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1983 STOKINGER LECTURE (AIHC)

Dr. Elkins received his PhD in physical chemistry from Harvard University. Subsequent to graduation, he sought an additional year of continued studies in Germany. Upon his return, he became the first chemist with the Division of Occupational Hygiene, Massachusetts Department of Labor and Industry. In 1951 he became the Director of that Division, a position from which he retired in 1973. Dr. Elkins is widely published, having authored over 50 technical papers and the book, *Chemistry of Industrial Toxicology*. He is highly respected as a long-time member of the Chemical Substance Threshold Limit Values Committee, which he chaired following Dr. Stokinger, and was responsible for the preparation of the Fourth edition of *Documentation of the Threshold Limit Values*. He has been honored by several professional societies including the Cummings Award from the American Industrial Hygiene Association (AIHA), the Meritorious Achievement Award from the American Conference of Governmental Industrial Hygienists, and was the first recepient of the Leslie Silverman Award presented by the Massachusetts Local Section of AIHA.

The real world or science fiction

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I consider it a great privilege to be selected to give the lecture honoring one ot the most eminent members, not only of the Conference, but of the Association, the Academy, and indeed the entire occupational health community.

My admiration for Herb Stokinger is only partially because of his profound knowledge of toxicology, and especially of the bases and selection of threshold limit values, impressive as it is. In fact, I have often disagreed with him, strongly in some instances, about the latter. It is rather the genius he showed in handling and building up the TLV Committee. Before Herb took over, the committee was made up of a small number of obscure state industrial hygienists, and it was successful only because other committees, with more famous members, could never achieve enough unanimity to make any recommendations. Under Herb it became *the* organization the entire Western world looked to for guidance in matters of standards for occupational exposures to chemical hazards.

He attracted leading toxicologists from industry as consultants, and somehow managed to extract from them their expertise without bowing to their prejudices. He made membership in the Committee one of the prized assignments of the Conference. Attendance at its meetings was phenomenal; they became miniature conferences on industrial toxicology.

Threshold limits, for occupational exposure, are based on a simple theory; to-wit, that any macroorganism can tolerate some dosage of any chemical without significant ill effect, and, conversely, almost any substance can cause serious ill effects if given in sufficiently high dosages. This is especially true when the substance is administered by inhalation, as is the case with a very high percentage of industrial poisons.

I need not go into the process by which TLVs are determined. Suffice it to say that it is a scientific method, based on all the available evidence. Even then, in many cases, it depends to a considerable extent on the judgment of the scientists on the Committee.

To be sure, the Committee makes mistakes. What group of fallible human beings can consider over 600 difficult problems each year, every one of which has an almost infinite number of possible answers, without selecting the wrong one sometimes? But they are honest errors, and most often quickly recognized and corrected, when the necessary evidence becomes available. They are not due to preconceived ideas, hypotheses, or prejudices.

About two years ago, I left the world of the TLV Committee and of science to enter what many consider the real world. Others might term it the world of science fiction.

It is a world where science and scientists play a minor role, the world of conservationists, environmentalists, and ecologists, many of whom would return this continent to its ante 1492 condition; the world of the consumer activist, whose purpose in life is to make things miserable for the producers of wealth; the world where the lawyer, the government bureaucrat, the media personality, the PR person, and the politician make the important decisions. It is also the world where the zero threshold, linear response hypothesis for

chemical and physical exposures, at least for carcinogens, is viewed with more reverence than the *Ten Commandments* or the *Constitution of the United States of America.*

The essence of this theory is that the number of cancer cases in a given population, with an exposure to a chemical or physical carcinogen, is proportional to the product of the mean dose of, or exposure to, the carcinogen, times the number of persons receiving exposure. It directly rejects, therefore, the basis of TLVs.

