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October 14, 1999

My name is John Graham. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health where I teach graduate courses on risk assessment, risk communication, and cost-benefit analysis. I am also the founding Director of the Harvard Center for Risk Analysis, a mission-oriented Center dedicated to promoting a more reasoned public response to health safety, and environmental hazards. Our Center applies formal analytic tools to the following four issues: environmental health, automotive safety, medical technology, and food safety. I am the author or co-author of seven books and over 100 articles published in peer-reviewed scientific journals. In 1995-96 I served as elected President of the International Society for Risk Analysis, a membership organization of 2,500 scientists and engineers dedicated to applying formal analytic tools to the resolution of risk issues. I am offering personal testimony today and thus my remarks do not necessarily represent the viewpoints of the University or the Society for Risk Analysis.

It was about ten years ago that I first testified before this Committee on President Bush's proposal to amend the Clean Air Act, a proposal that Congress expanded into what became the 1990 amendments to the Clean Air Act. We have learned a great deal during the past decade. The Clean Air Act has produced more regulations, more public health and economic benefits, and more costs to American businesses and households than any other federal program of environmental regulation. Thus, the stakes in the reauthorization debate are large.

Let me begin with some good news.

First, the total estimated benefits of the 1990 amendments appear to be greater than the total estimated costs of the amendments (EPA, 1999), at least if we are to believe EPA estimates of benefits and costs (see cautionary remarks below). But some parts of the 1990 Amendments are better "buys" than others (Smith and Ross, 1999). There are a significant number of clean air regulations that were adopted without a careful analysis of their risks, costs, and benefits (e.g., some of the MACT standards under Title III of the 1990 amendments). In many cases EPA estimates regulatory costs but does not attempt to quantify benefits in public health or economic terms (see, for examples EPA's regulatory impact analyses (RIAs) of the rules governing medical waste incineration and vehicle inspection and maintenance). Moreover, one study of 25 clean air rules adopted from 1990 to 1995 found that only ten of these rules would pass a strict cost-benefit test (Hahn, 1995). Thus, EPA's commitment to cost-benefit analysis varies enormously from rule to rule and the influence of cost-benefit analysis on EPA decision making is uneven (Morgenstern, 1997, Hahn, 1999).

Second, the "grand experiment" with incentive-based programs under the Act, particularly the sulphur-trading programs enacted to address acid rain, appear to have been a qualified success (Staving, 1998). Evaluations suggest that this program has been successful (compared to conventional "command-and-control" regulation) both

economically and environmentally. A case is now being made to expand this approach to trading of nitrogen oxides as well as sulphur oxides.

Third, as predicted (Graham 1985), EPA has made greater progress in regulation of air toxics through a technology-based approach that targets industry sectors ("source categories") rather than by determining acceptable risk on a pollutant-by-pollutant basis. Yet measuring success by the number of industries regulated is not very meaningful to public health. The big unknown in the toxics arena is whether the public health benefits of reduced human exposures to air toxics have been significant enough to justify the significant expenditure of agency and industrial resources that has taken place.

In my testimony today, I will focus on the role of risk analysis and cost-benefit analysis under the Clean Air Act. I will identify five problem areas that I believe are worthy of future Committee investigation as you develop legislation to reauthorize the Clean Air Act. In some cases I have only been able to identify a problem while in other cases I go further and recommend some possible solutions for your consideration.

Problem 1: SOME PROVISIONS OF THE CLEAN AIR ACT ARE DYSFUNCTIONAL BECAUSE THEY DO NOT REQUIRE OR PERMIT EPA TO WEIGH THE RISKS, COSTS, AND BENEFITS OF ALTERNATIVE POLICIES.

When multi-billion dollar rulemaking decisions are made, it is inevitable that regulators will consider the consequences of their actions as well as the reasonableness of the relationship between risks, benefits and costs. Yet some provisions of the Clean Air Act erect a legal fiction that regulators may not consider risk, cost and benefit when devising regulations. This legal fiction is dysfunctional because it (1) reduces political accountability for value judgments and political choices, (2) hides from public scrutiny claims that are made about risks, benefits and costs (since such claims are driven "underground" in the course of regulatory deliberations), (3) undermines EPA's credibility in the regulated community and the public because the agency is portrayed as being disinterested in science and economics, and (4) shifts public debate from risk-benefit and cost-benefit issues (which is where the debate should be) to spurious technical debates about whether breathing air pollution has been proven to be harmful (the "causation" issue, which is unlikely to be resolved conclusively at the low levels of air pollution now found in the USA due to the limitations of modern scientific methods of toxicology and epidemiology). Let me provide a concrete example of how legal restrictions in the Clean Air Act create a perverse public debate about clean air policy.

