

Abstract In this article, we scrutinize the ability of the Precautionary Principle to serve as a unifying principle for public health. Although most commonly invoked in environmental health regulatory debates, implicit and explicit invocations of the Principle have spread to other contexts. Here we seek to understand the potential uses of the Precautionary Principle for those concerned with population health by considering its invocation in five cases: vaccination, quarantine for SARS, needle exchange to prevent the spread of HIV/AIDS, e-cigarettes as an alternative to tobacco-cigarettes, and climate change mitigation. We ask whether the Precautionary Principle offers a philosophical approach precise and sufficiently stringent to guide health policy in a range of circumstances where evidence may be less than definitive and the course of action contested. We find there are far more ambiguities in the Principle's application than might appear at first and conclude that it is best used in concert with other frameworks for guiding action in the face of uncertainty.

11.1 Introduction

The Precautionary Principle was first articulated in the context of pollution control, where planners in the former West Germany sought to address "forest death" in the 1970s (EEA 2001; Jordan and Riordan 1999). At its most basic, the Precautionary Principle—which argues that any activity that may threaten human or environmental health be forestalled until proven harmless, and that the proponent of a new

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activity bear the burden of proving it safe—is captured by aphorisms such as "better safe than sorry" or "when in doubt, don't." Proponents are particularly focused on preventing potentially irreversible harms, such as the release of chemicals or genetically modified organisms that cannot be recalled, and on protecting current and future generations.

In its strictest interpretation, known as "deep" or "deep green" precaution, the principle holds that any suspicion of harm should be sufficient to trigger precaution, even "in the absence of any scientific evidence" and "without regard to cost" (Jordan and Riordan 1999). The principle expresses skepticism about the adequacy of the scientific method to demonstrate long-term harm and provide a basis for timely action, challenges the dominance of experts over those with community experience, and rejects cost-benefit approaches that are seen as arbitrarily assigning monetary value to life or environmental integrity and are particularly biased against money spent in the present to safeguard the future (Ashford 1999).

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Opponents, recently and preeminently Cass Sunstein, have referred to the Precautionary Principle as the "paralysis principle," arguing that it substitutes intuitive fear for scientific proof and that its hostility to cost-benefit analysis hampers action in the name of uncertainty (Sunstein 1995). Despite this debate, precautionary logic—whether explicitly invoked or implicitly accepted—has increasingly shaped debates over public health policy. For example, prevention advocates have invoked precaution in discussions of lead poisoning, Agent Orange, pesticides, synthetic compounds, energy production, blood safety, groundwater contamination, and electric and magnetic fields, among others (Wilson and Ricketts 2004; Goldstein 2001; Stoto 2002).

A growing literature has analyzed multiple permutations of the Precautionary Principle and various conditions for its usage. These include the seriousness of a potential harm, evidence indicating a risk, and opportunity costs and potential consequences of a regulatory action. It is not our goal to add to this conceptual debate, which often occurs at a level far more abstruse than that found in typical real-world practice. Rather, we move to the recent history of public health and consider invocations of the Precautionary Principle in five lived contexts: vaccination, quarantine for SARS, needle exchange to prevent the spread of HIV/AIDS, e-cigarettes as an alternative to tobacco cigarettes, and climate change mitigation. We ask whether the Precautionary Principle offers a philosophical approach precise and sufficiently stringent to guide health policy in a range of circumstances where evidence may be less than definitive and the course of action contested.

While this might seem a dissonant pastiche of examples, in fact they all capture the central challenges of public health: How do we mitigate existing harms? What level of risk can be acceptably borne by the public and what is our standard of comparison? Do we compare risks to a theoretical pristine state or do we compare the risks of action (or inaction) to prevailing risks? How much evidence do we need to justify action and when? Who should bear the burden of uncertainty of action or inaction? What standards of equity should guide those determinations?

11.2 Vaccination: Small Risks, Big Benefits, and the Dual Uses of Precautionary Logic

Indicative of the extent to which precautionary thinking has been embraced by public health policy makers is the 1999 decision to remove the mercury-based preservative thimerosal from vaccines in light of fears that it might cause autism or other adverse effects in children. Although used for many decades, thimerosal's potential for harm came to light only in the late 1990s as a result of a review initiated by the FDA of mercury in biological products. In a joint statement, the U.S. Public Health Service and the American Academy of Pediatrics conceded that "the large risks of not vaccinating children far outweigh the unknown and probably much smaller risk, if any, of cumulative exposure to thimerosal-containing vaccines over the first six months of life." But in an implicit expression of the Precautionary Principle, the statement declared that "because any potential risk is of concern," thimerosal should be removed from use as soon as possible (CDC 1999).

