Presumptive Innocence v. the Precautionary Principle:

The Story of PFAS Regulation in the United States

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In recent years, Americans across the country and the political spectrum have become increasingly concerned about the threats that per- and polyfluoroalkyl substances (PFAS) pose to human health. PFAS are in non-stick pans, firefighting foams, and many other materials, and have leached into the drinking water of millions of Americans. While a patchwork of state regulations has sought to address PFAS contamination, the federal government has been slow to act, despite increasing evidence of PFAS' toxicity. The federal government's failure to regulate PFAS is egregious on its own, but it is also a symptom of a larger issue that plagues the chemical regulatory framework: presumptive innocence towards toxic chemicals. This article tells the story of PFAS regulation in three parts. First, it covers attorney Robert Bilott's early discoveries of PFAS contamination and his pioneering tort claims, followed by the federal government's ability and failure to regulate PFAS under each pertinent federal regulatory scheme. It concludes with a discussion of compelling alternative regulatory frameworks, all of which embrace a version of the precautionary principle. While there have been many efforts to tell a coherent story about the toxic threat posed by PFAS, most popularly the 2019 film Dark Waters, this article situates the failure to regulate PFAS within the broader failings of our chemical regulatory system and offers an alternative vision for chemical regulation: one that embraces the precautionary principle and protects human health as the ultimate priority of the federal chemical regulatory scheme.

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I. INTRODUCTION

A quick scan of the Environmental Working Group's map¹ of sites contaminated by PFAS shows a crowded constellation of data points blanketing every state in the nation. Research shows that PFAS are found in the blood of the general population in every geographic region in the United States.² News outlets from the New York Times to regional blogs have highlighted the health dangers posed by PFAS, dubbing them the "forever chemicals."³ The Environmental Working Group estimates that up to 110 million Americans are exposed to dangerous levels of PFAS in their drinking water.⁴ Millions of Americans are asking: what is the federal government doing to protect us?

Very little, unfortunately. The failure to regulate PFAS exposes the fundamental failings of the United States' "innocent-until-proven-guilty" federal

¹ *PFAS Contamination in the U.S.*, ENV'T WORKING GROUP (2019), https://www.ewg.org/interactive-maps/2019_pfas_contamination/map/.

² Jeff B. Kray & Sarah J. Wightman, *Contaminants of Emerging Concern: A New Frontier for Hazardous Waste and Drinking Water Regulation*, 32 NAT. RESOURCES & ENV'T 36, 36 (2018), citing Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, 68 Fed. Reg. 18,626, 18,629 (Apr. 16, 2003).

³ See, e.g., Eric Lipton, Government Studying Widely Used Chemicals Linked to Health Issues, N.Y. TIMES (Dec. 5, 2019), https://www.nytimes.com/2019/12/05/us/politics/pfas-water-contamination.html.

⁴ David Andrews, *Report: Up to 110 Million Americans Could Have PFAS-Contaminated Drinking Water*, ENV'T WORKING GROUP (May 22, 2018), https://www.ewg.org/research/report-110-million-americans-could-have-pfas-contaminated-drinking-water.

chemical regulatory system. This article seeks to synthesize the vast story of PFAS in the United States and explain how this family of chemicals has evaded strict regulation under various pertinent regulatory schemes. This evasion presents a learning opportunity for American regulators and legislators, as PFAS demonstrates that American chemical regulation is not the airtight system is purports to be. This article contends that more stringent chemical regulatory frameworks—particularly those offering less deference to manufacturers, like the EU's REACH program and California's Green Chemistry program—present compelling alternatives for federal regulation of PFAS.

Part II of this article discusses the story of PFAS in the United States to the present day, illuminated largely by attorney Robert Bilott in his book, *Exposure*.⁵ Part III explains how PFAS managed to evade federal regulation despite the seemingly expansive American regulatory state. In that Section, this article explores the failure to regulate PFAS under the Safe Drinking Water Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation, and Liability Act, its subsidiary, the Emergency Planning and Community Right-to-Know Act, and the Clean Water Act. Part IV discusses alternative regulatory systems that provide templates for more effective and health-protective chemical regulation. Finally, Part V contains reflections and recommendations for the future of federal chemical regulation.

II. THE STORY OF PFAS IN THE UNITED STATES

PFAS is a generic term for a family of thousands of synthetic per- and polyfluoroalkyl substances that are used in various consumer products because they are fire resistant and effectively repel oil, grease, and water.⁶ They are found in firefighting foams, insulation, cleaners, textiles, clothing, and cookware.⁷ Due to their widespread use in consumer products and persistence in the environment, PFAS have been nicknamed "forever chemicals" and are now present in the environment worldwide.⁸ Domestically, the primary sources of PFAS are manufacturing (for products such as nonstick pans) and powerful flame retardant foams used most often in military exercises.⁹ PFAS have been linked to kidney and testicular cancers, thyroid disease, decreased fertility, and decreased response to vaccines.¹⁰

⁵ ROBERT BILOTT, EXPOSURE (2019).

⁶ Kray & Wightman, *supra* note 2, at 36. For a more technical discussion of the chemistry of PFAS, see Peter Zeeb, et. al., *The Use of PFAS at Industrial and Military Facilities: Technical, Regulatory, and Legal Issues*, 49 ENV'T L. REP. NEWS & ANALYSIS 10109, 10111 (2019).

⁷ Kray & Wightman, *supra* note 2, at 36.

⁸ See, e.g., Lipton, supra note 3.

⁹ Kray & Wightman, *supra* note 2, at 36.

¹⁰ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXICOLOGICAL PROFILE FOR PERFLUOROALKYLS, at 5-6 (2018).

PFAS have entered the popular consciousness in recent decades through the work of attorney Robert Bilott.¹¹ Mr. Bilott, a partner at Taft Stettinius & Hollister LLP in Cincinnati, set out on a long road of PFAS discovery when he took a West Virginia farmer named Earl Tennant as a client, on the recommendation of Mr. Bilott's grandmother.¹² Mr. Bilott's grandmother lived in Parkersburg, the same town as Mr. Tennant, whose farm abutted a large DuPont chemical factory that manufactured Teflon products.¹³ For years, Mr. Tennant watched cattle and wildlife die inexplicably while he and his family also suffered health problems.¹⁴ He spent years attempting to bring in the federal Environmental Protection Agency ("EPA") and the state Department of Environmental Protection to assess the property and diagnose the problem, which he believed stemmed from water pollution from DuPont's nearby landfills.¹⁵ An outfall from the DuPont plant's landfill spouted water into the creek near Mr. Tennant's property, and he reported difficulty breathing when "vapor clouds" rose from the aerator at one of the landfill's ponds.¹⁶ Despite his complaints, the federal and state agencies would not provide him with a detailed assessment of the problem.¹⁷ Out of desperation, Mr. Tennant turned to the courts.

Mr. Bilott took Mr. Tennant's case and unraveled a complicated story of environmental malpractice and corporate greed. Despite DuPont's own studies confirming the toxicity of PFOA—the main PFAS in Teflon, which was produced in Parkersburg—the company did not provide regulators with all of the information they had on PFOA's health risks, as they were required to under TSCA.¹⁸ 3M, another American chemical giant, had stopped manufacturing PFOA because it determined that PFOA was toxic. Instead of interpreting 3M's move as a warning against manufacturing PFAS, DuPont embraced 3M's absence from the market as an invitation to start manufacturing its own PFAS.¹⁹ By failing to report the toxicity data they found, DuPont circumvented the TSCA regulatory process—eventually resulting in a \$16.5 million fine—and was erroneously permitted to dispose of PFOA-contaminated sludge in an unlined landfill designated for non-hazardous waste.²⁰ Shortly after DuPont started disposing toxic waste this way, the company learned through its own water sampling that

¹⁷ Id. at 17-18.

¹⁸ *Id.* at 81-82. Under the Toxic Substances Control Act, chemical manufacturers must disclose data they uncover regarding hazardous chemicals. *See also infra* Sec. II.B.

¹⁹ Sharon Lerner, *3M Knew About the Dangers of PFOS and PFOS Decades Ago, Internal Documents Show*, THE INTERCEPT (July 31, 2018, 12:23 PM), https://theintercept.com/2018/07/31/3m-pfas-minnesota-pfoa-pfos/.

¹¹ Mr. Bilott's story is also the subject of a recent film, DARK WATERS (2019).

¹² ROBERT BILOTT, EXPOSURE 16 (2019).

¹³ Id. at 10, 16.

¹⁴ *Id.* at 18-19.

¹⁵ *Id.* at 5.

¹⁶ *Id.* at 19.

²⁰ ROBERT BILOTT, EXPOSURE 81 (2019).

PFOA was leaching out of its landfill into the creek on Earl Tennant's property.²¹ Mr. Tennant's hunch was confirmed: DuPont's leaking landfills were making him sick.