The primary ambient air quality standards for ubiquitous ("criteria") air pollutants are to be set at levels that are safe in the sense that such levels protect the public health with an adequate margin of safety. Yet such scientific information (alone) does not typically provide an intelligible basis for He setting of safe (yet non-zero) amounts of air pollution. Human and animal studies often find no discernible threshold in the dose-response function, particularly as more susceptible subpopulations are identified and more subtle health effects are considered to be "adverse" within the meaning of the Clean Air Act. The only concentration of some air pollutants (e.g. fine particles and lead) that is really safe to breathe appears to be zero, yet it is not economically realistic or appropriate for EPA to set air pollution standards at zero. Thus, EPA is forced to manufacture spurious

rationales for non-zero air quality a form of dishonest behavior that contributes to the atmosphere of arbitrariness, mistrust, and adversarialism (including litigation) that has characterized public debates about air quality standards.

The solution to this predicament is not necessarily to apply a strict cost-benefit test to any new or modified primary air quality standard. Cost-benefit analysis of primary air quality standards is particularly speculative because air quality standards, which need to be based primarily on public health data, are devised before the agency has had the opportunity to study the industrial economy and collect the kinds of engineering and cost information that identify cost-effective ways to prevent or control pollution. When EPA or the states propose emissions rules for specific industries or sources, it is feasible to gather more precise cost and effectiveness information, thereby supporting a more rigorous analysis of risks, benefits and costs.

Although it is feasible for EPA to make crude estimates of risk, benefit, and cost when a new or modified primary air quality standard is proposed, the cost-benefit test for decision making at this stage should be a more lenient one than is applied to federal or state emission standards that apply to particular technologies or industries. For example, Congress might permit or require EPA to consider whether the incremental costs of a tighter air quality standard are grossly disproportionate to the anticipated benefits of the proposed standard. Under this rather lenient cost-benefit test, EPA's recent fine particle standard would have been quite defensible, though the proposed modification to the ozone (smog) standard would have been vulnerable to legal challenge.

Problem 2: ALTHOUGH CLEAN AIR REGULATIONS ARE INTENDED TO REDUCE RISKS TO PUBLIC HEALTH, THEY SOMETIMES CAUSE UNINTENDED DANGERS TO PUBLIC HEALTH BECAUSE THE RISKS OF REGULATION WERE NOT ANALYZED CAREFULLY BY CONGRESS AND EPA WHEN POLICIES WERE MADE.

Risk-tradeoff analysis (sometimes called risk- risk analysis or risk-benefit analysis) is often easier than cost-benefit analysis because the units of measurement in the analysis are physical rather than monetary quantities. For example, the units used in risk-tradeoff analysis might include the net number of lives saved, life years saved, quality-adjusted life years saved, or even the net change in the amount of pollution emitted into the environment, with the mass emissions of each pollutant Freighted by their relative toxicity and/or exposure potential. In risk-tradeoff analysis, the public health benefits and risks of a new regulation do not have to be expressed in dollar units, one of the more complicated and controversial steps in economic evaluation. In order to avoid perverse situations where a well-intended clean air regulation kills more people than it saves, Congress should consider an amendment to the Clean Air Act Cat compels a risk-tradeoff analysis of future regulations (Graham and Wiener, 1995).

Experience the 1990 amendments illustrates trait Congress and EPA have not been as vigilant in conducting risk-benefit analysis as perhaps they should have been. Here are two examples

First, EPA's new air quality standards were overturned by a divided appeals court that employed some novel constitutional arguments. Yet less attention has been devoted to the fact that EPA's revised smog standard was overturned by a unanimous court because EPA did not perforce a risk-benefit analysis of the proposal (computing the health benefits of smog reduction to the health risks of greater ultraviolet radiation exposure that would result from diminished smog concentrations in the atmosphere). Public exposure to ultraviolet radiation is a serious public health concern since such exposures are associated with skin cancer, cataracts, and other adverse health effects. EPA contests whether the health risks caused by regulations are legally relevant under the language of the Clean Air Act but Congress should take a broad view of public health protection and require EPA to do "More good than harm." to public health in each regulation (Warren and Marchant, 1993).

