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Rescuing the Strong Precautionary Principle from Its Critics

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RESCUING THE STRONG PRECAUTIONARY PRINCIPLE FROM ITS CRITICS

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The Strong Precautionary Principle, a theory of risk regulation that shifts the burden of proof on safety, provides a valuable framework for preventing harm to human health and the environment. Yet Cass Sunstein and other scholars have consistently attacked it as paralyzing, inflexible, and extreme.

This Article undertakes a reassessment of the Strong Precautionary Principle, providing a counterweight to the mountain of critical scholarship. The Principle sends a clear message that firms must research the health and environmental risks of their products, before harm occurs. It does not call for the elimination of all risk, but through burden shifting, the Principle legitimately asks risk-creators to justify the risks they impose on society. By exploring where the Principle already operates successfully in American law – examples largely overlooked by the critics – I highlight the flexibility and coherence of Strong Precaution as a guide for risk decision making.

The Article uses chemical regulation as a case study in how the Principle can guide Congress in an ongoing controversy. Congress is now considering a major overhaul of the flawed Toxic Substances Control Act of 1976 (TSCA), and this Article advocates grounding a new statute in the Strong Precautionary Principle. I propose a licensing system in which chemical manufacturers would carry the burden to demonstrate that their products do not pose significant risks to human health or the environment. Implementing Strong Precaution in chemical regulation is the key to transforming TSCA into an effective statute that protects public health.

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INTRODUCTION

Congress is now considering the most significant change in American environmental law in a generation – an overhaul of the Toxic Substances Control Act (TSCA) of 1976.[1] The flaws in the existing statute are well-known. The American chemical industry produces or imports more than seventy-three billion pounds of chemicals *per day*,[2] yet TSCA does not require any form of routine chemical risk assessment. As a result, we lack basic toxicity data for the vast majority of chemicals used in cookware, toys, beauty products, food packaging, and other items. In June, when Kellogg's recalled 28 million boxes of cereal due to an oily smell, which turned out to be from 2-methylnaphthalene in the cereal bags, there was no data available on the health

[1] Toxic Substances Control Act, 15 U.S.C. §§2601-92 (2006).

[2] *See* U.S. ENVIRONMENTAL PROTECTION AGENCY, 2006 INVENTORY UPDATE REPORTING DATA SUMMARY 15 (2006), *available at* http://www.epa.gov/iur/pubs/2006_data_summary.pdf (reporting approximately twenty-seven trillion pounds of chemicals produced or imported in the United States in 2005). This figure is likely an underestimate of total U.S. chemical production, because low-volume chemical production, below 25,000 pounds per year at one site, did not need to be reported to EPA. *Id.* at 1.

risks of that widely-used chemical.[3] This is emblematic of the data drought in which the U.S. has attempted to manage chemical risks for decades. The potential population-wide harm is sobering. Carcinogenic chemicals once thought to be safely contained in consumer products are now present in the bloodstream and tissues of virtually all Americans.[4]

This year, there is more momentum for reform than at any time in the past three decades. In 2010, landmark TSCA reform bills were introduced in both houses of Congress,[5] and principles to guide the reform effort have been announced by the Environmental Protection Agency,[6] various U.S. states,[7] environmental groups,[8] and the largest chemical industry trade association, the American Chemistry Council.[9] As I described in a previous article,[10] the contours of a new statute are still under debate, but the stars are now aligned for significant legislative action.

At the same time, critics inside and outside the academy are attacking the theoretical principle that should be guiding the reform effort–the Strong Precautionary Principle. The Strong Precautionary Principle is a controversial approach to risk management that shifts the burden of proof on the safety of a product or activity from government regulators to private firms. I define it as the view that: 1) regulation should presumptively be applied when an activity or product poses serious threats to human health or the environment, even if scientific uncertainty precludes a full understanding of the nature or extent of the threats; and 2) the burden of overcoming the presumption in favor of regulation lies with the proponent of the risk-creating activity or product.[11]

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[3] *See* Lyndsey Layton, "U.S. Regulators Lack Data on Health Risks of Most Chemicals," WASH. POST, August 2, 2010. 2-methylnaphthalene is one of the highest production volume chemicals in the United States, but it has never been required under TSCA to be tested for its health effects, and it was never voluntarily tested as part of a 1990s program to test high-volume chemicals. *Id.*

[4] *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2009), available at http://www.cdc.gov/exposurereport/pdf/FourthReport_ExecutiveSummary.pdf. *See also* Richard Denison, *Ten Essential Principles for TSCA Reform*, 39 ENVTL. L. RPTR. 10020, 10023 (2009).

[5] Safe Chemicals Act, S. 3209, 111th Cong. (April 15, 2010); Toxic Chemicals Safety Act of 2010, H.R. 5820 (July 22, 2010).

[6] *See* U.S. Environmental Protection Agency, *Essential Principles for Reform of Chemicals Management Legislation*, http://www.epa.gov/oppt/existingchemicals/pubs/principles.pdf (last visited Feb. 10, 2010).

[7] *See States' Principles on Reform of the Toxic Substances Control Act* (Dec. 2, 2009), *available at* http://www.saferstates.com/attachments/StatePrinciples.pdf.

[8] *See Safer Chemicals, Healthy Families, A Platform for Reform of the Toxic Substances Control Act*, http://www.saferchemicals.org/PDF/SCHF_Campaign_Platform.pdf (last visited Feb. 10, 2010).

[9] *See* American Chemistry Council, *10 Principles for Modernizing TSCA*, http://www.americanchemistry.com/s_acc/ sec_mediakits.asp?CID=2178&DID=9938 (last visited Feb. 1, 2010).

[10] Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VANDERBILT L. REV. 1817 (2009).

[11] A variety of definitions for the Strong Precautionary Principle may be found in the literature. Two common elements of the Principle are an anticipatory approach to managing risks and a shift in the

A new chemical regulatory statute, grounded in the Strong Precautionary Principle, would shift the burden to chemical manufacturers to prove that chemicals do not pose significant risks to human health or the environment. This would reverse current practice under TSCA, where the government bears a stringent burden to demonstrate "unreasonable risk" from a chemical to enact restrictions.[12] That governmental burden, combined with the lack of available toxicity data, has crippled protective regulation. According to Dr. Lynn Goldman, who oversaw TSCA implementation during the Clinton Administration, TSCA will "never be effective" unless it is amended to include a shift in the burden of proof.[13]

Yet critics of the Strong Precautionary Principle, such as Cass Sunstein, Jonathan Graham, and Jonathan Wiener, have little interest in further application of the Principle in TSCA, or elsewhere. Instead, they want to bury it. Sunstein has derided Strong Precaution as "senseless,"[14] "paralyzing,"[15] and "worse than unhelpful."[16] He and other detractors have charged that the Strong Precautionary Principle provides no guidance on which risks to address and ignores so-called "risk-risk" tradeoffs in which a precautionary response to one "target" risk may lead to substitute risks that are even worse.[17] The Principle should be rejected, wrote Sunstein, "not because it leads in bad directions, but because it leads in no direction at all. The principle is literally paralyzing--forbidding inaction, stringent regulation, and everything in between."[18]

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burden of proof on whether the risky activity should be allowed to proceed. *See* CASS SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE (2005); A.W. Harris, *Derogating the Precautionary Principle*, 19 VILL. ENVTL. L.J. 1, 63 (2008); Justin Wade, *Sunstein's Blunder; Or, the Perils of Reconstructing Precaution*, 20 GEO. INT'L ENVTL. L. REV. 473, 485 (2008).

[12] 15 U.S.C. §2605 (2006).

[13] OVERSIGHT OF THE TOXIC SUBSTANCES CONTROL ACT AND THE CHEMICALS MANAGEMENT PROGRAM AT EPA: HEARING BEFORE S. COMM. ENVIRONMENT & PUBLIC WORKS, 109th Cong. 4 (2006) (testimony of Lynn R. Goldman).

[14] Cass Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1004 (2003).

[15] CASS SUNSTEIN, LAWS OF FEAR, *supra* note 9, at 26 (2005).

[16] Cass Sunstein, *Your Money or Your Life*, NEW REPUBLIC, March 11, 2004. *See also* AARON WILDAVSKY, BUT IS IT TRUE? A CITIZEN'S GUIDE TO ENVIRONMENTAL HEALTH AND SAFETY ISSUES, 1-2 (1995) (stating "profound" objections to the precautionary principle's "reversal of causality," in which "individuals and businesses must prove that they will do no harm.").

[17] *See*, *e.g.*, Jonathan Baert Wiener & John D. Graham, *Resolving Risk Tradeoffs*, *in* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT 226, 226 (Graham & Wiener, eds. 1995) ("Each intervention to protect against a target risk can simultaneously generate countervailing risks; these risk tradeoffs at least reduce the gross benefits of the intervention and in some cases mean that the intervention will do more harm than good."); Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Safety Protocol*, 35 TEX. INT'L L.J. 173, 195 (2000) ("The problem is that by focusing on one set of risks—those posed by the introduction of new technologies with somewhat uncertain effects—the precautionary principle turns a blind eye to the harms that occur, or are made worse, due to the lack of technological development."); Sunstein, *supra* note 13, at 1020 ("The most serious problem with the strong version of the precautionary principle is that it offers no guidance—not that it is wrong, but that it forbids all courses of action, including inaction.").

[18] Sunstein, *Beyond the Precautionary Principle, supra* note 13, at 1003.

This sharply critical scholarship is no mere academic sideshow to the current Beltway battle over chemical regulation. Many of the players in the debate over Strong Precaution hold prominent positions in the Obama Administration and in Congress. Sunstein himself heads the influential Office of Information and Regulatory Affairs in the Executive Office of the President.[19] If key policymakers continue to maintain that the Strong Precautionary Principle is illegitimate, then it is unlikely that TSCA will be reformed in a meaningful way. Congress may miss a once-in-a-generation opportunity to repair the moribund chemical regulatory system.

The stakes are high, yet few scholars have offered any sustained defense of Strong Precaution. Most scholars of the role of precaution in risk regulation have instead kept to the safer terrain of defending so-called "weak" versions of the Precautionary Principle, which do not involve burden shifting.[20] While literature advocating "weak" precaution is voluminous,[21] the scholarly terrain on the Strong Precautionary Principle has been ceded to its opponents.[22] Under their avalanche of criticism, some breathing space is urgently needed to reconsider the merits and practical applications of Strong Precaution. Indeed, resuscitating TSCA as an effective chemical regulatory regime depends, in no small part, on rescuing the Strong Precautionary Principle from its critics.

In this Article, I undertake this much-needed reassessment of the Strong Precautionary Principle. I conclude that the Principle, far from being indefensible, provides a cogent framework for managing health and environmental risks in many regulatory arenas. I also demonstrate how the Strong Precautionary Principle could be sensibly implemented in the particular

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[19] Benjamin Wallace-Wells, "Cass Sunstein Wants to Nudge Us," *New York Times Magazine*, May 11, 2010 (describing Sunstein's role at OIRA and his involvement in Obama Administration debates over cost-benefit analysis, valuation of human life, and climate change).

[20] I define terms, including the differences between "weak" and "strong" versions of the Precautionary Principle, *infra*, Part I. Clarity of definitions is vital. Confusing and inconsistent definitions of "precaution" and "precautionary principle" have clouded the scholarship in this area for decades.

[21] *See, e.g.,* John Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL. R. 13 (2002); Applegate, "Embracing a Precautionary Approach to Climate Change," *in* ECONOMIC THOUGHT AND U.S. CLIMATE CHANGE POLICY (David Driesen, ed. 2010); Robert V. Percival, *Who's Afraid of the Precautionary Principle?,* PACE ENVTL L. R. 23 (2005); Douglas A. Kysar, *It Might Have Been*: *Risk, Precaution and Opportunity Costs*, 22 J. LAND USE & ENVTL. L. 1 (2006); Gregory Mandel, *Cost Benefit Analysis Versus the Precautionary Principle: Beyond Cass Sunstein's Laws of Fear*, 2006 ILL. L. REV. 1037 (2006); Elizabeth Fisher, "Opening Pandora's Box: Contextualising the Precautionary Principle in the European Union" *in* UNCERTAIN RISKS REGULATED (Everson and Vos, eds. 2008).

[22] Advocates of the Strong Precautionary Principle write primarily outside of the legal academy, perhaps reflecting the marginalization of the Principle in past legal scholarship. For work supporting the Principle, see Carl Cranor. *Toward Understanding Aspects of the Precautionary Principle*, 29 JOURNAL OF MEDICINE AND PHILOSOPHY 259 (2004); collected essays in PRECAUTION, ENVIRONMENTAL SCIENCE, AND PREVENTIVE PUBLIC POLICY (Joel Tickner, *ed.* 2003); Sven Ove Hansson, *Can We Reverse the Burden of Proof*, 90 TOXICOLOGY LETTERS 223 (1997); collected essays in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE (Raffensberger & Tickner 2001).

context of TSCA reform legislation, while avoiding the parade of horribles presented by the critics. This debate over TSCA reform will likely determine the rules that will govern toxicity research, chemical exposure limits, and preventing cancer from environmental pollutants through the middle of the 21st Century. My aim, therefore, is not only to refute the dismissive scholarship on a theoretical level, but also to lay the groundwork for stronger next-generation chemical legislation in the United States.

This Article proceeds in three Parts. In Part I, I provide a brief introduction to the concept of precaution in risk regulation, distinguishing the Strong Precautionary Principle from its weaker versions. Then, directly considering the merits of Strong Precaution, I justify it both instrumentally, as an incentive to develop information on public health and environmental risks, and deontologically, as a confirmation of the moral obligations of those who seek to market potentially hazardous products.

In Part II, I counter the critics' objections to the Strong Precautionary Principle. Cass Sunstein and other critics contend that Strong Precaution represents a new and radical alternative to dominant risk management paradigms grounded in cost-benefit analysis.[23] I show, on the other hand, that Strong Precaution is already deeply rooted in American law. It forms the basis for numerous licensing, permitting, and pre-approval programs that are cornerstones of public health and environmental protection in the United States.[24] The Food and Drug Administration review process for new drugs is the most well-known of hundreds of examples.

I demonstrate that the Principle is not nearly as inflexible, extreme, or cost-insensitive as the Principle's detractors would have us believe. Sunstein's claim that Strong Precaution inevitably leads to "paralysis" is hyperbolic mischaracterization. Applied properly, the Strong Precautionary Principle helps to uncover regulatory alternatives and permits considerations of trade-offs, while raising a wider set of questions than traditional cost-benefit analysis.[25] I concede in Part II that Strong Precaution should not be universalized as a dogmatic solution for every risk our society faces, yet critics intent on blasting Strong Precaution are ignoring the Principle's "contextual

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[23] *See*, *e.g.*, John D. Graham, *supra* note __ ("[W]e do not recognize any universal precautionary principle. We consider it to be a mythical concept, perhaps like a unicorn."); Lawrence A. Kogan, *What Goes Around Comes Around: How UNCLOS Ratification Will Herald Europe's Precautionary Principle as U.S. Law*, 7 SANTA CLARA J. INT'L L. 23, 27 (2009) ("[T]he Precautionary Principle . . . entails a radical change in outlook.").

[24] Prior examples of government-as-risk-gatekeeper are not all success stories (witness the BP oil spill). Implementation is everything, and the success of a Strong Precautionary strategy depends critically on high-quality scientific information and capable oversight personnel.

[25] *See* JOEL TICKNER, "A Map Toward Precautionary Decision Making," *in* RAFFENSBERGER & TICKNER, PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT, *supra* note ___ (noting that the precautionary principle asks a different set of questions from traditional risk assessment: "How much contamination can be avoided while still maintaining necessary values? What are the alternatives to this product or activity that achieve the desired goal? Does society need this activity in the first place?").

rationality."[26] That is, they are ignoring the arenas of risk management where the Principle's default presumptions, burden shifting, and *ex ante* review of risks are eminently sensible.

In Part III, I argue that in toxic chemical regulation, protecting public health and the environment demands a Strong Precautionary approach with several components. I advocate shifting the burden of proof for the most hazardous classes of chemicals and allowing limited avenues for continued marketing of such chemicals (which I call "regulatory offramps") if the manufacturer can demonstrate that the chemical can be used safely. Shifting the burden of proof is, to be sure, just one element of dozens of needed changes in TSCA. It is also the game changer. It will dramatically alter incentives, loosen informational bottlenecks, and end our blithe acceptance of "flying blind" in chemical risk management.

I. STRONG PRECAUTION AND RISK REGULATION

Precaution in risk regulation is controversial, in part, because of a lack of consensus on what precaution means. A vast number of verbal formulations have been developed to describe the concept of precaution, from the simplistic "better safe than sorry" to complicated, multi-part definitions.[27] Collectively, these formulations are often called the Precautionary Principle, but more accurately they should be called Precautionary Principles, because they vary widely and are not synonymous with each other. In this Part, I distinguish "weak" versions of the Precautionary Principle from "strong" versions, clearing away some definitional confusion to crystallize this debate. I then directly address the merits of Strong Precaution, before turning, in Part II, to rebutting the critics.

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[26] David Dana, *The Contextual Rationality of the Precautionary Principle*, 35 Queen's Law Journal (2009).

[27] *See, e.g.,* James E. Hickey & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 VA. ENVTL. L.J. 423, 432-36 (1995) (identifying fourteen articulations of the precautionary principle in major international environmental instruments); Per Sandin, *Dimensions of the Precautionary Principle*, 5 HUMAN AND ECOLOGICAL RISK ASSESSMENT 889 (1999) (cataloging nineteen different versions of the precautionary principle); Joel A. Tickner, David Kriebel, & Sara Wright, *A Compass for Health: Rethinking Precaution and Its Role in Science and Public Health*, 32 INT'L J. EPIDEMIOLOGY 489 (2003) (describing the five-part definition of precaution in the 2001 Lowell Statement on Science and the Precautionary Principle).

