Chapter 1

Risk, Uncertainty and Precaution: Lessons from the History of U.S.

Environmental Law

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One of the most important functions of government is to protect public health and the

environment from exposure to environmental risk. Through the enactment of environmental

laws governments have established regulatory programs that seek to provide comprehensive

protection against environmental harm. Yet regulatory policy inevitably must confront

considerable uncertainty in assessing risks and determining how to control them most

effectively. As society struggles to forge rough consensus over appropriate approaches to

regulation in the face of this uncertainty, decisions to regulate or not to regulate individual

products, chemicals, or pollutants often generate enormous controversy.

The precautionary principle wisely counsels that lack of full scientific certainty should not

preclude the adoption of prudent precautionary measures to prevent harm. Although the

precautionary principle has been widely embraced, it often is misunderstood and it even has

become a focus of controversy (Percival 2006) Regulatory policy generally seeks to prevent

harm before it occurs, but the reality is that it usually has been more reactive than

precautionary, responding only after harm has become manifest (Percival 1998; Percival et al.

2009). As regulators seek to improve their responses to new and emerging environmental

risks, it is useful to consider what lessons can be learned from past experience with regulatory

policy.

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This chapter reviews controversies over regulatory policy through the lens of history. Part 1 discusses the precautionary principle and why it is valuable even if it does not purport to answer the question of how stringent regulatory policy should be. Part 2 considers recent studies that assess whether regulatory policy is more precautionary in the United States (U.S.) or the European Union (EU) and why it is difficult to make confident, comparative conclusions. Part 3 then examines the history of how precaution has been incorporated into U.S. environmental law. It demonstrates that, despite the law's promise to prevent harm before it occurs, regulatory policy has been largely reactive, concentrating primarily on highly visible problems only after harm has become manifest. After reviewing the state of contemporary regulatory politics in the U.S., Part 4 analyzes lessons that can be learned to improve future regulatory policy.

THE PRECAUTIONARY PRINCIPLE AND GLOBAL ENVIRONMENTAL LAW
Globalization and expanding world trade are creating new pressures to harmonize
environmental standards. Countries increasingly are borrowing legal and regulatory policy
innovations from one another, moving toward greater harmonization of regulatory policies.
As traditional distinctions between domestic and international law and private and public law
are blurring, I have argued that a new kind of 'global environmental law' is emerging.

(Percival 2009; Yang and Percival 2009; Percival 2011). Non-governmental organizations
(NGOs) and national regulatory officials increasingly coordinate their activities on a global
scale. Even countries with very different legal and political traditions are borrowing legal and
regulatory innovations from each other. For example, the European Union's program
requiring registration, evaluation, authorization and restriction of chemicals (REACH) is
becoming highly influential in shaping approaches to chemical regulation in countries outside
of the EU (see section II).

The Precautionary Principle

As global environmental law has developed, one of the most broadly adopted concepts has been the precautionary principle. Although there are different formulations of the precautionary principle, the most widely embraced is the one articulated in Principle 15 of the Rio Declaration, signed by representatives of 178 nations at the United Nations Summit on Environment and Development (UNCED) in 1992. This 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'. ¹ This version of the precautionary principle does not purport to dictate how precautionary regulatory policy should be. Rather it states only that if there are threats of significant harm, scientific uncertainty should not serve as an excuse to reject cost-effective, preventive measures. It does not specify how significant the harm must be to trigger a regulatory response or what particular preventive measures should be undertaken to address it. Thus, the precautionary principle should not be viewed as an effort to establish any particular, prescriptive decision rule.

The Rio Declaration's statement of the precautionary principle has been widely embraced in subsequent international agreements. Some argue that the principle now is so widely accepted that it should be recognized as customary international law. Others disagree (Zander 2010). Language virtually identical to the Rio Declaration's articulation of the precautionary principle was incorporated into the 1992 Framework Convention on Climate Change² and in the Preamble to the Convention on Biological Diversity. The EU has expressly endorsed the precautionary principle and incorporated it in some of its regulatory directives. The

Maastricht Treaty of 1992 adopted the precautionary principle without explaining what it provides, and today Article 191(2) of the Treaty on the Functioning of the European Union refers to the precautionary principle as part of environmental policy.

In February 2000 the European Commission issued a Communication on the Precautionary Principle to explain in considerable detail its views concerning what the principle is and how it should be applied in EU environmental policy decisions. The U.S. government has been reluctant to embrace the precautionary principle, even though it generally is consistent with the thrust of most U.S. environmental laws, as discussed below.

Criticisms of the Precautionary Principle

The precautionary principle has come under fire from critics who believe that it will exacerbate what they perceive as a overly stringent regulatory policies. Frank Cross argues that 'the precautionary principle is deeply perverse in its implications for the environment and human welfare' (Cross 1996). Bjørn Lomborg argues that if it is used to strengthen environmental regulations, 'the precautionary principle is actually all about making worse decisions than we need to' (Lomborg 2001). Robert Hahn and Cass Sunstein argue that 'taken seriously, the precautionary principle can be paralyzing, providing no direction at all' (Hahn and Sunstein 2005). Sunstein argues that the precautionary principle is incoherent, potentially paralyzing, and that it will lead regulators to make bad choices (Sunstein 2005). Implicit in their arguments is the notion that society faces greater peril from overly precautionary regulations than from risks whose effect on human health and the environment is not fully understood at present.

