⁰ But avoiding high regulatory costs for the chemical companies certainly cannot justify preempting any overlapping state regulations. By preempting state laws, federal regulations send the message that state regulations are either unimportant or, even worse—arbitrary. One justification for state law preemption could be that the uniformity makes it easier for chemical companies to know what they can and cannot do. However, this argument assumes that state regulations never add anything to federal regulations, but merely duplicate these laws.

Next, with respect to the argument that the LCSA will avoid duplicative fees, there is little support within the law itself. The LCSA adds yet another exemption to state regulation of chemicals under review for any information-based regulations that states would like to implement. So, even if the states do not require that chemicals are tested directly under the supervision of the state regulatory agency, the fact that a state can ask for chemical safety data means that the state can certainly impose indirect costs to the manufacturers, which undermines the argument for preemption based solely upon the benefits provided by decreased testing fees.

Finally, it may seem possible that federal regulation of toxic chemicals could prevent states from competing to attract manufacturers to their state through weak chemical regulations. However, state authorities have consistently enacted substantially more comprehensive regulatory systems than their federal counterparts. In fact, the biggest lobbyist for less stringent reform, the American Chemistry Council, mentioned state regulations being too burdensome when expressing support for the LCSA.¹⁵¹ Therefore, it is clear that federal regulations cannot be justified as a mechanism to prevent a race to the bottom; if anything, states may be the ones preventing overly manufacturer-friendly regulation at the federal level.

D. *Problems With Giving the Administrator the Final Say on All Reviewed Chemicals*

One of the most troubling aspects of the preemption mechanisms of the LCSA is that it vests the Administrator with complete responsibility to ensure that bad chemicals do not slip through the cracks. This is problematic because the LCSA has left little room for error. The law has created a series of hoops for states to jump through to continue regulating the chemicals they have reason to believe are potentially harmful. The law also assumes that evidence of potential harm can always be ascertained during initial testing, which is usually the basis for the Administrator's review. If it took forty years for DuPont and 3M to finally disclose the full breadth of the

PFOA debacle, a reoccurrence of this situation is not out of the realm of possibility.

If a situation like the one involving PFOA were to reoccur, it could once again take a significant amount of time for the risks associated with the chemical to become known to EPA. The Administrator not only has limited time to make difficult decisions about very complex chemical substances, but even chemists are not always aware of the effects that a substance will have on humans. This is precisely why companies like DuPont continue running tests after placing their product on the market. The bottom line is that there is a very real chance the Administrator will fall victim to human error. Unfortunately, when errors are made under the LCSA, states are legally prohibited from stepping in to help fix it.

Another shortcoming of the broad preemption of state regulatory powers is that it prevents states from enacting rules and regulations that go above and beyond what the federal regulations mandate. State regulations on toxic substances may encourage manufacturers to begin exploring potentially safer alternatives to the production or use of chemicals that the states have reason to believe will pose a risk to the safety and welfare of consumers or the environment. As illustrated by DuPont's response to suspicions about the safety of PFOA,¹⁵² it is foolish to rule out the possibility that chemical manufacturers will continue producing a harmful chemical, even in light of evidence indicating health risks, if there are significant financial benefits to the continued manufacturing and use of these chemicals. By allowing states to go above and beyond to regulate chemicals more stringently than the federal regulators, manufacturers will have a financial incentive to find better options to replace the regulated or prohibited products, which will push chemical manufacturers to research and utilize safer chemicals.

Finally, the collaboration between state and federal regulators can provide for a more efficient and creative approach to chemical regulation.¹⁵³ This can occur because the states can experiment with various regulatory approaches and learn from the successes and failures of other states.¹⁵⁴ The collaborative approach also provides the federal regulators the chance to learn from the outcomes of state regulations and devote time more appropriately to testing new chemicals. States have the opportunity to do much of the heavy lifting when it comes to creative regulatory approaches; something that should be welcomed by federal chemical laws.

E. *Why the Exceptions and Waivers do Not Adequately Mitigate the Problems With the LCSA's Preemption Provisions*

At the end of the day, no matter how counterintuitive the LCSA legislation is with respect to the role of states in chemical regulation, it is, unfortunately, the law. Moreover, the preemption provision, while unmistakably controversial, is unlikely to be repealed or significantly amended any time

149. See AM. CHEMISTRY COUNCIL, *supra* note 106.

150. See Light, *supra* note 59, at 3 (advocating for "recognition of risk-risk tradeoffs that requires weighing the default presumption [that states should never be preempted under conditions of regulatory uncertainty] against the benefits of more uniform legal rules.").

