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The scientist and health information: responsibility of the scientist

ROBERT E. ECKARDT, M.D., Ph.D.
Consultant
7355 E. Claremont Street
Scottsdale, AZ 85253

This has been, perhaps, one of the most difficult papers I have ever attempted to put together. At first I thought the assignment would be easy, but the more I thought about it, the more difficult it became. As a result, an empty pad of paper has been sitting on my desk top for weeks, waiting for thoughts to gel.

As a starting point, I think the first responsibility of the scientist is to himself. Throughout recorded history, scientists have been persecuted and even executed, because what the facts that they saw told them was considered heretical by others, or by society in general, because others did not know the facts known to the scientist, were incapable of understanding the significance of the facts, or refused to accept the facts for religious, superstitious, personal or a great many other reasons. Whatever the reasons, however, the scientist had to keep testing hypotheses with properly designed experiments and from the facts so developed construct concepts whether popularly received or otherwise. I don't believe the responsibility of the scientist has changed all that much over the years. I still believe that the first responsibility of the scientist is to himself, but obviously his responsibilities do not end there. I did not have the privilege to see what Dr. Reingold would be saying in his keynote address (this symposium), but the differences which arise between scientists do not arise, in most cases, over whether facts should be developed, but only in their interpretation and "misinterpretation."

It is probably fair to say that we will never produce enough health information. We can always use more, so that we will have to be prepared to extrapolate, introduce judgmental decisions, and otherwise arrive at interpretations of the significance of health information based on inadequate and incomplete data. We further must operate on the assumption that what is accepted as fact today may well become tomorrow's fallacy. I remember very well that at the time I was finishing my medical residency training, it was almost considered malpractice not to anticoagulate a patient who had had a coronary occlusion. This was based on a cooperative study coordinated by Dr. Irving Wright of Cornell-New York Hospital. Everyone thought that Dr. Wright's data were foolproof and ironclad. Yet today, as a result of the development of additional data, it would probably be considered malpractice to anticoagulate such a patient. It is this continuing flux of new facts and information, which leads to our having to do an about face perhaps once, or even more often, within a single lifetime which makes the health field so dynamic and interesting.

Man began to use energy for his own comfort and safety and probably also to his own detriment, before there was such a thing as a scientist, let alone a health scientist. He found that fire could be used to keep him warm, cook his food, and at times scare off animals that might be menacing his well being. But at times it smoked up his cave and made him choke and cough, and in light of what we know today probably had long-term effects on his health that he was totally unaware of, or perhaps because of his short survival time, he did not live long enough to develop those long-term effects.

The greatest need for health information in relation to energy production is good, sound epidemiologic data on humans. All of us know, I believe, how difficult this is to come by. The famous CHESS studies carried out

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by EPA were well intentioned and well conceived, but still came up far short of the goal of providing us with sound and reliable epidemiologic data upon which sound decisions could be made without a judgmental component. Perhaps the state of our epidemiologic basic science, or knowledge, is such that we may never be able to develop the epidemiologic information we need from general population studies.

We may then be forced to go to limited population studies, in which limited groups in the population are studied for health effects. My epidemiology friends tell me that such studies can be very dangerous because biases may be introduced into them, which may go unrecognized. One such limited group, of course, is the occupationally exposed group. In spite of the fact that many people refuse to acknowledge the usefulness of data obtained from the occupationally exposed worker, very helpful data have in the past arisen out of careful observations on this group. Obviously certain precautions need to be observed when using such data, not the least of which is an awareness of the so-called "healthy worker effect." Nonetheless, many environmentally caused health effects have first appeared in those occupationally exposed, including asbestosis, lead poisoning, gynecomastia in males excessively exposed to estrogens, and others. Often the diagnostic procedures useful in defining a particular disease, and therapeutic measures have first been developed in this group and subsequently applied more broadly. I am well aware of the fact that the occupational medicine record of the past has left much to be desired in some cases, but in other situations important progress was first made in this field. I am not claiming that such data are a panacea. I am only suggesting that where good data exist, they are not to be overlooked or ignored completely. More and more companies today are establishing well-qualified medical departments which may contain, in addition to physicians, toxicologists, industrial hygienists, and epidemiologists. I predict that out of these departments, more and more useful information will come in the future, and there will be less and less cause to look at such data with skepticism and disbelief. Industry, I think, has learned a very useful and bitter lesson from its past attempts to hide or cover up health difficulties that have developed among its employees. Further, occupational physicians, through their major professional society, the American Occupational Medical Association, have written themselves a code of ethics, which hopefully will overcome some of the difficulties they have encountered in the past. It is interesting that the American Management Association, in its publication, The Forum,[1] took cognizance of this code of ethics. This article also states that several occupational physicians have had to quit their jobs over ethical disputes, indicating that the code may be having some of the desired effects anticipated from it. Distressing to the occupational physician, at least, in this publication is the observation that medical policy is determined in the company boardroom, and maybe not all companies will be willing to accept and adopt this code of ethics for their physicians. If this be so, then the occupational physician, whom I class with the scientist, has a responsibility to mount an educational campaign that will convince most corporate boards that a code of ethics like this is truly in the corporation's best interests.