To a large extent critics of the precautionary principle (e.g., Cross 1996; Hahn and Sunstein 2005; Sunstein 2005) are attacking a straw man. Because the precautionary principle does not purport to dictate stringent precautionary regulatory policy should be, it cannot fairly be blamed for perceived instances of overregulation, as I previously have argued (Percival 2006). The essential notion embodied in the precautionary principle -- that uncertainty should not be used as an excuse to eschew cost-effective preventive measures – is unassailable. It does not require that innovation come to a halt whenever any risks may be conjured. Properly understood, the precautionary principle is neither incoherent, paralyzing, nor a prescription for overregulation. Rather it cautions that regulatory policy should be proactive in responding to uncertainty concerning potentially serious threats to human health and the environment, mindful of the potential consequences for future generations.

Critics of the precautionary principle concede that the formulation articulated in the Rio Declaration is unobjectionable, but they point to the 'Wingspread Statement on the Precautionary Principle', drafted by a group of academics attending a conference in January 1998. The Wingspread Statement includes the sentence: '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'. They use the Wingspread Statement as a straw man to imply that proponents of the precautionary principle seek to prohibit any activity that has the potential to cause harm. However, this is a gross distortion of both the Wingspread Statement and the precautionary principle. It has not been embraced by the larger environmental community or regulatory policymakers. The precautionary principle does not mandate that regulators ban or forego all new technologies. Instead it supports a nuanced range of regulatory responses and 'a flexible degree of risk aversion' (Applegate 2002). Its critics' claim that society should not ignore potential negative

consequences of precautionary regulation 'is a trivial observation for no serious proponent of the precautionary principle disagrees with it' (Kysar 2010). The critics' 'crudely absolutist' caricature of the precautionary principle is simply inaccurate because the principle is 'merely one aspect of a much more elaborate regulatory process in which the precautionary principle is applied with a view toward proportionality of response and adaptability over time' (Kysar 2010).

The most vociferous critics of the precautionary principle argue that cost-benefit analysis is a superior decision tool for regulatory policy because it promises objectivity (e.g., Graham and Wiener 1995; Sunstein 2005). Unlike the precautionary principle, which does not purport to dictate how precautionary regulation should be, cost-benefit analysis counsels that regulation should not be so stringent as to generate compliance costs that exceed the benefits of regulation. Yet the conceptual and empirical difficulty of estimating regulatory costs and benefits actually renders cost-benefit analysis to be a highly uncertain decision tool, albeit one that at its core lacks both 'the virtues of humility and self-awareness that lie at [the] core' of the precautionary principle (Kysar 2010: 250).

Critics of the precautionary principle believe that it will lead to overregulation and that it even may cause more harm than it prevents. They argue that it will deprive society of 'opportunity benefits' that could prevent even greater harm or that regulation that it inspires will induce substitution of products or activities that pose even greater risks than those caused by the regulatory target (Cross 1996; Graham and Wiener 1995). Yet there is no basis for assuming that risks that are sufficiently salient to spawn precautionary regulation are systematically more likely to be less risky that the unknown risks of potential substitutes. 'Risk-risk' tradeoff analysis is flawed as a decision tool because it focuses only on ancillary risks generated by

regulation while ignoring regulation's ancillary benefits (Rascoff and Revesz 2002). The ancillary benefits of regulation (e.g., the Montreal Protocol's phase-out of ozone-depleting substances also reducing greenhouse gases), often are highly significant and there is no reason to believe that they systematically would be less than any ancillary risks of regulation.

In his book *The Laws of Fear* Cass Sunstein argues that the public is overly fearful of certain immediate risks that are statistically less dangerous than what could substitute for them if regulators respond to public demands for precaution (Sunstein 2005). But Sunstein's account ignores the great difficulty of generating political support for regulations that impose immediate, and often visible, costs in order to produce diffuse, and less visible, future benefits (Dana 2003). Embrace of the precautionary principle actually may help overcome political obstacles to collective action to protect against environmental risks. Even Sunstein concedes that some form of the precautionary principle can be useful in responding to risks that are too uncertain to be amenable to cost-benefit analysis, such as particular catastrophic risks and the destruction of biodiversity.

The precautionary principle does not purport to dictate how precautionary regulatory policy should be. Instead it is directed only at deeming a particular argument ('lack of full scientific certainty') as unacceptable as a justification for postponing cost-effective actions to prevent serious or irreversible harm (Sandin *et al.* 2002). Decisions concerning how much protection to afford public health and the environment are embodied in the environmental laws countries adopt, which represent the authoritative declarations of how precautionary regulatory policy should be. These laws generally do not prescribe any all-encompassing decision rule for setting regulatory policy. Instead they embrace a wide range of regulatory approaches while

identifying a host of relevant factors for officials to consider in making regulatory decisions (Percival 2009).

The notion that embrace of the precautionary principle will result in overregulation also is amply refuted by the European Commission's Communication outlining guidelines for using the precautionary principle. The Communication, which was subsequently endorsed by both the European Parliament and the EU Council of Ministers, emphasized flexibility in applying the precautionary principle to combat 'potentially dangerous effects deriving from a phenomenon, product or process [that] have been identified', when 'scientific evaluation does not allow the risk to be determined with sufficient certainty'. The Communication advised that regulatory responses to risk should be 'proportional', 'non-discriminatory', and 'consistent with similar measures already taken'. It endorsed the use of cost-benefit analysis to inform regulatory decisions and it also recognized the importance of reviewing interim regulatory measures in light of new scientific evidence.

As contributors to Michelle Everson and Ellen Vos's book *Uncertain Risks Regulated* emphasize, various countries and institutions apply the precautionary principle in different ways when addressing particular sources of environmental risk. (Everson and Vos 2009). This is not surprising in light of the different social, cultural, economic and political factors that influence what risks are targeted by regulatory policy in different countries. As countries increasingly borrow regulatory innovations from one another, cross-cultural differences in regulatory policy are narrowing and the precautionary principle is becoming increasingly popular even though it does not purport to provide any specific decision rule to answers the 'how safe is "safe" question.