151. See AM. CHEMISTRY COUNCIL, *supra* note 106.

152. See *supra* Part II.B.

153. See Behnke, *supra* note 148, at 472.

154. See *id.*

soon. Under the law, however, states are given a few choices when the regulations they create—or hope to enact—are preempted. The first step a state can take is to look at the scope of review for the chemical it seeks to regulate to determine if the regulations it hopes to enforce are preempted in the first place. Next, the state can look to the statute to see if there are any useful exceptions the state can utilize. Finally, states have the option to apply for an exemption from preemption under the discretionary or required exemption provisions.

The first option states have when seeking to avoid the LCSA's preemption provisions is to determine whether the law they seek to implement overlaps in scope with EPA's scope of review for the chemical in question. The likelihood that a given state law will be preempted is determined by the scope of review set by the Administrator at the time the chemical is taken under review. For example, if the Administrator reviews a chemical with three different uses, the scope of review will determine whether the safety of the chemical is being reviewed for any, all, or a combination of those three uses. If the scope of review only covers the first two uses, state regulations can still cover the third use without preemption, since that use falls outside the federal scope of review. Consequently, the scope of review and the judicial interpretation of the scope of review will become particularly relevant for determining what laws are actually preempted. The implications of the scope of review are generally apparent. Unfortunately, states have no options if they want to regulate a chemical's use in a given product, and that product is covered under EPA's scope of review for that chemical.

If a state wants to regulate a substance that falls clearly within EPA's scope of review, another mechanism of the LCSA may permit the state to regulate the chemical's manufacture and use. To do this, states simply need to apply for an exemption with EPA that provides the state with a waiver of preemption. However, problems arise under both the discretionary and required preemption provisions.¹⁵⁵ The mechanisms through which a state may apply for an exemption depend on whether a new state law will be preempted by a previous risk determination, or whether an already existing state law is preempted by a new risk determination. Furthermore, states seeking to impose criminal penalties may only do so through a discretionary waiver, since the required waiver cannot waive preemption of state criminal penalties pursuant to a violation of a state toxic chemical law.¹⁵⁶

Assuming the state law at issue is not yet in force, and EPA has previously, or is currently undertaking the review of the chemical that the state law would regulate, the state's best option would be to apply for a required exemption. A required exemption must be granted for state laws that are pause-preempted by a recently initiated risk evaluation, but only if (1) the law is not unduly burdensome to interstate commerce; (2) the law will not cause a violation of another existing federal law, rule, or order; and (3) the state's concern for the specific chemical is based on peer-reviewed science.¹⁵⁷

The state is also required to finalize a statute or proposed or final agency rule that regulates a given chemical prior the end of the eighteen month period beginning when the Administrator begins the review.¹⁵⁸ The required exemption is simple, but it may be difficult for a state to show that a restriction on the manufacture, use, or distribution of a chemical will not burden interstate commerce, since some regulations may cause manufacturers significant financial losses, depending on the stringency of the state law. Ultimately, the required exemptions are applicable when the state wants to regulate something that EPA is currently reviewing.

Turning to discretionary exemptions, if a state law regulating a certain chemical is already in effect and the Administrator decides to take the same chemical under review, the state law is preempted and the state will have to file for a discretionary exemption.¹⁵⁹ It is difficult for states to determine the likelihood of receiving a preemption waiver under the discretionary exemption since the requirements for such an exemption can seem ambiguous. Proposed state laws may only be exempted under compelling circumstances and must not unduly burden interstate commerce. Furthermore, the stated need for the law must be based on the best available science, sound and objective studies, and the weight of scientific evidence. Almost all of the requirements for a state to meet the discretionary exemption are vague, which (1) deters states that have limited resources to expend in litigation from filing for the discretionary waivers, or, at a minimum, from challenging the denial of a waiver application, and (2) forces states to determine what each element of the discretionary waiver practically means through wasteful and expensive trial and error.

