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An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation

David Markell*

INTRODUCTION

The United States has enacted an alphabet soup of laws during the past forty years to try to reduce risks that the manufacture, use, and/or disposal of toxic substances pose to our environment and to human health.[1] Creation of this environmental legislative infrastructure has had significant effects on American society—on the environment in which we and other species live, on the health risks we face, and on the work we do.[2] One of the important early books about toxic substances, *The Dilemma of Toxic Substances Regulation*, suggests that this growth in government regulation has "radically

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1. For a list of twenty-one federal laws that focus on a variety of toxic substances, see ROBERT L. GLICKSMAN, DAVID L. MARKELL, WILLIAM W. BUZBEE, DANIEL R. MANDELKER & A. DAN TARLOCK, ENVIRONMENTAL PROTECTION: LAW AND POLICY 780, Table 8-2 (5th ed. 2007). Definitions of "toxic substances" vary. Andrew Hanan, *Pushing the Environmental Regulatory Focus a Step Back: Controlling the Introduction of New Chemicals under the Toxic Substances Control Act*, 18 AM. J.L. & MED. 395, 395 n.1 (1992) (noting that "[n]o standard legal definition of a toxic substance exists"). The Government Accountability Office ("GAO") has reviewed several of these statutes. For an example of one multi-program assessment, see U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM (2005) [hereinafter GAO June 2005].

2. One of the fascinating questions about environmental law relates to its "appropriate" scope. At the international level, at least in some circles, there has been considerable rhetoric that environmental protection objectives should be viewed in tandem with their impacts on economic opportunity under the rubric of "sustainable development." How the United States will navigate its way in defining "appropriate" levels of environmental protection in light of other objectives remains a work in progress.

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transform[ed] the economic roles of government and business as well as relations between them."[3]

As one might expect, there has been an enormous amount of debate concerning the nature, extent, and adequacy of this transformation. Two overarching questions this rich debate about our extensive environmental regulatory infrastructure raises are: Are we "there yet" in our approach to managing risks from chemicals and, related, how will we know?[4] Further, if we have not reached an "optimal" level of environmental and human health protection (I think it a safe guess that this would be the view of the vast majority of readers of this symposium volume), a host of other questions require attempts at resolution, including: what remains to be done; what are our options for moving forward; what path(s) should we take; how should we monitor our progress; and how should we structure our approach so we can shift course if and when needed?[5] In the early 1970s, during the most active phase of federal environmental law-making this country has ever seen,[6] the Council on Environmental Quality ("CEQ") alluded to some of these issues:

> The Nation['s voting] overwhelmingly for a cleaner environment. . . . has signaled a fundamental redirecting of our economy and society. . . . [N]ow, having decided that

3. JOHN M. MENDELOFF, THE DILEMMA OF TOXIC SUBSTANCES REGULATION ix (1988).

4. *See* A. Dan Tarlock, *Is There a There There in Environmental Law?*, 19 J. LAND USE & ENVTL. L. 213, 213–21 (2004). The questions of how we should measure progress and, related, the metrics we should use to gauge success, are important parts of this debate that remain unsettled, though Congress and others have offered guidance on numerous occasions in different contexts. *See, e.g.*, Government Performance and Results Act ("GPRA") of 1993, Pub. L. No. 103-62, 107 Stat. 285 (codified as amended in scattered sections of 5 U.S.C., 31 U.S.C, 39 U.S.C.).

5. There are substantial and interesting literatures on each of these questions in the context of toxic substances and beyond, including various law review symposia. *See, e.g.*, Symposium, *Breaking the Logjam: Environmental Reform for the New Congress and Administration*, 17 N.Y.U. ENVTL. L.J. 75 (2008); Symposium, *Twenty-Five Years of Environmental Regulation*, 27 LOY. L.A. L. REV. 779 (1994); Symposium, *New Directions in Environmental Policy*, 13 COLUM. J. ENVTL. L. 153 (1988).

6. For example, the CAA was adopted in 1970, the CWA in 1972, RCRA in 1976, and TSCA in 1976. National Environmental Policy Act ("NEPA") and CERCLA serve as legislative bookends for this extraordinary decade of legislative activity in the environmental arena. NEPA was adopted in 1969, and CERCLA in 1980. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321–4370 (2006); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601–9675 (2006).

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> environmental quality is a valuable good, we have to decide more precisely how much we want, how we will pay for it, and who will pay for it. These questions often require complicated analyses involving difficult tradeoffs.[7]

Elected officials, regulators, judges, scholars, and a host of others have suggested a wide variety of possible guideposts to help inform decision-making about these questions. To identify a few, formulators and implementers of environmental policy have been encouraged to be mindful of the "precautionary principle";[8] "technology forcing";[9] the notion of "polluter pays";[10] "sustainable development"[11] and, perhaps related, the need to consider costs and benefits in developing policy approaches;[12] the importance of meaningful public involvement;[13] the relationship between voluntary initiatives and coercive approaches;[14] whether to differentiate among different sources of pollution including, for example, the appropriateness of drawing distinctions between "old" and "new" sources;[15] the need for accountability and, related, the use of

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7. COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY: FOURTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 73 (1973) [hereinafter CEQ 1973 Report].

8. *See, e.g.*, U.N. Conference on Environment and Development, June 3–14, 1992, *Rio Declaration on Environment and Development*, Principle 15, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992).

9. The Clean Air Act ("CAA") is an example of a technology-forcing statute, with its requirements such as "best available control technology." 42 U.S.C. § 7475 (2006).

10. *See, e.g.*, U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, Principle 16, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992).

11. *See, e.g.*, U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, Principle 4, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992).

12. *See, e.g.*, U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, Principle 17, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992).

13. *See, e.g.*, U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, Principle 20–22, U.N. Doc. A/CONF.151/5/Rev.1 (June 13, 1992).

14. The HPV Challenge Program, discussed *infra*, is an example of a voluntary program. For review of such approaches in the compliance arena, see CLIFF RECHTSCHAFFEN & DAVID MARKELL, REINVENTING ENVIRONMENTAL ENFORCEMENT AND THE STATE/FEDERAL PARTNERSHIP (2003).

15. *See, e.g.*, Mark A. Greenwood, *TSCA Reform: Building a Program that Can Work*, 39 ELR 10034, 10039–40 (Jan. 2009).

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"sunlight" to create incentives for desired behavior;[16] and, in a world of limited resources, the value of prioritizing among different environmental concerns.[17] Despite the large literatures on many of these concepts, their meaning (and appropriate scope) remains somewhat unsettled. Resolution of the questions of if and how these different concepts should be considered together in the formulation and implementation of environmental policy remains a work in progress as well.

This Article is a very modest attempt to "tee up" some of these fundamental questions about the appropriate shape and content of environmental law through review of one part of the extraordinarily broad and diverse federal legislative infrastructure in place today, notably the screening and regulatory program contained in the Toxic Substances Control Act ("TSCA").[18] Congress enacted TSCA in 1976 because of growing fears about the risks that toxic substances posed to human health and the environment.[19] The Environmental Protection Agency ("EPA") Administrator at the time, Russell Train,

16. Justice Brandeis's famous quote, "[s]unlight is said to be the best of disinfectants, electric light the most efficient policeman." *See* LOUIS D. BRANDEIS, OTHER PEOPLE'S MONEY AND HOW THE BANKERS USE IT 92 (1914).

17. *See, e.g.*, U.S. EPA, Reducing Risk; CRS Report for Congress: The Toxic Substances Control Act (TSCA): Implementation and New Challenges 10–11 (Updated July 18, 2008), http://www.policyarchive.org/handle/10207/bitstreams/19946.pdf [hereinafter CRS Report] (discussing some of the prioritization efforts under TSCA); Greenwood, *supra* note 15, at 10036–37 (discussing the need to do a better job of setting priorities under TSCA, and also highlighting the resource constraints EPA faces in implementing TSCA—noting that "OPPT, the implementer of the TSCA program, is one of the most underfunded programs in all of EPA").

18. 15 U.S.C. §§ 2601–2692 (2006). My limited task in this symposium issue is to provide some contextual background on the development of TSCA and its implementation. I completed this Article during the summer of 2009; as a result, it attempts to address some of the key developments up to that point in time. In his Article Professor Adelman offers his perspective on how TSCA should be reformed to meet contemporary needs. *See* David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH. U. J.L. & POL'Y 377 (2010).

19. A great deal of uncertainty underlies our efforts to deal with concerns from toxic substances. As the Surgeon General stated in 1980 in reviewing human health effects: "We believe that toxic chemicals are adding to the disease burden of the United States in a significant, although as yet not precisely defined, way." GLICKSMAN ET AL., *supra* note 1, at 698 (citing S. COMM. ON ENV'T AND PUB. WORKS, 96TH CONG., HEALTH EFFECTS OF TOXIC POLLUTION: A REPORT FROM THE SURGEON GENERAL iii (Comm. Print 1980)).

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characterized TSCA as "'one of the most important pieces of 'preventive medicine' legislation' ever passed by Congress."[20]

Congress intended that TSCA be implemented in tandem with other statutes covered in this symposium on New Directions in Environmental Law, such as the Clean Water Act ("CWA") and Clean Air Act ("CAA"), which deal with the release of chemicals after their creation.[21] This symposium covers only a small subset of statutes Congress has enacted to address environmental concerns stemming from our use of chemicals, as indeed is inevitable given the number of such statutes in existence.[22] Beyond the CWA and CAA, there are still other regulatory statutes, such as the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), the Resources Conservation and Recovery Act ("RCRA"), and the Oil Pollution Act of 1990, that deal with the remediation or clean-up of contaminated sites.[23] There are a host of other statutes that take different approaches to advancing environmental protection, such as reporting statutes[24] and statutes that focus on pollution prevention.[25] In enacting TSCA, Congress hoped that the statute would add to the toolbox EPA could and would use to effectively respond to the risks toxic chemicals pose to our health and to the environment; indeed, in Train's words, it would be a "major step toward an increasingly effective preventive approach toward the

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20. Press Release, U.S. EPA, Train Sees New Toxic Substances Law as "Preventive Medicine" (Oct. 21, 1976), www.epa.gov/history/topics/tsca/03.htm.

21. RCRA, like the CAA and CWA, follows a very prescriptive approach to regulation of toxic substances; in the case of RCRA, hazardous wastes. *See generally* 42 U.S.C. § 6901–6992 (2006). These statutes follow a "standard-setting" approach to regulation. MENDELOFF, *supra* note 3, at 6. TSCA's purposes have been said to include encouraging EPA to coordinate activities of the media-specific statutes. John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 724–25 (2008).

22. *See supra* note 2. Federal statutes, in turn, only make up a subset of environmental law. State statutes and municipal laws, as well as the common law, all play important roles in establishing environmental expectations and norms as well.

23. Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. §§ 9601–9675 (2006); Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901–6992; Oil and Pollution Act of 1990, 33 U.S.C. §§ 2701–2710.

24. *See, e.g.*, U.S. EPA, the Toxics Release Inventory program, http://www.epa.gov/TRI/ (last visited May 18, 2010).

