T R A N S C R I P T O F P R O C E E D I N G S

U.S. ENVIRONMENTAL PROTECTION AGENCY

PUBLIC HEARING

ON

PROPOSED NATIONAL EMISSION STANDARDS FOR IDENTIFYING, ASSESSING AND REGULATING AIRBORNE SUBSTANCES POSING A RISK OF CANCER AND ADVANCED NOTICE OF PROPOSED GENERIC STANDARDS.

Room 208
Post Office & McCormack Bldg.
10 Post Office Square
Boston, Massachusetts

Wednesday, March 19, 1980
9:00 a.m.

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Wednesday, March 19, 1980
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BEFORE: Merrill S. Hohman, CHAIRMAN
Roy E. Albert, C)-CHAIRMAN

PANELISTS:

TODD M. JOSEPH, Esq.
ROBERT G. KELLMAN
DAVID R. PATRICK
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Room 208
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Post Office Square
Boston, Massachusetts

March 12, 1980

	Speaker	Organization
✓1	✓Richard Wilson	American Industrial Health Council
✓2	✓Anthony Cortese	Massachusetts Department of Environmental Quality Engineering
✓3	✓Rose Caterino	Somerville United Neighborhood
✓4	✓David Ozonoff	Individual
✓5	✓Charlotte Ploss	Mission Hill Planning Commission
✓6	✓Ed Calabrese	Individual
✓7	✓Peter Fairchild	Northeast ~~New England States~~ for Coordinated Air Use Management
✓8	✓John Groopman	Individual
✓9	✓Helena Brown	Individual
~~✓10~~	~~✓Herb Northrup, M.D.~~	~~Stauffer Chemical~~
✓11	✓Wayne Jaeschke	Stauffer Chemical
✓12	✓John Ronan	Stauffer Chemical
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✓14	✓Sheldon Krimsky	Individual
✓15	✓Ken Nelson ✓	ASARCO
✓16	✓John Barr ✓	Air Products
✓17	✓Bill Cavellini ✓	Cambridge ~~Port of Lions~~ Alliance
~~18~~	~~Gregor McGregor~~	~~Individual~~
~~19~~	~~Representative~~	~~Friends of the Earth~~
✓20	✓Richard Thompson ✓	Sierra Club
✓21	✓William Mendez ✓	Individual
~~22~~	~~Nancy Anderson~~	~~Massachusetts Association of Conservat~~
✓23	✓Barbara Fegan ✓ ~~Marcia Kaplow~~	Regional Cancer Control Committee Massachusetts League of Women Voters
✓24	✓John Hermos M.D. ✓	Brookline Citizens to Protect the Environment
~~25~~	~~Robert Dubrow~~	~~Individual~~
✓26	✓Fred Krupp - ✓	Connecticut Fund for the Environment
~~27~~	~~Representative~~	~~Physicians for Social Responsibility~~
✓28	✓Ed Loechler ✓	Individual
~~29~~	~~Annette Gattilia~~	~~Concerned Citizens for the Environment~~

ATTENDEES

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BOSTON MA.

PUBLIC HEARING--Proposed Airborne Carcinogen Policy

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I N D E X

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MR. HOHMAN: Good morning. I'd like to declare this public hearing open. I am Merrill S. Hohman, the Director of the Air and Hazardous Materials Division, EPA, Region One.

This is a public hearing to receive comments on EPA's Airborne Carcinogen Policy and EPA's advanced notice of proposed rule-making for generic standards for sources of carcinogenic organic substances, both documents as published in the Federal Register on October 10, 1979.

Today's hearing is the second in a series of three public hearings. The first was held in Washington, D.C. on Monday and Tuesday of this week, and the final session will be in Houston, Texas tomorrow.

The record of this hearing is open until April 14th for any supplemental testimony anyone wishes to make or any comments anyone wishes to make in rebuttal to the testimony we hear.

Let me introduce the panel, and I'll start on my far left is Bob Kellam, Standards Division, Office of Air Quality Planning and Standards, EPA; next to him, Roy Albert from the Cancer Assessment Group, EPA; on my immediate left, Joe Padgett, Strategies and Air Standards Division, Office of Air Quality

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Planning and Standards; on my immediate right, Todd Joseph, Office of General Counsel; next to him, Elizabeth Anderson from the Office of Health and Environmental Assessment; and David Patrick from the Emission Standards and Engineering Division, Office of Air Quality Planning and Standards.

The gentlemen and lady in back of us are representatives of Clemment Associates, a consulting firm engaged by EPA to assist in developing this policy. We also have three EPA staff people here available to help you. They're at the back of the room; Frank Kerwin, Margaret McDonough and Joe Bedilcia (phonetically). If any of you have any problems or need help in finding your way around or in any other way, they're available to help you.

Let me very briefly cover the ground rules for today's hearing. The hearings are informal. Individuals providing oral testimony will not be sworn, nor are there any formal rules of evidence to be followed. Following the testimony, questions may be posed by the EPA panel members, but there will be no cross examination by any other participant.

Questions from other participants may be submitted for consideration by submitting them in writing to me and then we'll consider those at that time,

and there are blank cards down at the back of the room if you want to write your questions out.

We are asking, because we have a long length of speakers, that all participants please try to limit your oral presentations to no more than ten minutes, that any more detailed statements and any referenced material that you refer to in your statement should be submitted for the record.

We have made special arrangements for the first speaker today to have more than the ten-minute time, but unless other arrangements are made by others, we're asking you to limit it to ten minutes.

When you come up to testify, please give us your name and the organization, if any, that you represent. Also, if you have copies of your statement, please give them to the hearing staff down at the back of the room.

These proceedings are being recorded by a court stenographer and a verbatim transcript will be prepared. Copies of that transcript will be available for inspection at the EPA Regional Office Libraries, including the one here in Boston at the John F. Kennedy Building, and at the EPA Central Docket Section in Washington, D.C. If anyone wishes their own copy, please contact the stenographer directly.

In the back of the room, we do have copies of the Federal Register with the proposed policy and advance notice of proposed rule making. There is an index, I believe, of written comments received to date on the policy, a listing of the hearing speakers and the agenda for today's hearing.

We will call witnesses in the order on that agenda. If any witness that is scheduled to testify knows of any delay, time conflicts that might give a problem, again, please see the hearing staff at the rear of the room.

If there is anyone who needs any audio-visual equipment for your presentation also, please contact the hearing staff down at the back of the room as soon as possible so we can make arrangements.

With that introduction, I'll call our first speaker, Richard Wilson, representing the American Industrial Health Council.

MR. BAYS: Mr. Chairman, I'm Jerry Bays (phonetically), associate counsel for AIHC and we have been working with Dr. Wilson for the last few weeks with respect to his testimony and we just have not had time to get copies made for the panel as we had yesterday and the day before in Washington, D.C., but we shall have copies made within the next few days and submit them for

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the record since it is a fairly lengthy submission. For being unable to submit it today, we apologize.

DR. WILSON: Good morning. My name is Richard Wilson. I'm a professor physics at Harvard University and although I was asked to give this testimony by the American Industrial Health Council, what I say is going to be my own opinion and the comment that I've had from the American Industrial Health Council is solely what other people have been saying on their behalf, and a correction of one or two pieces of my English. In no case have they adjusted my opinions.

Firstly, I agree with the general discussion in the Federal Register on the problems of carcinogens, but I want to point out that I disagree that they should be logically regulated in a very distinct way from other air pollutants such as sulfates. For neither sulfates nor carcinogens is there proof of a threshold below which adverse health effects are zero. I've reviewed all this in a forthcoming book on air pollution through coal burning and in particular, cancers caused by polycyclic aromatic hydrocarbons and by radiation, and I append those chapters from the book to the testimony. I believe there is evidence that air pollution may cause cancer, at least among cigarette smokers and the number of cancers is no more than about

one or two thousand per year.

These will be caused by polycyclic aromatic hydrocarbons which are produced by incomplete combustion. Coal used to be the source; now it is mostly automobiles. If we are not careful, wood burning will be the new major unregulated hazard. And now I agree that for other cancers, we cannot wait until people are dying before we take action.

Now, the procedure for using animal fats which I want to discuss is by analogy, as for example discussed in a paper by Crouch and myself which is published and I attach to the testimony. I find no direct evidence that any cancers are caused by the chemical industry of more than ten a year. Calculations show that no direct cancers of any cancers are caused and calculations show no more than ten per year from the chemical industry.

Even in the case of vinyl chloride, which is regulated, an upper limit of ten environmental cancers was derived from old exposures from EPA and these exposures are now reduced by a factor of 100. I have checked the EPA calculations. So, EDF and NRDC in its submission claimed that air dispersion calculations are too inaccurate to be useful, but if you look at the calculations, they are accurate to within a factor of 2, which is

quite good enough to be used for this. Less than 5 or less than 10 is not the question of issue here.

We can also estimate from work of Blot a moderately large number of cancers, in the tens per year, might come from arsenic if the Blot data is correct, though Blot thought my estimate from that of 30 per year was a bit too much. And I point out that arsenic from coal burning produces as much environmental arsenic as from anywhere else and is unregulated.

