Precaution in a Multirisk World

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Heads up: The "precautionary principle" is coming to a law near you. It aspires to answer a timeless question: How should society in general, and regulatory authorities in particular, respond to uncertain risks? This chapter addresses the normative and positive implications of adopting the precautionary principle.

Whereas many analyses have compared precautionary versus reactive regulatory strategies as applied to individual risks taken one at a time, this chapter examines precaution in a world of multiple risks. It distinguishes different versions of the precautionary principle, some of which are more sensible than others. It suggests that precaution against one risk may induce other countervailing risks, so that the ideal is a middle ground of "optimal precaution" rather than maximum precaution. It observes that real-world applications of the precautionary principle, in both the United States and Europe, have often been sensitive to this reality and therefore have moderated the degree of precaution as the legal instrument gains more regulatory teeth and as the countervailing risks rise.

32.1 BACKGROUND

The notion of precautionary regulation has a long history in both Europe and the United States. Prominent endorsements have appeared on both sides of the Atlantic since at least the 1970s (Applegate, 2000; Boehmer-Christiansen, 1994; Cameron & Abouchar, 1991; Sand, 2000). The cognate concept of *vorsorgeprinzip* in German law dates at least to the early 1970s (Boehler-Christiansen, 1994). In the United States, landmark cases such as *Ethyl Corp. v. EPA* (1976) and *Tennessee Valley Authority v. Hill* (1978) vindicated the notion of precautionary regulation under the Clean Air Act and the Endangered Species Act, re-
respectively. Premarket safety review of new drugs under the Federal Food, Drug and Cosmetic Act has an even older pedigree (Applegate, 2000).

In the last decade the ambition of the precautionary principle (PP) has been growing. It is paid homage in several important international agreements, including several treaties on Marine Pollution, the Rio Declaration, the Framework Convention on Climate Change, and the Cartagena Protocol on BioSafety (Bodansky, 1991; Hey, 1992; Sand, 2000; United Nations, 1992b). The treaty that constitutes the European Union (EU) expressly provides that EU policy on the environment “shall be based on the precautionary principle” (EU Treaty, 1993, Article 130R, now Article 174). Proponents have forecast that the PP “could become the fundamental principle of environmental protection policy and law” (Cameron and Abochaur, 1991:2). Some assert that the precautionary principle may already be so widely adopted that it is ripening into an enforceable norm of “customary international law,” a kind of international legal doctrine from which no nation can dissent (Sand, 2000; Sands, 1995:213). Most recently, the European Commission has formally articulated and endorsed the precautionary principle (European Commission, 2000).

Despite its adoption of a “precautionary preference” in some specific statutes (Applegate, 2000), the United States has not officially adopted the Precautionary Principle as a general basis for regulation. After endorsements of precautionary regulation in cases such as Ethyl Corp. v. EPA (1976) and Tennessee Valley Authority v. Hill (1978) in the 1970s, the U.S. Supreme Court held in the Benzene case (Industrial Union, AFL-CIO v. American Petroleum Institute, 1980) that the Occupational Safety and Health Administration (OSHA) cannot simply leap into regulating on the basis of conjecture about uncertain risks. This decision, and a 1983 guidebook from the National Academy of Sciences (NAS), spurred widespread adoption of risk assessment (albeit of ten employing precautionary default assumptions and methods) as the basis for American risk regulation (Jasanoff, 1986, 1995). Along these lines, the United States has resisted blanket statements of the PP in international fora. For example, the United States insisted on qualifying the statement of the Precautionary Principle in the Climate Change Convention (Bodansky, 1993), and the United States responded to the European Commission’s recent endorsement of the Precautionary Principle with a long list of skeptical questions (U.S. Department of State, 2000).

Given this history, a common inference today is that Europe endorses the precautionary principle (PP) and seeks proactively to regulate risks, while the United States opposes the precautionary principle and waits more circumspectly for evidence of actual harm before regulating (Lofstedt and Vogel, 2001; Lynch and Vogel, 2000; Richter, 2000). A closely related view is that American regulation is more rooted in the science of formally assessing risks before acting, whereas European regulation is more qualitative and permits action through informal decision making unfettered by science (Jasanoff, 1986, 1998). These juxtapositions partly explain the eagerness among advocates of the PP to have it made part of customary international law—so that the United States, among others, cannot resist it. Across a wide range of examples, observers paint the picture of a civilized, safe Europe confronting a violent, risk-taking America (Daley, 2000; McNeil, 2000).

This chapter suggests that this inference is incorrect, both descriptively and normatively. In a world of multiple risks, the reality is more complicated. First, although precaution can be warranted, it is not universally desirable. Sometimes it is for the best, but sometimes precautionary regulation is too costly, and sometimes—given multiple risks—precaution can even yield a perverse net increase in overall risk. Context is crucial. And different versions of the PP imply different outcomes, some superior to others. Second, when multiple risks are examined, it becomes clear that Europe is not more precautionary than the United States across the board; sometimes Europe does take a more precautionary stance than the United States, but sometimes the roles are reversed and the United States is the more precautionary regulator. Again, context is crucial. Ultimately, the PP offers important insights but remains too simplistic for a complex multirisk world. The PP needs to be refined toward a more mature and sophisticated concept of “optimal precaution” that responds to the reality of a world of multiple risks.

