Thank you very much for the opportunity to participate in this last of four informal dialogue sessions on the subject of precaution. On behalf of President Bush, I want to thank the sponsors and organizers of these sessions for bringing Europeans and Americans together to better understand how we should think about precaution. I also want to welcome all of the participants today -- and especially our European colleagues -- and thank everyone for your hard work and your willingness to travel in the face of the uncertain risk of hurricanes Ivan and Jeanne.

We all realize that these sessions have been conducted within a context of some strong disagreements between European and American policy makers. That disagreement exists at a fundamental level, concerning whether the so-called "precautionary principle" is a well-defined construct. The disagreement extends to real-world application of the construct on diverse issues such as genetically modified foods and global climate change.

Despite the persistence of policy disagreements, I believe these sessions have been successful. They have fostered greater understanding about the dilemmas faced by policymakers who confront incomplete scientific evidence about a potential hazard. As an American official, I have also learned that the European Commission sees the precautionary principle as a more subtle, nuanced construct than I originally realized.

In my remarks today, I will use the Commission's Communication on the precautionary principle (2000) to demonstrate some key points of agreement, or at least points that the US government finds reassuring. I will also conclude with some residual areas of concern that are triggered by the Communication and the evolving governance structure within the European Union.

We agree with the Commission that decision-makers are "constantly struggling" with the dilemma of how to make wise decisions in the face of scientific uncertainty about potential hazards. The following six points of guidance in the Commission's Communication are constructive and reassuring.

First, the scope for precaution includes environmental protection, but is also broader, and includes concern for potentially dangerous effects on human, animal or plant health. We would argue for an even broader scope for precaution, including concern for the
economic well being and the quality of life of people throughout the world, both today and in future generations. Just as it is legitimate to invoke precaution with respect to a concern for public health, it is legitimate to invoke precaution with respect to concern for economic well being. In fact, to summarize a complex literature, we should not forget that prosperity is healthier and greener than poverty. We are encouraged that the Communication acknowledges an important role for economics in the application of the precautionary principle, including an examination of potential costs and benefits of alternative measures.

Second, "the precautionary principle should be considered within a structured approach to the analysis of risk . . . including risk assessment, risk management and risk communication." (p. 3) This statement of the Commission is reassuring. It highlights that precaution is not a substitute for the risk-based approaches to decision making that the USA has developed over the past thirty years. In this respect, the Commission's view of precaution may differ somewhat from the views of precaution espoused by some environmental advocates and academics in the United States.

Third, "the implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty" (p.3) This statement is reassuring. It says the precautionary approach begins with science, rather than with popular opinion, media stories, perceptions, or politics. There is already ample room for politics in policy making on both sides of the Atlantic, and thus it is refreshing to learn that the Commission believes that implementation of the precautionary principle begins with an objective assessment of whatever science is available.

Fourth, "a wide range of initiatives is available in the case of (precautionary) action, going from a legally binding measure to a research project or recommendation." This statement is reassuring. Many of my American colleagues fear that the precautionary principle refers only to prohibitions or burdensome legal restrictions. While we understand that bans and binding rules are sometimes appropriate responses, it is reassuring that the Commission recognizes additional scientific research to better understand a potential hazard as a legitimate precautionary measure. For many potential hazards in the early stage of scientific understanding, additional research may be the most promising precautionary action. In some cases, an interim legal restriction on a product or technology, combined with further research, may be appropriate. We also fully concur that "precautionary measures should be reviewed in light of scientific progress and amended as necessary."

Finally, we are encouraged that the European Commission recognizes a need to "avoid unwarranted recourse to the precautionary principle" such as measures that are a "disguised form of protectionism." This statement is very reassuring. A subjective construct such as the precautionary principle is susceptible to misuse and we are pleased that the Commission forsees that potential problem. We also realize that the Commission has, on occasion, taken aggressive actions to block unwarranted use of the principle by
Member States. For example, when France refused to lift the ban on British beef (after the UK had implemented effective countermeasures against BSE), the Commission persuaded the European Court of Justice that France's recourse to the precautionary principle was unwarranted. More recently, the Commission blocked an unwarranted recourse to the precautionary principle by Upper Austria, in the context of permission to use a particular genetically modified seed.

When we consider the Communication as a whole, it is apparent that the European Commission's official view of the precautionary principle is thoughtful rather than simplistic. Having said that, we continue to have some serious concerns about the Communication, which I have discussed previously. We also believe that the letter and spirit of the Communication are not always followed in particular decisions, but that is a subject for a different forum. At the present time, the US government is most interested in how changes in European governance may influence the implementation of the precautionary principle. Please let me elaborate briefly.

While the Communication commits the European Union to responsible use of the precautionary principle, it is not entirely clear -- as an organizational matter -- what the checks and balances will be to ensure that the principle is used properly. We should expect that regulators will often use their authority responsibility. Nevertheless, in the United States, there are three principal external checks against misuse of regulatory power: My office at OMB, within the Executive Office of the President, has the expertise and authority to compel regulators to reconsider the quality of their analysis and their precautionary decisions; the federal judiciary has the power to review final rules; and the United States Congress has authority to overturn specific rules through the Congressional Review Act and other means. I would like to learn more about how the EU will be organized to provide external checks against the inevitable misuse of regulatory power.

On the subject of scientific and economic analysis, there are often concerns about whether a particular report is objective, comprehensive and transparent. In the USA, each regulator must establish information-quality guidelines, and prepare technical reports that adhere to these guidelines. My office at OMB -- in collaboration with the President's Science Advisor -- is developing government-wide standards for expert peer review of technical reports before they are released by regulators. My office has also developed mechanisms that permit members of the public, including industry and NGOs, to seek correction of erroneous information distributed by regulators. Thus, even if the regulator's peer review process does not detect an error, there is a timely mechanism for the public to use to seek a correction.

I would like to learn more about how the EU will be organized to ensure that the scientific and economic information marshalled to support precautionary regulation is dependable. I have no doubt that there is plenty of technical expertise in Europe; the issue I am raising is one of governmental process for tapping the best scientific talent and achieving quality control in official reports.
Finally, the Communication uses the term "transparent" about good regulatory process and endorses a role for "interested parties" to participate in the study of precautionary measures. In the United States, we have established means, under the Administrative Procedure Act, to ensure that the public has an opportunity to participate in regulatory decision making. These means include notice-and-comment procedures and public hearings prior to final actions. I would like to learn more about how the EU as a whole -- and the Commission in particular -- achieves transparency in precautionary decision making, and whether the regulators provide ample opportunity for meaningful public participation in the application of the precautionary principle.

Thank you very much for the opportunity to participate. I look forward to comments and questions.