COMPARATIVE STUDIES OF REGULATORY POLICY

In recent years a rich literature has developed comparing regulatory policies in different countries and assessing the influence of the precautionary principle. In addition to the literature cited above (Everson and Vos 2009; Zander 2010), David Vogel's study of *The Politics of Precaution* (Vogel 2012) and Jonathan Wiener's anthology on *The Reality of Precaution* (Wiener *et al.* 2011) provide detailed analyses of how regulatory policy in the U.S. and EU have responded to a wide range of environmental and safety risks. Both are excellent books that present valuable data, while reaching distinctly different conclusions concerning whether regulatory policy is more precautionary in the EU or the U.S.

Wiener's 'Regulatory Parity' Thesis

Wiener concludes that even though the EU has more explicitly embraced the precautionary principle, its member states are not more precautionary than the U.S. in addressing health, safety, environmental and security risks. Based on several case studies comparing the history of regulation in the EU and the U.S. and a quantitative analysis of a sample of 100 risks, Wiener believes that 'Europe and the United States have maintained rough parity across all risks over the past four decades' (Wiener *et al.* 2011: 521). Europe is more precautionary than the U.S. in dealing with some risks; the U.S. is more precautionary in dealing with others. Wiener concludes that the U.S. is now more precautionary than the EU in dealing with the risks of mad cow disease, diesel engine exhaust, particulate air pollution, environmental tobacco smoke, biodiversity loss and terrorism. The EU is now more precautionary in responding to the risks of growth hormones in beef, genetically modified foods, stratospheric ozone destruction, climate change, and chemical risks.

Wiener frames his conclusion as a surprise in light of the EU's more explicit embrace of the precautionary principle. Yet even if one accepts the notion of rough parity in regulatory stringency between the U.S. and EU, it does not contradict the notion that the EU more faithfully adheres to the precautionary principle in its regulatory policy. The relative stringency of regulation is not necessarily an accurate indicator of fidelity to the precautionary principle because the principle does not purport to dictate how stringent regulatory policy should be (Percival 2006).

To be sure, a nation that frequently succumbs to the argument that uncertainty precludes all regulatory action is likely to have less stringent regulations than a nation that faithfully embraces the precautionary principle. But countries in the former ('reactive') category may adopt stringent regulatory responses in reaction to highly visible disasters (e.g., terrorist attacks or a nuclear accident like the Fukushima Daiichi tragedy) that are less likely to occur in countries in the latter ('precautionary') category.

Vogel and the 'Flip-Flop' toward Greater Precaution in the EU

In his book *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* (Vogel 2012) David Vogel concludes that although the U.S. was more precautionary than Europe during the 1970s and early 1980s, the EU today is more precautionary than the U.S. in dealing with risks to human health and the environment. Vogel emphasizes tighter EU regulation of chemical substances, greenhouse gas emissions, agriculture, food, and consumer products.

According to Vogel, this shift is the result of political changes in both countries. He cites three factors. First, '[d]uring the last two decades, Europeans have perceived *more* health,

safety, and environmental risks caused by business to be both credible and politically unacceptable than have Americans' (Vogel 2012: 34). Second, the politics of regulatory policy in the U.S. has become more 'polarized along ideological and partisan lines' (Vogel 2012: 35) as politicians supported by business interests have sought to demonize regulation. Third, greater emphasis on risk assessment and less deferential judicial review in the U.S. has 'increased the level of scientific evidence necessary to justify new risk regulations'. Recent developments in the U.S., including the debate over regulatory policy during the 2012 U.S. presidential campaign, provide powerful support for Vogel's second and third arguments.

Comparative Regulatory Policy: An Assessment

Globalization and Regulatory Diversity

Both Wiener's and Vogel's studies provide powerful support for the notion that globalization is having a profound effect on the evolution of environmental law. In particular, they emphasize that neither the EU nor the U.S. should be viewed as a regulatory monolith. In the U.S. the state of California has adopted more aggressive policies to control climate change and exposure to toxic chemicals than the federal government. These policies have been modelled on the regulatory approach of the EU (Vogel 2012: 16). Vogel acknowledges that 'the nature and mechanisms of global regulatory emulation and policy diffusion have shifted', but he concludes that 'the EU, rather than the American federal government' is now the entity playing the most 'important role in strengthening the risk regulations of many of its trading partners'. He argues that the 'California effect' has become the 'EU effect' with other countries now importing regulatory innovations from the EU, rather than from California.

Wiener also acknowledges the diversity of approaches to regulation employed by California and different EU members. He concedes that the EU now regulates chemicals more stringently than the U.S., but he questions whether there has been any fundamental 'flop' toward greater regulatory stringency toward chemicals in the EU. Wiener appears to seriously underestimate the significance of the EU's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) program as well as EU directives on electronic waste and hazardous substances in electronics and electrical equipment. These programs represent enormous advances in precautionary regulation that have become highly influential in moving global regulatory policy in a more precautionary direction. REACH requires pre-market toxicity testing of chemicals, both old and new, and it creates incentives to substitute safer chemicals without requiring elaborate proof that harm actually has occurred. WEEE and RoHS seek to reduce the presence of toxic chemicals in various products and to ensure their safe disposal.

The Global Reach of REACH

The EU's REACH program has had a profound effect on chemical regulation worldwide. It established the European Chemical Agency (ECHA) to manage and coordinate chemical regulation and it requires registration of all chemical substances used in the EU, evaluation of those that may be harmful, and authorization for substances believed to pose the greatest risks. A data gathering process is required of all chemicals, both old and new, that are produced in or sold in quantities greater than one metric ton per year. This must be completed between 2007 and 2018, beginning with substances of very high concern (SVHC), substances known to be very toxic to aquatic organisms, and substances supplied in quantities greater than 1,000 metric tons per year. By 1 June 2018 all substances supplied in quantities greater

than 1 metric ton per year must be registered. Unregistered substances may not be manufactured in the EU or exported to the EU after 1 June 2018.