An example of the application of this hypothesis may be found in the Three Mile Island incident. The additional radiation exposure caused by the now famous incident at the facility to the few thousand people living in proximity to the reactor, was not sufficient to cause a single case of cancer, according to the calculations. But, if a much larger area, with a population of one million or more people was considered, the product of population and exposure was great enough to produce one additional case of cancer, even although these additional people were exposed quite a bit less than those near the reactor. The number of people increased more rapidly than the intensity of the radiation decreased. One cancer in one million or more people does not seem like a lot, when statistics show that one in four persons will get, although not necessarily die from, cancer.

Former HEW Secretary Califano, however, was unwilling, when pressed by a media person, to "justify" this one additional case. The typical reaction of the public to the argument that only one in a few million will be affected is, "Okay, but suppose that I or one of my family is the one?"

The real world is the one where 125,000 deaths each year, until passage of the Clean Air Act, were attributable to inhalation of air that had been polluted by chemicals, primarily from electric power plants and automobile exhaust.[1]

I could find only one of my former colleagues and associates who did not think this estimate ridiculous. But it appeared, without contradiction, not only in environmentalist publications, but in *The Wall Street Journal*,[2] of all places. I protested to the Audubon Society that this estimate was a gross exaggeration. Several of my friends told me that such a protest was useless. I can now tell them they were wrong. The latest estimate, in the current issue of *Atlantic*, is that only 50,000 annual deaths result from this source.[3] (All the statistics of death and disease which I quote refer only to the United States, unless otherwise stated.)

The real world is also the world of the Califano Cancer Estimates Report.[4] According to it, the expected average number of excess cancers in the next 25 to 30 years due to occupational exposure to asbestos, will be about 67,000 a year. Many of these will be in those whose only exposure to asbestos was in shipyards during World War II. Since a majority of these workers were presumably over 30 years of age at the time, they will be well over 90 years old 30 years hence.

Other substances which cause cancers of the respiratory passages considered in that report included arsenic, chromium, iron oxide, nickel and petroleum distillates. These substances were estimated to produce, among them, 34,700 cancers a year, for a total of over 100,000 cases from the six substances mentioned so far. This is approximately the number of all lung cancer deaths a year at the present time. To these 100,000 cases of respiratory cancer, add 1400 leukemia deaths a year due to benzene and 1900 liver cancer cases caused by vinyl chloride, for a total of 103,000 cases per year from occupational exposure to only eight substances.

These estimates, which amount to between 20 and 38% of all cancer deaths, represent only the tip of the iceberg, a favorite expression of the new world, for they do not include cancers resulting from occupational exposure to numerous other carcinogens, e.g., 2-naphthylamine and wood dust, or, even more important, those due to suspect human carcinogens, which means substances found, by bioassay or otherwise, to cause cancer in animals, but which have not as yet been reliably incriminated in cases of human cancer. While there is only a handful of proven human carcinogens, there are hundreds of suspect human carcinogens in industrial use.

The chemical I know the most about, of those in the Califano Report, is benzene. The calculation of 1400 leukemia deaths a year was derived primarily from seven cases, among the workers in a single company, which occurred over a 20 to 30 year period. This company was carrying out a rubber casting process, which has the potential for gross benzene exposure.[5] No reliable data on the actual exposures of these workers, at least during the war

years, are available. Thus, from one leukemia death in every three or four years, an estimate of 1400 cases, each and every year, was calculated. Many of the other estimates of cancer incidence from these chemicals appear to be extrapolations from similarly meager data. In other words, the incidence of cancer in a small group of workers who are heavily exposed is assumed to apply to inflated estimates of the numbers of all exposed workers, many of whom are marginally or negligibly exposed.

While this fallacy, inherent in the report, has been mentioned by one or two of its critics and the report itself has been repudiated by some of its authors,[6] the impact of its findings, which have appeared in the *Federal Register*, is still noticeable among officials of labor unions, many government agencies, the media, and the uninformed public.[7]

The real world is the world of hazardous waste hysteria; such waste, dumped in places where it can eventually find its way into ground water, has been described as a time bomb ticking away, with a potential for disaster, one would judge, equivalent to that of all the nuclear and hydrogen bombs stockpiled by the United States and the Soviet Union together.

