and mistreatment, exposure to cigarette advertising, violence, and drugs.

The lack of immunization against childhood diseases is a major problem. This has been emphasized by the Centers for Disease Control, which estimate that vaccination of children is at a rate of only 60%. Immunization of many children is needed against whooping cough, measles, mumps, polio, diphtheria, tetanus, rubella, and hemophilus influenza type B. The vaccines for all these diseases are available from public clinics. However, access to them is limited, and the immunization rate for children below the age of 2 is low, especially in the inner cities (only about 10%).

*Statement:* "We believe that EPA should consider using an additional factor of up to 10 when there is evidence of postnatal toxicity."

*Comment:* EPA uses this additional factor if studies have shown an effect on the developing fetus (i.e., prenatal toxicity). This precaution would appear to be sufficient to protect against postnatal toxicity.

## Summary

1) Analyses of foods show that in most cases pesticide residues were not detected, and in nearly all other cases, the residues were within tolerance limits. These findings show that the problem is a very minor one, regardless of other circumstances.

2) A National Cancer Institute spokesperson on Aug. 27, 1990, states he was "unaware of evidence that suggested that regulated and approved pesticide residues in foods contribute to the toll of human cancer in the U.S."

The National Center for Health Statistics states that age-adjusted cancer mortality rates among white children ages 0 to 14 years have decreased by 35% between 1973-74 and 1985-86.

3) Various public health authorities agree that protection against cancer by fruits and vegetables outweighs any effect of pesticide residues.

4) Pesticides kill pests. Plant protectant chemicals (pesticides) include fungicides. These make a contribution to prevention of cancer by destroying molds that produce carcinogens in food. Organic foods are not protected against molds.

5) Major problems for infants and children, outweighing pesticide residues, are immunization against childhood diseases and the need for adequate protection against traumatic injuries and nutritional deficiencies.

6) Tolerance limits for pesticides are set with a margin of safety of one-hundredth of the no-effect level. This is wide enough to protect infants, children, and adults.

7) Natural pesticides are present in food at levels approximately 10,000-fold the levels of synthetic pesticides.

8) The existing programs to analyze foods for pesticide residues are extensive and adequate. The concern about pesticide residues has been blown out of all proportion.

Conference Report

# U.S. health risk testing is 'worthless'

by Mark Wilsey

The legal and heath issues arising from governmental regulations were the focus of a conference entitled "Hazardous to Your Health: Toxics, Torts, and Environmental Bureaucracy," hosted June 8-9 in Washington, D.C. by the Independent Institute. The conference highlighted government policies that the participants contend are "seriously flawed both economically and environmentally," which have helped create a situation in which an explosion of litigation threatens to cripple the "competitiveness of American business and labor." Topics ranged from Superfund cleanup to risk and liability.

Aaron Wildavsky, Professor of Political Science and Public Policy at the University of California at Berkeley, spoke before the conference on a panel on hazardous substances. He has written numerous books and papers on the subject. In his talk, Wildavsky described the nature and magnitude of the problem as it pertains to the use of animal cancer tests in determining human cancer risks. He said that due to the faulty methodology of animal cancer tests, the results will never be good enough to be considered a valid basis for predicting human cancer. The simple fact is that humans will rarely, if ever, encounter the same high dosage of suspected carcinogens that are given to laboratory animals.

## Ludicrous extrapolations

To extrapolate from animal tests to humans, a number of assumptions must be made. It is assumed that the biology of the test animal is similar to that of humans, that an adjustment can be made for the huge human population compared to a limited number of test animals, and that the vast difference in dosage given to animals compared to human exposure does not render the results invalid. Depending on the assumptions made and the statistical models derived from them, the results can vary greatly.