All chemical registration applications must be accompanied by a technical dossier, a comprehensive set of information on the chemical's properties, and registration applications for chemicals produced in quantities above ten metric tons per year must be accompanied by a Chemical Safety Report. Authorization is required only for SVHC. These substances include those that cause cancer or mutations or disrupt reproductive processes (CMRs), persistent, bioaccumulative, or toxic substances (PBTs), very persistent or very bioaccumulative substances (vPvBs), persistent organic pollutants (POPs), and other chronic hazards.

Substances of very high concern (SVHC) must be specifically authorized before they can be used and their manufacturers must find safer replacement substances or ensure that they are 'adequately controlled'. If a SVHC is sold, the manufacturer must prove that the benefits outweigh the risks. Thus, manufacturers are faced with a strong incentive to find safer substitutes rather than endure the authorization process or have their products banned from the market entirely.

Because it applies to foreign manufacturers of products sold in the EU, REACH has had a significant influence throughout the world. Dow Chemical, which estimates that compliance with REACH will cost it between \$100 million and \$250 million over eleven years, announced in 2008 that it has decided to prepare REACH-qualifying dossiers for all its chemical products, not just those sold in the EU. (Vogel 2012: 169). REACH is a model for California's Green Chemistry Initiative, although California's approach is not as comprehensive as the EU's. Inspired by REACH, Massachusetts in 2008 unanimously passed a 'safer alternatives' law to encourage safer substitutions for ten toxic chemicals.

In January 2010 China introduced its updated chemical notification program, Measures on Environmental Management of New Chemical Substances, or Order 7. Order 7 became effective on 15 October 2010. Turkey has enacted chemical regulation legislation that resembles REACH; it came into force in January 2010. The law prioritizes testing of substances based on their potential effects on health and the environment and subjects substances with carcinogenic and mutagenic effects to 'specific scrutiny'.

Although Wiener's study questions the relevance of REACH to the precautionary principle, REACH promotes precautionary regulation in two fundamental respects. First, it shifts the burden of proving safety to manufacturers of chemicals (Naiki 2010). Secondly, it requires them to search for safer substitutes for chemicals shown to pose the greatest risks. When it adopted REACH, the 'European Parliament specifically rejected the United States' model of chemical regulation by adopt[ing] the precautionary principle; REACH, in effect, preempts complete scientific proof of the harm of a chemical by placing the burden of proving a chemical's safety on the industry' (Benedetto 2010).

REACH responds to uncertainty by mandating data gathering to reduce it. In 2001 the European Environment Agency completed an inquiry into why government regulators failed to prevent more than a dozen significant environmental problems caused by radiation exposure, benzene, asbestos, PCBs, MTBE and other harmful substances (European Environment Agency 2001). Its report, 'Late Lessons from Early Warnings', emphasized the importance of long-term monitoring and research to reduce ignorance concerning chronic environmental hazards, including those that may cause significant harm with a considerable latency period. REACH's chemical testing program represents a giant step in this direction.

'[M]ore data on chemicals have been assembled and made available to the supply chain and to the public at large than ever before,' as a result of REACH, which 'stimulates risk-management measures and chemical substitutions that enhance safety' (Abelkop *et al.* 2012: 11043).

The EU also has been a pioneer in promoting the notion of producer responsibility for waste and the importance of reducing the generation of toxic residues from electronic products. The EU's Restriction of Hazardous Substances (RoHS) has affected product regulation on a global scale. China, Korea, Taiwan, and Japan promptly responded to RoHS by adjusting product designs to eliminate the six toxic chemicals banned under RoHS to ensure continued access to the EU market.

The Influence of Historical Differences Between Civil and Common Law Regimes

Professor Noga Morag-Levine has conducted extensive research into the historical roots of differences in patterns of risk regulation between common law (the United Kingdom and the U.S) and civil law (continental Europe) countries (Morag-Levine 2011). She argues that contemporary regulatory policy differences between the EU and the U.S. actually can be traced to centuries of divergences between Europe's civil law tradition and the common law tradition inherited by the United States from the United Kingdom (Morag-Levine 2011). Professor Morag-Levine argues that European countries with a civil law tradition favour technology-based regulation as a product of their greater receptivity to the precautionary principle. She maintains that this is a more effective approach to preventing environmental harm than the 'the American regulatory paradigm', which 'aspires to scientific determination of the level of pollution mitigation required' (Morag-Levine 2003: 180).

While precautionary regulation emerged in Britain with the adoption of the Alkali Act in 1863, Morag-Levine argues that this Act was directly inspired by French and other continental regulatory models developed under the civil law tradition. This makes it 'easier to reconcile the civil law character of precautionary regulation with the evident presence of that instrument in Victorian Britain' (Morag-Levine 2011: 1). Since the 1980s, differences between British and continental approaches to regulation have narrowed significantly, but Morag-Levine maintains that the historical roots of these divergences still have considerable explanatory power in understanding contemporary differences between U.S. and EU regulatory policy.

U.S. environmental law may in fact be somewhat more precautionary than Morag-Levine's description (Percival 2004), but her conclusion that continental Europe historically has been more precautionary than the U.S. has considerable historical support. Her research into the historical roots of current regulatory policy differences suggests that divergences in legal traditions may remain an obstacle to greater harmonization of global regulatory policy.