25. *See, e.g.*, Pollution Prevention Act of 1990, 42 U.S.C. §§ 13101–09. For one overview of pollution prevention, see David Markell, *Pollution Prevention*, *in* ENVIRONMENTAL LAW PRACTICE GUIDE: STATE AND FEDERAL LAW § 18A (Matthew Bender, 1995).

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'environmental disease' that has been called the 'disease of the century.'"[26]

Part I of this Article provides a brief history of TSCA and reviews some of Congress's key underlying assumptions in enacting the statute. Part II reviews how things have played out in the implementation of some of the key features of TSCA. I conclude with a brief review of some of the overarching issues TSCA raises that have broader implications for environmental policy.

I. A BRIEF HISTORY OF TSCA AND A REVIEW OF KEY UNDERLYING ASSUMPTIONS

As noted above, Congress enacted TSCA in 1976. Congress's ultimate purpose in adopting TSCA was to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances."[27] A 1971 CEQ report, *Toxic Substances*, helped to spawn the effort to develop the legislation that became TSCA.[28] In this seminal early diagnosis of some of the challenges the

26. Press Release, U.S. EPA, Train Sees New Toxic Substances Law as "Preventive Medicine" (Oct. 21, 1976), http://www.epa.gov/history/topics/tsca/03.htm. In addition to raising several of the central issues of environmental policy referenced above, TSCA also raises fundamental questions about the appropriate role for the judiciary in overseeing the role of agencies. Many of the assessments of TSCA, for example, have pointed to judicial review as a deterrent to EPA action to regulate chemical substances. *See, e.g.*, Greenwood, *supra* note 15, at 10038 (noting that "[t]he argument can certainly be made that EPA's § 6 authority to impose controls on existing chemicals has been stymied by court interpretations of EPA's statutory burden, as was evidenced in the court decision on the Agency's asbestos ban," but also noting that "the courts have interpreted EPA's authority to impose testing requirements under . . . TSCA quite broadly"). And it raises issues about the proper structure of federalism, notably how responsibility should be arranged between the federal and state governments. For one collection and review of some of the literature on federalism, particularly in the environmental arena, see David Markell, *"Slack" in the Administrative State and Its Implications for Governance: The Issue of Accountability*, 84 OR. L. REV. 1 (2005).

27. S. REP. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491.

28. U.S. Council on Environmental Quality, Toxic Substances (Apr. 1971), *reprinted in* ENVIRONMENTAL AND NATURAL RESOURCES POLICY DIVISION, LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT 757 (1976) [hereinafter Toxic Substances]. *See also* Lynn L. Bergeson et al., *TSCA and the Future of Chemical Regulation*, 15 EPA ADMIN. L. REP. 1, 3 (2000); John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 723 (2008); ENV'T AND NATURAL RES. POLICY DIV., 94TH CONGRESS, LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT V, 159 (Comm. Print 1976) [hereinafter Legislative History of TSCA] (noting that the 1971 CEQ

nation faced in addressing concerns about toxic substances, the CEQ recommended TSCA's enactment based on its view that: (1) "toxic substances are entering the environment"; (2) "these substances can have severe effects"; (3) "existing legal authorities are inadequate"; and (4) "new legal authority is required."[29]

The CEQ notes that Congress envisioned that "[f]or the first time, the law [TSCA] empowers the federal government to control and even to stop production or use of chemical substances that may present an unreasonable risk of injury to health or environment."[30] How would this work in practice? In its Annual Report the year after Congress enacted TSCA, the CEQ summarizes:

> Manufacturers must give notice of plans to produce a new chemical or to market a significant new use for an old chemical. Producers may also be required to test selected chemicals or to report production quantities, uses, physical, chemical, and biological properties, and other information necessary for hazard assessment. In addition, the law requires recordkeeping and disclosure of significant health effects of dangerous chemicals.
>
> The new public policy expressed in the law is that manufacturers of chemicals have an obligation to test product safety and that government has the authority to regulate potentially dangerous chemicals and to take immediate action on those that are an imminent hazard.[31]

In the rest of this Part, I review two of the key underlying assumptions Congress brought to the consideration and enactment of TSCA, specifically the emerging concern about risks posed by toxic substances and the need for legal reinforcements to fill in extant gaps in legal authority so that, as a nation, we could address these risks effectively.

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report *Toxic Substances* was "the impetus for the original Toxic Substances Control Act legislation").

29. Toxic Substances, *supra* note 28, at 759–60.

30. COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY: THE EIGHTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 5 (1977) [hereinafter CEQ 1977 Report].

31. CEQ 1977 Report, *supra* note 30, at 5.

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A. Emerging Concerns about Risks Posed by Toxic Substances

During the 1970s, policy makers and others increasingly paid attention to the risks that toxic substances posed to human health and the environment. Some of the CEQ reports during this era demonstrate this. The CEQ 1971 report *White Paper*, referenced above, observed that significant numbers of new chemicals enter commercial use annually, that use of these chemicals is growing rapidly, and that, while "many of these substances are not toxic, the sheer number of them, their increasing diversity and use, and the environmental problems already encountered from some indicate the existence of a problem."[32] The CEQ, in the opening chapter of its 1975 Annual Report, suggests that "[a] disconcerting, growing body of evidence indicates that subtle, manmade hazards are supplanting famine and infectious disease as significant determinants of life expectancy in 20th century developed nations."[33] The CEQ 1977 Annual Report notes that the "importance of dealing with toxic substances comprehensively and systematically has been highlighted in recent years by growing recognition of the environmental—and, in particular, chemical—contributions to cancer."[34] The CEQ 1978 Annual Report similarly identifies a "[h]eightened awareness of toxic chemical problems"[35] and refers to the "urgency of the toxics problem."[36]

The legislative history of TSCA is to the same effect. It reflects that Congress enacted TSCA because of its growing concern about the risks that chemicals used in commerce posed to public health and the environment. For example, during a March 26, 1976, Senate debate about TSCA, Senator Pearson, one of the bill's sponsors,[37] stated that:

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32. Toxic Substances, *supra* note 28, at 759.

33. COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY: SIXTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 12 (1975) [hereinafter CEQ 1975 Report].

34. CEQ 1977 Report, *supra* note 30, at 4.

35. COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY: NINTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 183 (1978) [hereinafter 1978 CEQ Report].

36. *Id.* at 184.

37. Legislative History of TSCA, *supra* note 28, at 218.

> We can no longer operate under the assumption that what we do not know about a chemical substance cannot hurt us. Tragic results associated with too many toxic substances have taught us that lesson all too well. Chemicals, not people, must be put to the test.[38]

During the same debate, Senator Tunney, who was also a leading participant in the debate preceding TSCA's enactment,[39] noted that:

> [T]he National Cancer Institute has estimated that 60 to 90 percent of the cancers occurring in this country are a result of environmental contaminants. Many doctors and scientists now believe that cancer, which has been projected to kill as many Americans in 1975 as all the battle deaths in Vietnam, Korea, and the Second World War combined, appears particularly susceptible to a preventive approach through control of toxic substances.[40]

Congress was not, of course, operating in a vacuum as it expressed concern about the risk toxic chemicals posed. Popular media programs at the time highlighted concerns with toxic chemicals, and this media attention was not lost on members of Congress.[41] For example, Senator Tunney referenced a "60-minute CBS television special outlin[ing] the impact of environmental cancer on society" and "a cover story in Newsweek demonstrating the

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38. *Id.* at 215. *See generally* 15 U.S.C. § 2601(a)-(b) (2006).

39. Another Senator recognized Senator Tunney's involvement:

> I also compliment the Senator from California (Mr. Tunney) who has been working on this legislation for all these many years, who conducted long hearings, frequently doing it in a solitary operation, in which he was able to provide for a continued interest in the committee, and making sure that we did something affirmatively to control the detrimental effect of toxic chemicals in American society.

Legislative History of TSCA, *supra* note 28, at 217.

40. *Id.* at 208.

41. *See, e.g.*, M.E. Kraft, *Influence of American NGOs on Environmental Decisions and Policies: Evolution over Three Decades*, *in* NAT'L RESEARCH COUNCIL, THE ROLE OF ENVIRONMENTAL NGOS: RUSSIAN CHALLENGES AMERICAN LESSONS: PROCEEDINGS OF A WORKSHOP 141, 144 (2001) (noting that the "rising level of public concern about environmental problems, particularly threats to public health from pollution and toxic chemicals" contributed to "environmental and health groups in their quest for policy action").

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impact of environmental cancers on our society."[42] Much of the media attention focused on health threats from particular chemicals. Senator Tunney's comment during the TSCA debates, quoted below, signals Congress's awareness of the then-much-publicized dangers that several toxic chemicals pose:

> The need for this legislation has become increasingly clear. In the last 3 years, for example, I have chaired hearings before the Senate Committee on Commerce which have documented time and again the lethal dangers associated with chemicals like vinyl chloride, bischloromethyl ether—BCME—mercury and other heavy metals, arsenic, asbestos, and a multitude of others. In fact, over the 15 days of hearing conducted by the Committee on Commerce on this legislation over the past 5 years, in excess of 100 chemicals have been mentioned as candidates for regulation under this legislation.[43]

In a practical guide to TSCA published in the mid-1990s, three private attorneys summarize nicely the human health concerns that led Congress to enact TSCA:

> When enacting TSCA, Congress reacted to concerns about the potential adverse health and environmental effects of certain chemical substances that were widely used in commerce. The then-recent kepone contamination of the James River, as well as discoveries about dangers posed by polychlorinated biphenyls (PCBs) and methyl chloride, prompted congressional concern that many existing chemicals posed significant health and environmental risks, and that no legal mechanism existed to impede the introduction of the next generation of equally dangerous chemicals.[44]

Ed Brooks, of EPA's Chemical Control Division, suggests that three concerns "animated the drive for an authority to control existing

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42. Legislative History of TSCA, *supra* note 28, at 210.
43. *Id.* at 207–08.
44. Carolyne R. Hathaway, David J. Hayes & William K. Rawson, *A Practitioner's Guide to the Toxic Substances Control Act: Part I*, 24 ENVTL. L. REP. 10207, 10208 (1994) (citing S. REP. No. 94-698, at 5–6 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491, 4495).

chemicals:" (1) "[t]he cancer mortality rate had been accelerating since before World War II;" (2) "[i]ndustrial chemicals were believed to be a major cause of the increase;" and (3) "[a]uthorities to control many problems posed by industrial chemicals were either non-existent or inadequate."[45]

The basic point is that in the 1970s Congress became increasingly concerned about risks posed by toxic substances and took a series of legislative actions in an effort to respond to these risks. Congress did not believe that the challenges posed by toxic substances would be addressed easily or that TSCA alone would provide adequate tools for an effective response. Congress also acknowledged that the task was beyond EPA's capacity acting independently. For example, the 1977 CEQ Annual Report notes that the task of reducing risks from toxic substances "will not be accomplished easily. It will require coordination of research and regulation by many agencies under a dozen or more major federal laws, a program to fill information gaps and provide easy access to the data that exist, adequate funding, and intensive effort by trained people."[46]

The 1978 CEQ Report notes that "many other laws . . . complement TSCA authority. In all, at least 20 regulatory statutes apply to toxic substances control."[47] The CEQ notes that, for instance, "[t]he Clean Air Act Amendments of 1977 require EPA to consider regulations for several specific pollutants suspected or known to be toxic."[48] And, "[l]ikewise, the 1977 amendments to the Federal Water Pollution Control Act require best available technology by 1984 for . . . classes of toxic chemicals and provide for cleanup action [concerning] other potentially toxic chemicals by

45. Ed Brooks, *Evolution of Risk Management of Existing Chemicals under TSCA*, *in* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICE OF POLLUTION CONTROL AND TOXICS, TSCA AT TWENTY (1996), *available at* http://www.epa.gov/oppt/cie/archive/issue04j.htm.