Second, Congress and EPA mandated an increase in the oxygenated content of gasoline without performing a careful risk-benefit analysis of the most important chemical, MTBE, that has been used to comply with the provisions in the Clean Air Act More oxygen content in gasoline did promise air quality benefits: less carbon monoxide and toxic air pollution. Yet the risks of the rule were not considered carefully. Now that MTBE, a rather persistent chemical with low acute toxicity, has been discovered in both surface and groundwater (e.g., near leaking underground storage tanks), questions have been raised about whether MTBE exposures pose a risk to public health. A recent EPA stakeholder panel chaired by Mr. Dan Greenbaum of the Health Effects Institute recommended that EPA repeal or modify the mandate of oxygenated fuels, yet a careful risk -benefit analysis of the issue has still not been conducted by EPA.

Asking Congress and EPA to perform risk-benefit analysis is equivalent to asking for adherence to the Hippocratic oath in medicine: We should be vigilant about informing the public of the health risks and health benefits of clean air regulations, even in cases where some degree of risk is judged to be acceptable in light of the benefits.

Problem 3: CONGRESS AND EPA SOMETIMES PURSUE CLEAN AIR GOALS WITHOUT TAKING ACCOUNT OF OTHER NATIONAL OBJECTIVES SUCH AS ENERGY POLICY AND INTERNATIONAL TRADE POLICY.

Although the public health objectives of the Clean Air Act are compelling, they do need to be pursued with sensitivity to other national policy objectives such as energy policy and international trade policy. Two recent examples of policy conflict have caught my attention.

First, a recent trip to Europe, I discovered an interesting difference between European and American policies. I was surprised to learn that a large and growing fraction of passenger vehicles (cars and light Uncles as well as heavy trucks and buses) in Europe are powered by diesel engines. European vehicle manufacturers are also making major investments in advanced diesel engine technology that will reduce emissions of pollutants such as particulate matter and nitrogen dioxide. Yet the European Union regulations for nitrogen dioxide emissions may prove to be less stringent than California and USEPA regulations for an interesting reason. Europe is developing the diesel engine as an important element in the strategy to conserve energy and reduce carbon dioxide

emissions, as required by the Kyoto treaty on global climate protection. Modern diesel engines are significantly more fuel efficient than gasoline-powered engines and therefore offer significant promise as a strategy to control carbon dioxide pollution. Vehicle fuel efficiency in Europe also offers significant economic benefits to consumers, since fuel prices in Europe are $3 to $5 per gallon and diesel fuel is priced louver than conventional gasoline.

In the United States, domestic vehicle manufactures are also under political pressure to improve the energy efficiency of engines, but here we have very low fuel prices and consumers have shown a remarkable degree of interest in sport-utility vehicles (large and small), jeeps, and light trucks. There has been some interest in the use of diesel engine technology to power large sport-utility vehicles (in order to increase fuel efficiency) but the strict posture clean air regulators in the California and USEPA are discouraging use of the diesel in favor of less energy-efficient alternatives such as compressed natural gas and conventional gasoline. I have recently persuaded one of my doctoral students to conduct a risk -benefit analysis of the modern diesel engine because European and American policies toward this technology arc currently so divergent.

Second. EPA's toxic air pollution star cards applied to the coke production industry (so-called MACT and LAER standards) were designed to be "technology forcing" but have appeared to have had some unintended consequences in international trade. Coke is vital ingredient in the steelmaking process. Making coke from coal is a dirty process, though the industry has made significant progress in reducing pollution from coke batteries. The 1990 amendments to the Clean Air Act were designed to make greater progress by requiring 0% door emissions from any new coke plants built with conventional byproduct recovery technology. The theory was that this de facto prohibition on the traditional method of making coke would stimulate development of new and cleaner methods of making coke in the USA.

Preliminary experience with the 1990 amendments suggests that coke and steel makers have not always responded to the Act by making major new investments in clean coke-making technology (Graham and Hartwell, 1997). Although a few domestic firms have made major investments in different coke-making technologies, a number of integrated steel makers are instead phasing out their coke-making facilities and purchasing coke on the open market. Some steelmakers are making arrangements to import coke from a variety of countries in Eastern Europe and Asia (e.g. China), where more coke plants are being built with conventional technology and where batteries are operated with greater air emissions gases end particles than is typical of facilities in the United States. I recommend that the Committee follow the dynamics of this industry to determine whether the 1990 amendments are producing the consequences for clean air and international trade that were anticipated when the legislative compromise was negotiated in 1990.

