# V. Health and Ecological Effects Research



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## **ISSUES LIST**

1.	LONG-TERM STUDIES
2.	POLLUTANT SCREENING
3.	COORDINATED HEALTH RESEARCH
4.	MAINTAINING QUALITY EXTRAMURAL RESEARCH
5.	NOISE RESEARCH
6.	INDOOR AIR QUALTIY

## V. Health and Ecological Effects Research

## INTRODUCTION

The ORD Health and Ecological Effects program is basic to EPA's mission to protect human health and maintain and enhance environmental quality. To provide a scientific basis for EPA's criteria, standards, and guidelines, the program must aim for an understanding of the total effect of a vast number of chemical and physical agents on man and the ecosystem, including possible interactive and synergistic effects. This chapter addresses six issues relating to Office of Research and Development (ORD) research on health and ecological effects.

## Long-Term Studies

Because present primary standards are based on incomplete health-effect data, longterm studies of the health effects of chronic, low-level exposure to pollutants need to be made. Parallel to this effort, sequential studies are required during and following incidents when there is a temporary, sharp increase in pollutant levels. Such studies would help put standard setting on a firmer scientific base, The effects of agents in the environment upon health problems such as cardiovascular and chronic respiratory disease should receive as high a priority as carcinogenesis, A method of following the population under study for 20-40 years needs to be developed. It is not clear whether these long-term studies are best undertaken by EPA or by another governmental agency such as the National Institute of Environmental Health Sciences, In any case, EPA should have a strong planning and oversight role. (Issue 1)

# Selecting Chemicals and Agents for Study

It is within the scope of the research performed by ORD to formalize a system for predicting the presence of a pollutant in the environment and to rank its relative potential for harm. (Issue 2)

#### Coordinated Health Research

Although the ORD 5-Year Plan does attempt to summarize the efforts of other Federal agencies in environmental and health research, the document fails to describe the mechanisms through which such research will be coordinated and results shared. (Issue 3)

#### Extramural Research

When a research group depends on EPA for continued financial support, there is a danger that contractor-scientists may be compromised by perceptions of EPA's regulatory policy. (Issue 4)

#### Lack of Noise Research

EPA/ORD apparently was not funded to do noise research, although this is part of their mandate. The research being conducted elsewhere in the Federal Government on noise effects on human is not sufficiently detailed in the Plan to assess its adequacy. Because of indications that noise may aggravate the impact of other pollutants, there is reason for ORD to undertake its own noise research program. (Issue 5)

## Indoor Air Quality

The EPA 5-Year Plan makes only a brief reference to indoor air quality, and then only in relation to health effects. It apparently neglects research on effective environmental management strategies for indoor air quality improvement. This is an area for EPA/ORD both to research and to coordinate the programs of other agencies (Occupational Safety and Health Administration/National Institute for Occupational Health and Safety (OSHA/NIOSH), HUD, Consumer Product Safety Commission). (Issue 6)

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## **ISSUES**

#### LONG-TERM STUDIES

#### Issue 1

Both long-term studies of chronic exposure and followup studies of acute exposures are needed to determine effects of pollutants which do not cause immediately apparent injury.

## Summary

At present, EPA asks: "What are the long-term effects on health of chronic exposures to pollutants?" and "are the present primary standards safe?" If EPA postpones starting long-term studies designed to answer such questions, we shall still be asking these same questions in another 20 to 30 years. Such studies imply a long-term commitment of funds, equipment, and personnel.

Parallel to this effort, specific investigations are needed during and following an incident when there is a temporary increase in pollutant levels. These investigations could help to answer the question whether acute episodes have temporary or permanent effects. These, in turn, may serve as a basis for long-term studies if the effects appear to be chronic.

It seems appropriate that such studies be included in a Federal environmental research program. Long-term studies are particularly important as a means to determine the critically needed dose-effect curves for low levels of pollutants in air or water.

#### Questions

- 1. What role do long-term studies play in EPA's research plans?
- 2. What are the major scientific and non-scientific problems in such studies?

- 3. Does EPA have plans to develop longterm chronic exposure studies? If so, what are the plans?
- 4. Does EPA have a plan to take advantage of opportunity-laden episodes?