46. CEQ 1977 Report, *supra* note 30, at 3.

47. 1978 CEQ Report, *supra* note 35, at 180–82. The 1979 CEQ Report provides that, as of that time, there were more than two dozen federal laws controlling toxic substances in "various forms and places: from pesticides to foods, from the workplace to the nation's air and water." COUNCIL ON ENVIRONMENTAL QUALITY, TENTH ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 174 (1979).

48. 1978 CEQ Report, *supra* note 35, at 183.

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1987."[49] And, third, "[s]trong emphasis on toxics and human health concerns was written into [RCRA]" in 1976.[50] Congress's relatively contemporaneous strengthening amendments to other statutes' treatment of toxics shows that Congress intended for the scheme it established under TSCA to be implemented in tandem with greater attention to toxics and their release under these other statutory schemes as well.[51] TSCA, in other words, was intended to be part of this more comprehensive fix. In the next section, I turn to the nature of the regulatory gaps Congress perceived in the effort to address risks from toxic substances and Congress's actions to fill them.

B. Regulatory Gaps

Congress's view in adopting TSCA was that existing legislation had significant shortcomings that TSCA would help to cure. I focus on three of the shortcomings in this section.[52] First, existing legislation tended to have an "after-the-fact" focus. The CEQ's 1971 report, *Toxic Substances*, highlights this concern, noting that existing legislation "generally deal[s] with a problem only *after* it is manifest," and asserts that "[w]e should no longer be limited to repairing the damage after it has been done."[53] Then-EPA Deputy Administrator John Quarles made the same point in 1975 testimony before Congress on the importance of enacting TSCA: "While some authority exists to control the production of certain categories of toxic substances, such as pesticides, drugs, and food additives, most existing Federal authorities are designed to prevent harmful exposure only after the substances have been introduced into production."[54]

After describing health concerns posed by chemicals, the Senate Committee on Commerce provided in its Report Number 94-698:

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49. *Id.*
50. *Id.*
51. *Id.*
52. Related to the three reasons discussed in the text, Congress also thought there might be a need for additional regulatory authority beyond that contained in the extant statutes to address the risks from toxic substances.
53. Toxic Substances, *supra* note 28, at 783, 760.
54. Press Release, U.S. EPA, Quarles Testifies on the Need for Toxic Substances Act (July 10, 1975), *available at* http://www.epa.gov/history/topics/tsca/01.htm.

> In order to protect against these dangers, the proposed Toxic Substances Control Act would close a number of major regulatory gaps, for while certain statutes, including the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, may be used to protect health and the environment from chemical substances, none of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins.[55]

Similarly, in a 1976 Senate debate, a Senator recognized that "[a]t present, the only remedy available under such Federal statutes as the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act, is to impose restrictions on toxic substances after they have been first manufactured."[56]

An important congressional objective in TSCA was to complement the after-the-fact character of the primary regulatory statutes by focusing attention on toxics earlier in their development and use. In enacting TSCA Congress created a regulatory focus that did not yet exist—regulation of chemicals before they were manufactured.[57] As the 1978 CEQ Report notes: "The intent of [TSCA] is that the harmful effects of chemicals produced in the future shall be investigated and if possible discovered in the laboratory rather than turning up in injuries to human beings or the environment after full-scale production has begun."[58] Some commentators have referred to this goal as one of "creating 'upstream' protections against the introduction of new chemical

55. Legislative History of TSCA, *supra* note 28, at 161 (emphasis added).

56. *Id.* at 215 (emphasis added). One of the key features of early federal pollution control legislation was Congress's reluctance to "go up the pipe" and regulate industrial processes. Instead, Congress focused on discharges at the end of the pipe. Robert Glicksman & Christopher H. Schroeder, *EPA and the Courts: Twenty Years of Law and Politics*, 54 LAW & COMTEMP. PROBS. 249, 252 (1991).

57. 1978 CEQ Report, *supra* note 35, at 196.

58. *Id*.

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substances that could create serious health and environmental risks."[59]

Second, existing legislation tended to be media-focused. It did not take a holistic or comprehensive approach to pollution control. On this point CEQ declares that "[i]t is clear that current laws are inadequate to control the actual and potential dangers of toxic substances comprehensively or systematically."[60] It suggests that the media-based pollution laws, primarily air and water, did not adequately account for "individuals' total exposure to chemicals or for chemical pollution that shifts among media . . . . By regulating chemicals *per se*, TSCA was supposed to avoid these gaps or to fill them when they appear, as well as to regulate more efficiently and effectively."[61] As the CEQ put it in *Toxic Substances*, these "media-oriented authorities" had difficulties considering the "*total* exposure of an individual to a given substance" because of the possibility of human exposure in a variety of ways:[62]

> Most toxic substances are not exclusively air or water pollutants but can be found in varying quantities in air, water, soil, food, and industrial and consumer products. The multiplicity of ways by which man can be exposed to these substances makes it difficult for the media-oriented authorities to consider the *total* exposure of an individual to a given substance, a consideration necessary for the establishment of adequate environmental standards.[63]

Similarly, the July 14, 1976, House of Representatives Committee on Interstate and Foreign Commerce Report Number 94-1341 concludes that, based on *Toxic Substances*, "present authorities for protecting against hazardous chemicals are fragmented and inadequate."[64]

The felt need for additional information on toxic chemicals, while related to each of these two motivations for TSCA, was on its own a

59. Hathaway et al., *supra* note 44, Part I at 10208.
60. Toxic Substances, *supra* note 28, at 783.
61. Applegate, *supra* note 21, at 724, 726.
62. Toxic Substances, *supra* note 28, at 760.
63. *Id.*
64. Legislative History of TSCA, *supra* note 28, at 412.

strong impetus for Congress's decision to enact TSCA and deserves emphasis as well. As some of the statements quoted above reflect, Congress believed there was a significant need for additional information about toxic substances—about their toxicity, the possibility of exposure, and the risk they posed. The July 14, 1976, House of Representatives Committee on Interstate and Foreign Commerce Report Number 94-1341, relying on *Toxic Substances*, noted that additional "authority is needed to require testing of chemicals to determine their health and environmental effects . . . and to collect information on chemicals where necessary to protect the public health and using such information."[65] In its 1975 Annual Report, the CEQ noted that "[w]e know very little about the possible health consequences of these new [chemical] compounds."[66] EPA's then-Administrator, Russell Train, highlighted the information gaps as follows:

> [W]e know so little—so abysmally little—about these chemicals. We know little about their health effects . . . . We know little about how many humans are exposed, and how and to what degree. We do not even know precisely how many—much less precisely which—new chemical compounds are made and marketed every year.[67]

In its 1978 Annual Report, CEQ summarized TSCA's role in helping to develop new information about the risks toxic chemicals posed: "The [TSCA] gave the government a new mandate and broad new authority to gather information on the potential of chemicals to damage human health and the environment . . . . The result is more awareness on the part of government, industry, scientists, and the public of the problems of toxic chemicals."[68]

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65. *Id.* The Committee also noted the importance of regulatory authority to "impose use and distribution restrictions on chemicals where necessary to protect the public health and environment." *Id.*

66. CEQ 1975 Report, *supra* note 33, at 12.

67. Press Release, U.S. EPA, Train Sees New Toxic Substances Law as "Preventive Medicine" (Oct. 21, 1976), http://www.epa.gov/history/topics/tsca/03.htm.

68. 1978 CEQ Report, *supra* note 35, at 178.

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In the year after TSCA was enacted, the CEQ, in its 1977 Annual Report, succinctly summarized some of Congress's concerns and TSCA's anticipated role in addressing them:

> Until the [TSCA] was passed, there was simply no way to assess or control the development, production, and marketing of the flood of manmade chemicals. Many of these complex chemicals do a great deal of good and little harm, but some are among the most toxic and persistent substances ever introduced into our environment.
>
> Unhappily, the toxicity and persistence of chemicals have often been discovered *after* their widespread use and *after* they have become important to jobs, commerce, or agriculture. . . .
>
> [T]he major accomplishment of the new law is that it gives the government broad authority to control the production, distribution, and use of *all* potentially hazardous chemicals. It provides for testing of suspect chemicals before they become widely used and economically important. It emphasizes collection of information and freedom of access to research data so that the scientific community can note and assess potential problems.[69]

To be sure, other concerns were on Congress's radar screen as well, such as the need for additional regulatory authority to control manufacture and use of toxics where needed and the need to proceed in a "reasonable and prudent manner," and in a way that did not impede technological innovation.[70] Related to this last point, EPA

69. CEQ 1977 Report, *supra* note 30, at 1–3. The CEQ report pointed to the risks associated with PCBs as one example. *Id.* at 2. *See also* COUNCIL ON ENVIRONMENTAL QUALITY, ENVIRONMENTAL QUALITY: THE THIRD ANNUAL REPORT OF THE COUNCIL ON ENVIRONMENTAL QUALITY 2–3 (1972) ("One of the obstacles to adequate data collection on toxic substances is the absence of any Federal program for systematically regulating and collecting data. This gap would be filled by passage of [TSCA].").

70. 15 U.S.C. § 2601(b)(2), (3), and (c) (2006). The Committee on Interstate and Foreign Commerce noted in Report Number 94-1341 that "[t]he Committee has limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the Committee does not make." Legislative History of TSCA, *supra* note 28, at 423. Thus, "unreasonable risk" is used as the standard. *Id.* at 748.

argued that TSCA's costs to industry would not be significant; indeed, John Quarles testified that TSCA's premanufacture notification scheme should be "economically preferable to industry" because its role in identifying dangers early on would help to "avoid the serious disruption and losses attendant to remedial action after the fact" and that costs to industry would be "relatively modest" compared to the benefits.[71]

Further, to venture briefly into a slightly more in-depth review of Congress's understandings and objectives in enacting TSCA, Congress brought the then-extant understanding of toxicology to its consideration of TSCA. As the CRS points out, while toxicology "is an ancient area of study," its "modern form" "emerged . . . largely during the 1960s and 1970s. The first textbook of toxicology was published in 1972."[72] Reflecting then-contemporary perspectives, TSCA focused on individual chemicals and concerns about acute effects, birth defects, and cancer.[73] As the CRS notes, understandings of toxicology (and techniques for evaluating hazard and exposure) have evolved considerably during the past thirty years.[74]

In sum, while Congress's enactment of TSCA was informed by a variety of goals and then-extant understandings of hazard and risk assessment, from a big picture perspective, three of Congress's key assumptions in adopting TSCA were that we needed to: (1) embrace a more proactive or preventative approach to understanding toxics and limiting their risks; (2) approach risks from toxics in a holistic rather than fragmented way; and (3) develop a great deal of information in order to increase understanding about the toxicity of toxics and the risks they posed.