### 32.2 Risk and Uncertainty

A brief discussion of risk is warranted to make clear the baseline against which the precautionary principle is being applied. All activities involve risk. Risks beset even the most mundane necessities, such as eating (choking; foodborne disease), breathing (pollution; airborne disease), walking (falling), keeping warm (fire or other energy sources), and sleeping (apnea; bad dreams; oversleeping and missing an appointment). Dealing with risk is an inescapable element of the human condition (Bernstein, 1996). By risk we mean the likelihood (probability) that exposure to a hazard will cause an adverse outcome (harm) to occur, combined with the seriousness of that outcome (e.g. mortality, morbidity, or impaired quality of life). For example, as far as we know today, the probability that exposure to highway driving will cause a fatal accident is significant and clearly greater than zero, whereas the probability that exposure to a cellphone will cause a fatal brain tumor is very low and may well be zero. (Using a cellphone while driving, of course, might raise the probability of the highway accident.)

Some risks are well documented and understood, while others are highly uncertain. That is, our estimates of the probability of an adverse outcome can be more or less confident. For example, we regularly observe that highway accidents kill some motorists, and thus we can be fairly confident in our prediction of the probability of highway fatalities next year; but we are unsure whether cellphone ever cause any brain tumors, and thus we are extremely unsure of our prediction of such fatalities. Even for highway accidents, our prediction of the risk on a given day, or to a given individual, would be highly uncertain. Fundamentally this difference is a matter of degree. All risks are probabilistic and uncertain because we can never know the future with complete certainty (Knight...
Thus, all decisions about the future must be made in the face of uncertainty. We can never be completely certain that something will cause harm; we never have certainty about the risks we incur, or about the opportunities we seek.

A related point is that we can never be completely certain that something is free of risk. Any substance or activity could be a hazard that results in harm, if it is experienced in the wrong dose or at the wrong place or time. Even the necessities of life, such as water, salt, oxygen, sunshine, and vitamins, can be harmful or fatal in large quantities (e.g., oxygen poisoning, skin cancer) or in the wrong circumstances (e.g., water in the lungs, salt in the wound). Paracelsus taught that “the dose makes the poison” (Ottoboni, 1984). What is a hazard thus depends not on a classification of intrinsic good versus intrinsic bad, but rather on context.

Moreover, some risks are especially latent: Their adverse impact will only occur a long time (perhaps many years) after the event that set the risk in motion. For example, a highway accident typically causes fatality (if at all) within seconds or minutes after the accident; but if there are any brain tumors caused by cellphone use, it might take many years after the exposure to the cellphone before the tumors become manifest. The longer the latency period between cause and effect, then the earlier (relative to the adverse outcome) measures must be taken if they are to be effective in preventing the outcome. If we wait to observe the latent outcome, it can become too late to take preventive measures.

Meanwhile, the seriousness of the adverse outcome depends on how people evaluate the outcome and its context. A fatality from one cause (e.g., cancer) may be viewed as more serious than a fatality from another cause (e.g., an accident), even controlling for equal probability and latency (Tolley, 1994:323–344). A fatality caused by a familiar, routine hazard (e.g., driving or smoking cigarettes or radon gas in homes) may be viewed as more tolerable than a fatality caused by an unfamiliar, mysterious hazard (e.g., hazardous waste or genetic engineering or radiation from nuclear power plants) (Slovic, 1987). Experts sometimes neglect these differences in valuation and treat a death as a death; other analyses use willingness-to-pay or quality-adjusted-life-year formulations to measure public valuations of risks. Yet basing regulatory policy directly on these attitudes toward risks remains controversial because public risk perceptions and valuations may be based on heuristic errors or on prejudices that good government should discount (Wiener, 1997). If the source of disparate risk valuations is simply factual errors, then educating the public about expert knowledge may help reduce the disparity. On the other hand, if the source of disparate risk valuations is not factual errors but value choices, the question is more difficult. Should democracy reflect all public preferences? One may be tempted to say yes, but the question is not so simple (Sunstein, 1991). Doing so could foster inappropriate choices based on public values (Shrader-Frechette, 1991), but it might also elevate mass prejudice to public policy (Cross, 1997). For example, if the public is informed that some risk (say, nuclear power, or transgenic foods, or wolves, or immigrants, or urban youth, or the dark) is not really a significant threat to public well-being, but if the public persists in feeling dread of the unfamiliar (abject fear of the unknown) and therefore presses for regulatory protection, perhaps government should think twice before translating that dread into public policy. Democracy is not simple majority rule; rather, it usually combines majoritarian voting with countermajoritarian constraints such as constitutional rights and checks and balances among branches of government. Likewise, sound regulatory policy entails both responsiveness to public attitudes about risks and enlightened leadership by government officials (Wiener, 1997).

### 32.3 PRECAUTION AS A PRINCIPLE

In the face of uncertainty about a risk, we often take precautionary measures, such as posting warning labels, driving safely, cooking foods to kill microbes, and saving money for future needs. Yet we never know for sure if these precautionary measures are effective (since, if they are successful, they result in the absence of an adverse outcome that might not have occurred anyway), nor do we know whether they are directed at the most important risks. At the same time, we rarely forego beneficial activities entirely just because they might be risky; we do not forego eating for fear of choking (but we do chew more carefully), nor do we forego crossing the street even though there is an uncertain probability of death (but we do use crosswalks and look both ways). We choose prudent precautions that are proportionate to the expected risk, the cost of sacrifice, and the availability of alternatives.

The precautionary principle seeks to go further; it seeks to impose earlier and more stringent restrictions on potentially risky activities. It invokes common sense adages such as “better safe than sorry” (Margolis, 1996). In particular, it seeks to impose early preventive measures to ward off even those risks for which we have little or no basis on which to predict the future probability of harm.

In the face of probabilistic, uncertain, and latent risks, government has two basic strategies: ex post remedies, ex ante precautions, or both. Ex post remedies include tort law administered by the courts. Ex ante precautions include regulations administered by agencies. Regulations are precautionary measures taken to prevent anticipated future outcomes. Some regulations are more ex ante than others: On the time path over which the risk is forecast to become manifest, some regulations take effect earlier and more stringently than do others. As the reasons accumulate to anticipate a future adverse outcome from a present activity, regulatory agencies may act sooner, and more stringently, to ward off that outcome.