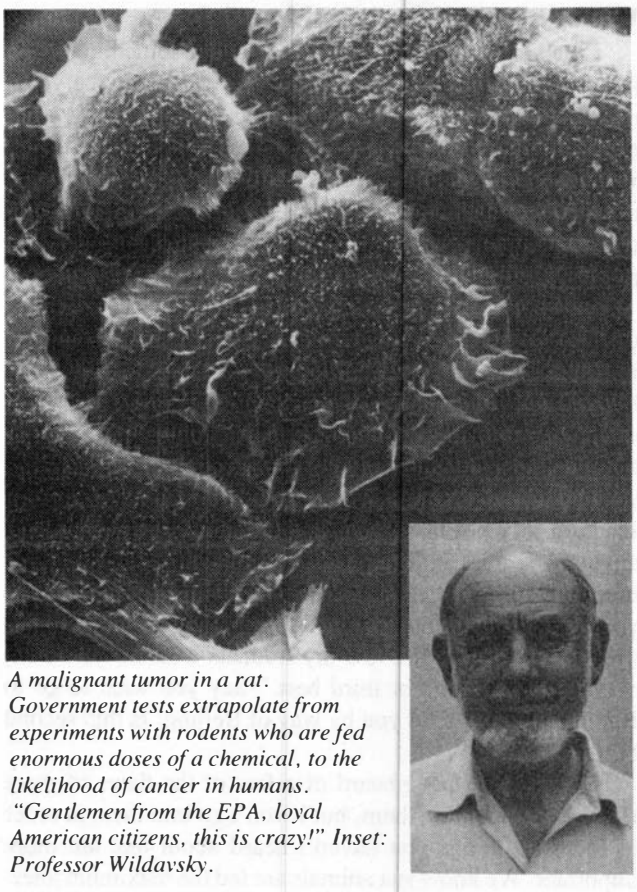
Wildavsky observed that if at the end of this exercise all we know is that the exposure to a chemical given to rats is thousands of times greater than human exposure, then we know nothing of value. And regulations based on such results make little sense, except to provide a spectacularly large margin of safety. He notes that there are limited health benefits in eliminating tiny amounts of synthetic chemical resi-

dues, when you consider the human body's ability to deal with the low level of natural carcinogens we are exposed to every day in our diet.

In addressing ways to reshape regulations, Wildavsky suggests that chemicals should be discussed in terms of carcinogenic or toxic *doses,* rather than simply labeling the chemicals carcinogenic or toxic. Also, there are no guarantees that any chemical dose will be absolutely safe. But, we can make good estimates as to what dose would be insignificant compared to other factors.

Wildavsky asked, "How can a citizen tell the difference between sense and nonsense?" It is his belief that a citizen who is willing to put in some time and read the scientific literature can understand it. He adds that if garden clubs, veterans groups, retired persons, or those who run computer bulletin boards were to study different issues—global warming, DDT, or whatever—and become "citizen experts," they could become powerhouses. A hundred such groups in the United States would make a very large difference in creating a better-informed citizenry.

Wildavsky's well-footnoted paper will appear in the conference proceedings to be published by the Independent Institute, which is due out sometime before the end of the year. What follows is Wildavsky's speech to the conference, slightly edited for publication.



*A malignant tumor in a rat. Government tests extrapolate from experiments with rodents who are fed enormous doses of a chemical, to the likelihood of cancer in humans. "Gentlemen from the EPA, loyal American citizens, this is crazy!" Inset: Professor Wildavsky.*

## Wildavsky: Environmentalist agenda is insane

I think we need to understand the enormity of what has occurred in order to answer the reasonable question of the gentleman from EPA [Environmental Protection Agency], "What should we do?"

A cup of coffee has, roughly, a thousand chemicals. Of these, we know something about 25 or 27 of them. It has been estimated that each cup of coffee—like the two I've had this morning—has, roughly, 15 grams of carcinogenic or poisonous material. How much is 15 grams? It's roughly equivalent to what each and every one of us would get from pesticide residues, from industry, in the food chain in one year. So, you want to make life safer, Mr. EPA? You want to show compassion for the poor SOBs who are getting cancer every 13 seconds? Tell them to drink one less cup of coffee each day.

The amount of natural carcinogens—in everything that grows and expects to survive evolution, most plants and vegetables being chemical factories—compared to the amount of synthetic chemicals we get from industry, the ratio between the two, natural versus synthetics, is roughly 99.99999 to 1. Put otherwise, the natural is 10-15,000 times greater by weight and potency per day than the synthetic.

The first question that every child should ask is not, how to kiss a whale this morning. It is, "What the heck are we doing?" This whole regulation business is a crock from beginning to end. There is no truth in it, because there is no harm in it at the very low levels of our concern.

What you should keep your eye on in this shell game is that technical thing called "risk assessment" or "criteria." It's the criteria that matter. If we could alter in a sensible way the criteria that EPA uses to regulate, or that our government in general uses to regulate, everything else would fall into place. We would greatly reduce abandoned hazardous waste sites. So if you say, "What is the one thing to pay attention to?" Pay attention to the criterion of choice. At the present time, EPA uses the following criterion: It regulates at 374,000 times below any damage to man or rodent.

EPA's standard is, you can't cause one in a million cancers. Where did we get one in a million from? I know where we got it from. Gentlemen, would you ever think of telling your girlfriend, "You're one in 10,000"? There's no more to it than that.

Go to your *Information Please,* or some other almanac. Don't let another day pass before you do that. Look at accident rates, morbidity, and mortality rates for the last 100 to 120 years. You'll see such an incredible example of progress. For black and white, for men and women, it's upward and onward in the most remarkable way.