A final observation in this brief introduction to the thinking at the time Congress enacted TSCA is that proponents did not believe hoped-for benefits from enactment would be easy to achieve, as the CEQ candidly acknowledged:

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71. Press Release, U.S. EPA, Quarles Testifies on the Need for Toxic Substances Act (July 10, 1975), http://www.epa.gov/history/topics/tsca/01.htm.

72. CRS, *supra* note 17, at 24.

73. *Id.*

74. *Id.*

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> But bringing toxic substances under control is more easily said than done. The number of chemical substances and the size of the chemical industry suggest the magnitude of the task. In November 1977, the registry of chemicals maintained by the American Chemical Society listed 4,039,907 distinct chemical compounds—and the registry includes only chemicals reported in the literature since 1965. The list has been growing at a rate of 6,000 per week. The number of chemicals currently in commercial production in the United States may be as high as 70,000; 50 are produced in quantities greater than 1.3 billion pounds per year. One hundred and fifteen thousand establishments are involved in the production and distribution of chemicals, and the business is worth $113 billion per year, about 7 percent of the nation's GNP.
>
> These numbers suggest two points. One is the astonishing dependence of modern life on chemicals that are synthesized or isolated from natural products. A second is the staggering task that faces industry and government in regulating the production and distribution of so many different entities.[75]

With this overview of some of Congress's key assumptions and objectives in enacting TSCA, I turn to a brief summary of some of the statute's important provisions.

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75. 1978 CEQ Report, *supra* note 35, at 178.

II. A BRIEF OVERVIEW OF KEY FEATURES OF TSCA AND ITS IMPLEMENTATION[76]

In Part II, I summarize four key features of TSCA and developments concerning each over the past thirty-plus years. As with the preceding Part, my purpose is to highlight a handful of key features rather than provide a comprehensive review.[77] I begin by reviewing TSCA's jurisdictional boundaries or scope. I then turn to some of the screening-related tools TSCA provides. Third, I discuss treatment of "new" chemical substances. Finally, I summarize some of the regulatory powers Congress assigned to EPA in TSCA.

A. TSCA's Jurisdictional Scope

TSCA has a potentially enormously ("overwhelmingly") broad jurisdictional reach.[78] This is because it covers a wide variety of activities involving "chemical substance[s]," including the manufactur[ing], process[ing], distribut[ing] in commerce, us[ing], or dispos[ing] of" such substances.[79] Congress further defines "chemical substances"[80] expansively as "[a]ny organic or inorganic substance of a particular molecular identity, including—(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined

76. Many sources provide very helpful overviews of how TSCA works. *See, e.g.*, CRS Report, *supra* note 17; LYNN L. BERGESON, TSCA: TOXIC SUBSTANCES CONTROL ACT (2000); a three-part practitioner's guide to TSCA, Hathaway et al., *supra* note 44, Parts I–III at 10207, 10285, 10357; and a number of the Government Accountability Office reports, such as JOHN B. STEPHENSON, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-217R, CHEMICAL REGULATION: APPROACHES IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION (2005) [hereinafter GAO November 2005]. The reader should refer to these and other more detailed discussions of TSCA for more in-depth and more complete coverage. The purpose of this section is simply to provide an overview of some of the more significant features of TSCA rather than a comprehensive picture of how the statute is structured and operates.

77. For example, I do not spend much time on the issue of transparency, a topic that has received considerable attention. *See, e.g.*, Noah Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817 (2009); Applegate, *supra* note 21.

78. Hathaway et al., *supra* note 44, Part I at 10209 (noting that "[t]he scope of TSCA is extraordinarily broad").

79. BERGESON, *supra* note 76, at 6–7 (2000); 40 C.F.R. § 710.3 (2009).

80. 15 USC § 2601(b) (2006).

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radical."[81] As EPA puts it, "TSCA defines 'chemical substance' broadly and in terms which cover microorganisms as well as traditional chemicals."[82]

There were approximately 62,000 chemicals in commerce and covered by TSCA as of the late 1970s, when EPA began reviewing chemicals under TSCA.[83] Congress anticipated that TSCA would apply to "existing" chemical substances and to "new" chemical substances and that EPA would maintain an inventory that would include both.[84] EPA has added more than 21,000 new chemicals to the inventory since the 1970s,[85] and it currently includes over 84,000 chemicals.[86] One of the (many) outstanding issues that has not been fully resolved during implementation of TSCA over the past thirty-plus years involves how EPA should prioritize among chemical substances in conducting its reviews.[87] Developing a workable prioritization scheme and assuring adequate resources to administer it are two of the issues TSCA's extraordinarily broad jurisdictional parameters raise in the context of possible reform.[88]

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81. *Id.* § 2602(2)(A); *see also* 40 C.F.R. § 720.3(e). TSCA specifically exempts some materials from the definition of chemical substances, such as pesticides, tobacco, foods, drugs, and cosmetics. 15 U.S.C. § 2602(2)(B) (2006).

82. Final Regulations under Toxic Substances Control Act, 62 Fed. Reg. 17,909, 17,911 (Apr. 11, 1997) (codified at 40 C.F.R. pts. 700, 720, 721, 723, 725); CRS Report, *supra* note 17, at 2 (describing the scope of TSCA as "very broad.").

83. U.S. EPA, What is the TSCA Chemical Substance Inventory?, http://www.epa.gov/opptintr/newchems/pubs/invntory.htm (last visited May 18, 2010). While EPA reports the 62,000 figure, some sources offer slightly different estimates. *See, e.g.*, CRS Report, *supra* note 17, at 3. As the CRS points out, the "potential chemical universe . . . has been described as 'unimaginably immense'." CRS Report, *supra* note 17, at 3 n.4.

84. Toxic Substances Control Act § 8(b); 15 U.S.C. § 2607(b)(1) (2006).

85. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-428T, CHEMICAL REGULATION: OPTIONS FOR ENHANCING THE EFFECTIVENESS OF THE TOXIC SUBSTANCES CONTROL ACT 3 (2009) [hereinafter GAO February 2009].

86. U.S. EPA, Chemical Assessment and Management Program (ChAMP), http://www.epa.gov/champ/pubs/basic.html (last visited May 18, 2010). EPA is currently developing a "TSCA Inventory Reset" in an effort to update the Inventory to "more accurately reflect chemicals" that are now in commerce. *Id.*

87. *See, e.g.*, Mark Greenwood, *supra* note 15, at 10036–37.

88. *Id.* at 10036; Applegate, *supra* note 21, at 763. Greenwood in particular highlights TSCA's resource shortfalls and the need to match resources to functions in his January 2009 article. Greenwood, *supra* note 15, at 10036. Another issue involves whether to extend TSCA jurisdiction to newer and emerging materials, such as GMOs and nanomaterials. *See, e.g.*, CRS Report, *supra* note 17.

B. Testing[89]

One of Congress's major objectives in TSCA was to increase the amount of information available about chemicals and the risks they may pose.[90] As a result, Congress included several provisions that provide for testing of chemical substances in different circumstances.[91] One provision that has received considerable attention, TSCA § 4(a), compels EPA to require testing of chemical substances in certain situations in order to assess their potentially harmful effects on health and the environment.[92] First, EPA must require such testing if it finds that: "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance . . . may present an unreasonable risk of injury to health or the environment";[93] there currently are "insufficient data or experience" to be able to reasonably determine or predict the effect of such substance on health or the environment; and testing is "necessary to develop such data."[94] Alternatively, EPA must require testing if it finds that: "a chemical substance . . . will be produced in substantial quantities, and it . . . may . . . enter the environment in substantial quantities or there . . . may be significant human exposure to such substance"; there are "insufficient data or experience" to be able to reasonably determine or predict the effect of such substance on health or the environment; and testing is necessary to develop such data.[95]

If EPA makes either of the sets of findings just described, EPA "shall by rule" require testing on the substance that is relevant to

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89. The GAO has suggested that six major sections of TSCA (§§ 4, 5, 6, 8, 9, 14) establish the parameters for the statute's role in addressing risks from chemicals in commerce. GAO June 2005, *supra* note 1, at 7.

90. *See* 15 U.S.C. § 2601(b)(1) (2006).

91. David Roe discusses the "apparently omnibus testing authority" in TSCA. David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 ECOLOGY L.Q. 623, 627 (2002). The testing framework in TSCA contains several steps and is quite complex. My objective in the text is to summarize some of the basic issues under § 4. See Hathaway et al., *supra* note 44, and BERGESON, *supra* note 76, among others, for more in-depth treatment. For discussion of section 8 requirements, including the Preliminary Assessment Information Reporting ("PAIR") requirements, see CRS Report, *supra* note 17, at 12.

92. Toxic Substances Control Act § 4(a); 15 U.S.C. § 2603(a) (2006).

93. 15 U.S.C. § 2603(a)(1)(A)(i) (2006).

94. *Id.* § 2603(a)(1)(A)(ii)-(iii).

95. *Id.* § 2603(a)(1)(B)(i),(A)(ii)–(iii).

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whether the substance "does or does not present an unreasonable risk of injury to health or the environment."[96] Alternatively, EPA has developed a process in which it may enter into an Enforceable Consent Agreement ("ECA") to have a party conduct the necessary testing.[97] In most instances, EPA directs "manufacturers" to conduct the necessary testing.[98]

Once EPA decides testing is appropriate, the Agency has "broad discretion" to require testing that the Agency believes is needed to evaluate the possible risks the chemical substances pose to human health or the environment.[99] EPA guidelines include testing for "chemical fate," environmental effects, and health effects.[100] EPA is to consider both the toxicity of a chemical substance and the potential for exposure in making risk judgments.[101]

The GAO's current take on this regime, as expressed in June 2005 testimony to Congress, is that "[f]acing difficulties obtaining such information [concerning the risk existing chemicals pose]. . . , EPA has made little progress in reviewing existing chemicals since EPA began reviewing chemicals under TSCA in 1979."[102] The GAO indicated that EPA officials stated that, because of the burdens involved, finalizing a test rule could take two to ten years and would require considerable financial resources.[103] The GAO concluded that

96. *Id.* § 2603(a).