A. DEFINING THE TERMS

1. The Weak Precautionary Principle

"Weak" versions of the Precautionary Principle stand for the proposition that regulators should be empowered to address risk in contexts of scientific uncertainty–that is, even before regulators fully understand the nature or extent of risk. One widely cited "weak" version of the Precautionary Principle is contained in the Rio Declaration, adopted by consensus by 175 countries (including the United States) at the Earth Summit in 1992. Principle 15 of the Rio Declaration states:

> In order to protect the environment, the precautionary approach shall be widely adopted by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as an excuse to postpone cost effective measures to prevent environmental degradation.[28]

The "weak" Precautionary Principle is a sensible guide for risk management. It reflects that risk assessment is an uncertain science and that serious harm might occur if we postpone regulatory action until all risks from an activity are fully understood. As a 2001 European Environment Agency study, *Late Lessons from Early Warnings* documented, there have been numerous cases on both sides of the Atlantic of governments' inability or refusal to regulate until long after risks were widely known, such as asbestos, DES, tobacco, and mad cow disease.[29]

"Weak" versions of the precautionary principle, similar to the Rio Declaration, have been adopted in the Treaty on the Functioning of the European Union, other multilateral treaties, and decisions of international tribunals.[30] Most of the U.S. environmental and public health statutes passed in the 1970s can be said to incorporate, implicitly, weak precautionary

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[28] Rio Declaration on Environment and Development, princ. 15, U.N. Doc. A/CONF.151/5/Rev. 1 (1992), *reprinted in* 31 I.L.M. 874, 879.

[29] *See* EUROPEAN ENVIRONMENT AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896-2000 (2001).

[30] *See* Treaty on the Functioning of the European Union, May 5, 2008, art. 191, 2008 O.J. (C.115); Convention on Biological Diversity, May 22, 1992, pmbl., 31 I.L.M. 818; United Nations Framework Convention on Climate Change, art. 3(3)May 9, 1992, S. Treaty Doc. No. 102-38 (1992), 1771 U.N.T.S. 108, reprinted in, 31 I.L.M. 849; Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa, Jan. 29, 1991, art. 4, ¶ 3(f)-(h), 30 I.L.M. 773, 781-82 (1991).

concepts.[31] Statutes such as the Clean Air Act and the Resource Conservation and Recovery Act have preventive goals, and they generally allow regulators to act on indications of potential harm from an activity without first obtaining "full" scientific certainty that harm will in fact occur.[32]

Cass Sunstein, who has been the most vociferous critic of Strong Precaution, notably favors embracing the Weak Precautionary Principle in risk regulation. According to Sunstein, that principle suggests "quite sensibly that a lack of decisive evidence of harm should not be a ground for refusing to regulate."[33] Because the Weak Precautionary Principle does not prescribe any particular regulatory measures, some commentators have argued that it is essentially vacuous–a "feeble addition to the regulatory landscape."[34] Sunstein agrees. He concludes that the Weak Precautionary Principle is a mere "truism," so "banal" as to be hardly worth further scholarly exploration.[35]

Sunstein's rather bland characterization is surprising, however, against a backdrop of two decades of acrimonious debates over the Weak Precautionary Principle, inside and outside the academy. Scholars have squared off over how the Weak Precautionary Principle should be implemented; whether it is consistent with quantitative risk assessment and cost benefit analysis, or represents an alternate paradigm; and whether actually animates American law or has instead been eroded through unreasonably stringent "hard look" review and judicial demands for comprehensive administrative records.[36] In Washington, there is a widespread perception that weak versions of Precautionary Principle give extra "weight" to environmental factors in risk decision-making and would lead to abandonment of decision

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[31] As John Applegate has noted, while there is no U.S. statute that explicitly references the Precautionary Principle, the Principle is reflected operationally in six kinds of provisions commonly found in U.S. environmental statutes: planning and alternatives analysis, special regulatory treatment of certain categories of harm, the transition from tort-based to risk-based regulation, adoption of margins of safety in standard setting, the policy of erring on the side of safety in risk management, and the shifting of the burden of proof in some contexts. *See* John Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUMAN AND ECOLOGICAL RISK ASSESSMENT 413, 420 (2000).

[32] *See* Daniel Bodansky, *The Precautionary Principle in U.S. Environmental Law*, *in* INTERPRETING THE PRECAUTIONARY PRINCIPLE 31-61 (O'Riordan & Cameron, eds., 1994). Despite clearly precautionary language in many U.S. environmental and health statutes, many scholars contend that the precautionary thrust of the statutes have been eroded through changes to the U.S. regulatory system since the 1970s, including comprehensive cost-benefit analysis requirements and more skeptical judicial review. *See, e.g.*, Applegate, *The Precautionary Preference*, *supra* note ___, at 430-31.

[33] SUNSTEIN, LAWS OF FEAR, *supra* note __, at 18. *See also* Jonathan Wiener, "Precaution in a Multirisk World," *in* HUMAN AND ECOLOGICAL RISK ASSESSMENT: THEORY AND PRACTICE (Dennis J. Paustenbach ed. 2002) (explaining that weak versions of the Principle are unobjectionable).

[34] Edward Soule, *Assessing the Precautionary Principle*, 14 PUBLIC AFFAIRS QUARTERLY 309, 315 (2000).

[35] SUNSTEIN, LAWS OF FEAR, *supra* note __ at 24.

[36] *See* Robert Percival, *Who's Afraid of the Precautionary Principle, supra* note __, at __ (arguing that "despite the regulatory statutes' commitment to preventative regulation," environmental law remains largely reactive, and regulation is rarely imposed until damage to public health has occurred).

making based on "sound science" in favor of regulation based on speculation and supposition of various threats to the environment. Public statements to this effect are voluminous.[37] These debates over the meaning of precaution are, in essence, a proxy battle for much larger debates over how stringent government regulation should be, what kinds of margins of safety should be built into it, and when it should be deployed.

Many of these same debates carry over to the Strong Precautionary Principle as well. Yet while weak versions of the Precautionary Principle have dozens of advocates in the legal academy, few scholars have offered a sustained defense of Strong Precaution. This perhaps reflects muddled definitions, as many scholars have advocated embracing the "Precautionary Principle" without defining which version of the Principle they mean.[38] The lack of attention to Strong Precaution might also reflect that weaker versions of the principle appear more "tame" or acceptable to policymakers, and scholars may find them easier to defend.[39] But Sunstein is right on one issue: compared to the Weak Precautionary Principle, the viability of the Strong Precautionary Principle is a much more provocative scholarly question.

2. The Strong Precautionary Principle

Both weak and strong versions of the Precautionary Principle emphasize anticipation of harm and taking preventive measures in the face of uncertainty, but there are some important differences between the two approaches. Whereas weak versions of the Precautionary Principle *permit*

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[37] *See* 150 CONG. REC. S11291-04 (2004) (statement of Sen. Inhofe) (global warming "alarmists often trot out a concept known as the precautionary principle–which is that it is better to be safe than sorry. But . . .[t]he science of global warming is uncertain, the costs of capping our economy with carbon restriction are high, and even if the doomsayers were correct, it would do little to nothing to reduce the temperature increases."); GARY E. MARCHANT & KENNETH L. MOSSMAN, ARBITRARY AND CAPRICIOUS: THE PRECAUTIONARY PRINCIPLE IN THE EUROPEAN UNION COURTS 1 (2004) ("Perhaps the most common criticism of the precautionary principle . . . is that it is inherently ambiguous and arbitrary."); Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 506-07 (2008) (stating that the precautionary principle asks legislators "to evaluate public risks based on political, ethical, and/or social science concerns, rather than upon common-sense or hard, empirical, sound science"); Soule, *supra* note ___, at 313; Partnership for Sound Science in Environmental Policy, Precautionary Principle Overview, http://cicc.org/jru/031306/PP_Overview.pdf (last visited Feb. 18, 2010) ("[T]he Precautionary Principle diverts the attention of regulators and resources from real issues to speculative concerns. . . . Implementing the Precautionary Principle can cause more harm than good . . .").

[38] The Treaty on the Functioning of the European Union is typical in this regard, as it declares that EU environmental policy "shall be based on the precautionary principle," without defining the principle in the treaty. *See* Treaty on the Functioning of the European Union, Article 174. The European Commission has issued its own (caveated) interpretation of the meaning of the precautionary principle. *See* EUROPEAN COMMISSION, COMMUNICATION ON THE PRECAUTIONARY PRINCIPLE, February 2, 2000.

[39] *See* John Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL. R. 13 (2002) (documenting progressively softer and less aggressive interpretations of the precautionary principle in risk regulation since the early 1990s).

government to regulate risks under conditions of scientific uncertainty, the Strong Precautionary Principle suggests that some precautionary regulation should be a *default response* to serious risks under conditions of scientific uncertainty. Such regulation could range from a blanket prohibition on a proposed technology or a dangerous activity to less aggressive defaults, such as use restrictions or warning requirements.[40] Furthermore, whereas weak versions are primarily concerned with the timing of *governmental* decision making, the Strong Precautionary Principle explicitly places the burden on the proponent of the risk-creating activity to overcome the default by proving that risks are acceptable or reasonable.[41]

As noted in the Introduction, I define the Strong Precautionary Principle as the view that: 1) regulation should presumptively be applied when an activity or product poses serious threats to human health or the environment, even if scientific uncertainty precludes a full understanding of the nature or extent of the threats; and 2) the burden of overcoming the presumption in favor of regulation lies with the proponent of the risky activity or product.

My definition roughly parallels the Wingspread Declaration, a statement on precaution adopted by a group of prominent physicians, scholars, and environmentalists in 1998. The Wingspread Declaration was primarily directed at emerging toxic risks, such as endocrine disrupting chemicals. Its language is broad, however, and it is often described in the literature as emblematic of the Strong Precautionary Principle:[42]

> When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context, the proponent of the activity, rather than the public, should bear the burden of proof.[43]

I do not adopt the Wingspread Declaration as my own definition, however, because it does not include the proviso that "threats" must be

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[40] The precautionary measures that can be applied under the Principle will necessarily vary, depending on the magnitude of the expected risk and the strength of the scientific evidence. *See infra* Part II.

[41] By emphasizing that precautionary measures "should be taken" in response to threats to human health or the environment, the Strong Precautionary Principle represents an affirmative call to action, whereas the Weak Precautionary Principle is phrased in the negative (scientific uncertainty should not be used as an excuse to postpone cost-effective regulatory measures) and, therefore, can be seen as less demanding or less action-forcing.

[42] *See, e.g.,* SUNSTEIN, LAWS OF FEAR, *supra* note __ at 19; EDWARD SOULE, MORALITY & MARKETS: THE ETHICS OF GOVERNMENT REGULATION 147 (2003).

[43] RAFFENSBERGER & TICKNER, *supra* note __ at app. A, 353-54 (quoting the Wingspread Statement on the Precautionary Principle). *See also id.* at 7-9 (discussing the history of the Wingspread Conference).

"serious." For the Principle to be workable, there must be some serious risk threshold for invoking precautionary measures and a shift in the burden of proof. Precautionary measures (such as bans, restrictions, or labeling/warning requirements) can be expensive and complex to implement, and they should not be invoked for trivial dangers, nor for dangers where there is no credible evidence of a risk.[44]

Looking at my definition of Strong Precaution, it is clear that some key issues, such as the degree of threat that will trigger burden shifting, the precise precautionary measures that should be taken, and how much information on risk the proponent must supply, are not specified in the Principle itself. These issues must be fleshed out in legislation and will necessarily vary from one regulatory context to another.[45] Legislation might specify, for example, that to commence with an activity or introduction of a product, the proponent must prove "no substantial risk" to human health. Or, the proponent might be required to prove that the benefits outweigh the risks, or that the activity will be conducted in accordance with predetermined safety standards. Like any principle, Strong Precaution outlines a framework or stance toward decision-making, not a meticulously detailed prescription for action. No serious advocate of precautionary approaches would contend that a one or two sentence principle is the total guidance that regulators need to manage complex health and environmental risks.[46]

Generality does not equate with vacuity, however. Strong Precaution is not an empty "truism." It creates a recognizable architecture establishing who carries the burden of proof on complex public health and environmental controversies. The Principle can be compared to other similarly broad principles of American government, such as Due Process or Equal Protection, whose meaning has been developed through repeated application in particular cases and controversies. Or, since I argue that the Principle need not be universally applied, the Principle can be compared to other, non-constitutional principles that have provided loose guidance to successive administrations,

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[44] There are many other formulations of the Strong Precautionary Principle in the literature, including some that suggest that any risk-producing activity must be halted until it is proven safe. These highly aggressive, zero-risk standards should be rejected, as I explain in Part II. These outliers need not deflect our attention from exploring versions of Strong Precaution that have some political viability, however. Defending the Strong Precautionary Principle does not mean aligning oneself with the most extreme, risk-intolerant formulations of it.

[45] *See* Douglas A. Kysar, *It Might Have Been*: *Risk, Precaution and Opportunity Costs*, 22 J. LAND USE & ENVTL. L. 1, 7 n32 (2006) ("Important implementation issues include: (1) the degree of credibility or seriousness of threat required in order to trigger the precautionary obligation; (2) the precise form that regulatory response should take; (3) and the manner in which the regulatory response should be revisited and revised over time.").

[46] *See* John Applegate, "Embracing a Precautionary Approach to Climate Change," *in* ECONOMIC THOUGHT AND U.S. CLIMATE CHANGE POLICY (David Driesen, ed. 2010) (noting that the Rio Declaration required 27 principles to outline a broad framework for sustainable development and that the precautionary principle is but one component of this framework).

such as the Containment Doctrine during the Cold War. The Containment Doctrine was broadly defined and was subject to multiple interpretations and bitter disagreements about its meaning.[47] Its full scope was determined only through implementation in particular decisions and crises.[48] Despite its generality, however, the Containment Doctrine provided a framework for action and helped to unite disparate factions of Congress and defense and foreign policy agencies against the Soviet military threat.[49] The Strong Precautionary Principle could serve a similar function by providing a framework for addressing serious environmental and public health risks.

One key architectural choice that needs to be made in implementing the Strong Precautionary Principle is deciding *who* will determine if the proponent of the activity has met its burden of proof. Literature on the Strong Precautionary Principle is rarely explicit about this core issue.[50] Indeed, in the literature, the identity of "the decider" has received scant attention. But the logic of Strong Precaution is that some entity must judge whether the "proponent of the activity" has presented sufficient evidence to demonstrate that risks are acceptable and that the proposed activity should be allowed to proceed.

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[47] The founding documents of the Containment strategy, such as National Security Memorandum 68, used broad and open-ended language to describe the kinds of U.S. responses that would be appropriate to counter Soviet power and expansionism. The meaning of Containment, therefore, was left to a discursive process of interpretation and implementation that occurred over decades among the White House, Congress, the Pentagon, and other national security agencies. NSC 68 stated, in part:

> For us the role of military power is to serve the national purpose by deterring an attack upon us while we seek by other means to create an environment in which our free society can flourish… Our free society, confronted by a threat to its basic values, naturally will take such action, including the use of military force, as may be required to protect those values. In the words of the *Federalist* (No. 28) "The means to be employed must be proportioned to the extent of the mischief." … Our aim in applying force must be to compel the acceptance of terms consistent with our objectives, and our capabilities for the application of force should, therefore, within the limits of what we can sustain over the long pull, be congruent to the range of tasks which we may encounter.

NATIONAL SECURITY COUNCIL, NSC-68: A REPORT TO THE NATIONAL SECURITY COUNCIL BY THE EXECUTIVE SECRETARY ON UNITED STATES OBJECTIVES AND PROGRAMS FOR NATIONAL SECURITY (Apr. 14, 1950), *reprinted in* U.S. DEP'T OF STATE, FOREIGN RELATIONS OF THE UNITED STATES: 1950 NATIONAL SECURITY AFFAIRS, FOREIGN AND ECONOMIC POLICY 234-93 (1974).

[48] *See* ROGER S. WHITCOMB, THE COLD WAR IN RETROSPECT: THE FORMATIVE YEARS 87-88 (1998).

[49] *See id.* at 93-101.

[50] The Lowell Statement on Science and Precautionary Principle, for example, states that "[r]esponsibility" should be placed on "originators of potentially dangerous activities to thoroughly study and minimize risks, and to evaluate and choose the safest alternatives to meet a particular need, *with independent review*." Tickner et. al., A Compass for Health, *supra* note 24. The entity that should conduct that independent review is not specified, however. *See also* Wingspread Declaration, *supra* note 40 (stating that the "proponent of the activity… should bear the burden of proof" but not identifying who will judge whether the proponent has met that burden).

In most cases, the decider will be a government agency, and the preventive thrust of Strong Precaution further implies that this governmental review of risks should occur *before* the activity commences or the potentially risky product reaches the market. For these reasons, I characterize the Strong Precautionary Principle as an *ex ante* approach to risk in which government acts in a risk gatekeeping role. If the Weak Precautionary Principle implies a relatively libertarian view of the world, in which regulators are empowered (but not required) to intervene in the marketplace to address externalities ("threats of serious or irreversible damage to the environment"), then the Strong Precautionary Principle implies a more vigorous role for government to determine, *ex ante*, whether certain activities should be allowed to commence, or certain products should be allowed to be marketed. In practice, Strong Precaution is usually operationalized through a governmental licensing, permitting, or pre-approval system. In this context, then, the private proponent bears both the burden of production (researching the nature and extent of risks and making such evidence available for governmental review) and the burden of persuasion (demonstrating to the decision-maker that specific statutory or regulatory safety standards have been met).