If general population studies or studies of limited population groups do not produce the necessary health information, then we shall have to rely solely on the results of animal studies. In today's world, it is likely that any major change or new development will have been subjected to at least some animal testing. In many cases this may be inadequate animal testing in terms of quantity, and sometimes even of quality. If the animal toxicological studies have been designed by a nonhealth (or nonbiologically) oriented individual they most assuredly will be deficient. This is particularly true if they are designed by the engineer, chemist, or scientist responsible for the new development. There are many reasons for this, but over the years I have become convinced that the most important is that the developer wants to make his new development as profitable,

either for himself or for the corporation for whom he works, as possible. He therefore looks on toxicological data as an increased development cost, the necessity for which, because of his background, he cannot fully comprehend.

The toxicologist, or other biologically oriented individual, who is advising the developer of a new idea or product, first needs to sit down with him and accumulate of a lot of information himself. What is the nature of the new development (or product)? How will it be made? What chemicals and/or catalysts will be involved? Are there intermediary chemicals involved, and if so, what happens to them? What is the size of the potential market? How will it be used? Are there waste products, and if so, what will be done with them? How does it react with other chemicals or materials? What happens to it when it is subjected to heat?—and many other questions. In other words, the biological scientist needs to know as much as is known about the new development or product, and may even have to suggest that additional information be developed. Based on this information, the biologically oriented person can then begin to design animal and/or other toxicological studies, which are adequate in both quantity and quality. As I outlined in the *American Journal of Public Health*,[2] the extent and nature of such toxicological testing will vary depending on the various factors outlined above. In addition, since 1970 new toxicological testing has been developed as a result of advances in basic science as outlined by Dr. Kraemer (this symposium). Such advances are going to continue into the future and an additional responsibility of the biological scientist will be to keep abreast of these new developments. As warranted, additional or modified tests will have to be added to those which previously were considered standard. After thalidomide, teratogenesis tests were added in some circumstances. Many laboratories, including those in industry, are evaluating a whole new battery of toxicological tests including various mutagenic tests with bacteria, direct- or host-mediated, cell transformation, DNA damage and repair mechanisms and others. If there has been some reluctance on the part of some people to embrace immediately all such tests, I think it is understandable. Dr. Ames and his coworkers, for instance, use several modified strains of Salmonella, and over the years their recommendations as to which modified strain or strains should be used have changed. It is my understanding that they are still working on additional modifications of strains, so it can be anticipated that their recommendations will continue to change in the future. Others use a series of strains of E. Coli. Still others use Neurospora. Some tests which are positive with Salmonella are negative with E. Coli or Neurospora and vice versa. If this is true, and if all bacteria have the ability to mutate, and there are perhaps a million different bacteria, it is easy to see why some people are reluctant to embrace such tests with impassioned fervor. I am sure that in time these problems will be resolved, but I think scientists have a responsibility to recognize that such problems do exist, and not be overcritical of those who may be moving more cautiously.