Although it is difficult to make confident conclusions concerning whether regulatory policy is more precautionary in the U.S. or the EU, comparative study of this history can yield some rich lessons for improving future regulatory policy.

A BRIEF HISTORY OF PRECAUTION IN U.S. REGULATORY POLICY

This section summarizes the history of environmental risk regulation in the United States, which I have discussed in more detail in previous work (Percival 2006). In the nineteenth and early twentieth centuries regulatory policy focused only on the most noticeable environmental risks such as exploding steamship boilers (Rabin 1986) or smelter pollution that visibly

altered the surrounding landscape (Percival *et al.* 2009). Highly publicized incidents of harm (e.g., workers dying in the first tetraethyl lead manufacturing plant or deaths from radiation exposure of workers using radium to paint watch dials) generated public clamour for action. Prior to the advent of comprehensive, national regulatory programs to protect public health, the official response to such incidents was to convene conferences of experts. However, regulatory policy rarely was able to prevent harm from less visible risks posed by chronic, low-level exposures to toxic substances such as lead. Common law liability actions provided some measure of redress for pollution that caused the most obvious environmental harm to private property, but the common law ultimately proved to be too crude a vehicle for safeguarding public health when humans are exposed to multiple environmental risks from numerous sources.

During the decade of the 1970s, the U.S. Congress adopted a series of comprehensive regulatory programs to protect public health and the environment. These programs were the product of an extraordinary outpouring of public support for environmental protection, fuelled by the publication of Rachel Carson's *Silent Spring* (Carson 1962), which helped inspire the first Earth Day in April 1970. The initial generation of regulatory programs to protect the environment incorporated a variety of approaches to determining how precautionary regulatory policy should be -- including technology-based regulation, health-based regulation, and risk-benefit balancing. Regulations issued to implement these new statutes spawned a host of legal challenges from regulated industries. U.S. courts hearing these challenges initially endorsed precautionary regulation, while expressing concern about how precautionary regulatory policy should be.

In December 1973, EPA issued its first regulations limiting the amount of tetraethyl lead that could be added to gasoline to 0.5 gpg for all gasoline produced. Lead-additive manufacturers challenged EPA's decision in court. In December 1974, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit struck down the regulations by a 2-1 vote. The court held that there was insufficient evidence to prove that lead emissions 'will endanger the public health or welfare', as required by the Clean Air Act because it found that 'the case against auto lead emissions is a speculative and inconclusive one at best'. The EPA appealed this decision to the full court, which agreed to rehear the case. In March 1976, the court by a 5-4 vote reversed the three-judge panel's decision and upheld the lead standard. ¹⁰

In a decision that stands as a landmark in its endorsement of precautionary regulation, the court ruled that there was sufficient evidence to regulate lead additives even though it could not be proven with certainty that they endanger public health. The court emphasized the precautionary nature of the Clean Air Act's regulatory mandate. 'Regulatory action may be taken before the threatened harm occurs; indeed the very existence of ... precautionary legislation would seem to demand that regulatory action precede, and, optimally, prevent, the perceived threat'.

The tetraethyl lead manufacturers argued that there was no definitive proof that emissions of lead from gasoline caused harm. They maintained that EPA was required to present some 'dispositive study' to demonstrate that lead additives in gasoline had caused lead poisoning in individuals. The court acknowledged the lack of 'hard proof of any danger', but it rejected the notion that such proof was necessary before precautionary regulation could be implemented. 'Undoubtedly, certainty is the scientific ideal — to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable

only after the fact ... Awaiting certainty will often allow for only reactive, not preventive regulation'. ¹¹ After reviewing the 10,000-page record, the court rejected the industry's claim that a 'dispositive study' had to support EPA's determination, noting that '[b]y its nature, scientific evidence is cumulative'. The court noted the difficulties inherent in determining whether or not lead emissions endanger health, including the existence of multiple sources of human exposure to lead and the difficulties of conducting controlled experiments on humans. However, it upheld EPA's regulation by emphasizing the precautionary purpose of the statute:

'Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served'.

The *Ethyl* decision remains a landmark in environmental law because of its endorsement of the precautionary principle long before it became a staple of global environmental policy. The decision established that precautionary regulation could be based 'on the inconclusive but suggestive results of numerous studies' indicating that exposure to a substance could endanger health even in the absence of conclusive proof that such adverse health effects actually had occurred. It also indicated that courts would be deferential in reviewing the judgment of the EPA Administrator in assessing the significance of scientific evidence.

Four years later, when confronted with the petroleum industry's claim that tighter limits on worker exposure to benzene would cripple the industry while providing scant benefit to public

health, the U.S. Supreme Court mandated that, prior to regulating workplace hazards, the U.S. Occupational Health and Safety Administration (OSHA) should use risk assessment to determine that the risks to be regulated were 'significant' and could be appreciably reduced by regulation. ¹² The Court did not specify any specific threshold of 'significance', but it indicated that it probably would lie somewhere between a 1 in 1000 risk that would be considered significant and a 1 in 1 billion risk that probably would not. A plurality of the Court concluded that a statutory command to establish a standard that 'most adequately assures, to the extent feasible, on the basis of the best available evidence', that 'no worker suffers material impairment of health of functional capacity', did not automatically require reducing exposure to carcinogens to the lowest feasible level. Instead the Court conditioned precautionary regulation on the making of threshold findings that such regulation would appreciably reduce risks that appear to be substantial.

The Court's plurality decision did not represent a wholesale rejection of the precautionary approach to regulation. In fact the Court expressly endorsed the notion that conservative default assumptions could be used in risk assessment (so long as 'they are supported by a body of reputable scientific thought'). The Court also specified that risk assessment need not be quantitative, particularly when uncertainty precludes confident quantitative assessments of risk.

