The Perils of the Precautionary Principle: Lessons from the American and European Experience

John D. Graham, Ph.D.
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

Regulatory Forum
The Heritage Foundation
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The concept of a universal precautionary principle apparently has its origins in early German and Swedish thinking about environmental policy, particularly the need for policymakers to practice foresight in order to prevent long range environmental problems. The concept was included in the Amsterdam Treaty – an important step toward establishment of the European Union – but the concept was left undefined and was applied only to environmental policy. In the last 20 years, there have been numerous references to precaution in various international treaties, statements of advocacy groups and academic writings, but the significance of the principle in international law remains uncertain.

In recent years there has been growing international interest in the subject of precaution. Reacting to criticism that the principle was too ambiguous, the European Commission in 2000 issued a formal "Communication" about the precautionary principle. This Communication extended the applicability of the principle to public health and consumer protection as well as environmental policy. For several years, the German Marshall Fund has been working with Duke University to sponsor several informal dialogue sessions involving governmental officials and academics from Europe and the USA. Several months ago, the Canadian government released a "Framework" document for the application of precaution in science-based decisions about risk.

The United States Government believes it is important to understand that, notwithstanding the rhetoric of our European colleagues, there is no such thing as THE precautionary principle. Indeed, the Swedish philosopher Sandin has documented 19 versions of the precautionary principle in various treaties, laws and academic writings. Although these versions are similar in some respects, they have major differences in terms of how uncertain science is evaluated, how the severity of consequences is considered, and how the costs and risks of precautionary measures are considered. The United States Government believes that precaution is a sensible idea but there are multiple approaches to implementing precaution in risk management.

Given the ambiguity about the precautionary principle, it may be useful to start with a dictionary definition. Webster's 2nd Edition of the NEW WORLD DICTIONARY defines precaution as "care taken beforehand" or "a measure taken beforehand against possible danger." Understood in this way, precaution is a well-respected notion that is practiced daily in the stock market, in medicine, on the highway and in the workplace. In both business and politics, decision makers seek the right balance between taking risks and behaving in a precautionary manner.

Before joining OMB, I served for 17 years on the faculty of the Harvard School of Public Health. In that capacity I learned that public health historians have documented the preventable pain and suffering that can occur from insufficient consideration of the need for precaution. In

the United States we felt that pain as a result of how we handled emerging science about tobacco, lead and asbestos. Historians teach us that the major health problems from these substances could have been reduced or prevented altogether if decision makers had reacted to early scientific indications of harm in a precautionary manner.

We should not belittle the scientific complexities in each of these examples. Take the link between smoking and lung cancer. Although this link now seems obvious, in the middle of the previous century the link was not obvious to many competent and thoughtful physicians. They knew that many lifetime smokers never developed lung cancer; they also knew that some lung cancer patients had never been smokers. Compounding the problem was the inability of laboratory scientists to produce lung tumors in laboratory animals exposed by inhalation. In the final analysis, it took large-scale statistical studies of smokers to resolve the issue. In fact, there was a large scale study of the health of British physicians that played an important role in building the medical consensus against smoking.

In each of these examples (tobacco, lead and asbestos), it was epidemiology rather than the experimental sciences that played the most pivotal role in identifying health risks. Ironically, it is epidemiology that is now one of the more controversial contributors to public health science.

There is no question that postulated hazards sometimes prove more serious and/or widespread than originally anticipated. Ralph Nader has previously argued that this is the norm in regulatory science, while the European Commission recently issued a report of case studies where hazards appear to have been underestimated. However, the dynamics of science are not so easily predicted. Sometimes claims of hazard prove to be exaggerated and in fact there are cases of predictions of doom that have simply not materialized.

Consider the "dismal theorem" of the Reverend Thomas Malthus (1798). He hypothesized that population would grow exponentially while sources of sustenance would only grow arithmetically. The result, he predicted, would be that living standards would fail to rise beyond subsistence levels. However, history has shown this theorem to be incorrect. Malthus did not foresee the technological advances that have allowed both population and standard of living to risk steadily and substantially.

A more recent example in the USA concerns the popular artificial sweetener saccharine. FDA declared the regulatory equivalent of war against this product on the basis of experimental laboratory test results. The finding was that huge doses of saccharine cause bladder cancer in rodents. While FDA attempted to ban saccharine based on this evidence, the US Congress overturned FDA's action. With the benefit of hindsight, it now appears that FDA's attempted ban may have been poorly grounded in science. Just recently, the federal government in the USA removed saccharine from the official list of "carcinogens" for two reasons: experimental biologists have found that saccharin causes bladder tumors in rodents through a mechanism (cell proliferation) that is unlikely to be relevant to low-dose human exposures; and large-scale epidemiological studies of saccharine users have found no evidence that the product is linked to excess rates of bladder cancer in people.

Students of risk science are aware that the number of alleged hazards far exceeds the number that are ever proven based on sound science. Consider the following scares: electric power lines and childhood leukemia, silicone breast implants and auto-immune disorders, cell phones and brain cancer, and disruption of the endocrine system of the body from multiple, low-dose exposures to industrial chemicals. In each of these cases, early studies that suggested danger were not replicated in subsequent studies performed by qualified scientists. Efforts at replication or verification were simply not successful. At the same time, when early studies are replicated by independent work, such as occurred with the acute mortality events following exposure to fine particles in the air, it is important for public health regulators to take this information seriously in their regulatory deliberations.