## We've been doing something right

Conclusion: We must have been doing something right. It's one thing if the stretcher-bearers are carrying the youth of America away. I used to joke to myself, and say this is the only country in the world that has a simultaneous crisis of Social Security and early deaths. In other words, without understanding the sheer insanity and inanity of what is being done, neither you nor I nor EPA employees can make any progress whatsoever. . . .

The bulk, way over 90%, of governmental regulation of chemicals is based on animal cancer rodent tests. Like you, it never occurred to me that I should ever study such a subject, let alone write about it. But if you understand that the criterion for choice is the essential issue in all of this, and that rodent tests are the devices used, then you realize that either you have to claim ignorance or you have to go into the inner sanctum. My position is very straightforward. I don't want anybody to miss it. These tests are worthless—absolutely, unmitigated, worthless. Moreover, within the next few years you'll see that scientific opinion is moving irreparably and irrevocably against it. Now my students would say, "Well, maybe it's a second or third best." Say you want to go to Baltimore, and I send you by way of Beijing. Is that second best?

Most of you have heard of a few of the flaws of these tests, so I'll mention them, but I won't go into them in order to focus on things you haven't heard about that are more important. We know test animals are fed the maximum tolerated dose. This is very important because in comparing a mouse to a man, they are very small, we are very big. They get fed huge doses—tens of thousands of times larger, sometimes, than us—so you have to control for that. So they say, "Well, these are specially grown mice, they're supposed to have cancers." They consider a benign tumor just the same as a cancerous one because a benign one could become cancerous. But that is not the essence of the matter. Even the difference between the Food and Drug Administration (FDA) and EPA—whereas the EPA uses one criterion and the FDA uses another, they differ by a factor of four—that's not the essence of it. All the things you've heard about "megamouse" experiments are not the essence. The essence is the statistical argument.

In order to extrapolate from a rodent to a human, it is necessary to control for dose and size. Well, there are many dozens of statistical models that could fit the data, but unless you know how cancer is caused, unless you have a mechanistic explanation of cancer causations, there is no way to choose a statistical model. Immediately the small number of social scientists here should tell us, "Is this the case where the choice of the model over-determines the results?" You bet it is. EPA uses what it calls a default model. So I will give you my jaundiced view of this: It's a default of understanding. But I do them a disservice because they do know what they're doing, as I will explain. But it's not something that we should support.

What difference does it make what model you choose? Roughly, it makes this difference: When you've gone through this $1-3 million per chemical test, and you've followed the procedures punctiliously—which is not easy to do because you've got to slaughter the animals and put stuff on slides, and it's very long, and tedious, and expensive and, possibly, full of error. Even after all of this is done, what do you know? Well, I will give you my rough translation. You know within 4,000 to 4,000,000 times what's right. That's the margin of error. That's how we bound the uncertainties. Gentlemen from the EPA, loyal American citizens, this is crazy!

I need to say one more thing. Bruce Ames and Lois Gold have a theory called mitogenesis which goes like this: The tests we give these animals are creating the cancers we find. That is, you're poisoning the poor creatures with such high doses, they are engaging in tremendous cell division. It's well known among cancer specialists and in the literature that high rates of cell division lead to cancer. So, as we say, "You take out what you put in." And that theory, while not yet proven, is gaining adherents.

What's the rationale that EPA gives for these tests? "Well, it's the best we have." So, I have news for you: If the best you know is between 4,000 and 4,000,000, it's no good.

## What should be done

There are two other things we could and should do, some of which we do now. We could use epidemiology—the study of human subjects. We could have bigger samples and do it better by diverting some of the resources from rodent cancer tests. What's the objection to that? The objection is that epidemiology only catches bigger effects. I'd say that's what we want. We don't want to be chasing chimeras. If you look at the morbidity and mortality statistics—promise me you'll go home and look at the almanac, because unless you rub your nose in it and you see how brilliantly we have been doing—why are we looking for smaller and smaller effects? Why this romance with minuscule causes and infinitesimal effects? Well, we could expand epidemiology. But we're still going to miss some things. I stipulate that. But because we don't know what we're doing with animal cancer tests, we're missing things there, too. The only thing you get is, at random, you might find some cause of harm to human beings, but, otherwise, you haven't the foggiest. So it's not as if the preferred method is catching things that epidemiology won't.

The second alternative is called mechanistic studies, learning about the mechanisms of cancer causation as we have recently done with dioxins. If you know the mechanism, then you can choose much more appropriate statistical models. You can do real science.