By requiring OSHA to assess risks and to determine that they are 'significant' enough to warrant regulation, the Supreme Court fashioned its own kind of 'regulatory common law'. It placed a greater burden on agencies seeking to adopt precautionary regulation, but ultimately this has not proven to be a significant barrier to regulation. In the wake of the Supreme Court's *Industrial Union* ('Benzene') decision, U.S. regulatory agencies have relied heavily

on risk assessments to justify regulatory decisions even though many risks are impossible to assess with precision. Risk assessment models are most highly developed for carcinogens that pose health risks in probabilistic fashion, but ecological risks and non-cancer health effects are far more difficult to model (U.S. Environmental Protection Agency 1987). Enormous uncertainties also surround the risks of new and emerging technologies, such as biotechnology and nanotechnology.

The Supreme Court's decision ultimately meant that workers had to tolerate exposure to dangerous levels of benzene for nearly a decade longer than OSHA initially had intended when it promulgated an emergency temporary standard in 1977. That standard had been invalidated by a lower court that held that the agency had failed to demonstrate the need to act on an emergency basis. Although it was not until 1987 that OSHA ultimately lowered the permissible exposure limit for benzene to the very level it had sought to adopt a decade earlier, by then the evidence of the significant risks posed by benzene had become so overwhelming that OSHA's decision was not even challenged in court.

The enactment of environmental legislation often has required some 'trigger event', usually a highly publicized incident of visible environmental harm that generates immediate public concern (Percival 1998). Examples include the 'Superfund' legislation adopted in 1980 after highly publicized contamination of homes in Love Canal by previously buried hazardous wastes, the Emergency Planning and Community Right to Know Act adopted in 1986 in response to the Bhopal tragedy, and the Oil Pollution Act of 1990 adopted in response to the Exxon Valdez oil spill.

As Vogel cogently demonstrates, U.S. regulatory policy depends in large part on the policy preferences of political leaders (Vogel 2012: 34). Because President Reagan was ideologically opposed to regulation, Congressional distrust of his executive agencies spawned a backlash that led Congress to strengthen the U.S. environmental laws during the 1980s. When it reauthorized the federal regulatory statutes, Congress added new provisions specifying actions that regulatory agencies must take coupled with statutory deadlines for completing them. It also adopted far-reaching legislation in 1986 requiring companies to make annual public disclosures concerning their emissions of toxic chemicals. During the same year California voters adopted the highly precautionary Proposition 65, which prohibits companies from exposing humans without warning to significant risks from carcinogens or reproductive toxins and which places the burden of proof of companies to show that risks are insignificant.

Even though nearly all U.S. environmental statutes authorize regulation prior to definitive proof of harm, it is easier to identify hazards and to predict harm *after* it occurs. In part due to enormous political pressures from the regulated community, federal agencies usually wait for proof of harm before adopting regulations. Most of the chemicals that have been stringently regulated in the U.S. became the focus of regulatory attention only after highly publicized incidents in which they caused visible and substantial harm (Percival 2006). This reflects the facts that regulation is most politically salient when it responds to highly visible harm that already has occurred. Rather than realizing its promise of preventative regulation, U.S. environmental policy usually has been saddled with the far more difficult task of remediating environmental contamination after it has occurred.

The European Environmental Agency's *Late Lessons from Early Warnings* study is one of the few studies to examine why society has failed to prevent chronic environmental harm from

toxic substances, such as lead and asbestos, that long were known to be extremely hazardous. Because the neurological harm caused by exposure to lead is largely invisible, efforts to control lead exposure were only successful after decades of damage to public health. This stands in sharp contrast with the regulatory response to the stratospheric ozone depletion problem, a rare instance in which truly precautionary regulation was undertaken solely in response to a seemingly compelling scientific theory before actual harm to public health had been demonstrated (Benedick 1991).

As noted above, the judicial system has played an important role in developing U.S. environmental policy through judicial review of agency regulatory decisions. The U.S. Administrative Procedure Act and the federal environmental statutes generally authorize judicial review of agency action at the behest of anyone adversely affected by it. Although the U.S. Supreme Court has instructed lower courts to defer to agency interpretations of ambiguous regulatory statutes, ¹⁴ significant regulatory initiatives have been derailed by the courts. In 1989, after a decade-long investigation, the U.S. Environmental Protection Agency (EPA) issued a regulation phasing out nearly all remaining uses of asbestos. The agency concluded that only a phase-out 'will adequately control' the life cycle of asbestos exposure risks that occur whenever the substance is mined, used in manufacturing, released into the environment through deteriorating asbestos-containing products, or is disposed. ¹⁵ Despite the well-documented dangers of asbestos, this regulation was struck down by a reviewing court which concluded that the agency had failed to perform sufficiently detailed cost-benefit analyses of banning not only each particular use of asbestos, but also of all intermediate alternatives short of a ban. The court required such highly detailed proof, on a product-byproduct basis, that benefits outweighed costs, as to render the Toxic Substances Control Act virtually impotent as a regulatory tool. ¹⁶

The *Corrosion Proof Fittings* court applied a kind of reverse precautionary principle. Its decision essentially declared that for a substance known to cause serious and irreversible damage to health, lack of certainty concerning the costs and benefits of all regulatory alternatives should be used as a reason for not regulating it. The court echoed critics of the precautionary principle who charge that precautionary regulation may create greater risks than it prevents, by chastising EPA for failing to perform detailed analyses of the risks of any potential substitutes for asbestos. Surprisingly, however, the court upheld the government's ban on new uses of asbestos without requiring *any* cost-benefit analysis, noting that 'EPA cannot possibly evaluate the costs and benefits of banning unknown, uninvented products'. ¹⁷ This represented a rare endorsement of truly precautionary regulation by permitting future products to be banned even before there was clear evidence to confirm that they actually caused harm.

