Reenergizing Public Health Through Precaution

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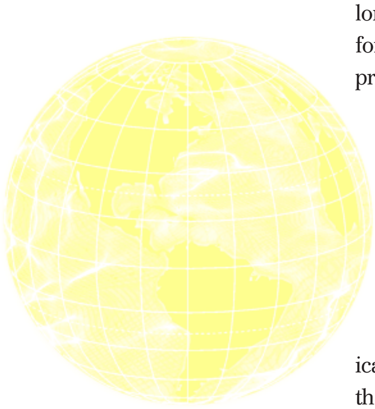
The precautionary principle has provoked a spirited debate among environmentalists worldwide, but it is equally relevant to public health and shares much with primary prevention. Its central components are (1) taking preventive action in the face of uncertainty; (2) shifting the burden of proof to the proponents of an activity; (3) exploring a wide range of alternatives to possibly harmful actions; and (4) increasing public participation in decision making.

Precaution is relevant to public health, because it can help to prevent unintended consequences of well-intentioned public health interventions by ensuring a more thorough assessment of the problems and proposed solutions. It can also be a positive force for change. Three aspects are stressed: promoting the search for safer technologies, encouraging greater democracy and openness in public health policy, and stimulating reevaluation of the methods of public health science.



IN MARCH 1999, THE LOS Angeles Unified School District, the nation's largest school district, announced a new policy on use of pesticides in its school buildings. The district committed to a policy of integrated pest management, giving priority to nonchemical approaches to pest control, and set a long-term goal of eliminating all chemical controls. In establishing this policy, the school district invoked the precautionary principle, saying:

> The Precautionary Principle is the long-term objective of the District. The principle recognizes that:
> 1. No pesticide product is free from risk or threat to human health, and
> 2. Industrial producers should be required to prove that their pesticide products demonstrate an absence of [human health risks] rather than requiring that the government or the public prove that human health is being harmed.[1]

By stating a set of basic tenets (all pesticides are potentially harmful, and nonchemical methods shall be preferred) and a long-term objective ("to provide for the safest and lowest risk approach to control pest problems while protecting people, the environment, and property"), the policy stimulates the search for safer alternatives without tying the hands of the district when no alternative to a pesticide can be found. The policy is also significant for what it does *not* include: there is no list of banned substances, nor a stipulation of an "acceptable" level of risk.

Whether or not one agrees with this approach to pesticide management (we do), it seems clear that the school district's invocation of the precautionary principle raises important issues for public health scientists and activists.

In this commentary, we briefly describe the key elements of the precautionary principle, emphasizing several aspects important to public health. Our perspective is informed by a university–community collaborative effort to refine the meaning of the precautionary principle and develop strategies for applying it to environmental health policy.[2,3] We argue that the precautionary principle is good for public health because it promotes the search for safer technologies, encourages greater democracy and openness in public health policy, and stimulates reevaluation of the methods of public health science.

PRECAUTIONARY PRINCIPLE DEFINED

The definition of the precautionary principle developed for the Rio Declaration of 1992 is often cited,[4] and the 1998 Wingspread Statement contains similar language: "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 scientifically."[5] The statement also lists 4 central components of the principle: (1) taking preventive action in the face of uncertainty, (2) shifting the burden of proof to the proponents of an activity, (3) exploring a wide range of alternatives to possibly harmful actions, and (4) increasing public participation in decision making.

The term "precautionary principle" was introduced into English as a translation of the German word *Vorsorgeprinzip*. An alternative translation might have been "foresight principle," which carries a connotation of anticipatory action—a positive, active idea—rather than precaution, which to many sounds negative. In German environmental policy, the *Vorsorgeprinzip* stimulates social planning for innovation, sustainability, and job creation.[6]

In the United States, the precautionary principle is being promoted by environmental and public health advocates.[3] To these groups, US environmental policy often seems to be more reactionary than precautionary, requiring a high degree of certainty of harm before preventive action is taken and emphasizing management of risks rather than prevention. The precautionary principle is viewed as an opportunity to shift the terms of environmental debates by calling for preventive action even when there is uncertainty (but with credible evidence of potentially significant impacts), by shifting the burden of monitoring and hazard assessment onto those who propose potentially hazardous policies and by emphasizing alternatives and democracy.[5]

The American Public Health Association recently passed a resolution reaffirming its support of the principle and urging its application in the protection of children's health from environmental hazards.[7] Strong support for precaution is also found in the environmental policies of the European Union.[8]

The precautionary principle has been advocated for public health because of the importance of anticipating unintended health consequences of well-intentioned public health interventions.[9] Seeking to avoid creating new problems while solving existing ones is an important aspect of the precautionary principle, but it is not the only way in which precaution can benefit public health.

FORESIGHT AND THE STIMULATION OF NEW TECHNOLOGIES

The identification of safer alternatives and opportunities for prevention is central to the precautionary principle. Too frequently, policymakers ask the question "How much risk does this activity pose, and is it significant?" or "What level of risk is acceptable?" These questions, deeply ingrained in the regulatory approaches of many government agencies, tend to focus on the quantification of potential hazards rather than the prevention of pollution.[10–12] They often provoke a sharp debate about whether the risk has been characterized accurately. When public health advocates and environmentalists enter into this debate, they may inadvertently be ceding the most powerful position, that of questioning whether the hazardous substance or intervention is needed at all.