Although Mr. Tennant's experience presented a particularly egregious example of corporate malfeasance, his consumption of PFAS-contaminated water is far from unique. An August 2016 study found that the drinking water of at least six million people contained PFAS at concentrations exceeding the level deemed healthy by EPA.²² Our knowledge of the toxicity of PFOA comes from an epidemiological study of a class of 69,030 plaintiffs in Parkersburg and the surrounding area that was part of Mr. Bilott's litigation with DuPont.²³ Scientists discovered PFOA in the class members' blood at rates five times higher than normal.²⁴ Subsequent studies established links between PFOA and six adverse health outcomes: pregnancy-induced hypertension and preeclampsia, testicular cancer, kidney cancer, thyroid disease, ulcerative colitis, and high cholesterol.²⁵ These massive epidemiological studies demonstrate the overwhelming effort required to overcome the presumptive innocence baked into the federal chemical regulatory system: originally slated to take two years at a cost of \$5 million, the 2009 study took seven years and cost \$35 million.²⁶ Most people harmed by PFAS simply do not have the time or resources to gather this type of data.

In addition to Mr. Bilott's advocacy, PFAS are rapidly entering political conversation because of improved analytical methods for detecting the presence of PFAS and, consequentially, an increase in available data and academic awareness about their pervasiveness.²⁷ As a result, PFAS have been exposed to increased media coverage, public concern, and lawsuits.²⁸ However, the federal government still has not comprehensively regulated PFAS under any relevant environmental laws.

In response to the increased awareness of PFAS contamination, some states have made significant headway in regulating PFAS, primarily those that have high concentrations of PFAS in their soil and water. In Merrimack, New Hampshire,

²¹ Id. at 82.

²² See Xindi C. Hu, et al., Detection of Poly- and Perfluoroalkyl Substances (PFAS) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants, 3 ENV'T SCI. TECH. LETTERS 10, 344-350 (Aug. 9, 2016).

²³ S.J. Frisbee, et. al., *The C8 health project: design, methods, and participants*. 117 ENV'T HEALTH PERSPECT. 12, 1873-1882 (Jul. 13, 2009).

²⁴ Id.

²⁵ David Andrews & Bill Walker, *Poisoned Legacy: The C8 Science Panel*, ENV'T WORKING GROUP (May 1, 2015), https://www.ewg.org/research/poisoned-legacy/c8-science-panel.

²⁶ Id.

²⁷ Kray & Wightman, *supra* note 2, at 37.

²⁸ The Social Science Environmental Health Research Institute at Northeastern University updates a daily digest of PFAS-related news from around the country at the following URL: https://pfasproject.com/. Multiple reports from news outlets across the nation are added every day, with titles like "Should you be concerned about what's in your drinking water?" and "Manmade chemical has contaminated wells, could trickle into communities across Wisconsin."

officials identified 34 PFAS in concentrations as high as 70,000 parts per trillion ("ppt") in water within a 65-mile radius of the Saint-Gobain plastics factory.²⁹ In response, New Hampshire has set a groundwater quality standard of 12 ppt approximately 0.0002% of the high concentrations found near Merrimackmeaning that the state believes any more than a few droplets in an Olympic-sized swimming pool would be an unsafe level of contamination.³⁰ In Vermont, liquid with PFOA or PFOS concentrations over 20 ppt is considered hazardous waste and is subject to hazardous waste regulation.³¹ A few states have set enforceable drinking water standards, including Michigan, which recently enacted stringent maximum contaminant levels: 8 ppt for PFOA and 16 ppt for PFOS.³² Before Michigan, New Jersey led the way by setting a 14 ppt maximum contaminant level for PFOA.³³ States have started to increase pressure on EPA, as attorneys general from California, New York, Illinois, and Massachusetts have called on EPA to set drinking water standards far below its current non-enforceable health advisory level of 70 ppt.³⁴ In their public comments under EPA's preliminary determination that a National Primary Drinking Water Regulation ("NPDWR") is appropriate for PFOA and PFOS, the attorneys general explained that they did not have the resources to pull off the regulation themselves: "Without a federal NPDWR and [maximum contaminant level] for PFAS, public water systems in many states will not be required to monitor or address PFAS contamination."35

As the state attorneys general point out, the federal government has been slow to act. The FDA has banned three PFAS in food packaging,³⁶ but EPA has not utilized its primary regulatory tools to remedy PFAS contamination. In 2016, EPA issued a "lifetime health advisory" level for PFOA and PFOS in drinking water of 70 ppt under the Safe Drinking Water Act's ("SDWA") authority.³⁷ This advisory level is non-binding, however, and EPA has no authority to enforce that level against contaminators or utilities.³⁸ EPA has not formally committed to

²⁹ Tom Perkins, *The 'forever chemicals' fueling a public health crisis in drinking water*, THE GUARDIAN (Feb. 3, 2020, 5:00 AM), https://www.theguardian.com/society/2020/feb/03/pfas-forever-chemicals-what-are-they.

³⁰ Kray & Wightman, *supra* note 2, at 38. The illustration of "a few droplets" is from Brian Henthorn & Christopher Loos, *PFAS Rolling into Regulation*, NAT'L L. REV. (Nov. 4, 2019), https://www.natlawreview.com/article/pfas-rolling-regulation.

³¹ Kray & Wightman, *supra* note 2, at 38.

³² Garret Ellison, Michigan to adopt PFAS drinking water limits after new rules clear legislature, M LIVE (July 22, 2020), https://www.mlive.com/public-interest/2020/07/michigan-to-adopt-pfasdrinking-water-limits-after-new-rules-clear-legislature.html.

³³ Kray & Wightman, *supra* note 2, at 39.

³⁴ Juan Carlos Rodriguez, *Move Quickly to Regulate 'Forever Chemicals,' EPA Hears*, LAW360 (June 11, 2020), https://www.law360.com/articles/1282241/move-quickly-to-regulate-forever-chemicals-epa-hears.

³⁵ Id.

³⁶ Kray and Wightman, *supra* note 2, at 39.

 $^{^{37}\,}$ U.S. ENV'T PROT. AGENCY, EPA-822-R-16-004, DRINKING WATER HEALTH ADVISORY FOR PERFLUOROOCTANE SULFONATE (May 2016).

³⁸ Kray & Wightman, *supra* note 2, at 39.

creating a maximum contaminant level ("MCL") for PFAS under SDWA, although EPA announced in February 2020 that it is considering an enforceable drinking water standard for PFOS and PFOA.³⁹ PFAS are still not listed as hazardous under any federal chemical regulation, even though Congress added 172 PFAS to the Toxics Release Inventory, which requires companies to disclose annual reports of their PFAS releases into the environment under the Emergency Planning and Community Right-to-Know Act.⁴⁰ However, for many affected communities, disclosure is meaningless if the contamination continues, and federal efforts remain too little, too late.⁴¹ These failures are discussed in greater detail in the following pages.

In the face of governmental failures, the tort system has served as a crucial regulatory backstop for exposing and stopping PFAS contamination. Without the tort system, we would not have the knowledge that we currently do about the harms from PFAS. This data had to be extracted from DuPont in the crucible of trial, and the PFOA study still provides the most comprehensive information available about any PFAS. And the courtroom battles continue: lawsuits have been brought by people exposed to PFAS, like Earl Tennant, as well as utilities, local governments, and even shareholders facing financial risk.⁴² In February 2017, DuPont settled 3500 lawsuits in Ohio and West Virginia for an eye-popping \$670.7 million.⁴³ Judges in South Carolina and Ohio are handling hundreds of lawsuits consolidated in multidistrict litigation related to firefighting foams, and class actions are pending in Vermont, Michigan, North Carolina, and New York against PFAS manufacturers DuPont, 3M, Saint-Gobain Performance Plastics Corp., and Wolverine World Wide Inc.⁴⁴ An Ohio firefighter, Kevin Hardwick, assisted by Mr. Bilott, is also attempting to certify a class of plaintiffs exposed to PFAS through firefighting foams and is requesting a nationwide epidemiological

³⁹ U.S. ENV'T PROT. AGENCY, EPA ANNOUNCES PROPOSED DECISION TO REGULATE PFOA AND PFOS IN DRINKING WATER (2020).

⁴⁰ Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting, 85 Fed. Reg. 37,354 (June 22, 2020) (to be codified at 40 C.F.R. pt. 372).

⁴¹ See, e.g., Kyle Bagenstose, *Frustrations continue at military meeting on PFAS cleanup*, BUCKS CNTY. COURIER TIMES (Dec. 12, 2018, 8:12 PM), https://www.buckscountycouriertimes.com/news/20181212/frustrations-continue-at-military-meeting-on-pfas-cleanup.

