QUANTITATIVE RISK ASSESSMENT

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Thank you for giving me the opportunity to speak to you today about carcinogens in drinking water and water quality standards.

In the United States today, many if not most public water supplies contain chemicals that cause cancer in animals when, in laboratory tests, the animals are exposed to high levels of the chemical. Most of these chemicals are man-made, but there are exceptions, such as the chlorinated methanes and, probably, related compounds. These chemicals are the byproducts of chlorinating our water supplies. Thus, one of our most important public health measures has an adverse side effect. Another exception is arsenic, which is ubiquitous in the earth's crust and is commonly found in groundwater and surface water. Ironically, according to the Environmental Protection Agency's risk assessment, these chlorinated methanes and arsenic are two of the most potent carcinogens.

Man-made pollutants in water do not necessarily come from chemical dump sites, although these sources attract the most public attention. They also come from chemicals used in industry, in agriculture, and in the home.

In industry, work practices frequently permit chemicals that may be carcinogenic to enter the environment. For instance, wood is treated with pentachlorophenol, or PCP, to protect it from fungi and rot. PCP is an animal carcinogen. Even with the strictest safety measures, when the wood is being treated, some of the chemical spills on the floor. Furthermore, when PCP is being sent from the manufacturer to the user, it may spill from valves as the containers are being loaded and unloaded. The spilled PCP finds it way, through dust, air, and wet cleaning to water supplies. If the wood is cut, sawed, or drilled, the waste that is created will eventually be deposited on soil, and this means that it can leach out into water supplies. When treated lumber is used for power poles or fence supports, PCP is forced into the ground. Thus, both the manufacturer and the user may contaminate our water supplies.

In agriculture, the chemicals in pesticides and herbicides may be dispersed as dust and deposited in surface waters. Chemicals that penetrate the soil are likely to appear later in the groundwater. Ethylene dibromide, or EDB, a soil fumigant, has polluted groundwater far away from the land on which it was used.

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In the home, carcinogens are by no means rare. They are in paint thinners, in paint-brush cleaners, in degreasing solvents, gasoline for lawn mowers, weed and pest killers, and products used in our kitchens and workshops and to purify the water in swimming pools. Chemicals from all these products are very likely to enter aquifers or surface water, either directly, by being spilled or disposed of on the soil, or indirectly, through sewage and centralized disposal systems.

When we consider airborne pollutants--whether they come from industry, agriculture, or the home--we must recognize that they can reach our surface waters, but we really know very little about the effect of air pollution on water quality.

Regardless of what we think about the adequacy of animal data for predicting human risk and the adequacy of models for high-to-low-dose extrapolations, we are clearly at some risk of cancer from exposure to at least some of the many carcinogens that may be in our drinking water. We can also logically assume that the risk will increase if the concentrations of the chemicals increase. We can all agree, therefore, that regulating water quality with regard to carcinogens has at least one purpose: to set a limit for the amount of pollution to be tolerated and thus to the amount of risk to be tolerated.

Regulators all over the world seem to be pragmatic about setting limits to water pollution. They agree that a total absence of carcinogens is unrealistic and that regulations should not be aimed at the impossible. In general, their goal is to reduce the pollution to the lowest practical level. This was true long before quantitative risk assessment came into use as a tool in environmental health.

The problem in developing water quality regulations boils down to three basic, interrelated questions: (1) What is the lowest possible level of pollution? (2) Is technical feasibility the only criterion? and (3) Should reducing pollution levels be independent of the degree of the cancer risk to humans?

The first question--about the lowest possible level--is especially difficult because we can measure chemicals at lower and lower levels--in some cases, to parts per quadrillion. Failure to detect a chemical at detection level does not mean it is not there below those levels. The third question--about cancer risk to humans--is especially difficult because it implies that we have something we do not have--namely, a reliable and accurate method for determining the risk to humans of exposure to low doses of carcinogens in water.

The socioeconomic impact of any regulation dominates discussions of the questions. I do not wish to dwell on this subject, but, clearly, any quality standard will have a direct or indirect impact on the cost of living, on employment, on the development of new water supplies and of new technology, on setting priorities in government and community budgets, and on the public's involvement in these matters.

Furthermore, what should we do with carcinogens that we remove from the water? This problem hasn't received much attention. Disposing of them in rivers and in the air or storing them under or above the ground does not solve the problem because when we do any of these things, we have simply moved the carcinogens to be dealt with later--we haven't destroyed them. At present, incineration after causing carcinogens to be adsorbed by activated charcoal--seems to be the only workable, though expensive, method of destroying them. Thus, our dilemma is: do we want to protect our water supplies at any cost or do we want to accept some contamination and, consequently, some risk determined by the balance of risk, technology, cost, and other socioeconomic factors. If we look at this dilemma from a medical and epidemiologic point of view, we can perhaps find a way out.