B. THE SALUTARY SIGNALS OF STRONG PRECAUTION

In a 1999 magazine article, Ronald Bailey, a libertarian science writer, lampooned the Strong Precautionary Principle, arguing that the Principle warps the "proverbial wisdom" of "look before you leap."[51] The Principle, he wrote facetiously, commands that citizens justify every leap in order to receive their "leaping license" from a "Federal Leaping Commission."[52] "In effect," Bailey charged, "before you or anybody else can leap, you will not only have to look beforehand in the prescribed manner, you will have to prove that if you leap, you won't be hurt, nor will any other living thing be hurt, now and for all time. And if you can't prove all of that, the commission will refuse to grant you a leaping license."[53]

This is amusing parody, but it completely ignores why Strong Precaution is fully justifiable in some regulatory contexts, including chemical regulation.

Strong Precaution sends salutary signals to risk-creators: it compels them to research the risks of their activities and sends an unmistakable message that we will not wait until damage is done before requiring some investigation and justification of the potential hazards. This framework makes sense where a risk-creator's "leap" might cause widespread harm to others

[51] Ronald Bailey, *Precautionary Tale*, REASON MAGAZINE (April 1999).
[52] *Id.*
[53] *Id.*

(think of mercury pollution from a power plant or a manufacturers' decision to use endocrine disrupting chemicals in children's toys). What Bailey is missing is that serious externalities turn private choice into public risks. If *ex post* tort remedies or *ex post* regulatory interventions are likely to be inadequate in the event that damage does occur, then it becomes reasonable to ask the "leaper" to justify why that activity should take place and to place some limits upon it, before potential harm occurs.[54]

A likely prospect of *ex post* regulatory failure, in other words, enhances the desirability of *ex ante* regulatory gatekeeping. In the context of toxic chemicals, "leaping" (introducing untested chemicals into commerce) may lead to harm that is nonconsensual or unknown to the injured party, to diffuse low-level harms, or to serious harm that may occur decades after the leap occurs. Given that diffuse harm from chemicals is poorly addressed through tort suits or post-market regulatory interventions, requiring a chemical manufacturer to undertake *ex ante* investigation and justification of risks, far from being excessive or extreme, is sensible public policy.

Strong Precaution establishes this risk gatekeeping mechanism. It is both a procedural tool for incentivizing risk research and a substantive mechanism for protecting public health.

Procedurally, the Principle provides a profit motive for firms to undertake research on the health and environmental risks of their products and activities.[55] Bearing the burden of proof, firms will have a keen interest in developing the risk assessment data that will facilitate expeditious approval by government regulators (consider the investment that drug manufacturers make in their clinical trials and in their New Drug Applications to the FDA). The Principle flips the perverse incentives that occur under a regulatory regime with a governmental burden of proof, in which regulated firms stand to gain by not developing, or by obfuscating, important risk assessment data.

With some exceptions, a governmental burden of proof is the norm in American environmental and public health law.[56] As Wendy Wagner has observed, the governmental burden of proof under TSCA has encouraged chemical manufacturers to maintain "strategic ignorance" by not developing

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[54] *See* DOUGLAS KYSAR, REGULATING FROM NOWHERE at __ ("Proponents of the precautionary approach . . . emphasize the limits of human knowledge and the frequency of unpleasant surprises from technology and industrial development; thus, they advocate an ex ante governmental stance of precaution whenever a proposed activity meets some threshold possibility of causing severe harm to human health or the environment.).

[55] The informational benefits of the Precautionary Principle have been widely noted in the literature. *See* Applegate, The Precautionary Principle: An American Perspective (2000); Carl Cranor, "Asymmetric Information, the Precautionary Principle, and Burdens of Proof," *in* RAFFENSBERGER & TICKNER, supra note ___.

[56] *See* Administrative Procedure Act, 5 U.S.C. §556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.").

toxicity data on their own products.[57] TSCA does not establish routine risk assessment requirements for chemicals, but instead authorizes EPA to order risk assessments on a case-by-case basis (each EPA test rule is a major rulemaking requiring two to ten years for the agency to finalize).[58] As a result, thirty-five years after TSCA's enactment, we still lack basic toxicity data for the vast majority of chemicals in commerce today.[59] As Wagner and David Dana have explained, the threat of tort liability does make up for this deficiency. In fact, the tort system likely reinforces strategic ignorance, as it provides an incentive to avoid any research on product hazards that could trigger *ex post* liability.[60]

A regulatory regime that combines a high burden of proof on an agency with a data-starved informational environment is likely to lead to regulatory paralysis. This has been the story of TSCA since its enactment.

In contrast, the Strong Precautionary Principle recognizes that the supply of data on the risks of a given product or activity is not exogenous to the regulatory system. Rather, incentives built into the regulatory system help determine whether firms will undertake basic research on the health and environmental effects of their products and activities.[61] As Jim Salzman and Doug Kysar observed, shifting the burden of proof "works to counterbalance certain perceived structural asymmetries of the unregulated market" and "actively deploy[s] private actors in service of the public's informational needs."[62] The Strong Precautionary Principle, in other words, acts as an information-forcing device. It promotes data gathering to inform governmental risk assessment. It also provides risk information to private markets so that individuals can make choices about the risks they want to take on and companies can compete on safety as well as product characteristics.

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[57] Wagner, *Commons Ignorance*, *supra* note __, at 1685.

[58] Government Accountability Office, Options Exist 19 (2005).

[59] This "data drought" has many causes, including that: 1) TSCA provides no mandate for routine toxicity testing for most chemicals on the market, 2) the statute in practice requires the EPA to assemble substantial information on the risks of a chemical just to issue an order to require testing; and 3) industry has frequently litigated over the few testing orders that EPA has issued. *See* Sachs, *Jumping the Pond*, *supra* note ___, at 1827-28 (outlining features of TSCA that limit data supply).

[60] *See* Wagner, *Commons Ignorance*, *supra* note __ at ___; *see also* Dana, *The Contextual Rationality of the Precautionary Principle*, *supra* note __, at ___ (explaining that "rational, profit-maximizing corporations and other actors will not invest in testing and monitoring" under certain conditions, including "when particular products pose theoretical risks but not empirically-established ones; when any adverse effects would likely occur only in the distant future, and when the link between the product and any distant adverse effects could well escape notice, or at least be difficult to establish as a matter of 'but for' causation").

[61] Kysar, *It Might Have Been*, *supra* note __ at 24 ("Proponents of the Precautionary Principle recognize that uncertainty itself is a subject of power, influence, and control… Thus, the content of scientific knowledge and the manner of its production are not treated exogenously by the Precautionary Principle, but instead are made a central focus of the regulatory program.").

[62] Douglas A. Kysar & James Salzman, *Harnessing the Power of Information for the Next Generation of Environmental Law*, 86 TEX. L. REV. (2009).

New European Union chemical legislation, called Registration, Evaluation, and Authorization of Chemicals (REACH),[63] provides one prominent example of the information-forcing incentives of the Strong Precautionary Principle. In REACH, the EU implemented the concept of "No Data, No Market," under which manufacturers and importers are obligated to submit a basic toxicity data set for any chemical produced or imported in the EU in a volume of ten tons or more.[64] Unlike TSCA, REACH is a true market-access regulation. The submission of the data set is made a precondition of access to the €537 billion European chemical market.[65] By rewarding knowledge and making firms responsible for data production, REACH is helping to end the data drought that plagued European chemical regulation since the early 1980s.[66] U.S. chemical firms doing business in Europe are already subject to REACH, and as I showed in my previous article,[67] the implementation of REACH is likely to undermine objections of U.S. chemical manufacturers that routine toxicity testing is too expensive or cumbersome.

While providing an important framework for gathering data, the Strong Precautionary Principle should be viewed as more than an informational tool. In chemical regulation, a strategy of "filling" data gaps with more research can only take us so far.[68] Uncertainty about key issues, such as low-dose effects of chemicals, may not be resolvable even through extensive testing. The Strong Precautionary Principle also offers an important means of "bridging" scientific uncertainty. It alters default decision rules for how government should respond when scientific uncertainty prevents a complete assessment of environmental or health risks.

The primary goal under Strong Precaution is to avoid Type II (false negative) decision errors. In other words, Strong Precaution aims to avoid the false conclusion that there is low risk for products and activities that in fact pose grave risks. Through shifting the burden of proof, if the proponent can

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[63] Commission Regulation 1907/2006, 2006 O.J. (L396) 1 (EC) [hereinafter REACH].

[64] Sachs, *Jumping the Pond*, *supra* note __, at 1834-35.

[65] *Id.* The preamble to REACH states that the regulation "is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment." REACH, art. 1(1)(3).

[66] Only 70 chemical risk assessments were required by government regulators in the prior 30 years, out of a universe of more than 30,000 chemicals produced in quantities greater than one ton. Sachs, Jumping the Pond, *supra* note __ at 1333-34.

[67] *See id*. at 1862-67 (analyzing the extra-territorial impacts of REACH).

[68] John Applegate has helpfully distinguished strategies to develop more risk assessment data in chemical regulation ("filling strategies"), which he argues have limited effectiveness, from strategies designed to "bridge" the data gap by reducing the regulatory demand for information. Bridging strategies include technology standards, shifts in the burden of proof, and incentives for safer substitute chemicals. *See* John Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Informatio*n, 86 TEXAS L. REV. 1365 (2008). *See also* David E. Adelman, *A Cautiously Pessimistic Appraisal of Trends in Toxics Regulation*, 32 WASH U. J. OF L. & POLICY 377, 381 (2010) ("toxics regulation should avoid the deep epistemic gaps to the extent that it can.").

develop only scant information on the nature or extent of risk, Strong Precaution applies a default prohibition (or at least restriction) on the activity or product. Many analysts have described this as placing a "hold" on the risk-producing activity until more informed consideration of the risks is possible.[69] Strong Precaution provides a window of opportunity for advance review of risks,[70] and in implementing the Principle in a particular statute, legislators are making a decision to err on the side of caution when there are conflicting studies or insufficient information to characterize risks accurately.[71]

In contrast, many current regulatory regimes, including TSCA, place a premium on avoidance of Type I (false positive) errors. They start with the assumption that risks are zero, unless a government agency gathers data and affirmatively proves the presence of substantial risk to trigger regulation. Under TSCA, EPA must meet this burden – to prove "unreasonable risk" under Section 6 -- under searching standards of judicial review, and the agency has succeeded in restricting only five chemicals under that standard in the thirty-five year history of the Act. The ostensible regulatory authority of the EPA has been crippled in practice since 1991, when EPA's regulation banning most uses of asbestos was struck down by the Fifth Circuit in *Corrosion Proof Fittings v. EPA*.[72] That case has been widely viewed as the death knell for EPA regulation of existing chemicals under TSCA.

Regulatory regimes designed to avoid Type I errors, such as TSCA, are not value neutral. They in fact reflect an implicit assumption that the current economic order and mix of products in the marketplace is to be particularly valued and should not be disturbed absent a very high threshold showing by the government.[73]

Each default decision rule has its potential drawbacks. Legislation designed to avoid Type I errors raises the possibility of regulation that comes "too late" or that is underprotective, while Strong Precaution raises the possibility of regulation that is "too early" or overprotective. But some default decision rule must be chosen, and we should not dismiss the default presumptions of Strong Precaution out of hand. Rather, the most pressing

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[69] RAFFENSBERGER & TICKNER, *supra* note __ (introduction); Applegate, *Precautionary Preference*, *supra* note ___.

[70] *See* Joel Tickner, *A Map Toward Precautionary Decision Making*, *in* RAFFENSBERGER & TICKNER, *supra* note ___ at 163 ("[The] shift in presumption places the responsibility for demonstrating safety and preventing harm on those undertaking potentially harmful activities. Accordingly, humans and the environment receive the benefit of the doubt…, rather than a particular substance or action.").

[71] Sven Ove Hansson, *Can We Reverse the Burden of Proof?*, *supra* note ___ at 227 (arguing that in implementing a burden shift in chemical regulation, where there are "diverging but scientifically sound interpretations of toxicological data, precedence should be given to the interpretations that support the most pessimistic predictions with respect to human health.").

[72] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

[73] Carl Crannor, *Toward Understanding Aspects of the Precautionary Principle*, 29 JOURNAL OF MEDICINE AND PHILOSOPHY 259, 271 (2004).

question is deciding which default decision rules makes sense in particular areas of law.

In chemical regulation, it has become clear that Congress erred on the side of unsafety, or as Wendy Wagner put it, "unprecaution."[74] As I explain in Part III, implementing the Strong Precautionary Principle would redress many of the historic flaws in TSCA. The question is: will Congress adopt this framework for chemical risk management, given how the critics have tarnished it?

II RESCUING THE STRONG PRECAUTIONARY PRINCIPLE FROM ITS CRITICS

The Strong Precautionary Principle has become a punching bag for many scholars of risk regulation. Cass Sunstein and other prominent scholars have unsparingly attacked it, and lacking many defenders, the Principle's reputation has been battered.

In this Part, I respond to these critiques in an effort to rehabilitate the Strong Precautionary Principle. My rebuttal here is qualified. I fully concede that the Strong Precautionary Principle cannot be a universally-applicable approach to all health and environmental dangers that society faces. But it can serve as the platform for protective risk decision-making in discrete areas of law, including chemical regulation. By caricaturing the Principle as extreme and dismissing it out-of-hand as unworkable, the Principle's detractors have overlooked both its utility and the myriad examples where it already operates successfully in American law.

A. THE VIEWS OF THE CRITICS

The Strong Precautionary Principle has been chastised from many angles, but some common themes emerge in the literature of the critics. For example, critics often maintain that the Principle is extreme, inflexible, anti-science, anti-growth, or anti-technology.[75] Because Strong Precaution shifts the burden of proof, critics allege that its implementation would prevent promising new technologies from getting off the ground, especially in emerging fields with a high degree of uncertainty about risks.[76] Harvey Miller

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[74] Wendy E. Wagner, *The Precautionary Principle and Chemical Regulations in the U.S.*, 6 HUM. & ECOL. RISK ASSESSMENT 459, 468 (2000) (arguing that TSCA reflects an "unprecautionary principle").

[75] *See, e.g.*, J. Morris, *Defining the Precautionary Principle*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE (2000); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996). John Graham, The Perils of the Precautionary Principle: Lessons from the American and European Experience, Heritage Lecture #81 (January 15, 2004).

[76] *See* SUNSTEIN, LAWS OF FEAR, *supra* note___ at 25 (arguing that the Precautionary Principle would "eliminate technologies and strategies that make human lives easier, more convenient, healthier, and longer"); Graham, The Perils of the Precautionary Principle, *supra* note __(questioning what would have happened to "electricity, the internal combustion engine, plastics, pharmaceuticals, the Internet, the

and Gregory Conko, charge, for example, that "[i]f the precautionary principle had been applied decades ago to innovations such as polio vaccines and antibiotics, . . . that precaution would have come at the expense of millions of lives lost to infectious diseases."[77] Many critics also suggest that Strong Precaution requires that manufacturers prove "zero-risk" or "absolute safety" for an activity to proceed,[78] which are impossible standards to meet. Others suggest that the Principle will be applied on the mere "conjecture"[79] or "speculation"[80] of a threat to health or the environment, suppressing important technologies without any scientific basis. In addition, because of the strong government role and the shift in the burden of proof, critics have argued that Strong Precaution is overly statist; its "guilty-until-proven-innocent" approach to addressing risk is allegedly contrary to American values.[81]

Cass Sunstein, the leading academic critic of Strong Precaution, has attacked the Strong Precautionary Principle from a different vantage point. He claims that the Principle is, ultimately, paralyzing as an approach to risk decision-making. If the Strong Precautionary Principle presumptively requires regulation of activities that present serious threats to health, safety, or the environment, then, according to Sunstein, the Principle will paralyze decision makers because threats may be created both by regulatory inaction (allowing an activity to continue) and by regulatory action (prohibiting the activity). Regulation itself has costs and potential risks. For instance, harm may potentially occur from the introduction of genetically modified foods, but harm may also occur (from increased hunger or more widespread pesticide use) if genetically modified foods are prohibited.[82] With respect to drug approvals, Sunstein notes that the stringent FDA review requirements for new drugs may help to avoid introduction of dangerous medications, but the delay involved in FDA review (so-called "drug lag") means that life-saving drugs may not reach patients who need them.[83] Sunstein questions: "Is it precautionary to require

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cell phone and so forth" if a strong version of the precautionary principle had been in place since 1850);

[77] Harvey I. Miller and Gregory Conko, *The Science of Biotechnology Meets the Politics of Global Regulation,* Issues in Science and Technology Online (2000), available at http://www.nap.edu/issues/17.1/miller.htm.

[78] *See, e.g.*, Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 601-03 (2008).

[79] *See* Miller & Conko, *The Science of Biotechnology Meets the Politics of Global Regulation, supra* note ___.

[80] *See* Robert W. Hahn & Cass R. Sunstein, *The Precautionary Principle as a Basis for Decision-Making*, 2 THE ECONOMIST'S VOICE (2005) (claiming that the precautionary principle "attempt[s] to prevent even speculative harm").

[81] *See* Miller and Conko*, supra* note ___*;* Ronald Bailey, *Precautionary Tale*, *supra* note ___. Lawrence A. Kogan, *supra* note ___, at 601-03 (contrasting the Precautionary Principle with the "founding principles of our society, chief among them economic and political freedom and the rule of law").

[82] SUNSTEIN, LAWS OF FEAR, *supra* note __, at 31.