Now, I want to proceed -- leaving that -- to what I think is a logical structure for control, and I will quote a statement by Mr. Train who used to be my boss on May 25, 1976.

"I believe that it is important to emphadize the two-step nature of the decision-making process with regard to the regulation of a potential carcinogen. Although different EPA statutory authorities have different requirements, in general two decisions must be made with regard to each potential carcinogen. The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce the risk.

"Once the detailed risk and benefit analyses are available, I must consider the extent of the risk, the benefits conferred by the substance, the

availability of substitutes, and the costs of control of the substance. On the basis of careful review, I may determine that the risks are so small or the benefits so great that no action or only limited action is warranted. Conversely, I may decide that the risks of some of all uses exceed the benefits and that stronger action is essential."

It is important to start with a structure such as this because even though there are information gaps in the structure, without a structure illogical actions may be suggested.

Firstly, it is clear from the general wording of the proposed rule that the desired result is the improvement of public health. It is important that we want to use our efforts to improve public health in the best possible way, although we may not always quite know what it is. We may not be able to find that optimum, but we can put bounds on what's sensible and rule out some foolish procedures.

Now, I want to show how a logical structure can sometimes lead to a risk benefit analysis when information is available, on occasions when the risk is very high, one can even sometimes justify best available control technology -- though I don't like it -- but never can one justify zero risk.

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Now, although on Page 58654, Section D, the EPA outlines a sensible proceudre for risk assessment which roughly corresponds to mine, they seem to reject risk benefit analysis in what I call a very extraordinary section on Page 58658, which I would like to discuss.

Firstly, in the third column of that page, the logical structure seems to be rejected and a straw man set up in the paragraph, "Cost Per Life" goals. It stated incorrectly that, "the basic assumption is that it is appropriate to assign a single monetary value to human life." I think that's an incorrect assumption of risk benefit analysis. It's true that if one does assign a monetary value to human life and does a cost benefit analysis, one has a workable algebra. But it is not necessary to assign any value to life -- and certainly not a single one -- to have a workable rish benefit calculation.

What is necessary is to decide how much society wishes to pay in effort, other lives, and other currencies such as money, to save lives. Society cannot pay more than it has -- however mush it may wish to do so -- whatever the "value" of human life. If I was asked to pay a million dollars ransom for my children and only had -- or could only borrow -- a couple of

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dollars, I couldn't save their lives no matter what their value.

There are indeed ethical problems in discussing the value of a life, as pointed out by the administrator, but discussion of these can be to a considerable extent avoided by proper restriction to the discussion at issue, and not allowing the discussion to wander into addressing unnecessary decisions.

There are far bigger ethical problems in spending all society's substance in trying to prevent a circumstance in which one life might be lost and leaving none for anybody else, and it is important to remember that the whole discussion in this application of the Clean Air Act is hypothetical; no one can tell for sure whether even one life will be saved by reducing the small exposures of the chemical industry, whatever the expense. As shown below, some lives have been and will be lost by trying to reduce them. Ignoring the pleas from others whose need for society's substance is as great or greater is grossly immoral.

Now, also stated in the column, "the internalized and externalized expenditures for protection of human lives in American society ranges across a vast spectrum," but EPA does not prove that this range is not due to ignorance and incompetence of regulators

and merely states that it is due to variations in desires of the American people. I doubt that that's true. But even if the EPA implications were right, that does not rule out a proper risk benefit analysis. It merely points out that in some cases society wants the benefit to exceed the risk by much more than in other cases and that no one number can suffice to account for society's willingness to pay -- a set of numbers must be used. A rationale for one such set has been given in a paper by Howard of Stamford University.

The administrator's next sentence is also a straw man. Any good risk benefit analysis does, "consider the balance of equities between those benefitting from the activity creating the risk and those who may die as a consequence of the activity." This is sometimes called disaggregation of the risk benefit balancing. We might have several analyses for different subgroups. The way society balances these matters can vary in different cases; a reduction of real estate tax for those living near a polluting plant which is much greater than for someone living further away. We traditionally treat occupational exposures differently from the environmental ones. This sentence also seems to deny the possibility of carrying out the risk analysis demanded on another page, 58654, 2nd Column, Section D

1 (e).

Finally, the administrator sets up a straw man in implying that a sensible risk benefit analysis, "ascribes more certainty to the risk assessment and cost estimates underlying its use than is justifiable." This may be true of EPA and possibly of FDA, but it is certainly not true in general. I append to this testimony some notes on uncertainty in calculation of risk which I presented to the FDA addressing this very question.

This section seems to be trying to satisfy others who (incorrectly) oppose risk benefit analysis on this ground. One common statement is that since risk assessments are uncertain by a factor of a million, then they are of no use. In one sense, risk assessments are uncertain by a infinite factor. There are those who seriously believe there is no risk at low exposures and the cautious procedure proposed by EPA, with which I agree, is to assume proportionality of cancer incidence (risk) to exposure, and therefore calculate a finite risk. A finite risk divided by a zero risk is infinity. Yet, this does not make the analysis meaningless. For few people seriously propose that the risk is greater than given by the proportional relationship and so the risk so calculated becomes a reasonable upper limit and useful for public policy purposes. The statement, there-

fore in Reference 8 I have, is a red herring and I am glad the EPA did not endorse it, and I hope they continue not to.

The whole section I find here is full of straw men and one way of solving the energy crisis is to take the straw and burn it.

I would point out that in this section, although it is a different act, the Toxic Substances Control Act requires the EPA to compare risks and benefits.

Now, the right thing to do, in my view -- and I append the section of a book which we're just getting ready on the subject, is firstly to assess the risk; secondly to assess the uncertainties and highlight the uncertainties -- not ignore them, highlight them --; thirdly to assess the benefits and the uncertainties thereof; fourthly to compare the risks and benefits and disaggregate the comparison groups; and finally, to display the results as clearly as possible both for the decision maker and the general public.

Unless each of these is done, and clearly done, the decision will be correctly attacked as arbitrary and capricious, including the EPA proposal here.

Now, when we discuss how much money one should figure society should spend on reducing can-

cer, there is one agency I know that's done it -- they've made an attempt -- and that's the Nuclear Regulatory Commission. It faced up to this after a long, three-year hearing (the so-called As-Low-As-Practicable Hearing) and they suggested that if exposure to radiation could be reduced at a cost of $1,000 per man rem, it should be.

The risk of radiation corresponds, according to the BEIR report to 10^{-4} per man rem, calculated on a linear, non-threshold basis. That $1,000 per man rem corresponds to about $10 million per life saved. The NRC considered this to be a temporary figure and suggested a large, long public hearing, probably with other agencies involved, to decide on this number. Meanwhile, they chose $1,000 per man rem as being a round number larger than any other presented in testimony at the hearing.

The cost of reducing risk has also been addressed by the International Commission on Radiological Protection. They have a slightly different unit, the sievert, which corresponds to 10,000 man rems, and they quote, translated into older units, anywhere from $10 to $250 per man rem, not the $1,000 for NRC. So, this risk factor comes to anything between $100,000 and $2,500,000 per life saved with the same procedure.

Now, another point to bear in mind, another way of looking at it is that if you spend money on control equipment, lives will necessarily be lost in the process, the secondary effects of the decision process, but since these decision processes are involved with small items, we musn't ignore the secondary results because the primary result is small.

Now, half the expenditure on reducing occupational exposure -- reducing environmental exposure might be expected to be on capital equipment - often construction equipment. In construction work, people have all sorts of accidents from bulldozer accidents to falling off roofs. The oft-quoted example is that three people died in building the Brooklyn Bridge. The total number of workers killed in construction work in 1975 in the United States was 2,200.

Now, I can calculate as follows: The receipts from the construction industry were $164 billion in 1972, containing a great deal of duplication due to subcontracts, so let's divide that by two to get a rough guess of what was primary construction, and that gives you a number of about $36 million spent in construction, one life will be lost.

Thus, for this secondary effect alone, we should be spending more than $72 million merely to

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save one life, particularly when that life is hypothetically calculated and may not be a fair statement at all.

Now, the NRC figure of $10 million to save a life may be low, but a lot of distinguished men think it high. I quote Nobel Laureate Joshua Lederberg, now president of Rockefeller University: "We might be willing to double our health expenditures for 20% improvement in health; this would imply a willingness to invest $400,000 to prevent a death, which is on the high side of present day political judgments."

Now, McCarroll of Electric Power Research Institute pleads for not spending too much on air pollution control, and reminds some advantages of cheap electricity to public health. Now, I pointed out that if you properly set such a number, we will automatically avoid over-expenditure on pollution control. I will also remind you that there are many cases in medicine where lives can be saved for $100,000 or less. An artificial kidney unit costs $30,000 and an intensive care unit often costs $20,000 per life saved. An average cost of cancer treatment, from the figure I got from Boston about two or three years ago, was $50,000 and saves perhaps 30% of all cases, corresponding to about $150,000 per life saved.

