**RISK AND PRECAUTION**

**John D. Graham, Ph.D., Administrator**
**Office of Information and Regulatory Affairs**
**Office of Management and Budget**
**Executive Office of the President**

**Remarks Delivered at the Brookings-AEI Conference on "Risk, Science, and Public Policy: Setting Social and Environmental Priorities," St. Regis Hotel, Mount Vernon Room, October 12, 2004**

Thank you very much for the opportunity to participate in this Conference. From my days as a public health scholar, I have had a strong interest in the question of how to expend lifesaving resources wisely. I believe conferences like this one, as well as more intensive analytic efforts, such as the Copenhagen Consensus, play an important role in advancing the national and international dialogue on lifesaving investments.

This morning my topic is risk and precaution, as these concepts have arisen in the translantic policy debates about regulatory policy. For the past two years, my colleagues and I have been participating in an informal dialogue with EU officials on how to better understand regulatory policies in the USA and the EU. Sponsored by the German Marshall Fund and Duke University, these useful sessions -- conducted under the Chatham House rules that encourage an unusual degree of candor -- have been successful in causing some mutual education on both sides of the Atlantic. Obviously, these discussions occurred in the context of heated policy disagreements about issues such as the Kyoto approach to global climate change, the safety of hormone-treated beef, and the future of genetically-modified foods.

The regulatory system in the United States, particularly as it applies to public health, safety and environmental issues, is evolving. According to Professor Cass Sunstein of the University of Chicago, the US system is becoming the "Cost-Benefit" regulatory state. I believe President Bush's first term, when studied by historians, will be considered a period of refinement and reinforcement of the cost-benefit perspective. At OMB, for example, we (1) have reaffirmed the important cost-benefit principles stated by President Clinton in Executive Order 12866, which amplified those originally advanced by President Reagan; (2) have used authority in the Information Quality Act to enhance the quality of data and analysis used by federal regulators, (3) have modernized OMB's analytic guidance to agencies through OMB Circular A-4, and (4) have proposed minimum standards of independent peer review of regulatory science by qualified specialists. Taken together, these modest steps by OMB are intended to strengthen the roles of science, engineering and economics in federal regulatory policy.

While the USA moves in this science-based direction, we fear that the European Union is moving in a different direction. Professor David Vogel of the University of

California at Berkeley recently completed a comparative study of USA and EU regulatory policy. In his article published in the European Journal of Environmental Law, he noted that "The precautionary principle has emerged as a critical component of the new European approach to risk regulation as well as an important focus of disagreement between the US and Europe. . . Europeans are seeking to widen the basis upon which a country may exclude products on the grounds that they pose either unknown or unacceptable risks, while the US is seeking to strengthen the role of risk assessment in order to limit the ability of its trading partners to use regulations as non-tariff barriers."

As US policy makers, we realize that advocacy of the precautionary principle is here to stay and we must learn to understand the origins and ramifications of this advocacy. It appears that "the precautionary principle", stated as such , has its origins in Swedish and German environmental policy. The intent is to promote longrun foresight in response to emerging yet persistent environmental problems. Policy makers are urged to anticipate and respond to potential problems, rather than waiting for perfect science to take protective steps. The principle was explicitly mentioned in the Amsterdam Treaty governing the creation of the European Union, though it was originally applied only to environmental policy. More recently, the European Commission clarified, in its 2000 "Communication", that the principle applies to consumer protection (including plant and animal health) as well as to environmental protection. At international meetings, representatives of the EU have repeatedly sought to have this principle recognized as an internationally important legal construct.

In the United States we recognize that precaution is a sensible idea. Public health historians have taught us that tragedies can occur from insufficient consideration of precaution in risk management. Prominent illustrations in this literature include tobacco, asbestos and lead. Concerning the health risks of each of these substances, historians have argued that harm could have been mitigated or prevented altogether if policy makers had acted upon preliminary indications of danger to public health.