[83] *Id.* at 29.

extensive pre-market testing, or to do the opposite?"[84] The Strong Precautionary Principle allegedly provides no guidance. According to Sunstein, the Principle "forbids all courses of action, including regulation. It bans the very steps it requires."[85]

Given the presence of risk-risk tradeoffs, the critics say, a principle that calls generally for caution in the face of risk, or that calls for shifting the burden of proof in response to "threats" to human health or the environment, is logically incoherent. Strong Precaution only *seems* appealing as an approach to risk because we naturally focus our attention on certain novel "target" risks (such as genetically modified foods or a chemical recently in the news, such as Bisphenol-A) and ignore both the opportunity costs of regulation and the risks presented by the status quo.[86] The way out of these decision-making dilemmas, Sunstein alleges, is comprehensive cost-benefit analysis,[87] or, as Graham and Wiener advocate, "risk tradeoff analysis."[88] Through careful quantitative analysis, regulators will be able to assess and compare the risks that would be created by different decision-making paths.[89] Once these risks are identified, regulators can then choose the most cost-effective risk reducing interventions.

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[84] *Id.* In another example, Sunstein notes that many chemical agents may be carcinogenic at very low levels, while others may be beneficial at very low levels even if harmful at high levels (the so-called "hormesis" effect). *Id*. at 30-31. Therefore, the "simultaneous possibility of benefits at low levels and harms at low levels makes the Precautionary Principle paralyzing." *Id.*

[85] SUNSTEIN, LAWS OF FEAR, *supra* note __ at 26.

[86] Sunstein believes five different cognitive biases operate to make the Strong Precautionary Principle appear functional: (1) individuals focus on salient risks that come to mind from media reports or recent memory, and they ignore less visible risks; (2) probability neglect leads people to concentrate on worst case outcomes, even if they are highly improbable; (3) loss aversion causes people to avoid changes from the status quo, even if the status quo poses its own risks; (4) a widespread belief that nature is benign makes human-created risks seem particularly suspect; and (5) system neglect prevents people from appreciating opportunity costs and the substitute risks that may arise when a particular technology or product is restricted. *See* SUNSTEIN, Laws of Fear, *supra* note ____, at 36-49; Sunstein, *Beyond the Precautionary Principle*, *supra* note __, at 1011 (arguing that the principle's "puzzling appeal" reflects its dependence on cognitive biases).

[87] Sunstein, Laws of Fear, supra note __ at 129 (cost benefit analysis gives people "a more accurate sense of the actual harms against which protection is sought" and provides "a clearer sense of the stakes.")

[88] GRAHAM & WIENER, *supra* note ___ at 19-22. Graham and Wiener describe Risk Tradeoff Analysis as a three-part process that identifies tradeoffs that might result from an intervention, weighs the comparative importance of target risks and countervailing risks, and analyzes the possibility of risk-superior moves that might result in overall risk reduction. *Id.*

[89] Hahn & Sunstein, *supra* note __ at 6 ("We do not believe there is any principled way of making policy decisions without making the best possible effort to balance all the relevant costs of a policy against the benefits.").

B. COUNTERING THE CRITICS

To defend use of the Strong Precautionary Principle, I make three principal claims. First, I demonstrate that Strong Precaution already operates successfully in American law, undermining critics' arguments that the Principle is somehow inherently unworkable or paralyzing. Second, I show that the critics' charge of extremism is, to put it bluntly, overheated. The Principle does not require prohibiting all risky activities, and in fact provides flexibility for policy makers to determine how much risk will be tolerable or acceptable in a given area of law, as well as flexibility to determine proportionate regulatory responses. Finally, I show that the critique that Strong Precaution is "paralyzing" because of risk-risk trade-offs is overstated, especially against the backdrop of its practical implementation in U.S. law. The Principle commands neither extreme regulation nor an abdication of judgment.

1. *Strong Precaution in Existing Law*

Critics often paint Strong Precaution as a new kid on the block, a yet-to-be-tried alternative to cost benefit analysis, or an exotic import from Europe that has not been embraced in the United States.[90] These are gross mischaracterizations, because the Strong Precautionary Principle already operates successfully in American law.

The Food and Drug Administration's review process for new drugs is a prime example. Under the Federal Food, Drug, and Cosmetic Act,[91] enacted in 1938 and amended substantially in 1962, all substances meeting the definition of a drug[92] are presumptively banned from sale in the United States, unless the manufacturer produces relevant data on risks, side effects, and efficacy; conducts clinical trials; and receives affirmative FDA approval for sale.[93] In this system, the FDA stands in the exact gatekeeping role called for by the Strong Precautionary Principle. Indeed, the FDA's new drug review system can be viewed as a particularly potent form of Strong Precaution, because the precautionary measure implemented as a response to "serious threats to human health" from untested drugs is a complete prohibition. That prohibition, backed by criminal penalties,[94] remains in place (without any cost benefit analysis) until the drug manufacturer can overcome the default and carry its

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[90] *See*, *e.g.*, Kogan, *supra* note ___, at 494.

[91] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. (2006)

[92] *See* 21 U.S.C. §321(g) (definition of "drug") and §321(p) (definition of "new drug").

[93] Cite needed for sections of the Act related to review process for new drugs.

[94] 21 U.S.C. § 333 (2006) ("[A]ny person who violates [the Food, Drug, and Cosmetic Act] by . . . knowingly selling, purchasing, or trading a drug . . . shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.").

burden of proof on safety and efficacy.

Belying the argument that a gatekeeping role for government is inherently anti-science or anti-technology, the United States has maintained this FDA review process for decades while also developing the most innovative and profitable pharmaceutical industry in the world. As noted above, some critics point to antibiotics as the leading example of a useful product that would have been squelched if the United States had embraced Strong Precaution decades ago. But pharmaceutical manufacturers have developed life-saving antibiotics since the 1940s and will continue to do so, within a regulatory system that reflects Strong Precaution.[95] Allocation of the burden of proof to drug manufacturers has neither extinguished the market for, nor the supply of, life-saving antibiotics.

The EPA's registration system for pesticides is another example of government serving as an *ex ante* gatekeeper for risk. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[96] a pesticide manufacturer carries both the burden of production (compiling data on health and environmental effects of pesticides proposed for registration) and the burden of persuasion (showing that the pesticide complies with specific statutory standards, including that "it will perform its intended function without unreasonable adverse effects on the environment.").[97] EPA's role is to review the submitted risk data, determine whether the applicant has met the statutory criteria, and if so, approve labeling language and any use restrictions.[98] The regulatory default, in advance of the pesticide manufacturer meeting its burden of proof, is to prohibit the introduction of the new pesticide.[99]

The rationale for EPA pre-approval for pesticides and FDA pre-approval for new drugs is similar: to prevent serious harm by requiring risk assessment, data disclosure, and agency review of risks before the product is placed into widespread circulation.

John Applegate, who has written extensively on the role of the precautionary principle in risk regulation, has argued that FIFRA is the only

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[95] Ironically, it was the *unregulated* introduction of an antibiotic that caused widespread illness in the 1930s and led to public outcry in favor of a pre-market government review system. The purported antibiotic was called "Elixir Sulfanilamide," and more than 100 people were poisoned by it in Tennessee before the FFDCA was enacted. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1761-64 (1996) (describing the political origins of the FFDCA).

[96] Federal Insecticide, Fungicide, Rodenticide Act of 1972, 7 U.S.C. §136 et seq. (2006).

[97] 7 U.S.C. §136a(b)(5) (2006).

[98] *See* U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDES, REGULATING PESTICIDES, at www.epa.gov/pesticides/regulating/index.htm ("EPA must first ensure that the pesticide…can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants.").

[99] *See* FIFRA §3a, 7 U.S.C. §136a(a) ("Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act.").

example of a true burden-shifting statute in American environmental law.[100] But far more examples can be identified if we broaden the lens beyond statutes that license particular products to statutes that regulate environmentally hazardous activities. Strong Precaution is currently being applied not just in one federal regulatory program, but *pervasively*, in thousands of local, state, and federal permitting and licensing programs. From special use permits in local zoning laws to air emissions permits and nuclear power plant licenses, legislatures routinely establish regulatory regimes that contain a prohibition on engaging in an activity that *may* pose serious threats to human health or the environment. Such programs prohibit, on an *ex ante* basis, a class of activities suspected of posing potential risks, without any consideration of the economic benefits from individual activities within the class. The prohibition is overcome only when the proponent has applied for permission, researched and disclosed relevant risk data, met statutory standards, and received affirmative approval from a governmental entity.

The Clean Air Act, for example, prohibits operation of an entire class of industrial facilities and electric generating plants ("major sources"), until the facility obtains a permit from federal or state regulatory authorities.[101] The operator of the source has the burden of demonstrating, through its own computer modeling, that the emissions from the source will not cause violations of the health-based National Ambient Air Quality Standards (which are set without any cost-benefit analysis)[102] and other statutory requirements. In toxics regulation, the Resource Conservation and Recovery Act prohibits operation of any hazardous waste transport, storage, or disposal facility without a license.[103] Years of problems with responding to hazardous waste spills after-the-fact prompted Congress, in 1976, to turn to this *ex ante* licensing mechanism to ensure that operators are qualified, have adequate insurance, and undertake proper safety precautions.[104]

Scholars have rarely recognized such permitting and licensing programs as examples of the Strong Precautionary Principle already operating in American law, but these programs clearly exemplify the architecture of the Principle.[105] Critics are overlooking that the Principle can provide a workable

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[100] *See* Applegate, *Precautionary Preference*, *supra* note ___, at 430 ("With the notable exception of FIFRA, the burden of proving the existence and magnitude of an environmental risk is uniformly placed on the agency seeking to impose restrictions.").

[101] Clean Air Act § 502(a), 42 U.S.C. §7661a(a) (2006).

[102] *See* 42 U.S.C. §7409 (2006) (requiring EPA to set National Ambient Air Quality Standards (NAAQS) at a level that "protect[s] public health" with "an adequate margin of safety"). In 2001, the Supreme Court affirmed that the NAAQS are health-based standards that EPA must set without reliance on cost-benefit analysis. *Whitman v. American Trucking Assns, Inc.,* 531 U.S. 457 (2001).

[103] Resource Conservation and Recovery Act §3005, 42 U.S.C. § 6925 (2006).

[104] *See id.* §§ 1002(b)(6), 3004(a)(6), 42 U.S.C. §§ 6901 b(6), 6924(a)(6).

[105] To be sure, there are also many examples of U.S. regulatory regimes grounded in precautionary standard setting without a switch in the burden of proof, such as the initial establishment of the NAAQS under the Clean Air Act. There are also many examples of *ex post* interventions, such as the product

accommodation between the needs of industry and the need to ensure adherence to ecological limits and safety standards. Specifically, putting government in a risk gatekeeping role serves several important purposes, including:

- Ensuring that the applicant is competent to engage in the activity and has the required expertise and resources;
- Regulating the location of potentially risky activities and ensuring that they occur in places where risks to the public are minimized;
- Ensuring that activities presenting serious threats to public health or the environment can be prohibited (or safety precautions placed on them) before harm occurs;
- Ensuring, through establishing a uniform review process for every applicant, that the cumulative amount of a risky activity does not exceed limits that would be damaging to the environment or human health;
- Minimizing risks while further research is conducted, in situations where scientific uncertainty precludes a complete understanding of the nature or magnitude of risk.
- Establishing minimal safety standards in cases where tort-based deterrence is weak because harm may be difficult to prove on an *ex post* basis (such as harm from pesticides or air pollution) or because a risk-creator may be judgment proof if harm occurs (such as the operator of a hazardous waste storage facility).

I am not trying to defend every permitting and licensing scheme, of course. Government permitting programs can be burdensome and prone to political favoritism and rent-seeking behaviors. They are often complex. If inadequately funded and staffed, an *ex ante* review process may be no more than a fig leaf of risk management (witness the BP oil spill and the lax oversight of the Minerals Management Service). But the long-standing practice in American law of establishing government agencies as *ex ante*

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recall authority of the Consumer Product Safety Commission, 15 U.S.C. §2064(b), or the authority of the Environmental Protection Agency to issue removal orders in response to hazardous substance releases. Comprehensive Emergency Response, Compensation, and Liability Act § 106, 42 U.S.C. § 9606(a). Taken as a whole, the United States approach to addressing health and environmental risks is a complex pastiche of different kinds of *ex ante* and *ex post* interventions.

gatekeepers for risk does suggest that the Strong Precautionary Principle cannot be so easily dismissed. It is not as alien to American law and American values as the critics would have us believe, and it hardly seems "paralyzing" in the many contexts in which it has been applied.

2. *Countering the Critique of Extremism*

Rather than seriously grapple with examples of Strong Precaution in existing law, many critics instead challenge a straw man–a jumble of extremist positions and hard-to-defend results that allegedly flow from Strong Precaution. Critics frequently contend, for example, that the Strong Precautionary Principle amounts to an intolerable command for proponents of potentially harmful technologies to prove zero risk.[106] As Ronald Bailey charged, "manufacturers would have to prove that their creations wouldn't cause harm--ever--to the environment or human health before they would be allowed to offer them to the public. It's like demanding that a newborn baby prove that it will never grow up to be a serial killer, or even just a schoolyard bully. . ."[107]

If zero risk is indeed what the Principle aims for, then the Principle must be rejected because many products and activities that pose risks to human health and the environment also bring enormous benefits to human welfare (e.g., aviation, pharmaceuticals, manufacturing facilities etc.). Zero risk is an undesirable and unattainable goal.[108]

Cass Sunstein is one of the critics who paints the Principle as almost comically extreme. After discussing weaker versions of precaution, he defines the Strong Precautionary Principle as the view that "regulation is required whenever there is a possible risk to health, safety, or the environment, even if the supporting evidence is speculative and even if the economic costs of regulation are high."[109]

This is the definition of the "Precautionary Principle" that Sunstein then excoriates in eight chapters of *Laws of Fear* and in his major article in *Pennsylvania Law Review*, where he encourages us to move "Beyond the Precautionary Principle."[110] But notice that his definition does not at all

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[106] *See, e.g.*, Giandomenico Majone, *What Price Safety? The Precautionary Principle and its Policy Implications*, 40 J. COMMON MARKET STUD., 89, 101 (2002); Christopher Stone, *Is There a Precautionary Principle*?, 31 ENVTL. L. REP. 10790 (2001).

[107] Bailey, *supra* note ___.

[108] *See Indus. Union Dept. v. Am. Petroleum Inst.*, 448 U.S. 607 642 (1980) ("'Safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day–such as driving a car or even breathing city air–that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.'")

[109] SUNSTEIN, LAWS OF FEAR, *supra* note ___, at 24; SUNSTEIN, *Beyond the Precautionary Principle*, *supra* note __, at 1018.

[110] Sunstein, Beyond the Precautionary Principle, *supra* note ___. In *Laws of Fear*, Sunstein also

reflect the Wingspread Declaration, which is widely considered to be emblematic of the Strong Precautionary Principle. Sunstein's definition does not mention any burden of proof, or who should bear the burden of proof. In fact, he rarely discusses the appropriate role of burden shifting or pre-market review mechanisms in his work on precaution, other than to note that a shift in the burden of proof usually means, for a risky activity, that the burden of proof cannot be met.[111] Sunstein thereby neglects that most formulations of Strong Precaution specifically contemplate that activities posing serious health or environmental threats can proceed as long as their risks are justified, by their proponents, as tolerable or acceptable. Strong Precaution does not require the elimination of all risk, nor the elimination of risk at any cost.

What Sunstein has done is to take, as the basis for his definition, some of the most radical formulations of the Precautionary Principle ever committed to paper.[112] Because Sunstein defines the Strong Precautionary Principle in this way, it is not surprising that he is able to attack it at length, and it is also not surprising that he denigrates it as a "position that no one is ultimately willing to hold."[113]

Most formulations of the Strong Precautionary Principle, including my own definition and the Wingspread Declaration, offer far more flexibility than this extreme portrait painted by the critics.[114] The Strong Precautionary

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states that the Precautionary Principle can be viewed "as a plea for aggressive regulation of risks that are unlikely to come to fruition." Laws of Fear, *supra* note __ at 224.

[111] *See, e.g., id.* at 1023 (discussing nuclear power and other risky activities and noting that "if the burden of proof is on the proponent of the activity or process in question, the precautionary principle would seem to impose a burden of proof that cannot be met."). *See also* LAWS OF FEAR, supra note __ at 28 (same). Jonathan Wiener appears more supportive of shifts in the burden of proof in risk regulation. He recommends shifting the burden of proof to the party "best able to generate the information needed to make the decision," analogizing such shifts to Calabresi's conception of the cheapest cost avoider. *See* Weiner, Precaution in a Multirisk World, *supra* note __ at 1517 ("It may often make sense to ask industry rather than the government to produce much of the data on risk.").

[112] In particular, his definition echoes the First Declaration of the First European "Seas at Risk" Conference, as well as 2002 testimony of the President of Friends of the Earth before a congressional subcommittee on the subject of human cloning. He discusses both formulations in Chapter 1 of *Laws of Fear* as being at the "extreme" end of a continuum and as requiring a "fundamental rethinking of regulatory policy." *See* SUNSTEIN, LAWS OF FEAR, *supra* note __ at 18-20.

[113] SUNSTEIN, LAWS OF FEAR, *supra* note __, at 24. There are indeed some formulations of the Precautionary Principle that suggest that activities that might threaten human health or the environment should be prohibited entirely until scientific evidence shows that the threatened harm will not occur. *See, e.g.*, Final Declaration of the First European "Seas at Risk" Conference, Annex I, Copenhagen 1994 ("[I]f the 'worst case scenario' for a certain activity is serious enough then even a small amount of doubt as to the safety of that activity is sufficient to stop it taking place."); 1982 World Charter for Nature, G.A. Res. 37/7, U.N. Doc. A/RES/37/7 (Oct. 28, 1982) ("[W]here potential adverse effects are not fully understood, the activities should not proceed."). These amount to zero-risk standards, however. They should be rejected, and they have never had much influence on the practical design of regulatory regimes in the United States.