A year or so ago, it was reported that waste containing trichloroethylene was being dumped in the Quabbin Reservoir, the chief water supply of the Metropolitan Boston area.[8,9] A team from EPA was rushed to the location, some 60 miles west of Boston. Pollution of this great water supply would be a calamity of the first magnitude.

What do you think the team of experts found? That some out-of-the way corner of the reservoir was being used by midnight dumpers to dispose of their lethal cargoes? Not exactly. It seems that some fisherman had decided to build a float, which was kept within plain sight of the headquarters building. It was supported by four empty 55-gallon drums, one of which, according to its label, had once contained trichloroethylene.

Residents of some of the outer Boston suburbs, however, which rely on wells for their water supplies, have been terrorized by the finding that the water in some contained a few micrograms per liter of trichloroethylene. As a result of closing these wells, some communities suffer water shortages. Until recently, the usual water analysis would not have revealed such small traces of chemicals. One shudders to think that people may have unknowingly been consuming this polluted water for years. Yet the economic treatment and safe disposal of chemical waste is prevented by the refusal of any community anywhere to permit the construction of the necessary facility within its borders.

In the real world, one of the most urgent problems is that of acid rain. Not only has it killed the fish and indirectly other wildlife, in a number of lakes and ponds here and abroad, (a fact that has been well documented[10]) but, according to recent testimony at a congressional hearing:

1. It may threaten farms and forests by hindering timber and plant growth.
2. Threaten public health by corroding water pipes and contaminating water with lead and asbestos.
3. It may endanger people, plants and wildlife by leaching dangerous metals from soils.
4. It could lead to staggering increases in health care, environmental pollution costs, and economic losses.

Yet, in this real world, the one proven major source of energy that does not pollute the atmosphere by massive emission of the oxides of sulfur, nitrogen, and carbon, namely, nuclear fission, is considered an anathema. One of every two cars in this world carry bumper stickers, and half of these stickers read, "No Nukes."

It is the world where the cure is worse than the disease. EPA is said to have estimated that between 20,000 and 200,000 cases of cancer each year are caused by chloroform and other chlorinated compounds which result from the chlorination of water to destroy pathogenic organisms.[3]

EPA has also ascribed 10% of lung cancer cases, or about 10,000 a year, to inhalation of radon.[11] This number will no doubt increase when the impact of energy-proofing homes becomes apparent 20 years hence.

In the real world, the penalty for insulating one's home with urea formaldehyde foam may be up to $100,000, for such houses are said to be unsaleable. Why? Because rats, exposed for a lifetime to levels of formaldehyde that would be intolerable for human beings, may develop cancer of the nasal sinus. Who would buy a house if told it would

give him cancer if he lived in it? And to sell such a house without so stating is close to a capital offense in some jurisdictions. All this in spite of the fact that formaldehyde has been used in industry and technology for over 100 years without, to the best of my knowledge, any reliable evidence being presented of its being associated with cancer in human beings.

What has been the reaction of industry to these apparently exaggerated claims of hundreds of thousands of cancer and other deaths each year due to the presence of chemicals in the environment? Industry employs the best toxicologists, the best chemists and engineers, the best lawyers and PR persons. It even, one reads, controls the votes of some members of Congress. Managing these industries are the royalty of America; the movers and shakers of the economy, the men and women who hire and fire and make the decisions when, where, and what new factories will be built to employ thousands of workers, make more satisfactory the lives of millions of consumers, and pay billions of dollars in taxes and dividends.

To reach the top on the fast track in American business, one must have taken the measure of tough labor union officials, outwitted shrewd Swiss bankers, survived unbelievable competition from wily Japanese counterparts, as well as countless American companies, and faced down complaining shareholders. Such super persons are not likely to cave in to the demands of bird watchers, consumers groups, TV anchor persons and, above all, government bureaucrats.

