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RESCUING THE STRONG PRECAUTIONARY PRINCIPLE FROM ITS CRITICS

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University of Illinois Law Review, Vol. 2011

The Strong Precautionary Principle, an approach to risk regulation that shifts the burden of proof on safety, can provide a valuable framework for preventing harm to human health and the environment. Cass Sunstein and other scholars, however, have consistently criticized the Principle, rejecting it as paralyzing, inflexible, and extreme. In this reassessment of the Strong Precautionary Principle, I highlight the significant benefits of the Principle for risk decision making, with the aim of rescuing the Principle from its dismissive critics. 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, nor does it ignore tradeoffs, as Sunstein has alleged. Rather, through burden shifting, the Principle legitimately requires risk creators to research and justify the risks they impose on society. By exploring where the Principle already operates successfully in U.S. law—examples often overlooked by the critics—I highlight the Principle's flexibility and utility in regulatory law.

This Article uses chemical regulation as a case study in how the Principle can guide Congress in an ongoing controversy. Congress is considering a major overhaul of the flawed Toxic Substances Control Act of 1976 (TSCA), and this change could be one of the most significant developments in environmental law in a generation. This Article advocates implementing the Strong Precautionary Principle in a replacement statute for TSCA. Under my proposed licensing system, chemical manufacturers would carry the burden to demonstrate that their products do not pose significant risks to human health or the environment. The TSCA example shows that the Strong Precautionary Principle is not a vague abstraction, as critics have alleged, but can instead provide practical guidance for strengthening a troubled, and underprotective, chemical regulatory regime.
(pp. 1285-1286)

… In this Article, which builds on my prior study of TSCA reform,11 I use the chemical regulation debate as a lens for a broader reassessment of a controversial approach to risk management, called the Strong Precautionary Principle. **The Strong Precautionary Principle 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.12**

The Strong Precautionary Principle can be contrasted with the dominant regulatory framework in the United States, in which government agencies usually bear the burden of proof to show unacceptable risk prior to restricting a product or activity. TSCA's requirement that the EPA prove "unreasonable risk" to restrict a chemical is emblematic of that regulatory approach, and that choice to put the burden of proof on the EPA has crippled chemical regulation in the United States.13 According to Dr. Lynn Goldman, who oversaw TSCA implementation during the Clinton Administration, TSCA will "never be effective" unless it is amended to shift the burden of proof on chemical safety to chemical manufacturers.14

A preventive regulatory framework grounded in a shift in the burden of proof is attractive for a number of reasons, yet prior literature on **the Strong Precautionary Principle** has been almost uniformly critical. **Cass Sunstein, John Graham, Jonathan Wiener, and other critics of the Principle have little interest in its further application in TSCA, or elsewhere. Instead, they want to bury it.**
(p. 1288)

… This sharply critical scholarship is not a mere academic sideshow to the Beltway battle over chemical regulation.20 If influential scholars and key policy makers 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.21**
(p. 1289)

While literature advocating "weak" precaution is voluminous,22 the scholarly terrain on the Strong Precautionary Principle has been ceded to its opponents.23 Under their avalanche of criticism, some breathing space is urgently needed to reconsider the merits and practical applications of Strong Precaution.
(pp. 1289-1290)

… This Article undertakes this much-needed reassessment of the Strong Precautionary Principle.

…Part II counters the critics' objections to the Strong Precautionary Principle. **Cass Sunstein and other critics contend that Strong Precaution represents a new and untested alternative to dominant risk-management paradigms such as cost-benefit analysis.24** I show, on the other hand, that Strong Precaution is already deeply rooted in U.S. law. It forms the basis for numerous licensing, permitting, and preapproval programs that are cornerstones of public health and environmental protection in the United States.

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24. *See, e.g.*, John D. Graham, Admin., Office of Info. & Regulatory Affairs, The Role of Precaution in Risk Assessment and Management: An American's View, Address at The US, Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World (Jan. 11–12, 2002), http://www.whitehouse.gov/omb/inforeg/eu_speech.html ("[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.").**

(p. 1290)

… I. STRONG PRECAUTION AND RISK REGULATION

… *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 172 countries (including the United States) at the Earth Summit in 1992.29 Principle 15 of the Rio Declaration states:

> In order to protect the environment, the precautionary approach shall be widely applied 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 a reason for postponing cost-effective measures to prevent environmental degradation.30

(p. 1292)

… Although Sunstein himself accepts the Weak Precautionary Principle, others have attacked the Principle in three decades of acrimonious debates, 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 it actually animates U.S. law or has instead been eroded through unreasonably stringent "hard look" review and judicial demands for comprehensive administrative records.38 **In Washington, there is a widespread perception that weak versions of the Precautionary Principle give extra "weight" to environmental factors in risk decision making and would lead to abandonment of "sound science" in favor of regulation based on speculation and supposition of various threats to the environment. Public statements to this effect are voluminous.39** **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**.