So, the important feature of the discussion

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here is that there was almost no objection during the long NRC hearing to having some number being used by NRC -- only a discussion of the exact number and as noted above, NRC chose a number larger than anyone had suggested. I suggest you might start off by doing the same and if someone objects, then you can consider it more carefully. Better still, hold the public hearing.

I now want to go into the reason why I feel there is no logical basis for best available control technology or zero risk in most cases. Now, there are studies of non-carcinogenic air pollutants and one of them is the Brookhaven Studies, that suggest that about 50,000 people a year may have their lives shortened by an air pollution related disease. As I say, may. These are probably due to small respirable particulates, though whether they are due to sulfate particulates or not is still a matter of controversy too.

Now, if we were to assign the $10 million as a sum society is willing to spend to remove this possibility, then we'd have to spend $500 billion a year to stop this air pollution, which is a huge number and would give very serious dislocations to society.

So, even if we say let's weight this number of $500 billion by a probability of 1/3, assuming the Brookhaven is correct, and weight the decision, then

you come to $160 billion per year, which is still a large number.

In this case, you might say, "We can't do that. We want to do the best we possibly can," and you could then say, "I'll use the best available control technology," where you can take some degree of expense into account.

Now, the number of cancers produced by polycyclic aromatic hydrocarbons is maybe about 1,500 per year and again, this recipe would give you $15 billion per year - still higher than most people would think reasonable to control benzyl chloride and other poly-aromatic hydrocarbons. So, we probably would gain by using best available control technologies.

But there is, and never was, for example, best available control technology justification for vinyl chloride exposures. Let me go into that one. The need to reduce occupational exposure (with which everyone agreed) caused enclosure of much of the systems, so the environmental emissions were already reduced by a factor of 10 before EPA acted upon vinyl chloride. So the EPA standard only reduced the hypothetical cancer rate from one per year to one in ten years, and I reiterate that if there is a threshold, the standard did nothing. The NRC rules suggest that regulation of this

sort was necessary if it cost $10 million or less, but not otherwise. In fact, it cost much more. We now know it cost $200 million capital and $90 million annual operating cost. Not only that, but due to unnecessarily short deadlines, there was unseemly haste and therefore unnecessary cost. Moreover, lives were lost; two people are identified as lives lost in the construction process.

Now, we might consider the list which is circulated by EPA which I attach -- I don't know how I got it, but it's here. It's certainly from EPA -- of pollutants which might be considered under this rule. Only the risks calculated by ethylene dibromide gives a large number which might need regulation. The reason why ethylene dibromide is it comes in huge quantities out of one's automobile exhausts, not because it's done -- maybe it should be stopped. It's the only one I can think of that you can right now apply this hearing to.

The administrator is correct in rejecting zero risk approaches, in my opinion, but incorrect in the discussion thereof on Page 58660, Column 3. "Where Congress has intended to require safety from the risk of cancer to be absolute, it has known how to express that intention clearly as it did in the Delaney Cause of the Food and Drug Act." This is a careless and

incorrect reading of that Act. The Act does not discuss zero risk or zero exposure. The clause as I find it reads as follows: "no (food) additive shall be demed to be safe if it is found to induce cancer when ingested by man or animal or when it is found after tests which are appropriate for the evaluation of food additives to induce cancer in man or animal ..." The word, "zero," is not used.

The clause goes on to ban the use of any such additive in "any detectable quantity."

A chemical which is not found to be carcinogenic can nonetheless be present and therefore present a finite risk because it may be carcinogenic. A chemical not detected may still be present and present a finite risk. It is clear that Congress, even in the Delaney Clause, rejected zero risk in favor of a more workable law. The law, though workable, produces incentives for bad experiments and bad practices as stated so eloquently in the paper by Schneiderman and Mantel.

The language of 112 is even weaker than that of the Delaney Clause and so zero risk must be rejected even more decisively than the administrator states.

I now want to propose a procedure. I propose, and some definition which you haven't defined

and I think you should, a risk should be regarded as significant if it is calculated to be one in a million per year or greater. This risk may be significant only to a small group of people, but nonetheless, if this group can be defined, it must still be regarded as significant.

For preliminary matters, the rish should be calculated according to the standard procedures that you outlined and other people have, linear, non-threshold, basis and so on. Uncertainties must be combined and I've suggested a procedure for combining them.

In combining the uncertainties, the important point is that for an individual, it is not relevant whether getting cancer is uncertain because it is intrinsically undertain, an intrinsically random process, or whether it is just not known. That enables you to combine these uncertainties, including a linear dose response relationship all together, and you then take Risk (corrected for uncertainty) = Risk (uncorrected) multiply by the exponential [½ (σ_1^2 + σ_1^2)] where σ_1 and σ_2 are standard derivations of the log normal distributions for above-normal distributions for the exposure and carcinogenic potency. This typically multiplies the risk by about a factor of 2 or 3.

Now, in cases where the exposure is wide-

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spread and all the U.S. population has a risk of one part per million, you may wish to take a stronger action because that would still be calculated to 200 cancers per year, as in the saccharin case. Reducing individual rick only to one in a million per year may not be adequate. In such cases, you may also want to calculate the total societal impact and reduce that to ten per year. I would, of course, add to the proposed method of risk calculation the possibility that a chemical changes its form after emission and becomes more troublesome. Thus, sulfur dioxide becomes sulfate particulates and in purification of water, chlorine turns organic matter to chloroform, as found out by one of my colleagues, and that's a known carcinogen in animals. I twas at pains to point out that vinyl chloride, in that article, that vinyl chloride breaks down in light and becomes less dangerous in the environment. This may not always be true and we should watch for it.

Now, I suggest that significant risks must be reduced if it can be done for a reasonable cost. Like NRC, I don't know what is reasonable and expect that a set of numbers is necessary. Like NRC, I suggest $10 million to save a hypothetical life is a large number which you could reasonably take as a first approximation.

I suggest also that the above can only

be the general rule. As noted before, it is generally conceded that the linear, non-threshold extrapolation gives a pessimistic estimate of the hazard although it is one which is easy to understand. The analysis, therefore, must be preliminary; if an important technology may be allowed to proceed without too much expense for control, no more analysis will be needed. Perhaps you might not want to put it on your list or maybe have two lists, one which is a real list and the other one your private list of what you're doing calculations on. If it means that an industry would close, it should be permitted -- the industry should be permitted to make a case for using whatever more realistic response they may be able to justify, including, of course, human epidemiology which if negative could show an effect as being not as severe.

Likewise, if a case can be made, by anology, for using a sum less than $10 million per hypothetical life in any circumstances, that reduced expenditure should be permitted.

Finally, and most importantly, continuing efforts must be made to find better and cheaper ways of reducing the remaining residual risk. There are a variety of ways of doing this, none of which were mentioned in the EPA proposal and I'm not going to waste

time doing that here, which is a long business.

I now want to make some miscellaneous comments. There was on reference, Reference 17, of the Federal Register pointing out that occupational cancer is a source of information on what is carcinogenic and what is not. However, it is possible to have low occupational -- the connection between that may not be relevant because it is possible to have low occupational exposure and fairly important and high environmental exposure and vice versa. That reference, in this context then, is of dubious relevance and the most important point, however, is that particular reference, a reference to a draft estimate produced by Mr.Califano in a speech on September 11, 1978 has been heavily discredited; it had contributors, not authors, and to the best of my knowledge, no single scientist has stood up to say that he is willing to support that document, including -- as far as I know -- none of the contributors. On this, the contributor allows his draft to be quoted as if it were an ordinary scientific document. It should be scrupulously ignored. It is unnecessary to quote this anyway because there are many good references to the fact that occupational exposures have caused cancer and many good references to the fact that they may cause more and any one of these references could be used.

Thank you.

MR. HOHMAN: Thank you, Dr. Wilson. Are there any questions? Betty?

MS. ANDERSON: Yes. I'm not sure which microphone I'm speaking to.

MR. HOHMAN: Either one.

MS. ANDERSON: If you can't hear me, raise your hand. Dr. Wilson --

MR. HOHMAN: Louder.

MS. ANDERSON: -- as you probably know in the Federal Register notice, the EPA specifically solicited comments on the nature of the airborne carcinogen problem. We have heard from a number of witnesses on this. One witness stated that the nature of the problem was absolutely negative. In other words, no impact whatsoever from air pollution.

Another witness stated that it was practically negligible, although did not state it in such absolute terms. A third witness said that he regarded the contribution as very significant, but could not attach numbers to it.

Did I hear you correctly that you said in your testimony that you think between 1,000 and 2,000 cases of cancer result from air pollution, mostly attributable to POM?

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DR. WILSON: Well, I think one could make all these statements consistent. Of course, it depends what different people call significant. I would remind you Richard Dahl (phonetically) in a paper on this subject, who is one of the experts on these things, took pains to point out that if there are effects due to air pollution, they are a very small fraction of those due to cigarette smoking - no more than 5%, and of course, in lung cancers 5% is still 4,000 a year in the United States.