⁴² Ellen Gilmer, Forever Litigated 'Forever Chemicals': A Guide to PFAS in Courts, BLOOMBERG ENV'T (Jan. 13, 2020, 6:01 AM), https://news.bloombergenvironment.com/ environment-and-energy/forever-litigated-forever-chemicals-a-guide-to-pfas-in-courts. In October 2019, a plaintiff shareholder filed a securities suit against Chemours, a spin-off of DuPont that manufactures PFAS, alleging that Chemours (and DuPont) vastly understated its known environmental liabilities exposure. Kevin LaCroix, Environmental Liability-Related Securities Suit Filed against DuPont Spin-off Chemours, D&O DIARY (Oct. 13. 2019), https://www.dandodiary.com/2019/10/articles/environmental-liability/environmental-liabilityrelated-securities-suit-filed-against-dupont-spin-off-chemours/.

⁴³ ROBERT BILOTT, EXPOSURE 364 (2019).

⁴⁴ Gilmer, *supra* note 42.

study of PFAS-related health effects.⁴⁵ Mr. Hardwick is not seeking damages, only much-needed research into the toxicity of PFAS.⁴⁶ The explosion of litigation after decades of exposure to contamination from PFAS begs the question: how have these chemicals gone unregulated for so long?

III. PRESUMPTIVE INNOCENCE, REGULATORY INERTIA, AND THE FAILURE TO FEDERALLY REGULATE PFAS

In a House Oversight Committee hearing on PFAS regulation, actor Mark Ruffalo-who plays attorney Robert Bilott in the 2019 film Dark Waters, based on Mr. Bilott's book—summed up the situation powerfully: "In America, it falls to us, the ordinary people, to prove that these chemicals are toxic before the chemical is regulated by our government. That is simply backwards."⁴⁷ As law professors Steve Gold and Wendy Wagner recently observed in Science magazine, "assessments for PFAS chemicals appear to have been conducted-at best-on an ad hoc basis and primarily through negotiated agreements."48 This informational asymmetry is the fundamental barrier to effective, health-protective chemical regulation, along with reticent agencies and onerous statutory obligations on regulatory bodies. The United States purports to have a comprehensive chemical regulatory system: the Toxic Substances Control Act ("TSCA") to regulate chemicals in production and distribution, a variety of workplace safety laws governing the use of chemicals in employment, the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") and Resource Conservation and Recovery Act ("RCRA") to regulate disposal of chemicals, the Clean Water Act and SDWA when the chemicals enter our waterways, as well as disclosure requirements like the Toxics Release Inventory. The House Committee on RCRA went so far as to say that RCRA "eliminates the last remaining loophole in environmental law."49 But, as the PFAS saga shows, this is not the case.

EPA has made only hesitant steps towards using its authority to address the PFAS problem. EPA lauds its 2010/2015 PFOA Stewardship Program as one such proactive step taken to address PFOA contamination⁵⁰ —the PFAS used in

⁴⁵ Id.

⁴⁶ Alex Ebert, *Firefighter Wants Study—Not Money—in Fluorinated Chemicals Suit*, BLOOMBERG ENV'T (Oct. 9, 2018, 1:10 PM), https://news.bloomberglaw.com/environment-and-energy/firefighter-wants-studynot-moneyin-fluorinated-chemicals-suit.

⁴⁷ Rebecca Beitsch, *Mark Ruffalo pushes Congress for action on 'forever chemicals'*, THE HILL (Nov. 19, 2019, 5:41 PM), https://thehill.com/policy/energy-environment/471178-ruffalo-pushes-for-action-on-forever-chemicals-from-congress.

⁴⁸ Steve C. Gold & Wendy E. Wagner, *Filling gaps in science exposes gaps in chemical regulation*, 368 SCI. MAG. 1066 (June 5, 2020).

 $^{^{49}\,}$ Resource Conservation and Recovery Act of 1976, H.R. Rep. No. 94-1491, 94th Cong., 2d Sess. 4.

⁵⁰ U.S. ENV'T PROT. AGENCY, FACT SHEET: 2010/2015 PFOA STEWARDSHIP PROGRAM (2018) [hereinafter *PFOA Stewardship Program Fact Sheet*].

Teflon, and the subject of the West Virginia contamination brought to light by Mr. Bilott. The Stewardship Program invited eight major PFAS manufacturers⁵¹ to commit to a ninety-five percent reduction in PFOA emissions—using a baseline of the year 2000—and work towards complete elimination by 2015.⁵² Consistent with the broader self-monitoring theme in chemical regulation, all participating companies self-reported that they had met the PFOA Stewardship Program goals.⁵³ However, EPA confessed that after the conclusion of the Stewardship Program, existing stocks of PFOA could still be used, and some PFOA could still be imported in products.⁵⁴ Allowing this type of residual usage is particularly problematic when dealing with a so-called "forever chemical." In addition, PFOA, despite its historical prevalence, is only one of thousands of potentially harmful PFAS present in the environment. Given the scale of PFAS contamination, this voluntary PFOA cleanup program was a drop in the bucket. Moreover, it is possible that the PFOA Stewardship program was a band-aid solution that may have slowed EPA's more comprehensive PFAS regulatory efforts at the time.

This article explores multiple potential avenues for regulation that have been substantially unused for PFAS thus far, despite some incremental regulatory steps taken under each statute. These include SDWA, TSCA, CERCLA and its subsidiary, EPCRA, as well as the Clean Water Act. Under each statute, this article explores the progress made towards PFAS regulation and the barriers to fully utilizing the statutory authority to address the PFAS problem. Of the laws discussed here, TSCA potentially provides the most regulatory tools to the federal government, while SDWA addresses the pressing problem of contaminated drinking water, like in Earl Tennant's situation. Regulation under CERCLA would likely be quite effective for remediating PFAS contamination, but it would expose polluters to enormous liability, and industry groups have pushed back against CERCLA regulation. The Clean Water Act is a comparatively rare avenue for pollutant regulation, but some legislators are hoping to use it to address the PFAS problem. There is significant overlap among these laws, but no combination has yet been used successfully to comprehensively regulate the PFAS family of chemicals.

A. Safe Drinking Water Act

SDWA is the primary federal regulatory tool for protecting drinking water in America. No PFAS are currently regulated as contaminants under the SDWA, even though EPA is monitoring certain PFAS under SDWA authority. Every five

⁵¹ According to the fact sheet, *id.*, the companies involved in the PFOA Stewardship Program were Arkema, Asahi, BASF Corporation, Clariant, Daikin, 3M, DuPont, and Solvay Solexis.

⁵² U.S. ENV'T PROT. AGENCY, *supra* note 50.

⁵³ Id.

⁵⁴ *Id.* This loophole has since been closed via a Significant New Use Rule for PFOA, finalized in July 2020. See text accompanying note 85, *infra*.

years, EPA publishes a list of contaminants that are known or likely to exist in public water systems and may require regulation under the SDWA, known as the "contaminant candidate list."⁵⁵ PFOA and PFOS—the two most prevalent PFAS—were included in the 2009 contaminant candidate list⁵⁶ and remained on the renewed 2016 list, committing EPA to "further evaluation," but EPA has yet to issue any regulations regarding those PFAS.⁵⁷

Under the SDWA, EPA also has authority to issue non-binding health advisories for contaminants, even if EPA declines to regulate a contaminant.⁵⁸ These health advisories provide information on "health effects, testing methods, and treatment techniques for such unregulated contaminants of concern."⁵⁹ As mentioned previously, EPA has issued a non-binding health advisory level of 70 ppt for PFOA and PFOS in drinking water, separately or combined.⁶⁰ To generate further data, EPA required roughly 5,000 water systems to monitor for certain PFAS, finding that approximately 5.5 million people were receiving drinking water with PFOA and/or PFOS levels above the EPA health advisory level of 70 ppt.⁶¹

To regulate a contaminant under SDWA, EPA must find that (1) the contaminant may have adverse effect on health of humans, (2) there is a known or substantial likelihood that the contaminant will occur at the frequency or levels of public health concern in public water systems, and (3) regulating the contaminant will provide a meaningful opportunity for reductions of health risks.⁶² EPA has not officially made these conclusions for any PFAS chemical, which would trigger the regulatory process, despite mounting evidence of the toxicity of PFAS and their prevalence in drinking water. The EPA Administrator signed preliminary determinations to regulate PFOA and PFOS on February 20, 2020;⁶³ however, as of this writing in November 2020, no substantial process had been made to regulate PFOA and PFOS under the SDWA.⁶⁴ Thus far, SDWA

⁵⁵ Safe Drinking Water Act (SDWA), 42 U.S.C. § 300g-1.

⁵⁶ U.S. ENV'T PROT. AGENCY, CONTAMINANT CANDIDATE LIST (CCL) AND REGULATORY DETERMINATION, https://www.epa.gov/ccl/contaminant-candidate-list-3-ccl-3#federal-registernotices.