97. U.S. EPA, Managing Existing Chemicals, http://www.epa.gov/oppt/ar/2007-2009/managing/index.htm (last visited May 18, 2010); *see also* BERGESON, *supra* note 76, at 12. National Res. Def. Council v. EPA, 595 F. Supp. 1255 (S.D.N.Y. 1984), held that such voluntary programs did not provide for public comment and did not always have enforcement mechanisms. EPA responded with a rulemaking intended to address the court's concerns. For a review of this case and subsequent EPA efforts, see GAO June 2005, *supra* note 1, at 19–24. EPA continues to use Enforceable Consent Agreements today. U.S. EPA, Managing Existing Chemicals, http://www.epa.gov/oppt/ar/2007-2009/managing/index.htm (last visited May 18, 2010).

98. 15 U.S.C. § 2603(b)(3)(A) (2006); 40 C.F.R. § 790.42; BERGESON, *supra* note 76, at 11. Because of the enormous number of chemical substances, EPA relies upon the Interagency Testing Committee ("ITC") and other sources of expertise for recommendations concerning substances that warrant testing. *See* 15 U.S.C. § 2603(e)(1)(A) (2006); BERGESON, *supra* note 76, at 11–12; GAO June 2005, *supra* note 1, at 21, 26.

99. BERGESON, *supra* note 76, at 14.

100. *See* 40 C.F.R. §§ 796–798 (2009); BERGESON, *supra* note 76, at 14–15.

101. 15 U.S.C. § 2603(e) (2006).

102. GAO June 2005, *supra* note 1, at 19.

103. *Id.* at 26.

"TSCA's authority to require testing is difficult to use in support of the agency's review process" and, as a result, "[a]ccording to EPA officials, EPA's toxicity and exposure data on existing chemicals is often incomplete."[104] The GAO stated that: "[g]iven the difficulties involved in requiring testing, EPA officials do not believe that TSCA's authorities under section 4 provide an effective means for testing a large number of chemicals."[105]

While the CRS's 2008 Report for Congress indicates that, in an apparent change of position, the then-head of EPA's toxic substances office, Assistant Administrator James Gulliford, testified to Congress in 2006 that EPA authorities were adequate for it to ensure "effective, timely, chemical management decisions,"[106] in its 2009 testimony to Congress, the GAO echoes and reinforces its previous findings that EPA's testing authority is flawed. It reports that EPA does not routinely assess the risks of the roughly 80,000 industrial chemicals in use.[107] The GAO reports that EPA has issued rules or entered into agreements requiring testing "for only about 200 chemicals" because of the time and resources involved.[108] For the same reasons, EPA has performed "internal reviews" of "an estimated 2 percent of the chemicals that were in the TSCA inventory when EPA began chemical reviews in 1979."[109] The GAO concludes that the TSCA regime "places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe."[110] The GAO indicates that EPA advises that the Agency could review "substantially more chemicals in less time if [it] had the authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial

104. *Id.* at 19.
105. *Id.* at 26.
106. CRS Report, *supra* note 17, at 14–15.
107. GAO February 2009, *supra* note 85, at 5–6; GAO June 2005, *supra* note 1, at 4, 26. For a helpful summary of EPA's treatment of testing under the panoply of testing authorities, see CRS Report, *supra* note 17, at 11–14.
108. GAO February 2009, *supra* note 85, at 5; *see also* GAO June 2005, *supra* note 1, at 4, 18. The CRS reports that EPA has issued test rules under Section 4 for approximately 254 existing chemicals: "60 chemicals using [ECA's], 24 chemicals under negotiated testing agreements, and about 170 chemicals covered by final test rules." CRS Report, *supra* note 17, at 13.
109. GAO June 2005, *supra* note 1, at 18.
110. GAO February 2009, *supra* note 85, at 5.

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production volume, assuming EPA had first determined that these data cannot be obtained without testing."[111] The GAO notes that it has "long held a similar view," and observes that it "continue[s] to believe that providing EPA with more authority to obtain test data from companies would enhance the effectiveness of TSCA."[112] Others have echoed the GAO's concerns.[113]

Implementation of the statutory testing regimen is not the entire story with respect to TSCA testing, however. Non-governmental organization ("NGO") studies in the late 1990s, twenty years after TSCA was enacted, found that toxicity data were not publicly available for most of the roughly 2,800 high productive volume ("HPV") chemicals manufactured or imported in the United States.[114] A former Senior Environmental Defense lawyer, David Roe, characterized the findings of this work in powerful terms:

> In 1997–98, however, the assumption that we have any real grasp of which chemicals are toxic was definitively shattered. . . . The studies' [conducted by Environmental Defense, EPA, and the Chemical Manufacturers Association] implications were acutely unsettling: in a regulatory system that depends on identifying target chemicals before regulating them, less than 10% of the largest potential targets had been properly scanned for toxic effects.[115]

Following these studies, in 1998 EPA collaborated with chemical companies and environmental groups and established the HPV Challenge Program, in which the agency seeks to have manufacturers voluntarily develop basic toxicity data for these chemicals pursuant

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111. *Id.* at 6; GAO June 2005, *supra* note 1, at 26–27.

112. GAO February 2009, *supra* note 85, at 6.

113. *See, e.g.*, Applegate, *supra* note 21, at 734–36; RICHARD A. DENISON, ENVIRONMENTAL DEFENSE, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE (July 2007), http://www.edf.org/documents/6653_HighHopesLowMarks.pdf.

114. HPV's were defined to be those produced at one million pounds or more per year. GAO November 2005, *supra* note 76, at 11; GAO June 2005, *supra* note 1, at 4; BERGESON, *supra* note 76, at 16. An environmental group, Environmental Defense (then EDF) undertook one study, while an industry trade group, the American Chemistry Council (then the Chemical Manufacturers Association) undertook another. Roe, *supra* note 91, at 627–28.

115. Roe, *supra* note 91, at 627–28.

to a Screening Information Data Set ("SIDS") program that the OECD had developed.[116]

The GAO reports that "[s]ince 1998, EPA has focused its efforts on obtaining information on existing chemicals through voluntary programs, such as the HPV Challenge Program."[117] Environmental Defense, one of the key environmental NGOs involved in the initiative, notes that the HPV Challenge Program "represents the only systematic effort by the [EPA] to foster the development of and public access to basic hazard data on a relatively large number of chemicals in commerce."[118] Environmental Defense elaborates as follows: "The program is developing and making public basic hazard information for more chemicals in much less time than any prior effort, and it represents the first significant step taken in the US toward closing the gap between what we know and what we should know about widely used chemicals."[119]

The GAO paints a somewhat mixed picture of the HPV program. On the one hand, it indicates that some of the early results are promising. Companies have "sponsored, or agreed to provide data for," a significant majority of HPV chemicals. On the other hand, in 2009 testimony, the GAO indicated that "there are currently over 200 high-production-volume chemicals for which chemical companies have not voluntarily agreed to provide the minimal test data that EPA believes are needed to initially assess their risks."[120] Further, the GAO asks whether the data that are provided will prove sufficient for EPA to determine whether chemicals being reviewed present an unreasonable risk.[121]

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116. BERGESON, *supra* note 76, at 15–16; Roe, *supra* note 91, at 629 (describing the HPV Challenge Program as a "unique quasi-voluntary initiative"). The OECD is the Organization for Economic Cooperation and Development. GAO November 2005, *supra* note 76, at 10; GAO June 2005, *supra* note 1, at 13. The court in *Physicians Comm. for Responsible Med. v. Leavitt*, 331 F. Supp. 2d 204 (S.D.N.Y.2004), considered the legality of the HPV program and upheld it. The Second Circuit affirmed this holding in *Physicians Comm. for Responsible Med. v. Johnson*, 436 F.3d 326 (2d Cir. 2006).

117. GAO June 2005, *supra* note 1, at 18.

118. RICHARD B. DENISON, ENVIRONMENTAL DEFENSE, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE 3 (July 2007), http://www.edf.org/documents/6653_HighHopesLowMarks.pdf.

119. *Id.*

120. GAO February 2009, *supra* note 85, at 5.

121. GAO June 2005, *supra* note 1, at 41.

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While some industry and environmental groups collaborated with EPA and each other to develop the Challenge, their perspectives on it differ significantly. For example, Environmental Defense, in its 2007 report on the HPV program entitled *High Hopes, Low Marks*,[122] concludes that the Challenge is "limping as it approaches the finish line, with considerable amounts of the data [it promised to deliver] yet to be made available."[123] The American Chemistry Council disagreed with the Environmental Defense assessment, highlighting the work companies had done in participating in the Challenge and concluding that "[t]he HPV program has made more health and environmental data publicly available faster than any other regulatory or voluntary initiative before it."[124]

EPA initiatives in this arena continue to evolve. EPA reports, for example, that it "broadened its efforts to ensure the safety of existing chemicals with the creation of the Chemical Assessment and Management Program (ChAMP)."[125] EPA used ChAMP to "build on" the HPV Challenge Program to complete screening and other actions on "high- and moderate-production (MPV) chemicals [produced at quantities greater than or equal to 25,000 pounds per year]."[126] Mark Greenwood describes ChAMP as "an ambitious effort . . . to assess and address the hazards and risk of over 6,000 chemicals

122. RICHARD A. DENISON, ENVIRONMENTAL DEFENSE, HIGH HOPES, LOW MARKS: A FINAL REPORT CARD ON THE HIGH PRODUCTION VOLUME CHEMICAL CHALLENGE (July 2007), http://www.edf.org/documents/6653_HighHopesLowMarks.pdf.

123. *Id.* at 31. Environmental Defense graded the Challenge based on a series of metrics. Environmental Defense gave the Challenge good marks on some metrics and not-so-good grades on others. *Id.* at 11–21.

124. AMERICAN CHEMISTRY COUNCIL, HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM: A LANDMARK PROGRAM MAKING MORE HEALTH AND ENVIRONMENTAL DATA PUBLICLY AVAILABLE THAN EVER BEFORE (2007), http://www.americanchemistry.com/s_acc/bin.asp?CID=181&DID=6668&DOC=FILE.PDF. For EPA's 2004 assessment of the HPV Challenge (the most recent listed on EPA's website as part of the HPV coverage when this Article was being prepared), see U.S. EPA, "STATUS AND FUTURE DIRECTIONS OF THE HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM" REPORT AND TRI-FOLD BROCHURE, *available at* http://www.epa.gov/hpv/pubs/general/hpvstatr.htm.

125. U.S. EPA, *Managing Existing Chemicals*, http://www.epa.gov/oppt/ar/2007-2009/managing/index.htm (last visited May 18, 2010).

126. *Id.*

by the end of 2012."[127] EPA's website provides a resource for the interested reader to monitor developments.[128]

The GAO offers the following conclusion:

> While TSCA allows EPA to require the testing of existing chemicals through the rulemaking process, EPA has found it difficult and costly to make the findings necessary to promulgate rules, including findings that a chemical may pose unreasonable risks or that the chemical will be produced in substantial quantities, and that there is or may be substantial human or environmental exposure to the chemical. Consequently, to obtain the test information needed on existing chemicals, EPA relies extensively on the chemical industry to perform tests of . . . chemicals under (1) consent agreements . . . and (2) voluntary industry efforts under the HPV Challenge Program.[129]

The Congressional Research Service ("CRS") offers the following conclusion regarding the state of testing, including under the HPV and other voluntary programs:

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127. Greenwood, *supra* note 15, at 10035.