Given that the dynamics of science are not predictable, it is important to consider the dangers of excessive precaution. One of those is the threat to technological innovation. Imagine it is 1850 and the following version of the precautionary principle is adopted: no innovation shall be approved for use until it is proven safe, with the burden of proving safety placed on the technologist. Under this system, what would have happened to electricity, the internal combustion engine, plastics, pharmaceuticals, the Internet, the cell phone and so forth? By its very nature, technological innovation occurs through a process of trial-and-error and refinement, and this process could be disrupted by an inflexible version of the precautionary principle.

Many risk specialists in the USA regret some of the prior policy steps we have taken on the basis of precaution. In US energy policy, for example, the Three Mile Island incident had a large policy impact, though even today there is no evidence of significant public health harm caused by the accident at Three Mile Island. In fact, there has been a de facto moratorium on the construction of new nuclear power plants in the USA. We have become more deeply dependent on fossil fuels for energy, and now precaution is being invoked as a reason to enact stricter rules on use of fossil fuels. Part of the answer may rest with clean coal technologies and renewable energy but we should not foreclose the advanced nuclear option.

In comparing the actions of different countries and regions, it is important to avoid the fallacy that Europe is precautionary while the USA is not. The late Aaron Wildavsky, in his studies of risk regulation, observed that cultures engage in risk selection. Some have argued that the USA is more tolerant than Europe of the possible risks of bioengineered foods, global climate change and industrial chemical exposures. However, a fair analysis would also show that Europe has been less precautionary than the USA on diesel engine exhaust, environmental tobacco smoke, and lead in gasoline. In fact, the recent comparative research by Professor Jonathan Wiener of Duke University has found no evidence to support the popular myth that Europe is generally more precautionary than the USA.

A subjective concept such as "the precautionary principle" is itself dangerous because it permits what conservative scholars have called "precaution without principle". In particular, the principle may be easily manipulated by commercial interests for rent-seeking purposes. According to Conko and Miller, students of biotech policy, the EU policy on genetically modified organisms "creates a bizarre bureaucratic distinction that favors certain classes of products widely made in Europe." This practice is hardly new. That is precisely what the World

Trade Organization found in its earlier decision against the EU ban on hormone-treated beef, a ban that had no grounding in public health science.

Although there are many reasons to be skeptical about Europe's stance on precaution, there are recent signs of progress from Europe. Take the response of Brussels to "mad cow's disease". Once the British government and industry had taken all reasonable steps to address this problem, Brussels instructed Member States of the EU to lift their bans on beef imports from the UK. All member states complied except France, who argued that French beef might still be safer than British beef and that France has the right to invoke the precautionary principle. Brussels took France to the European Court of Justice, where the Court ruled against France, indicating that speculative appeals to the precautionary principle must have some grounding in science.

Much more recently, the EC has rejected an unauthorized use of the precautionary principle by the provincial government of Upper Austria. In March of this year Austria notified Brussels of its proposed ban of genetically modified seeds that the EC had approved for cultivation under the EC Directive 90/220. Upper Austria appealed to the precautionary principle but Brussels overruled them: "Recourse to the precautionary principle presupposes that potentially dangerous effects . . . have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty." The EC noted that Upper Austria had not made this case and there was certainly nothing unique about the safety of GM seeds in Upper Austria.

While it is fashionable to criticize Europe on the subject of precaution, and much of that criticism is deserved, it should also be noted that the EC's official views on precaution are becoming more nuanced. In the February 2000 Communication, for example, we found the following views that are similar to the perspective of the US government:

1. Precaution is a necessary and useful concept but it is subjective and susceptible to abuse by policy makers for trade purposes.

2. Scientific and procedural safeguards need to be applied to risk management decisions based on precaution.

3. Adoption of precautionary measures should be preceded by objective scientific evaluations, including risk assessment and benefit-cost analysis of alternative measures.

4. There are a broad range of precautionary measures including bans, product restrictions, education, warning labels and market-based approaches. Even targeted research programs to better understand a hazard are a precautionary measure.

5. Opportunities for public participation – to discuss efficiency, fairness and other public values – are critical to sound risk management.

In OMB's 2003 Report to Congress on the Costs and Benefits of Regulation, we also emphasize the important role that analytic tools have in informing regulatory judgments about precaution. There are offshoots of cost-benefit analysis called value-of-information analysis and

decision analysis that were designed precisely for the purpose of analyzing problems with large degrees of scientific uncertainty. These tools are already widely used in engineering and business and are increasingly applied to environmental issues. We urge readers to consult OMB's report for references to this growing analytic literature on precautionary regulation.

In summary, there are two major perils associated with an extreme approach to precaution. One is that technological innovation will be stifled, and we all recognize that innovation has played a major role in economic progress throughout the world. A second peril, more subtle, is that public health and the environment would be harmed as the energies of regulators and the regulated community would be diverted from known or plausible hazards to speculative and ill-founded ones. For these reasons, please do not be surprised if the US government continues to take a precautionary approach to calls for adoption of a universal precautionary principle in regulatory policy.