A different, and potentially more precautionary, way to think about uncertain risks is to begin from a different set of questions: Is the proposed activity needed, and if so, how much contamination can be avoided while still achieving societal goals? and Are there alternatives to this activity that clearly avoid hazards? For example, chlorinated solvents fulfill a cleaning function that can often be accomplished by aqueous solutions. This shift in perspective requires a set of skills not always found in regulatory agencies—technology and product design, full-cost accounting and other management systems. It also requires the broadest possible perspective on the potential unintended consequences of policy choices.

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A variety of methodologies exist with which to evaluate policy alternatives and identify potential unintended consequences. Trade-off analysis has been proposed as an alternative to traditional cost– benefit analysis and risk assessment; in trade-off analysis, the full range of risks and benefits of competing technology options are assessed without the requirement to translate the potential impacts into a single quantitative figure.[13] Health impact assessments provide a means to detect the negative health implications of non–health-related governmental policies.[14] Work-environment impact assessments can be used to identify ways in which an intervention in the work environment may result in unanticipated health risks to workers,[15] and the Pollution Prevention Options Analysis System provides a comprehensive semiquantitative approach to comparing and evaluating the potential adverse effects of technologies designed to reduce chemical use and waste.[16]

Shifting the questions that frame the problem reorients the focus of environmental policy from quantification of risks to analysis of solutions and thus permits a broader examination of all the available evidence on hazard, exposure, uncertainty, and alternatives. The precautionary principle is a means of saying yes to innovative, cleaner technologies (although critics have argued that it will only lead to stopping new technologies). A thorough alternatives assessment may identify needs for cleaner technologies, which in turn can inform the planning of sustainable economic development activity.[11]

Quantitative risk assessment plays a central role in environmental health policy in the United States. Weighing policy alternatives will inevitably involve assessing and comparing risks, but the determination of whether a risk is too big depends in part on whether there are alternatives to reduce that risk. Availability of a safer alternative can obviate the need for a costly, contentious, and potentially misleading quantitative risk assessment.

The decision to ban the use of certain phthalate plasticizers in toys provides an illustration. The Danish Environment Agency justified this action with the following reasoning: There is evidence of children's exposure and evidence of toxicity to animals; children are particularly susceptible to many toxic substances; alternative materials exist; and the product serves no necessary function. The agency concluded that the plasticizers should not be used in toys (L. Seedorf, MS, Director, Chemicals Division, Danish Environmental Protection Agency, oral communication, May, 1999). The US Consumer Product Safety Commission reached a similar decision, but only after a costly, time-consuming quantitative risk assessment. The commission concluded that given uncertainties in the size of the risk, manufacturers should voluntarily remove these substances from toys.[17] In the end the outcomes were the same, but the decision-making approach and the costs to the public were quite different.

Foresight should involve setting long-term goals, a practice that is fairly common in public health. Examples are the smallpox eradication campaign, the US Public Health Service Healthy People 2010 priorities, and national nutrition goals. Goal setting focuses not on what future events are likely to happen but rather on how desirable future outcomes can be obtained.[18] Once established, goals help to focus attention on the development of policies and measures to achieve goals while minimizing social disruption and unintended consequences.

With regard to hazardous substances, goals could include reducing exposures to such substances, reducing production of hazards (e.g., phasing out the most hazardous chemicals), and reducing the incidence of environmentally related diseases. Another suggested goal is to reduce general population body burdens of broad classes of potentially toxic substances by 5% to 10% per year.[19] Such an effort is likely to have a positive health impact, even though it may never be possible to understand all of the ways in which mixtures of low concentrations of chemicals may affect health.

DEMOCRACY AND PRECAUTION

Participation and transparency are essential components of a more precautionary approach to public health decision making. Fiorino has identified several reasons for democratizing environmental decision making. First, because nonexperts think more broadly and are not bound by disciplinary constraints, they see problems, issues, and solutions that experts miss. Second, lay judgments reflect a sensitivity to social and political values and common sense that experts' models do not acknowledge. Third, the lay public may be better than experts at accommodating uncertainty and correcting errors.[20] Openness brings different perspectives, which may reduce the danger of an unintended consequence. Also, the weighing of alternative policies should include many points of view, because the benefits and costs of public health and environmental policy choices may accrue to different groups.

When there is much uncertainty about alternative courses of action, it is risky for experts to decide without input from affected communities. The usual strategy is to attempt to present the options as clear and the science as convincing. However, a long series of public health and environmental crises that were apparently unforeseen by scientists have undermined public confidence, making it more difficult for simple reassurances to be effective. The list includes the Three Mile Island and Chernobyl nuclear accidents, Love Canal, the destruction of the ozone layer, and global warming. An increasingly educated citizenry has begun to challenge the apparent confidence of the experts. Add to this the successful campaigns of AIDS activists and breast cancer survivors to participate in the planning of health research, and it appears to be time to fundamentally change the way that the public participates in the use of public health science.