We should not overlook the scientific complexities that underpin each of these examples. Take the link between smoking and lung cancer. In the middle of the previous century, many thoughtful clinicians were skeptical of this link. They treated lung cancer patients who never smoked. They also treated heavy smokers who never developed a lung ailment. It ultimately took large-scale statistical studies, including a prominent one of British physicians, to buttress the medical case against smoking.

Some observers have argued that postulated risks usually or always turn out to be worse than originally anticipated. This was a view expressed by consumer advocate Ralph Nader to ABC's John Stoussel in the prime-time TV special "Are We Scaring Ourselves to Death?" (April 1996). The European Commission appears to agree with this perspective, at least as indicated in a recent report issued by the EC's environmental division. The report documents 17 case studies where hazards proved worse than originally anticipated; they claim to have been unable to find any cases of reassuring science.

I would venture to say that the dynamics of science are not as predictable as Nader and the EC suggest. Consider first the well-known "dismal theorem" advanced by the late Rev. Thomas Malthus (1798). Malthus hypothesized that population would grow exponentially while sources of sustenance would grow arithmetically. He therefore predicted that global living standards would eventually fall to subsistence levels. While his thesis is prominent, contemporary textbooks cite an important flaw in his prediction. Malthus did not account for the technological advances that would permit both population and living standards to rise together.

There are more contemporary examples of postulated dangers that did not materialize. In American regulatory history, the most prominent illustration would be FDA's regulatory equivalent of war against the artificial sweetener saccharin. FDA was alarmed when it was shown that rodents developed bladder cancer after consuming large, sustained doses of saccharin. However, the US Congress overturned FDA's attempted ban on saccharin -- in this case an incriminated product was protected by popular opinion. After 25 years of additional science, it now appears that Congress may have been on to something. Experimental biologists have demonstrated that the rodent tumors occurred because of cell proliferation, and this response does not occur at the lower doses of saccharin that are typical of human consumption. Epidemiologists have also learned, based on long-term studies of saccharin users, that no elevation in bladder risk can be detected. Recently, the US Department of Health and Human Services quietly recognized the scientific realities by removing saccharin from the agency's official list of carcinogens.

Even more recently there was an allegation that low-dose mixtures of industrial chemicals are a threat to the endocrine system of the human body. Prior to this allegation, the conventional view was that sufficiently low doses of individual chemicals were safe, assuming such doses were determined through standard toxicity tests. However, an explosive contrary experiment was published in one of the best scientific journals in the USA. This experiment found that low-dose exposures to a mixture ("soup") of industrial chemicals can disrupt the endocrine system, even though single chemical exposures may be safe. This provocative finding helped provoke the US Congress to add new "endocrine testing" provisions to the Safe Drinking Water Act Amendments of 1996. However, few people realize that the veracity of this finding was later questioned, quite seriously. To make a complex story short, the investigative arm of the NIH examined this finding and determined that it arose from errors in the scientific process. The findings have been retracted and, to the best of my knowledge, this particular allegation of danger has never been verified.

If those examples are not sufficient, consider the hypothesis that magnetic fields from electric powerlines are associated with the development of human cancers. Early published studies found that living near a powerline was associated with childhood leukemia and brain cancer in adults. The US Congress launched a multi-year $50 million research effort to verify this hypothesis. When the entire program was concluded several years ago, the US government concluded that there was no consistent support for this

hypothesis in biology or epidemiology. I find it interesting that the World Health Organization continues to examine the hypothesis, and is holding international meetings about appropriate precautionary approaches to this concern. While concern about magnetic fields from powerlines has diminished in the USA, lawsuits have been filed against cell-phone companies on the grounds that brain cancer may be related to use of cellular phones. It will be instructive to follow this hypothesis in the years ahead.

With these scientific case studies as background, I would like to share with you some of the reasons why officials of the US government are reluctant to embrace what the EU refers to as "the" precautionary principle.

First, there is no such thing as "the" precautionary principle. The Swedish philosopher Sandin has documented 19 different versions of the principle. While certain themes are similar, crucial details vary (e.g., the degree of scientific evidence necessary to justify precaution and the role of economics in decisions made on grounds of precaution). Even the EC's 2000 "Communication" on precaution, though it provides constructive guidance to policy makers, does not provide an explicit definition of the principle.