I have spoken thus far of “the” precautionary principle, but the literature reveals no single formulation of the principle. Statements of the precautionary principle are varied and often vague (Applegate, 2000:414–415). One review identified 19 different formulations (Sandin, 1999). Here I will treat the precautionary principle in two ways. First, I will treat it as a statement about the preferred degree of precaution. The precautionary principle seeks to advance
the *timing* and tighten the *stringency* of ex ante regulation (cf. Applegate, 2000:415–420). On these sliding-scale dimensions, regulation is “more precautionary” when it intervenes earlier and/or more stringently to prevent uncertain future adverse consequences. Second, I will distinguish three particular narrative versions of the precautionary principle (cf. Wiener and Rogers, in press). These versions mark three points along the spectrum of degrees of precaution, each a more precautionary exhortation than the last.

### 32.3.1 Version 1: Uncertainty Does Not Justify Inaction

In its most basic form, the PP permits precautionary regulation in the absence of complete evidence about the particular risk scenario. The most common phrasing is: “Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation” (Bergen Declaration, 1990). In short, uncertainty does not justify inaction.

This formulation was, for example, the basis for the court’s opinion in *Ethyl Corp. v. EPA*. It was deployed to permit the U.S. Environmental Protection Agency (EPA) to regulate lead in gasoline before EPA could demonstrate physical ill effects in exposed human populations. Specifically, it was deployed to counter the argument made by industry that in the face of uncertainty, EPA should not regulate. Similarly, version 1 has been asserted in response to industry’s argument that uncertainty about future climate change requires waiting before restricting emissions of greenhouse gases.

But this version of the PP does not go very far. First, it only permits action, rather than compelling it. Second, it only responds to the situation of “lack of full scientific certainty,” but there is never “full scientific certainty”; we always face uncertainty, and we must always make decisions under uncertainty. Thus, “lack of full scientific certainty” is not a special difficult case for decision making; it is the general case of all decision making. This version of the PP does not answer the real question, which is what action to take in the face of (inevitable) uncertainty. Ban the substance? Require warnings? Investigate options? If we face very high uncertainty about what causes what, it may not even be clear what measures would effectively prevent the anticipated future harm. Even if uncertainty is low, some measures would be disproportionate to the harm to be prevented or would cause other harms. So it is not enough to call for action; the real question is which action.

This version of the PP does, at least, make clear that uncertainty is not a sufficient reason to sit on our hands; it rebuts the oft-heard contention (usually by those arguing to be regulated) that uncertainty itself precludes regulation. If this contention were valid, ex ante regulation would always be unwarranted (as would all sorts of personal precautions against future risks). If we are ever to act preventively, before deaths occur, then we must act in the face of uncertainty. This first version of the PP states that we may (but it does not say what we should do).

The PP is viewed by some actors as the “antiscience” opposition to “science-based” regulations. But an intelligent version of the precautionary approach can be consistent with scientific principles (Stirling, 1999). Once we get beyond simplistic lists of good and bad substances, we need science to identify which substances and activities pose what degree of risk in what circumstances. One needs to know what to be precautionary about. Because risk assessments inevitably address and involve scientific uncertainty, science remains a necessary element of risk management decisions (and yet science is insufficient to make policy because policy requires forecasting and weighing the consequences of alternative policy options). Thus, version 1 of the PP can be understood as a call for “action” that includes more scientific research to reduce uncertainties and guide the deployment of effective regulatory measures.

### 32.3.2 Version 2: Uncertain Risk Justifies Action

A second version of the PP is somewhat more aggressive; it says that uncertain risk justifies action. An American conference produced the statement: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established” (Wingspread, 1998:353). Similarly, the German Federal Interior Ministry wrote: “The principle of precaution commands that the damages done to the natural world (which surrounds us all) should be avoided in advance and in accordance with opportunity and possibility… it also means acting when conclusively ascertained understanding by science is not yet available” (Boeher-Christiansen, 1994:37). Or: “According to the precautionary principle, the more uncertain the risk, the more justified is some form of regulatory intervention” (Wagner, 2000:461).

Like the first version of the PP, this version is based on a truism because cause-and-effect relationships are never “fully” or “conclusively” established (even in retrospect); we always deal with uncertain and probabilistic relationships. This version, while calling for proactive precautionary measures, still does not address the real question of what measures should be taken. Such measures might include banning the activity, restricting it, requiring warning labels, requiring disclosure of information, or additional research to learn more about the activity, its risks, and its alternatives.

Still, version 2 is more precautionary than version 1, insofar as version 2 impels regulatory intervention rather than just permitting it. Version 2 is not merely a rebuttal to assertions that uncertainty warrants inaction; it is also an affirmative basis for regulation.

### 32.3.3 Version 3: Shifting the Burden of Proof

A third version of the PP is even more adamant; it insists that uncertainty about risk requires forbidding the potentially risky activity until the proponent
of the activity demonstrates that it poses no (or acceptable) risk. “As described in the Wingspread Statement on the Precautionary Principle, the applicant or proponent of an activity or process or chemical needs to demonstrate to the satisfaction of the public and the regulatory community that the environment and public health will be safe. The proof must shift to the party or entity that will benefit from the activity and that is most likely to have the information” (deFur, 1999:345–346).