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Broader public participation processes may increase the quality, legitimacy, and accountability of complex decisions. Given the public nature of environmental decisions (which involve highly uncertain, contested values), more effective processes for involving affected communities could increase trust in government. Such processes must be both fair and competent, meaning that they allow all those who want to participate to have substantive access to the decision-making process from the beginning and that they provide financial and technical resources so citizens can participate on equal terms with experts.[21] In addition, there must be clearly defined mechanisms by which citizen input is fed into the policymaking process.

A long-term educational strategy to increase the public's understanding of the strengths and limits of scientific evidence is needed as part of increasing public participation. The Danish Board of Technology has been experimenting for several years with innovative forms of decision making on broad technology policy decisions. These "consensus conferences" involve lay panels trained in the science and other aspects of a contemporary concern, resulting in a focused dialogue between the general public and experts. To date, more than 20 such conferences have been held in Denmark, informing government policy on topics including genetically modified foods, the human genome project, and air pollution.[22]

SCIENCE FOR PRECAUTION

Environmental scientists study highly complex, poorly understood systems, in which causal links between exposures and disease are difficult to quantify. In this uncertain terrain, what are the appropriate standards of evidence for science to inform public health policy? The answer must be tailored to the task. We believe that there are ways in which the methods of scientific inquiry often implicitly impede precautionary action, making it more difficult for policymakers to take action in the face of uncertainty.[2] Often, scientific research focuses on narrowly defined quantifiable aspects of a problem while the reality is more complex, requiring systems-level thinking and interdisciplinary research methods.

Public health scientists may be able to assist in the cause of precaution by choosing research methods, well within the bounds of good practice, that would be more helpful to policymakers faced with high-stakes decisions and scientific uncertainty. For example, more and better investigation and communication of uncertainties (what we know, what we do not know, and what we cannot know) in study results will assist a more open decision-making process. Public health scientists could also use qualitative methods more effectively to characterize the complexities of the populations, communities, and ecosystems from which quantitative results are drawn.

Finally, the precautionary principle should challenge scientists to explore new areas of research—interactions, cumulative effects, and effects on different levels of systems (individuals, families, communities, nations)—and new collaborations between disciplines and scientists and the lay public. Multidisciplinary teams will be more likely to develop hypotheses that lead to insights not possible from narrow disciplinary viewpoints, as well as to identify data that may not be accessible to one particular group. The development of the environmental endocrine disruption hypothesis provides one example.[23]

The precautionary principle represents a call to reevaluate the ways in which science informs policy, and in particular the ways in which scientific uncertainty should be handled. Scientific research plays an essential role in evaluating the costs, risks, and benefits of proposed public health policies, but the scientific data are often limited by large areas of uncertainty. In these gray areas, activities that potentially threaten public health are often allowed to continue because the norms of traditional science demand high confidence to reject null hypotheses and so detect harmful effects. This scientific conservatism is often interpreted as favoring the promoters of a potentially harmful technology or activity when the science does not produce overwhelming evidence of harm. Being "conservative" in science is not the same as being precautionary.

When there is substantial scientific uncertainty about the risks and benefits of a proposed activity, policy decisions should be made in a way that errs on the side of caution with respect to the environment and the health of the public.[2]

PRECAUTION OR REACTION?

The precautionary principle has been criticized for being overly vague.[24,25] To some extent the critics are correct, but much work is now under way to define what precaution means in practice and how it can improve decision making regarding uncertain, complex hazards.[2,26,27] This is an opportunity for the public health community to affect the ways in which precaution is defined in practice. At the same time, there is a risk that proponents of the principle will be held to an unrealistically high standard—an assumption that all public health problems should somehow be resolved through the application of precaution. Where science and politics collide, there will always be ambiguity and contention, and it seems unreasonable to expect any single new idea to sweep these away entirely. We should be careful not to overuse the precautionary principle, particularly when there is clear evidence that damage has been done or there is no reasonable evidence to suspect a risk to public health.

If the precautionary principle represents a desirable goal in public health, one may ask, What is the "not sufficiently precautionary principle" on which policies are currently based? Too often, we believe, public health and environmental policies are based on a principle of *reaction* rather than precaution. Government regulatory agencies are often put in the position of having to wait until evidence of harm is established beyond all reasonable doubt before they can act to prevent harm. A shift from reaction to precaution is entirely consistent with the core values of public health practice. We believe that public health officials, researchers, and advocates should embrace the precautionary principle as an opportunity to reinvigorate the great preventive tradition of public health action in the face of uncertainty. ■

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The Precautionary Principle and Electric and Magnetic Fields

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Current environmental regulation represents a paternalistic policy, more concerned to avoid false positives than false negatives, limiting opportunities for individuals to make choices between risk-avoidance and risk-taking alternatives. For example, many exposures to magnetic fields could be reduced at little or no cost but are not considered seriously, owing to the uncertainty of risk and the concern to avoid false positives.

