"Risk, Precaution, and Regulation"

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President Cantor, President-Elect Goldstein, Past Presidents of SRA, the SRA Executive Committee, members of the SRA Council, officers from SRA chapters, sections and specialty groups, and the membership of SRA, I thank you for the opportunity to attend this meeting and address you this morning. On behalf of the Bush Administration, we applaud your efforts to build, validate, and apply the tools of risk analysis – to the many risks faced pre-9/11 and the many new (or newly recognized) challenges we face since 9/11. We also applaud the work of SRA's social scientists and lawyers, those seeking to both understand how the public perceives risks, how people balance risks and benefits, and how we can build more competent, accountable, and trustworthy risk-management organizations.

Today my substantive remarks will be in two areas: (1) what we are doing at OMB to promote better risk regulation in the Federal government, and (2) what the Bush Administration sees as the appropriate role of precaution in risk management and how that role is similar to, yet also different than, the so-called precautionary principle espoused by our European colleagues on the other side of the Atlantic.

Before turning to these topics, I would like to provide a more extended thank you to the many colleagues, former faculty advisors, former students, and SRA collaborators in the room this morning. I must confess that I was surprised when the President nominated me for this post last March. I did not work on the Bush campaign and was not well known in the inner circle. Indeed, some reporters have had fun with the public record showing that I made a personal contribution to Elizabeth Dole's short-lived

Presidential campaign. I also entered this job with 20 years of university activity but no significant government experience. These first 18 months at OMB have been a learning experience for me. And I have depended heavily on my experiences at the Harvard Center for Risk Analysis and my principal professional society, the Society for Risk Analysis. In particular, I would highlight two aspects of my SRA experiences that have served me well in this job. First, I have learned to appreciate the critical roles that various disciplines have to play in making sound public policy. Through SRA I learned to look beyond the perspective of a decision scientist and learn the perspectives of engineering, toxicology, epidemiology, law, psychology, sociology and so forth. Second, through SRA I had the opportunity to appreciate the international dimensions of risk issues – bioengineered foods, global climate change, and WTO – to name a few. These SRA experiences have helped me tackle my job with some confidence and I thank all of you affiliated with SRA for that opportunity.

Let me turn to the first question – What are we doing at OMB to promote better Federal regulation? President Bush has instructed me to pursue an agenda of smarter regulation. Although this is a slogan, it has important ramifications. Smart regulation is neither uniformly pro-regulation or anti-regulation. Science, engineering, and economics have important roles to play. Regulators are expected to (1) adopt new rules when market or local choices fail to serve the public interest, (2) modify existing rules to make them more effective and/or less costly and intrusive, and (3) eliminate existing rules whose benefits do not justify their costs. We have pursued the smart-regulation agenda under the terms of EO 12866, the Clinton-Gore Executive Order on Regulatory Planning.

We believe this Order contains some sound principles and procedures, although we are not convinced that the Order was always faithfully executed during the previous Administration.

As we pursue smart regulation, I have strived to establish a climate of openness at my office at OMB. We are making greater use of the Internet to explain to the public what rules we are reviewing and what general directions we are giving to agencies and my staff. We are even posting on the web a daily update of our meetings with outside parties: the date of the meeting, the subject of the meeting, and the participants and their organizational affiliations. You can track our daily activities at www.whitehouse.gov/omb/regulatorypolicy.

I learned from my SRA colleagues in the social sciences that openness can build some degree of trust and cooperation. Of course, it does not necessarily create consensus or reduce controversy. Indeed, openness can sharpen controversy by making technical and policy disagreements more apparent to everyone. Although I believe there is still more room for progress on openness at OMB, there is no way OMB can operate in a complete fishbowl. Moreover, we have no intention of compromising the need for public servants to protect their pre-decisional deliberations in the Executive Branch.

I am also working to reverse the 20-year staffing decline at OIRA and diversify our mix of technical expertise. For 20 years, we have had a strong professional staff in economics, statistics, information technology and policy analysis. We have recently

hired the first OIRA professionals with specialized expertise in risk-related fields such as toxicology, epidemiology, engineering, and pharmacoeconomics. Several of these hires are SRA members. We believe that emphasis on health and environmental sciences properly reflects the growing role of health, safety and environmental concerns in Federal regulatory activities. This new expertise will enhance OMB's ability to collaborate with science-based agencies while helping us ask more penetrating technical questions about the underpinnings of agency proposals.

Some people expect a Republican Administration to be reflexively anti-regulation. Yet this President sees regulatory policy as a complex mater with important impacts on the daily lives of the public. He supports professional analysis to help judge what policies make sense. And sometimes these analyses support more regulation. Since the events of 9/11, for example, OMB has reviewed and cleared 60 new homeland security rules on topics ranging from immigration control and food safety to financial assistance to communities and businesses harmed by the terrorist attacks. In more traditional fields of public health, we have also urged or approved new rules in several areas: consumer labeling of the trans-fat content of foods to reduce heart disease, new standards and penalties to reduce the amount of pollution from diesel engines used on-road and off-road, and a new rule to enhance crash protection for motorists involved in frontal crashes that are "off center" (meaning not exactly head on). Late Friday of last week, OMB also cleared a proposed rule that will increase the fuel efficiency of light trucks (sport utility vehicles, vans and pick-up trucks). The details of the rule will be disclosed in the near future but the proposal will advance two Administration policies –

the energy security of the country and the need to curtail the carbon intensity of the transportation sector of the economy. We are also working with DOE, DOT, and EPA to identify promising reforms of fuel-economy policies that can simultaneously save fuel and save lives.