This version of the PP is more precautionary than versions 1 and 2. It goes beyond permitting or compelling regulation of uncertain risks, by providing an answer to the question that versions 1 and 2 leave unaddressed: what action to take. Version 3 specifies a particular action to take in the face of uncertain risk: Forbid the activity unless a certain standard of proof is met by the proponent. Version 3 has two key components: shifting the burden of proof (who must demonstrate risk or safety—must the regulator demonstrate risk, or the regulatee demonstrate safety?) and setting a standard of proof (how risky or how safe—must the regulatee demonstrate no risk, de minimus risk, acceptable risk, or something else?).

Version 3 could invite overregulation, depending on the standard of proof for lifting the ban. What counts as demonstrating that the environment and public health will be “safe”? Some interpretations of version 3 of the PP would impose a standard of proof criterion of “no risk.” For example: “One would first compile a list of substances that were known to be toxic. For premarket statutes, firms would not be permitted to introduce substances chemically similar to those on the list without proof beyond a reasonable doubt that they were not toxic. For postmarket statutes, . . . (one could) require them to be phased out over time [unless firms] could show beyond a reasonable doubt that any exposures posed no risk of harm or posed no threats of serious damage to health or the environment” (Cranor, 1999:94). Such a measure would represent overregulation where the risk of the substance is small relative to its benefits. For example, many medicines are toxic (at some dose—as are vitamins and oxygen), and no drug company could offer “proof. . . . that they were not toxic” or “posed no risk of harm.” It is often the very toxicity of medications that enables them to provide a net health benefit (e.g., by killing microorganisms or cancer cells within the body). More generally, because “the dose makes the poison,” potentially every substance would have to banned if “proof of no toxicity or no harm” were the universal principle.

As a result, real-world applications of version 3 tend to employ a more balanced standard of proof. In the Benene case, the Supreme Court held that “safe” does not mean “no risk” but rather means “no significant risk,” and then left it up to OSHA to determine which risks are “significant” (Industrial Union Dept., AFL-CIO, 1980; cf. Fischhoff et al., 1981). Laws requiring premarket approval of new products typically require that product proponents “demonstrate acceptable risk” or “show no unreasonable risk.” For example, the drug licensing provisions of the U.S. Federal Food Drug & Cosmetic Act grant approval if the proponent demonstrates net benefits to the target patient population. The restrictions on new substances in the Toxic Substances Control Act (TSCA) and the federal pesticides law (Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA) both condition approval on whether the substance poses “unreasonable risk.”

Even if a balanced standard of proof is employed, the disincentives to innovation posed by version 3 of the PP may be amplified by the compounding risk aversions of the regulator and the researcher. The regulator will likely want to avoid approving even a net beneficial product that might later prove harmful, while the researcher will want to avoid investing in a beneficial product that is forbidden by the regulator. Hence even with a standard of proof such as “net beneficial,” the dual risk aversion of both regulator and researcher may suppress many products that would meet the standard.

On the other hand, version 3 of the PP does contain the useful idea of putting the burden of proof (which is different from the standard of proof just discussed) on the party best able to generate the information needed to make the decision. That is analogous to the notion of putting the burden of accident avoidance on the least-cost avoider (Calabresi, 1970). It may often make sense to ask industry rather than government to produce much of the data on risk. California’s Proposition 65 takes this approach: Substances initially found to be carcinogenic must be accompanied by warning labels (not a prohibition on use), and manufacturers can have the warning requirement lifted if they generate the information needed to demonstrate that the substance falls below a threshold of carcinogenicity.

The stringency of versions 2 and 3 can also be seen by analogy to their use in the area of criminal law. Violence is a problem of public risk and public health. In this context, the precautionary principle would favor earlier and more stringent interventions to prevent the “future dangerousness” of persons who may, with considerable uncertainty, be forecast to commit violence in the future. Version 2 would commit the state to pursuing people who may be future felons but whose latent violence is uncertain. Version 3 would shift the burden of proof from “innocent until proven guilty” to “guilty until proven innocent.” On these premises, everyone would be a proper subject of precautionary incarceration or at least monitoring by the state. The real-world example of this strategy is the effort, particularly in the United States, to incarcerate and even execute juvenile offenders to prevent their future dangerousness (Pfeiffer, 1998; Rimer and Boner, 2000; Winterdyk, 1997)—despite scant evidence of any real increase in youth violence (Zimring, 1998). This is just the kind of anticipatory regulatory approach that adherents of the PP advocate for new and potentially risky technologies, but here as applied to young and potentially risky persons. Similar concerns are raised by precautionary sanctions applied to the mentally ill and to athletes suspected of drug use.) The example is helpful in testing our thinking because it catches most advocates (on both sides) with their shoes on the other feet. Liberals may like precautionary environmental regulation, but recoil at precautionary criminal law; conservatives may have the opposite reaction. Perceptions of dread may attach to synthetic chemicals for some but to
32.4 PRECAUTION AMIDST MULTIPLE RISKS

All of these versions of the PP, and indeed all choices between ex ante and ex post legal systems, confront the trade-off between two kinds of errors: false negatives and false positives. False negatives occur when an initial finding of no (or acceptable) harm later turns out to have been incorrect. We risk false negatives by presuming “innocent until proven guilty.” Waiting before regulating can incur the cost of false negatives. For example, a substance or activity initially deemed unworthy of regulation could later turn out to be harmful; this might be a drug that turns out to pose adverse side effects, or a genetically engineered food (or any food), or an energy source that turns out to emit greenhouse gases or radiation, or a person suspected of a violent crime but not initially prosecuted. By contrast, false positives occur when an initial finding of (unacceptable) harm later turns out to have been incorrect. We risk false positives by presuming “guilty until proven innocent.” Precautionary regulations can incur the cost of false positives. For example, a substance or activity banned or restricted could later turn out to be benign; this might be a drug with beneficial therapeutic effects, or a genetically engineered food (or any food), or an energy source that is less hazardous than initially feared, or a person wrongly prosecuted for a crime she did not commit.