128. *See, e.g.*, United States EPA, Basic Information, Chemical Assessment and Management Program (CHAMP), http://www.epa.gov/champ/pubs/basic.html (last visited May 18, 2010); U.S. EPA, High Production Volume (HPV) Challenge, http://www.epa.gov/hpv/ (last visited May 18, 2010). For example, in December 2008, EPA proposed an "Inorganic HPV Challenge Program" similar to the organic Challenge Program. U.S. EPA, Basic Information Chemical Assessment & Management Program, http://www.epa.gov/champ/pubs/basic.html (last visited May 18, 2010). EPA has also built on the HPV Challenge Program to develop a "Voluntary Children's Chemical Evaluation Program" ("VCCEP"). U.S. EPA, Potential Chemical Risks to Children, http://www.epa.gov/oppt/ar/2007-2009/managing/risks_to_children.htm (last visited May 18, 2010).

129. GAO June 2005, *supra* note 1, at 34–35. EPA has initiated other voluntary programs as well. For example, in 2000 it began the Voluntary Children's Chemical Evaluation Program ("VCCEP") in an effort to "help[ ]the public better understand the potential health risks to children associated with certain chemical exposures." U.S. EPA, Potential Chemical Risks to Children, http://www.epa.gov/oppt/ar/2007-2009/managing/risks_to_children.htm (last visited May 18, 2010). *See also* Implementation of the Pilot Voluntary Children's Chemical Education Program, 71 Fed. Reg. 67,121 (Nov. 20, 2006); GAO June 2005, *supra* note 1, at 41–42. In its Spring Regulatory Agenda, the EPA indicated that the program was not currently involved in rulemaking and that the pilot program was nearing completion. U.S. EPA, Semiannual Regulatory Agenda—Spring 281–82 (2009), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809844c2.

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> Despite the noteworthy progress being made through these voluntary programs [HPV and others], which is greater than under any previous TSCA initiative, most existing chemicals still lack toxicity data relevant to hazard assessment. Data also are lacking on production volume and use, which are critical for determining the potential for human and environmental exposure and for risk assessments that would permit priority setting for EPA action.[130]

In sum, a primary purpose of TSCA is to address concerns about potentially toxic chemical substances by identifying the subset of the enormous number of chemical substances that pose potential risks and then requiring that manufacturers and others develop relevant data so that risk can be better understood. As this section reflects, one important question the experience with the TSCA § 4 regime raises, which Professor Adelman addresses,[131] is whether TSCA's statutory scheme, as augmented by various "voluntary" initiatives, strikes the right balance. If not, what can and should be done to reform the structure TSCA creates? These questions are also of central importance for the "new" chemicals regime TSCA creates, to which I now turn.

C. Treatment of "New" Chemicals and Chemicals Intended for Significant New Uses under TSCA § 5: Pre-Manufacture Notification

"New" chemicals, and how best to be preventive in approach while not unduly impeding technological progress and economic opportunity, were issues of major concern to Congress in its enactment of TSCA, as discussed in Part I. TSCA creates a "pre-manufacture notification" ("PMN") scheme for "new" chemicals and for other chemicals under certain circumstances.[132] It provides that any person who wants to "manufacture a new chemical substance"[133]

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130. CRS Report, *supra* note 17, at 17.

131. David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH. U. J.L. & POL'Y 377 (2010).

132. The GAO reports that, as of 2005, approximately "700 new chemicals are introduced into commerce each year." GAO June 2005, *supra* note 1, at 1. TSCA also exempts certain chemical substances from PMN requirements. BERGESON, *supra* note 76, at 20.

133. Toxic Substances Control Act § 5(a)(1)(A); 15 U.S.C. § 2604(a)(1)(A) (2006).

or "manufacture or process any chemical substance for a use which . . . is a significant new use"[134] must submit a PMN to EPA at least ninety days before manufacture.[135]

The PMN is supposed to include basic data (such as the identity of the submitter and of the chemical substance), the anticipated production volume, uses, exposures, and environmental fate.[136] TSCA does not require a manufacturer to test a new chemical substance before submitting a PMN, and the GAO reports that companies "typically do not voluntarily perform such testing."[137] EPA has received about 40,000 PMNs since 1976, generally between 1,000 and 2,000 each year.[138] The CRS reports that about thirty-three percent of PMN submissions include test data on chemical properties and about fifteen percent include data on health effects.[139] The submitter is supposed to submit any data within its possession or control that relate to the health or environmental effects of the chemical substance.[140]

EPA generally is supposed to complete its review of PMN's within ninety days. During the ninety-day review, EPA assesses the risk associated with the substance and whether its manufacture, use, etc., may present "an unreasonable risk of injury to health or the environment."[141] The GAO reports that, because of limited data, EPA often predicts potential exposure and toxicity of new chemicals through modeling and comparisons of chemicals with similar molecular structures for which data are available.[142] The GAO

134. Toxic Substances Control Act § 5(a)(1)(B); 15 U.S.C. § 2604(a)(1)(B) (2006). For simplicity's sake, I do not discuss "significant new uses" in the text. For background on EPA's treatment of such uses, see BERGESON, *supra* note 76, at 43–46.

135. 15 U.S.C. § 2604(a)(1) (2006).

136. 40 C.F.R. § 720.45–.50 (2009).

137. GAO June 2005, *supra* note 1, at 3.

138. CRS Report, *supra* note 17, at 9.

139. *Id.* at 10.

140. "The PMN Form must be accompanied by test data in the submitter's possession or control relating to the health or environmental effects of the new chemical substance." Hathaway et al., *supra* note 44, Part I at 10218. This information must include: "health effects data, ecological effects data, physical and chemical properties data, environmental fate data, and monitoring and other data relating to human exposure or environmental releases." *Id.* (citing 40 C.F.R. § 720.50(a)(2)).

141. *Id.* at 10215; BERGESON, *supra* note 76, at 21.

142. GAO June 2005, *supra* note 1, at 3.

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indicates that, despite "weaknesses" in assessment capacity, EPA believes that the models, information on other chemicals, and the information companies provide in their PMNs relating to production volume, anticipated uses, etc., enable the agency to conduct a "reasonable review of new chemicals."[143] The GAO indicates that about twenty percent of the PMNs received each year go through a more detailed review process after they are screened initially because EPA is able to determine based on its screening models that such chemicals pose limited risks.[144]

The GAO reports that, as of June 2005, EPA's new chemical reviews resulted in "some action being taken to reduce the risks of over 3,500 of the 32,000 new chemicals that companies had submitted for review."[145] The GAO elaborates that these actions ranged from chemical companies voluntarily withdrawing their notices of intent to manufacture new chemicals [for over 1,600 chemicals], chemical companies entering into consent orders with EPA to produce a chemical under specified conditions [for over 1,200 chemicals], and EPA promulgating significant new use rules requiring chemical companies to notify EPA of their intent to manufacture or process certain chemicals for new uses prior to manufacturing or processing the chemicals for such uses [for about 570 new chemicals submitted for review].[146]

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143. *Id.* at 4.

144. *Id.* at 12.

145. GAO November 2005, *supra* note 76, at 2. In its November 1, 2005, comments to GAO, EPA's OPPT indicates that the agency "is proud of the progress [it] has made in protecting human health and the environment. . . . TSCA authority has provided the Agency the ability to review more than 40,000 new chemicals prior to introduction into the marketplace and we have restricted or otherwise regulated over 1,600 of these chemicals while a similar number have been withdrawn by the manufacturer, often in the face of EPA action." The GAO notes that this does not include EPA's review of chemicals the agency had exempted from PMN requirements because EPA was satisfied the chemicals will not present an unreasonable risk. *Id.* at 2 n.4. TSCA authorizes EPA to exempt new chemicals from PMN requirements under a variety of circumstances. *See* Toxic Substances Control Act § 5(h)(3)(A), 15 U.S.C. § 2604(h) (2006). Other exemptions are considered "self-executing" and do not require EPA approval. *See* BERGESON, *supra* note 76, at 29–37. For example, EPA may approve an exemption from PMN requirements for a chemical substance that will be manufactured in low volume ("LVE") and does not present a serious risk to health or the environment. *See* 40 CFR § 723.50(a), (c), (d) (2009); BERGESON, *supra* note 76, at 37–40.

146. GAO June 2005, *supra* note 1, at 15–16. For a more in-depth review, see BERGESON, *supra* note 76, at 41–46; GAO November 2005, *supra* note 76, at 5. EPA has authority to take

As the ABA Basic Practice Series book on TSCA reflects, "[i]n most cases, EPA reviews PMN submissions and does not elect to control the manufacture, processing, distribution, use, or disposal of the new chemical substance."[147] EPA's website indicates that "[a]lmost 90 percent of PMNs submitted to EPA complete the review process without being restricted or regulated in any way."[148] After the ninety-day PMN period expires, the submitter may begin to manufacture the chemical substance without any restrictions.[149]

The GAO's view is that the PMN process has produced limited benefits in terms of generating new data about new chemicals.[150] It offers several possible reforms to TSCA to enhance the quality of information provided to EPA pre-manufacture, including: (1) requiring companies to test their chemicals and submit the results to EPA with their PMNs, while tying the need for such testing (and its extent) to various triggers, such as production volume (used in Canada and the European Union), or gaps in EPA information (*e.g.*, to require testing where "EPA's analysis models do not adequately predict toxicity"[151]); and (2) perhaps shifting testing to the pre-marketing time period rather than pre-manufacture stage since about half of the pre-manufacture notices EPA receives are for new chemicals that "never enter the marketplace."[152]

This issue of screening new chemicals is one of the significant areas of ongoing debate concerning TSCA implementation, as Professor Adelman notes.[153] The CEQ offers a helpful summary of some of the options Congress considered, and its ultimate approach, in its report the year after TSCA was enacted:

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action (via a rule, order, or injunction) under § 5(f) if it determines that a new chemical substance presents or will present an unreasonable risk before EPA can issue a § 6 rule. *See* BERGESON, *supra* note 76, at 42–43; Toxic Substances Control Act § 5(f); 15 U.S.C. § 2604(f) (2006). EPA has used this § 5(f) authority rarely—as of 2000, EPA had issued only three such rules. BERGESON, *supra* note 76, at 43.

147. BERGESON, *supra* note 76, at 41.

148. U.S. EPA, Possible Outcomes of a PMN Review, http://www.epa.gov/opptintr/newchems/pubs/possible.htm (last visited May 18, 2010).

149. BERGESON, *supra* note 76, at 41.

150. GAO February 2009, *supra* note 85, at 7.

151. *Id.* at 8.

