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THE NATURE AND EXTENT OF SCIENTIFIC KNOWLEDGE

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March 19, 1984

There are four myths that abound in this country of ours concerning the potential health problems associated with low dose chronic human exposure to toxic substances in our environment. The myths are that:

- These problems can be solved by hands on physical examinations of individuals.
- These problems can be solved by establishing registries of all individuals exposed to hazardous substances.
- These problems can be solved by the collection of information on the occurrence of diseases in all individuals and the analysis of this voluminous set of data.
- The scientific process available for studies in humans can give conclusive cause and effect information for an individual's state of health.

However, the fact that I recognize these as myths does not mean that I think we cannot reasonably estimate risks from exposure among population groups.

Over the past decade, scientists have expended many millions of public and private research dollars in efforts to investigate and understand the complex relationships between human health and exposure to suspected environmental pollutants. The basic tools for this ongoing search are laboratory studies in

animals and epidemiologic studies on humans. Properly done, animal experiments and epidemiologic studies provide a basis for identifying associations between various human health risks and environmental factors, from which public health and environmental protection policies are developed to minimize the risks to current and future populations. Information obtained from the use of these tools--animal toxicology studies, and human epidemiologic investigations--have been misapplied in many instances to diseases in individuals because of a failure of the scientific community to make clear the nature and the limitations of our knowledge about environmentally related health risks. We know there is an imminent threat that this knowledge will be misunderstood and misapplied by those who do not understand the process and want to use it for other purposes; we should be careful to prevent that from happening.

A number of diseases exist which are known to be caused by exposure to certain chemical or physical agents. For some diseases, there is no other known cause. Such diseases include asbestosis, radiation sickness, Caisson's disease (decompression illness), and mesothelioma, which is usually caused by asbestos. Most documented frank illnesses caused by chemicals are encountered as (1) occupational diseases; (2) effects of mishandling or overexposure to pesticides including germicides; and (3) acute and chronic poisoning episodes (e.g., those involving arsenic, mercury, and lead).

In the case of some other illnesses, the chemical-disease link is strong, but not unique. Vinyl chloride causes a rare cancer of the liver, the

Two areas present us with some of the most complex and perplexing scientific problems faced by public health officials today. These are related to the establishment and maintenance of registries of exposed persons and to determining the relationships between exposure to toxic substances and illnesses. We are attempting to answer the question: What are the increased risks of long-term health effects to persons exposed to hazardous substances? One of the most commonly recommended tools for studying the chronic or long-term effects of exposure is to construct a registry of persons exposed. The persons in the registry can be tested periodically to determine their health status and eventually to determine the cause of their death.

Registries cannot be used to give quick conclusive answers to the many questions that people ask about the effects of toxic chemical exposure on their health, the health of their families, or the health of their future children. Even the most active and aggressively pursued studies using registries may require decades to produce meaningful results. It is also true that even when the results of long-term studies are made available, the findings are likely to be hotly debated by scientists who honestly represent different points of view. Other important limitations of registries are infeasibility due to mobility and privacy and inability to detect conditions with a low attack rate after exposure; even cost must be considered. I point out these inherent limitations in registries to call to your attention the fact that expectations for registries being used as tools to answer in the near future the questions before us today may be unrealistically high.

Some questions are:

- What measures of exposures should be used to set guidelines for eligibility for inclusion in a registry?
- To what extent are people willing to participate over the course of a lifetime in active followup registries--a constant, stressful reminder of the fact that they were exposed to a toxic substance?
- How can we assure that a commitment made today to establish and maintain a registry will be carried through over a period of 10, 20, 30, or 40 years?
- What level of followup is necessary, scientifically, to provide estimates of risk which can then be used to make sound decisions to manage the risk?

Even with these limitations, the Public Health Service has a commitment to the use of registries, where appropriate, to attempt to clarify the link between toxic exposures and adverse health outcomes. We now have a group trying to determine where they are appropriate.

We are likewise committed to use the other tools at our disposal --epidemiologic and other--to demonstrate the links where they exist. Many of the epidemiologic tools, unless impeccably used with large enough populations

will yield inconclusive results--neither positive or negative. Unfortunately some people will use inconclusive results that tend toward the negative as definitely negative results; others claim inconclusive results which tend toward the positive as unequivocally positive results. Both are incorrect. Inconclusive results are simply that, inconclusive!

What becomes evident is that many factors influence the development of disease. Since some illnesses, including many cancers, may have latency periods of 20 to 40 years; and since in general, environmental exposure to man-made chemicals has been at relatively low concentrations through a variety of routes--that is, inhalation, ingestion, absorption through the skin--it is presently impossible to determine for the individual precisely what events led to the development of disease. The state of the art in medical science or epidemiology is not such that we can predict with certainty whether a person who has been exposed to chemicals will ultimately develop a particular disease or condition. In most cases then, the conclusion must be drawn that the scientific data base presently available does not permit with certainty a determination of whether exposure has a causal relation to illness occurring in an individual or not. Presently available data do provide sufficient evidence to reduce exposure, and thus possibly prevent disease in the future. There is a reason for this dichotomy between prevention and attribution of cause. The studies which generate information about the chronic low dose toxic effects of chemicals do not permit predictions with full confidence about the health of an individual, but rather only about the health of a population and what the degree of risk a given population will run if it continues to be exposed.



Proper use of the scientific data can lead to important collective public health benefits; use of the data for that purpose would be both responsible and just. On the other hand, to press such data into service to respond to causal effects for an individual's disease holds high potential for misuse of the data.

Epidemiologic studies almost never prove cause and effect, though in a few instances reasonable people would accept them as such. For example, in looking at the pathway of exposure and body burden, the association of the reduction of lead used in gasoline production and the reduction of mean blood lead levels in the U.S. population. Over a 4-year period when the lead phasedown in gasoline was occurring, we were conducting a study of blood lead levels in the U.S. population, the Second National Health and Nutrition Examination Survey. Two things, declining blood lead levels in children and lead used in gasoline production, were associated with a correlation coefficient of .95; this could have occurred by chance in less than one in 10,000 times. We removed over 200 possible confounders from the association and the coefficient did not appreciably change.

Yet many said this did not demonstrate cause and effect. We agree! The only way in this situation to conclusively prove cause and effect would be to place children in chambers breathing air contaminated with differing lead levels and then measuring the blood lead levels in these children. Fortunately, we live in a society where this kind of study is not possible! It is not ethical to purposely expose individuals to hazardous substances. Studies done in humans must use only inadvertent exposure where that occurred.

We will continue to respond to specific incidents of human exposure to toxic or hazardous substances. We will also continue our efforts to measure both the immediate and long-term health effects and to make sound recommendations for the attenuation of the risks.

Although the results of our studies may not provide the conclusive answers about health risk which are so much in demand, we have hope that we can demonstrate strong associations, where they exist, between exposure and adverse health outcomes so that reasonable people can take reasonable actions to protect public health and the environment. Thus, we see the public health role as primarily one of prevention. Causal attribution in an individual must be done with great caution and except in rare circumstances cannot be done with certainty when the exposure has indeed been of the low dose, chronic form.