Because we must always decide in the face of uncertainty, we always confront the dilemma of whether to try harder to avoid false negatives or false positives. We will not be perfect; we will err, and the question is how to optimize our errors. Some have argued that regulators should be more averse to false negatives (and hence should err on the side of overregulation) on the premise that the cost of underregulating false negatives is health and environmental damage, whereas the cost of overregulating false positives is only money (Page, 1978). That premise is, however, incorrect: The cost of regulating false positives can just as well be health and environmental damage, because the substances and activities restricted offer their own health and environmental benefits (e.g., a therapeutic drug, or genetic engineering that reduces the need for chemical pesticides, or an energy source that reduces emissions of greenhouse gases), or because the substitutes pose risk, or because exaggerated warnings spur panic (and, later, public cynicism), or because overregulating false positives implies restrictions on personal freedom (e.g., prosecuting an innocent suspect of a crime, or restricting consumer choice) (Wiener, 1998).

Put another way, any precautionary intervention can yield unintended side effects. Risk regulation, like medical care, can both heal and hurt (Janicke, 1990; Moynihan, 1993; Wiener, 1998). Reducing a target risk can increase a countervailing risk (Graham and Wiener, 1995). To cite just a few examples: Aspirin treats headaches but causes stomachaches; surgery treats injuries but risks infection; automobile airbags save some adults but kill some children; suppressing forest fires reduces their initial frequency but increases their ultimate severity; regulating pollution into one medium may induce cross-media shifts; hazardous waste cleanups protect future residents but put present workers at risk; banning asbestos reduces cancers but may increase highway accidents from less effective brake linings; regulating outdoor pollution may induce firms to seal the plant and increase indoor pollution; controlling urban ozone may protect lungs but expose skin to more intense ultraviolet radiation; banning drugs may reduce addiction but increase violence; police pursuits may catch fleeing felons but injure bystanders (Graham and Wiener, 1995; Cross, 1996; Sunstein, 1996; Wiener, 1998). These are classic problems; in Joseph Lister’s 19th century England, hospital-acquired wound infections killed between 25 and 50 percent of surgical patients; in the United States today the rate of iatrogenic mortality is down to about 0.4 percent, but that rate still implies somewhere near 50,000 to 100,000 deaths a year caused by medical care (Wiener, 1998). Like Odysseus navigating between Scylla and Charybdis, the modern regulator must weigh competing risks.

The basic phenomenon driving these risk−risk trade-offs is the interconnectedness of multiple risks, derived from the interconnectedness of environmental and social systems. As the pioneering environmentalist John Muir put it, “when we try to pick out anything by itself, we find it hitched to everything else in the universe” (Muir, 1869: 110). Squeezing the balloon (or tugging the web) at one point puts pressure elsewhere. A general shortcoming of the PP is that it addresses risks one at a time as if uncertainty were the crucial issue. But the reality is that risks are multiple and trade-offs are the crucial issue. The PP thus neglects interconnectedness and neglects the potential adverse health and environmental effects of precautionary measures themselves (Graham and Wiener, 1995; Cross, 1996; Margolis, 1996; Wiener, 1998). Ironically, the PP neglects the ecological insight of interconnectedness.

The PP also speaks as though government regulation were an exogenous remedy for environmental and social ills. It says: Risk warrants regulation. But government regulation is not an exogenous solution to social problems; it is itself an endogenous and fallible human activity, and as such it can create risks—risks that are as real as the risks of market activities. This was the essential message of the National Environmental Policy Act (NEPA), the flagship U.S. environmental law that requires environmental impact statements for government projects. It is also the essential problem of iatrogenic injury and of risk−risk trade-offs: sometimes care heals, and sometimes care hurts. That is not to say that regulation can never improve things (Hirschman, 1991); it is just to say that regulatory interventions, like medical care interventions, affect multiple risk variables and generate a portfolio or vector of consequences. Regulatory law can be improved by confronting these trade-offs among target risks and countervailing risks, and designing regulations to minimize overall
risk. The problem is not pollution or market failure per se; the problem is flawed human institutions, including both markets and government. The challenge is to minimize the sum of market risk and regulatory risk.

Optimal regulation in the face of a target risk (TR) and a countervailing risk (CR) would take both seriously and strive to maximize their difference (ΔTR – ΔCR). Uncertainty is not the crucial problem—trade-offs are. Even certain risks would not justify regulatory action if ΔCR > ΔTR (such that regulating TR would yield negative net benefits). Meanwhile, standard advice to “muddle through” by “ignoring side effects” (ignore ΔCR) (Lindblom, 1959) is too lax; it will yield more net harm (because of neglected CR) than maximizing (ΔTR – ΔCR) whenever CR is positive and CR can be reduced at less than equal increases in TR. And standard advice to “do no harm” (ensure zero ΔCR), as in the Hippocratic oath, is too stringent; it will yield more net harm (because of neglected TR) than maximizing (ΔTR – ΔCR) whenever CR is positive but squeezing CR to zero will mean larger increases in TR (Wiener, 1998).

Furthermore, version 3 creates an ironic twist: If precautionary measures themselves are human activities that pose some risk, then version 3 of the PP—which forbids any risky “activity” until its proponents demonstrate acceptable risk, or no risk—would forbid many or all precautionary measures themselves. In short, the PP would swallow itself (cf. Cross, 1996). The way out of this paradox is to recognize that all human activities (including regulation) pose risk, and that the real question is not whether to act under uncertainty (we always must), but rather what action to take from among the portfolio of alternatives with different risks, costs, and benefits. The astute regulator should optimize across risk–risk trade-offs, minimize overall risk, and seek risk–superior moves that reduce multiple risks in concert (Graham and Wiener, 1995). At the same time, not every countervailing risk deserves extensive attention: The regulator should seek to avoid regulatory side effects up to the point that the benefits of doing so (improved policy outcomes) justify the costs of doing so (chiefly delay) (Wiener, 1998).