Even though precautionary approaches that focus on avoiding false negatives often do not lead to adverse economic consequences or irrational choices, such approaches usually are not taken. The value of autonomy and the proper role of governmental paternalism with respect to environmental policy need to be considered more carefully in environmental decision making.

A clear distinction should be made between what is not found by science and what is found to be non-existent by science. What science finds to be non-existent, we must accept as non-existent; but what science merely does not find is a completely different matter. . . . It is quite clear that there are many, many mysterious things.

His Holiness the Dalai Lama[1]

THE PRECAUTIONARY principle came to prominence in Europe in the 1970s, and over the last 2 decades it has increasingly figured in international law and policy.[2] It is best thought of as a family of principles rather than a single principle. Some versions would appear to virtually banish technology (e.g., "where potential adverse effects are not fully understood, the activities should not proceed"[3]), while other versions border on the trivial (e.g., lack of "full scientific certainty shall not be used as a reason for postponing cost-effective measures"[4]). At its core, the precautionary principle is related to the familiar adages "An ounce of prevention is worth a pound of cure" and "It is better to be safe than sorry."

The precautionary principle can be contrasted with the "polluter pays" principle. The "polluter pays" principle, which is based on a long and respected tradition in Anglo-American jurisprudence, holds that those who cause harm to others through their polluting activities should pay for setting things right. For this principle to be applicable, (1) it must be possible to identify the polluter, (2) the effects of the pollution must be reversible, and (3) it must be politically and socially feasible to compel the polluter to reverse the effects of the pollution.

Clearly, in many cases of pollution, conditions 1 and 2 are, at best, difficult to satisfy. In many cases it is difficult to identify the polluter, or the sources of pollution are so widespread that it is difficult to identify particular agents as polluters. Also in many cases, such as those that cause death or the loss of irreplaceable ecologic goods, the effects of pollution are not reversible, at least on human timescales. Although some economists argue that the loss of any good can be compensated in monetary terms, this argument is not widely accepted in society.

Another alternative to the precautionary principle is a cost–benefit approach. However, in cases in which the precautionary principle comes into play, markets play only a small role and good cost–benefit information is not available (although people often will perform cost–benefit calculations anyway). Even when costs and benefits can be reliably computed, there may still be questions about the distributions of benefits and costs.

In any case, it is when conditions 1 and 2 are difficult to satisfy that discussion of the precautionary principle comes into play. For a wide range of cases, it seems reasonable to institute the precautionary principle. When it is difficult to identify specific causes and to link them conclusively to specific individual deleterious effects, it may be plausible to regulate substances that may have such effects even if the relationship has not been proven.

However, for the precautionary principle to be applicable, some link must be established between an exposure and some possible harm, although it is not easy to say what threshold of confidence should be required. Will a single complaint suffice, a single case, a single animal study, a single human study, some combination, or more? Should the regulatory cost, both in dollars and to society, be part of the decision-making process? In addition, if one chooses to go forward, one must identify specifically what to regulate in light of the scientific uncertainty.

AN EXAMPLE: ELECTRIC AND MAGNETIC FIELDS

A case in which the precautionary principle has loomed large is the possible risk of childhood leukemia from residential exposure to electric and magnetic fields (EMFs). In 1979, Wertheimer and Leeper published the first modern study of the health effects from exposure to EMFs.[5] That study showed that children born in Denver, Colo, who died of leukemia were more likely to have lived in homes that had high EMFs (as characterized by a wire coding scheme) than in homes that had low EMFs. The conclusions of that study ran counter to current scientific knowledge, as there is no generally accepted toxicologic or physical mechanism by which nonionizing radiation, such as that produced by EMFs, causes cancer.

Several similar studies of EMF exposure were conducted in the United States and elsewhere, including a replication in Denver. In general, they produced similar but weaker results, lending some credence to the suggested association. The most recent reviews and expert panels have judged that although the results were not "consistent and conclusive," there is an association between exposure to EMFs and the occurrence of childhood leukemia[6–10] and EMFs are a possible human carcinogen.[7] Nonetheless, the plausibility and existence of the association continue to be debated in the scientific community.[11] The questions these studies raise in the context of the precautionary principle are what, if anything, should be done to limit or prevent exposure and possibly disease, and what data would be sufficient to warrant such actions.

As soon as the early EMF studies began to accrue, activists called for changes in the electrical systems in the United States to limit exposure. Their goal was to prevent possibly dangerous exposures even at the cost of preventing exposure to a nonhazardous situation. In the spirit of the precautionary principle, they were more concerned with avoiding false negatives than false positives.

Those who were more skeptical believed that the data were not sufficient to force the overhaul of the electric power delivery system. They sought to prevent costly exposure reductions, even if that resulted in putting some people at unnecessary risk. They sought to avoid false positives rather than false negatives. In part, this position was a response to the fact that we all depend so heavily on electrical devices day in and day out—exposure is ubiquitous, and discontinuing electrical use is not feasible. Modifications to appliances, residential wiring systems, and electrical power delivery systems are all possible, but potentially costly.