For instance, states cannot be certain how the Administrator will interpret "compelling conditions." The language of the LCSA is also unclear about just how many degrees of separation can exist between the safety threat and the chemical substance before the threat is dismissed by the Administrator as illegitimate. Meaning, if adequate scientific studies show that a chemical has the potential to cause serious harm to human health or the environment, but there is not enough data to make a conclusive judgment as to immediate safety risks, nothing indicates whether this would be interpreted as "compelling."

Likewise, the validity of the science used by a state to support its concern over a certain chemical is also a potential headache for states because current laws provide no real guidance on how the studies should be conducted. In particular, the requirement that a state must have the weight of the scientific evidence to support an assertion that a chemical may be a carcinogen is a serious threat to the legitimacy of toxic chemical research as a whole. For every study conducted by the state that indicates a link between a chemical and health risks, the chemical manufacturer could conduct two more studies questioning the very same conclusion. Once again, DuPont exhibited the very same behavior that is described here when it provided West Virginia environmental regula-

155. See *supra* Part III.B.

156. 15 U.S.C. § 2617(f)(1)(A).

157. *Id.*

158. *Id.* § 2617(f)(2)(B).

159. See *id.* § 2617(f)(1).

tors with studies questioning the seriousness of the health risks posed by PFOA.¹⁶⁰ The burden is simply too high for states seeking to demonstrate that the safety of a chemical should be questioned. Federal chemical regulations should not encourage litigious behavior or a battle of the experts.

The absence of ascertainable standards for evaluating preemption waiver applications severely degrades the compromise that Congress intended when it put the exemption provision in the law. If states are not given clarity on what “compelling circumstances” means under the waiver provision and how scientific study standards will be implemented, states will be unable to demonstrate when federal regulation of a chemical is too slow or ineffective to prevent imminent harm.

V. Solution

The problems with the preemption portion of the LCSA are never-ending, but improvements could be made to the current application of the law to increase the practicability of some of the LCSA’s most important provisions. There is opportunity for collaboration between federal and state authorities, through the clarification of the requirements for obtaining a discretionary exemption, the broad issuance of state law preemption waivers, and the increased utilization of the informational disclosure obligations that states have the freedom to enact.

The first step toward improvement would require the Administrator to issue guidelines for state regulators seeking an exemption to preemption under the discretionary preemption provision. The exemption provision requires two particular things from the states that are inadequately articulated. First, compelling circumstances must warrant the waiver, though there is nothing that clarifies what types of risks constitute compelling circumstances. To remedy this, EPA should provide guidance outlining the appropriate definition of a compelling circumstance. Two particular factors that warrant further clarification are (1) whether an environmental harm will be considered equally as compelling as a health risk, and (2) whether the risk posed by exposure to the chemical must be severe or likely to cause permanent damage to those exposed to the chemical.

Next, EPA should provide guidance on how the requirements regarding scientific studies should be interpreted. Specifically, EPA should allow scientific studies to satisfy the discretionary exemption, which requires that the weight of scientific evidence supports the state’s application, if: (1) the studies demonstrate a link between the chemical in question and a risk to human health or the environment, (2) the studies are based on peer-reviewed science, (3) there is no substantial and credible contradicting scientific evidence, and (4) the determination is made irrespective of whether the scientific community has reached a consensus.

To further clarify the scientific evidence standard, EPA should issue guidance establishing that, if a study is funded directly or indirectly by the manufacturer of the chemi-

cal, this must be a factor considered when determining the weight given to the study. If the study is the product of a conflict of interest, meaning the study was funded by interested parties, EPA should grant the requested state waiver by default, unless extenuating circumstances, such as a constitutional concern, would dictate otherwise. By doing this, EPA can discourage manufacturers from arbitrarily discrediting concern over chemical safety that would be financially detrimental to the company.

In sum, the ideal guidelines would entail a rough summary of what each element means in practice, and what states can do to stay safely within and clearly outside of each element. Much like the Revenue Rulings issued by the Internal Revenue Service, which often feature an example of how the provision of the law might look in practice,¹⁶¹ it could be useful for EPA to issue similar guidance so that states are not forced to waste valuable time and resources applying for waivers that will not be granted. By issuing guidelines that empower states to have a viable chance of regulating toxic chemicals under review or previously reviewed by EPA, this strengthens the collaboration between state and federal authorities, allowing the Administrator to share the burdens of the fast-growing chemical industry’s constant production of new and untested chemicals with state regulatory bodies.