If EPA plans such studies, the following specific questions might be asked:

- What parameters would ORD select to follow in the population?
- How would ORD propose to maintain contact with a population sample for 30-40 years?
- What criteria would ORD use to determine the pollutants to be studied and the timespan of the study?
- How would ORD insure that the levels measured truly represented the exposure or dose to the population? and
- What criteria would ORD use to terminate a given long-term study?
- 5. What is the present status of EPA's support of the Community Health Effects Surveillance Studies (CHESS) program? Is a thorough analysis of accumulated CHESS data contemplated?

## Background

Chronic degenerative diseases, including cardiovascular disorders, chronic bronchitis and emphysema, renal disease, and arthritis, are the major causes of death and disability in the United States. Evidence is accumulating that suggests there are significant environmental factors involved in the causation or aggravation of these disorders. Hence, there is a great need for better information on the effect of long-term exposures to pollutants on health over and beyond that of a possible carcinogenic effect. For example, present air



Cropdusting of sulfur on grapevines south of Fresno, California to retard mildew. Long-term effects that pesticides may have on the environment need to be determined.

pollution standards are almost totally based on acute pollutant effects, plus the inclusion of a safety factor. There is controversy concerning the stringency or inadquacy of each standard In some cases, slight alterations in primary air quality standards translate into billion; of dollars of control costs, potentially significance health effects, and possibly a sub - stantial impact on individual lifestyles. The inclusion in the standards of a safety factor below observed acute effects appears to be reasonable and prudent considering the relative absence of information concerning possible long-term toxicity. Accordingly, it is of utmost importance to determine whether exposure to pollutants at levelsapproximating

the current standards do or do not have an effect after many' years of exposure.

Rough approximations of exposure can be estimated from historical data, but are always suspect and imprecise. Thus, retrospective-prospective studies have limited value, though they can be used to develop hypotheses to be tested. Of greater potential value are prospective studies of defined populations for whom exposure levels are carefully monitored. Such studies will require a long-term commitment with respect to money, personnel, equipment, and planning. Because of the present commitment of EPA to respond to acute situations and external pressures to investigate a specific situation, EPA has not been able to develop a strong long-term research capability.

Long-term research to establish historical profiles is not only important in studying human health problems but also in determining impact on ecological processes. Long-term monitoring of various animal or plant species can detect changes in ambient conditions and can serve as an early-warning system, This can give EPA and other agencies the capability to identify the problem before it becomes acute and to take appropriate action.

Considerable information can also be obtained by studying effects during acute episodes. For example, an inversion and accumulation of pollutants occurred over western Pennsylvania. Another such acute episode recently occurred in the Los Angeles area as the result of an extensive fire. Such episodes can be exploited in more detail than they have been in order to obtain information on their immediate effects. A followup study after the pollution has subsided is also necessary to see whether there have been any long term effects or whether the changes, if any, were reversible. After the followup study, a decision would then be made whether to stop at that point or to continue with a more prolonged study.

Contingency plans are required that can be activated to respond to such episodes. Each one may require different techniques with respect to details, but the basic principles and modus operandi could be developed

beforehand. Studies of such events have been spotty. In the instance of the Donora, Pa., exposure, the study in 1948 and followup 10 years later have been good. In others, they have been inadequate or nonexistent.

Studies of the effects of long-term and acute episodes could be run as (1) in-house research with careful scrutiny by a qualified advisory committee, or as (2) an extramural project under grant or contract with similar advisory committee oversight, or (3) this responsibility could reside in another governmental agency such as the National Institute of Environmental Health Sciences (NIEHS).

EPA must develop a philosophy concerning long-term health research commitments which consider the balance of long-term and short-term studies, the support structure for these commitments, and the various mechanisms that can be used to guarantee continuity of the committed program.

#### POLLUTANT SCREENING

#### Issue 2

It is within the capabilities of ORD to provide EPA with information to more effectively predict and forestall future chemical environmental problems.

### Summary

Observers not connected with EPA were the first to bring several pollution problems to the attention of EPA and the public. Notable examples are vinyl chloride and nitrosamines in air and chloroform in water. This suggests the need to enhance the ability of EPA to detect and predict environmental problems, It is within the scope of the research carried out by ORD to develop a system for predicting pollutant existence in the environment and assessing its relative potential for harm.