So that if you say 5% is hard to find in the middle of the background of lung cancers, however, I am now talking second-hand, but I remind you there was a paper by Dahl and Petow (phonetically), which points out the significant result that cigarette smoke due to, he believes, air pollution effects is statistically insignificant for non-smokers, and it would be smaller than for cigarette smokers, so that number would --

The other question was, there was evidence by influence but not by direct data that if you believe, for example, that data available for high doses of poly aromatic hydrocarbons upon coke oven workers, upon asphalt workers is extrapable by a linear relationship to the lower levels of available air pollu-

tion, even though the combination of hydrocarbons is widely different. Then you get a number of about this amount.

As you well know, the Carcinogen Assessment Group have come up with a number which is a little smaller than mine. But the main point is that number is, at the moment, certainly unproven. It's probably unproven.

MS. ANDERSON: But the 1,000 to 2,000, are you including cigarette smoking in that?

DR. WILSON: This would be the number additional to -- this is including cigarette smokers, but the cigarette smokers will probably have less lung cancer.

MS. ANDERSON: Do you think it's possible to subtract out the contribution from cigarette smoking?

DR. WILSON: Well, subtracting, of course, as you know, due to multiplicity is a funny way. If you ask the effect on non-smokers, the effect on non-smokers according to the studies, is probably smaller, and sounds reasonable, and is certainly not statistically significant. But I think no one has claimed, to my knowledge, to have found evidence which satisfies it statistically that there is any effect on non-smokers.

MS. ANDERSON: In trying to grasp the

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significance of the contribution to cancer from airborne carcinogens, we are certainly interested in any of your calculations, but I notice that you also -- I believe you said that you think perhaps ten cancer deaths a year could be attributed to the chemical industry.

I wondered in these calculations several things. One, if you were able to take any co-carcinogens into account and also in just looking at the numbers you quoted for vinyl chloride, I believe you said you reduced the ten per year by a hundred fold and from the Blot data on arsenic, you reduced thirty to ten per year and it seemed to me just, if I'm correct in understanding you, that just with two chemicals, you're getting close to the ten per year contribution from the chemical industry. So, in other words, I'm wondering, does your ten per year take co-carcinogenesis into account and how did you calculate it?

DR. WILSON: Well, let me explain. Let me explain that in slightly more detail. Firstly, the ten per year I don't think are direct evidence. If you take the data of old exposures before there was any control of vinyl chloride and carcinogenic air dispersion calculation. I particularly follow the calculations of Cusmack and McCormack from EPA which I've checked -- McCormack was one of my students at

one time -- they would give you about ten per year cancers on a linear proportional basis. However, we know the exposures are now reduced

environmentally depends on the particular plant and they're still coming on down because people are finding small, fairly cheap ways if you give them time to reduce them.

So they're now down a factor of a hundred. That was one of the big ones in a certain sense. Now, the arsenic is probably not -- Blot's paper was concerned with smelters not the chemical industry, and he didn't actually give a number. I calculated a number for him and wrote it up and later I gave it the occupational carcinogen test on the calculation, but he thought that was, in a private letter to me, thought I'd overestimated when I said thirty per year.

MS. ANDERSON: All right, just to insert something here, Cusmack's policy covers smelters as well as the chemical industry, so when you speak of ten per year, you're really talking about the contribution just from the chemical industry.

DR. WILSON: That's right.

MS. ANDERSON: And so if you add smelters in, the petroleum industry and so forth --

DR. WILSON: Smelters might be ten per

year by themselves and the ethylene dibromide is high. I haven't calculated it, but of course, one of the reasons why that's high is because one of the purposes of making ethylene dibromide is to deliberately put it into gasoline and deliberately permit it to the general public just at the level at which it goes into our services.

MS. ANDERSON: I see. I think we would be interested in your calculations if those could be submitted as part of the record.

DR. WILSON: I could submit my calculation on arsenic, I suppose, and Mr. Blot's letter saying he thought I was pessimistic.

MS. ANDERSON: Yes, because I was wondering in our calculations on arsenic, I recall something in the neighborhood of 7 to 10, but we were taking into account smelters and all sources of air pollution covered by this policy.

DR. WILSON: But I was trying to be pessimistic in my calculation. I was not trying to be realistic. I want to emphasize that. And indeed, I understand there's evidence that -- I want to emphasize that paper by Blot was entirely circumstantial evidence, nothing on which -- it should not be regarded from a scientific point of view as suggested and I would not even regard it as that.

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MS. ANDERSON: Okay, and so then overall, in trying to get a handle on what you're saying the contribution from air pollution might be in terms of cancer deaths per year, we would have some from the chemical industry and then some others which you have not calculated?

DR. WILSON: Right. I haven't gone through this whole list in detail, but I've just looked at the numbers because I haven't got exposure data on most of them. The ones, however, which stand out to me and which I know are strong carcinogens in this listing, ethylene dibromide as you well know is a carcinogen, and we just have to know it's a very strong agent. That's the one which we just brought out.

MS. ANDERSON: I had just two other things. One, you stated that you -- I believe you said that you don't think that the overall contribution from the chemical industry, that is, ten cancer deaths per year, would be substantially improved by regulation.

I wondered, if I heard you correctly, the basis for that.

DR. WILSON: No, I'm not sure I did say that and I didn't mean to say that. It might be improved by regulation. My point is that if you have too tight a regulation, you'll spend a fantastic amount of money

and then end up by reducing the ten to three with several billion dollars and then in that process of spending several billion dollars, you will even kill more people. And so that's not a particularly good trade-off.

So, I am suggesting a calculation by a procedure by which you decide which parts of the chemical industry or any industry are worth paying attention to and which parts are not. And one of them, incidentally, I wish should be paid attention to is the desire of some people to burn wood in open fireplaces.

MS. ANDERSON: And something else I thought I heard you say and let me just check on it, that anybody dealing in risk assessment should be able to choose whatever model they like.

If I heard you correctly, I'm sure you know from the saccharine report issued by the NAS that depending upon models, you can make the number vary five million times, and it seems to me if anybody chooses any model they want, it would serve little purpose except to perhaps discard any consideration of quantitative risk assessment altogether.

Did I understand you correctly and is that what you really meant?

DR. WILSON: No. If I used those words, I said the wrong ones. I said for preliminary analysis,

I think it's appropriate to use a linear proportion model because most people believe that that is a pessimistic model and a reasonably bounding model. If you can accept something since you want to lean over probably on the side of protecting public health, if you can accept something on that linear proportion model, then you can accept it and then forget about it.

If, however, you can't accept it and then you find yourself in a dilema, you can't accept it and it's much too expensive to control it and you find in the dilema, do I shut down the automobile industry or do I do something else? Then it is quite reasonable to spend the extra effort on to very carefully what that risk benefit analysis is, and to ask yourself, can I justify a more reasonable dose of response relationship than the linear one.

Now, I don't say that you should automatically let the risk assessor choose what he wants, but you should not rule him out by some legal process saying, you must take the linear hypothesis. Take the linear hypothesis, if you can accept something, fine, but don't leave out the possibility of someone coming back in this particular case, I think might justify taking a quadratic term because of some evidence, animal test or some such test, come back and justify that

in this case, it can be done. It would clearly take much more work. The risk analysis would be required to be more and amybe the emphasis would shift slightly, but nonetheless, it should be allowed, and I think there would be such cases.

MS. ANDERSON: I think just to comment on that, the RRLG document on the scientific basis for risk assessment in EPA's general approach has certainly recognized that where such data can be generated, it certainly would be used.

DR. WILSON: That's right.

MS. ANDERSON: Okay, that's all.

MR. HOHMAN: Just one question I have. I take it from what you say, you're convinced that there is a problem with air pollution, that air pollution, you're convinced, does cause some number of cancers. The question that you have is basically, how many, and the cost for control and the quantitative approach to risk analysis and benefit analysis to establishing control. That's basically --

DR. WILSON: More or less. I will explain. I was brought up in London in the 1930's. Anyone brought up in London in the 1930's finds it hard to believe that air pollution is good for you, so instinctively, I think that it's -- so, I tend to judge

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the evidence on that basis.

MR. HOHMAN: In the last several days, we've heard, of course, pro and con in hearings in Washington, but there have been several rather strong statements to the effect that there basically is not an air pollution problem.

DR. WILSON: Well, I think it's -- I believe the cancer problem due to air pollution is smaller than the problem due to sulfate particulates which is also present and not being properly regulated and which I think, again, that's an unprovable problem and unproven. Certainly unproven. There are strong parties on either side and it's almost certainly not provable in any rigorous way.

And the carcinogen problem, more so, is unprovable in that rigorous way, except we can use analogies slightly more, and it is only by anology, by believing there might be a dose response relationship, if it's there, but there are distinguished people who believe the numbers of 2,000 may be too high.

MR. HOHMAN: One more question, then I'll get off the microphone because we do have a lot to cover today, but in your thinking about risk and the impact of these pollutants, there are basically two approaches. One is the risk to the individual, and another is the

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cumulative risk to populations.