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In the case of vaccines, however, the language of precaution has primarily been mobilized by those who have opposed mandatory public health immunization programs and, especially, school entry requirements. As new vaccines were developed in the twentieth century, they often went into wide use based on the results of trials that would not meet today's standards for evaluating safety and efficacy, and even in light of incidents in which improperly prepared vaccines caused illness and death (Baker 2000). The high toll of morbidity and mortallity from diseases such as diphtheria, pertussis, and polio provided the warrant for sweeping public health action. Those who insisted that vaccines not be widely administered without better proof of heir value remained politically marginal for most of the twentieth century. Public health officials generally held that the favorable effects of widespread vaccination were self-evident and far outweighed the isolated instances of illness and even death caused by vaccines. Highly publicized events that might have prompted a shift toward a more precautionary stance—such as the 1955 incident in which contaminated lots of Salk polio vaccine caused more than 200 cases of polio and eleven deaths—did not alter the policy in favor of deploying new vaccines on a wide scale (Brandt 1979).

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More recently, a small group of vocal and politically astute activists has chalenged the public health establishment to rethink its views of the risks and benefits of universal childhood immunization. The increasing visibility of anti-vaccination views has come, ironically, even as the technology for producing safe and effective vaccines has improved. The outlook of these activists implicitly embodies the Precautionary Principle, though they do not typically invoke it by name. They contend that the apparent rise in the incidence of chronic disorders such as autism is due to the effects of vaccines on a minority of children who, for unknown reasons, have biological susceptibilities to vaccine-related injury. While they do not recommend discontinuing the use of vaccines altogether, they reject current policies of mass immunization that do not allow parents to make choices about which vaccines their children receive. "Because so little research has been conducted on vaccines identified to the conducted on vaccine side."

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Against these claims, public health advocates have asserted that the demand for certitude represents an unacceptable standard, one that would evicerate the possibility of serving the public good. Indeed, they have argued, that small, measurable risks are an acceptable price that we must be willing to pay for big public gains.

11.3 Quarantine for SARS: Risks, Liberty, and the Dual Uses of the Precautionary Claim

The Precationary Principle was explicitly embraced as a core public health value during the worldwide outbreak of Sudden Acute Respiratory Syndrome (SARS) in 2002. In this instance, it was leveraged in support of broad quarantine practices (Gostin et al. 2003). In several respects, SARS tested the limits of scientific certainty, returning society to a pre-therapeutic era: a non-specific case definition, the absence of an assay that could distinguish between the infected and the merely exposed, and no effective vaccine or treatment (Gerberding 2003). Proposals to confine those who were potentially exposed thus raised questions about the level of risk that justified loss of liberty. Was suspicion of infectiousness or even exposure sufficient to detain?

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Countries with diverse socio-political and constitutional traditions, ranging from China, Hong Kong, Vietnam, and Singapore to Canada answered these questions with precautionary logic and broad quarantine (Bloom 2003). In other words, with no means of knowing who amongst the exposed would actually spread the disease to others, precaution dictated that all of the exposed should be quarantined. Quarantine received a ringing endorsement from the World Health Organization (WHO): "At the beginning of an outbreak, it is sound public health policy to institute maximum control measures needed to prevent further spread" (WHO 2003). The CDC explained, "Applying quarantine too narrowly in the midst of an extensive outbreak can...blunt the efficacy of policy if missed cases result in additional generation of transmission" (CDC 2004). Set within a precautionary rubric, those exposed to SARS became equivalent to chemicals of uncertain toxicity, and authorities regulated their circulation until it was clear that no harm would be done by their release. In Canada, one of the epicenters of the epidemic, a consistent lay reaction to sweeping quarantine efforts was, quite literally, "better safe than sorry" (Editorial 2003; Goldstein 2003; Talgapa and Powell 2003).