To avoid undue duplication of effort, a program to select chemicals and agents for study should include, as a first step, the determination of the extent to which such hazards are under study by other agencies. Second, the understanding that a substance could on the basis of chemical and physical properties and environmental access represent a potential hazard should be used to screen suspects. At that point, research priorities could be assigned to the remaining candidates. The information derived from the screening and research program would be fed into the appropriate EPA program offices for determination of regulatory action or consideration for further effects or control technology research.

#### Questions

- 1. Presently, how does EPA/ORD make a determination as to when and under what circumstances a particular problem area will be investigated?
- 2. What priority does EPA/ORD assign to developing a pollutant-prediction capability? What is the state of development of EPA/ORD's capability to foresee environmental hazards?
- 3. What are EPA/ORD's present thoughts on the problems inherent in developing a continuously updated list of pollutants worthy of detailed examination and assigning research priorities to the potential hazards on the list?
- 4. How will ORD use and develop screening procedures in order to predict the effects of individual pollutants and combinations of pollutants?
- 5. What is EPA/ORD's estimate of the resources required to develop an effective early-warning system for environmental hazards?
- 6. How will ORD approach synergistic problems in specific ecosystems?

### Background

The basic elements of one possible pollutant screening system are as follows:

The first step is to determine qualitatively that a particular substance or its precursor will be emitted into the air or water or placed onto the land. Such information may be gathered from previously performed analyses of industrial effluent streams, domestic sewage sludges, or air emission streams. Once a listing of substances has been compiled, a qualitative assessment of their chemical reactions and transport is required in order to assess the distribution of the pollutant in the environment. The pollutant dispersion from emission points should be ranked according to whether it is widespread or localized in nature.

A toxicity ranking based on acute effects, dose-response toxicological studies, occupational studies, and biological monitoring data (if available) should be made. The pollutant then should also be ranked in terms of its emissions, its biosphere persistence, and its tendency to accumulate in the food chain, ground water, soil, sediments, or the atmosphere. The results of these rankings would assist in determining the pollutants which pose a more serious threat to society.

It is assumed that an interdisciplinary group drawn from various ORD research programs and familiar with appropriate sources of scientific literature would be responsible for screening. Once the rankings have been completed, the substances of greatest importance will become objects of new experimental research. One research sequence would include analysis of future emissions and their potential distribution. This would be based on economic and engineering analysis of the industrial use or generation of the substance or its precursor (s). Simultaneous research on control technology would also be done. Once emission patterns have been determined, research on the movement from the sources to the ecosystems can be carried out. Simultaneously, dose-response research with and without synergisms can be carried out. If the substance is already known to be in the environment, epidemiological studies should be done to attempt to understand the substance's effects on human populations. The research results would then be communicated to EPA program offices, where cost/benefit analyses would be performed at various levels of control for ultimate use in standard-setting procedures.

New pertinent information is continuously generated by EPA as well as non-EPA organizations. The determination of both the relative priorities of environmental problems, and the priority for studies and control efforts within each problem area should be subject to extensive ongoing review so that EPA does not become locked into unneeded research and can respond to newly perceived problems.

We recognize that in establishing priorities for R&D, EPA is generally dealing with imprecise areas. In assigning such priorities, EPA will have to exercise sound judgment in interpreting existing data as well as including many other factors besides obvious ones such as acute effects and environmental dispersal. Decisions concerning R&D expenditures will require not only estimates of potential harm but also insights into the likelihood that the proposed research will pay off. Moreover, the difficulties in establishing priorities for research among known harmful agents are different than those inherent in detecting unrecognized environmental toxicants.

## COORDINATED HEALTH RESEARCH

#### Issue 3

The ORD 5-Year Plan does not describe the mechanisms through which interagency environmental and health research planning will be coordinated and results shared.

## Summary

EPA is charged with coordination of the environmental-related activities of Federal agencies. Although the ORD 5-Year Research Plan does attempt to summarize the efforts of other Federal agencies in environmental and health research, the document fails to describe the mechanisms through which such research will be coordinated and results shared. Effective coordination is vital in order to avoid unnecessary duplication of research and to iden-

tify relatively neglected, but important, areas of research.

#### Questions

- 1. How are interagency activities in environmental health research coordinated to insure that significant hazards are addressed by the proper agency in a timely fashion?
- 2. What procedures are in force to avoid unnecessary duplication of research?
- 3. What role should ORD play in the field of carcinogenesis research, and how does this role fit into the entire Federal carcinogenesis research effort?