It used to be that when toxicological (or health) information was developed nobody heard about it or knew of it. True, some of it was published in the literature, particularly if it was important that a company warn its customers, its intermediary handlers, or perhaps even its competitors, if they were in the same business. Actually customers and intermediary handlers could be informed through product information brochures, but often a section on toxic properties or hazards was left out of such brochures. Competitors in the same business were often told verbally at trade association meetings. But if these data were interpreted to be negative, it was quietly filed away and no one heard of it but the company that developed it. Some scientists thought that this was not a desirable practice and there was much talk at one time of a "Journal of Negative Results." The principal journals that were used, if publication did occur, were the *American Industrial Hygiene Association Journal*, the *Journal of Occupational Medicine* (then called *Industrial Medicine and Surgery*), and the *Archives of Environmental Health* (which has gone

through numerous name changes over the years). Today, numerous other journals have appeared, not the least of which is *Toxicology and Applied Pharmacology* (the official journal of the Society of Toxicology, which was not even in existence then). About the mid-50s, under pressure from the government, much more extensive labeling, and much more extensive information on the label began to appear on almost every product. In fact, there were those who predicted that over-labeling would defeat the original purpose of labeling, and I have no doubts that in some situations this did occur, and still does occur. Intensive campaigns by FDA and others helped this situation some by encouraging people to read the label. Today, however, with the passage of the Toxic Substance Control Act, it is going to be necessary to report all data, positive and negative, to the government. Additionally, the data will be reviewed by others, presumably disinterested parties, for their adequacy in quantity and quality. What does worry industry, including the biological scientists in industry, has been alluded to earlier in this paper. No matter how many data we have, we will never have enough so that decisions can be made without judgmental inputs. It therefore could be very easy for governmental regulators to insist on more and more data to the point that new developments are stifled. There are those who believe such has occurred in the field of new drug development in this country. Whether the charge is justified or not, I am not in a position to evaluate. It is, however, a factor that must not be ignored, and the regulators in Washington or elsewhere must be made aware that at some point they will have to make judgmental decisions even in the face of what may be considered incomplete data. Obviously some of these decisions will be contested because they will find respectable scientists supporting both sides of the argument. Such dichotomy may be perfectly sensible, and scientists should be able to recognize the legitimacy of other scientists who do not agree with their own interpretations. I think a good example of this is the dispute that has raged for several years now about the use and/or dangers of use of oral antidiabetic drugs. The results of the cooperative university study suggest that diabetics who use such drugs suffer a higher mortality than those who use insulin, or who control their diabetes by diet alone. Almost to a man, the diabetologists have disputed the findings of this study and defended the use of some of these oral antidiabetic agents. Can it be that all of them are wrong? Or is it more likely that there may be some legitimate grounds for disagreement. Perhaps only time will answer those questions. but I do not believe that name-calling will add much to the solution. Thus, I think scientists have a responsibility at least to listen respectfully to other scientists who may not share their views. As I pointed out in a recent editorial in the *Journal of Occupational Medicine*,[3] there is a tendency on the part of some regulators to force their own decisions through three tactics, which scientists should avoid. These approaches are: obfuscation of the facts, smear tactics, and the creation of strawmen.

Summing up, then, I would say the scientist has several responsibilities. First, he has a responsibility to himself. Second, he has a responsibility to design meaningful, epidemiological studies, recognizing fully their limitations and shortcomings. Third, if epidemiological studies seem impossible or impractical, he has a responsibility to design meaningful animal, or other organism, toxicological studies of adequate quantity and highest quality. Fourth, he needs to interpret such studies and their significance in an unbiased and honest fashion. Fifth, he needs to keep up with the newer developments in his field, acknowledging when such developments may have their own limitations and deficiencies. Sixth, he needs to review his data and interpretations with other scientists, soliciting their differences of opinion when compared with his own. Finally, he must acknowledge that other scientists are going to disagree with him, that such disagreements may be perfectly legitimate, and he must resist the temptation to name-call.

references

1. **Anonymous:** A Code of Ethics for Company Doctors: New Grist for Management Policy-makers' Mills. American Management Association's *The Forum:*31-33, (July 1978).
2. **Eckardt, R. E.:** Innovations in Occupational Health: Toxicological Evaluation of Industrial Chemicals. *Am. J. Pub. Health 60:*2011-2015 (October 1970).
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discussion

The need to design meaningful toxicologic studies exists where adequate human epidemiologic data are not available. Negative data are lacking in the literature, and perhaps the scientist is at fault. The scientist uses high levels to understand some biological system not toxicology *per se*. Even a three-level toxicologic study produces no response, some response, and all response; the latter two are taken out of context and used by most nonspecialists. The physician can use these grossly high-level studies; by knowing the target organ in the animal, he can look for organ response in the worker.