[114] The Wingspread Declaration, for example, states that "the burden of proof shall be borne by the proponent of the activity," but it does not itself supply the standard for determining when the burden of proof is met. Wingspread Declaration, *supra* note 40.

Principle does not impose a burden on any party to prove zero risk, nor does it state that all activities that pose a possible risk must be prohibited. Rather, the Principle, while shifting the *burden of proof*, deliberately leaves the governing *standard of proof* open-ended and subject to democratic deliberation. The Principle requires that a proponent demonstrate that its product or activity meets a specified standard (pre-determined through legislation) for how much risk is tolerable or acceptable in a given issue area. Policymakers may set that standard at the level at which marginal benefits just equal the marginal costs of achieving it, or they may also set it by reference to values other than economic efficiency, such as protection of future generations or protecting baseline levels of ecosystem services.[115]

In the hazardous waste context, for example, the Principle would not forbid a firm from engaging in long-term storage of hazardous waste, but it would impose a default prohibition on that activity until the firm can demonstrate, *ex ante*, that the storage will be conducted safely – meaning in accordance with prescribed standards for construction, monitoring, labeling, and emergency response. More broadly, a statute implementing the Strong Precautionary Principle might provide that the proponent must demonstrate, as a condition of engaging in a regulated activity, that risks are "reasonable," that the activity will not cause "substantial harm," or that the benefits of the activity outweigh the costs. Such terminology is broad, but it is no more vague than the burden of proof that U.S. environmental statutes routinely place on government agencies.[116]

In any risk regulatory regime, wherever the burden of proof lies, this standard-setting is an unavoidably political process. Culture, politics, the costs of regulation, and choices about weighing risks to present generations versus future generations are all important factors in deciding how clean is clean, or how much risk will be considered "safe" or "reasonable."

Under the Strong Precautionary Principle, the governing risk standard and the precise conditions for shifting the burden of proof must be decided through democratic processes in the enactment of legislation. Critics such as Sunstein are asking far too much from a brief principle when they criticize it for failing to answer complex questions about the valuation of human life[117] or the distributional consequences of risk decision-making.[118] The Principle was

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[115] Sunstein himself supports regulatory standard-setting with reference to values other than economic efficiency. *See* Laws of Fear, *supra* note __, at 129 ("Efficiency is relevant, but it is hardly the only goal of regulation. Citizens in a democratic society might well choose to protect endangered species, or wildlife, or pristine areas, even if it is not efficient for them to do so.").

[116] *See* TSCA §6(a), 15 U.S.C. §2605(a) (EPA must prove "unreasonable risk" to restrict a chemical); Clean Air Act §109 (EPA required to set ambient air quality standards at a level "requisite to protect public health" with an "adequate margin of safety").

[117] *See, e.g.,* Hahn & Sunstein, *supra* note ___ ("Without helping to answer" questions such as the tradeoff between present and future risks and the valuation of a life, "the principle is not useful.")

[118] *See* SUNSTEIN, LAWS OF FEAR, *supra* note ___, at 50 ("The Precautionary Principle is a crude,

never intended for these purposes; the proper venue for resolution of these questions is implementing legislation.

The necessity of interpretation through implementation does not, however, carve out so much from the Principle itself that the Principle dissolves into vacuity.[119] Rather, the Principle still plays an important role in structuring rights, obligations, and regulatory defaults in the face of scientific uncertainty. It calls for a distinct regulatory architecture in which private sector proponents carry a burden of proof, in contrast with most environmental and health legislation that places a burden of proof on a government agency.

There is little point in shifting the burden of proof if the ultimate burden the proponent must carry is a *de minimis* one. As Sunstein aptly points out, "everything depends on what those with the burden of proof must show in particular." [120] But in most examples of Strong Precaution operating in practice, the proponent is asked to do more than prove that the pope is Catholic. In the *ex ante* regulatory regimes described *supra*, the proponent bears a substantial burden to prove that risks or impacts will be within acceptable bounds – a burden that normally takes significant investment of time and resources to meet. The burden-shifting mechanism therefore does real "work" in allocating responsibilities.

In addition to providing flexibility to design risk standards, the Strong Precautionary Principle also affords flexibility to design default regulatory responses in the time period before the proponent has met its burden of proof. The extremist critique suggests that the only response of regulators, acting in accordance with the Strong Precautionary Principle, is to ban activities that pose possible or potential risks.[121] But the Strong Precautionary Principle can be implemented through a variety of defaults beyond simplistic, binary (ban or no-ban) choices.[122] Appropriate defaults might include partial prohibitions,

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indirect, and sometimes perverse way of incorporating distributional concerns."). *But see* John Applegate, *Embracing a Precautionary Approach to Climate Change, supra* note ___ (arguing that it is "patently not the purpose" of the precautionary principle to resolve distributional concerns).

[119] Dana, *A Behavioral Economic Defense of the Precautionary Principle, supra* note ___, at 1317-18 ("Principles can express and reinforce value commitments and procedurally structure decision making without dictating a single set of specific, substantive outcomes.").

[120] SUNSTEIN, Laws of Fear, *supra* note ___, at 19. *See also* Henk Van de Belt, *Debating the Precautionary Principle: "Guilty Until Proven Innocent" or "Innocent Until Proven Guilty,"* 132 PLANT PHYSIOLOGY 1122 (2003) ("the burden we want to put on the shoulders of one or the other party becomes more or less heavy depending on whether we set our standards of proof more or less highly.").

[121] Lawrence A. Kogan, *The Extra-WTO Precautionary Principle, supra* note __, at 506-07 (The precautionary principle "favors banning or severely restricting broad classes of substances, products, and activities if it is merely possible that they . . . pose potentially serious but unknown health or environmental harm."); Dave Owen, *Probabilities, Planning Failures, and Environmental Law*, 84 TUL. L. REV. 265, 270 n.31 (2009) ("A strong precautionary principle might . . . ban environmentally threatening activities.").

[122] Indeed, it would be a gross waste of resources to implement the same precautionary measures for chemicals whose effects on human health cannot be determined with accuracy as for chemicals that are known carcinogens. "Precautionary measures should be taken in both cases, but with different degrees of

worker safety precautions, locational restrictions, or warnings. And even where a regulatory regime provides for a default policy of complete prohibition (as is common in most governmental licensing and permitting programs), the Strong Precautionary Principle clearly provides that the default can be overcome by proof of acceptable risks submitted by the applicant.

3. Countering the Critique of "Paralysis"

No one seriously disputes that regulation has opportunity costs, and no serious scholar of risk regulation believes that opportunity costs should be ignored. The FDA approval process for new drugs, FAA pilot and airport licensing requirements, and SEC registration requirements for securities all consume public and private sector resources that cannot be deployed elsewhere. Moreover, stringent regulation of one activity might lead private parties toward substitute activities that pose risks of their own.

The presence of trade-offs, however, does not mean that the Strong Precautionary Principle is incoherent or paralyzing. Because of the centrality of the "paralysis" theme in the literature of the critics, I devote substantial attention to it here.

Some scholars have already explored how weaker versions of the Precautionary Principle apply to risk-risk tradeoffs. David Dana suggests, for example, that the Precautionary Principle helps us choose among alternative regulatory actions (including no action) by countering the tendency to avoid decisions that involve upfront costs and more distant benefits.[123] Stefan Hansen and Joel Tickner argue that true risk-risk tradeoffs are less prevalent than the critics have alleged,[124] and John Applegate asserts that even where risks inhere on many different sides of a decision, the Precautionary Principle still plays a useful role by ruling out arguments that *all* decisions should be postponed due to scientific uncertainty.[125] In a thoughtful examination of risk-risk tradeoffs, Doug Kysar has noted that while the opportunity costs of regulation must be considered, the Precautionary Principle offers a more contextual, dynamic approach for making these trade-offs than cost-benefit analysis.[126] The Precautionary Principle, according to Kysar, approaches

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stringency." Hansson, Can We Reverse the Burden of Proof, *supra* note ___ at 234.

[123] David Dana, *A Behavioral Economic Defense of the Precautionary Principle*, *supra* note __, at 1333 (the precautionary principle "may have a role to play as a corrective of cognitive biases" in situations where we face "choices between the avoidance of sure, immediate losses and the avoidances of unsure, future losses").

[124] *See* Hansen &Tickner, *supra* note ___ (arguing that many purported risk-risk tradeoffs are hypothetical, never emerged in practice, or were adequately addressed through precautionary regulation).

[125] John Applegate, *Embracing a Precautionary Approach to Climate Change*, *supra* note ___ at ___ (explaining that the function of the precautionary principle is "primarily procedural and evidentiary.").

[126] Kysar, *It Might Have Been*, *supra* note __ , at 8 ("Undoubtedly, CBA proponents are correct to

complex trade-offs through deliberation, moral reflection, and appreciation of the limits of human cognition, while cost-benefit analysis "proceeds awkwardly in the absence of fully characterized risk" and involves questionable monetization of environmental and health harms.[127]

I do not intend to revisit this wide-ranging debate in full here. Instead, I offer three responses, underdeveloped in prior literature, to the critique that Strong Precaution is paralyzing and ignores trade-offs – responses that are particularly pertinent to my case study of chemical regulation.

a. The Problem of Trade-offs in Legislation

My first response is that the comprehensive risk trade-off analysis that Sunstein, Wiener, Graham, and other critics advocate is often impractical in the legislative process. Enactment of legislation is both the primary focus of this Article and the proper focus of analysis of the Strong Precautionary Principle. The Principle should be viewed primarily as a framework to guide legislators, rather than a framework to guide regulators, because, at least in American law, the shift in the burden of proof usually requires some legislative authorization.[128]

In deciding whether to enact a new regulatory program, legislators should of course consider the trade-offs involved, including opportunity costs and any countervailing risks. This is simply good decision-making. They should, to use Sunstein's terminology, deploy a "wide viewscreen"[129] in anticipating how proposed legislation will function in a world of multiple risks.

But there is a limited ability, in the run-up to passage of new legislation, for legislators or their staffs to perform a comprehensive cost-benefit analysis on all possible decision-making paths.[130] Legislators cannot easily predict, for example, how citizens and firms will adjust their behavior in response to various legislative options. Indeed, in enacting a regulatory regime

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note that no society should flatly ignore the opportunity costs of precautionary regulation. But this is a trivial observation, for no serious proponent of the Precautionary Principle disagrees with it.").

[127] *Id.*

[128] Scholarship on weak versions of the precautionary principle has focused overwhelmingly on the decisions of regulatory agencies. *See*, e.g., Elizabeth C. Fisher & Ronnie Harding, *The Precautionary Principle and Administrative Constitutionalism: The Developments of Frameworks for Applying the Precautionary Principle* (Oxford Legal Studies Research Paper No. 31/2006, 2006), *available at* http://papers.ssrn.com/so13/papers.cfm?abstract_id=908644. ("The principle applies to "administrative activities" that are "delegated by a primary law maker to a non-elected secondary law maker."). But the Strong Precautionary Principle more directly addresses legislative design, given that the key choices, such as the degree of risk that will trigger burden shifting and the showing that must be made to overcome default prohibitions, are usually legislative choices.

[129] Sunstein, Beyond the Precautionary Principle, *supra* note __ at 1005.

[130] While cost-benefit analysis is mandated for federal regulatory agencies through executive order, E.O 12866, 58 Fed Reg. 51735, October 4, 1993, Congress has chosen, wisely, not to bind itself formally to that requirement through its own rules of procedure.

based on delegated authority, legislators cannot be sure of the stringency of the regulations that will be promulgated by an agency, nor can they predict which particular products or activities will be prohibited or allowed, because these decisions will usually be made years later by regulatory agencies. Therefore, it may very well be impossible to know, in advance, the risk tradeoffs that will flow from a piece of legislation.[131]

Even in an ideal world where legislators could presciently name all the benefits and costs (including countervailing risks) that might flow from legislation, monetizing the benefit side of the equation (*e.g.,* ecosystems protected, cancers or birth defects avoided, or life-years saved) is notoriously problematic. The literature critiquing Cost Benefit Analysis is voluminous,[132] and I do not repeat those critiques here. Even within the literature supporting Cost Benefit Analysis, major problems of valuation are often overlooked.[133]

Risk trade-off analysis depends on being able to accurately characterize and monetize risk, but if probabilities cannot be attached and dollar values cannot be assigned, we are in the realm of uncertainty or ignorance – precisely the realm where Strong Precaution has the most salience. The call for comprehensive cost-benefit analysis on all potential tradeoffs might result only

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[131] Even in the regulatory arena, where formal risk assessment and cost benefit analysis are strongly institutionalized in American law, it is often difficult to forecast risk-risk tradeoffs or to estimate their magnitude. Consider a risk-risk tradeoff explored by Sunstein in a 2002 article: that promulgating strict standards for arsenic (10 parts per billion or less) under the Safe Drinking Water Act might incentivize households, because of the expense of complying with the standard, to switch to private wells, which often contain polluted or contaminated water. Cass Sunstein, *The Arithmetic of Arsenic*, 90 GEO. L.J. 2255, 2294-95 (2002). Sunstein describes this as a classic risk-risk tradeoff and reports that EPA Administrator Christine Todd Whitman "expressed concern" about this possibility in a television interview. *Id.* But he does not explain how that risk-risk tradeoff could be quantified. It is doubtful that regulators could quantify how many users might actually switch to private wells, how polluted private wells are in those communities, and how users' health would be affected by exposure to diverse contaminants in private wells. More broadly, it is often possible to spot the *existence* of a countervailing risk from regulation, yet exceedingly difficult to quantify it or to judge whether the existence of the countervailing risk warrants abandoning or restructuring a regulatory proposal. Where risks cannot be accurately characterized, quantified, or compared, cost-benefit analysis becomes an awkward tool for regulatory decision making.

[132] *See, e.g.,* Gregory Mandel, *Cost Benefit Analysis Versus the Precautionary Principle: Beyond Cass Sunstein's Laws of Fear*, 2006 ILL. L. REV. 1037, 1045-46 (describing hurdles of uncertainty and valuation in conducting Cost Benefit Analysis); DOUGLAS KYSAR, REGULATING FROM NOWHERE (2010); FRANK ACKERMAN AND LISA HEINZERLING: PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2004); Robert Percival, *Whose Afraid of the Precautionary Principle*, PACE ENV. L. REV (noting that the imperative to quantify the costs and benefits of regulation "may distort decisionmakers' perceptions of the levels of uncertainty associated with them.").

[133] To provide just one example, Sunstein supports regulatory use of a Value of a Statistical Life (VSL) to measure the monetary value of lives saved from a regulation, and he argues that the VSL should be determined from studies of people's Willingness to Pay (WTP) to avoid the harm being measured. He then notes that the degree of regulation should be tailored to individual differences in WTP, so that, for example, "[i]f people in New York are willing to pay more to reduce arsenic risks than people in Montana, then regulators should attend to that fact." LAWS OF FEAR, *supra* note __ at 152. He neglects the enormous informational constraints of measuring each sub-population WTPs accurately, let alone tailoring federal regulation to match sub-population variances in WTP.

in delay in addressing those harms to human health or the environment that *have* been identified as being serious. Indeed, the quest for quantifying all tradeoffs -- what Donald Hornstein has called "super-synopticism"[134] – may lead to a different kind of "paralysis" than the one that Sunstein says is inherent in Strong Precaution: paralysis by analysis.[135]

This concern -- that protective health and environmental legislation will be undermined by demands for comprehensive risk tradeoff analysis -- is not just hypothetical. The primary reason that EPA has become crippled in its ability to restrict chemicals already on the market is that TSCA commands EPA to perform extensive cost-benefit balancing on any decision to restrict, including identifying the "least burdensome alternative" that will address the risk.[136] The courts have interpreted this requirement to mean that the agency must conduct cost-benefit analysis not only on the proposed regulatory action, but also on a tiered ladder of other possible regulatory alternatives with varying stringency.[137] The massive information needs of such a task have meant, in practice, that EPA has not been able to pull known hazardous substances off the market, including even asbestos.[138] The U.S. environmental statute most committed to post-market cost-benefit balancing for toxic risks, in short, is the one that has been least effective.

Despite this historical background, Sunstein continues to champion extensive governmental cost-benefit analysis in restricting a chemical. In a coauthored article, Sunstein and Adrian Vermeule explain that "there is general agreement that whether a particular substance ought to be regulated depends on the overall effect of regulation on human well-being."[139] This question can be answered, they say, only through a comprehensive analysis of tradeoffs – calculating the total costs and benefits of regulating the substance – and this analysis must include the foregone economic benefits if the substance is restricted.[140]

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[134] Donald Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 386 (1993). *See also* Bradley Karkainnen, *Framing Rules: Breaking the Information Bottleneck,* 17 N.Y.U ENVTL. L.J. 75, 81-82 (2008) (criticizing "comprehensive bureaucratic rationality" as an approach to risk).

[135] *See, e.g.*, Hansen & Tickner, *supra* note __, at ___ ("It is useful to consider realistic and reasonable risk-risk tradeoffs," but "this should not keep us from acting on a risk for which there is scientific evidence indicating concerns."). *See also* Percival, *Who's Afraid of the Precautionary Principle, supra* note ___ at __ (rejecting the proposition that "a never-ending quest for improved information should indefinitely postpone sensible regulatory measures."); Rascoff and Revesz, *The Biases of Risk Tradeoff Analysis: Toward Parity in Environmental and Health-and-Safety Regulation*, 69 U. CHIC. L. REV. 1763 (2002).