In other arenas, we are proposing to streamline, simplify or eliminate Federal regulations. Under the Clean Air Act, for example, our more flexible approach to reviewing routine maintenance and repair activities at industrial facilities will reduce pollution and boost the economy by encouraging businesses to invest in efficiency improvements. In the transportation sector, we have proposed to reduce regulation of airline ticketing services in order to promote competition and reduce prices to the consumer. In the health care sector, we are looking into a variety of regulatory reforms to reduce administrative and paperwork burdens on hospitals and physicians offices without reducing the quality of medical care provided to patients.

Our 2002 Annual Report to Congress on the Costs and Benefits of Regulation is scheduled to be released later this month. This final Report will set in motion a process of agency evaluation of 300+ rules and guidance documents proposed for reform by over 1.700 public commenters. We will work with agencies to identify the smartest reforms, regardless of whether they increase, modify or reduce the overall amount of regulation. The five agencies to be most affected by reform will be HHS, DOT, EPA, Labor and Agriculture.

Finally, we are taking steps to enhance the quality of information used by agencies and the quality of analysis used to support agency decisions. The Information Quality Law of 2000 has spawned new thinking at OMB and the agencies about how to enhance the quality of agency information, which includes the dimensions of objectivity, clarity to the user (utility) and security. The new OMB guidelines on information quality set some important minimum standards in the areas of reproducibility, peer review, and risk assessment. We appreciate the public comments that many of you contributed during the OMB's guideline-development process. Although it is too early to know exactly what will happen under the new law, it is OMB's hope that the law will cause agencies to be more accountable about the quality of information that they disseminate to the public.

Now let me turn to the important subject of precaution in risk management. I shall be brief because my thoughts on this subject are already posted on OMB's web site.

There are possible risks in daily life that are subject to substantial scientific uncertainty – indeed there may be no risk at all – but that, for one reason or another, trigger significant public concern. Under these circumstances, what is the appropriate role for precaution in the responses of risk managers? I have in mind risk managers in both the public and private sectors.

What do I mean by precaution? I can assure you that I do not intend to define any universal precautionary principle. As you know, the US government supports

precautionary approaches to risk management, but we do not recognize any universal precautionary principle. We consider it to be a mythical concept, perhaps like a unicorn.

I do believe that a dictionary definition of "precaution" is a useful starting point. WEBSTER'S Second College Edition of the NEW WORLD DICTIONARY defines precaution as "care taken beforehand." Or more precisely, as "a measure taken beforehand against possible danger." I presume that the word "beforehand" means before science has resolved all the key technical questions about the hazard of interest or at least before the actual occurrence of the event. Precaution is a well-respected concept: people practice it regularly in the stock market, in hospitals, and on the highway.

Indeed, Americans have experienced the pain and suffering that can result from insufficient precaution in risk management. The health risks of smoking, the neurotoxic effects of lead, once used as an additive to gasoline, and the respiratory diseases from exposure to asbestos in the workplace: each became major public health problems in the United States. Public health historians teach us that these problems could have been reduced or even prevented altogether if early signals of danger had stimulated precautionary measure by risk managers.

We should not belittle the scientific challenges in each of these examples. Consider tobacco. Although the causal link between smoking and lung cancer now seems obvious, in the middle of the previous century it did not seem obvious to many well-trained and thoughtful physicians. They argued that they had treated many smokers

for a lifetime who never developed a significant lung ailment. Likewise, they had treated patients with lung cancer who were not smokers. The science of toxicology did not resolve this dilemma because it proved difficult to produce tumors in laboratory animals with tobacco exposures via inhalation. The field of science that proved to be most decisive is the one that some people now trust the least: epidemiology. There was in fact a large statistical study of the health of British physicians that played an important role in building the medical consensus against smoking. Interestingly, epidemiology also played a pivotal role in uncovering the neurotoxic effects of lead and the diseases associated with exposure to asbestos on the job.

If we knew that scientific progress would always verify early signals of danger or show that hazards are worse than predicted, then the challenge of precaution would be much easier. A recent report from the European Commission makes the point that uncertain environmental hazards often prove to be worse than anticipated. Yet the dynamics of science are not so easily predicted. There are in fact many cases of postulated or claimed hazards that have not been confirmed.

Early indications that drinking coffee might cause bladder cancer were not confirmed. In the 1970s, the US Food and Drug Administration declared a virtual war against the artificial sweetener saccharin, after animal tests revealed bladder cancers following administration of huge doses to rodents. The American people resisted the FDA's conclusion and possibly for good reason. After thirty years of biological experiments and large-scale statistical studies of the consumers of saccharin, it now

appears that the prediction of a human cancer risk may have been incorrect. Indeed, the US government recently took steps to remove saccharin from its official list of carcinogens. More recently, scientific findings were publicized claiming that low doses of chemicals now in widespread use may be doing harm to the endocrine systems of the human body. Yet further science has revealed that some of these early findings about so-called "endocrine disruptors" cannot be replicated by qualified scientists.

