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National Institute for
Occupational Safety and Health

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Occupational Exposure and Cancer

March 6, 1997

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Occupational Safety and Health

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Occupational Exposure and Cancer

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Foreword

NIOSH presented this testimony at the U.S. Senate Cancer Coalition's March 6, 1997 hearing on future cancer research and policy. Dr. Lawrence Fine presented this testimony on behalf of NIOSH Director, Dr. Linda Rosenstock

Occupational Exposure and Cancer

Good afternoon, Senator Feinstein and Members of the Senate Coalition. I am Dr. Lawrence Fine, Director of the Division of Surveillance, Hazard Evaluations, and Field Studies, National Institute for Occupational Safety and Health (NIOSH), a component of the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (DHHS). NIOSH is the only federal agency mandated to conduct research on workplace illnesses and injuries. Our goal is to keep the nation's workers healthy. The Occupational Safety and Health Act of 1970 created NIOSH "to assure safe and healthy working conditions for every man and woman in the nation". I am pleased to appear here today to discuss future directions for research and policy related to cancer. I will address issues surrounding workplace exposure to potential carcinogens. Additionally, I hope to show through my presentation how investment in occupational cancer research is an investment in non-occupational cause of cancer with substantial benefit to our society.

The Magnitude of the Occupational Cancer Problem

Approximately 500,000 people die from cancer in the United States each year. A conservative estimate is that 4% (20,000) of these deaths are due to exposures in the workplace.

Approximately 500,000 people die from cancer in the United States each year. A conservative estimate is that 4% (20,000) of these deaths are due to exposures in the workplace. A recent report funded by NIOSH estimates that 6% to 10% of all cancer is due to workplace exposures. About 10% of lung cancers, 21% to 27% of bladder cancers, and nearly 100% of mesotheliomas in the U.S. are thought to be related to occupational exposure to recognized carcinogens. The total annual costs for occupational cancer are between $4 and $10 billion. For occupational lung cancer, the direct medical costs total $500 million.

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The impact of carcinogenic exposures is felt only decades after the initial exposure of workers, because many cancers take 20 years or more to develop. Consequently, cancers continue to occur among exposed workers long after exposures have ceased. For example, it was estimated that at least 27 million U.S. workers were exposed to asbestos between 1940 and 1979. Due to the long lag time between exposure to asbestos and the development of cancer, about 8,000 persons will continue to die of asbestos-related cancer, each year well into the next decade.

Occupational Cancer Research Helps to Solve Environmental Cancer Dilemmas

In the early 1900s canaries were routinely taken into the mines to determine if hazards were present. Unfortunately, workers have been the canaries for identifying the general population risks from human chemical carcinogens present in our environment. Many substances of concern today in our environment were produced in industrial processes. Workers were the ones to receive the initial and often higher exposures.

Questions about which current workplace exposures may be causing cancer are a major concern for NIOSH, industry, workers, and the workplace regulatory agencies- the Occupational Safety and Health Administration (OSHA), and the Mine Safety and Health Administration (MSHA). On one hand, there is worry that we will fail to take preventive actions until it is too late, as happened with asbestos. On the other hand, there is the concern that premature actions based on limited scientific information may cause major financial expenditures or disruption in the production and use of common products. The tension occurs between failing to take preventive action and taking premature actions based on limited scientific information. Today, for example, we are faced with questions about the carcinogenicity of diesel exhaust, synthetic fibers, metalworking fluids, silica,

asphalt, some pesticides, and solvents. We have major research and information dissemination activities involving all of these agents and mixtures.

Most of the knowledge we have today about human health risks from environmental carcinogens came from studies of workers.

It is difficult to estimate the numbers of workers exposed to carcinogens. However, NIOSH estimates that at least several million U.S. workers are potentially exposed to the 180 substances that the World Health Organization- affiliated International Agency for Research on Cancer (IARC) classifies as "agents that are carcinogenic to humans". In addition, more than 72,000 substances are in commerce and about two thousand new chemicals are introduced each year, for which little information exists regarding human health risks.