Do you have any feeling as to which of those two should predominate in the thinking?

DR. WILSON: I normally would like to argue, at least in the preliminary analysis, that you should assume that both groups must be satisfied. That is to say -- that's why I'm taking pains to point out in my proposed procedure that the risk is regarded as significant if it's greater than one in a million per year for either any significant group of people and identify, and that might mean within a small community, not just people as a whole.

Now, I believe that if you were to satisfy that, there's enough variation throughout the country, the total societal impact -- if that were constant throughout the country, then you might still be getting 200 cancers a year from this cause, which in the saccharine case is about the number we're talking for saccharine and on the borderline of what people believe you should regulate or not.

However, if it's more variability, you might want to give it a try.

MR. HOHMAN: But if your preliminary analysis, as you say, indicated a concern greater than, say, one in a million for an individual, that would be

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cause for getting into it in a little more detail.

DR. WILSON: That's, of course, not necessarily for banning it, but going into it in more detail, firstly doing more detailed calculations -- well, if I was in industry and I had gotten to that level, I would firstly say, spend a reasonable amount of money saying, can I reduce it, and of course if it comes to a huge amount of money, then I'd start arguing instead.

MR. HOHMAN: And then do you have any feel for the concern as to total number of individuals per year that might conceivably get cancer? Is there some analogy to the one in a million that comes to mind when you're thinking about the seriousness of a problem?

DR. WILSON: Well, I don't think the problem is so serious that you've got to -- it's not like, for example, the risk of a coal miner in his work which is so big that it's a national scandal that we've allowed it to persist for so long and which must be reduced almost at all cost.

What we're talking about here is a risk which in any case, even the number which -- I'm saying a number and as Elizabeth was about to say earlier, that other people have testified to you and said that they don't believe there's any number provable. That means

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they say the number is very small. I agree it's very small, much smaller than from cigarette smoking, and probably smaller than being a passenger in the MBTA where they still allow cigarette smoking, although it's against the law.

MS. ANDERSON: I had a note on the same question and that is, I thought you said that you would be concerned if the nation-wide impact exceeded ten deaths per year.

I wondered if you meant per chemical or overall?

DR. WILSON: Oh, I hadn't really thought that through very carefully. I would certainly per chemical. I think overall, I think if you were to do that, I don't think you'd find more than about half a dozen chemicals we'd in fact be concerned with in any detail at that point, so I think the difference is not very big.

MR. HOHMAN: Roy?

MR. ALBERT: As I hear you speak, I believe that your central point or points are that if one does quantitative risk assessment using a linear, non-threshold extrapolation model, one would find that the risk from most chemical pollutants is trivial, and I think this is the basis that you object to in the

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current policy.

So, the central issue here is the plausibility of the linear, non-threshold extrapolation model which is being seriously challenged in this policy because the policy essentially says that it doesn't put much credence in it.

Your position is that it's a plausible upper limit risk, basis for assessing risk. How would you express the degree of uncertainty in that sort of thing? Let's skip the issue of the statistical uncertainty of the experimental data that you used to derive the linear non-threshold model. If you come up with an estimate of twenty extra deaths per year and you're trying to talk to a decision maker who's got to do the regulation and he says, "How good is that number? What would you tell him?

DR. WILSON: Let me first correct one thing. I'm not sure I'm objecting so much to that part of the policy. There seem to be some inconsistencies in what was written down here and that definition of what you call significant risk and things like this, and with that I thought ought to get clarified and I'm suggesting that procedure.

MR. ALBERT: Well, the policy clearly eschews doing a risk benefit assessment before taking

action.

DR. WILSON: Yes, I think that's probably -- I wasn't even clear of that as I read it. It seemed to me a policy constructed to say all things at once and therefore nothing at all.

What uncertainty would I apply? I think the main uncertainty clearly will have to come from the -- comes from the ability to use animal data or in vitro data before assessing carcinogenic potency in man. Now, if we have epidemiological data --

MR. ALBERT: What do you propose we do so there isn't any argument about it?

DR. WILSON: -- then I think the uncertainty is primarily uncertainty in exposures and that can vary in the individual case. I mean, for example, in the best of epidemiological data, which we have, we don't really know what those poor workers were exposed at. We know it was pretty high because a relative of my wife's, from Johns Manville, used to come out -- as an executive, used to come out with his suit absolutely white at the end of the day. That no longer happens.

Now, what that means in terms of exposure, no one knows, so that it's very hard to make anything but a very crude estimate on exposure in that

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case. So, it will vary from case to case, but in the vinyl chloride case, I think it's fairly good with that amount of uncertainty. You know, it's very hard to be up more than a factor of two or three.

MR. ALBERT: But if you just take the linear, non-threshold model per se, and let's assume that we know the exposures down to a gnat's eyelash and that we're dealing with data that is obtained on humans and it's very solid and very accurate, we still have the issue of the uncertainty in the linear extrapolation. And how would you describe it to somebody who is trying to get a feel for the goodness of the number?

DR. WILSON: Well, firstly, it is and must inherently be --

MR. ALBERT: I'm asking you because I find this an exceedingly vexing problem.

DR. WILSON: Of course it is, yes. I was only --

MR. ALBERT: And it's a central issue of the whole business.

DR. WILSON: It is a central issue. I believe the other one's even more central, but -- is more tricky, but this one is indeed central and it comes up in radiation and everything else. I would say that what happens at low doses must inherently be a

theoretical assumption because it is an area where we, at low dose levels, we have no data and in a very real sense, I hope we never will have data because if we have good data then the evidence may be on the wrong thing, and so far the ideas, any of the theoretical ideas we have about cancer all suggest -- almost all suggest that this straight line, proportional basis, is slightly pessimistic and most of them fall below that line.

The basic random nature of radiation-induced cancer, for example, whether or not a photon induces damage in a cell, automatically gives a straight line. Then you have to put in -- you assume that a human being has some repair mechanisms -- we are remarkably able to adapt to society -- which will get results below that straight line in almost all cases.

MR. ALBERT: Well, does your position boil down to the fact that if one comes up with an estimate of twenty cases a year and strips that estimate of uncertainties of the statistics from the cancer data itself, and just consider the uncertainties in the linear extrapolation model per se, then would you say that that represents an upper limit and the uncertainty is downward?

In other words, it's from twenty down, is the uncertainty, not twenty up?

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DR. WILSON: I would say it's a reasonable upper limit. I think the trouble is, any absolute statement is likely to be wrong. It used to be said that the only thing certain in life is death and taxes, but people have been known to avoid paying taxes, but death is certainly certain. Nothing else I know is certain, so in that sense, I would say it has to be just a reasonable upper limit and for that reason, that in any case that one should not completely forget about anything one does. One decides to continue to manufacture a chemical completely enclosed and you think there's no exposure. Why don't you continually watch it because maybe there's a little hole somewhere you haven't thought of and things of that sort.

So, I don't think even though I think that i s perfectly reasonable for public policy purposes, as soon as you insist on anything stronger, then you get into the possibility of the necessity of controlling and even banning every human action.

MR. HOHMAN: Okay. Just a couple of more short questions. Todd?

MR. JOSEPH: Yes, I do have some questions, Dr. Wilson. If you concluded that the data you had available were too uncertain to -- the data on risk and the data on benefits were too uncertain to do a meaning-

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my hypothesis as given.

DR. WILSON: No, but I reject that for the following reason. Because it is not a real decision you're asking me to deduce. If you present me a case which is a real decision, then you can address that real decision. In risk benefit analysis, most of the controversy, most of the discrepancies, most of the problems arise when people try and address questions which are not real.

I said, what is the decision you're trying to ask and what are the possible alternatives? That, you can address. If you try to address something hypothetical like what's the value of life, then you start getting into problems which you'll just go on talking forever.

MR. JOSEPH: Okay, let me ask you a few other questions. About the -- you've discussed the NRC's proceeding to determine a value for as low as possible, the ALAP proceeding.

DR. WILSON: Yes.

MR. JOSEPH: My understanding is that that proceeding was based solely in the context of nuclear power plants. That's right, isn't it?

DR. WILSON: I believe it was all radiation which was regulated by the Nuclear Regulatory Commi-

ful risk benefit or cost benefit analysis, would that affect your recommendations to us?

DR. WILSON: I think you can usually give some limits. I mean, if there's an unknown chemical you haven't started producing yet, and then is when you get into certain problems. It will depend a little bit on what your decision is at that time if you haven't started manufacturing the chemical or considered closing down an industry.

But, I think the important feature to bear in mind on any risk benefit calculation is the more uncertain the result, the more necessary is the calculation because only when you've attempted to put a number on a risk, including its uncertainties -- I want to stress that you've got to include the uncertainties -- only then are you sure that someone's thought the problem through.

If someone doesn't attempt to do that, then he is probably doing no better than tossing a coin.

MR. JOSEPH: What if you were unable to conclude anything more than that the cost per life were somewhere between $1,000 and $100 million?