In sum, version 1 of the PP is helpful to decision makers as a rebuttal to the mistaken claim that uncertainty warrants inaction. Latent risks mean that inaction under uncertainty may invite future harms. Failing to take action against uncertain risks means incurring the social costs of false negatives in the future. Many cases of latent risks do warrant some precaution: Examples include lead in gasoline, losses of endangered species and biodiversity, resource depletion spurred by the tragedy of open access, and climate change. Simultaneous exposure to multiple stressors may warrant heightened precaution. But PP version 1 leaves unaddressed the serious question, which is what action we should take in the face of uncertain and latent risks. Saying that some precautionary action is warranted does not assist us in deciding which action—whether, say, to reduce greenhouse gas emissions by 5 percent, or 30 percent, or ban all fossil fuel combustion, or let emissions grow unabated while we invest in more resilient adaptation to climate change, or something else. Thus version 1 is helpful but incomplete. On the other hand, versions 2 and 3 of the PP are unhelpful and could be counterproductive. They incur the social costs of unnecessarily regulating false positives. Moreover, version 2 and especially version 3—designed to promote ex ante regulatory action against a single risk—become entangled in the real-world web of multiple risks. By focusing on one risk at a time, they neglect the countervailing risks of regulation; by viewing government intervention as exogenous rather than endogenous, they highlight market failures but neglect government failures. In the real world of multiple risks and imperfect government, aggressive precaution can induce countervailing risks that weaken or even reverse the case for regulation. Precaution itself may be a risky activity; amidst multiple risks, the PP implies that precautions are needed against excessive precaution. Given the reality of multiple interrelated risks, we need a principle of “optimal precaution” rather than of maximum precaution. Precautionary regulation should be followed by continuing surveillance and research to foster learning and adaptive revisions. And we need to seek risk–superior options that reduce multiple risks in concert. Just as Joseph Lister devised antisepsis to reduce wound infection and thereby make surgery safer, we need to devise ways to make precautionary regulation safer (Wiener, 1998).

32.5 PRECAUTION AS APPLIED

The real-world experience of the PP in application illustrates that unbridled precaution could be perverse and that governments therefore apply the PP moderately. Here I offer two perspectives on the real-world application of precaution. First, I argue that the more binding the legal instrument in which the PP is enshrined, the more moderate is its application. Radical versions of the PP are thus more rhetoric than reality. When real regulatory powers (or “teeth”) are being exercised, governments have applied the PP more moderately and pragmatically, couching it in balanced criteria for decision making.

Second, I argue that the United States and Europe have not taken simple opposing positions on the PP. In reality, the relative degree of precaution on each side of the Atlantic has varied considerably across topics. The pattern is complex; sometimes Europe is more precautionary, and sometimes the United States is more precautionary. Thus, when the PP is applied in the real world, pragmatic context matters more than ideology.

32.5.1 Precaution and the Teeth of Legal Instruments

Arriving at statements of the PP along the sliding scale of “degree of precaution” supports the hypothesis that the PP is stated more strongly in less legally binding texts, and less strongly in more legally binding texts. The strongest statements of the PP—such as the strong form of version 3, forbidding an activity until its proponents demonstrate that it poses no risk—appear in the academic literature (e.g., Cranor, 1999) and in declarations by advocacy groups (Wgangscheid, 1998).

When the PP is adopted by governments in international fora, it becomes more moderate. The Bergen Declaration (1990)—adopting version 1 (unce-
tainty does not justify inaction)—was a statement of environment ministers; it bears some governmental imprimatur but has no binding legal effect and represents the views of the arm of government (environment ministries) most likely to favor a strong PP. When the Bergen Declaration’s statement was inserted into the Rio Declaration (United Nations, 1992b), it was qualified with the term “cost-effective” added before “measures” (Applegate, 2000:415). Sand (2000:447) reports that this term was inserted by the U.S. lawyer at the fourth session of the UNCED Prepcom in March 1992 over the objections of Europe and Japan. My recollection, however, is that the term “cost-effective” had already been proposed by the United States, and agreed to by other countries, in the preceding negotiations on the Framework Convention on Climate Change; thus the term “cost-effective” appears in the statement of the precautionary principle in Article 3.3 of the Climate Change Convention (United Nations, 1992a). In either case, the point here is that as the PP moved from the declaration of environment ministers at Bergen to the more official (though still non-binding) declaration signed by presidents and prime ministers at Rio, and the even more potent (signed, ratified, and legally binding) climate change treaty, the PP was moderated. The climate change treaty further moderated the PP by placing it in Article 3 on “principles,” the legal effect of which was debated by the parties and doubted by the United States (Bodansky, 1993); the real teeth of the Climate Change Convention were in Article 4, setting emissions limitation obligations, which does not advert to the PP.