### Background

Several Federal agencies in addition to EPA have extensive environmental research programs. The total budget to support these programs has been estimated at \$1.3 billion. EPA has a research budget of \$257 million, with approximately \$100 million assigned to health and ecological research.

Although EPA has been charged with coordinating the environmental research of other Federal agencies, it is not clear from the 5-Year Plan what coordinating procedures are in place or how well they work.

The identification of projects already underway or in the planning stage would avoid unnecessary duplication of effort. On the other hand, there are some cases where the nature of the scientific work or the importance of the information are such that some deliberate, informed, selective duplication is advantageous. It is as important to identify programs where duplication and verification are necessary as those where it is wasteful. These considerations are particularly applicable to ORD's planned entry into carcinogenesis research.

A close coordination with another agency could often allow EPA to obtain information pertinent to its mission. For example, there are a number of potential public health problems described in the EPA/ORD document where useful information could be obtained by studying the work force in facilities producing

the polluting agent. Such studies may be given a relatively low priority by NIOSH in terms of their total mission, perhaps because of the relatively small size of the work force. There should be some mechanism to insure that occupational health or other studies pertinent to the general population are not overlooked because of formal agency boundaries.

It is also vital for EPA to maintain a capability to react quickly to newly identified significant hazards in concert with other agencies. One can be reasonably certain that during the next 5 years some urgent environmental problem will develop that is not foreseen in the EPA/ORD document and that, although within the responsibilities of EPA, will require input for its solution from non-EPA scientists.

## MAINTAINING QUALITY EXTRAMURAL RESEARCH

#### Issue 4

Because contractors for extramural research are limited, continuing relationships with particular contractors tend to develop from repeated use and may lead to the loss of independence among such contractors.

## Summary

If EPA is to obtain an objective scientific base to support its regulatory responsibility, these data must be carefully constructed and managed. The presentation of these data must openly acknowledge the weaknesses as well as the strengths of their design, collection, and analysis. Because such information, by its very nature, never provides unequivocal and absolute conclusions, it must be subject to continuous review. This review process should aid in defining the relative magnitude of the environmental problem, the scale of future allocations of resources for its study, and the appropriateness of existing or proposed regulations. The mishandling of any of these issues can have serious ecological and economic consequences.

To meet these concerns, objective scientific review is imperative. However, the reality remains that the scientists involved might be compromised since the economic survival of their research organization may become largely dependent upon the Agency's continued support. Given the limited availability of professionals, recommending expansion of such a resource pool neither resolves present needs, nor is it necessarily feasible or even desirable. With the range of individual and organizational expertise and skills that inevitably emerge, choosing those most competent may once more lead to a narrowing of the potential advisers. Exploring alternatives probably will require careful examination of the EPA as both the provider and consumer of environmental scientific data in its primary role as a regulator. Totally divorcing such a research capability from the enforcement agency may, however, produce other impediments to the ultimate goal of protecting environmental quality. To pursue long-term research in some areas of basic environmental science requires that EPA assist in developing contractor capabilities where none exist. This implies a long-term commitment to some contractors.

#### Questions

- 1. Given the limited number of nongovernmental research resources of quality, what mechanisms are employed to assure that an objective, independent response to EPA needs are obtained?
- 2. If nongovernmental researchers were funded by transfer from another agency, how can one be assured that such an agency would continue to provide support if it perceives these activities to be peripheral to its own mission?
- 3. Given the temptation to extend analyses beyond the limits of the data bases and to exclude or emphasize data consistent with perceived or explicit policies, how can the researchers producing such data provide an objective presentation of their work? How can

they provide independent opinion without risk of jeopardizing their continued fiscal support?

## Background

Perceived policy goals, whether responsive to explicit agency mandates or to supposed positions, will tend to subtly mold the viewpoint of a researcher. This is especially true where positions become specific as in rulemaking and the standard-setting processes. At one extreme, the viewpoint of contractor-researchers may be influenced by their own internal biases rather than by a customer agency. At the other extreme, the establishment of a standard (and, inter alia, the procedural impediments to its subsequent adjustment) may impair objectivity if, for example, data contrary to a stated EPA position are subsequently generated by con tractor researchers. In other words, the scientists may tend to develop a "vested interest" or an emotional commitment to the standard that they have helped establish. Present realities of fiscal support of university-based researchers do not preclude such conflicts if these scientists are used as contractors.