In the work I've done, I carry on an argument with Leo Levinson, a student who wrote some stuff with me and who

was a former project director for EPA. . . . Leo says, "Let's go back to something less insane." In the olden times we didn't separate what caused cancer from what caused other things. If we had some reason to worry about a chemical, we would say, "Let's use whatever knowledge we have and let's increase that by a hundred as a safety factor." If there's some special reason to worry, we increase it by a thousand. And Leo said, rightly, "That would be better."

I am not in favor of idiot economics. I am not in favor of the argument that says, "Here is something stupid for which we are going to pay $900 billion, I can get it wholesale for $600 billion." There are things that ought not to be done. . . .

My objection to what Leo wants, to using the old rule of thumb which worked well for centuries, is that it doesn't get to the nub of the matter. It doesn't speak truth to power; it doesn't tell you what is right and what is wrong. It would cut way down on the craziness, but it's not what we should do. What should we do? The first thing is, we should reject the current system root and branch. Now, I don't mean I know how to get us to do that. I will confess immediately my great weakness. What I mean is intellectually, by whatever reason is left in our minds, we should reject it, because it is false. There is no truth in it and, therefore, there is no health in it. We can make our people sicker and poorer at the same time in the name of health. What sort of compassion is that?

What I prefer to do is to say, "Stop the romance with minuscule causes and infinitesimal effects." Replace it with what we know how to do, with mechanistic studies and with epidemiology. Now environmentalists are turning against mechanistic studies. How can you turn against studies of cancer causation? Not easy. But they've noticed something important. The more we know, the less dangerous everything appears. You say, "What's the result of all these studies?" Study, study, study, do less, that's anti-environmental, right? So we should focus on the key question, the question of the criterion of choice.

## The environmental paradigm

Now I want to end by placing my remarks in the context of the environmental paradigm. I placed this question to myself: Why is it that science seems so poor? I thought at first of scientists doing terrible work. But, it's not that. What it is, is that the environmentalists' paradigm has devalued science. Not directly; nobody says, "I'm doing this by witchcraft."

The first proposition is the replacement of probabilities with possibilities. Before, when you had to show probable harm, you had to show preponderant evidence. Now, possibility is it. If anything could possibly be harmful, then you have to regulate it. Well the only way to prove that something is not possible is through a scientific impossibility theorem, not your everyday cup of tea. So that's the first one, the replacement of probabilities with possibilities.

The second one is the replacement of positive evidence with negative evidence. Show me it *won't* do harm. That ain't so easy to do, as anyone who has ever tried to defend himself or herself against an accusation, like, when did you stop beating your mother up, or whatever.

Third, no dose response level. As I tell my students, in this business dose is everything. Never allow yourself to utter a sentence about contamination without saying "what" and "how much," compared to which. It's hard to discipline yourself but it is essential. The third environmental proposition is that every exposure is harmful.

There is a wealth of evidence in the history of toxicology, the study of science of poisons, that in the very large majority of cases there's a level below which there is no harm, and there may even be some good. This is denied by environmentalists.

By putting these propositions together, environmentalists have substituted assertion for evidence. What is the possibility? Science might say something like, "I think it likely that," or, "There's a high probability that"—that's no good any more. You have to show perfection. They've shifted the burden of proof. You have to have 100% knowledge.

What we have to do is reject these theses, especially the last one. The last thesis of environmentalism is the "precautionary principle"—don't be half safe. If there's any possibility that something will do harm, you have to stop it. In a book called *Searching for Safety,* I argued that this would destroy the progress of western civilization; make everybody sick and poor.

Why did the Greeks and Romans only live to 35? We have more than doubled that longevity because we didn't follow the precautionary principle. Then I realized that I've been foolish. We all know what this is. We all learned about it in school. Don't you remember? It's called "Pascal's Wager." Should you believe in God, or not? Well, if you believe and God doesn't exist, what have you lost? But if you disbelieve and God does exist, you have lost eternal life, so you should believe. . . .

This precautionary principle . . . is the nub of environmentalism which is used everywhere—it is fallacious in its whole, it is fallacious in its part, it can leave us in a devastated condition. Under capitalism, there is no chance we will have a situation where we run out of resources; that is, that we will not have a sustainable society. The only way we will create an unsustainable world is if we adopt the environmentalist paradigm. . . .

We must reject the environmental paradigm and the regulatory criteria that stem from it, and replace it with criteria like preponderant evidence. It's true that in some cases, evidence is evenly divided. But in most cases you see where science can come in and say, "Yes, it's likely that there's more danger or less danger one way or another." If we did that, we would be on the road to sanity, and we would improve people's health. There is a real place for regulation, but not when we deprive it of all sense.