In the face of these considerations, 3 strategies were proposed: (1) do nothing unless the health effects data become more consistent; (2) allow individuals to make personal choices to limit exposure ("prudent avoidance"[12,13]); or (3) regulate power lines and appliances. These strategies differ markedly in terms of cost and exposure reduction[14] as well as in terms of whether they can be accomplished by individuals or must be implemented by manufacturers or utilities.

Further research has shown that technology offers a wide range of choices both in terms of cost and in terms of exposure reduction. The simplest solution to reducing residential exposure is to increase the minimum distance of the power line from the residence, reducing exposure exponentially as this distance increases. The cost is for the land and its maintenance only, but it can be high in more densely populated areas.

> *"Despite the diversity of precautionary approaches, the public policy debate . . . has focused on regulatory extremes: do nothing until the data are conclusive, or restructure major portions of the electric power delivery system."*

An alternative solution is to configure the wires on the poles in ways that reduce exposure. This option is less effective but also less costly. For new lines being constructed, the additional costs are minor. For existing lines, the cost is mainly that of rehanging the wires. For multiple-circuit lines (those with 6 or more wires), specific phasing of the electric current can markedly reduce exposure, again at little cost other than the initial setup of the wires, although certain technical issues about power delivery also must be addressed. For subtransmission and distribution lines (lower voltages), the lines can be placed underground, eliminating virtually all residential exposure. This option has the interesting trade-off of greater cost at installation and greater cost of repair but markedly less likelihood of accidental or weather-induced line breakage than occurs with lines on poles (i.e., greater reliability); it also has aesthetic benefits.

For appliances, redesign has offered some approaches to exposure reduction. Some manufacturers have reconfigured the internal wiring in electric blankets to reduce exposure (in a manner similar to rephasing of power lines), letting the marketplace guide personal choice and exposure reduction.

Despite the diversity of precautionary approaches, the public policy debate over the possible effects of exposure to EMFs has focused on regulatory extremes: do nothing until the data are conclusive, or restructure major portions of the electric power delivery system. Regulations to limit the rate at which exposure is increasing by restricting construction of new power lines to the lower-exposure configurations met with fierce opposition in some locations from people who do not believe that the association between EMFs and cancer has been proven and thus contend that no action should be taken.

Since the scientific uncertainty is unlikely to be resolved in the foreseeable future, policy decisions must be based on the possibility of risk and the cost and technology of reducing exposure. Whether such decisions should be dictated by personal choice in the marketplace (what to buy, which appliances to use) or governmental regulation (where to build or whether to modify the electric power delivery system) depends in part on how one views the precautionary principle and its implications.

PATERNALISM AND THE PRECAUTIONARY PRINCIPLE

No regulatory principle will be error-free. Most will produce false positives and false negatives, but each principle will have a bias about what proportions of false positives and false negatives are tolerated. The precautionary principle is biased in favor of preventing false negatives. In contrast, many of our current regulatory policies are biased in favor of preventing false positives. For example, most air and water emissions from commercial activities are permitted unless they are specifically regulated.

The reason for avoiding false positives is to avoid panic, anxiety, and negative social and economic impacts. Some individuals have become extremely concerned over high exposures to EMFs and have paid to have their homes moved farther from power lines; some have paid to have power lines near a school reconfigured and buried underground to avoid what may be a nonexistent risk.

False negatives should be avoided to prevent unnecessary disease and potentially harmful exposures. It is estimated that if the association between exposure to EMFs and childhood leukemia is real, EMFs may be responsible for between 3% and 11% (depending on assumptions and models) of all childhood leukemias in the United States, or between 50 and 250 cases each year.[8,10]

In our personal lives, most of us favor precaution except when we voluntarily consent to greater risk. We prefer that our doctors seek to avoid false negatives rather than false positives. I can handle (or not) the anxiety and panic of false positives. If I am informed of the superset of risks, then I can decide which risks I want to take and which to avoid. If I am informed only of a subset of risks, then I will be subjected to risks to which I have not in any way consented. This suggests that we favor precautionary approaches because they respect our autonomy and enable us to choose which risks we are willing to bear. On the other hand, the bias in favor of avoiding false positives is paternalistic—it seeks to protect us from panic and anxiety, rather than providing us with knowledge that we can respond to as we wish.

> *“Even if we suppose that adopting the precautionary principle would lead consumers to react irrationally, this is an argument for educating consumers, not for depriving them of control over their own lives.”*

It is surprising that so much of our environmental and public health regulation is paternalistic in this way, given that our society is generally moving away from paternalistic policies. This trend is especially striking in medical practice,[15] but it can also be seen in various other social policy innovations, such as proposals to privatize all or part of Social Security.

One reason why the precautionary principle has had little effect in the United States may be the difficulties, previously noted, in framing a fully adequate version of the principle. Another reason may be a concern about the economic consequences of adopting a precautionary approach. In a nutshell, the worry may be that if we give every individual the information he or she would need in order to act autonomously, this would lead to bad economic consequences for everyone, since people react irrationally to risk. Here are 3 responses to this concern.