Problem 4: THE RISK ANALYSES USED BY EPA TO MAKE PUBLIC HEALTH DETERMINATIONS ARE NOT ALWAYS CLEAR, OBJECTIVE, OPEN TO PUBLIC SCRUTINY, AND ROOTED IN THE BEST AVAILABLE SCIENCE

The problems the agency faces in using public health science in risk assessment are important to sound implementation of He Clean Air Act but these same problems affect EPA's implementation of other environmental laws, such as the Safe Drinking Water Act and the Resource Conservation and Recovery Act. Here I shall cite several examples to illustrate the general point that Congress needs to take greater interest in the scientific integrity of EPA's public health determinations and the technical processes of risk assessment that support these determinations.

First, cancer- risk determinations will play a critical role in EPA's implementation of the residual- risk provisions of CAAA-90, yet EPA has still not modernized it's cancer risk assessment guidelines to account for advances in biological understanding of the mechanisms of cancer induction. These advances can have a critical impact on which chemicals are classified as "carcinogens" for regulatory purposes and what dose-response relationships are assumed in quantitative modeling of cancer risk. EPA has proposed reforms but is moving at a slow pace to adopt them. The agency's recent decision to ignore mechanistic science regarding chloroform has sent a signal in the scientific community of the agency's weakened commitment to modernize methods of cancer risk assessment (Chloroform is a chemical shown to cause cancer in animals at high doses that mechanistic science suggests is unlikely to cause human cancer at low doses).

Several years ago I served on a Science Advisory Board (SAB) Committee charged with assisting EPA in performing its reassessment of dioxin, a chemical of clear regulatory significance that has been the subject of extensive scientific study. EPA prepared a lengthy draft risk assessment but, despite several years of "talk", has never attempted to respond to the written comments of the SAB Committee and has not issued a final risk assessment of dioxin. When EPA falls years behind its published schedule to make progress in risk assessment, it undermines the credibility of the agency as well as the agency's risk assessment process. The Congress should look into what is happening to cancer risk assessment at EPA.

Second, a mayor National Research Council Report (1994), Science and Judgment in Risk Assessment, made numerous recommendations aimed at enhancing the quality and transparency of EPA's risk assessment process. With the exceptions of some notable improvements in human exposure assessment, the bulk of the NRC recommendations have not yet been implemented by EPA. EPA's recent report to Congress on plans to implement the residual risk provisions of the Clean Air Act makes very little use of the NRC report or of a subsequent report by the Commission on Risk Assessment and Management appointed by Congress and the President As Congress considers reauthorization of the air toxics provisions of the Clean Air Act, they should examine why EPA has given relatively little priority to improving the agency's risk assessment and management processes.

Third, the controversy over EPA's effort to establish a new primary air quality standard for particles illustrated how EPA may seek to use scientific studies whose original data are not available for public scrutiny. Two important studies of the chronic health impacts of breathing fine particulate matter (Dockery et al, 1993; Pope et al 1995) were cited by USEPA in support of the new particle standard but the agency has not succeeded in making the original data from these studies available for public scrutiny. The Health

Effects Institute has played a constructive role in reviewing and reanalyzing these original data but the goal of providing public access to original date supporting regulatory determinations has not yet been accomplished under the Clean Air Act. The Office of Management and Budget is currently working on implementation of a congressional requirement to solve this problem for future rulemakings; the success of OMB's effort should be followed closely by the Congress.

Finally, EPA continues to publish benefit estimates for the Clean Air Act that are based on a dubious "value-of-statistical life" (VSL) method. As employed by EPA the same VSL is applied in all situations, regardless of whether a citizen: loses 1 year of life expectancy or 40 years of life expectancy from air pollution. The VSL method also ignores the functional quality of the life years that are lost. Better methods are available in the field of health economics but EPA does not yet use them.

