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1. TESTIMONY NOVEMBER 16, 1993 KENNETH OLDEN, PH.D DIRECTOR NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HOUSE SCIENCE, TECHNOLOGY, ENVIRONMENT AND AVIATION RISK ASSESSMENT RESEARCH

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Body

STATEMENT

Of

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Director

National Institute of Environmental Health Sciences

and

National Toxicology Program

for

United States House of Representatives

Subcommittee on Technology, Environment, and Aviation

Committee on Science, Space, and Technology

16 November 1993

I am pleased to speak to you today. My name is Ken Olden and I serve as Director both of the National Institute of Environmental Health -Sciences. (***NIEHS***), and the National Toxicology Program (NTP). I will be representing both these organizations in responding to the Office of Technology Assessment (OTA) report on Federal research activities in support of risk assessment.

Organizational Background: The National Institute of Environmental Health Sciences (***NIEHS***), located in the Research Triangle Park, North Carolina, is a component of the National Institutes of Health. The mission of the

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NIEHS is to determine how human health and human disease are affected by the interactions of our individual genetic susceptibilities with the environmental exposures we encounter over the course of our lifetime. In fulfilling this mission **NIEHS** provides the science base needed for public policy decisions, helps translate this information into prevention and intervention strategies, and communicates this information to professional and lay groups. Clearly **NIEHS** provides much of the structural underpinnings of our national health risk assessment research efforts. **NIEHS** supports its research efforts through investigator-initiated research grants and Center grants at research institutions throughout the country, through competitive contracts with private sector R&D firms, and in our intramural laboratories.

The National Toxicology Program (NTP) is an umbrella organization that provides a forum for coordinating and stimulating the toxicology research efforts, and thus the risk assessment efforts, of ten federal agencies. Four of these ten agencies -- **NIEHS**, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR) of the CDC, and the National Center for Toxicologic Research (NCTR) of the Food and Drug Administration, and -- contribute to NTP-specific research efforts. **NIEHS** accounts for over 90% of the NTP research effort.

The backbone of risk assessment methodology is data generated from animal testing and human epidemiologic studies. NTP is the major source of federal animal testing activities. Over the past decade, NTP has established the international gold standard by which testing data is judged. NTP studies have formed the basis for hundreds of federal and state regulatory risk assessment decisions over the last ten years. Our Nation's ability to generate high quality risk assessments relies on our ability to generate the reliable data needed for these assessments.

The work of **NIEHS** and NTP complement each other in supporting the nation's risk assessment research efforts. **NIEHS** scientists explore the fundamental mechanisms of environmental toxicities and refine risk assessment methodologies used by regulatory agencies. NTP conducts animal studies which, in combination with human studies, provide a rational basis for risk assessment.

Future Plans for Risk Assessment Research: Current risk assessment schemes are still largely based on the types of data that could be obtained in the past. These risk schemes have incorporated animals to humans. Because of the uncertainties, risk assessment schemes have incorporated arbitrary "safety factors" and other default approaches. Since these factors are not derived experimentally they may well over-estimate or under-estimate risks.

Recent developments in molecular biology and genetics provide exciting opportunities for improving risk assessments and reducing uncertainty. By understanding the biochemical and pathological pathways that lead to environmentally induced effects we can now begin to relate effects found in animals to those expected in humans. For example, it WM become increasingly possible to explain cancer formation in terms of altered gene regulation and to relate the events in animals with those in humans. The NTP is already collecting tissues and analyzing for genetic alterations in tumor cells. As new mechanisms are discovered, scientists can return to this tumor archive and reinterpret past studies based on newly evolving information and technologies. Other promising lines of investigation include explaining study results in terms of a chemical's ability to disrupt critical cellular functions such as the chemical pathways by which cells communicate with each other. Such testing advances will reduce the uncertainties currently hampering risk assessment as a science. With these advances we look forward to a future in which risk assessment can be more .relevant to the human condition and will be able to protect public health in a rational and cost-effective manner.

We at the **NIEHS** and the NTP are doing what we can to realize the future potential of risk assessment. **NIEHS**, drawing upon a multidisciplinary array of scientists, including biostatisticians, toxicologists, epidemiologists, and molecular biologists, is uniquely positioned to ensure that new insights from laboratory and human clinical studies are incorporated into risk assessment schemes. Intramural **NIEHS** scientists are collaborating with NTP scientists to assure that more mechanistically based information is generated during routine testing. Scientific experts from academia, industry, and regulatory agencies are being recruited, on a case-by-case basis, to help in study design

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and interpretation of research findings. Such collaborations will serve to strengthen the science of risk assessment and to ensure effective transfer of this technology.