While the *Corrosion Proof Fittings* decision effectively precluded EPA from banning existing uses of asbestos, most other developed countries have done so and the World Trade

Organization (WTO) has upheld such bans in light of the demonstrated dangers of asbestos.

As of August 2012, 54 countries, including most EU members, have banned asbestos. ¹⁸ In

September 2000, a WTO dispute resolution panel upheld France's ban on imports of
chrysotile asbestos, rejecting arguments by Canada that it was an unjustified restriction on
trade, an argument representatives of the Canadian asbestos industry had raised
unsuccessfully during the EPA rulemaking. ¹⁹ The panel concluded that the risks of asbestos
had been so thoroughly researched that the ban was justified as necessary to protect human
health.

Despite overwhelming proof of harm to health caused by tobacco products, when the U.S. Food and Drug Administration sought to regulate them stringently, the U.S. Supreme Court by a 5-4 vote rejected the agency's finding that cigarettes were 'drug delivery devices' for nicotine that could be regulated by the agency. The Court refused to apply the *Chevron* doctrine of judicial deference to agency interpretations of ambiguous statutory directives because it did not believe that Congress intended to allow the FDA to regulate tobacco.

Despite some judicial reversals of important regulatory initiatives, the regulatory infrastructure of U.S. environmental law generally has survived persistent survived legal attacks. In 2001 the U.S. Supreme Court unanimously rejected an industry argument that unless the Clean Air Act was interpreted to require that regulations be based on cost-benefit analysis it would be an unconstitutional delegation of legislative authority to the executive. In 2007 the Court by a 5-4 vote ordered EPA to reconsider its refusal to regulate greenhouse gas (GHG) emissions as arbitrary and capricious. As a result of this decision, the U.S. EPA was able to promulgate regulations controlling GHG emissions under the existing Clean Air Act, even though efforts to enact new legislation establishing a comprehensive, national capand-trade program had failed. In June 2012 a panel of the U.S. Court of Appeals for the D.C. Circuit unanimously rejected all industry challenges to these regulations in a decision deferring to EPA's findings concerning the contribution of GHG emissions to global warming and climate change.

Yet ideological splits over the wisdom of environmental regulation persist in the U.S. judiciary. In August 2012 a panel of the U.S. Court of Appeals for the D.C. Circuit invalidated EPA's latest effort to control interstate air pollution in a controversial 2-1 decision. ²⁴ The court's decision was the second time in four years that EPA's effort to tighten

such standards was rejected in court.²⁵ It came despite EPA's estimates that the new regulations would prevent between 13,000 and 34,000 premature deaths each year, generating annual benefits of between \$120 billion to \$280 billion at a projected annual cost of \$2.4 billion. The court's decision has been sharply criticized as the product of 'a new breed of activist judges [who] are waging a determined and largely successful war on federal regulatory agencies' through the use of 'legal sophistry, procedural hair-splitting and scientific conjecture' (Pearlstein 2012).

The U.S. Congress also is sharply split on issues of precautionary regulation. The Republican takeover of the U.S. House of Representatives in the 2010 elections produced the most antienvironmental house of Congress in U.S. history. In the twenty months that it was in session before adjourning on 21 September 2012, the 112th Congress has seen 315 anti-environmental measures pass the House. Rearly all of these measures have failed to become law because they cannot win passage in the U.S. Senate, which is controlled by Democrats more sympathetic to environmental regulation. Due to the partisan split in the two houses of Congress it has become virtually impossible for Congress to enact any new environmental legislation.

CONCLUSION: LESSONS FROM THE HISTORY OF U.S. REGULATORY POLICY

It is far easier to generate political support for controlling risks that cause immediate and highly visible harm than it is for regulating less visible risks that cause harm far into the future. This is well illustrated by the history of U.S. regulatory policy. The first federal regulatory intervention in the U.S. to protect public health was undertaken in 1832 to stop steamship boilers from exploding. In 1915 the U.S. Supreme Court issued its first injunction to control pollution in order to reduce highly visible damage emissions from copper smelters

in Tennessee had caused by destroying all vegetation in a huge swath of land extending far into the state of Georgia.²⁷

With the exception of the remarkable public response to the theory that CFCs could deplete the ozone lawyer, which led EPA to ban ozone-depleting substances in the early 1970s, U.S. regulatory policy has been largely reactive, rather than precautionary. Regulation generally has responded only after harm has become manifest. While the dangers of lead and asbestos were well-known to scientists in the early 20th century, regulatory policy did not respond to them for decades, even as enormous harm to public health accumulated, because the harm they caused was not immediately visible (Percival 2006). The eventual, reactive regulatory responses to the hazards of gasoline lead additives and worker exposure to asbestos, have produced enormous benefits to public health, albeit belatedly. Despite this history, U.S. regulatory policy has not aggressively focused on potentially emerging risks posed by the products of biotechnology or nanotechnology (Lin 2007).

Political theory teaches that it is a veritable miracle that the U.S. has such comprehensive and durable environmental statutes. 'It is much easier to understand why environmental laws are needed than it is to comprehend how they came to be adopted' (Percival 1998). Mancur Olson's classic work *The Logic of Collective Action* argues that the political process will not favour collective action to impose concentrated costs on well-organized industry groups in order to prevent diffuse harms to the public (Olson 1965). Yet this theory seemingly is contradicted by the remarkable burst of legislative activity to protect the environment by the U.S. Congress during the 1970s and 1980s. As noted above, many of these statutes were the product of a highly publicized 'trigger' event, such as Earth Day, Love Canal, the Bhopal tragedy, and the *Exxon Valdez* oil spill (Percival 1998).