[136] TSCA §6(a), 15 U.S.C. §2605(a).

[137] *See* Corrosion Proof Fittings, 947 F.2d 1201 (5th Cir. 1991).

[138] See discussion of Corrosion Proof Fittings, *infra* Part II.

[139] Cass Sunstein & Adrian Vermeule, *Is Capital Punishment Morally Required?* 58 STAN. L. REV. 703, 708 (2005).

[140] Notably, Sunstein and Vermeule restrict this calculus to "human well-being," leaving impacts on non-human species out of the equation.

There are two problems with this approach. First, it neglects the hurdles to performing cost-benefit analysis in a context of the historic drought of data on chemical risks in the United States. A major goal of implementing a Strong Precautionary approach in chemical regulation is to incentivize risk research so that identification and comparisons of chemical risks can be made in the context of abundant risk assessment data. Under the current system, we usually lack the data to do exactly the kind of analysis Sunstein and Vermeule advocate. The failures of TSCA should give pause to Sunstein and other critics of the Strong Precautionary Principle who contend that the only proper approach for chemical risk management is for a government agency to compile risk assessment data, monetize the health risks and compare them to the economic benefits of each chemical, and then regulate on a chemical-by-chemical basis when risks can be shown to be greater than the economic benefits. With the chemical industry producing or importing 73 billion pounds of chemical per day, with 83,000 chemicals having been introduced into commerce, and with EPA devoting only about 200 personnel to the toxics program,[141] that agenda is a recipe for snail's-pace risk management. It practically guarantees regulatory paralysis. It will result in continued ignorance and delay, and in the meantime, Americans will remain "guinea pigs in a great unknown commercial and legal experiment."[142]

The second problem with the approach to chemical risks suggested by Sunstein and Vermeule is that in designing a successor statute for TSCA, the legislative task is not to perform a utilitarian calculus on the costs and benefits of banning or restricting specific chemicals. Rather, it is to determine the best legislative architecture for assessing and managing the risks of the universe of 83,000 chemicals that have been introduced into commerce. The questions that Congress confronts at the legislative stage are much broader than the substance-specific question posed by Sunstein, and here, cost-benefit analysis has limited utility. Congress must determine what decision-making procedures and default rules should be put in place for *all* chemical substances subject to the statute. What kinds of rules would be protective of human health and the environment, given what we know about chemical exposures and toxicity? What kinds of authorities should be given to regulators to compel testing? Who should bear the burden of proof? What must chemical manufacturers show about the risks of a chemical prior to marketing? Should there be trade secret exemptions from public disclosure of toxicity data? What kinds of toxicity tests will be acceptable for risk assessment? On these questions, it is not at all clear how risk tradeoff analysis would apply.

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[141] *See* Mark Greenwood, *supra* note __ at 10036-37 (noting that the Office of Pollution Prevention and Toxics, which implements TSCA, is "one of the most underfunded programs in all of EPA.").

[142] Carl Crannor, *Toward Understanding Aspects of the Precautionary Principle*, 29 Journal of Medicine and Philosophy 259, 267 (2004).

Legislators must, in the end, make a difficult *judgment* about the best approach to a particular class of risks, one that "represents the self-expressed commitments of an integrated political community."[143] Legislators should consider knowable tradeoffs where they can be quantified, but they should also view their role as more than utility maximizers, summing up individual preferences. The need to accept agency and responsibility in decision making is particularly acute in the enactment of environmental legislation, which raises fundamental questions about duties to current and future generations and stewardship of ecosystems.[144] As Doug Kysar put it, "environmental, health, and safety regulation is not merely an opportunity to maximize an existing set of individual preferences or interests, but rather a moment to consider the regulating body's obligation to its present and future members, to other political communities, and to other species."[145]

b. Why Strong Precaution Need Not Be Paralyzing

One threshold judgment that a legislative body must make in the design of public health and environmental statutes is whether a Strong Precautionary approach should be implemented, in which a government agency is placed in a risk gatekeeping role, with the burden of proof on the applicant. Or, on the other hand, should a particular arena of risk be addressed through more laissez-faire mechanisms, such as some minimal post-market supervisory authority of a government agency, or perhaps by no regulation at all.

In making this judgment, a choice to implement a Strong Precautionary risk gatekeeping mechanism need not "paralyze" legislators. To see why this is so, it is helpful to consider some examples outside the context of environmental law.

Consider first the licensing of doctors and nurses. There is clearly a risk-risk tradeoff in a decision on whether to enact a licensing statute, with human lives at stake "on all sides" of the choice, to use a favorite phrase of the critics.[146] Not requiring a license could result in untrained people performing

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[143] KYSAR, REGULATING FROM NOWHERE, CHAPTER 9.

[144] In other environmental statutes, Congress has frequently made the judgment that natural resources and human health should be protected, without engaging in comprehensive risk-risk analysis of what that protection will cost. Doug Kysar has noted, for example, that the Clean Water Act's command not to degrade the nation's pristine waters is a fairly absolute one that does not consider tradeoffs regarding how this protection might limit economic development. The Endangered Species Act can also be seen as a deontological, non-utilitarian statute reflecting a national value that species should be protected. Such protective legislation establish firm ecosystem constraints on human activity. According to Kysar, policymakers have forgotten these animating impulses of American environmental law from the 1970s, and cost-benefit analysis, even if could be accomplished accurately, cannot "fully map the terrain of ethical and political determination." KYSAR, REGULATING FROM NOWHERE: ENVIRONMENTAL LAW AND THE SEARCH FOR OBJECTIVITY, CHAPTER 9 (2010).

[145] KYSAR, REGULATING FROM NOWHERE, *supra* note __ at 24.

[146] Sunstein, *Beyond the Precautionary Principle*, *supra* note __, at 1054.

surgeries and prescribing medications. Yet requiring a license clearly limits the supply of doctors and nurses, which could have put lives at risk in medically underserved communities.

But why should applying the Strong Precautionary Principle be "paralyzing" here? Would we really say that either decision would be equally precautionary, or that a precautionary legislator would find it impossible to decide? Consistent with the Strong Precautionary Principle, legislators have made a judgment (in all fifty states) that it is better to have a default precautionary rule prohibiting unlicensed medical practice, with the applicant bearing the burden of proof on their qualifications for the license, rather than to allow any person to practice medicine, and then respond to any resulting harm on an *ex post* basis.[147] We do not consider the costs and benefits of medical licenses in deciding whether a particular nurse or doctor should be allowed to sell their labor in the market for medical services (as Sunstein and Vermeule suggest we should do for chemical substances). We instead implement a firm systemic rule that applies to all practitioners in every state: if you want to practice medicine, you must prove, *ex ante*, that you have the required skills, training, and knowledge. That there are some inevitable tradeoffs in grounding medical licensing rules in the Strong Precautionary Principle does not eviscerate the coherence of Strong Precaution as an approach to risk.

As another example of why a Strong Precautionary approach need not be "paralyzing" in the presence of tradeoffs, consider federal and state laws requiring applicants to receive *ex ante* government approval for construction and operation of new airports.[148] The goals of such statutes are to avoid overcrowding in the skies from locating airports too close to each other and to guarantee some minimal safety standards for airport facilities.[149] The statutes clearly do not call for cost-benefit balancing or for risk trade-off analysis. The FAA does not determine whether the benefits of a proposed airport (measured in terms of economic growth, tax revenue, or recreational enjoyment) exceed the potential risks. Rather, airport pre-approval statutes say to the operator: given potential serious threats to public safety from a poorly located or poorly operated airport, government will hold you to prescribed safety standards and forbid you from engaging in airport operation if you cannot meet the standards, *even if there are significant foregone economic benefits from prohibiting*

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[147] *See, e.g.,* cites needed on state medical licensing

[148] *See* Federal Aviation Administration airport notification and licensing requirements, 15 CFR Part 157; FAA Form 7480 (Notice of Landing Area Proposal); Minnesota Statutes 360.018 ("The general public interest and safety, the safety of …persons and property on the ground, and the interest of aeronautical progress require[e]… that airports, restricted landing areas, and air navigation facilities should be suitable for the purposes for which they are designed."); Minnesota Admin. Rules 8800.1400 *et seq* (establishing notification and licensing requirements for new airports).

[149] *See* http://www.faa.gov/airports/central/engineering/part157/ ("Notification allows the FAA to identify potential aeronautical hazards in advance thus preventing or minimizing the adverse impacts to the safe and efficient use of navigable airspace.").

operation of the airport. The Strong Precautionary Principle's salutary signals are very much present here: legislators demand compliance with minimum safety standards, place the burden of proof on the applicant to show that risks will be acceptable, and allow vigorous competition to occur within that framework.

c. Addressing Trade-offs Within Precautionary Legislation

My final response to the criticism that Strong Precaution necessarily ignores risk-risk tradeoffs is that such tradeoffs can often be addressed *within* regulatory regimes grounded in Strong Precaution. There are numerous examples of permitting, licensing, and pre-approval statutes that implement a default prohibition on a certain targeted activity, yet they also contain procedures to address known countervailing risks of the prohibition. In drug approvals, for example, the FDA has developed three separate programs (fast track, accelerated approval, and priority review) to reduce "drug-lag," shortening the time in which breakthrough drugs can move to market.[150] Pharmaceutical manufacturers under those programs still cannot market a new drug until they receive FDA approval, but they proceed down a separate and faster track within the agency.[151] Environmental statutes that rely on licensing and pre-approval mechanisms are replete with "minor source," "minor use," and "experimental use" exemptions, to avoid applying strict research, pre-approval, and pollution control requirements to activities that, as a class, pose less severe risks.[152]

In arguing that the presence of risk-risk tradeoffs makes precaution incoherent, Sunstein, Frank Cross, and other critics often pull out the same trump card: DDT.[153] The critics explain that banning DDT could lead to increased deaths from malaria in the developing world. Given this countervailing risk of a DDT ban, critics suggest, a vague command to be

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[150] U.S. Food and Drug Administration, Fast Track, Accelerated Approval, and Priority Review, http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm. (last visited __)

[151] *Id.*

[152] *See, e.g.,* Clean Air Act §165, 42 U.S.C. §7475 (applying preconstruction review requirements of the Prevention of Significant Deterioration program only to "major emitting facilities," defined by pollutant tonnage thresholds); Resource Conservation and Recovery Act §__ (less stringent storage and labeling requirements for "small quantity generators" and "conditionally exempt small quantity generators."); Federal Insecticide Fungicide and Rodenticide Act §18 (emergency use exemptions from the registration and pre-approval process for pesticides); *Id.* at § 5 (experimental use exemptions).

[153] *See* INDUR GOKLANY, THE PRECAUTIONARY PRINCIPLE: A CRITICAL APPRAISAL OF ENVIRONMENTAL RISK ASSESSMENT, Cato Institute (2001); SUNSTEIN, LAWS OF FEAR, *supra* note __ at 32; Cass Sunstein and Adrian Vermeule, *Is Capital Punishment Morally Required?,* 58 STAN. L. R. 703, 707 (2005); Frank Cross, *supra* note ___ at ___; *See also*, RICHARD TREN AND ROGER BATE, COMPETITIVE ENTERPRISE INSTITUTE, WHEN POLITICS KILLS: MALARIA AND THE DDT STORY 25-27 (2001), available at http://cei.org/PDFs/malaria.pdf.

cautious is paralyzing. Is it cautious to ban DDT, or to do the opposite? Yet when international negotiators actually confronted this trade-off, in the design of the Stockholm Convention on Persistent Organic Pollutants, they formalized a global ban on the production and use of DDT, then provided an exception for parties that register their intent to continue to use DDT for mosquito control.[154] Through permitting opt-outs from the global ban, negotiators achieved a compromise that addresses both the target risk (environmental and health harms from DDT) and one countervailing risk of a ban (malaria).

Strong Precaution does not inexorably lead to an abdication of judgment. It does not doom legislators to extremist positions in which known countervailing risks and the costs of legislation must be ignored. Rather, as the above examples illustrate, legislators can structure a Strong Precautionary regulatory regime to address both the "target risk" and countervailing risks.

For a particularly elegant example of this in chemical regulation, consider REACH, the EU chemical legislation discussed *supra.* The EU explicitly grounded the legislation in the precautionary principle,[155] and the legislation heavily relies on burden shifting. In particular, REACH imposes a default sunset date after which a chemical identified as "very high concern" cannot be marketed in the EU.[156] "Very high concern" is a term of art, defined in the statute in reference to the intrinsic properties and hazards of the chemical (such as carcinogenicity or bioaccumulative properties). REACH further provides that chemical manufacturers can overcome the default and receive authorization to market a "very high concern" chemical through demonstrating, among other things, that the socio-economic benefits of the chemical exceed potential costs.[157]

REACH provides an important reminder that a Strong Precautionary regulatory regime need not preclude consideration of the costs and benefits of regulation. In a twist on prevailing approaches in the United States, however, REACH shifts the burden of conducting the cost-benefit analysis to the manufacturer that seeks to continue to market a chemical substance with known hazardous properties.[158] REACH also requires that manufacturers, in the authorization process, analyze whether less hazardous substitute chemicals

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[154] Stockholm Convention on Persistent Organic Pollutants, opened for signature May 23, 2001, UN Doc. UNEP/POPS/CONF/4, *reprinted in* 40 I.L.M. 532 (2001). Under Annex II of the Convention, continued use of DDT is subject to developing an implementation plan that includes a search for suitable alternatives to DDT. *Id.*

[155] See REACH preamble, par. 69.

[156] *See* Noah M. Sachs, *Jumping the Pond: supra note ___,* at 1834-38 (2009) (providing an overview of REACH).

[157] *Id.*

[158] *See* Wagner, *The Precautionary Principle and Chemical Regulation in the U.S., supra* note __ at 473 (noting that a system in which cost-benefit analysis is used by manufacturers to rebut precautionary health-based regulation would be consistent with the precautionary principle.).

exist.[159] In this way, the "stop and think" mechanism of Strong Precaution, far from ignoring tradeoffs, becomes the spur for a formal alternatives analysis that has never been a prominent part of U.S. chemical regulation.

C. THE LIMITS OF STRONG PRECAUTION

Some advocates of the Strong Precautionary Principle want to universalize it as a guiding polestar for all risk decision making. As the authors of the Wingspread Declaration put it, "Corporations, government entities, organizations, communities, scientists and other individuals must adopt a precautionary approach *to all human endeavors*."[160]

The Principle has some significant limitations, however, and it needs to be applied judiciously.[161] For one thing, many forms of human health and environmental risks have no "proponent" to which the burden of proof can be shifted. Consider natural disasters, the spread of contagious disease, or the remediation of historic contamination at a hazardous waste site. We need government to take appropriate preparations for these risks, and in the case of historic waste sites, to set appropriate clean-up standards, but there is no private "proponent of the activity" who can bear the burden of proof. Climate change is another example of a problem not easily addressed through burden-shifting mechanisms. A climate change strategy must include promoting energy efficiency and pricing greenhouse gas emissions,[162] and arguments over burden of proof would merely distract from those urgent national tasks.

A second reason that Strong Precaution should not be viewed as universally applicable is that putting government in a risk gatekeeping role can be complex, potentially anti-competitive (because it can restrict the products and services that enter commerce), and expensive. PhD-level government personnel would often be needed to review risk data compiled by private parties and to determine (subject to layers of judicial review) whether the proponent has met its burden of proof. Because government would be in the position of reviewing the risks of thousands of products and technologies that might ultimately prove to be harmless, indiscriminate application of Strong Precaution could result in an expansion of the government risk assessment bureaucracy. This would be a counterintuitive outcome from a principle

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[159] *See* Sachs, Jumping the Pond, *supra* note __, at 1841-42 (discussing REACH's incentives for development of substitutes for hazardous chemicals).

[160] *See, e.g.*, Wingspread Declaration, *supra* note ___. The context of this quotation makes it clear that the authors were describing the Strong Precautionary Principle, as the Declaration goes on to provide a definition of precaution that includes burden shifting.

[161] *See* EUROPEAN COMMISSION, COMMUNICATION ON THE PRECAUTIONARY PRINCIPLE 21 ("Reversing the burden of proof and placing it on the producer, manufacturer, or importer…cannot be systematically entertained as a general principle" of risk regulation.).

[162] *See* Noah M. Sachs, *Greening Demand: Energy Consumption and U.S. Climate Policy,* DUKE ENVTL L. & POL'Y. FORUM (2009).

designed to shift the burden of proof *away* from government.

For these reasons, the gatekeeping mechanism of the Strong Precautionary Principle should be reserved for serious threats that cannot be addressed through less intrusive mechanisms. For many forms of risk, there is no need to resort to the aggressive *ex ante* approach to risk implicit in the Strong Precautionary Principle. Consider, for example, the construction of a skyscraper, the marketing of a dangerous recreational activity (e.g., sky diving), or the manufacture of a dangerous power tool (e.g., chainsaw, jackhammer). These all raise serious safety risks, but the liability system, insurance, and tort-based deterrence have performed reasonably well for addressing these risks in the United States. Or, consider the case of pioneering, risky surgical procedures, where the United States has relied principally on information disclosure, informed consent, and tort-based deterrence to allocate risk. A Strong Precautionary approach would suggest that the surgeon should be subject to a government pre-approval process. Meanwhile, the patient could die on the operating table. There is no need to institute such a complex mechanism for risks that are already being handled acceptably through less aggressive means.