NIOSH has been a leader in conducting occupational research that is used to estimate community risks.

Most of the knowledge we have today about human health risks from environmental carcinogens came from studies of workers. The workplace often has small numbers of people exposed to high levels of hazards. The reverse is true in communities. Communities often have large numbers of people exposed to low levels of hazards. That is why studying worker populations is valuable for understanding environmental community risks. For example, cancer risks found in miners exposed to radon and chemical workers to dioxin are used by the Environmental Protection Agency (EPA) to estimate risks in the general population. NIOSH has been a leader in conducting occupational research that is used to estimate community risks.

Progress in Solving Occupational/ Environmental Cancer Problems

We are making progress in occupational cancer research and prevention. Laboratory and human studies have provided evidence of human carcinogenicity for a number of substances, leading to reduction or elimination of these known carcinogens. Examples include the elimination of dioxin from the workplace and reduction in asbestos and benzene exposures. In some instances, a new substance has been substituted for a carcinogen, such as toluene for benzene and fibrous glass for asbestos. A potential new problem can arise if the substitute later is suspected to be a possible carcinogen, as has occurred with fibrous glass, the subject of studies today.

NIOSH uses a comprehensive strategy aimed at preventing workplace exposures and work-related cancer. The strategy consists of surveillance, laboratory and field research, identification of control technology solutions, and information dissemination. The OSH Act requires NIOSH to forward scientific information to OSHA in the Department of Labor for use in setting standards. This information is also used in many cases by EPA to guide its actions regarding environmental exposures.

OSHA regulates 18 substances or classes of compounds that are potential occupational carcinogens. Of these, 22 are specifically regulated

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as carcinogens and are identified with this label in commerce. NIOSH recommends that an additional 21 substances occurring in workplaces, also, be treated as potential carcinogens. These include substances currently being studied by NIOSH such as, asphalt, diesel exhaust, perchloroethylene and dioxin. Information regarding potential carcinogens is evaluated and disseminated regularly by several key groups. The National Toxicology Program (NTP) operated by NIOSH, the National Institute for Environmental Health Sciences (NIEHS), and the Food and Drug Administration (FDA) produces a biennial report on carcinogens. Carcinogen assessments are also published by EPA and by IARC, which issues and updates cancer monographs. This evaluative information to which NIOSH is a key contributor, is used by employers worldwide. It has an enormous impact not only on the protection of workers, but also on the entire field of cancer prevention.

While large companies with expertise in occupational health may be well-served by such available scientific information, small companies, unaware of dangers to employees, may not have access to this information or the resources to invest in workplace controls to reduce environmental contamination. NIOSH has attempted to bridge this information gap by making information available to both small and large businesses. The NIOSH *Pocket Guide to Chemical Hazards* has been the second

best-selling Government Printing Office technical publication since 1991. With more than one million copies distributed, it is widely used throughout the U.S. and in other countries. This Guide contains easy-to-use information about health effects, exposure limits, and protective equipment recommendations for about 670 chemicals.

NIOSH works with small businesses to evaluate hazards and to develop cost-effective control technologies. For example, in the past, asbestos was permitted to be used to insulate brakes in cars and trucks because substitute products are not as effective. OSHA requires strict control of worker exposures, and until recently the methods available were quite expensive. NIOSH identified several less expensive but equally effective approaches to control asbestos exposures during brake repair, including an inexpensive aerosol can. This device is now recognized by OSHA as a safe way to protect workers. We are currently working with small dry cleaners to demonstrate utility of new technology to reduce perchloroethylene exposures.

To know the level of exposure of workers, one must be able to measure the level of the chemical, dust, fiber, or radiation. Additionally, many workers are exposed to mixtures or combinations of chemicals such as diesel, asphalt, and metalworking fluids. It is sometimes difficult or impossible to measure the components to determine which particular component in a mixture is the carcinogen.