DR. WILSON: Well, you're asking a very hypothetical question and if any --

MR. JOSEPH: But I'm asking you to take

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ssion, which includes hospitals and all radioactive isotopes in hospitals, but in principle, the main effort was nuclear power plants. You're correct.

MR. JOSEPH: And the premise of the proceeding was that there was already an upper, never-to-be-exceeded limit, isn't that right?

DR. WILSON: That's correct.

MR. JOSEPH: So that the proceeding was to determine how much residual, if you will, residual risk ought to be permitted beyond some fixed limit?

DR. WILSON: It was also to determine that upper limit, whether that upper limit was right. In fact, that upper limit was lowered in that proceeding.

MR. JOSEPH: Well, all right, but there was an existing federal upper limit, government-wide upper limit of 500 millirems, was there not?

DR. WILSON: Right. I mean, if you're asking should there be an analagous thing here, I would answer, in general, yes. In particular, I suspect at the moment it's unnecessary because the upper limits one is talking about would only be reached by the fossil fuel burning type of carcinogen. That's part of the distinction one makes between best available control technology when it might be applicable and the time when a risk benefit analysis is certainly more personal.

MR. JOSEPH: I wasn't clear in your recommendations on how you, taking your $10 million per life suggestion as an upper limit on cost --

DR. WILSON: It wasn't mine. That's NRC's suggestion.

MR. JOSEPH: Well, you suggested it as a reasonable sort of thing, just whatever the number might be. How does that address the risks borne by the individuals most exposed? Were you recommending that their risks be reduced towards one in a million --

DR. WILSON: Yes.

MR. JOSEPH: -- in addition to the population risk?

DR. WILSON: I was assuming significant groups, significant definable groups of people. I don't mean the crackpot who is going to lie down just outside the effluent of a chemical plant and breathe the stuff in.

MR. JOSEPH: I understand. I understand, but I mean, people living in the immediate vicinity of the emissions, for example.

DR. WILSON: People living in the immediat quarter of a mile, half mile, or else if it becomes larger, then one must discuss that particular case and discuss particular -- maybe compensation measures, what-

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ever one wants.

MR. HOHMAN: One more question.

MR. JOSEPH: One more question. If EPA has a mandate here to, in the regulation of airborne carcinogens to protect the public health with an ample margin of safety, do you think allowing a specified allowing a calculable deaths per year would fulfill that mandate if that number were one or greater?

DR. WILSON: Well, I think the risk of one in a million is lower than risks to which we're normally exposed. The risk of being killed in an automobile accident, for example, is two in ten thousand or a little more. The risk of -- the average risk of airplane accidents is higher. Certainly, the risk of living with a smoker is probably higher, ten times higher.

So, I think there is already in that suggestion of going to the ten to the minus six per year, a margin of safety.

MR. JOSEPH: But that's individual risk. I'm asking for the whole population.

DR. WILSON: Well, again, we have a considerable margin there in that ten per year is considerably less than 200,000, which is the total cancer rate. Now, indeed, I think one ought to steadily work on the cancer rate and bring it down and we know,

for example, from epidemiology, incidentally, not from this other work which cause possibly half the cancers, cigarette smoking, asbestos, alcohol and so on. We must change our lifestyle to get them down and we should work on them, but we don't start work at the bottom end and work to the top.

MR. JOSEPH: Thank you.

MR. HOHMAN: Bob?

MR. KELLAM: Dr. Wilson, you, in attempting to assess the cost that society might be willing to bear for a human life or to reduce the risk of cancer, would you see any dinstinction between the risks that we bear voluntarily as individuals compared to those which we might bear involuntarily as a result, say, of industrial emissions?

DR. WILSON: Oh, yes, of course. That's part of the question of the different numbers one might put in, and all of what I was addressing here, in fact, for quoting NRC, was deliberately addressing involtary risk. It's well known cigarette smoking is clearly voluntary and traveling in a bus with a cigarette smoker is involuntary.

I traveled here on the Green Line and you can say that if you might consider traveling -- the risk of a car as a necessity in Boston and you travel

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on the Green Line, therefore car accidents can hardly be called involuntary.

MR. KELLAM: So that if we looked across the spectrum of costs that have been applied or can be calculated for the reduction of risk in various types of environmental hazards, then you would agree that in the case such as air pollution, you might, in each case, assign a higher value to a life saved than you would, say, in the case of the location of a traffic signal or location of a railroad crossing or other types of cost benefit calculations that have been made?

DR. WILSON: Well, traffic signals and railroad crossings are to avoid the deaths taken involuntarily. The voluntary one might be, for example, the seatbelt. I mean, even though you have seatbelts installed, many people don't buckle them, and even installing a seatbelt, a rough calculation gives you $5,000 per life saved even if you haven't paid for it. The fact that you don't buckle it is really rather stupid.

MR. HOHMAN: All right, thank you very much, Dr. Wilson. Dr. Cortese?

DR. CORTESE: Good morning. I have a prepared statement and rather than read it -- I'm sure you've all received copies of the draft outlining some

of the concerns.

MR. HOHMAN: I'm sorry, do we have copies?

DR. CORTESE: I'm not sure you have received copies.

MR. HOHMAN: I don't think we have copies.

DR. CORTESE: Well, I did bring some copies and I gave them to a member of your staff.

MR. HOHMAN: Okay, thank you.

DR. CORTESE: At this time, I'd like to basically say several things. First, cancer is currently the second leading cause of death in Massachusetts, and that is quite a big problem.

On the whole, we support the proposal that you put forward as a reasonable approach to the controllin of airborne carcinogens. However, I do have some specific comments I'd like to make, and I hope constructive criticisms for handling the policies.

First of all, we have some concern over the judgmental approach used in determining unreasonable residual risk after the application of best available control technology. Our concern there is that when you allow a judgmental approach, it is likely in some cases the benefits of the substance or activity will be national while the risks to the public will be localized. And if you allow a judgmental approach with changing

political leadership in differing areas of the country and in Washington, along with the ability of the lobbying efforts of those potentially being regulated may result in an inconsistent application of this policy, and we have a concern about this and we hope that you can find some way to address that.

We strongly support the methodology proposed in performing a preliminary evaluation of risk. In particular, we believe that the evidence from epidemiological studies and/or at least one well designed mammalian study is sufficient to enable a judgment to be made that a substance is a "high probability" carcinogen.

Without going into more detail, I think that if you ask for more information than that and you ask for a second study to attempt to replicate the first, you can get into problems if you use a different animal model which may not represent the most sensitive individuals in the general population.

It is especially important that the results from preliminary evaluations of the probability of human carcinogenicity and preliminary evaluation of population exposures be made available to the states for review.

The reason for shis is very simple. A

substance or an industry may not be a problem from a national standpoint, but it may -- and therefore not merit high priority for your control, but if it is a localized problem in a given state, we not only should but we must deal with it and therefore any information that you have available, we would appreciate making it available to the states as quickly as possible.

If quantitative risk assessments are to be used when making a determination of unreasonable residual risk, we would propose that a predetermined decision rule be established. A suggested acceptable risk might be one chance of getting cancer out of a million or ten million or a hundred million or whatever EPA decides is the most acceptable risk factor to use, but I think a decision rule is imperative.

And I'd like to digress for a minute here and express a concern that I have and I hope that through the cancer assessment group that you may be able to address this. And that is that in looking at safety factors and risk levels that we have set for environmental standards, I believe there is a difference in the risk level that we have allowed for drinking water versus air versus other means of exposure in the environment.

And my feeling is that after you have

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quantified the differences in exposures and the differences in dose, that the risk level ought to be the same. You know, assuming that you're taking into account an absorption rate and detoxification of the body and things of that nature. And I don't find that to be the case and I have a concern about that.

Sometimes -- I've asked for some research to be done on this issue because I believe that in some cases -- for example, in drinking water -- we have accepted a lower risk level than for air, and what bothers me about that is that people drink about two to three litres of water a day and you breathe several thousand litres os air a day, and so for an equivalent concentration, the total body burden is much greater from the air we breathe than from the drinking water.

For that reason, I can't see why we would have a greater risk being allowed in the air route than in the drinking water route, so I ask that you address this problem and I think that it is significant.

We do oppose the requirements for new and modified sources as outlined in the proposal. And the reason for this is that our concern is with the plan to locate new sources in unpopulated areas. We have the responsibility of protecting each individual

to the same degree. A family living next door to a facility emitting a carcinogen would be at risk whether they were located in a rural or urban area, and should be given the same protection. Under EPA's proposal, it is conceivable that a source whose emissions might be predicted to result in one case of cancer per 100,000 individuals exposed would be prohibited from being in Boston where the population density is very high. However, it is also conceivable that the facility could be built in the Berkshires where the population density is low. A criticism could be made that EPA is not protecting rural dwellers to the same degree as urban dwellers.

The ramifications are also great with regard to the future growth potential of the area in which the new source might locate. Do we plan to restrict future residential, commercial and industrial growth in a currently unpopulated area in order to allow a source to emit a carcinogenic substance? I think not. It would seem that if our society needs the benefits of these substances, then we must accept the cost of control.