When the PP is adopted by governments in national legislation, it becomes more moderate still. Although the EU treaty (1993) states that EU environmental policy shall be “based on the precautionary principle,” it does not say what that means. When the organs of European government turned to giving that statement teeth (European Commission, 2000), they translated the PP into a heavily qualified and caveated explanation of what amounts to pragmatic consequentialist decision making. The Commission’s statement begins with version 1 (uncertainty does not justify inaction), but then it adds numerous other criteria for ex ante regulation, such as the need for precautionary measures to be proportionate to the risk involved, to maximize net benefits, to take account of the costs and risks of alternatives, to assess the alternative of no action, and to be accompanied by ongoing research to reduce uncertainties and possibly reverse the decision even after the initial precautionary measure has been adopted. Despite having several ambiguities and potential shortcomings, the Commission’s communication is in many ways similar to the U.S. guidelines for regulation in Executive Order 12866 (Clinton, 1993) (which requires, among other things, that regulations be based on sound science and maximize net benefits). In both cases, the national governments have articulated sensible, moderate frameworks for risk-based regulation. Of course, the actual regulatory outcomes will depend on how that framework is interpreted and implemented. The point here is that as the European Union has moved from treaty rhetoric to binding implementation, it has moved the PP a long way toward the pragmatic approach to risk regulation already in place in the United States. In particular, the European Union has recognized the problems of false positives and countervailing risks due to excessive precaution and has attempted to write the concomitant qualifications (such as proportionality, net benefits, comparing alternatives, study, and reconsideration after adoption) directly into its conception of the PP.

Member states of the European Union have likewise moderated the PP in actual application. British judicial decisions have so far declined to adopt a strong form of the PP (Sand, 2000:449). France has been inconsistent, sometimes championing the PP (e.g., against imports of British beef and of Swiss bioengineered corn) and sometimes opposing it (e.g., when it was invoked against a French nuclear power plant) (Sand, 2000:448, 450). The French statute (the “Loi Barnier” of 1995) adopting the PP added the qualifications that precautionary actions must be “commensurate” with the risk and “at economically acceptable cost” (Sand, 2000:450). In Germany, where nuclear power plants have the burden of proving safety, the courts have nonetheless held that the PP does not require eliminating all risk and moreover that under the PP the public must tolerate some “residual risks”; the German administrative implementation of the PP requires that precautionary decisions be based on risk assessments and be commensurate with the risk (Sand, 2000:451). Indeed, German law has a general principle of “proportionality” which constrains precautionary regulation (Emiliou, 1996; Jackson, 1999:604). Sweden takes a more stringent approach, closer to version 3, but even there the strong form of version 3 is only occasionally applied (Sand, 2000:448–449).

Similarly, the application of precaution in the United States has usually been moderate. Although the FFDCA (for new drugs), TSCA (toxic substances), and FIFRA (chemicals) impose premarket screening that shifts the burden of proof to manufacturers, they employ a moderate standard of proof of net benefits or reasonableness (avoidance of unreasonable risk). As to food additives, the Delaney Clause formerly imposed a stringent “no carcinogens” standard of proof (regardless of the triviality of the risk or the countervailing health benefits of the substance), but the 1996 Food Quality Protection Act has moderated that standard (slightly) to a “reasonable certainty of no harm.”

The Endangered Species Act (ESA), while prohibiting any federal agency from “jeopardizing” the survival of an endangered species [sec. 7(a)] as a matter of “institutionalized caution” and regardless of the cost (Tennessee Valley Authority v. Hill, 1978), nonetheless provides for exemptions that maximize net benefits [sec. 7(h)], and for the determination of a species’ “critical habitat” based on economic criteria [sec. 4(b)]. Even though it prohibits persons from “taking” endangered animal species (sec. 9), it allows persons to obtain “incidental take” permits (sec. 10) that immunize such takings if incidental to other valuable economic activities such as agriculture and forestry. It also defines “species” [in secs. 3(16) and 3(8)] in a way that omits microorganisms, perhaps because the drafters viewed the protection of bacteria, fungi, and viruses as not worth the costs; and it allows the government to omit insects that pose an overwhelming risk to humans [sec. 3(6)]. These qualifications of the ESA’s otherwise stringent
prohibitions on harming endangered species may or may not be desirable. My point here is simply that the initial precautionary edict has been moderated in application.

Another useful example is the phasenout of chlorofluorocarbons (CFCs). The international treaty calling for this phasenout (Montreal Protocol, 1987) cited the PP as part of its rationale. The phasenout regulated different CFCs in proportion to their ozone depletion potential [see 42 USC 7671a(e)]. In implementing this phasenout, national laws allowed for some continued production of CFCs for “essential uses” such as airplane safety and medical devices [42 USC 7671c(d), 7671(d), 7671i(d)] and for fire suppression if no safe and effective substitutes are available [42 USC 7671c(g)]. In addition, the U.S. statute implementing the phasenout directly confronted the problem that substitutes for CFCs might pose countervailing risks: It instructed EPA to regulate CFC substitutes to “reduce overall risks to human health and the environment,” including risks of ozone depletion, global warming, toxicity, and other hazards (42 U.S.C. 7671k). Thus, the precautionary effort to protect the stratospheric ozone layer was moderated to treat different CFCs in proportion to their risks, to include caveats for high costs of abatement (“essential uses”), and to deal with the complexities of multiple countervailing risks.

Of course, strict versions of the PP could be enacted into binding law. There are undoubtedly some such examples in place today. The Delaney Clause is one example—though one that has been sharply criticized for being excessive and counterproductive. Another example is the rise of stringent precautionary measures in the criminal law area. There, although the government bears the burden of proof, some stringent precautionary standards have been adopted to incapacitate and deter future dangerousness, such as mandatory minimum sentences and “zero-tolerance” policies on adolescent alcohol use. My point here is simply that, in general, as law becomes more binding, its precautionary tendencies become more moderate. The precautionary rhetoric of crime prevention is arguably even more absolutist than its admittedly absolutist application. And judges may moderate stringent criminal laws in many cases.