⁵⁷ Drinking Water Contaminant Candidate List 4-Final, 81 Fed. Reg. 81,009, 81,106-8, (proposed Nov. 17, 2016).

⁵⁸ Safe Drinking Water Act (SDWA), 42 U.S.C. §300g-1(b)(1)(F).

⁵⁹ CONG. RSCH. SERV., IF11219, REGULATING DRINKING WATER CONTAMINANTS: EPA PFAS ACTIONS (2020) [hereinafter CRS REPORT].

⁶⁰ Id.

⁶¹ *Id.* This was under the SDWA's unregulated contaminant monitoring rule, promulgated every 5 years, requiring water systems operators to test for no more than 30 contaminants (42 U.S.C. 300j-4(a)(2)(B)(i)).

⁶² Zeeb et al., *supra* note 6, at 10,114.

⁶³ CRS REPORT, *supra* note 59.

⁶⁴ *Id. See also* Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14,098 (proposed Mar. 10, 2020).

regulatory power remains substantially unused for regulating PFAS in drinking water.

Some observers have recommended that EPA utilize the Urgent Threat and Emergency Powers provisions of the SDWA to set a nationwide PFAS drinking water standard to remedy the pressing problem of PFAS contamination of drinking water.⁶⁵ The Urgent Threat provision allows EPA to bypass the traditional rulemaking process when a contaminant's presence in drinking water requires immediate attention.⁶⁶ However, EPA has never used the Urgent Threat provision.⁶⁷ Moreover, in its 2019 Action Plan, EPA affirmed that it intended to follow the traditional SDWA rulemaking process to regulate PFAS.⁶⁸ Similarly, EPA has stated that the Emergency Powers provision-which also allows EPA to sidestep the traditional regulatory process when public health is imminently threatened—cannot be used to set a nationwide drinking water standard.⁶⁹ EPA has used the Emergency Powers provision to require PFOA/PFOS decontamination of water at four sites, including three Department of Defense sites,⁷⁰ but this site-by-site adjudication is not sufficient to address PFAS contamination of drinking water. Thus, despite the potential promise of these provisions, they will not be used by the current EPA to regulate PFAS in drinking water.

B. Toxic Substances Control Act

TSCA allows the government to regulate chemicals apart from their impact on drinking water. TSCA gives EPA the authority to require reporting, record-keeping, and testing of chemicals, and restrict the use of chemical substances.⁷¹ Under Section 8 of TSCA, EPA keeps a list of each chemical substance that is used in the United States under TSCA authority, known as the TSCA inventory.⁷² All substances in the inventory are deemed "existing" substances, meaning that new chemical regulations generally do not affect use of those substances. However, an inventory listing is not accompanied by any regulatory requirements.⁷³ EPA reports that of over 600 "existing" PFAS in the TSCA

⁶⁵ Hannah Levine, Zombie Chemicals–Learning From Our Past to Prevent Haunting in the Future: Why the EPA Should Regulate PFAS Chemical Compounds, 21 VT. J. ENV'T L. 177, 195-99 (2019).

⁶⁶ *Id.* at 195. *See* 42 U.S.C. § 300g-1.

⁶⁷ *Id.* at 195.

 $^{^{68}\,}$ U.S. Env't Prot. Agency, EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan (2019), at 21.

⁶⁹ Id. at 15.

⁷⁰ CRS REPORT, *supra* note 59.

⁷¹ U.S. ENV'T PROT. AGENCY, SUMMARY OF THE TOXIC SUBSTANCES CONTROL ACT, https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act.

 $^{^{72}}$ U.S. ENV'T PROT. AGENCY, ABOUT THE TSCA CHEMICAL SUBSTANCE INVENTORY, https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory.

⁷³ Id.

inventory, EPA has reviewed almost sixty percent of them for hazardous properties and taken some actions to restrict the use of PFAS it has deemed hazardous.⁷⁴ Despite these steps, there are significant obstacles to comprehensively regulating PFAS and other chemicals under TSCA.

Analyses of TSCA by the National Research Council, Government Accountability Office, EPA, and others have widely concluded that TSCA has failed to meet the intent of Congress in enacting a comprehensive chemical regulatory system.⁷⁵ Federal regulation under TSCA has required testing of only 200 chemicals and banned or restricted fewer than 10 of those chemicals in the forty years since TSCA was enacted.⁷⁶ Scholars at U.C. Berkeley's Center for Occupational and Environmental Health observe that TSCA has produced three "gaps" in U.S. chemical policy: a data gap, because investigation and reporting requirements are insufficient; a safety gap, because the government lacks the tools it needs to mitigate health and environmental risks; and a technology gap, because lax chemical regulation has discouraged green chemistry research into safer alternatives.⁷⁷ These data and safety gaps in particular are crucial to understanding how PFAS have gone largely unregulated under TSCA.

When TSCA was passed in 1976, it grandfathered in the 62,000 existing chemical substances that were already in commercial circulation-including PFOA and other PFAS-essentially deeming these chemicals innocent until proven guilty.⁷⁸ That deferential approach extended to new chemicals as well. Under TSCA's original scheme, before EPA could require manufacturers to produce hazard and exposure data for the chemicals they produce, EPA had to establish for each individual chemical either (1) that a chemical may present an unreasonable risk to human health or the environment, or (2) that there is either significant human exposure potential or substantial quantities of a chemical released into the environment.⁷⁹ Thus, EPA had to meet a significant burden before requiring chemical data under TSCA. This evidentiary burden exacerbates the "safety gap" because EPA can only regulate a dangerous chemical if it makes a finding that the benefits outweigh the costs to industry and presents the "least burdensome" means of addressing the risk.⁸⁰ Further, although TSCA requires manufacturers to notify EPA of any new or unpublished chemical hazard information, this creates a perverse incentive for manufactures to avoid

⁷⁴ U.S. ENV'T PROT. AGENCY, EPA PFAS ACTION PLAN: PROGRAM UPDATE FEBRUARY 2020, at 10 [hereinafter *EPA PFAS Program Update*].

⁷⁵ Michael P. Wilson & Megan R. Schwarzman, *Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health*, 117 ENV'T HEALTH PERSPS. 1202, 1202 (2009).

⁷⁶ Valerie J. Watnick, *The Lautenberg Chemical Safety Act of 2016: Cancer, Industry Pressure, and a Proactive Approach*, 43 HARV. ENV'T L. REV. 373, 385 (2019).

⁷⁷ See Wilson & Schwarzman, *supra* note 75, at 1202.

⁷⁸ Id. at 1205.

⁷⁹ Id. at 1205 (restating requirements under TSCA section 4).

⁸⁰ *Id.* at 1205 (restating requirements under TSCA section 6).

investigating the hazardous nature of their chemicals.⁸¹ Although these requirements have been somewhat modified by the Lautenberg Act, discussed *infra* Sec. III.B, recent history indicates that the Act's improvements have not yet been truly effective, and the "gaps" in TSCA will persist if the Lautenberg Act's TSCA amendments are not properly implemented.

Instead of regulating the use of existing PFAS like PFOA under TSCA authority, EPA has relied on more permissive Significant New Use Rules ("SNURs").⁸² Under Section 5(a) of the Toxic Substances Control Act, EPA can use a SNUR to require manufacturers to notify EPA before using chemicals in ways that may create concerns.⁸³ In 2015, EPA announced a SNUR for PFOA, requiring manufacturers and importers of PFOA and some PFOA-related chemicals to notify EPA at least 90 days before using these chemicals.⁸⁴ In February 2020, EPA issued a supplemental proposal that would require it to review new uses of imported products containing certain PFAS as a surface coating.⁸⁵ EPA posits that this rule closes "an important loophole that currently allows products containing certain PFAS chemicals that have been phased out in the United States to still be imported"—the PFOA loophole left open after the PFOA Stewardship Program.⁸⁶ In July 2020, five years after being announced, the SNUR for PFOA was finalized.⁸⁷

Concerning new PFAS, according to its February 2020 program update, EPA has reviewed around 300 new PFAS chemical notices and regulated approximately 200 of them with consent orders and/or SNURs under TSCA authority.⁸⁸ (Note that this is separate from EPA's review of *existing* PFAS in the TSCA inventory, discussed earlier in this section.) However, these case-by-case adjudications for new and existing PFAS do not marshal all of EPA's TSCA authority to provide the protections the public needs against PFAS. New variations of PFAS continue to be introduced into the environment and persist indefinitely.⁸⁹ The burden TSCA places on EPA before it can regulate a substance, combined with an industry-friendly EPA, present significant obstacles to comprehensive PFAS regulation under TSCA. EPA should require toxicity data from PFAS manufacturers and use that information to implement rules under

⁸¹ Id. at 1205 (restating requirements under TSCA section 8(e)).

⁸² EPA PFAS Program Update, supra note 74, at 10.