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39. *See* 150 CONG. REC. 23,369 (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 36, at 313; PARTNERSHIP FOR SOUND SCIENCE IN ENVIRONMENTAL POLICY, PRECAUTIONARY PRINCIPLE OVERVIEW 1, (n.d), http://cicc.org/jru/031306/PP_Overview.pdf ("[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 . . ." (emphasis omitted)).

(p. 1294)

… 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. **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.
(p. 1304)

… *A. The Critics' Complaints*

The critics share some common objections. They often maintain that the Principle is extreme, inflexible, anti-science, anti-growth, or antitechnology. 88 Because Strong Precaution shifts the burden of proof on safety, 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.89 Sunstein claims that the Strong Precautionary Principle would "eliminate technologies and strategies that make human lives easier, more convenient, healthier, and longer."90 John Graham names the internal combustion engine, electricity, plastics, and the Internet as examples of technologies that would have been prohibited.91 Harvey Miller and Gregory Conko further charge 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."92

The claim that Strong Precaution is antithetical to technological progress is closely related to another view in the critical literature: Strong Precaution requires that manufacturers prove "zero risk" or "absolute safety" for an activity to proceed.93 These, of course, are impossible standards to meet (and the Strong Precautionary Principle, as I and others have defined it, does not impose them). Other critics suggest that the Principle will be applied on the mere "conjecture"94 or "speculation"95 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 U.S. values.96**

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88. *See, e.g.*, Julian Morris, *Defining the Precautionary Principle*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE 1 (Julian Morris ed., 2000); Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996); Graham, *supra* note 24.
89. *See, e.g.*, Graham, *supra* note 24.
90. SUNSTEIN, *supra* note 12, at 25.
91. Graham, *supra* note 56, at 3.
92. Henry I. Miller & Gregory Conko, *The Science of Biotechnology Meets the Politics of Global Regulation*, ISSUES IN SCI. & TECH. ONLINE (2000), http://www.nap.edu/issues/17.1/miller.htm.
93. *See, e.g.*, Kogan, *supra* note 39, at 601–03.
94. *See* Miller & Conko, *supra* note 92.
95. *See* Cass R. Sunstein, *The Precautionary Principle As a Basis for Decision Making*, 2 ECONOMISTS' VOICE 1, 5 (2005) (claiming that the Precautionary Principle "attempt[s] to prevent even speculative harm").

96. *See* Bailey, *supra* note 59, at 37; **Kogan, *supra* note 39, 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");** Miller & Conko, *supra* note 92.

(p. 1305)

… *B. Countering the Critics*

To defend use of the Strong Precautionary Principle in regulatory law, I make three principal claims. First, I demonstrate that Strong Precaution already operates successfully in U.S. law, undermining critics' arguments that the Principle is somehow inherently unworkable or paralyzing. Second, I show that the critics' charge of extremism is overheated. The Principle does not require prohibiting all risky activities, and in fact it 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 tradeoffs is overstated, especially against the backdrop of its practical implementation in U.S. law. Properly implemented, the Principle allows regulators to consider tradeoffs and alternatives. It commands neither extreme regulation nor 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.107 These attempts at delegitimization fail to recognize that the Strong Precautionary Principle already operates successfully in U.S. law. From Capitol Hill to state houses, legislators have frequently (and sensibly) turned to *ex ante* gatekeeping mechanisms to protect public health and the environment against serious risk.

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107. See, e.g., Kogan, supra note 39, at 493.

(p. 1307)

… 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 the 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.142 But the Strong Precautionary Principle can be implemented through a variety of defaults beyond simplistic, binary (ban or no-ban) choices.143** Appropriate defaults might include partial prohibitions, worker-safety precautions, locational restrictions, or warnings.

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142. Kogan, *supra* note 39, at 494 (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.").

(p. 1315)