In sum: the most aggressive versions of the PP appear in rhetorical and nonbinding declarations. In general (though there are no doubt exceptions), the more binding a legal instrument, the more moderate its application of the PP. This illustrates the move from the absolutist “precautionary principle” toward a more pragmatic “optimal precaution” as precaution must confront the reality of a multirisk world.

32.5.2 Precaution Across the Atlantic

A second illustration of the move toward pragmatic consequentialism in the application of the PP can be seen in the comparison between the United States and Europe. As noted above, the conventional wisdom is that Europe favors precautionary regulation and the United States opposes it. The reality is that the United States and Europe both respond to risks in context. Sometimes Europe is more precautionary; sometimes the United States is more precautionary. (For a more detailed comparison on which this section draws, see Wiener and Rogers, in press.)

For example, Europe appears to have been more precautionary than the United States about several types of risks, including the safety of genetically modified foods (Lynch and Vogel, 2000), hormones in beef, including bovine somatotropin (BST) (European Council, 1990, 1999; Vogel, 1995, 1997; Wiener and Rogers, in press), toxic substances, climate change (Sullivan and Jordan, 1997; Wiener, 1999), guns (United Nations, 1998), and antitrust/competition policy (Richter, 2000; Raghavan and Mitchener, 2000).

By contrast, the United States appears to have been more precautionary than Europe about several types of risks, including the licensing of new drugs (e.g., thalidomide, which was licensed in Europe but not in the United States), lead in gasoline (which the United States phased out much earlier and more quickly than did Europe) [compare EPA (1985) with United Kingdom (UK) Department of the Environment (1991)]; depletion of the stratospheric ozone layer (the United States began with a ban on CFCs in spray cans in 1978, almost a decade before Europe acted) (Lifitin, 1994:64–67); highway safety (the United States has more stringent speed limits on major highways) (Ibibio, 2000); nuclear energy (the United States has regulated nuclear power plants more tightly than have France and Germany); bovine spongiform encephalopathy (BSE) or “mad cow disease” (the United States banned imports of affected beef years earlier than did Europe, and maintains that ban while Europe has relaxed its restrictions) (Lyall, 2000; European Commission, 1996; U.S. Department of Agriculture (USDA) 1991, 2000; UK, 2000; Wiener and Rogers, in press); BSE in blood donations (the United States has banned blood donors who have spent time in Europe) (Hernandez, 2001; Tagliabue, 2001; Wiener and Rogers, in press) choking hazards embedded in food (Harris, 1997) “right to know” requirements [the United States has a suite of provisions such as the Freedom of Information Act (FOIA), Toxics Release Inventory (TRI), Clean Air Act sec. 112(r), Calif. Prop 65, and the OSHA Hazard Communication Standard, while Europeans “can only dream” of this kind of precautionary measure (Sand, 2000:452)]; and legal restraints on dangerous persons such as violent youths (Stanford v. Kentucky, 1989), mental health patients (Telbot, 2000), and recovering sex offenders, whose location is publicized in American towns but not in Europe (Hood and Baldwin, 2000).

This is not to say that European or U.S. policy is “better” on any of these examples. As emphasized above, the more precautionary approach is not always the superior approach, or even the more protective approach (given countervailing risks). Rather, this enumeration of conflicting examples only illustrates that neither the European Union nor the United States has a claim to being more precautionary across the board. Relative precaution is context-specific. Thus, this enumeration of transatlantic examples adds further support to the hypothesis that in real-world applications, the precautionary principle is moderated by pragmatic considerations. It does not, however, prove that these
real-world applications are converging toward optimal precaution. Nor does it explain what social, political, cultural, economic, or other factors account for the complex observed pattern (see Wiener and Rogers, in press).

32.6 CONCLUSIONS

Some forms of the precautionary principle (PP) could be helpful to policymakers, who must inescapably act in the face of uncertainty about risk. The PP reminds us that there are real costs of inadequate precaution: false negatives and latent harms that may be left unaddressed or may be exacerbated as regulators watch for signs of greater certainty. But most formulations of the PP seem to have been designed as if regulators addressed one risk at a time, and the only question was how certain they are about this risk. In the real world, regulators are uncertain about all risks, and the real questions are how to deal with multiple risks and alternative actions. In the real world of multiple risks, the PP must be qualified by the recognition that there are real harms from excessive precaution: false positives, cost, inhibited innovation, and the countervailing risks of regulatory interventions.

Of the three versions of the PP examined here, version 1 makes sense but is incomplete: It does not answer the serious question (namely: what action should we take in the face of inevitable uncertainty?). Versions 2 and 3 are flawed insofar as they neglect the countervailing risks of actions to combat target risks. Indeed, if precautionary action itself poses countervailing risks, then a strong version of the PP (such as version 3) swallows itself: It requires precaution about precaution. Hence the PP needs to be qualified to guide intelligent regulation. It must avoid overreacting to false positives, deal with multiple countervailing risks, minimize the sum of market risk and regulatory risk, seek risk-superior moves, and be dynamic and adaptive in the face of changing information.

In practice, the PP has indeed been qualified when actually implemented in binding law. There is no single formulation of the PP. Empirically, the more binding the legal instrument, in general, the less absolutist the version of the PP it contains, and the more it moderates the PP with pragmatic consideration of consequences and alternatives. Across countries and over time, application of the PP has therefore been highly context-specific, variegated, and even inconsistent. This reality sharply undercuts the case for enshrining "the" precautionary principle as a norm of customary international law. If there has been any convergence toward some consensus state practice (which is doubtful), the trend has been toward pragmatic consequentialism, not ideological precaution.

The challenge, then, is to seek risk-superior ways of reducing multiple risks in concert. As with medical care and our daily lives, the goal should be not maximum precaution but an "optimal precaution" that addresses both the risks of inaction and the risks of action.

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