Problem 5 - CONGRESS AND EPA CONTINUE TO BE PREOCCUPIED WITH OUTDOOR AIR POLLUTION, EVEN THOUGH A SUBSTANTIAL BODY OF SCIENTIFIC INFORMATION SUGGESTS THAT INDOOR AIR POLLUTION IS A MORE SERIOUS PUBLIC HEALTH PROBLEM.

The legislation we are discussing today would more appropriately be entitled the "OUTDOOR Clean Air Act" because the provisions of the law and the resulting compliance expenditures made by industry and households are devoted primarily to reducing exposure to outdoor air pollution from outdoor sources. Controlling outdoor sources of air pollution will have secondary benefits inside homes and offices because outdoor air pollution is a significant cause of indoor air pollution. Yet Tic major sources of indoor air pollution are not regulated by the Clean Air Act (e.g., environmental tobacco smoke, naturally occurring radon gas, and a variety of building materials, consumer products, and cooking practices). As a country, we have made so much progress in reducing outdoor sources of air pollution that leading scientists believe that indoor sources of air pollution are of equal or greater public health concern compared to the residual amounts of outdoor air pollution (Cross, 1990; National Research Council, 1991; Samet and Spengler (eds), 1991).

A recent conference stimulated by EPA and OSHA scientists arose out of recognition that efforts to control outdoor air pollution could inadvertently exacerbate levels of air pollution indoors (e.g., if the MACT regulations governing air toxics cause factories to reduce ventilation rates in buildings and concentrate pollutants indoors where workers will be placed at greater risk). Yet we have only scratched the surface ~ public discussions of the indoor air quality issue because Congress has given the greatest priority to further regulation of outdoor sources of air pollution. The first reauthorization hearing of the Clean Air Act is a good the to consider whether some of the priority assigned to cleaner outdoor air could be better expended ~ efforts to enhance the quality of indoor air.

Thank you very much for the opportunity to provide this testimony. I am certainly willing and eager to provide any additional information that could assist the Committee's reauthorization efforts.

REFERENCES

Cross FB, Legal Responses to Indoor Air Pollution, Quorum Books, NY, NY, 1990

Dockery DW, Pope CA, Xu X, Spengler Jay, Ware JH, Fay ME, Ferris E3C;, Speizer FE, "An Association Between Air Pollution and Mortality in Six Cities," New England Journal of Medicine, vol. 329, December 9, 1993, pp. 1753-1759.

Environmental Protection Agency, "The Benefits and Costs of the Clean Air Act, 1990 to 2010," Washington, DC, September 1999 (draft).

Graham ID, "Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act, 77 Duke Law Journal., 1985, pp.100-150.

Graham ID, Wiener JW (eds), Risk Versus Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press, 1995.

Graham JD, Hartwell JK (eds), The Greening of Industry: A Risk Management Approach, Harvard University Press, Cambridge, MA, 1991.

Hahn RW (ed), Risks, Costs, and Lives Saved: Getting Better :Results from Regulation, Oxford University Press, NY, 1995.

Hahn RW, "Regulatory Reform: Assessing the Government's Numbers," Working Paper 99-6, AEI-Brookings Joint Center for Regulatory Studies, Washington, DC, July 1999.

Morgenstern R (ed), Economic Analyses at EPA: Assessing Regulators Impact, Resources for the Future, Washington, DC, 1991.

National Research Council, Human Exposure Assessment for Airborne Pollutants: Advances and Opportunities, National Academy Press, Washington, DC, 1991.

National Research Council, Science and Judgement in Risk Assessment, National Academy Press, Washington, DC, 1994.

Pope CA, Thun MJ, Namboodiri I, Dockery DW, Evans JS, Speizer FE, Heath CW, "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of US Adults," Am J Respir Crit Care Medicine, vol. 151, 1995, pp. 669-674.

Samet JM, Spengler JD (eds), Indoor Air Pollution: A Health Perspective, Johns Hopkins University Press, Baltimore, MD, 1991.

Smith AE, Ross MT, "Benefit-Cost Ratios of the CAAA by Title," Charles River Associates, Washington, DC, October 1, 1999 (draft).

Stavins RN, "What Can We Learn from the Grand Policy Experiment? Lessons from S02 Allowance Trading," Journal of Economic Perspectives, vol. 12, No 3, Summer 1998, pp. 69-82.

Warren E, Marchant G. "More Good than Harm: A Hippocratic Oath for Environmental Agencies and Courts," Ecology Law Quarterly, vol. 70, 1993, pp 379-440.