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The Role of Laboratory Studies

In an ideal world, molecular, *in vitro*, and animal study techniques would identify the carcinogenic potential of substances early enough so that solutions could be identified before workers were exposed. Long-term animal studies have played a major role in assessing potential carcinogenic risks for humans. However, these take several years, are costly, and usually assess one substance at a time. Molecular and cellular studies contribute to our understanding of mechanisms of carcinogenicity. However, at the present time, laboratory methods alone are not precise enough to fully predict human risk.

Today, the revolution in molecular biology is opening promising research approaches. Advances in understanding the mechanisms of cancer causation are beginning to improve the ability of scientists to use laboratory research to evaluate the carcinogenic potential of a substance and to describe the hazard to humans with ever-increasing accuracy. More research is needed on comparative mechanisms of toxicity to develop rapid and inexpensive systems to improve animal toxicity

tests. Validated biomarkers of exposure and effect should be developed to determine the human burden of chemicals and the possible health consequences. The tools of molecular biology should be used to explain interactions of chemicals with critical target genes and to develop accurate, inexpensive methods to estimate worker exposure to chemicals.

NIOSH strengthened its capability to protect today's diverse workforce with the opening of a new research facility in Morgantown, West Virginia. This new building provides state-of-the-art laboratory facilities in which NIOSH scientists conduct focused, applied, and preventive laboratory research, develop intervention programs, and design and implement effective methods for health communication. These investigators collaborate with researchers throughout NIOSH, colleagues in other agencies such as NIEHS, the National Cancer Institute (NCI), and EPA, and experts in other public and private institutions to apply the latest scientific research to workplace health problems.

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The Roles of Occupational Epidemiology Studies and Surveillance

Because we cannot rely solely upon laboratory studies to estimate human carcinogenic risks, we will remain dependent for the foreseeable future upon well-designed epidemiologic studies. The classic type of epidemiologic study used

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successfully to establish chemicals as a human carcinogen is the retrospective cohort mortality study. In this type of study, the numbers and causes of deaths among workers exposed to the suspected carcinogen are compared to deaths expected based upon the national rates or an internal comparison group. The data for this type of study include work history records, work process details and exposure data from the earliest years of the relevant chemical production. These studies often involve industrial hygiene measurements of exposures and require years of painstaking effort to estimate individual worker exposures for dose response analyses. NIOSH is well respected for its contribution made over the years by its numerous workplace studies to society's understanding of human risks from both occupational and environmental exposures. NIOSH studies of asbestos in manufacturing workers, dioxin in chemical workers, and radon in miners have provided evidence of carcinogenicity among workers that was used by EPA and other agencies to estimate risks to the general population.

Research is needed to improve the imprecise estimation of levels of exposure experienced by individual workers, often cited as the major limitation of these studies. Researchers need to develop new methods to address the paucity of exposure assessment approaches needed to support accurate epidemiologic studies in the complex environments of today's workplaces. Practical

measurement techniques are needed that can be applied at reasonable cost. There is a need for validated methods to measure exposure and total dose data directly from biological samples that can be obtained by relatively noninvasive techniques.

The public health term "surveillance system" refers to a data collecting system that monitors the occurrence of cancer (disease surveillance) or the distribution of exposures to potential carcinogens (hazard surveillance).

Disease surveillance systems locate problems, determine how frequently problems occur, plot whether they are increasing or decreasing, and evaluate whether prevention efforts have been effective. Surveillance systems provide an early warning to alert us to situations where epidemiologic studies should be designed. Substantial progress has been made in the last decade in developing occupational disease surveillance systems, such as, cancer registries and databases that collect and code occupational information from death certificates. Nevertheless, much remains to be done to improve the methods and the scope of cancer surveillance systems.

Hazard surveillance systems, which identify and quantify exposure of workers to carcinogenic chemicals, are less well developed than are disease surveillance systems. We have no national system comparable to EPA's Toxic Release Inventory

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(which shows what chemicals are being released into the environment) to inform us about worker exposures. Such a system would record worker exposures to carcinogens and allow earlier recognition of risks than systems that tabulate cancers after they have occurred. This information could be used to target interventions for high-risk groups.