⁸³ U.S. ENV'T PROT. AGENCY, ACTIONS UNDER TSCA SECTION 5, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs.

⁸⁴ EPA PFAS Program Update, supra note 74, at 10.

⁸⁵ Id.

⁸⁶ Id.

⁸⁷ Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 40 C.F.R. § 721 (2020).

⁸⁸ See EPA PFAS Program Update, supra note 74 at 10.

⁸⁹ See, e.g., John W. Washington, et al., Nontargeted Mass-Spectral Detection of Chloroperfluoropolyether Carboxylates in New Jersey Soils, 368 SCIENCE 1103 (2020).

TSCA authority. Once PFAS are introduced into the environment, however, other laws provide opportunities for regulation.

C. Comprehensive Environmental Response, Compensation, and Liability Act

CERCLA—also known as the Superfund law—allows EPA to hold emitters of hazardous substances strictly liable for their past emissions.⁹⁰ It is the bedrock law for environmental liability, requiring reporting of emissions as well as environmental remediation and cleanup.⁹¹ However, reporting and remediation can only be required under CERCLA if a chemical is designated as a "hazardous substance."⁹² For hazardous waste currently being emitted, RCRA applies, and designation as a RCRA hazardous substance would trigger liability under CERCLA as well.⁹³ Groups such as Public Employees for Environmental Responsibility and the UC Berkeley Environmental Law Clinic have initiated parallel efforts to use RCRA to designate certain PFAS as hazardous substances.⁹⁴ However, CERCLA designation is the focus of this section because CERCLA has a broader scope than Subtitle C of RCRA, and the most harmful PFAS, like PFOA, are largely stored—CERCLA's domain—and not manufactured much anymore, which RCRA would cover.

During a speech in September 2019, EPA's General Counsel Matthew Leopold indicated that EPA was actively considering designating PFOA and PFOS as CERCLA hazardous substances by the end of 2019.⁹⁵ Doing so would allow EPA to set reportable quantities for PFAS under CERCLA and require parties responsible for contamination to clean up their sites.⁹⁶ EPA did not accomplish this in 2019, and Congress removed provisions in the 2020 National Defense Authorization Act which would require EPA to designate PFAS as hazardous substances, rendering the liability provisions of CERCLA unusable.⁹⁷

If PFAS are designated as hazardous substances, PFAS polluters would be liable for cleanups and remediation of contaminated sites—a terrifying possibility for large private polluters like DuPont and government actors like the Department of Defense. There is evidence from Department of Defense memoranda that they knew of the contamination threat posed by military firefighting foams since the

⁹⁰ U.S. ENV'T PROT. AGENCY, SUPERFUND LIABILITY, https://www.epa.gov/enforcement/superfund-liability.

⁹¹ Id.

⁹² CRS REPORT, *supra* note 59.

⁹³ 42 U.S.C. § 101(14).

⁹⁴ Community Groups Step Up Push on EPA to Regulate PFAS Under RCRA, INSIDEEPA.COM (January 15, 2020), https://www.law.berkeley.edu/wp-content/uploads/2020/01/PFAS-combined-clips.pdf.

⁹⁵ See Henthorn & Loos, supra note 30.

⁹⁶ CRS REPORT, *supra* note 59.

⁹⁷ Congress Fails to Protect Americans from PFAS Pollution, ENV'T WORKING GROUP (Dec. 10, 2019), https://www.ewg.org/release/ongress-fails-protect-americans-pfas-pollution.

1980s, but only recently started investigating the issue.⁹⁸ By 2001, the Department had concluded that the PFAS firefighting foam they used was "persistent, bioaccumulating, and toxic."99 Despite this knowledge, the department continued to require military firefighters to use these PFAS-based foams, and military bases have some of the highest PFAS levels recorded anywhere in the country.¹⁰⁰ PFAS levels at Langley Air Force Base, for example, exceeded 2.2 million ppt.¹⁰¹ (Recall that EPA health advisory level is 70 ppt.) PFAS contamination has been confirmed at almost 300 military installations, with many more sites being tested.¹⁰² EPA reports in its 2020 PFAS Program Update that CERCLA enforcement action has been taken against one PFAS polluter, Wolverine World Wide, in Michigan;¹⁰³ however, on closer examination, the federal CERCLA action was actually related to other hazardous waste, while the state environmental authorities compelled action on PFAS contamination.¹⁰⁴ Rep. Debbie Dingell's PFAS Action Act of 2019, passed by the House in January 2020, would require EPA to designate PFAS as hazardous substances under CERCLA, but the bill is still being considered in the Senate.¹⁰⁵ There is little question that if EPA designates PFAS as hazardous substances and requires reportable quantities similar to the health advisory maximum contaminant level, the designation would expose polluters to enormous liability for cleanup. Thus, while EPA has the potential to require stringent clean-ups of PFAS under CERCLA, significant opposition exists to designating PFAS as CERCLA hazardous substances.¹⁰⁶

D. Emergency Planning and Community Right-to-Know Act

There has been some minor progress towards gathering toxicity data under the EPCRA. EPCRA is a subsidiary of CERCLA and contains the Toxics Release Inventory. The Toxics Release Inventory is purely a disclosure mechanism, a resource for learning about toxic chemical releases reported by industrial and

⁹⁸ Kray & Wightman, *supra* note 3, at 36.

⁹⁹ Scott Faber, *To Support Military Families, Congress Must Pass the PFAS Action Act*, ENV'T WORKING GROUP (Jan. 9, 2020), https://www.ewg.org/news-and-analysis/2020/01/support-military-families-congress-must-pass-pfas-action-act.

¹⁰⁰ Id.

¹⁰¹ *Id*.

¹⁰² Id.

¹⁰³ EPA PFAS Program Update, supra note 74, at 13.

¹⁰⁴ U.S. ENV'T PROT. AGENCY, WOLVERINE WORLD WIDE TANNERY, https://www.epa.gov/mi/wolverine-world-wide-tannery.

¹⁰⁵ PFAS Action Act of 2019, H.R. 535, 116th Cong. (2019).

¹⁰⁶ See, e.g., Glen G. Lammi, Consequences Must Be Carefully Assessed Before PFAS Are Pushed Into the Superfund Quagmire, FORBES (Sept. 26, 2019, 3:47pm), https://www.forbes.com/sites/wlf/ 2019/09/26/consequences-must-be-carefully-assessed-before-pfas-is-pushed-into-the-superfundquagmire/#7c12a7846c37. The author, a lawyer for the conservative nonprofit Washington Legal Foundation, explains that designating PFAS hazardous as a class would "overwhelm regulators," "spook developers," and require public utilities to shell out enormous sums of money.

federal facilities, added to CERCLA in 1986 through EPCRA.¹⁰⁷ It carries no regulatory enforcement power.¹⁰⁸

The 2020 National Defense Authorization Act included a provision to add 172 PFAS to the Toxics Release Inventory list ("TRI"),¹⁰⁹ which was finalized on June 22, 2020.¹¹⁰ As such, the TRI provides the core mechanism for information about how PFAS manufacturers and handlers treat and dispose of PFAS-contaminated waste.¹¹¹ While this information sheds light on how dangerous PFAS are being handled, the disclosures are wasted if they do not prompt regulatory action to keep PFAS contamination within safe levels, which thus far the TRI disclosures have failed to do. As Scott Faber, the senior vice president for governmental affairs for the Environmental Working Group, points out, "[w]hen your water is polluted with toxic PFAS, it's not much comfort to know who is polluting it."¹¹²

E. Clean Water Act

The Clean Water Act contains a Toxic Pollutants List for substances which must be regulated. Section 307 of the Clean Water Act authorizes EPA to designate certain contaminants as toxic pollutants.¹¹³ Under Section 307, when a contaminant is listed in the Toxic Pollutant List, EPA is authorized to promulgate Effluent Limitation Guidelines that establish requirements for those pollutants.¹¹⁴ Adding pollutants to the Toxic Pollutant List triggers additional requirements for states, requiring them to adopt standards for pollutants on the list.¹¹⁵ However, since the adoption of the initial list in 1978, the list has not changed substantially.¹¹⁶ Representatives Chris Pappas (NH-01) and Annie Kuster (NH-02) introduced legislation on July 2, 2019¹¹⁷ that would add certain PFAS to the Clean Water Act's Toxic Pollutants List, but these efforts have been unsuccessful

¹⁰⁷ U.S. ENV'T PROT. AGENCY, TOXICS RELEASE INVENTORY (TRI) PROGRAM, https://www.epa.gov/toxics-release-inventory-tri-program. *See* Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. § 11023.

¹⁰⁸ 42 U.S.C. § 11023.

¹⁰⁹ U.S. ENV'T PROT. AGENCY, LIST OF PFAS ADDED TO THE TRI BY THE NDAA, https://www.epa.gov/toxics-release-inventory-tri-program/list-pfas-added-tri-ndaa (Apr. 2, 2020).