The most pressing issue for legislators, therefore, is how to make the fundamental judgment alluded to in the prior section: determining when it makes sense, despite attendant complexity, to implement the Strong Precautionary Principle as the basis for a risk regulatory regime. Relevant criteria should include the administrative costs of establishing an *ex ante* review mechanism or permitting program; the suitability of tort remedies or criminal penalties to address the risk; whether risk-creators are likely to be judgment proof in the event that harm occurs; whether the risk is one to which participants consent (as in dangerous recreational activities), or is in the nature of a nonconsensual externality; and whether the risk could be addressed adequately through post-market regulatory mechanisms.[163]

In this Article, I do not intend to explore every arena of risk in which the Strong Precautionary Principle should be applied, but I have provided numerous examples of its successful operation. As I argue below, Congress should implement the Principle in chemical regulation -- a field defined by serious potential risks, uncertainty regarding health hazards and exposure pathways, and deficient post-market mechanisms for addressing the risks.

[163] Steve Shavell explored some of these criteria thirty years ago in his classic article on the merits of liability rules versus public regulation in risk management. Steven M. Shavell, *Liability for Harm Versus Regulation of Safety*, NBER Working Paper W1218 (1983).

III. IMPLEMENTING STRONG PRECAUTION IN CHEMICAL REGULATION

The current system of U.S. chemical regulation is deeply flawed. It leaves Americans exposed to thousands of untested synthetic chemicals that could cause cancer, birth defects, and infertility. Although Congress intended the statute as an early warning system for chemical risks, TSCA has failed to generate basic toxicity data for the vast majority of chemicals now in commerce. Indeed, U.S. law permits chemicals to be used in consumer products, food packaging, clothing, toys, plastics, and other products with little or no inquiry into whether those chemicals pose health and environmental risks. As a result, American children now enter the world "pre-polluted," having been dosed *in utero* with dozens of industrial chemicals (through the mother's lifetime exposure) that have never been tested for their health effects.[164]

TSCA reform is likely this decade, but it is still an open question whether the statute will continue to rely on a governmental burden of proof and complex cost-benefit balancing, or whether it will be grounded in Strong Precaution. The political space that has opened around TSCA reform should be used for a much-needed conceptual debate about the meaning of the precautionary principle in American environmental law.

In this Part, I provide a brief summary of what has gone wrong in U.S. chemical regulation, supplementing a prior article where I discussed the flaws in TSCA at some length.[165] I then outline how the Strong Precautionary Principle should be implemented in the next generation of American chemical regulation to remedy these problems, putting chemical regulation on a far more protective footing. My goal here is to concretize the debate over the Strong Precautionary Principle, which often dissolves into airy abstraction. I aim to show that the Principle is not only defensible – it is the key to protecting Americans from serious harms from toxic chemicals.

A. TSCA'S TROUBLES

TSCA reflects neither the Strong Precautionary Principle nor even the Weak Precautionary Principle. Instead, it reflects an "unprecautionary principle."[166] It imposes no default requirements to test chemicals on the

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[164] ENVIRONMENTAL WORKING GROUP, http://www.ewg.org/kid-safe-chemicals-act-blog/kid-safe-chemicals-act. *See also* ENVIRONMENTAL WORKING GROUP, POLLUTION IN PEOPLE: CORD BLOOD CONTAMINANTS IN MINORITY NEWBORNS (2009), available at http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf.

[165] Sachs, Jumping the Pond, *supra* note __, at 1825-32.

[166] Wendy Wagner, The Precautionary Principle and Chemical Regulation in the U.S., *supra* note __ at 468.

market, it requires that EPA amass a high degree of evidence on risk before the agency can restrict chemicals, and it imposes complex procedural requirements just for the agency to seek additional data on a chemical's risks. The statute is reactive, at best. It can hardly be said to be anticipatory.

Wendy Wagner has suggested that there is a precautionary "pocket" within TSCA in its program for review of new chemicals.[167] About seven hundred new chemicals are manufactured each year,[168] and for these new chemicals, manufacturers must submit a Pre-Manufacture Notice (PMN) to EPA listing the structure and properties of the substance.[169] The agency has ninety days from receipt of this notice to assess risks.[170] EPA relies principally on computer modeling in this process, and given resource constraints, only twenty percent of PMNs submitted receive a detailed review.[171] Significantly, TSCA does *not* require that manufacturers submit toxicity data or conduct any safety testing on new chemicals as part of the PMN process, or as a condition of reaching the U.S. market.[172]

Consequently, while TSCA's new chemicals notice program bears a superficial resemblance to an *ex ante* review process, it cannot be said to reflect the Strong Precautionary Principle at all. Some scholars have referred to TSCA's PMN procedure as an example of burden-shifting in U.S. environmental law,[173] but as John Applegate has explained, "the PMN requirement is less a licensing mechanism than a sieve."[174] Unlike U.S. law governing pharmaceuticals and pesticides, TSCA imposes no affirmative burden on the manufacturer to research the toxicity of new chemicals being developed for sale, and manufacturers have no obligation to prove that a new chemical poses acceptable, non-significant risks to human health.

Due to resource constraints and statutory hurdles to testing, the far larger class of more than 60,000 "existing" chemicals (those that were in

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[167] *Id.* at 464-465. *See also* Renn & Elliott, *infra* note 176 (arguing that the PMN program has been relatively successful).

[168] *See* GAO: CHEMICAL REGULATION: OBSERVATIONS ON IMPROVING THE TOXIC SUBSTANCES CONTROL ACT 2 (2009).

[169] TSCA §5(a), 15 U.S.C. §2604(a).

[170] *Id. See also* Adelman, *Cautiously Pessimistic, supra* note __ at 389 (calling the PMN review process "perfunctory" and noting that the 90-day window for EPA review is often "preclusive of regulatory action.").

[171] GAO, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 12, 17-18 (2005).

[172] Manufacturers must disclose toxicity information about a new chemical only if such information is in the manufacturer's "possession or control" or if it is "known to or reasonably ascertainable by" the submitter. 40 CFR §§720.50(a) and (b). Under this "disclose it if you have it" model, it is not surprising that only fifteen percent of PMNs contain any health and safety information. GAO, Options Exist, *supra* note __ at 12, 17-18.

[173] *See, e.g.,* Dan Bodansky, *The Precautionary Principle in U.S. Environmental Law*, *supra* note __ at 210; Wiener, *Precaution in a Multirisk World*, *supra* note __ at 1523.

[174] Applegate, *Precautionary Preference, supra* note __ at 432.

commerce before 1979) has received little regulatory scrutiny.[175] In enacting TSCA, Congress grandfathered these existing chemicals, setting up a sharp division between new chemicals (subject to pre-manufacture notice), and existing chemicals, which are not subject to any formal risk assessment except on an *ad hoc* basis through post-market testing requirements under Section 4 of the Act. EPA has exercised this post-market testing authority for only two hundred chemicals, however.[176] The grandfathering of existing chemicals has no basis in toxicology, of course, and the legislative choice to exempt existing chemicals from routine testing now means that comprehensive toxicity data is available for a just a fraction of all chemicals used in the United States – by some estimates less than two percent.[177] The main problem that TSCA was meant to address –lack of data on chemicals—has not been solved, thirty-five years after TSCA's enactment.[178]

Where scientific evidence *does* suggest that a chemical poses serious risks to human health or the environment, TSCA raises significant barriers for the EPA to restrict a chemical – the opposite of precautionary risk management.[179] TSCA places the burden on EPA to prove, through complex statutory procedures, that a chemical poses "unreasonable risk" to human health or the environment, and it requires that the agency balance risks with the economic benefits of the chemical, after oral evidentiary hearings. Furthermore, TSCA subjects EPA risk determinations to exacting standards of judicial review.[180] While the Strong Precautionary Principle calls for proportional regulatory responses, TSCA creates a one-size-fits-all system in which EPA must meet the same statutory burden of proving "unreasonable risk" whether it wants to enact a complete ban or simply restrict certain uses or

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[175] Existing chemicals represent about 78% of all chemicals that have been introduced into commerce in the United States. GAO, OPTIONS EXIST, *supra* note ___ at ____. But by volume, pre-1976 existing chemicals still account for ninety-nine percent of the chemicals in commerce. David E. Adelman, *A Cautiously Pessimistic Appraisal, supra* note __ at 390. So if the new chemicals program is viewed as a precautionary "pocket" in the statute, it is a narrow pocket indeed. While TSCA authorizes testing of existing chemicals, "it generally provides no specific requirement, time frame, or methodology for doing so . . . As a result, EPA does not routinely assess the risks of the more than 83,000 commercial chemicals in use." GAO, OBSERVATIONS ON IMPROVING THE TOXIC SUBSTANCES CONTROL ACT, *supra* note ___ at 4.

[176] Cite needed.

[177] Cite needed.

[178] These statutory flaws have been exacerbated by insufficient funding for TSCA. Historically, the number of agency personnel devoted to TSCA implementation has been less than the number devoted to implementation of FIFRA, the statute governing pesticides, despite the fact that pesticides represent a far smaller universe of chemicals. *See* Mark Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ENVTL. L. RPTR. 10034 (2009).

[179] For example, EPA can enact restrictions on a chemical only after a full trial-type hearing; it must make a series of statutory findings prior to restrictions; it must choose the "least burdensome" regulatory requirement that will adequately protect against the risk, and it must demonstrate that no other statute could address the concern. TSCA § 6(a) and (c).

[180] TSCA §6(a), 15 U.S.C. §2605(a).

impose labeling requirements on a chemical.[181] Given the mismatch between EPA's high burden of proof and inadequate data supply, it is not surprising that EPA has attempted to impose regulatory restrictions on only five "existing" chemicals in the thirty-five year history of TSCA.[182] The last attempt to do so, for asbestos, was set aside by the Fifth Circuit in *Corrosion Proof Fittings*, discussed in Part II.[183]

TSCA is fundamentally unprotective – the "lapdog of American environmental law."[184] In 2009, the Government Accountability Office named EPA's toxics regulatory program a "high risk" government program, needing "broad based transformation" and priority attention from the Obama administration and Congress.[185] EPA Administrator Lisa Jackson testified in 2009 that TSCA is "outdated" and "does not provide the tools to adequately protect human health and the environment as the American people expect, demand and deserve."[186] Even the American Chemistry Council, long a defender of the status quo, now acknowledges that Congress should "begin the effort to modernize TSCA."[187]

At the same time that the weaknesses of TSCA have become apparent, it has also become clear that the tort system does not provide an adequate backstop or substitute for regulatory oversight. In a recent book comparing European and U.S. risk regulation, Donald Elliott and Ortwinn Renn suggest that despite clear flaws in TSCA, the overall system of chemical regulation in the United States remains protective of human health and is roughly as precautionary as Europe's.[188] "The potent civil liability system in the U.S." they allege, "is at least as important a regulatory system for chemicals as is

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[181] *See* Richard Denison, *supra* note 3, at 10222 (discussing TSCA's general "unreasonable risk" standard and comparing it to the goal of proportionality of regulatory response in the precautionary principle.)

[182] The five chemicals or chemical classes are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium.

[183] *Corrosion Proof Fittings vs. EPA* 947 F.2d 1201 (5th Cir. 1991). As the GAO has noted, *Corrosion Proof Fittings* was widely considered to be a severe blow to EPA and to the effectiveness of TSCA because "asbestos is generally regarded as one of the substances for which EPA has the most scientific evidence or documentation of substantial adverse health effects." GAO, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS 20 (2007).

[184] Sachs, Jumping the Pond, *supra* note ___, at 1818.

[185] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO THE CONGRESS, HIGH RISK SERIES: AN UPDATE 22 (2009) ("Without greater attention to EPA's efforts to assess toxic chemicals, the nation lacks assurance that human health and the environment are adequately protected.").

[186] Testimony of EPA Administrator Lisa Jackson, Senate Committee on Environment and Public Works, January 2010.

[187] REVISITING THE TOXIC SUBSTANCES CONTROL ACT OF 1976: HEARING BEFORE THE SUBCOMM. ON COMMERCE, TRADE AND CONSUMER PROT. OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 111TH CONG. 2 (2009) (Statement of Cal Dooley, Pres., Am. Chemistry Council).

[188] Donald Elliott and Ortwinn Renn, "Chemical Regulation" *in* REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE (Jonathan B. Wiener et al, eds. 2010).

EPA regulation under TSCA."[189] But this conclusion runs contrary to decades of scholarship highlighting the inadequacies of the tort system for addressing chemical exposures, given long latency periods and difficulties of proving causation and identifying the proper defendant.[190] The threat of future liability does not provide an incentive for chemical manufacturers to conduct toxicity research. More likely, the tort system provides incentives for manufacturers *not* to conduct toxicity research, given that the plaintiff will bear the burden of proof in any civil suit.[191]

The weaknesses of existing regulatory and tort remedies for harms from toxic chemicals justify a more aggressive *ex ante* licensing and review system for chemical risks. There is a fundamental difference between chemical risks and other kinds of risks, such as those from recreational activities, power tools, and other activities described *supra*, which can be handled reasonably well through informed consent, mutual bargaining, or tort-based deterrence regimes: In the case of chemical exposures, a person harmed is usually unaware of the exposure, the level of risk posed by the exposure, or the entity that produced the harmful product. Concepts of informed consent, assumption of risk, or Coasian bargaining make no sense in this context. Regulation, rather than litigation or de-centralized risk allocation through contract, must be the primary legal mechanism for addressing chemical risks, and regulatory review should ideally be applied before harm occurs.

As Congress takes up TSCA reform, it should ground any new statute in the Strong Precautionary Principle, aligning chemical regulation more closely with the way we regulate pesticides and pharmaceuticals. TSCA is a prime example of a statute that never lived up to the ambitious expectations of its drafters,[192] who envisioned TSCA as the "capstone" statute of American environmental law.[193] Shifting the burden of proof would return the statute to

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[189] *Id.*

[190] *See* sources cited in note 23, *supra*. *See also* John T. Nockleby, "Faces of the Tort Pyramid: Compensation, Regulation, and the Profession," *in* AN UNFINISHED PROJECT: LAW AND THE POSSIBILITY OF JUSTICE (Scott Cummings, ed. 2010) (arguing the regulatory function of tort law is severely compromised by the vagaries of litigation, such as the desire of plaintiff's lawyers to seek "ideal" plaintiffs with easy-to-prove injuries, high damages, and claims against financially solvent defendants).

[191] *See* Wendy Wagner, Commons Ignorance, *supra* note ___.

[192] Some of the main players in the congressional debate viewed TSCA as a highly anticipatory statute in which chemical manufacturers would bear the principal burdens of research, testing, and disclosure. *See* Legislative History of the Toxic Substances Control Act, 94th Congress at 218 (statement of Senator James Pearson) ("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.").

[193] *See* James T. O'Reilly, "Torture by TSCA: Retrospectives of a Failed Statute," *Natural Resources and Environment*, Summer 2010. O'Reilly, currently a professor at the University of Cincinnati College of Law, was a lobbyist for Procter & Gamble in the 1970s and participated in many of the crucial negotiations that led to the passage of TSCA. He recently concluded that: "This was a lobbying effort so effective, in retrospect, that TSCA has been far less successful than its sponsors had hoped. My 'side' won in 1976. TSCA has failed and left us with a mere façade of effective

many of its original goals, and at the same time, it would be a watershed development in American environmental law.

B. VISIONING THE NEXT GENERATION OF CHEMICAL REGULATION

A successor statute for TSCA must have a clear mission, set priorities, and provide EPA with tools to carry out the mission. It must be based on the best scientific information, but should not preclude action where there is residual or unresolvable scientific uncertainty. Below, I sketch the elements of a Strong Precautionary approach to chemical regulation – one that is faithful to the Principle while avoiding the parade of horribles predicted by the critics.[194]

1. *Precautionary Research Requirements*

A Strong Precautionary approach to chemical regulation must include default chemical testing requirements. Indeed, it is hard to see how any chemical regulatory regime could be deemed protective of human health without an initial, default requirement to compile risk assessment data for most chemicals on the market.

Congress should eliminate the elaborate statutory hurdles in TSCA that restrict EPA's ability to obtain information. Instead, Congress should mandate that chemical manufacturers and importers develop a basic set of toxicity data for each chemical they produce or import above some minimum threshold (such as one or ten tons per year), implementing "No Data, No Market" in the United States. There should be no distinctions in the required tests for "existing" and "new" chemicals, but the minimum data set could be expanded for the highest volume chemicals sold in the United States, such as benzene and formaldehyde. Congress could also mandate that testing proceed according to a "priority list" of chemicals suspected of posing the greatest risks, an idea at the heart of the TSCA reform bill introduced by Senator Frank Lautenberg in April 2010. Any chemical for which manufacturers fail to submit the required data would be prohibited from sale in the United States.[195]

Imposing the burden of data production on chemical manufacturers would make the private profit-motive the engine of toxicology research in the

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environmental action." *Id.*

[194] Here, I provide only a brief outline of some Strong Precautionary concepts in chemical legislation, as it is beyond the scope of this Article to cover every element of successor legislation for TSCA.

[195] To avoid duplicative animal testing, a new statute should contain provisions for joint research and data sharing, similar to provisions in REACH establishing Substance Information Exchange Fora in the registration process. *See* REACH Art. 29; *See also* "REACH Consortia Database," available at chemicalwatch.com/REACH_consortia (listing joint research consortia that have been established for over one hundred substances).

United States.[196] Default testing requirements would remedy the data drought in the United States and permit risk management to be based on hard data on risks and alternatives.