The Occupational Safety and Health Act required NIOSH to establish a Health Hazard Evaluation (HHE) program whereby U.S. workers or employers could request an evaluation of potential health hazards in the workplace. Several years ago, NIOSH was asked by a union to investigate a seemingly high number of bladder cancers that had occurred at a New York State chemical plant. Workers were exposed to *ortho*-toluidine, a recognized animal carcinogen. To measure exposures of the workers for use in the epidemiologic study, NIOSH laboratory scientists developed a method to measure the levels of *o*-toluidine in urine. Working collaboratively with New York state personnel, NIOSH investigators used the New York Cancer Registry to identify bladder cancer cases among previous and current plant workers. The researchers found that workers employed more than 10 years in the process using *o*-toluidine had a 27-fold increased risk of bladder cancer. This finding provided the first evidence of human carcinogenicity. NIOSH recommended methods to reduce exposure to *o*-toluidine and

issued also an *Alert* to notify producers and users of this chemical that it should be controlled as a carcinogen.

The *o*-toluidine study illustrates the value of the NIOSH HHE program as a mechanism for identifying public health problems. Using a multidisciplinary team comprised of epidemiologists, industrial hygienists, analytical chemists, and other health professionals, NIOSH is able to rapidly disseminate practical information to protect workers.

The *Alert* issued following the *o*-toluidine cancer incident study illustrates one of the most powerful tools for prevention: the effective dissemination of information to those who can take direct action to reduce exposures. NIOSH notifies all workers of the results of the studies in which they participated. When there is a significant risk NIOSH notifies each individual by letter. The materials are prepared in cooperation with workers, unions, and management to effectively and simply convey the results of the research. Study participants receive the information they need to further protect their health by reducing exposures to occupational carcinogens.

The New York State Cancer Registry was essential to this study but New York is one of only four states that have registries old enough to be utilized in occupational cohort studies. In 1992, Congress passed legislation to create cancer registries in all states. Federal Public Law 102-515

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established the National Program of Cancer Registries. The law assists states to improve (or create) cancer registries that will collect standardized information about all cancers diagnosed in the state each year. The CDC has been charged with providing grants and expertise to help the states. This new national surveillance program requires the collection of information on the occupational history of individuals with cancer to the extent that such information is available from the same record. This information can provide an early and inexpensive means to generate and test hypotheses related to workplace-related cancers. The key to success lies in having appropriate occupational information on the medical records. Therefore, grants were given recently to Washington, California, Massachusetts, and New Jersey for demonstration projects to address issues in collection of occupation/industry data as part of the population-based cancer registration. NIOSH is providing consultation to staff at the state registries.

Better Technology is Needed to Control Exposures

The ultimate goal of occupational safety and health research is the reduction of worker exposures to hazards. Exposures to occupational hazards can be managed by the application of engineering controls, work practices, administrative policies, and personal protective equipment. Engineering controls

include substitution of a safe material for a hazardous one, design changes to equipment, ventilation, or modification of work methods to eliminate or reduce hazard. Changes in work practices, management policies, and training programs are examples of administrative controls. In some cases where it is not possible to maintain a healthy work environment, personal protective equipment, such as respirators and protective clothing, can isolate workers from the hazard.

Although, a great deal of research has been conducted to develop ways to control workplace hazards, there is a crucial need for increased research in control technology and protective equipment. Limited information exists to predict the effectiveness of existing or proposed engineering controls. Also, as new workplace hazards are identified, new control measures must be developed. Rapid advances in technology are dramatically increasing both the need for and new ways to provide improved worker protection. Robotics, computers, and satellite navigational systems may allow dangerous work involved in pesticide application and hazardous waste remediation to be carried out without exposure to workers. New materials in clothing could improve protection from hazardous chemicals. Micro sensing devices might assess workers' exposures to environmental contaminants, notify workers before chemicals seep through protective clothing and identify failures in contaminant systems.