Strikingly, precautionary logic was also invoked by those who opposed the imposition of quarantine. For example, one infectious disease expert in Canada noted that quarantine was a "scary" measure to take for a disease with a case-fadity rate less than hospital-acquired pneumonia: "You don't do that for a minor thing" (Singer 2003). Legal scholar George Annas, one of the most ardent defenders of civil liberties in the context of public health, has included quarantine among the excesses against which sound policy must guard. Without denying the role for quarantine in some situations, Annas rejects the presumption that "a trade-off between the protection of civil rights and effective public health measures" is essential or even productive. Civil liberties, rather, must be safeguarded in the absence of "empirical evidence" that quarantine measures are "necessary and effective" (Annas 2002). We may not trifle with civil liberties unless the risks are certain and compelling. In other words, quarantine is the "threat" that must be proven necessary and effective before its introduction.

These claims were given substance by what evidence ultimately revealed about the threat posed by SARS. By the Fall of 2003 it became clear that the isolation procedures used during the initial outbreak had been fat roo expansive. The CDC reported that individuals quarantined after contact with an asymptomatic SARS patient "had no detectable risk" of infection and that 66 % fewer people might have been quarantined without reducing the efficacy of the procedure (CDC 2003). The CDC accordingly modified its quarantine guidelines. Nonetheless, even if they proved overly restrictive, precautionary measures were largely credited with rapid control of SARS: the epidemic did not spread beyond its epicenters, and WHO explicitly advised application of precautionary quarantine for air-borne epidemics when it was "unclear whether human-to-human" transmission was occurring (WHO 2004).

11.4 Needle Exchange: Precaution and the Competing Concept of Harm Reduction

An outbreak of hepatitis B among injection drug users (IDUs) in Amsterdam in 1984 led to the first syringe exchange program (Oppenheimer 1993). Needle exchange provided IDUs with sterile injection equipment, thus eliminating the need to share potentially contaminated "works." Recognition of the efficiency with which HIV was spread by contaminated needles and the overwhelming and relentless number of deaths from AIDS led to wide and rapid expansion of this intervention. Proponents justified needle exchange for those unwilling or unable to abstain from Illicit drug use based on the fact that AIDS was almost invariably fatal and that, in the absence of action, further spread of the epidemic was certain. They were propelled by an emerging and contending philosophy of public health, that of harm reduction, which pragmatically accepts that drug use is inevitable but seeks to

minimize the public health and population level consequences. Like the Precautionary Principle, it values lay knowledge in the face of palpable threats.

In the United States, where temperance and neo-temperance movements, such as Nancy Reagan's "Just Say No" campaign, had long dominated drug policy, critical of needle exchange adopted a precautionary stance and warned that such programs might in fact entice more people to use heroin. Early in the epidemic, when the evidence regarding the efficacy of the intervention was scanty, the opponents of needle exchange were found not only among politicians and the public, but also public health officials. "Passing out tools of addiction," commentators in the Maryland Department of Health warned, "could condemn even larger numbers of citizens to wasted lives and others to a life of crime" (Silverman and Rusinko 1988). Others worried that collateral damages, such as needle stick injuries to schoolchildren or accidents and crime involving heroin addicts, would occur near needle exchange sites. Wrote one physician, "I am concerned that we may increase the risk of AIDS in the community at large by such distribution. With access to free sterile needles, what care should we expect in the disposal of used contaminated needles? A careless drop in a garbage can, on the street or in an alley could very well be the accidental source of infection (by needle prick) to a building superintendent, sanitation worker or child at play" (Hoskins 1986).

As increasing numbers of public health officials came to embrace needle exchange and evidence of its efficacy came to light, opponents of needle exchange drew particular attention to the risk that syringe distribution represented for future generations. Opposition, to be sure, was not based solely on lingering questions of scientific uncertainty. "Needle exchange programs send the wrong message to our children by condoning illegal drug use," insisted Governor Christine Todd Whitman of New Jersey in 1998. In keeping with precautionary rhetoric, the governor implied that the release of needles would steer a generation of children toward drug addiction, and would be exceedingly difficult or impossible to reverse (Richardson 1998).