That is what you think and, in general, it may be true. But when we come to specific cases, especially involving the word "cancer," the captains of industry have only two mottos. The first is: *"Those who fight and run away, will live to fight another day;"* and the other, *"Every man for himself, and the devil take the hindmost."*

Just about two years ago, a story appeared in *The Wall Street Journal* about the problems the Xerox Company had, as a result of a laboratory finding that carbon black used in some of its toners gave a positive Ames test.[12] This news was received in the company headquarters with about the same consternation as the sinking of the Titanic caused in the office of the Cunard Steamship Lines. Nevertheless, the company confidently stated that operation of their machines did not produce a cancer hazard. Certainly xeroxing is not a particularly dusty operation in comparison, for example, with the compounding of rubber, which also employs carbon black.

However, that was the public reaction from the company. Internally, the chemists of Xerox and its supplier were told to get rid of the offending ingredient, which turned out to be a nitrophyrene, or else. This was done, and that fact was given a great deal more publicity than the orginal Ames test finding, even though it was claimed, and I personally would judge correctly, that there was never any danger anyway.

In another Massachusetts crisis, water, which had passed through newly installed asbestos cement water pipes, was found to contain traces of perchloroethylene, in a few instances even above the EPA recommended standard. It seems that Johns-Manville, the maker of the pipes, had coated the inner surfaces with a plastic, which had been dissolved in perchloroethylene.

Some local genius proposed that several miles of pipe be dug up, and the plastic coating removed mechanically. Johns-Manville, however, to whom cancer scares are no novelty, assured the public that there was no hazard. They also stated that, to make a sure thing doubly sure, they were replacing perchloroethylene with another unspecified, presumably noncarcinogenic, solvent when manufacturing new pipes. Apparently, after a few weeks, all the perchloroethylene had leached out of the pipes, for the story ceased to be front-page news without, to my knowledge, any pipe being dug up.

To understand the lack of backbone among our business leaders, one only has to look at our judicial system. Recently, an inmate of one of our prisons was bludgeoned to death. One of his companions was suspected, but the evidence was skimpy. In the hope of finding traces of blood, his hands were moistened briefly with a reagent containing a dilute solution of benzidine. This less-than-admirable citizen then sued the State, the prison authorities and, probably, the manufacturers of the reagent, and a jury of his peers awarded him $75,000 in damages for this exposure to a weak carcinogen.

Most of the projections and estimates of death and disease from environmental pollution, which I consider gross exaggerations, and the laws, regulations and actions taken to prevent them, which I

hold to be unreasonable, have one thing in common. They do not accept the basic premise on which the TLV Committee functions, that there are thresholds for toxic effects. While applied chiefly by some only to carcinogens, mutagens and teratogens, the opposite hypothesis, that any quantity of almost any toxic agent can be harmful, or even lethal, is widely accepted in the real world.

The EPA has compiled a list of some 129 priority pollutants, of which 61 are carcinogens or suspected carcinogens.[13] For each of these 61 substances, allowable limits are proposed, based on the probablity that there will be one additional case of cancer in every 100,000 persons "exposed" for a lifetime to water containing the pollutant. Since this criterion may not be strict enough for some, alternative proposals, which would permit only one additional case per million, or per 10 million, persons, are made. The concentration that will produce one case in 10 million people is 100 times less than that required to cause one cancer in only 100,000 persons.

This method of calculation, called the linear response model, usually predicts a greater number of cases than other methods, such as the log probit model; 10 to 100 times more in the case of vinyl chloride. The beauty of this model is that only two points are needed to define a straight line and, with a zero threshold assumed, you already have one point. One only needs a single experiment, under which a measured does gives a positive response, to construct the entire dose-response curve.