Alternative approaches should be considered, although their inherent shortcomings must be recognized. If research activities are "passed through" to other agencies, without regulatory responsibility, the newly responsible agency may regard such an acquisition as dissipating its total resources. Even if required by statute to provide continuing support, future fiscal exigencies may imperil research activities. The flow of data output may be impeded by organizational channels not geared to regulatory needs.

In sum, unless objective scientific data are forthcoming, environmental regulations being established, *or* already in place, will not be readily open to reassessment or change in the light of new information. The quality of objectivity need not be distorted by bad intent or even conscious desires, but its subtle impairment can influence the substance of regula - tions.

#### NOISE RESEARCH

#### Issue 5

Despite the passage of the Noise Control Act of 1972 which authorizes EPA to conduct and coordinate research programs in environmental noise, EPA/ORD is not presently studying noise, nor does its Research Plan propose such research.

## Summary

Noise causes behavioral, psychological, and physiological changes in humans and animals, and may through such changes alter the susceptibility of organisms to other pollutants. As a potential modifier of the impact of other pollutants, noise deserves study by ORD despite the presence of analyses of the effects of noise itself by other agencies. Moreover, although the hearing ranges of animal species differ and their susceptibility to direct noise impacts probably diverge, there appears to be no Federal research involving the effects of noise on species other than man and selected laboratory' animals.

#### Questions

- 1. Does EPA feel it has sufficient information on the human health and psychological effects of noise to promulgate and enforce reasonable regulations on noise?
- 2. Does EPA think it has sufficient coordinating authority, and that sufficient funds exist within the Federal establishment, to secure further information needed to establish and enforce noise regulations?
- 3. To what extent are possible interactive effects between noise and other pollutants being investigated?
- 4. Why is there no mention of noise research in the EPA Research Plan?
- 5. What has EPA done to evaluate the responses of wildlife to noise, particularly at frequencies which are inaudible to man?

6. What has EPA done to evaluate the effects of sudden irregular bursts of noise such as sonic booms on wildlife?

## **Background**

Americans inhabit an environment in which noise levels have been rising as inexorably in recent decades as have other forms of pollution. The potential magnitude of noise impacts in routine life is exemplified by recent data which found teenagers to have hearing loss comparable to that of a 55-year-old group. While this hearing loss was surely in large part self-inflicted by voluntary exposure to excessively amplified sound, it means that such groups have little margin of safety with respect to hearing, because the effects of noise on hearing are cumulative and irreversible. Preliminary NIEHS data have indicated that noise can aggravate the adverse effects of chemical pollutants in laboratory animals. The adverse effects of certain kinds of noise on reproduction of chickens and lactation in cows have also been observed, Wildlife populations can be disturbed significantly in mating, reproduction, and other behavior by the noise from construction (e.g., Alaska pipeline), off-the-road vehicles (e.g., southwest desert), transportation (SST's, cars), and other sources. Aquatic organisms, like whales and dolphins, can also be substantially disturbed by noise. Noise and inaudible vibrations may be an important contributor to psychological and physiological ill health, work efficiency loss, and other effects.

Research may be needed on effects of noise on wildlife because none now exists within the Federal establishment, despite its importance to the survival of wildlife populations. Animals do not sense noise in the same way as humans do. Rather, they respond to a different set of frequencies, and often in different and more dramatic ways. Regulation controlling the noise generated by machines adequate for human protection may not be adequate for wildlife (e.g., off-the-track vehicles).

At present, EPA has no research program on noise. It is entirely dependent on what

other information may be available on this topic, and seems ill prepared to respond quickly to problems of environmental noise which may arise. Unless some further attention is paid to problems of general noise, annoyance of sonic booms, and other noiserelated questions, the importance of these factors in human and ecosystem health will remain unclear. The research being conducted elsewhere in the Federal Government on noise effects on human health is not sufficiently defined in the Plan to enable an assessment of its adequacy. In particular, it appears that EPA has the clearest responsibility to appraise the psychological and esthetic impacts of incongruous noises upon the environment.

### **INDOOR AIR QUALITY**

#### Issue 6

Although ORD has stated that it will study indoor air quality, the Plan does not disclose the size, distribution of research effort, or techniques to be used.