I would like now to address specific points raised by the OTA's report.

Commit For the Long-Term: Congress can best foster research on risk assessment methodology by ensuring sustained, long-term commitment to this endeavor. A long-term approach is necessary if complex issues are going to be resolved through scientific investigation. Research is a long-term investment and full return on that investment is only realized when we can follow through on the initial support. I will use two examples of **NIEHS** research efforts to illustrate the value of long-term commitment.

We have supported research into the health effects of air pollutants in six communities in set from the **NIEHS Six Cities Study to reassess the health risks of particulate matter and other criteria pollutants. This analysis suggests that certain pollutants were considerably more hazardous than earlier suspected and that the regulations established under the Clear Air Act were a far better investment than previously calculated using data from animal studies.**

Similarly, over 15 years ago, the **NIEHS** began to study the mechanisms by which dioxin causes toxic effects in animals. Today, fundamental knowledge about these mechanisms from the long-term **NIEHS** project is being used by EPA and other scientists in an entirely novel approach to risk assessment. This approach is biologically based and includes information on mechanisms of action in a number of animal species including humans exposed to high levels of dioxin. It will become a model method for converging animal testing data, mechanistic research, and human studies into rational assessments of risks of low- dose exposures in communities and the work place.

Target Research to Address the Most Significant Threats: Scientists and managers of federally funded risk assessment research should concentrate on the most significant threats and the most promising opportunities. There will always be some level of debate about which environmental factors should be assigned highest research priority on the basis of their threat to health. In addition, such issues as environmental equity and justice must be considered in assigning priorities for research. This debate should be encouraged and priorities must be reassigned as research produces new findings, as new technologies emerge, as social and economic conditions change, and as trends in exposure and disease patterns are noted. In general, I believe that scientists can and should be encouraged to take part in a national discussion on priorities for risk assessment research and that opinions of dispassionate scientists must be used creatively to offset the public fears of poorly understood environmental risks. Such entities as the NTP offer models of the type of collaborative network needed to structure such priority setting. Let me note that at the NTP our collaborations extend beyond the federal government. We seek input from state regulators, academia, industry, environmental advocacy groups, and labor unions. I would encourage solicitation of all stakeholders in setting research priorities.

Promote Collaboration and Technology Transfer: The **NIEHS** and the NTP provide useful examples of the opportunities for collaborative efforts. Most recently the NTP, working with the Health Effects Institute, conducted long-term rodent studies on the air pollutant, ozone. These studies were requested jointly by the State of California and the Health Effects Institute. The **NIEHS** solicited its university- based research community for competitive research proposals in which they would answer important research questions by using exposed animals and tissues that NTP would make available throughout the study. By fostering collaboration with academia, we multiplied by several fold the amount of information from this study. This large body of research, generated from one NTP study, will vastly improve our understanding of ozone's toxicity and consequently improve risk assessments for this agent. As I speak to you today, results of these studies are being publicly presented and peer reviewed at our North Carolina' facility.

The NTP is also committed to expanding its base of partners in toxicology research. These partners include governmental agencies, academia, industry, environmental advocacy groups, and labor unions. We are currently initiating more extensive outreach to the three latter groups. Based on the outcomes of our most recent meetings, I would echo the OTA recommendation that, should industry be compelled to sponsor health risk assessment

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research, mechanisms must be in place to assure the public that business interests do not influence study design or interpretations.

Conclusion: I would like to conclude by saying that risk assessment is only as good as the scientific information upon which it is based. At present it suffers from a degree of uncertainty and attempts to accommodate that uncertainty through safety factors that have little experimental basis. We should aim at protecting both the public health and our economic viability. The relevance and power of risk assessment will be greatly enhanced when the biological mechanisms that lead to adverse effects are known and are incorporated into risk assessments. The Congress can help move the Nation toward this goal by continuing its commitment over the long-term to support research for risk assessment and by encouraging the development of rational research priorities and ongoing research programs that rely on collaboration of all stakeholders.

Thank you for your attention.

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