¹¹⁰ Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances; Toxic Chemical Release Reporting, 40 C.F.R. § 372 (2020).

¹¹¹ U.S. ENV'T PROT. AGENCY, BASICS OF TRI REPORTING, https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting.

¹¹² See supra note 97.

¹¹³ LAURA GATZ, CONG. RSCH. SERV., R45998, CONTAMINANTS OF EMERGING CONCERN UNDER THE CLEAN WATER ACT 14 (2019).

¹¹⁴ *Id.* at 8.

¹¹⁵ Id.

¹¹⁶ Id.

¹¹⁷ Press Release, Chris Pappas, Rep. N.H. 1st Cong. Dist., Pappas and Kuster Introduce Legislation to Decrease PFAS Contamination and Hold Polluters Accountable (July 2, 2019), https://pappas.house.gov/media/press-releases/release-pappas-and-kuster-introduce-legislation-decrease-pfas-contamination-and.

thus far. As an example of how these various regulatory schemes overlap, substances added to the Toxic Pollutant List are cross-listed as hazardous substances under CERCLA.

IV. REGULATORY ALTERNATIVES THAT EMBRACE THE PRECAUTIONARY PRINCIPLE

The preceding sections outline how PFAS have slipped through the cracks of federal regulation for decades, despite the complex and seemingly extensive federal chemical regulatory scheme. Due to prohibitive statutory requirements, opposition from the powerful chemical lobby, and fear of liability, in recent years an industry-friendly EPA has allowed numerous opportunities for meaningful PFAS regulation to pass by, and many of the substantive provisions of the nation's bedrock environmental laws gather dust while American soil and water are contaminated.¹¹⁸ Ultimately, however it manifests, EPA has used these statutes to embrace or allow forms of "presumptive innocence" towards chemical manufacturers, and the American people pay the price.

The PFAS saga offers an opportunity to critically examine our chemical regulatory framework and consider compelling alternatives to the system we currently have in place. The most effective of these alternatives—EU's REACH and California's Green Chemistry approach—embrace the precautionary principle: "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."¹¹⁹

A. A Recent Attempt at TSCA Reform

In response to TSCA's well-documented failings, Congress passed improvements to TSCA in the summer of 2016 through the Frank R. Lautenberg Chemical Safety for the 21st Century Act, one of the first major environmental laws passed in decades.¹²⁰ As discussed in Section II.B, in its original form, TSCA did not allow EPA to require testing of a chemical without adequate prior data about that chemical, but it also did not allow EPA to request such information from the industry unless it already believed that the chemical presented an unreasonable risk to public health or the environment.¹²¹ In other words, TSCA

¹¹⁸ See, e.g., Washington, et al., *infra*. note 171.

¹¹⁹ Devid Kriebel et al., *The Precautionary Principle in Environmental Science*, 109 ENV'T HEALTH PERSPECTIVES 871, 871 (2001). *See generally* PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT IMPLEMENTING THE PRECAUTIONARY PRINCIPLE (Carolyn Raffensperger & Joel Tickner eds., 1999).

¹²⁰ Toxic Substances Control Act, 5 U.S.C. § 53.

¹²¹ Watnick, *supra* note 76, at 385.

only allowed EPA to request safety data from manufacturers if it *already knew* that the chemical was dangerous.¹²²

Through the Lautenberg Act—named after the former New Jersey Senator who introduced the TSCA reform bill-Congress required that new chemicals be reviewed for safety before being introduced into the market and eliminated the requirement that EPA make a preliminary finding of risk before requiring manufacturers to submit more data about a chemical.¹²³ For existing chemicals, EPA must now designate substances as high or low priorities based on their potential risk, then issue a rule within two years of finding that the substance poses an unreasonable risk to health or the environment.¹²⁴ The Lautenberg Act also places more stringent regulations on pre-manufacture notices, which allow manufacturers to commercialize new chemicals without adequate testing data if the new chemicals had a similar compound structure to an existing chemical.¹²⁵ If applied to PFAS, the Lautenberg Act could prevent new harmful PFAS from being introduced and allow EPA to regulate existing PFAS more easily. Under it, EPA could require manufacturers to submit more data about PFAS' hazardous properties and could designate the PFAS family of chemicals as high priority, providing an immediate path to regulation by weakening the presumption of innocence.

For new chemicals, although pre-manufacture notices can still be used, EPA can now require additional testing data from parties without showing that the chemicals pose a health risk during review of the notice.¹²⁶ For the first time, EPA can also restrict the distribution of a chemical by order if the data are insufficient to determine if a chemical presents an unreasonable risk, if the chemical will be produced in a large volume, or if the chemical's use presents a risk under the conditions of use.¹²⁷ While still requiring cost-benefit analyses in risk assessment, the TSCA amendments make clear that such analyses should not control whether or not a substance is regulated.¹²⁸

The Lautenberg Act, while progress, is a compromise between industry and environmental advocacy groups. The cornerstone provisions of the law require pre-market safety reviews of new chemicals and preempt states from regulating EPA-designated "high priority" chemicals once EPA decides to regulate that chemical itself.¹²⁹ Industry groups advocated for the latter, as it meant manufacturers would not be exposed to multiple different state regulations of

¹²⁸ Id. at 393. See 15 U.S.C. § 2605 (2016).

¹²² See discussion supra Section II.B

¹²³ Watnick, *supra* note 76, at 390.

¹²⁴ Id. at 393.

¹²⁵ Id. at 386.

¹²⁶ Watnick, *supra* note 76, at 392.

¹²⁷ *Id.* at 392-93.

¹²⁹ Id. at 390.

"high priority" chemicals.¹³⁰ The Lautenberg Act emphasizes regulation of existing chemicals, because many of the more than 80,000 chemicals on the market are untested for human health effects.¹³¹ However, the years since the Act's passage demonstrate that simply updating statutory language is not enough to overhaul the TSCA regime.

Although the Lautenberg Act offers promising improvements to TSCA, the Trump administration has been bent on pressing its de-regulation agenda and diluting EPA's power in the process. Before the Obama administration's EPA could finalize rules implementing the Act, the Trump administration took the reins at EPA and finalized its own rules.¹³² The Trump administration removed the planned default high-priority designation for existing chemicals, recommending that EPA take a "low-priority" approach instead for most existing chemicals.¹³³ In seeming direct contradiction to the Lautenberg Act's intent to regulate chemical substances from manufacture to disposal, EPA stated that it would not consider all exposures to existing chemicals from manufacture to disposal, instead allowing the EPA Administrator to determine what conditions of use should be considered for existing chemicals.¹³⁴ EPA's rationale for limiting evaluation of existing chemicals in this way is that other EPA laws, like the Clean Air Act and Clean Water Act, regulate exposure during the life of the chemical.¹³⁵ EPA's narrow approach to reviewing existing chemicals excludes "legacy uses" as wellexposures from ongoing uses as well as disposals of chemicals that are no longer being made for that use-which restricts EPA's review of many PFAS (like PFOA).136

For new chemicals, the Trump administration's EPA stated that it would consider their effects in "intended, known, or reasonably foreseen" uses, instead of considering the whole life of the chemical as the statute requires.¹³⁷ This interpretation significantly limits EPA's power to regulate dangerous chemicals, as it narrows the scope of hazards that EPA is allowed to consider. Additionally, instead of using its authority to issue orders restricting uses of harmful chemicals, EPA has pivoted to using SNURs for PFAS, which require persons to report any "significant new use" of designated chemicals.¹³⁸ By requiring this reporting, EPA

¹³⁰ Id. at 389-90.

¹³¹ Toxic Chemicals, NAT. RES. DEF. COUNCIL (last visited Aug. 18, 2020), https://www.nrdc.org/issues/toxic-chemicals.

¹³² Watnick, supra note 76, at 396.

¹³³ *Id. See* Procedures for Prioritization of Chemical Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753, 33,760 (July 20, 2017) (codified at 40 C.F.R. pt. 702)..

¹³⁴ Watnick, supra note 76, at 397. See Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control, supra note 130, at 33,729.

¹³⁵ Toxic Consequences: Trump's attacks on chemical safety put our health at risk, ENV'T DEFENSE FUND 7 (June 2019), http://blogs.edf.org/health/files/2019/06/EDF_Toxic_Consequences_Report.pdf [hereinafter *EDF Report*].

¹³⁶ *Id.*

¹³⁷ Watnick, *supra* note 76, at 397.