The average lifetime dose of perchloroethylene resulting from drinking water containing 2 μg/L of perchloroethylene, the concentration which, according to EPA, will produce a 1/100,000 risk of cancer, is about 0.2 gram. In comparison, the yearly intake of perchloroethylene which would result from an 8-hour/day workplace exposure at the former TLV of 100 ppm for this solvent would be nearly 1700 grams or almost 10,000 times higher.

NIOSH has estimated that 500,000 workers are exposed to perchloroethylene. Our limited data suggest that the average exposure to this solvent in dry cleaning plants would be of the order of 12 ppm.[14] If a dose of 0.2 gram gives a 1/100,000 probability of cancer, the yearly exposure of 500,000 workers in plants where the average concentration is 12 ppm, should produce 4830 cancers. Presumably these would be chiefly liver cancers, since the site of the cancers produced in mice by perchloroethylene was the liver. If we add to these, the results of occupational exposure to seven other chlorinated hydrocarbons (carbon tetrachloride, chloroform, trichloroethylene, tetrachloroethane, 1,1,2-trichloroethane, vinyl choride, and hexachloroethane) similarly calculated, an additional 860 liver cancers would be caused each year, for a total of 5690.

The liver is not the favorite target of most human carcingens, according to the statistics of this disease. A recent summary failed to include the liver among 14 important sites of cancers.[15] Another reference does give an estimate of 3500 liver cancers each year among males. The total number, therefore, may be around 7000.[16] Thus, about 80% of the liver cancers in this country would appear to be due to occupational exposure to these eight chlorinated compounds. Incidentally, this calculation predicted only 208 cancers a year from vinyl chloride, about one-tenth the number cited in the Estimates Paper.

If we consider the additional cases from other chlorinated solvents, pesticides, and the ever-present polychlorinated biphenyls, and the fact that other carcingoens, such as the nitrosamines, also cause liver cancer, it is clear that practically all liver cancers must be due to occupational exposure to carcinogenic chemicals. But wait just a minute! Some one has reported the EPA has calculated that between 20,000 and 200,000 cancers a year result from drinking water that has been treated by chlorination, and contains chloroform and other chlorinated compounds. If such an estimate was actually made, and it seems incredible to me, it must have been assumed that cancers of other organs, such as the colon and rectum, stomach, kidney, and pancreas, are also caused by chloroform, and, presumably, other chlorinated compounds, otherwise we would not have such a small incidence of liver cancers. It seems to me to be stretching things quite a bit to assume that a dose of a carcinogen that will cause liver cancer in mice, will cause an equal incidence of colon cancer in humans.

The highest estimate, 200,000, equals half the total number of cancer deaths in the entire country. Attempts to associate chlorinated drinking water

with an increase in cancer incidence have so far failed to produce any real evidence of correlation, I am told.

It seems strange to me that no one has observed a marked increase in cancer, especially liver cancer, among dry cleaners, and other workers exposed to other chlorinated solvents, such as trichloroethylene. It did not take too long for the association between vinyl chloride exposure and liver cancer to be detected. And vinyl chloride is a less potent carcinogen, by a factor of about 250, than perchloroethylene, according to EPA.

It is my opinion that there are a great many fewer cancers due to environmental exposure to chemicals, occupational or otherwise, than a lot of people would have us believe, and that reason is that there is a threshold for most, if not all, carcinogens, and if this threshold is not exceeded, no cancer will be caused. Moreover, I doubt that the response to carcinogens bears a linear relationship to dosage, except the approximate one at low concentrations.

If we accept the premise that there is no threshold for carcinogens, we shall need to re-think some of our occupational health practices. A recent paper on arsenic exposure in smelters indicates that rotation of workers is necessary to keep the total exposure of every worker below an average of 10 μg arsenic/m^3 of air.[17] According to the zero threshold theory, this is a waste of time. The same number of cancers will be produced, regardless of whether 100 workers are exposed to the environment for 40 years, or the exposure is shared by 4000 workers, each of whom only works in the plant for one year. The risk to each individual is diminished, but only by spreading it among others.