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Risk Assessment

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Risk assessment is essential for setting occupational safety and health policy. Risk assessment is a process in which hazard, exposure, and dose-response data are evaluated to estimate whether a particular (generally low) exposure poses an elevated risk of disease. The risk assessment process has become increasingly formal and sophisticated over the past decade. Many support an expanded and more formal role for risk assessment in establishing national priorities and justifying regulatory actions. In occupational safety and health regulation, that process began when the U.S. Supreme Court ruled in the "benzene decision" [Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 , (1980)] that OSHA could not issue a standard without demonstrating a significant risk of material health impairment. The ruling allowed (but did not demand) that numerical criteria could be used to determine whether a risk is "significant". As a result of that Supreme Court ruling, risk assessment became standard practice in OSHA rulemaking for health standards, and quantitative risk assessments are preferred whenever data, modeling techniques, and biological understanding support their development.

It is remarkable to note the much higher level of risk that our society tolerates in the workplace relative to that permitted from environmental

sources. Substances producing environmental cancer risks are generally regulated to allow less than 1 death in 100,000 or even less than 1 death in 1,000,000. In contrast, substances generating workplace cancer risks are regulated, if the economic and technologic burden is not too great, to allow less than 1 death in 1,000. NIOSH recognizes the constraints imposed by economic and technologic considerations and uses a variety of approaches, including quantitative risk assessment, to describe the risks associated with a variety of workplace exposure conditions. Input from NIOSH partners has been critical in helping NIOSH to develop practical recommendations for workers and employers. For example, after receiving many comments from our partners regarding the utility of the NIOSH "no risk" recommendations regarding carcinogenic workplace exposures, we adopted a new exposure limit policy. NIOSH now recommends levels that can be feasibly achieved by engineering controls and measured by analytical techniques including but not limited to those exposure levels achieving "zero risk".

Research to improve risk assessment methodology is needed from a wide range of scientific disciplines. Innovative and practical approaches to modeling are needed. Research should be directed to the following areas: design of epidemiologic and toxicologic studies to improve assessment of exposure-response relationships;

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generation of more data on which to base models that address intake, distribution, metabolism, and elimination; development of biologic markers of exposures and effects; and utilization of existing data to ensure that human observations complement and validate risk estimates derived from animal data. Research is also needed to evaluate how successfully risk assessment estimates are used in risk management, communicated to the public, and perceived by workers and employers.

Occupational and Environmental Health Policy in the Future

Effective policies will recognize that environmental and occupational exposures are two sides of the same coin, and that investment in occupational research, control technology, and policy development can inform policies to reduce the environmental impact of workplace substances. The Environmental Health Policy Committee (EHPC) of the DHHS provides a recent model for this approach to policy. Chaired by the Assistant Secretary for Health, EHPC is comprised of the Directors of DHHS institutes and agencies responsible for occupational and environmental health as well as representatives of departments with special jurisdiction in these areas, including the EPA and the Department of Energy. This interagency collaboration recently brought a single federal voice to environmental radon and dioxin policies. In both

cases the science underlying the environmental policy decisions came from studies of exposed workers.

Until recently, there has been little research on the economic or social impact of work-related illnesses in the United States. Future policy decisions need solid data about the true costs to employers, workers, and society of occupational and environmental cancer. Although the costs are tremendous, both in human and economic terms, little attention has been paid to describing and measuring these costs. Developing and conducting research to fill this tremendous information gap will require collaboration with multiple partners in the occupational and environmental communities, including workers and their representatives, employers, and researchers in other federal and state agencies, academia and the private sector.

Partnerships are the Wave of the Future

Research in occupational and environmental health is conducted by federal and state agencies, academia, industry and labor unions, but there is always a need for continued coordination to set priorities. Additionally, both public and private sector efforts face increasing fiscal constraints. These financial challenges, in the face of the large burden of work-related disease, injury, and death led

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NIOSH to work with its partners in the public and private sectors to develop the National Occupational Research Agenda (NORA). Released on April 29, 1996, the 25th anniversary of NIOSH, NORA provides a framework to guide occupational safety and health research throughout and health research throughout the next decade, not only for NIOSH, but for the entire occupational safety and health community. This attempt to guide and coordinate research nationally is responsive to a broadly perceived need to address systematically those topics that are most pressing and most likely to yield gains to the worker and the nation.