¹³⁸ Zeeb et al., *supra* note 6 at 10,114. *See* discussion, *supra* Part II.B.

has an opportunity to evaluate the risk posed by new PFAS-related manufacturing. However, SNURs do not apply to existing uses and hamper EPA's power, as they cannot be easily modified and significantly slow down the regulatory process.¹³⁹

Finally, because EPA has failed to embrace the TSCA regulatory power offered to it by the Lautenberg Act, it is unclear whether the Act's burden-shifting provisions will have their intended effect. If EPA simply fails to pursue regulation under the reformed TSCA, there is no opportunity for the evidentiary burden to be placed on chemical manufacturers. Thus, although the Lautenberg Act presents a significant step towards overhauling federal chemical regulation, it is only as powerful as its implementers allow it to be.

B. The European Union's REACH Program

Legislators in the European Union have taken a more proactive stance for regulating chemicals. On June 1, 2007, the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) law went into force.¹⁴⁰ The law requires all chemical manufacturers who produce or import more than one metric ton of a chemical per year to register the product by submitting data about the properties of the chemical and its uses-including how risks associated with the chemical should be managed-to the European Chemicals Agency.¹⁴¹ It disposes of the distinction between "existing" and "new" chemicals, opting instead for a default requirement that manufacturers produce data on their chemicals.¹⁴² Registration is required for all new chemicals entering commerce.¹⁴³ The European Chemicals Agency reviews the data submitted and highlights chemicals that could have negative effects on human health.¹⁴⁴ Manufacturers of chemicals deemed "substances of high concern" may have to apply for authorization of their intended uses for the substances, which are granted only if the manufacturer can demonstrate that the risks to human health can be adequately controlled.¹⁴⁵ If a company does not obtain authorization, they will be prohibited from manufacturing, importing, or using that chemical after a specified date.¹⁴⁶ Further, manufacturers are required to submit an analysis of potential substitutes for the harmful chemical or a research and development plan if there is no adequate substitute.147

¹³⁹ Watnick, *supra* note 76, at 399.

¹⁴⁰ JERRY H. YEN, CONG. RESEARCH SERV., RS22673, CHEMICAL REGULATION IN THE EUROPEAN UNION (EU): REGISTRATION, EVALUATION, AND AUTHORIZATION OF CHEMICALS 1 (2013).

¹⁴¹ *Id*.

¹⁴² Noah M. Sachs, Jumping the Pond: Transnational Law and the Future of Chemical Regulation, 62 VAND. L. REV. 1817, 1834 (2009).

¹⁴³ Yen, *supra* note 140, at 1.

¹⁴⁴ *Id.* at 2.

¹⁴⁵ *Id.*

¹⁴⁶ *Id*.

¹⁴⁷ Id.

REACH makes a concerted effort to close data and safety gaps in chemical regulation by requiring more disclosures of data than the corresponding American framework requires under TSCA.¹⁴⁸ The European Chemicals Agency publishes a list of restricted substances for which manufacture, sale, or use is limited or banned in the EU.¹⁴⁹ PFOA—the PFAS first discovered on Earl Tennant's farm—has been included on that list.¹⁵⁰ No manufacturer in the EU can produce or market PFOA after July 4, 2020, with a few narrow exceptions that are to be phased out over a longer timetable.¹⁵¹ This regulation was possible because the European Chemicals Agency deemed PFOA a substance of high concern for its negative effects on human health, and no authorized use can be permitted to override the potential harm PFOA poses.¹⁵²

REACH provides a template for a better way to regulate PFAS. In contrast with TSCA, it requires all chemical manufacturers of a certain volume to provide data about the chemicals, rather than requiring disclosure only when hazardous environmental effects are discovered by the manufacturers. REACH also provides regulators with broader authority to regulate potentially dangerous substances and shifts the burden to producers to demonstrate that the risks to human health from their product will be adequately controlled. This burden-shifting sends a message to chemical manufacturers in the EU that chemical risks must be controlled, eliminated, or justified by manufacturers.¹⁵³ Under the REACH system, scientific uncertainty around chemicals of concern is resolved in favor of disallowing a chemical to enter the market.¹⁵⁴ Applied to American chemical regulation, this type of burden shifting would not allow industry resistance—embodied as purportedly inconclusive safety data—to prevent regulation.

As REACH demonstrates, it is sensible to require the producers—who have the capacity and the motivation to refute accusations that their products are hazardous—to bear the burden of proving the appropriateness of regulation. Further, REACH does not allow pre-existing chemicals to evade regulation by being "grandfathered in" to the scheme. REACH's benefits are fourfold: (1) without sufficient safety data, chemical manufacturers cannot market their products in the EU; (2) the burden of proof is shifted to industry for chemicals of concern; (3) chemical risks are communicated more clearly with the public; and (4) companies are incentivized to substitute safer chemicals.¹⁵⁵ The benefits of

¹⁴⁸ Wilson & Shwarzman, *supra* note 75, at 1202.

¹⁴⁹ Substances restricted under REACH, EUROPEAN CHEM. AGENCY, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e181e91f73.

¹⁵⁰ Annex VII to REACH, Entry 68, EUROPEAN CHEM. AGENCY, https://echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c.

¹⁵¹ Id.

¹⁵² Candidate List of substances of very high concern for Authorisation, EUROPEAN CHEM. AGENCY, https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db2ba.

¹⁵³ Sachs, *supra* note 142, at 1836-37.

¹⁵⁴ Id. at 1837.

¹⁵⁵ *Id.* at 1817.

REACH have been extensive, as multinational manufacturers who do business in the EU and United States must comply with the law, creating an incentive for producers in the American market to be more transparent as well.¹⁵⁶ The adoption of a similar regulatory system in the United States would likely have similar farreaching benefits.

C. California's Green Chemistry Approach

Domestically, California has taken federal regulatory reticence as an opportunity to craft its own precautionary chemical regulatory programs. In response to the fears that federal toxic chemical regulation does not go far enough to protect human health, California has passed laws to implement a "green chemistry" framework.¹⁵⁷ California has long been a leader in chemical safety and disclosure, familiar to any American consumer who has seen or heard the words "this product is known to the state of California to cause cancer."¹⁵⁸ The state's "green chemistry" approach seeks to avoid the use of toxic chemicals altogether, rather than accepting such chemicals as essential and subsequently attempting to mitigate their harmful effects.¹⁵⁹ The first "green chemistry" law in California, passed in 2008, created the Safer Consumer Products program, which empowered the state to identify and prioritize chemicals of concern in consumer products used in California.¹⁶⁰

Under the Safer Consumer Products program, the Department of Toxic Substances Control ("DTSC") promulgated regulations requiring manufacturers to seek safer alternatives to harmful chemical ingredients in consumer products.¹⁶¹ The regulations proposed a four-step program for DTSC to use when regulating chemicals in the state: (1) establish a list of candidate chemicals that have harmful qualities, (2) identify "priority products" that contain one or more candidate chemicals and notify manufacturers of such products, (3) require manufacturers to analyze alternatives for limiting exposure to environmental harm, and (4) implement any regulatory responses that will protect public health and maximize the use of alternatives to dangerous chemicals.¹⁶² Under the second step in this scheme, DTSC has listed products containing PFAS as priority products and is

¹⁵⁶ Wilson & Shwarzman, *supra* note 76, at 1202.

¹⁵⁷ Oladele A. Ogunseitan, *Embracing Global Warmth and Climate Resilience Through Green Chemistry Legislation*, 25 HASTINGS ENV'T L. J. 301, 304 (2019).

¹⁵⁸ See Safe Drinking & Toxic Enforcement Act of 1986, CAL. SAFETY & HEALTH § 25249.14 (2018). Such disclosures are required under California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, which became law in 1986.

¹⁵⁹ Ogunseitan, *supra* note 157, at 304.

¹⁶⁰ Id. at 304 (detailing the codification of the law as AB-1879).

¹⁶¹ *Id.* at 305.

¹⁶² CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL, WHAT ARE THE SAFER CONSUMER PRODUCTS REGULATIONS?, https://dtsc.ca.gov/what-are-the-safer-consumer-products-regulations/.

reviewing public input for these proposed regulations.¹⁶³ This approach is both science-based and protective of public health, offering a model for other states and nations to follow.

The second law, also passed in 2008, directs the state DTSC to create a Toxics Information Clearinghouse, with the goal of increasing public knowledge about the potential hazards associated with chemicals used in California, thereby decreasing the informational asymmetry so prevalent in chemical regulation.¹⁶⁴ Requiring manufacturers to submit data on potentially harmful substances allows the public to understand the risks associated with certain chemicals and reduces the burden on the government to gather toxicity data for regulatory purposes. In its final statement of reasons for the regulations, DTSC explained that the regulations will "set in motion a preemptive strategy that reduces the use of toxic substances in the design of products."165 The Department views its regulations as a "possible national model for chemical reform."¹⁶⁶ California's approach effectively combines increased enforcement power and maximal public disclosures to protect its citizens from harmful substances like PFAS. Recently, California has also extended its proactive approach towards PFAS to drinking water sources, requiring water sources with more than 10 ppt of PFOA or 40 ppt of PFOS to be treated or removed as water sources.¹⁶⁷ These types of enforceable, health-protective standards flow downstream from the state's green chemistry approach.