First, it is not clear that precautionary approaches lead to bad economic consequences for everyone. Consider, for example, the resistance to labeling genetically modified foods. Even if it were true that consumers would actively avoid genetically modified foods, this would not be bad for everyone. It would be bad for those farmers and businesses that rely on producing genetically modified foods, but it would be an advantage to those farmers and businesses involved in producing non–genetically modified foods. And insofar as there are free markets involved in agriculture, we would expect farmers and businesses to move in the direction of satisfying consumer preferences. Indeed, the idea that consumer preferences are sovereign and unchallengeable is at the heart of free-market economics. Similarly, many precautionary measures could be taken to reduce EMF exposure at little or no cost and with no adverse consequences.

Second, even if we suppose that adopting the precautionary principle would lead consumers to react irrationally, this is an argument for educating consumers, not for depriving them of control over their own lives. Educating consumers about risk involves at least making clear the ubiquity of the risk (we are all exposed to EMFs, at home, at work, and elsewhere) and also making clear that trade-offs among risks are unavoidable (few if any of us would consider living without the convenience and safety offered by electricity, even though some exposures cannot be avoided easily). For example, there is a great deal of room for improvement in how statistical information is represented.[16]

Finally, even if precautionary approaches would lead to bad collective outcomes and people were uneducable, there still would be some reason for favoring precautionary approaches. In American society, we generally suppose that people should be free to make irrational choices, even ones that damage the public good, so long as these choices do not involve acts of violence. For example, we allow people to drive sport utility vehicles despite the fact that they are major contributors to climate change, and we allow people to teach their children that evolution is false. Limiting one's EMF exposure, even if unnecessary, is easy to accomplish and can be done at little cost to the individual or society.

CONCLUSION

Here we have used EMF policy as an example of failure to implement the precautionary principle even though it could be done relatively easily and cheaply. We have not argued for any particular EMF policy, nor have we tried to define and characterize the full array of precautionary approaches. Instead, we relate the discussion of the precautionary principle and EMFs to larger questions about human agency and public authority. Reluctance to regulate on the grounds of avoiding false positives that may scare and upset people is paternalistic. In our view, concerns about the proper role of government paternalism are at the heart of questions about regulating environmental and health risks and therefore should be as central to the discussion as economic and epidemiologic data. ■

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The Precautionary Principle Also Applies to Public Health Actions

The precautionary principle asserts that the burden of proof for potentially harmful actions by industry or government rests on the assurance of safety and that when there are threats of serious damage, scientific uncertainty must be resolved in favor of prevention. Yet we in public health are sometimes guilty of not adhering to this principle.

Examples of actions with unintended negative consequences include the addition of methyl tert-butyl ether to gasoline in the United States to decrease air pollution, the drilling of tube wells in Bangladesh to avoid surface water microbial contamination, and villagewide parenteral antischistosomiasis therapy in Egypt. Each of these actions had unintended negative consequences. Lessons include the importance of multidisciplinary approaches to public health and the value of risk–benefit analysis, of public health surveillance, and of a functioning tort system—all of which contribute to effective precautionary approaches.

Bernard D. Goldstein, MD

PUBLIC HEALTH ADVOCATES around the world have increasingly invoked the precautionary principle as a basis for preventive actions.[1–9] This has been particularly true for environmental and food safety issues, in which the precautionary principle has moved from being a rallying cry for environmental advocates to a legal principle embodied in international treaties.[2,6,8–11] Definitional issues have become more important as the term has made the transition from a noble goal to a component of legal requirements. For the purposes of this commentary, a useful definition is one that is contained in the 1989 Rio Declaration[12]: "Nations shall use the precautionary approach to protect the environment. Where there are threats of serious or irreversible damage, scientific uncertainty shall not be used to postpone cost-effective measures to prevent environmental degradation."

The upsurge in use of the term "precautionary principle" has been relatively sudden. For example, changes in the approach to hazardous air pollutants in the 1990 US Clean Air Act Amendments embody the precautionary principle. Until then, control of individual air pollutants in this category depended on a risk-based approach in which the burden of proof was on the US Environmental Protection Agency (EPA) to demonstrate that environmental levels of the air pollutant were likely to produce adverse effects. Further, the extent of imposed control measures was based on the feasibility of reducing risk. Instead, the 1990 amendments state that maximal available control technology is to be used on each of more than 180 pollutants unless the pollutant can be clearly shown to be harmless.

Shifting the burden of proof and moving away from risk science to a technology-based approach were much debated at the time, but the term "precautionary principle" was not part of the debate. Now it certainly would be, although whether this precautionary approach will be more successful than the previous risk-based approach is still open to debate. For example, germane to the broader issue of the value of the precautionary principle is the question of whether regulating specific air pollutant emission control technology will stifle the invention and application of newer, more effective technology.