Today, however, even highly publicized environmental disasters such as the April 2010 Deepwater Horizon oil spill in the Gulf of Mexico and the March 2011 Fukushima Daiichi nuclear disaster in Japan have not generated any legislative response. The 1989 *Exxon Valdez* oil spill in Alaska broke more than a decade of legislative gridlock over oil pollution legislation, resulting in the adoption by Congress of the Oil Pollution Act of 1990 ('OPA90'). Yet because legislators always seem to respond to the last disaster, OPA90 focused almost entirely on the kind of oil spill that had just occurred -- a spill from a tanker transporting oil. The law did not focus on pollution from offshore oil platforms, the genesis of the Deepwater Horizon disaster. Indeed, OPA90 actually limits liability for oil spills from offshore facilities to \$75 million plus removal costs. ²⁸ Yet in the wake of the Deepwater Horizon disaster, efforts to repeal this cap failed to pass either house of Congress. One could view these developments as another indication of a perceived 'crisis' -- this time the global financial crisis -- serving as a 'trigger' for reactive policies, this time policies founded on the false dichotomy that regulation inevitably hurts the economy.

What does seem clear is that the bipartisan consensus concerning the importance of environmental protection that spawned ambitious U.S. environmental legislation during the 1970s and 1980s has now disappeared. During the 2012 U.S. presidential election campaign, the political parties and the electorate were sharply split in their views concerning regulatory policy. Republicans blamed environmental regulation for high unemployment and slow economic growth while Democrats generally tried to change the subject. Yet until the 2008 global financial crisis, which produced the greatest economic downturn next to the Great Depression, the U.S. economy prospered despite stringent environmental regulation. Extractive industries, newly freed from the restrictions of campaign finance laws by the

Supreme Court's decision that they have a First Amendment free speech right to spend directly on election campaigns, ²⁹ flooded the airwaves with ads blaming high unemployment on environmental regulation. Opponents of regulation usually describe it as 'job-killing' and never as 'life-saving'.

Despite all-time record temperatures and hurricanes that have caused unprecedented devastation to coastal areas, climate change has disappeared from U.S. political discourse. During the 2012 U.S. presidential candidates climate change was never once mentioned during three 90-minute debates between the presidential candidates. President Obama's reelection in November 2012 and his political party's gains in both houses of Congress indicate that his opponents' anti-regulatory rhetoric was not decisive with voters. But there is little prospect of bipartisan agreement new on environmental measures, though legislation purporting to bar U.S. airlines from paying EU emissions charges was signed into law on November 27. Thus, Vogel's theory that the U.S. has become less precautionary than the EU because of political polarization is amply supported by recent events.

The political process rarely rewards government officials for focusing on problems that have not been obvious enough to generate demands for immediate action. Vogel explains the EU's adoption of REACH as reflecting 'not only the influence of the precautionary principle, but also several highly visible food safety failures in Europe, as well as the ongoing debate over the safety of GMOs' (Vogel 2012: 177). By adopting the REACH program the EU set in motion a long-term process for uncovering chemical risks that will greatly facilitate precautionary regulation. Although the U.S. has long resisted adopting a similar testing program for chemicals, there is one rare example of U.S. officials trying to discover risks in advance of harm. For several years the National Aeronautics and Space Administration

(NASA) has been searching for 'Near Earth objects', such as asteroids, that may pose a danger of colliding with Earth.³⁰.

Vogel also argues that the U.S. is less precautionary than the EU because greater emphasis on risk assessment and less deferential U.S. judicial review has 'increased the level of scientific evidence necessary to justify new risk regulations' (Vogel 2012). While there is some recent evidence to support this claim, the Supreme Court's encouragement of risk assessment in its 1980 'Benzene' decision has not greatly handicapped regulatory agencies. Even the Ethyl Corporation court expressly endorsed risk assessment in its 1976 decision endorsing precautionary regulation. The very year after it decide the 'Benzene' case the U.S. Supreme Court upheld OSHA regulations to protect workers from exposure to cotton dust because they were supported by an agency risk assessment. The Court rejected the argument that OSHA was required to base its decisions on cost-benefit analysis, wisely eschewing an effort to paralyze regulatory action.

Yet Vogel clearly is correct that the U.S. judiciary has impeded precautionary regulation in several cases, including the decision to strike down regulation of tobacco by the federal Food and Drug Administration,³² the invalidation of EPA's asbestos phase-out regulations,³³ and the August 2012 decision striking down EPA's latest effort to tighten controls on interstate air pollution.³⁴ Like Congress, the judiciary remains closely split between opponents and proponents of precautionary regulation. The opponents have been particularly active in striking down regulations issued in response to the Dodd-Frank Wall Street Financial Reform legislation, seizing on vague language in the statutory charter of the Securities and Exchange Commission (SEC) to demand that SEC rules meet ever more stringent cost-benefit tests.³⁵

The enormous (and growing) political clout of regulated industries in the U.S. essentially guarantees that U.S. regulatory agencies cannot adopt overly precautionary policies that significantly over-regulate industry. Thus, it is hardly surprising that it has been virtually impossible to identify instances in which precaution has produced significant over-regulation by U.S. agencies. While one can identify some U.S. regulatory policies that are more stringent in controlling particular risks than in the EU, the EU clearly has been more innovative in embracing precautionary regulation through programs like REACH, WEEE and RoHS. These programs have been enormously influential in the development of regulatory policy throughout the world. Thus, despite current retrenchment in the U.S., the forces of globalization and the EU's warmer embrace of the precautionary principle ultimately may move the world in a more precautionary direction.

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