Most of the carcinogens that have been identified in water have been shown to be carcinogenic for animals, not humans. And, they have shown their cancer-causing effects in tests with dose levels far higher than will ever be found in the environment. Therefore, if we use animal data to estimate the risk of environmental exposure for humans, we must extrapolate these laboratory findings across species and from high to low doses. We do not have enough scientific data on which to base these extrapolations, so, as an alternative to fact-based hypotheses, we must make assumptions. This is not objectionable, as long as we keep in mind that we are dealing with assumptions, not facts. Unfortunately, in discussions, scientific reviews, rule making, and cleanup activities, this has rarely been emphasized.

When assumptions are the basis for our actions, research aimed at validating the assumptions is of the highest priority, but this is rarely done. In addition, the person making the water quality rules, or standards, on the basis of these assumptions must recognize the possible fallacy of the assumptions, and this should encourage him or her to make the standards flexible rather than rigid. In planning cleanups, we should be aware that some assumptions are probably incorrect and that the rationale for the planned activities may, therefore, be meaningless or dead wrong. In this case, the funds allocated to the cleanup may be inappropriate. When chemicals are selected for long-term and, thus, expensive cancer tests on the basis of wrong assumptions, the wrong chemicals may be selected. These are just a few of the problems associated with the assumption-based theories of qualitative and quantitative risk assessment.

Now, let's look at six of the assumptions that are most crucial in making a quantitative assessment of cancer risk.

The first is that regardless of how low the carcinogen level is--it may even be below the detection limit--there is still a finite risk. A zero risk would only be compatible with the absolute absence of the carcinogen. This is the so-called zero-threshold assumption.

The second assumption is that experience with animals can be transposed to humans by using a dose scale of milligrams of carcinogen per kilogram of body weight per day, or by following EPA's scale of milligrams of carcinogen per centimeter squared of body surface per day. The EPA scale results in a higher risk than the other scale; it is 7 to 12 times higher, depending on whether data from mice or rats are used.

The third is that the dose-response relationship observed at the very high dose levels used in bioassays is the same as the relationship at the very low dose levels found in drinking water.

Number four is that the observed concentration of a carcinogen in water is not altered by any treatment at the water plant; by boiling at home; or by any other treatment used to convert tap water into bottled water, carbonated or other soft drinks, alcoholic drinks, tea, or the like.

The fifth assumption is that the exposure is for a lifetime--that is, that the level of exposure will not change in a full life span or, if it does change, that the changes will balance each other out. This assumes no movement out of an area, no change in water treatment, no change in groundwater flow--and a continuous source of contamination, not a temporary source, such as a one-time spill.

The sixth of the most crucial assumptions in a quantitative assessment of cancer risk is that the real dose-response relationship in human carcinogenesis equals the relationship in the mathematical model used to determine the dose-response relationship in rodents from test results.

I leave it for you to judge the correctness of these assumptions. What I am trying to convey is that risk assessments and risk estimates are based on assumptions and that these assumptions need to be validated. So-called conservative assumptions will not suffice. We must also strive to learn how far and in what direction these assumptions differ from the truth. In considering the data base underlying the proposed rule making and in communicating risk estimates to the public or to anyone using the estimates, we should be acutely aware of the great impact that errors in these assumptions may have on the estimates.

Cancer risk estimates, as presented by EPA, are the 95% upper bound of the point estimates, and they address risks to populations, not individuals. Thus, a risk of 1 in 100,000 indicates that the best risk estimate, accepting all assumptions to be valid and correct, is much lower or may even be zero. Let me make a conservative choice by translating a 1 in 100,000 upper bound risk to a 1 in 200,000 point estimate of a lifetime risk. In more understandable terms, this is a risk, over a century, of an average of 1 cancer case a year in a population of 1.4 million people, or not 1 case in an average community of 10,000 people observed for a century. This one case may be a 100% curable skin cancer or, at the other extreme, a fatal lung cancer. To put this estimate in perspective--in the United States, 10,000 cases of new cancers have been observed, with a high degree of accuracy, to occur in the same 1.4 million people because of the risks we are already taking, knowingly or unknowingly. In considering these risks, we should keep in mind that the estimated 1 case a year per 1.4 million people is obtained with a risk model based on very conservative assumptions--that is, they err on the side of caution. The real risk may be far lower than the estimated risk.

Comparing one carcinogen-induced case of cancer with 10,000 "naturally" occurring cases changes drastically if the assumptions underlying the risk estimate are wrong. And at least some assumptions are obviously wrong. This is one of the big problems in deciding what level of risk can or should be declared tolerable and in establishing water quality standards to fit that level. The Occupational Safety and Health Administration, the Food and Drug Administration, the International Agency for Research on Cancer, which is associated with the World Health Organization, and other agencies go so far in some instances as to not accept quantitative estimates derived from mathematical models as a basis for setting standards. Some of the alternative approaches, however--such as that described in the Delaney clause--may be less defensible from a scientific standpoint, and even undesirable.

In conclusion, I'd just like to say what I'm sure you already know--and it is that, despite the many problems, we must continue to work together, at the local, state, and Federal levels, to keep our drinking water safe. In the absence of other more certain data, risk assessment is all there is. Just as it should not be denigrated as unhelpful because of its inevitable limitations, neither should it be oversold as a panacea. We must apply it with the soundest professional and scientific judgment available in order to shape public policy that is scientifically defensible.

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