At its core, the precautionary principle contains many of the attributes of good public health practice, including a focus on primary prevention and a recognition that unforeseen and unwanted consequences of human activities are not unusual. Yet there are at least 3 recently reported examples of actions taken in the name of improving public health that would better have been avoided or at least considered more carefully beforehand. I argue that the precautionary principle needs to be applied to public health actions as well as to actions pursued by government and industry for competitive and economic reasons. It is not my intention to provide a well-rounded critique of the precautionary principle, which is discussed by Kriebel and Tickner[13] and by Jamieson and Wartenburg[14] in this issue of the Journal.

MTBE AIR AND GROUNDWATER CONTAMINATION

The 1990 US Clean Air Act Amendment also contained requirements for the use of oxygenated automotive fuels, both to decrease carbon monoxide emissions and to lessen oxidant air pollutant precursors. Unfortunately, these requirements were implemented without a thorough evaluation of the potential human health and environmental consequences. As many as 100 million Americans were exposed to fuel oxygenates in air. Almost immediately, a controversy developed concerning symptomatic responses among exposed individuals, as well as animal data suggesting that methyl tert-butyl ether (MTBE), the major fuel oxygenate, might be a carcinogen. However, there was no retreat from MTBE use until there was belated recognition of MTBE's contamination of water supplies, a recognition that appears to have been anticipated by industry.

This episode vividly illustrates how failure to act in a precautionary manner can inappropriately shift the burden of proof. Once MTBE became a major part of the nation's gasoline supply, the appropriate question—whether there was sufficient assurance about the safety of MTBE to expose humans and the environment—became moot, and the question asked by regulators was whether there was sufficient evidence of harm to remove MTBE from gasoline. EPA responded by conducting repeated reviews of the existing evidence while providing only a meager amount of support for obtaining new evidence. This resulted in an 8-year delay in making the appropriate decision.[15] Even now, MTBE remains in use, although in substantially decreasing amounts.

Perhaps most distressing is that US environmental authorities appeared to have learned little from the MTBE debacle. Oxygenated fuels continue to be required by EPA, resulting in the replacement of MTBE by compounds such as tertiary amyl methyl ether, for which even less toxicological and environmental information is available than for MTBE.

ARSENIC IN BANGLADESH AND WEST BENGAL, INDIA

Diarrheal infectious diseases caused by human consumption of sewage-contaminated surface waters have long been a major public health problem in Bangladesh and the adjacent West Bengal area of India. Tapping into sterile subsurface water supplies would seem to be an obvious solution to this problem. The use of relatively low-technology approaches to drill local tube wells has been advocated by many international agencies, including UNICEF.

Encouragement and assistance by these agencies and local health authorities have led to the drilling of a few million wells, of which perhaps as many as 2 million are contaminated with arsenic levels above drinking water standards. Arsenic toxicity is now evident in large numbers of individuals in these villages. In a study of 11 180 randomly selected individuals from affected areas in Bangladesh and 29 035 from affected areas in West Bengal, Chowdhury et al. reported the incidence of arsenic-induced skin lesions as 24% and 15%, respectively.[16] They also found arsenical neuropathy in 37% of 413 arsenicosis patients. Significant increases are anticipated in the incidence of cancer of the skin and internal organs, and in diabetes and vascular disease, now that the latency period for these disorders is approaching.[17–19]

How could the rationale of improving public health lead to 100 million people's being put at risk for arsenic toxicity, including cancer? Arsenic contamination of well water with significant resultant toxicity was not unknown and in fact had been reported, primarily in Asia. Although testing for arsenic is not part of routine practice, high levels of arsenic in water could readily have been detected more than a decade before there were overt and unmistakable signs of arsenic toxicity in the population. The precautionary principle can be defined in terms of not undertaking activities about whose impact there is scientific uncertainty. With a minimum of precaution, arsenic toxicity in Bangladesh and West Bengal could have been averted, or at least minimized.

HEPATITIS C IN EGYPT

Egypt has an exceptionally high prevalence of hepatitis C infection, with correspondingly high morbidity and mortality due to cirrhosis and hepatocellular carcinoma. This high prevalence has been traced to transmission of the hepatitis C virus during campaigns of mass inoculation with antimony compounds for the treatment of endemic schistosomiasis, campaigns that continued until the early 1980s.[20,21] In areas of Egypt where the schistosomiasis treatment campaigns were concentrated, such as the Nile Delta, the prevalence of hepatitis C virus antibodies is higher than 50% among persons of an age to have received those injections.[21,22] Although oral therapy has replaced parenteral therapy, the high rate of persistence of hepatitis C means that these individuals provide a reservoir for continued transmission. There is evidence that parenteral antischistosomiasis therapy was a factor in hepatitis B transmission as well.

Schistosomiasis has been a major public health problem in Egypt for millennia.[23] The Egyptian public health community has been justifiably proud of its ability to mobilize to combat schistosomiasis through a wide range of activities. It has been joined in this effort by international public health organizations and by the academic public health community. The centerpiece of this public health campaign was administration of a series of 12 to 16 intravenous injections of potassium antimony tartrate in high-risk villages. Frank et al. point out that a major change in the time course of the injections occurred in 1960, when they were spaced out to once weekly rather than given more intensively over a 2- to 3-week period.[21] This may have contributed to the likelihood of hepatitis C virus transmission, given that observed sterilization procedures were improper or nonexistent. The risk of transmission of bloodborne pathogens through improper sterilization of needles was certainly appreciated before the 1960s.