The precautionary charge that needle exchange might directly or indirectly perpetuate heroin use and community problems held particular resonance for African American communities, where the prevalence of illicit drugs was seen as the consequence of "malignant neglect" by the government and public health entities (Kirp and Bayer 1993). In these arguments, not only lillicit drugs but also clean needles were conceptually akin to potential toxins being introduced into the community. Coming after decades of failure to provide adequate drug treatment in African American communities, some saw needle exchange as a kind of malpractice neglect in keeping with the legacy of Tuskegee (Fairchild and Bayer 1999). The practice, then, could not be evaluated purely in terms of risk, but had to be set within a broader historical frame.

While a literature would begin to accumulate during the 1990s suggesting that syringe exchange programs did, in fact, reduce HIV infection and other harms associated with injection drug use without increasing such use, it has not proven decisive (Des Jarlais 2000; Moss 2000; Coutinho 2000). At the state level, resistance to needle exchange weakened in the face of evidence showing that it does not promote drug use and can reduce the spread of HIV. There were only 63 known needle

exchange programs operating by the mid-1990s; in 2000, there were 127 (Des Jarlais et al. 2004). The continued federal ban on funding of programs that provide sterile syringes, however, demonstrates the strong grip of precautionary thinking linked to a prohibitionist perspective on public health policy in this arena.

11.5 The Debate Over E-Cigarettes: Precaution as a Call for Restraint

E-cigarettes—battery operated nicotine delivery devices that vaporize and use propylene glycol to capture the look and feel of smoking—first appeared in European and American markets less than a decade age (Noel et al. 2011). Sales have reach \$650 million a year in Europe and are estimated to reach \$1.7 billion in the US this year (Higgins and Richtel 2013; Mangan 2003). Though a fraction of cigarette sales, e-cigarettes represent a significant market achievement with some predictions that they may eventually eclipse tobacco cigarettes. On October 26, 2013 the New York Times business section devoted a cover story and two full pages to a discussion of the market share of this new product. The introduction of e-cigarettes, which, like their tobacco twins contain nicotine, an addictive but generally benign drug, generated controversy that has closely mirrored the pitched battles over needle exchange (Richtel 2013).

On one side of the dispute are the forces of tobacco control, determined to keep this product off the market until it has been proven safe and effective. Although not explicitly stated, opponents view e-cigarette through the lens of the Precautionary Principle, which requires proof of safety and efficacy in advance of allowing them onto the marketplace. They are haunted by the specter of e-cigarettes as a "gateway" or "bridge" product, eventually leading to an uptick in underage smoking (Cobb and Abrams 2013). Further, opponents put great weight on studies highlighting youth experimentation with e-cigarettes and those that suggested that adolescents who used e-cigarettes were less likely to have quit (Lee et al. 2013). Simon Chapman and Melanie Wakefield, two important figures in the tobacco control movement in Australia, warn that, whether amongst adults or youth, the goal of the industry is actually "dual use," meaning e-cigarettes are not meant to serve as an alternative to tobacco cigarettes but rather are a means of ensuring that smokers on't quit. "This," they conclude, "could be a harm-increasing outcome when assessed against the status on of ever-declining smoking neveloces" (Chapman and Wekefield 1013).

status quo of ever-declining smoking prevalence." (Chapman and Wakefield 2013).

By contrast, as was the case with needle exchange, proponents of e-cigarettes assert that given the known risks of tobacco use and the vast public health consequences, a harm reduction model should inform policy in the face of uncertainty. Advocates cite surveys suggesting that the vast majority of those who use e-cigarettes treat them as smoking-cessation aides and self-report that they have been key to quitting (Etter and Bullen 2011; Etter 2010). They note as well that e-cigarettes help to reduce tobacco cigarette consumption, even for users who have no intention of

giving up tobacco cigarettes. Data, they argue, indicate that e-cigarettes are probably at least as effective at helping smokers quit as nicotine replacement therapies like the patch and nicotine gum (Siegel et al. 2011; Bullen et al. 2013; Caponnetto et al. 2013). Additionally, harm reduction advocates frame an abstinence-only stance as "moralistic," even arguing that "it is nonsensical to dismiss an alternative" by demanding absolute safety (Sweanor et al. 2007). Further, for harm reduction advocates, not only e-cigarettes but also smokeless tobacco products hold "the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century" (Sweanor et al. 2007).

The fundamental risk aversion of the Precautionary Principle is, in this case, brought head to head with harm reduction and its toleration for risk in lower doses as an alternative framework for thinking about trade offs in public health policy.