If EPA and states are at odds, toxic chemical reform is genuinely impossible. The federal regulators have been given broad power under the LCSA to preempt the safety determinations made by states.¹⁶² However, if federal authorities take a friendly approach to states seeking to enact protections for their citizens, the dangerous elements of the LCSA’s preemption provisions can be mitigated.

Finally, the states need to begin to utilize the tools the LCSA provides for them. The preemption exemption with respect to informational disclosures should be thoroughly utilized by state regulators. Ensuring that consumers are aware of the dangers of toxic chemicals means that consumers and related parties are empowered rather than harmed by the LCSA’s treatment of state regulatory authority. States are free to implement laws and regulations that implement “reporting, monitoring, or other information obligation for the chemical substance not otherwise required” by the LCSA or other federal law.¹⁶³ This approach would be similar to how U.S. securities laws have developed, by adopting a disclosure-based system of regulation.¹⁶⁴ This same approach is utilized by California’s Proposition 65, which requires that business entities provide consumers with a “clear and reason-

161. See *Understanding IRS Guidance—A Brief Primer*, INTERNAL REVENUE SERV., <https://www.irs.gov/newsroom/understanding-irs-guidance-a-brief-primer> [https://perma.cc/GGW2-2GKD] (last visited Jan. 5, 2018) (“A revenue ruling is an official interpretation by the IRS of the Internal Revenue Code, related statutes, tax treaties and regulations. It is the conclusion of the IRS on how the law is applied to a specific set of facts.”).

162. See generally 15 U.S.C. § 2617.

163. *Id.* § 2617(d)(1)(A).

164. Simon Wong, *Failings of US Disclosure-Based Regulation*, FINANCIAL TIMES (Feb. 28, 2010), <https://www.ft.com/content/fca44ab2-2308-11df-a25f-00144feab49a> [https://perma.cc/SJH8-WDL9] (“Disclosure underpins the US approach to regulating securities markets.”).

160. See *supra* Part II.B.

able warning” if the consumer will be exposed to a chemical that causes reproductive toxicity or is a known carcinogen.¹⁶⁵

Conversely, EPA should use a very light hand when policing the state information-based regulations. The LCSA provides very little guidance on what is and is not allowed under the provision permitting reporting, monitoring, and other informational obligations. If states are vigilant about gathering information on certain substances, the states can provide incredible value to federal regulators, who may not have the time and resources needed to stay abreast of developments with respect to all potentially harmful chemicals, especially when a chemical is only a serious problem in a small region of the country. If EPA collaborates with states by creating a healthy exchange of information, EPA will be able to focus on national issues with fewer distractions from smaller, regional concerns.

The most dangerous toxic chemicals are those that go unnoticed and prevent consumers from making informed decisions about their health. If consumers know what they are exposed to, then education, rather than regulation, becomes the main tool in the regulatory arsenal for preempted states. And while public education campaigns will not be as effective as chemical bans, state utilization of waiver requests and the creation of a comprehensive disclosure regime will be an excellent first step toward ensuring that toxic chemical reform is not stopped in its tracks by adversarial state and federal regulatory systems.

VI. Conclusion

The implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act is a clear success for those in favor of comprehensive toxic chemical reform. The Act closed many of the loopholes in the initial Toxic Substances Control Act legislation, allowing EPA to more thoroughly and effectively regulate toxic substances. However, the preemption of state laws operating concurrently to the LCSA creates major issues for the objectives of the new law. Not only are states unable to regulate chemicals if EPA has those same chemicals under review, but more importantly, the Administrator’s determination of a chemical as “low-risk” functions as a permanent bar to state evaluation or regulation of that same chemical.

The LCSA will only work effectively if the burdens of chemical regulation are spread between federal and state authorities in a way that allows both to do their jobs thoroughly and with minimal impact on the chemical manufacturing industry. To achieve this objective, EPA must clarify and streamline the process by which states can obtain an exemption to the preemption of the states’ regulations. Further, states should use the LCSA’s preemption carve out extensively by implementing regulatory systems that utilize disclosure-based regulations, so that even if the states cannot directly ban or restrict the use of a harmful chemical, consumers are still aware of possible risks posed by chemicals in consumer goods and the surrounding environment.

165. Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code § 25249.6 (West).