The Agenda, which identifies 21 priority research areas, is a first step in what will be an ongoing, concerted effort to coordinate partnerships to conduct focused occupational safety and health research. The occupational safety and health community was broadly represented, with active participation by employers, workers, safety and health professionals, public agencies and industry and labor organizations. Approximately 500 organizations and individuals outside NIOSH contributed to the Agenda and its priorities reflect a remarkable degree of concurrence.

Although the Agenda was created for the occupational health community, many of the research topics apply directly to the needs of environmental agencies. Federal environmental agencies were also involved in creating the Agenda,

NORA Priority Research Areas

Category	Priority Research Areas
Disease and Injury	Allergic and Irritant Dermatitis Asthma and Chronic Obstructive Pulmonary Disease Fertility and Pregnancy Abnormalities Hearing Loss Infectious Disease Low Back Disorders Musculoskeletal Disorders of the Upper Extremities Traumatic Injuries
Work Environment and Workforce	Emerging Technologies Indoor Environment Mixed Exposures Organization of Work Special Populations at Risk
Research Tools and Approaches	Cancer Research Methods Control Technology and Personal Protective Equipment Exposure Assessment Methods Health Services Research Intervention Effectiveness Research Risk Assessment Methods Social and Economic Consequences of Workplace Illness and Injury Surveillance Research Methods

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including the EPA, the Agency for Toxic Substances and Disease Registry, NIEHS, NCI, and CDC's National Center for Environmental Health.

The research topics that apply in a major way to environmental as well as occupational cancer include the following:

- Cancer Research Methods
- Surveillance Research Methods
- Risk Assessment Methods
- Special Populations at Risk
- Exposure Assessment
- Mixed Exposure

Topics with some relevance include the following:

- Control Technology and Personal Protective Equipment
- Intervention Effectiveness Research
- Social and Economic Consequences of Workplace Illness and Injury

Implementation of NORA is underway. NIOSH has formed 21 partnership teams, one for each priority area. These teams include occupational safety and health professionals from industry, labor, academia, federal and state agencies. NIOSH is committed to working with these NORA partners to refine the research agenda and to stimulate research throughout the nation in each priority area, to use the Agenda to guide intramural and extramural funding decisions, to encourage and stimulate other government agencies to include NORA priorities in

their internal and external research programs, to develop procedures and capacity to track the impact of NORA activities on health and safety outcomes using existing tracking models, to update NORA, and periodically to review and communicate the overall role and effectiveness of NORA in occupational safety and health. The first annual NORA meeting is scheduled for July 1, 1997 at the National Academy of Sciences in Washington, D.C. Throughout the process of implementing the Agenda, NIOSH will seek to build upon and extend its partnerships to improve coordination throughout the national occupational safety and health community, with the expectation that these activities hold great promise for improving the protection and well-being of workers. The advances in occupational research will simultaneously benefit the environmental community.

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Summary

Despite major advances in reducing exposures to occupational carcinogens, progress in research on the carcinogenic risks to humans and on technologic control is not adequate. We do not know the toxic effects of most chemicals in use today and we do not know the precise numbers of workers or citizens exposed to carcinogens. Substances with unknown health consequences continue to enter the workplace and the environment. The economic and human toll of our inadequate knowledge and limited actions is

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likely high. Work remains to adequately address the special needs of small business. Laboratory and field research, and risk assessment methodology need improvement. Better systems to collect data and to disseminate information are needed. In sum, we are missing opportunities to prevent large numbers of cancer of many types. On the positive side, millions of workers have been protected from carcinogenic exposures. Occupational studies have helped to inform environmental risk management decisions. Molecular biology progress holds promise. Finally, a broad range of diverse stakeholders recently agreed on national research priorities for the next decade that will directly benefit the quality of occupational and environmental research.

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