One fact which seems to me of considerable significange appears to have received little attention from the environmental-cancer community. Two of the more important human carcinogens, arsenic compounds and benzene, have not been shown to cause cancer in experimental animals. Does that mean that it is possible that some of the substances which induce cancer in lower animals may pose no cancer threat to humans? Or does it indicate that many other chemicals, considered non carcinogenic on the basis of animal studies, might be found, if adequate investigations were made, to cause cancer in people after all? In that case, we would be back to square one, in the early days of industrial hygiene, when many authorities scoffed at the idea of TLVs, and recommended only that the concentrations of all industrial air pollutants be kept as low as possible.

I have seen some evidence that the occupational health community is considering this matter. A recent American Academy of Industrial Hygiene newsletter asked for opinions, as I recall it, about thresholds for cancer causing substances.[18] It started out, however, by saying that "good science" had not yet been able to establish the existence of such thresholds, for carcinogens, that is.

On the other hand, a committee from the Society of Toxicology (SOT) examined the report of the massive ED_{01} study of cancer incidence in mice receiving low dosages of the potent carcingoen, acetylaminofluorene, which concluded that no evidence of a threshold was found. The SOT committee, however, disputed this claim, stating that *"the tumor-free period as a function of dose has a slope that is indistinguishable from zero over a considerable region . . ."*[19]

It has been proposed that we accept the fact that any exposure to a carcinogen, occupational or otherwise, may result in death through cancer, and establish standards based on the degree of risk we are willing to tolerate. The EPA proposed water standards are based on this philosophy. Let me submit that if this is done, TLVs for carcinogens should not be recommended by the scientists on the TLV Committee, but should be left to social scientists, demographers, economists, religious organizations, and politicians.

It may seem that I consider that occupationally induced cancer, air and water pollution, and chemical waste disposal are not serious problems. This is far from the truth. Even if "only" 4% of all cancer deaths are due to occupation, that would amount to about 16,000 a year, nationwide. Massachusetts' share would be about 480. It is hard for me to believe that 480 Massachusetts workers and retired workers die each year from work-related cancer.

Back when benzene was used as a rubber and lacquer solvent, Massachusetts had between 10 and 20 deaths from benzene poisoning over a period of several years. That was considered a scandal and disgrace, as indeed it was.

Workers deserve an environment in which they can enjoy good health, not merely survive. Threshold limits are designed to prevent even minor signs and symptoms of poor health, such as headache, cough, lachrymation, detectable reduction in pulmonary function, nausea, irritability, mild anemia, and intolerance to alcohol (a symptom most often seen in workers exposed to low concentrations of trichloroethylene). It is hard for me to believe that the concentrations of pollutants in the atmosphere, generally far lower than work place TLVs, would produce any significant number of fatalities, even when allowance is made for the greater susceptibility of the infant, the aged and the infirm and their continuous exposure.

It has been reasonably well established that DDT has endangered certain species of wildlife. For this reason, I support restrictions on its use, even though it appears not to be a hazard to human health. Acid rain also has reduced the abundance and variety of wildlife in many areas where ponds and lakes have little buffering capacity. I believe measures to reduce its intensity, even although we have a lot to learn about its causes and the costs may be great, should be enforced. However, I see no immediate direct hazard to human health from acid rain.

Contamination of soil and groundwater by chemicals, at present of relatively small magnitude, in my opinion, should be prevented. Let me suggest that in the snow belt, at least, salt applied to roads to reduce highway accidents, is probably a much greater problem than trichloroethylene and similar chemicals.

The achievements of Herb Stokinger and his colleagues provide a basis for the rational solution of many of these problems. Let us return to the world of science and scientists. The beliefs of the world of science fiction, which I have termed the real world, can only lead to calamity if followed to their logical conclusion, with the eventual destruction of much that science and technology have achieved for the human race.

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