From an energy conservation viewpoint, we would not necessarily recommend locating major industrial sources in unpopulated areas. Transportation of workers from their homes in a populated area to their

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place of employment in an unpopulated area could be energy intensive and add to the pollution burden with other kinds of chronic respiratory disease. Also, little is known about the bioaccumulation of many chemicals. It may not be wise to locate such sources in rural agricultural areas where carcinogenic materials may in fact get into the foodchain.

We endorse the idea of the presumptive national emission standard as proposed and believe that the criter for getting a waiver should be very stringent. It seems likely that permitting a waiver to best available control technology, including the option for an alternative source specific standard, will be cumbersome and resource intensive. I don't think either EPA or the states have the manpower to administer this and it's conceivable that most new facilities would apply for a waiver to best available control technology or an alternative standard since both options would be less expensive to meet. And I think we might just be opening up a Pandora's box in terms of making that kind of decision.

We also have a concern about the offset business, and our concern about the idea of offset is not from the standpoint of whether the total risk to society would be changed. I understand that what you're

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proposing is that the total risk be the same if an offset is allowed, but the problem in siting any particular facility is the specific people that live in the area, and if you offset an existing carcinogenic risk in one community by giving it to another community, that is not going to be acceptable to the second community, and I assure you there would be great opposition to that kind of policy.

Finally, I do hope that in making a determination which I think is a good one, in judging an unreasonable residual risk, you would look at the range of expected cancer incidents from the operating of existing sources. And presumably if a plant was only going to be around five or ten more years, you might not consider that an unusual residual risk.

I just caution you that in making that calculation, you have to go back and determine whether or not that source was emitting a carcinogenic substance for twenty or thirty or forty years before that because that extra ten years might be the difference in chronic dosage between whether or not people do get cancer or not. We don't know that and can't say that for sure, but I do recommend that we go back and take a look at how many years it has been operating before as opposed to just just looking at the future. I know

that's not an easy thing to do, but I think we must do it if we are to regulate it properly.

So, that is the sum and substance of my comments and I'd be glad to answer questions.

MR. HOHMAN: Questions? Betty?

MS. ANDERSON: Tony, I have just a couple of questions. When you mentioned the judgmental approach, did your concern go primarily to what you said about having a decision rule for residual risk or are there other parts of the policy that you regard as too judgmental, such as the weight of evidence approach to discussing carcinogenicity or other factors?

DR. CORTESE: The concern, the original concern that I expressed was really the idea that in determining unusual residual risk after the application of best available control technology.

MS. ANDERSON: And just one other thing. You mentioned that you thought that it's your perception that the drinking water is accepting a lower risk than air.

I was unaware of this, and I wondered if you could give us some examples or set us on the right track to figure this out.

DR. CORTESE: Yes, I can try to give you some idea about that. My concern is not so much with

the carcinogenic standards that have been set, but in the other area in which the greatest safety factors have been used in drinking water and I think can be used in air contanimants because I'm more familiar with that as a Chemist, but I also am concerned that we take a look at total dosage and some of the lowest concern that we're expressing in drinking water, if we were to translate those into air levels, it would be much more stringent than I think has been proposed to date for existing types of pollution sources.

MR. HOHMAN: Todd?

MR. JOSEPH: Just one question. I'm not sure from your suggestion that we use a decision rule for residual risk. I take it you're talking about the level of risk to individuals.

Do you have a comment on the suggestion we heard earlier this morning that perhaps it would be appropriate to permit a certain number of projected deaths every year among the population even though individual risk was reduced?

DR. CORTESE: I didn't hear the comment. I'm not sure I understand it.

MR. JOSEPH: Well, we're considering risks of two kinds. One is the level of risk to each individual who may be exposed, and often, usually there

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will be a group of individuals living near a facility with levels or risk or exposure higher than those of the rest of the community, and particularly if we're talking about a large metropolitan area.

And we might, if the number, total number of people exposed is large enough, we might still project that a certain number of people would contract cancer even though we had reduced the maximum risk to each individual, just by multiplication.

And there was a suggestion earlier, if I understood it, that in deciding -- that we shouldn't spend more than a certain amount of money to avoid those deaths.

DR. CORTESE: I think that's the most difficult public policy decision of the rules I have to make. I don't we should do that -- I think we ought to spend as much money as possible, as much as we can afford, to be able to reduce the cancer rate unless the cost is so out of line with the benefits, and that's a very difficult calculation to make.

I think that's going to be the essence of the problem. If you have a low probability carcinogen, but the exposure to the general population is great, for the amount of chemicals in use, I'm not so sure it isn't a good idea to control that because while

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the probability of cancer may be minimal, the exposure to the population is so great that you may want to regulate that from a national standpoint more than a higher probability carcinogen which may cause only a localized problem.

I just don't have a good answer for how you make that judgment.

MR. JOSEPH: Thank you.

MR. KELLAM: Mr. Cortese, I'd like to ask you the same question as Mr. Padgett asked Dr. Wilson, and that is, there are really two ways of looking at risk. One is the maximum risk to the individual and the second is to aggregate that risk across populations.

In determining whether or not a substance should be regulated as a carcinogen, would you give precedence to either of those risks? In other words, would you consider the maximum risk to the individual more important than the estimated incidence of cancer to the entire population exposed?

DR. CORTESE: I think it would depend on the substance involved if I were making the judgment. For example, if the substance were the type that one exposure or several short-term exposures to a particular substance could cause cancer over a lifetime -- because it actually is a real lifetime exposure like asbestos

where the fibers remain in the lungs for a long period of time -- it's like a continuous exposure over the entire lifetime -- then I would consider the maximum risk to the individual as extremely important because a short-term exposure because of

or something like that might be very important.

If it was a chemical that you were reasonably certain that you had to have an exposure over a lifetime, a continuous exposure over a lifetime, then I think the population-kind of calculation would be more important. So I think it really depends upon the substance that you're looking at, and I would encourage EPA to look at it in that respect.

MR. KELLAM: Thank you.

MR. ALBERT: Tony, you expressed concern over the judgmental approach in determining unreasonable risk after the application of best available technology largely on the basis that some groups may sustain the risk whereas other groups, the benefits.

But isn't this a problem that generally applies to risk benefit judgments and is part of the game, particularly in areas where the law calls for doing this as under TOSCA (phonetically) and under FIFRA (phonetically)?

DR. CORTESE: Yes, sure. I understand that, but you have to be in my position for awhile a hear that a local group of people does not want to experience that risk at all for somebody else's benefit, and we see that in the siting of hazardous waste disposal facilities. People don't want a hazardous waste disposal facility in their town because -- particularly if you were to site it--to use the EPA, their carcinogen policy -- and try to site it in an unpopulated area, the attitude of the people there is that, look, those hazardous wastes are generated in industrial areas, we don't want it in our town, and that's a uniform kind of reaction that you find around the country, not just here in Massachusetts.

So, I think while in fact it may be a matter of law under TOSCA (phonetically) that you have to do it that way, the fact of the matter is that in the real world, the public doesn't perceive it that way.

MR. ALBERT: But I'm not clear what your point is. Are you objecting to the use of risk benefit weighings or are you just cautioning the agency that if they're going to get involved, they better watch out for the pitfalls?

DR. CORTESE: I'm cautioning the agency and I'm asking the agency to try, as much as possible, to see that it is uniformly applied and not applied

differently in different parts of the country. That's my point. I guess that's really my concern.

MR. HOHMAN: Okay, thank you very much.

DR. CORTESE: Thank you.

MR. HOHMAN: Rose Caterino?

MS. CATERINO: I have come here as a citizen representing a group from Somerville and I belong to the Public anonymous, of which I'm a member.

We have a problem in that we feel the D E Q E hasn't been able to resolve and I feel and I'm asking that the DEQE have tighter regulations to solve such problems.

Now, the problem we have in Somerville deals with the smoke pollution by foundries, and on occasion different groups have gotten together in Somerville trying in some way to get the DEQE responsible as to measure the pollution coming from that smelting plant. The pollution creates much, much soot. Everyone's complaining about that. There is one man, depending on which way the wind blows, especially on the down wind, he complains of, especially on those days, of burning of the skin from these fumes that are being spewed from this smelting plant.

Now, we find, as a group, or as concerned people in Somerville, that the DEQE cannot do what we

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would expect them to do simply because they are not equipped with the authority necessary to prohibit such acts by either the smelting company or a factory.

Now, we have definite proof that there are people being absolutely -- oh, what is the word -- they're just sick from the pollution that is coming out of this smelting plant.

I did not prepare a speech because I am not educated in a manner that you people understand. I only know that we breathe and we can only tell you that what we breathe is affecting us personally. There are people that have gone to the hospital as a result of being unable to breathe. They're either coughing, choking. There could be many, many things coming from this smelting plant that we are not aware of simply because the DEQE has no way of measuring such elements in that area.

So, I am here speaking for all us of involved in some kind of disability as a result of this kind of pollution.