152. *Id.*

153. Adelman, *supra* note 131.

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> Enactment of the Toxic Substances Control Act in October 1976 culminated nearly 6 years of executive and congressional deliberation. . . .
>
> During the 6 years it took to pass the law, controversy centered on how to assess potentially harmful chemicals before marketing. Some advocated positive clearance by the Environmental Protection Agency before any new chemical or new use for a chemical could be marketed. The opposing argument was that such a massive clearance procedure would create an impossible regulatory burden and might impede progress and beneficial use of chemicals. Some in industry wanted no premarket notification at all; others proposed notification only for groups of chemicals that had been officially designated as hazardous.
>
> The Act as passed takes a middle position, requiring manufacturers of all new chemicals and chemicals for new uses to give EPA 90 days' notice before manufacture begins. Any chemical not listed on an inventory of existing chemicals will be considered new. Positive clearance for each new chemical is not required before marketing, but EPA can stop the manufacture, sale, or use of any chemical that may present an unreasonable risk.[154]

Two decades ago, John Mendeloff identified the key issue for "screening" approaches as follows:

> In screening programs there is only one key policy issue: "how high to set the standard of proof that firms have to meet to show that their products are not too risky." On the one hand, "[i]f the standard of proof is set too high, many worthwhile products (some of which might even reduce risks) will be stillborn." On the other if the standard of proof is "set too low, too many hazardous products will be approved."[155]

154. 1977 CEQ Report, *supra* note 30, at 5–6.
155. MENDELOFF, *supra* note 3.

On its website, EPA describes its new chemicals program under TSCA as "one of the Agency's premier risk management programs," which "serves a key gatekeeper function."[156] As the commentary reflects, and as Professor Adelman reviews in more detail,[157] the question of whether the "middle position" embodied in TSCA is the "right one," or whether, in Mr. Mendeloff's terms, the standards are "too high" or "too low," has triggered substantial debate.[158]

Before moving on to TSCA's regulatory authority under § 6, I offer one addendum to Mr. Mendeloff's take on the role of screening regimes. In addition to Mr. Mendeloff's point that the effectiveness of such regimes depends in part on where they set the bar, another possible feature involves the tools such regimes provide to facilitate learning. EPA's Sustainable Futures Program, which EPA launched in 2002 as a voluntary pilot project, is an example of this possible role for screening regimes.[159] As the GAO notes, EPA's goal in the program is to "help industry develop new chemicals that are sustainable economically and environmentally."[160] EPA offers the following summary of the program on its website:

> The Sustainable Futures (SF) Initiative is a voluntary program that encourages chemical developers to use EPA's models and methods to screen new chemicals for potential risks early in the development process. The goal is to produce safer chemicals more reliably and more quickly, saving time and money. This means getting safer chemicals into the market and in use. In some cases, it means providing alternatives to more risky chemicals—this is pollution prevention in its purest form.[161]

Thus, EPA educates interested companies about the agency's screening protocols so the companies can use the protocols to screen

156. U.S. EPA, Reviewing New Chemicals, http://www.epa.gov/oppt/ar/2007-2009/review newchem/index.htm (last visited May 18, 2010).

157. *See* Adelman, *supra* note 131.

158. *See* MENDELOFF, *supra* note 3, at 50.

159. Sustainable Futures—Voluntary Pilot Project Under TSCA New Chemicals Program, 67 Fed. Reg. 76,282–76,286 (Dec. 11, 2002).

160. GAO June 2005, *supra* note 1, at 42; Sustainable Futures, 67 Fed. Reg. at 76, 282.

161. U.S. EPA, Sustainable Futures, Basic Information, http://epa.gov/oppt/sf/pubs/basic.htm (last visited May 18, 2010).

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their chemicals. EPA suggests that such "learning" approaches hold promise for producing a variety of benefits, including the following:

> Identification and commercialization of safer chemicals, Increased Pollution Prevention (P2) opportunities, Increased innovation, More focused testing, More efficient processes, and Reduced generation of chemical waste.
>
> Avoiding problem chemicals and the potential high costs associated with those chemicals, sometimes called chemicals "left on the cutting room floor," may well be the source of the greatest cost savings to companies participating in Sustainable Futures. The ultimate identification and commercialization of safer chemicals benefits the participant, as well as the general public and the environment.[162]

D. Regulation under § 6 of TSCA

A fourth key issue Congress faced in considering TSCA (in addition to its jurisdictional scope, information-gathering regimes for existing chemicals, and screening approaches for new chemicals) involved the type of legal regime it should establish to empower EPA to regulate chemicals in situations in which EPA concluded the chemicals posed a risk. In § 6 of TSCA, Congress gives EPA a broad range of tools to regulate chemical substances when EPA finds that there is a "reasonable basis" to conclude that the chemical substance "presents or will present an unreasonable risk of injury to health or the environment."[163] EPA's options include prohibiting the manufacture of the substance, limiting the amount that may be manufactured, only allowing particular uses and/or concentrations, requiring various types of warnings or other notifications, and requiring that manufacturers retain records of their manufacturing processes.[164]

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162. U.S. EPA, Benefits to Sustainable Futures Graduates, http://www.epa.gov/oppt/sf/pubs/benefits.htm (last visited May 18, 2010).

163. Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (2006).

164. Toxic Substances Control Act § 6(a)(1)–(6), 15 U.S.C. § 2605(a).

http://digitalcommons.law.wustl.edu/wujlp/vol32/iss1/11

Congress established procedural requirements for EPA to follow in imposing controls. EPA must initiate a rulemaking proceeding to take action. The agency must include a statement that discusses: (1) the effects of the substance on health, and "the magnitude of the exposure of human beings to such substance"; (2) the effects of the substance on the environment and the magnitude of the exposure of the environment to such substance; (3) the benefits of the substance for various uses and the availability of alternatives to the substance; and (4) the "reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health."[165]

Section 6 mandates that EPA pass rules that "protect adequately,"[166] and that EPA use the "least burdensome" of its options.[167] In addition, § 6(c) provides that EPA should not act under TSCA to regulate a risk if the risk could be addressed under another federal law that EPA administers, unless EPA determines that it is in the "public interest" for the Agency to regulate the risk under § 6.[168] TSCA directs EPA to compare the estimated costs of compliance and relative efficiency of acting under TSCA versus under a different statute.[169]

The GAO observes that the TSCA § 6 framework described above creates a "legal threshold that has proven to be difficult for EPA."[170]

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165. 15 U.S.C. § 2605(c).

166. Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a).

167. *Id.*

168. 15 U.S.C. § 2605(c)(1). *See* Toxic Substances Control Act § 9(a)(1), 15 U.S.C. § 2608(b); *see also* Hathaway et al., *supra* note 44, Part I at 10207, 10208 (citing S. Rep. No. 698, 94th Cong., 2d Sess. 5–6 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4495). *Id.* at 10210 ("These exemptions reflect Congress' intent in enacting TSCA to impose controls on chemicals that are not adequately regulated under existing law, while avoiding the application of duplicative or overlapping regulations to those chemicals otherwise subject to pervasive regulatory oversight" (citing Inventory Reporting Requirements, 42 Fed. Reg. 64572, 64586 (Dec. 23, 1977)). Materials that are "pervasively regulated" under other federal legislation include "pesticide[s], . . . tobacco . . . [nuclear] source material . . . special nuclear material, or byproduct material . . . firearms and ammunition . . . and . . . food[s], food additive[s], drug[s], cosmetic[s], and device[s]." *Id.*

169. 15 U.S.C. § 2605(c)(1).

170. GAO February 2009, *supra* note 85, at 9.

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> EPA has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and consequently should be banned or have limits placed on their production or use. In fact, since Congress passed TSCA nearly 33 years ago, EPA has issued regulations under the act to ban or limit or restrict the production or use of only five existing chemicals or chemical classes [the Agency has also placed controls on four new chemicals under § 5(f)]. Significantly, in 1991, EPA's 1989 regulation broadly banning asbestos was largely vacated by a federal appeals court decision that cited EPA's failure to meet statutory requirements.[171]

The courts have played an important role in the implementation of this framework. In *Corrosion Proof Fittings v. EPA*,[172] the Fifth Circuit held that EPA had not sufficiently considered and ruled out other, less burdensome alternatives before placing a total ban on asbestos.[173] In addition, the court held that EPA needed to consider the extent to which substitute products were available.[174] The GAO reports that after completing the 1989 asbestos rule challenged in *Corrosion Proof Fittings*, EPA has "completed only one regulation to ban or limit the production or use of an existing chemical (for hexavalent chromium in 1990). Further, EPA has not completed any actions to ban or limit toxic chemicals under section 6 since the court rejected its asbestos rule in 1991."[175] In sum, EPA has "rarely

171. *Id.* at 10; GAO June 2005, *supra* note 1, at 18 (noting that EPA has regulated five chemical substances or groups of chemical substances under § 6; and the "last final action EPA took to control existing chemicals under section 6 was published in 1990."). The GAO also noted that, as of 2005, EPA has required companies to submit notices of any significant new uses for 160 existing chemicals, which provides EPA the chance to review risks the new use poses. GAO June 2005, *supra* note 1, at 27. For the CRS's summary of EPA's use of its § 6 authority, see CRS Report, *supra* note 17, at 18.

172. 947 F.2d 1201 (5th Cir. 1991).

173. *Id.* at 1229.

174. *Id.* at 1230. Section 2605 addresses a number of chemical substances in particular, such as PCBs and mercury, but I do not cover these substances here. *See* 15 U.S.C. § 2605(e) and (f). Similarly, I do not address TSCA's authority to address imminently hazardous substances.

175. GAO February 2009, *supra* note 85, at 11. The GAO notes that state and some other federal actions have established controls for toxic chemicals outside the bounds of TSCA. *Id.*

banned, limited the production, or restricted the use of existing chemicals."[176]

The GAO has identified several reforms to TSCA that the GAO believes would enhance EPA's ability to regulate dangerous chemical substances, including changing the current § 6 "unreasonable risk" standard for regulating existing chemicals, relaxing judicial review, and changing the "least burdensome" requirement.[177] Again, Professor Adelman addresses this suite of issues in his Article.[178]

CONCLUSIONS

In its 2008 report, the CRS suggests that three key policies inform TSCA's approach to regulation of chemical substances:

> TSCA regulates potential risks of industrial chemicals in U.S. commerce, based on three policies: (1) Chemical manufacturers are responsible for testing chemicals to determine their potential effects on health and the environment; (2) EPA should regulate chemicals that present an unreasonable risk to health or the environment; and (3) EPA's implementation of the law should not create unnecessary economic barriers to technological innovation.[179]

The CRS concludes that "[f]ew have expressed concern about the last TSCA purpose," but "TSCA's progress in achieving the first two goals has been debated: where some see success, others see failure, and both sides of the debate point to EPA's history of implementation and its voluntary initiative for collecting data on high production volume chemicals in support of their views."[180]

Now is a propitious time for this symposium issue on New Directions in Environmental Law to consider the important issues TSCA raises, not only for how the issues relate to environmental regulation generally, but also for how policymakers might consider their treatment of these issues in the context of TSCA itself. As

176. GAO June 2005, *supra* note 1, at 18.
177. GAO February 2009, *supra* note 85, at 11–12.
178. Adelman, *supra* note 131.
179. CRS Report, *supra* note 17, at Summary, 2.
180. *Id.* at Summary.