There were undoubtedly great exigencies requiring mass campaigns against the major public health threat of schistosomiasis in a developing country. But the adverse public health legacy in Egypt is substantial and will continue.

LESSONS

The need for a breadth of outlook that goes beyond the initial problem is an obvious lesson from these examples. Perhaps the most egregious example is the most recent. Because of a lack of communication within a single federal agency, the EPA, those responsible for protecting the nation's water paid no attention to what their colleagues in the air pollution office in the same building were doing to that water. All 3 of these examples point up the need for multidisciplinary and multiorganizational approaches to public health problems. They also argue for the routine use of the framework for risk assessment and risk management advocated by the Presidential/Congressional Commission of Risk Assessment and Risk Management.[24]

Multidisciplinary approaches are not easy to accomplish, particularly in government and academia, which, far more than industry, have inherent difficulties in fostering and rewarding any but the narrower approaches to problem solving. The MTBE fiasco, for example, occurred in a federal agency whose leadership has repeatedly recognized the importance of multimedia approaches to environmental regulation and which, during the last 2 administrations, has made great strides in this direction. And it occurred despite warnings from the EPA's own scientists.[15,25] Perhaps a major contributing factor is that the EPA inherently has difficulties in acting as a public health agency,[24] although in the other 2 examples described here there was major input from public health organizations.

RISK–BENEFIT CONSIDERATIONS

Public health actions should always consider risks as well as benefits. In all 3 cases described above, it is conceivable that even with complete foreknowledge of the adverse consequences, the public health action would be seen as beneficial overall. The best case for this can perhaps be made for the drilling of wells in Bangladesh and West Bengal, where the adverse consequences of possible arsenic contamination might have been balanced against the undoubted benefit of a cleaner water supply. The benefits of MTBE are far more controversial.[27] Of note is that the petrochemical industry has written off perhaps a billion dollars in investments for a problem it could have anticipated and avoided.[15]

> *"The core maxim of the precautionary principle is that an action should not be taken when there is scientific uncertainty about its potential impact."*

SURVEILLANCE

We frequently speak about the importance of surveillance as a public health tool. Yet too often we do not advocate surveillance in relation to public health activities to ensure both that the intended beneficial effect does occur and that there are no unforeseen adverse consequences. In all 3 of the examples given here, the assumption was that benefit would accrue and that there was no need to install a surveillance system capable of early detection of adverse consequences. Public health agencies in each case initially expressed disbelief or surprise when early signs of an adverse consequence began to appear.

The precautionary principle provides an additional rationale for public health and environmental surveillance activities. Surveillance is needed to detect threats of adverse consequences as early as possible to maximize the value of precautionary activities. Surveillance also helps to put threats in perspective. For example, it could be argued that the mostly decreasing levels of DDT and other persistent organic compounds in human fat tissue and biota make such compounds less of a concern for precautionary action than global climate changes that appear to be increasing over time and for which the maximum adverse impact is far less certain.

TOXIC TORTS AND THE PRECAUTIONARY PRINCIPLE

The toxic tort system in the United States is in disarray. Yet to the extent that it makes an industry think twice before introducing a chemical into commerce, it functions in a manner consistent with the precautionary principle. Plaintiffs' lawyers for individuals claiming adverse health effects due to MTBE and for municipalities whose water sources have been affected are seeking to sue the petrochemical industry. Meanwhile, lawyers for MTBE-producing companies are working hard on a defense that to a large extent consists of hiding behind the federal government, although there is evidence suggesting the companies' own culpability as well. Had MTBE been a newly patented fuel additive distributed on the basis of a single petrochemical company's claims, this company would now be seeking the protection of a bankruptcy court. In Bangladesh, whose toxic tort system is not as fully evolved as that of the United States, there has been an attempt to sue UNICEF for the damage caused by arsenic contamination.

The precautionary principle is still evolving and does not have a firm operational definition. To some, the precautionary principle is already included in the usual risk-assessment approaches to environmental health and food safety; to others, it transcends these approaches; to still others, it is antithetical to risk assessment.[8,28–31] There are issues related to the legal definition of the term, to the role of science, to its use as a justification for economically motivated trade barriers, and to whether it will stifle innovation or interfere with a true understanding of the cause of problems.[32–37] In public health policy, Wainwright has used the term "precautionary principle" as a negative, blaming the stifling of innovative change in the British National Health Service on the desire to avoid adverse consequences.[38]

No matter how the precautionary principle evolves, the value of acting in a precautionary manner is obvious to those in public health. It is a form of primary prevention, avoiding problems by not engaging in activities until it is reasonably certain that they will not produce harm.

The core maxim of the precautionary principle is that an action should not be taken when there is scientific uncertainty about its potential impact.[39] We in public health must recognize that the precautionary principle applies to our own actions, that when a public health action is proposed, the burden of proof—to ensure that all risks and consequences are taken into account—rests on us just as surely as it rests on others. ■

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