V. CONCLUSION AND RECOMMENDATIONS

As the preceding pages show, some small victories have been won in the fight to protect Americans from PFAS. Most recently, in July 2020, the House Armed Services Committee passed amendments to the 2021 National Defense Authorization Act that would require four primary responses from the Department of Defense: (1) phase out the use of products containing PFAS; (2) meet state PFAS cleanup standards if they are higher than federal standards (as they are currently in some states); (3) publish results of PFAS water testing near military

¹⁶³ Comment Period Detail on the Regulatory Proposal for PFAS in Carpets and Rugs, CALSAFER, https://calsafer.dtsc.ca.gov/cms/commentpackage/?rid=12751 (last visited Oct. 24, 2020); Comment Period Detail on the Regulatory Proposal for PFAS Treatment of Textiles or Leathers, CALSAFER, https://calsafer.dtsc.ca.gov/cms/commentpackage/?rid=12746 (last visited Oct. 24, 2020).The products include carpets and rugs containing PFAS (https://calsafer.dtsc.ca.gov/cms/commentpackage/?rid=12751) and treatments containing PFAS for textiles and leathers (https://calsafer.dtsc.ca.gov/cms/commentpackage/?rid=12746).

¹⁶⁴ Ogunseitan, *supra* note 157, at 305 (detailing the codification of this law as SB-509).

¹⁶⁵ CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL, R-2011-02, FINAL STATEMENT OF REASONS, SAFER CONSUMER PRODUCTS 9 (first proposed July 27, 2012).

¹⁶⁶ *Id*.

¹⁶⁷ Jeffrey Dintzer & Peter Masaitis, *California Takes the Lead in Regulating PFAS Chemicals in Drinking Water*, LAW.COM (Feb. 24, 2020 at 1:15pm), https://www.law.com/therecorder /2020/02/24/california-takes-the-lead-in-regulating-pfas-chemicals-in-drinking-water/.

sites; and (4) require funding and research into the risks of PFAS contamination.¹⁶⁸ However, these small victories—amendments, state rules, disclosure requirements, and others—fall far short of the comprehensive federal regulatory effort required to protect Americans from PFAS contamination. And the contamination from PFAS continues, with endless variations on the same toxic mixture.

In 2009, DuPont heralded the arrival of its newest PFAS, called GenX, manufactured in a plant on the Cape Fear River in North Carolina. ¹⁶⁹ Responding to fears that the area would become the next Parkersburg, DuPont explained to worried locals that GenX was a safer chemical than the ones produced in West Virginia and elsewhere.¹⁷⁰ They explained that this new PFAS was designed to be less persistent in the environment than their previous products.¹⁷¹ However, in the following decade, PFAS were identified in the water¹⁷² and cancer levels spiked among the 250,000 people who relied on the Cape Fear River for drinking water.¹⁷³ These revelations come like clockwork. In June 2020, scientists disclosed that they found new variations of PFAS compounds in New Jersey soils.¹⁷⁴ Very little is known about these recently-discovered PFAS variants present in the environment, but little evidence suggests that these new substances are any less toxic than their predecessors.¹⁷⁵

For all of EPA's talk of PFAS regulation, the agency is poised to approve four new varieties of PFAS in 2020, and new chemical notices for the chemicals indicate potential threats to human health.¹⁷⁶ No health studies, chemical names, or other pertinent data have been disclosed for these chemicals.¹⁷⁷ In the last three years, EPA has approved 15 new PFAS compounds, and at least 600 PFAS

¹⁶⁸ PFAS Reform Provisions Included in Defense Spending Bill, ENV'T WORKING GROUP (July 21, 2020), https://www.ewg.org/release/pfas-reform-provisions-included-defense-spending-bill.

¹⁶⁹ Tom Perkins, *The Environmental Protection Agency Keeps Approving Dangerous Chemicals*, HUFFINGTON POST (Feb. 4, 2020), https://www.huffpost.com/entry/epa-pfas-dangerous-chemicals_n_5e384be0c5b69a19a4b39504.

¹⁷⁰ Id.

¹⁷¹ See Sharon Lerner, New Teflon Toxin Causes Cancer in Lab Animals, THE INTERCEPT (Mar. 3, 2016), https://theintercept.com/2016/03/03/new-teflon-toxin-causes-cancer-in-lab-animals/.

¹⁷² Mark Strynar, et al., *Identification of Novel Perfluoroalkyl Ether Carboxylic Acids (PFECAs)* and Sulfonic Acids (PFESAs) in Natural Waters Using Accurate Mass Time-of-Flight Mass Spectrometry (TOFMS), 49 ENV'T SCI. & TECH. 19, 11622-11630 (Sept. 22, 2015).

¹⁷³ Perkins, *supra* note 169. The advocacy group Clean Cape Fear reports the spike in cancer levels, based on the National Cancer Institute's North Carolina State Cancer Profile, accessible at https://statecancerprofiles.cancer.gov/.

¹⁷⁴ John W. Washington, et al., *Nontargeted mass-spectral detection of chloroperfluoropolyether carboxylates in New Jersey soils*, 368 SCIENCE 6495, 1103-1107 (June 5, 2020).

¹⁷⁵ Sharon Lerner, *New PFAS Chemical Contamination Discovered in New Jersey*, THE INTERCEPT (June 4, 2020, 2:00 PM), https://theintercept.com/2020/06/04/pfas-chemicals-new-jersey-solvay/.

¹⁷⁶ Perkins, *supra* note 169.

¹⁷⁷ Id.

compounds in the decade between 2006 and 2016.¹⁷⁸ PFAS manufacturers, reacting to new disclosure requirements, have utilized the "low-volume exception" to withhold data, which is granted when companies plan to produce less than 22,000 pounds of a chemical.¹⁷⁹ However, EPA does little to verify that companies stay below that threshold.¹⁸⁰

One of the main hurdles to PFAS regulation is the current EPA's desire to interpret its regulatory mandate as narrowly as possible, perhaps because it is led by a former coal lobbyist-as well as a former American Chemistry Council senior official, a Koch Industries researcher, and an American Petroleum Institute senior attorney—who worked on behalf of clients who militantly oppose EPA's regulatory power.¹⁸¹ The power of agency interpretation has been strikingly effective in its ability to weaken the Lautenberg Act's reforms of TSCA. These reforms could open the door for comprehensive PFAS regulation if EPA can free itself from the self-destruction that has characterized the Agency in the Trump era. During the brief period after the Lautenberg Act was passed, and before the Trump administration took over, EPA scrutinized new chemicals as it was supposed to and slowed down the approval process for new chemicals.¹⁸² But the success of the Lautenberg Act was short-lived. In order to embrace the precautionary advantages embedded in the Lautenberg Act, EPA must take a more active role, similar to the European Chemicals Agency, by requiring safety data before allowing chemicals to market, placing the evidentiary burden on manufacturers, and restricting dangerous uses of toxic chemicals.

The PFAS saga demonstrates the major gaps in American chemical regulation and suggests that the industry's fears of liability influence EPA's regulatory decisions. Plausible regulatory alternatives are emerging that could fill those gaps, notably the EU's REACH and California's Green Chemistry approach. Both alternatives embrace the precautionary principle, prioritizing human health and scientific conclusions over industry concern. These laws leverage their large constituent populations to shape global policy, offering models for the federal government of the United States.

It is clear that any successful PFAS regulation must tackle the chemicals as an entire class and provide regulators with the tools to gather data on potential harms from the chemicals, shifting the burden onto manufacturers to prove that their products are not harmful.¹⁸³ But disclosure is not enough—it must be paired with increased enforcement power. With the now well-documented history of harmful

¹⁷⁸ Id.

¹⁷⁹ Id.

¹⁸⁰ *Id.*

¹⁸¹ EDF Report, supra note 132, at 5.

¹⁸² Perkins, *supra* note 169.

¹⁸³ Carol F. Kwiatkowski, et. al., *Scientific Basis for Managing PFAS as a Chemical Class*, 7 ENV'T SCI. TECH. LETTERS 8, 532-543 (June 30, 2020), explaining that a class-based approach is necessary to regulate toxic PFAS.

effects of PFAS around the world, federal regulators have an opportunity for selfevaluation. They must leave behind the "innocent-until-proven-guilty" approach to chemical regulation and embrace the precautionary approaches now underway in California and the European Union. At a minimum, EPA should enforce the Lautenberg Act to achieve the goals that Congress intended when it passed the law. Advocates can hope that a Biden Administration's EPA will at least enforce the Lautenberg Act, but a paradigm shift is necessary to leave these dangerous chemicals in the past: regulators must consider human health first and foremost and adopt regulations that reflect this reordering of priorities.