## Summary

According to the 5-year Plan, ORD will study indoor air quality. However, neither the magnitude nor the distribution of research efforts are clear. Moreover, there are no apparent plans to investigate techniques for indoor air-quality improvement. Some effort should be committed to investigating impact and possible control of toxic air pollutants either released in, or accumulating indoors. Studies could be made of ways to reduce indoor air pollution levels through improved building and ventilation system design, the restriction of toxic-vaper-generating products, and attention to interior furnish i rigs. Interactions between indoor pollutants and nonpollutant factors such as air temperature, humidity, and air movement in relation to health effects should also be studied. In addition, there is evidence that tobacco smoking may be an important source of exposure to carbon monoxide, respirable particles, nitrogen oxides, and airborne carcinogens to smokers and nonsmokers alike.



Noise Pollution: Noisy construction equipment such as the type being utilized here by a Washington, DC. construction worker is common throughout the United States.

### Questions

- 1. What overall priority will EPA assign to monitoring indoor air quality and to finding effective management strategies for its improvement?
- 2. What will be the distribution of effort within the indoor air-quality research

program between research on health effects, and the development of effective management programs to improve air quality?

3. What steps does the EPA plan to determine the seriousness of the release of toxic agents and how to control it? Similarly, what investigations are underway to examine the

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#### **Health and Ecological Effects Research**

accumulation of outdoor pollutants indoors, as, for example, the buildup of jet fuel fumes in airport terminals?

- 4. What emphasis should be given to the contribution of tobacco smoking to indoor air quality relative to other sources?
- 5. What steps will be taken to broadly disseminate the results of such studies?

## Background

Despite progress in cleaning the ambient air outdoors, Americans continue to be exposed to adverse air conditions indoors.

At present, the focus is upon industrial plant atmospheres, but other indoor working environments-such as offices, garages, other service shops, laboratories, warehouses, and stores—also come under the jurisdiction of OSHA and may ultimately be regulated. Indoor air quality in the home is the sole research responsibility of EPA, but there are other physically confined space areas which must not be forgotten. For many public buildings such as schools and theaters which are technically workplaces for a few but are occupied by a much larger number of persons, research responsibility is presumably shared between EPA/ORD and OSHA/NIOSH. Even for industrial plants the responsibility is shared between the two agencies. Exhaust fumes from such plants can be hazardous to the ambient air. This was probably first recognized in the case of beryllium-using plants during World War II. Since then, asbestos, vinyl chloride, and arsenic emissions have also ceased being solely matters of occupational concern.

Nonpollutant factors in indoor air quality, notably temperature, humidity, and air movement, possibly have a greater influence on health, especially the upper respiratory tract, than is generally realized. Research is needed into this area.

There is also considerable potential for toxic pollutant exposures in the American home. Millions of Americans are sporadically exposed indoors to high concentrations of toxic vapors and particles from domestic cleaning fluids, floor polishes, and fresh paint as well as from pressurized aerosol sprays which can be retained in the deep lung to produce pneumoconioses. Asbestos fibers, of proven carcinogenic properties, can become suspended in the domestic air from exposed insulation of boilers and pipes, from the incorporation of asbestos in domestic building and surfacing materials, and from the use of some brands of talcum power in the bathroom. Potentially dangerous aerosol sprays are used in confined spaces (kitchens and bathrooms) by three-fourths of the adult population. Cigarette smoke contains particulate and carbon monoxide which are of potentially toxic significance to exposed persons in confined areas. Domestic cooking and heating devices are potential sources of nitrogen oxides and carbon monoxide.

Very little is known about how to encourage safe use of toxic products in homes and schools. The EPA could exercise leadership in this area through public education, air management in Federal public buildings, and recommendations for building design and ventilation. EPA's Office of Toxic Substances should provide data to FDA and the Consumer Product Safety Commission on regulation of the contents of products to be used in the home, including the proscription of certain constituents, the limitation of others, and precautionary labeling. Development of cheap, portable pollutant-monitoring devices would be of great value in ascertaining the extent of indoor air pollution.

The current EPA research Plan conveys no sense of the priority regarding these problems. If they are not vigorously addressed, costly ambient air cleanup efforts may yield fewer health benefits than anticipated in improving human health.