

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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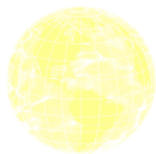
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## The Precautionary Principle Also Applies to Public Health Actions

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.

#### PUBLIC HEALTH ADVOCATES

around the world have increasingly invoked the precautionary principle as a basis for preventive actions.<sup>1–9</sup> This has been particu-

ly 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.<sup>2,6,8–11</sup> 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<sup>12</sup>: “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 Protec-

tion Agency. The approach was “where there are threats of serious or irreversible damage, scientific uncertainty shall not be used to postpone cost-effective measures to prevent environmental degradation.”

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tion 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 in-

tention to provide a well-rounded critique of the precautionary principle, which is discussed by Kriebel and Tickner<sup>13</sup> and by Jamieson and Wartenburg<sup>14</sup> 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 re-

move 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.<sup>15</sup> 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 individu-

als 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.<sup>16</sup> 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.<sup>17–19</sup>

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 schistosomi-

asis, campaigns that continued until the early 1980s.<sup>20,21</sup> 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.<sup>21,22</sup> 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.<sup>23</sup> 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.<sup>21</sup> 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.<sup>24</sup>

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.<sup>15,25</sup> Perhaps a major contributing factor is that the EPA inherently has difficulties in acting as a public health

agency,<sup>24</sup> 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

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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.<sup>27</sup> 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.<sup>15</sup>

### 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. Sur-

veillance 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.<sup>8,28-31</sup> 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.<sup>32-37</sup> 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.<sup>38</sup>

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.<sup>39</sup> 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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