Critics of Strong Precaution often argue that the Principle is anti-innovation, but they have never clarified how, exactly, a requirement that manufacturers research and justify the risks from their products interferes with innovation within a firm. In chemical regulation, default testing requirements would likely *spur* product innovation. Such testing requirements would promote the growing "green chemistry" movement in the United States by providing risk data to the marketplace and allowing chemical manufacturers to compete on product safety as well as chemical characteristics.[197]

Critics of Strong Precaution also contend that the Principle locks in a "status quo bias."[198] By adopting a stance of skepticism for new products or technologies, they contend, the Principle ignores the risks posed by existing products and technologies.[199] In chemical regulation, however, it is current law that locks in status quo bias, by grandfathering all "existing" chemicals that were on the market when TSCA was enacted. To end this unjustifiable distinction, Congress could make the same risk assessment procedures, required on an *ex ante* pre-market basis for new chemicals, applicable to existing chemicals as well. It could do this by providing for a phase-in period of three to five years that would allow manufacturers to gather data on chemicals already on the market. Strong Precaution is usually viewed as an *ex ante,* pre-market review mechanism, but we need to make some concessions to practical politics here: it would be undesirable and impractical to require that all chemicals be pulled off the market until toxicity testing is performed.

Fortunately, the financial barriers to obtaining risk assessment data for existing chemicals have been lowered considerably because most major U.S. chemical manufacturers are already conducting the necessary testing of existing chemicals to comply with the EU's REACH regulation.[200] Cost estimates for REACH indicate that the cost of comprehensive toxicity testing for all chemicals on the EU market sold in volumes above ten tons is between €3 billion and €13 billion over eleven years, a reasonable cost burden for the

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[196] Placing the burden of data production on industry would represent a return to the original vision of TSCA, whose preamble states that development of toxicity data "should be the responsibility of those who manufacture and those who process . . . chemical substances and mixtures." TSCA §2, 15 U.S.C. §2601. The substantive provisions of TSCA, however, place the burden on EPA to prove that testing should be conducted for chemicals already on the market. *See* TSCA §4. Wendy Wagner notes that this is just one example of TSCA's "schizophrenic regulatory approach." Wendy Wagner, *The Precautionary Principle and Chemical Regulation in the U.S., supra* note ___, at 464 n.6. *See also* WILLIAM ROGERS, ENVIRONMENTAL LAW 489 (1994) ("TSCA is teeming with contradictions").

[197] See Sachs, Jumping the Pond, *supra* note _, at 1840.

[198] *See, e.g*., SUNSTEIN, LAWS OF FEAR, *supra* note __ at 42-45.

[199] *Id.*

[200] *See* Sachs, Jumping the Pond, *supra* note ___ at ___ (discussing the informational spillover effects of REACH).

global chemical industry, which has *annual* revenues approaching $1 trillion.[201] That testing data will be made publicly available, and chemical manufacturers could submit substantially similar data to EPA under a successor statute for TSCA.[202]

The cost estimates for REACH implementation are a significant contribution to the debate over the Strong Precautionary Principle. One of the major criticisms of establishing a licensing system for chemicals, in which manufacturers bear the burden of proof on safety, is that it will impose exorbitant costs on private industry and require an expansion of government risk assessment personnel to review the new data.[203] Critics also allege that comprehensive testing requirements are a needle-in-a-haystack approach because, of thousands of chemicals that may need to be reviewed, only a few may turn out to pose significant health or environmental effects worthy of regulatory attention. But REACH shows that the necessary investments in risk assessment personnel and toxicity testing are not exorbitantly expensive. The research costs for the private sector should be seen as a fully appropriate internalization of an externality.[204] Moreover, the cost of overhauling chemical regulation in the United States is likely to be less expensive than in Europe. The United States has a second-mover advantage here, since much of the testing likely to be required of U.S. chemical firms is already being conducted, by these same firms, for REACH compliance.

2. Shifting the Burden of Proof

The second major element of a Strong Precautionary approach to chemical regulation is a shift in the burden of proof. If initial required testing demonstrates a serious threat to human health or the environment (as defined below), there should be statutory presumption that the chemical will be banned from sale (or its use restricted). The burden would then shift to the manufacturer to show why that chemical should continue to be marketed in the United States, despite the threat.

Under this regulatory structure, persistent scientific uncertainty about the

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[201] *Id.* at 1842-43 (discussing REACH cost estimates).

[202] *See* Sachs, Jumping the Pond, *supra* note ___ at 1864-68 (discussing informational spillover effects of REACH in the United States).

[203] *See* Valerie J. Brown, *REACHing for Chemical Safety*, 111 ENV'T HEALTH PERSPECTIVES A 766, A768 (2003) (criticizing REACH and noting that the "combination of the increased financial burden of testing, the bureaucracy of registration and authorization, and the requirement of applying the precautionary principle will discourage innovation and could ruin many small and medium size enterprises.").

[204] *See* FRANK ACKERMAN & RACHEL MASSEY, GLOBAL DEV. & ENVT. INST., THE TRUE COSTS OF REACH 10 (arguing that if a chemical essential to downstream users is withdrawn from the market because its manufacturer believes it is not worth paying testing costs, then the chemical is probably underpriced).

nature or extent of the risk will be resolved *against* the chemical, in contrast to current law, in which scientific uncertainty undercuts EPA's ability to enact precautionary restrictions. Moreover, industry will have a financial incentive to resolve scientific uncertainties and to identify means of reducing risks from chemicals with known hazardous properties, to overcome the default regulatory presumption.

To structure this burden shift, Congress should implement both priority-setting mechanisms (which I call "precautionary triggers") and some avenues for manufacturers to overcome default prohibitions by demonstrating acceptable risk (which I call "regulatory offramps"). Both are explained in more detail below.

a. Precautionary Triggers

The task of risk assessment and risk management will quickly become unwieldy if burden shifting is applied to tens of thousands of chemicals simultaneously. If government is to serve as a risk gatekeeper, there must be priority-setting mechanisms, as a matter of practical necessity, to control the number of products being reviewed at one time. To set priorities and reduce costs, Congress should rely on precautionary triggers for burden shifting, under which the burden of proof would shift to chemical manufacturers only for the subset of high-priority chemicals that meet the trigger, not for the entire universe of chemicals on the market. Focusing on subsets of hazardous chemicals is fully consistent with the Strong Precautionary Principle because, as I argued in Part I, the Principle calls for burden shifting for *serious* threats to human health and the environment, not for every possible risk.

One such precautionary trigger could be the intrinsic hazards of a chemical, as determined through animal testing, *in vitro* analysis, ecological fate and transport studies, or computer modeling. Here, the relevant regulatory question is whether the chemical is *capable* of causing cancer, reproductive harm, or other adverse health or ecosystem effects. The advantage of relying on intrinsic hazard as the threshold inquiry, rather than the actual risk of harm to humans,[205] is that hazards can be identified relatively easily through laboratory experiments and an understanding of the physical and chemical properties of the substance. Detailed human exposure assessment or assumptions are not necessary.

[205] Risk is generally characterized as a combination of a chemical's intrinsic hazard and the degree of human exposure. *See* APPLEGATE, GABBA, LAITOS & SACHS, REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTE (Foundation Press, forthcoming 2011). Under the precautionary trigger proposed here, intrinsic hazard would trigger burden shifting. Exposure issues, including whether safety precautions such as ventilation or protective equipment could reduce human exposures, could then be raised by manufacturers as an argument for why the chemical should not be withdrawn. The overall regulatory architecture would therefore remain risk-based, not solely hazard-based.

Under REACH, chemical hazards that trigger burden-shifting in the authorization process include carcinogenicity, mutagenicity, toxicity for reproduction, persistence in the environment; and the ability of a chemical to accumulate in the food chain.[206] The European Commission predicts that approximately 1,500 chemicals, or 5% of the 30,000 chemicals expected to be registered under the law, will fall into this "very high concern" category.[207] A Strong Precautionary regime needs some mechanism for delineating the class of chemicals that will be deemed to pose "serious" threats, and intrinsic hazard is a logical, feasible starting point for that line-drawing. TSCA, on the other hand, provides no mechanism for deciding which characteristics of chemicals should trigger a regulatory response, other than the vague framework of "unreasonable risk." If Congress adopted a precautionary hazard trigger for burden shifting, there would inevitably be line-drawing issues and potential litigation over whether a particular substance falls into one of these categories.[208] But the categories represent a necessary step in delineating the substances that should be subject to heightened concern and scrutiny.

A second potential trigger for burden-shifting could be the results of biomonitoring studies. Biomonitoring is the study of the presence of industrial chemicals in humans. In several studies in the past decade, the Centers for Disease Control and Prevention has demonstrated that dozens of industrial chemicals are commonly found in the blood and urine of representative samples of the U.S. population.[209] The Environmental Working Group, in its own testing, found that of 210 synthetic chemicals tested in a population of volunteers, 167 chemicals were found in at least one person, and some chemicals, such as brominated flame retardants, were present in nearly all the volunteers.[210] Most prior biomonitoring studies have had limited sample sizes,[211] but if they were significantly expanded, the data could be used to compile a list of synthetic chemicals commonly found in Americans. These chemicals could then be presumed unsafe – the precautionary trigger. The

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[206] REACH Art. 57. *See also* REACH preamble, par. 69 ("substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention."). Similarly, the Maine Toxic Chemicals in Children's Products Act classifies chemicals of "high concern" as those that can cause cancer, reproductive or developmental harm; those that disrupt the endocrine system; and those that are persistent, bioaccumulative, and toxic. Maine Revised Statutes, Title 38, Chapter 16-D, Sec 1693.

[207] EUROPEAN COMMISSION, REACH IN BRIEF, at 16.

[208] Congress could limit that potential for litigation delay. The Lautenberg bill, for instance, makes EPA decisions on which chemicals should be on the priority list immune from judicial review. Safe Chemicals Act, S. 3209.

[209] *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, FOURTH NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS (2009), available at http://www.cdc.gov/exposurereport/pdf/FourthReport_ExecutiveSummary.pdf.

[210] *See* JANE HOULIHAN ET AL, ENVIRONMENTAL WORKING GROUP, BODY BURDEN: THE POLLUTION IN PEOPLE 3 (2003).

[211] *See* Denison, *supra* note 3 at 10025 ("Government has yet to conduct broader, more exploratory biomonitoring – aimed at identifying the full range of xenobiotics to which humans are exposed, as one means of identifying chemicals that are priorities for further scrutiny.").

burden of proof for continued marketing of this class of chemicals would then switch to manufacturers, on the grounds that manufacturers should have an affirmative obligation to demonstrate that chemicals widely dispersed inside our bodies are not causing any substantial harm to human health.

The American Chemistry Council challenges the regulatory utility of biomonitoring data, claiming that it "provides a snapshot of substances present in the body at a single point in time, but it alone does not tell us where a substance came from, when a person was exposed to it, the amount of exposure over time, or if there will be any health effects."[212] To be sure, the presence of an industrial chemical in human tissues does not by itself indicate harm, but given the widespread uptake of certain chemicals by humans, that presence should at least trigger a shift in the burden in proof – an affirmative requirement to prove the lack of substantial harm.

The Safe Chemicals Act, introduced by Sen. Frank Lautenberg in April 2010, relies heavily on precautionary burden shifting. It requires EPA, within eighteen months after enactment, to establish a rotating "priority list" of 300 substances. For any substance on that list, the burden would switch to the manufacturer to prove a "reasonable certainty of no harm." The bill states that chemical substances should be added to list "at the Administrator's discretion, based on available scientific evidence, and consideration of their risk relative to other chemical substances, based upon presence in biological and environmental media, use, production volume, toxicity, persistence, bioaccumulation, or other properties indicating risk."[213]

b. Regulatory Offramps

Strong Precaution does not require banning all risky products or activities, nor does it require banning all chemicals with intrinsically hazardous characteristics. Many hazardous compounds offer important benefits for the economy and human welfare. For example, mercury, a potent neurotoxin, is used to make compact fluorescent light bulbs and flat-panel computer monitors. Properly construed, the Strong Precautionary Principle should provide an opportunity for a chemical manufacturer to justify why marketing of a chemical should be permitted, overcoming any default presumption against sale. In a successor statute to TSCA, for example, manufacturers should be provided an opportunity to show that a chemical with hazardous characteristics should still be permitted to be marketed because: 1) the actual risks to human health or the environment are not substantial; 2) the risks can be controlled through limiting exposure; or 3) the benefits of the chemical to

[212] ACC Biomonitoring website, available at http://www.americanchemistry.com/s_acc/sec_mediakits.asp?CID=216&DID=565

[213] Safe Chemicals Act, *supra* note __, sec. 7.

society outweigh any risk.

Through these provisions, the overall regulatory structure would remain focused on the actual risks of a chemical to human health and the environment, not just the intrinsic properties of the chemical. Moreover, Congress could choose to incorporate cost-benefit analysis into a regulatory system grounded in Strong Precaution, but notably, it would be the manufacturer, rather than the government, that would conduct the analysis and bear the burden of proof.[214]

I refer to these mechanisms as "regulatory offramps." They help to counter the charge of many critics that Strong Precaution is a straight-jacketing approach that offers no regulatory flexibility. They also alleviate concerns about risk-risk tradeoffs, because if significant economic damage or welfare loss will result from restrictions on a chemical, the manufacturer will have the opportunity to make the case that restrictions are unwarranted.

As noted in Part II, the EU has pioneered use of regulatory offramps in REACH. Under REACH, regulators may grant a time-limited authorization to continue to market a "very high concern" chemical if the manufacturer or importer can demonstrate that the risks to human health and the environment are "adequately controlled," or if this showing cannot be made,[215] the manufacturer or importer must demonstrate: 1) that the socio-economic benefits exceed the risks; *and* 2) that are no suitable substitute chemicals or technologies.[216]

Regulatory offramps are the back-end of the Strong Precautionary mechanism in chemical regulation. The key question is not whether a chemical is hypothetically or potentially harmful, but rather whether a chemical is likely to be harmful in its actual uses and applications in commerce. My proposed regulatory offramps provide an opportunity for a manufacturer to show that a substance, although hazardous in laboratory tests, actually poses no substantial risk to human or ecosystems because of the way it is used (e.g., that it is sealed in polymers; that there is limited potential for inhalation, digestion, or dermal exposures; or that environmental releases can be prevented through strictly supervised disposal). But to do this right, we need much more information than we have currently about how chemicals are actually used in the supply chain, and what exposures may be occurring. TSCA does a very poor job of generating this information currently.[217]

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[214] The experience under TSCA shows that if cost-benefit balancing is a governmental responsibility, regulation will be infrequent due to the complex informational demands of that task. *See* GAO, OBSERVATIONS ON IMPROVING THE TOXIC SUBSTANCES CONTROL ACT, *supra* note __ at 9.

[215] REACH presumes that risks cannot be adequately controlled for persistent and bioaccumulative chemicals and for chemicals that do not have a known safe threshold below which a lack of adverse effects can be documented. REACH, Article 60(3).

[216] REACH, Article 60(4).

[217] *See* CONGRESSIONAL RESEARCH SERVICE, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 17 (July 18, 2008) ("Data are also lacking on production volume and use, which are critical for determining the potential for human and environmental

Regulatory offramps should be a component of TSCA reform legislation. But in implementation, regulators should be skeptical about manufacturers' arguments that known hazardous chemicals actually present little risk because exposures are minimal or because risks can be controlled through warnings or improved technology. Historically, the United States has done a poor job of tracking uses and exposures to chemicals once chemicals are put on the market. And because many of the most hazardous classes of chemicals also persist in the environment for decades, it can be difficult to predict the degree of human exposure over time.[218]

Substitution analysis should also be a required component of the regulatory offramp process. If a chemical manufacturer seeks to market a chemical with known hazardous properties, or that is already widely present in the bodies of Americans, it should also have an obligation to investigate whether any less hazardous substitute chemicals are available that could serve the same purpose. Alternatives analysis is a core component of the Strong Precautionary Principle, though not of TSCA. The goal of a successor statute for TSCA should not only be scientifically-sound analysis of the risks of a particular chemical, but also incentivizing reductions in the use of all hazardous chemicals over time.

CONCLUSION

The Strong Precautionary Principle provides a useful framework for managing risk in the face of scientific uncertainty. Widely derided as inflexible, unworkable, counterproductive, or anti-innovation, the Principle has been consistently attacked in the academic literature on risk regulation. Yet as this Article has shown, the Principle already animates many successful risk regulatory regimes in the United States. It is not blind to risk-risk tradeoffs nor to considerations of the cost of regulation. But it does reflect the intuition that those who introduce potentially risky products to the marketplace should bear the burden of researching and justifying the risks. The Principle is particularly useful in areas, such as chemical regulation, where there is a potential for serious harm, where there is scientific uncertainty about the nature of risk, and where less aggressive, decentralized mechanisms are clearly inadequate to address the risk.

Indeed, chemical regulation provides a helpful case study of Strong

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exposure…").

[218] *See* HOUSE ENERGY AND COMMERCE COMM., SUBCOM ON COMMERCE, TRADE, AND CONSUMER PROTECTION March 4, 2010 (Testimony of Linda Greer, Natural Resources Defense Council) ("Because risk assessments require a quantification of exposure levels, and because the levels of [Persistent, Bioaccumulative, and Toxic compounds] will continue to rise for as long as the contaminant is released into the environment or the food chain, [regulators] cannot adequately evaluate the harm posed by this class of compounds.").

Precaution's utility. Widely viewed as a "broken statute,"[219] the current TSCA regime needs more than incremental reform. Shifting the burden of proof would dramatically alter the perverse incentives of the existing statute and would end the data drought that has plagued chemical regulation since the 1970s. As Congress considers a successor statute for TSCA, which will govern chemical risks for much of the 21st Century, it should accordingly ground any new legislation in the Strong Precautionary Principle. The Principle provides a sound theoretical basis for protecting public health and reforming TSCA's unprotective, unprecautionary system of chemical regulation.

[219] Mark Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ENVTL. L. RPTR. 10034 (2009).