Global predictions of risk are also fallible. When I was a college student in the 1970s, there were scholarly predictions of a Malthusian global catastrophe, in part stimulated by reports of the Club of Rome. There were also economists predicting that the world price of oil would rise so high, due to limited petroleum reserves, that the price of gasoline at the pump in the United States would increase dramatically. Looking back, some of these predictions were erroneous. As an academic, I contributed to the erroneous predictions when I forecasted that front-seat airbags would save 9,000 lives per year in the United States. It now appears that the correct number will be somewhere around 3,000 lives saved per year.

As we contemplate the role of precaution in risk management, we must remember that sometimes possible risks prove far worse than expected; other times predictions of doom simply do not materialize.

It is therefore useful to draw a distinction between the role of precaution in the scientific assessment of risk and the role of precaution in risk management. When

analysts assess risks, they may introduce conservative assumptions or safety factors into the analysis to account for unknowns. These protective practices may be intended to establish an upper bound on the true yet unknown risk. When considering the role of precaution in risk management, it is appropriate for policy-makers and the public to inquire about the degree of precaution embedded in the risk assessment.

The use of precaution in risk management is sensible but susceptible to misuse. If precaution is taken to an extreme, it can be very harmful to technological innovation. Consider the following thought experiment: Imagine it is 1850 and a decision is made that any technological innovation cannot be adopted unless and until it is proven to be completely safe by the proponents of the innovation. Under this scenario, what would have happened to electricity, the internal combustion engine, plastics, pharmaceuticals, the computer, the Internet, the cellular phone and so forth?

In the United States we have also learned the hard way that the urge for precaution can lead to unfortunate outcomes. In energy policy, for example, some of us regret our historical decisions regarding nuclear energy. The possible risks of nuclear power generation, coupled with the desire for precaution and rising costs of construction, caused a virtual halt in the construction of new nuclear plants in the United States. Thirty years later, we now find ourselves even more deeply dependent on fossil fuels, which are a major source of environmental concerns and calls for precaution. Part of the answer lies in cleaner coal technologies, renewables and energy conservation, but it also may be very unwise to foreclose the advanced nuclear option.

Reasonable people can disagree about what is precautionary and what is dangerous. Consider whether the diesel engine should be used in passenger cars and light trucks. Regulators in the State of California have set the tailpipe emission standards for particles and nitrogen dioxide so stringently that it may not be feasible to offer diesel-powered cars for sale in the future. California's regulators see this rule as a measure to protect public health from the known or possible health risks of smog and soot in the air. Meanwhile, European regulators and finance authorities have facilitated the growth of the diesel-engine market in Europe to the point that a substantial share of new cars in Europe are equipped with diesel engines. From a global climate perspective, the pro-diesel policy in Europe looks precautionary since the diesel offers significant fuel efficiency advantages over gasoline-powered vehicles. Yet we should also not forget that the price of gasoline at the pump is three to four times larger in Europe than it is in the United States, reflecting European tax policies.

The diesel example reminds us that a zero-risk policy is rarely feasible. More often, policy makers are engaged in an exercise of risk selection and we should not permit any rhetoric about complete safety to obscure this truth.

In preparing for this conference, I re-read the European Commission's February 2000 Communication on precaution and related comments from committees in the European Parliament. I was encouraged by these documents, even though we have many differences of opinion about specific risk-management issues and even though the

documents do not provide a definition of the precautionary "principle" while asserting its existence. Based on these documents, I detected the following points of possible conceptual agreement between the EC and the US government.

First, precaution is a necessary and useful concept but it is also subjective and susceptible to abuse by policy-makers for trade purposes and other reasons. Consider a recent decision from the European Court of Justice. The Court sided with the EC over France on a BSE matter, suggesting that France may have over interpreted the precautionary principle. Second, scientific and procedural safeguards need to be built into risk management decisions that are based in part on precaution. Third, adoption of precautionary measures should be preceded by a scientific evaluation of the hazard and, where feasible, a formal analysis of the benefits, risks, and costs of alternative precautionary measures. Fourth, concerns for fairness, equity and public participation need to be reflected in risk management. Finally, the set of possible precautionary measures is large, ranging from bans or product restrictions to education or warnings to market-based reforms. Even the initiation of a targeted research program to better understand a possible risk is a precautionary measure. When the precautionary principle is characterized along the lines suggested by the European Commission, it basically sanctions the various fields of inquiry supported by the Society for Risk Analysis.

I conclude on notes of both optimism and caution. Precaution is a perfectly sensible concept that is built into many health, safety, and environmental laws in the

United States. At the same time, it may be wise to apply a precautionary approach to any attempt to enact a universal precautionary principle into American law.

Thank you very much for the opportunity to deliver these opening remarks. I look forward to questions and comments.