11.6 Climate Change: Precaution in the Face of a Certain

Climate change differs in many respects from the previous cases, above all in its scope and seale. Environmental health scientists, policymakers, and lay activists have increasingly embraced a rhetoric of crisis as they identify the public health ramifications of climate change, some already observed, some projected (Frumkin et al. 2008; Epstein and Ferber 2011). Fueling conflict over how to address the crisis are the unequal distribution of climate-change burdens and the intergenerational character of the consequences. Small low-lying nations without the protective infrastructure to sustain rapid ecological transformation will be hardset hit, while future generations will bear the biggest burden if no action is taken (Broome 2012). The cumulative gravity of the problem has led, in turn, to increasing calls for a strategy of primary prevention, as a number of bodies, most prominently the Intergovernmental Panel on Climate Change (IPCC), have called for drastic reductions in carbon emissions, as much as 60–80 % by 2050. Precautionary logic pervades these calls. Now, the general trends and causes of anthropogenic climate change are no longer in credible scientific dispute. Few advocate, at this point, waiting for even more precise evidence of harmful effects to accumulate before taking policy action. But debate centers on what forms this action will take and how to realize it politically. While the most prominent part of the debate has centered on cost-benefit questions, critical questions around precautionary rationales have also emerged.

The gravity of the problem persists when one switches analysis from the global aggregate to the regional level. There, concern has mounted over the potential health effects posed by dominant forms of energy production, particularly coal-generated electricity, one of the chief contributors to anthropogenic climate change. Recent high-profile policy critiques of coal have highlighted its broad environmental health impacts; documented threats to air and water quality in local ecosystems; identified its outsize role in carbon emissions; and have made retribinary attentions tal assessing

the high external fiscal costs of these byproducts (Epstein et al. 2011; NRC 2010). Two recent catastrophic accidents related to coal—an ash spill in Tennessee in 2008 and leakage in West Virginia of a toxic chemical used to prepare coal for burning in 2014—have only heightened broader public concerns and put coal on the defensive. Although coal still accounts for a large percentage of electricity production in the United States—42 % in 2011—its usage has unexpectedly fallen in recent years, with natural gas replacing it for the first time as the United States's primary source of electricity (EIA 2013). These trends occur as a number of environmental scientists and prominent panels have called for drastic decreases in coal-based energy and a move to large-scale, low-carbon energy production.

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Recent policies, both enacted and proposed, range from the more conservative, such as emissions trading, to the more radical, such as new taxes on emissions, limits on certain modes of energy production, and major infrastructural investment in renewable energy experiments and public transportation by nation-states. In 2010, environmental scientists, writing in Science, went as far as suggesting a moratorium on the most ecologically disruptive of extractive methods—so-called the mountaintor permoval (MTR)—because of potential health effects (Palmer et al. 2010). Here, as at the global level, these policy appeals are made despite evidentiary uncertainty on the exact causal pathways between human health consequences, on one hand, and resource extraction and greenhouse gas emissions, on the other.

With climate change, the Precautionary Principle's invocation resembles its use in parallel debates over mass-produced products or compounds, where it has produced the products or products or compounds, where it has produced the most prescriptive clarity. In those instances, precautionary advocates have clearly asserted that public health concerns override various economic imperatives and patterns of consumption with which regulation might interfere. As in those cases, climate debate is about whether or not cost-benefit analysis and economic imperatives should trump precautionary thinking. Still, though the precautionary approach to climate change comes with fewer obvious ambiguities than do the previous cases, it is hardly free from issues. In particular, certain proposed medium-term solutions may introduce new harms. Critics of emissions trading, to date the most comprehensive framework developed to address climate change (with mixed results), have argued that, at worst, it simply provides a legitimating institutional edifice for continued carbon emissions (Lohmann 2012).