Second, Americans recognize that sensible precautions are an important feature of wise decision making. In fact, there are established approaches to precaution defined in both decision theory and economics. We do not see why a universal new principle is needed to cover what is already embedded in the existing theories of "option value" and "value-of-information" analysis.

Third, if an extreme version of precaution were adopted, it could thwart the technological innovation that has supported rising living standards throughout the world. Consider the following thought experiment: It is 1850 and the following strict version of the precautionary principle is being applied: No innovator may market a new technology unless it meets an evidentiary standard of absolute safety, including consideration of longterm effects. What would have happened to electricity, the internal combustion engine, plastics, pharmaceuticals, the Internet, cell phones and so forth? Innovation is a process of trial, error, and refinement -- a critical process that could be disrupted by overly simplistic views of precaution.

Fourth, the proponents of the precautionary principle need to explain more clearly how the principle addresses the risks of precautionary action. For example, the USA has learned that when FDA regulation of new drugs became too stringent, it caused harmful delays in the introduction of effective therapies into medicine. Should the precautionary principle apply only to the potential hazard of immediate concern, or should it also apply to the potential risks of precautionary measures?

Finally, we see the precautionary principle as potential camouflage for protectionism, even though the principle is often advocated to advance such lofty objectives as protection, democracy and ethics. As the EC Communication recognizes, it is important to make sure that the principle is not abused for illegitimate trade proposes.

Yet one of the early decisions of the World Trade Organization, concerning the EC's ban on hormone-treated beef, illustrated how the EC had attempted to justify a permanent ban on certain hormone-treated products when the issue should have been handled under provisional authority that is receptive to scientific advances. For years the USA has also been making the case in Europe -- with limited success -- that genetically-modified foods should be regulated based on science and risk assessment. Our backs are now against the wall, and we are doing what this Administration does not like to do: we are litigating the GMO issue in the World Trade Organization in order to uphold the future viability of this promising technology.

Although we have intense policy disagreements with our European colleagues, we have seen indications that the EU does recognize the need to subject the precautionary principle to reasoned checks and balances. For example, the EC's 2000 Communication on precaution describes the principle within science-informed decision making that includes risk assessment, risk management and risk communication. The Communication also describes a role for cost-benefit analysis as well as other principles of risk managment such as proportionality. More recently, the European Commission has issued papers outlining a more rigorous process of "Better Regulation" where the tools of regulatory impact analysis recommended by the OECD will be used more consistently and transparently.

Even in the domain of specific regulatory decisions, there are some signs of light from a US government perspective. The Commission's handling of the aftermath of the BSE fiasco is a case in point. When the UK had implemented a broad range of effective countermeasures to address BSE, the Commission recommended that all Member States lift their precautionary bans on importation of British beef. In the final analysis, only one Member-State -- France -- refused to do so. Citing the precautionary principle, the French argued that French beef may in fact be safer than British beef. Brussels found little evidence to support the French position and contested the French decision in the European Court of Justice. The Court sided with Brussels, indicating that even a position based on the precautionary principle must have some basis in science.

More recently, the European Commission has taken modest steps to authorize some genetically-modified seeds. Officials in Upper Austria took a different view, invoking the precautionary principle to preclude use of an authorized GM seed in Upper Austria. Brussels rejected Upper Austria's position on the grounds that the authorized GM seed should not have any greater risks in Upper Austria than elsewhere in Europe. Again, Brussels stressed that appeal to the precautionary principle must have some basis in science.

In summary, I have suggested that advocacy of the precautionary principle is here to stay. Precaution is a sensible concept and is built into modern tools of economic and decision analysis. The notion that a universal precautionary principle is necessary should not be endorsed until (a) it is defined, (b) it is shown to offer distinct advantages to the science-based approaches to risk management currently employed in the USA. In

other words, the US Government will continue to take a precautionary approach to universal adoption of "the" precautionary principle.