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several commentators have suggested, reform may be on the table in the near future.[181] This would be a marked departure from TSCA's first thirty-plus years, when Congress left its basic structure largely alone.[182]

As I note above,[183] my modest role in this symposium is to provide some of the contextual backdrop for TSCA's enactment and implementation; Professor Adelman's contribution provides a perspective concerning the changes needed in light of what we have learned. In closing, however, I stray briefly from my charge in order simply to highlight what strike me as some of the more interesting issues that would benefit from careful consideration. I list five such issues here.

First, for a host of critical issues—*e.g.*, what types of testing and other information gathering should be required under particular circumstances, and what types of limitations on manufacture, distribution, use, etc., are appropriate—the debate about possible TSCA reform presents a terrific opportunity for meaningful debate at a conceptual level about the meaning of the precautionary principle and the concept of sustainable development, hopefully in tandem with careful consideration of how they should be applied together to address real-world policy challenges. Each concept has proven difficult on its own to pin down. Efforts to consider the two in tandem are even less advanced. TSCA, REACH, and other

181. Greenwood, *supra* note 15, at 10034 (suggesting that "[t]he time for TSCA reform is basically now or never."); CRS Report, *supra* note 17, at 1; Sachs, *supra* note 77, at 1818–23. The CRS suggests that there are competing views about the merits of reforming TSCA. CRS Report, *supra* note 17, at 35 (noting that "[s]ome analysts, and most in the regulated community, believe that TSCA has performed as intended, and they support TSCA in its current form."). On the other hand, in February 2009, Cal Dooley, President of the American Chemistry Council, testified before Congress that "there are several reasons why Congress should begin the effort to modernize TSCA." Revisiting the Toxic Substance Control Act of 1976: Hearing Before the H. Subcomm. on Commerce, Trade, and Consumer Protection, 111th Cong. (2000) (statement of Cal Dudey, President, American chemistry Council).

182. As one former EPA official and current prominent practitioner puts it, "TSCA is one of the oldest federal environmental statutes that has never seen substantial reform." Greenwood, *supra* note 15, at 10034; *see also* CRS Report, *supra* note 17, at 1 (noting that "[t]he basic TSCA provisions in Title 1 have never been amended."). For a list of the amendments Congress has enacted, see CRS Report, *supra* note 17, at 1 n.2.

183. *See supra* note 19.

initiatives[184] seem intended to embrace each concept, yet their approaches are very different.

Related, this debate about how to incorporate the precautionary principle and sustainable development into possible TSCA reform legislation ought to be expanded to grapple with the larger challenge of evaluating how best to "manage" chemicals throughout their life cycle in a way that is both precautionary and sustainable. My guess is that there is even more support today than in 1976 for the adage that an ounce of prevention is worth a pound of cure, and that we should be focusing on opportunities for pollution prevention, or "front-end stewardship of chemical production and use," in an effort to limit or minimize the need for pollution control and remediation.[185] TSCA reform offers a chance to consider domestic experience under TSCA, the pollution control statutes, the reporting and remediation statutes, as well as experience under other countries' counterparts, to inform our thinking about how best to manage chemical substances in a way that is sustainable and precautionary. While there have been a number of efforts to grapple with the application of these "precepts" of environmental law in particular contexts, [186] TSCA reform efforts present an opportunity for transparent consideration of how these concepts or principles should fit together in a TSCA-like regime that operates in tandem with statutes that focus on different aspects of chemicals' life cycles to produce effective public policy.

A second, very different question that also has normative as well as procedural implications is: What role should TSCA carve out for the public and, more generally, for "sunshine approaches" designed to enhance environmental protection? I did not have the space to explore this issue in detail. But the idea of incorporating such approaches as a part of the policy tool box has become increasingly popular in recent years,[187] and it is an important one in the TSCA

184. For discussions of REACH and other approaches, see, e.g., Applegate, *supra* note 21; Sachs, *supra* note 77; U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS, GAO-07-825 (2007).

185. Hathaway et al., *supra* note 44, Part I at 10208.

186. *See, e.g.*, Applegate, *supra* note 21.

187. *See* David Markell, *"Slack" in the Administrative State and Its Implications for Governance: The Issue of Accountability*, 84 OR. L. REV. 1 (2005).

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arena that already has engendered considerable debate.[188] As noted above, because of the perceived paucity of data about possible risks from chemical substances, generation of risk-related information (about toxicity, risks of exposure, etc.) has long been a central goal of TSCA. Critics of TSCA complain about an "information deficit" because of the lack of data and argue that addressing this deficit would, in addition to helping regulators regulate effectively, help businesses and consumers "choose safer chemicals" and thereby improve efficient operation of the market.[189]

Part of this issue involves determining appropriate parameters for dissemination of information.[190] It is clear that other "stakeholders" (states, etc.) could benefit in performing their responsibilities from access to information about chemical substances and their characteristics, including the possible risks they pose.[191] Further, many commentators have suggested that there are other benefits to dissemination of information, including the incentives openness creates for "regulated parties" to bolster protective practices (the TRI program has frequently been identified as a successful example in this respect), the signals it provides government to enhance its operations, marketplace benefits, and the added legitimacy it creates through a more informed citizenry. The CRS notes that "EPA protects from disclosure the identities of as many as 90% of . . . new chemicals due to formal assertions by manufacturers that the information is confidential business information."[192] In any reform effort, the balance TSCA currently strikes between openness and preserving confidentiality is likely to shift in the direction of greater openness because of institutional structure questions involving the role of the states (discussed below) and the impacts of globalization (also discussed below).[193] Careful consideration of other benefits of

188. *See, e.g.*, Sachs, *supra* note 77.

189. CRS Report, *supra* note 17, at 21 (internal citation omitted).

190. Sachs, *supra* note 77, at 1826–32; Applegate, *supra* note 21, at 729.

191. *See, e.g.*, Greenwood, *supra* note 15, at 10040 (suggesting that "there is fairly broad support across the political spectrum for statutory change" that allows states access to chemical information so long as states are able to protect it from disclosure).

192. CRS Report, *supra* note 17, at 9 n.25 (also noting that the percentage "drops to 65% for new chemicals that actually enter commerce").

193. Professor Sachs, for example, suggests that REACH is likely to have "transnational effect[s]" in the realm of information disclosure. Sachs, *supra* note 77, at 1819.

reporting and transparency, discussed in the rich literature on the TRI program among other places, should be incorporated into discussions about this issue as well.

Third, TSCA raises front and center another issue that has received considerable attention during the implementation of our environmental regulatory infrastructure, notably the appropriate roles for different types of strategies ranging from "command-and-control," to "market-based," to "voluntary." As noted above, TSCA has relied extensively on voluntary initiatives. The experience under TSCA should be reviewed closely for insights about the possibilities for structuring approaches to incorporate a variety of regulatory, market-oriented, and voluntary strategies. Cliff Rechtschaffen and I have reviewed some of the track record of cooperative and coercive approaches in the compliance arena.[194] The empirical and theoretical work we discuss, and additional contributions to these literatures (as well as literatures concerning voluntary and coercive approaches under environmental and other statutes), may be helpful in considering possible alignments of cooperative or voluntary and more coercive approaches as part of any TSCA reform.

Fourth are questions concerning TSCA's institutional structure. Unlike most of the major environmental regulatory statutes (notably RCRA, the CWA, and the CAA), TSCA does not follow a cooperative federalism approach. Instead, the federal government has taken the lead in TSCA implementation.[195] An obvious question is: how is this approach working out and, related, would other structures likely lead to better results? Given the experiences to date, both with TSCA and approaches adopted under other laws, and the nature of the challenges TSCA is intended to address, what insights should we glean from these experiences and how should these insights inform the structure Congress establishes for TSCA implementation as part of any reform initiative? Part of this inquiry will include review of the increasing number of state initiatives, such as California's Prop

194. We discuss this issue in the compliance arena in CLIFF RECHTSCHAFFEN AND DAVID MARKELL, REINVENTING ENVIRONMENTAL ENFORCEMENT AND THE STATE/FEDERAL PARTNERSHIP (2003).

195. *See, e.g.*, CRS Report, *supra* note 17, at 6–7, 20–22 for discussion of TSCA's institutional structure and the role of the states in regulation of toxic chemicals.

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65.[196] Borrowing Justice Brandeis's famous phrase, it is important to consider states' roles as "laboratories of democracy,"[197] as well as states' capacity as potential co-regulators, and possible "marketplace imperatives" such as the economy of scale issues that have received considerable attention in connection with the Clean Air Act.[198] The CRS, among others, has suggested that the expanding patchwork of state laws, and the possibility that some state laws may be "less firmly based on sound science," may lead manufacturers to support more uniform regulation at the federal level.[199] Various commentators, including Mark Greenwood, have suggested that, particularly with increases in state capacity, interest, and action, it no longer is politically possible to "design a chemical management law that ma[kes] only passing reference to the states."[200] There is a rich literature about when and how best to allocate different levels of responsibility between the federal and state governments. This will be an important institutional structure issue for policymakers to consider as part of any initiative intended to reform TSCA.

Finally, there is the question of what role initiatives outside the United States should and will play in TSCA reform. What incentives (and perhaps disincentives) will REACH and other non-U.S. initiatives create for particular TSCA reforms? The "globalization of commerce" is likely to complicate efforts to administer TSCA in isolation from other regimes.[201] Data information developed under one regime may well impact the need for data under another; multiple regimes inevitably will have implications for data transparency under each; and the existence of different approaches is similarly likely to influence choices of regulatory strategies to address problematic chemical substances (and the universe of chemicals for which companies are required to implement various types of controls). The

196. Roe, *supra* note 91, at 631–33 (discussing Proposition 65); CRS Report, *supra* note 17, at 22 (noting an increase in state and local restrictions on chemicals).

197. David Markell, *States as Innovators: It's Time for a New Look to Our "Laboratories of Democracy" in the Effort to Improve our Approach to Environmental Regulation*, 58 ALB. L. REV. 347(1994).

198. Applegate, *supra* note 21.

199. CRS Report, *supra* note 17, at 22.

200. Greenwood, *supra* note 15, at 10040–41.

201. CRS Report, *supra* note 17, at 22.

GAO, CRS, and a variety of commentators have tackled this issue over the past couple of years, and Professor Adelman covers it in detail in his Article, but I would be remiss not to at least mention the likely influence on TSCA of non-U.S. initiatives, and international agreements.[202]

In tandem with Professor Adelman's much more in-depth treatment of some of these questions (and no doubt others as well), I hope the reader leaves the volume somewhat more informed about Congress's goals in enacting TSCA, with a bit better appreciation for some of the issues that have arisen during implementation of the statute, and also with a sense of some of the framework questions that should be on the table during discussions about TSCA reform and about possible revisions to our environmental legal infrastructure more generally.

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202. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS, GAO-07-825 (2007); CRS Report, *supra* note 17, at 22–24; Applegate, *supra* note 21; Sachs, *supra* note 77, at 1819 (contending that "[c]hemical regulation in the United States is now being transformed . . . through the transnational effects of foreign legislation").

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