Another high-profile example of new solutions begetting potential harms comes

Another high-profile example of new solutions begetting potential harms comes from climate change scientists who argue for increased generation of baseload electricity from natural gas and nuclear power. But these proponents claim that the known health risks of the latter two sources are dwarfed by the demonstrable toll of predominant coal-based energy and its high attendant greenhouse gas emissions (Clapp 2005). Hydraulic fracturing for natural gas comes with its own set of risks, including unanswered questions about the toxicity of chemicals used in the process; safety of drinking water sources proximate to sites; its geological effects; and the amount of methane gas emitted in the process, which the Environmental Protection Agency is addressing in an ongoing assessment (EPA 2012; Wilder 2012). As for nuclear energy, in a recent and controversial open letter, climate scientists James Hansen, Kenneth Caldeira, Kerry Emanuel, and Tom Wigley made a precautionary

case for its increased use. Acknowledging the inherent risks, they write that "no energy system is without downsides." The authors add, however, that "while it may be theoretically possible to stabilize the climate without nuclear power, in the real world there is no credible path to climate stabilization that does not include a substantial role for nuclear power." The temporal urgency of mitigating climate change supercedes risks of possible solutions. In their words, "with the planet warming and carbon dioxide emissions rising faster than ever, we cannot afford to turn away from any technology that has the potential to displace a large fraction of our carbon emissions." Although precautionary language is used here to bolster a case for nuclear energy, its invocation is far less clean-cut given the introduction of new risks (Caldeira et al. 2013).

11.7 Precaution: Ethic or Ethos?

Even if the Precaution: Ethic or Ethos?

Even if the Precautionary Principle does not paralyze, its actual implementation is much less straightforward than proponents sometimes presume. In some of the cases we have discussed, parties on opposites sides of a debate predicate their case on precaution. In other instances, precautionary logic competes with other values of contemporary public health practice, including harm reduction, evidence-based decision-making, and civil liberties concerns. All of this calls for more precise examination of the Precautionary Principle's purview and the exact circumstances in which it can serve as an effective guide to policymaking.

Deep precaution as an ethic has the virtue of consistency, demanding and prohibiting certain courses of action when evidence is contested or unavailable. It has served as a trump argument it is hostile to the notion of trade offs, seeing in them perilous compromise. The great strength of deep precaution, then, is its uncompromising stance. But this is also its inherent limitation.

That public health has among its seminal functions the duty to protect and, in so doing, enhance the wellbeing of populations is clear. It is because of that mission that it seemed almost uncontroversial that public health would sciez upon the Precautionary Principle as an overarching framework for guiding policy. But because precaution is Janus-faced in the context of competing harms, the Precautionary Principle cannot serve as effectively as a unifying principle for public health policy in the way it has for debates over the introduction of toxic substances into the environment. It is not a coincidence, after all, that almost all the cases; (some historical, some contemporary) in a recent handbook published by the European Union's European Environmental Agency (EEA) on the Precautionary Principle deal with environmental health risks (EEA 2013). In that sphere, regulators and advocates have advanced precaution as a measure to forestall harms that have not yet occurred, th

the status quo itself that threatens, provoking debate about whether proposed interventions are themselves potentially more harmful than beneficial. In such circumstances we must always examine the costs of acting as well as failing to act.

In an effort to make it better suited to actions that address existing problems and weigh the consequences of inaction, long-time advocates of environmental protection have articulated "softer," more flexible versions of the Precautionary Principle. Nick Ashford, for example, recommended "societal distribution of possible costs and benefits of policies and technologies" as a critical precautionary Principle. Nick Ashford, for example, recommended "societal distribution of possible costs and benefits of policies and technologies" as a critical precautionary Principle costs and benefits of policies and technologies" as a critical precautionary element. He offered "trade-off analysis" as a means of evaluating the benefits and burdens of different policy options within the precautionary framework (Ashford 1999). Ashford viewed this as a form of social justice that would have us distribute risks fairly. Others have argued that a precautionary stance must be balanced by the principle of proportionality, which would strike a balance between the nature of the threat or risk and the public health response (Jordan and Riordan 1999). While "light" precautionary efforts that try to forge a more balanced approach are responsive to the realities of public health practice, softening the Precautionary Principle too much presents a baby-bathwater dilemma. Light precaution can quickly become difficult to distinguish from risk-henefit analyses to which deep precaution is osciensibly opposed. Blurring the boundary with risk- and cost-benefit analyses in turn, hamstrings the principle's ability to assert boldly the public's health and safety as a paramount value. In the case of climate change, to take just one example, risk- and cost-benefit anapropers and the proper and the proper and the prop

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11 Beyond the Precautionary Principle: Protecting Public Health...

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