MR. KELLAM: Okay, thank you very much. I assume you and Tony have been talking from time to time about --

MS. CATERINO: I have never met Tony. In fact, this is the first time I've seen him. I've seen

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Bruce and I've heard Bruce talk quite fluently, but I felt that he was limited and that we as a group are helpless when we found that one person that we depend upon for at least clearing the air in our vicinity cannot do very much.

MR. KELLAM: Well, we appreciate your bringing it to our attention. If Merrill Hohman from the regional office were here -- he started out as chairman and will be back shortly -- I'll make sure it's brought to his attention too and we'll see what we can do to follow up.

Are there any questions which the panel has?

(No response)

MR. KELLAM: Okay, thank you very much. David Ozonoff? If I'm not pronouncing your name correctly, please correct me.

DR. OZONOFF: My name is David Ozonoff, ozone as in the well-known air pollutant (Laughter).

I'm a physician. I'm the Chief of the Environmental Health Section of the Boston University School of Public Health. Let me say that I appreciate the opportunity to appear before you today here in Boston to give my views on what is a much needed policy for regulating airborne carcinogens. It's a policy that I

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think will be helpful to those people in the Department of Environmental Quality Engineering to have the necessary regulatory tools at their disposal to tackle the kinds of jobs that Ms. Caterino was talking about in the densely populated neighborhood of Somerville. I'm a neighbor of hers in the city next door in Cambridge. I know that many of the people who are testifying here today live out in the suburbs in less densely populated areas where they are not subject to these kinds of exposures, but I invite them to come to our neighborhood to see what it's like.

I would like to give my very strong support to the notion which seems to be in dispute, very much to my surprise, that some uniform and efficient regulatory policy is necessary to deal with airborne carcinogens and suspected carcinogens.

In the view of many of us, this proposed policy is long overdue. The evidence -- the link between human cancers and physical and chemical agents in the environment has been presented so very many times before in hearings held by this agency and other agencies charged with protecting human health in the environment, and one would think that it should not have to be recounted again, and the same has to be said, I think, for the scientific principles which underlie the common-

ly accepted methods for identifying those agents which pose a cancer risk to human beings. Yet, it seems that with each and every rule-making, the same issues are argued again and in the inevitable court challenge, they are re-litigated again. It goes without saying that this is very wasteful of resources and results in inordinate and costly delays for implementing much needed regulations and I think it is very heartening to see that EPA is following the lead of OSHA in establishing some kind of firm ground rules that just won't have to be gone over each and every time contended at each and every rule-making.

The evidence that chemical and physical agents found in the environment are principal determinants of human cancer rests on several well-known lines of argument. In brief, it's known -- it's been observed for some time that cancer rates among geographically separated populations vary enormously. They are very high in some places and low in others, both internationally and within the United States, as the Cancer Atlas demonstrates, and that if one looks at sub-populations which migrate from one place to another, one is able to infer that a large proportion of cancers, and the usual figure is 60% to 90%, are environmental in origin, that is, that they do not stem from the genetic make-up

of the populations involved. We have other lines of evidence, of course, not the least of which is the very large number of specific chemical and and physical agents which are known to cause either cell transformation or tumors in human beings and animals, and in addition, there is almost a complete lack of evidence that any biological agents such as viruses are capable of causing cancers. And I think with all the information, the case is well made and I haven't cited any particulars in this testimony because these facts are so well known and they are not ordinarily disputed.

However -- and this is a subject that's come up already in the first hour of these hearings -- to say that important factors in causing cancer in human beings are environmental in nature does not identify or locate them further. And a great deal of effort -- I think fruitless effort -- has been expended in recent years arguing about whether the responsible environmental exposures are the result of so-called voluntary activities like smoking or an imprudent diet -- I don't know how voluntary smoking is, I'm not a smoker myself, but I know that most people who smoke, if you asked them why they smoke, they say, "I'd love to quit, but I can't." If that's how you describe a voluntary behavior, I'm mystified by that use of the English

language.

However, to argue about whether they're voluntary or involuntary such as we might suffer by incidentally having to breathe the air in our living or working environment, I think is really not a very fruitful line of argument. The truth is that no data now exists or probably ever will exist that would allow us to partition the blame amongst voluntary and involuntary behaviours.

In any event, since we know that there are synegistic relationships between both carcinogens and non-carcinogens which promote carcinogenesis in the environment, there's probably enough carcinogens out there to go around for everybody and with one in every four people getting cancer in their lifetime and one out of every six dying from it, it seems that the prudent policy would be to reduce all unnecessary exposures to carcinogens to an absolute minimum. And this is especially true, I think, for community air pollutants where the exposure is involuntary and where the entire spectrum of the population, the unborn fetus, the old, the young, the acutely and chronically ill, as the relatively young and healthy are exposed.

I'll leave to others -- I hope that they will do so -- the task of commenting on specific cri-

teria that the EPA has set up for evaluating substances for carcinogenic risk, but I want to comment on one aspect of it, and again, it came up in Professor Wilson's testimony already today.

I think that the policy, when it's finally issued, should be very explicit about what will not be acceptable by the administrator as counter-evidence of carcinogenicity. I believe it is very important to state in that final policy that non-positive results from human epidemiological studies will not be considered by the administrator when other positive results from human or mammalian tests are available. The reasons for the policy, again, are terribly well known, although they seem to be consistently ignored. so I'd like to go into them briefly.

There are two principal reasons for not relying heavily on human observational studies, that is, epidemiological studies, for identifying or even setting risk limits on carcinogenic substances. The first is the extreme insensitivity of these studies. They're insensitive not only because they're very difficult to do -- I am an epidemiologist and we are continually plagued with a whole host of confounding factors, uncertainties in exposure and substantial time analysis which make analysis difficult -- but they're

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also insensitive for more important reasons, I believe, because the sample sizes are invariably too small to be able to detect cancer increases which may have enormous significance when applied to large populations such as would exposed in a community environment.

For example, the smallest increase in cancer risk that has confidently been detected by epidemiological methods is the 30% excess of childhood leukemia in the offspring of women irradiated in their third trimester of pevimetric measurements. That's a 30% increase and that took us many decades to be sure of.

Yet even a 10% increase in the bladder cancer rate in the Greater Boston area would result in almost 5,000 cases from that source alone. I base that on an approximate lifetime incidence of 150 cases per 10,000 population, and surely 5,000 cases is an unacceptable level in almost any instance for one city.

And for more common cancers such as cancer of the trachea or bronchus or the lung, the burden of morbidity and mortality would be much larger, yet would not come close to approaching detectability by even the largest and most refined epidemiological study that one could realistically imagine.

The second reason for not relying on non-

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positive epidemiological studies, that is what is sometimes called a negative study although it is not negative, it's merely non-positive, is the very long latency period that has to elapse between exposure and the development of the signs and symptoms of a clinical cancer. This latency period is typically twenty years or more and thus agents that have been in the environment for a lesser period of time will not produce any actual increases in cancer.

It's shocking to see how often this is ignored. The latest issue of the New England Journal of Medicine has a non-positive study on saccharine. Saccharine has only been in the environment to any significant extent for ten years and one wouldn't expect to see any increase.

On the other hand, if one did see an increase after an appropriate lag time, the immediate removal of that offending agent won't do any good because we're going to continue to suffer cancers from that agent for the entire period of the lag time.

Therefore, epidemiological studies, used as a sentinal system or to set up for bounds is insufficient because it's too late on two counts. First, it takes decades before it can detect the effect and after those decades have elapsed once you're detected it, it's

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too late - you're going to have them for several more decades -- the cancers for several more decades still.

To sum up, epidemiological studies are likely to be non-positive for all but the very most powerful carcinogens, and even very powerful carcinogens like oxogenous estrogens, perhaps, cigarettes, and so on, it's taken us decades of arguing over it - probably because the stakes are very high - before we've been sure, and even for those powerful agents, they'll be non-positive until the lag periods have elapsed and by that time, it's going to be too late. Therefore, you have to use other methods to identify and assess carcinogens and the mainstay of any prudent policy would be the use of the commonly accepted mammalian systems supplemented by short-term tests. And I believe that the EPA policy is proper in relying heavily on those methods.

I just want to be clear here since there has been confusion in the past about this, that I am not contesting the value of positive epidemiological studies. They are very important and in fact extremely ominous because it means that we are dealing with a powerful carcinogen. But non-positive studies should never be allowed to outweigh positive human or animal evidence and I think this should be made explicit in the final policy.

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There are a number of other things that have already been discussed, so I won't go into them in great length. One that hasn't is the length of time it's going to take from the first identification to listing to the final rule-making. I'm not at all clear -- first of all, I'm not at all clear from reading the Federal Register on the order of events. I found it rather confusing, and I would like to see some estimates of the time periods or the time scales involved to accomplish each of these steps.

Tony Cortese has already mentioned the problem of siting. We've already lost a lot of industry to the south and south-west in this state and I think that this policy is going to compound that problem further. And from the public health point of view, it doesn't make any sense anyway because many of these contaminants -- in fact, probably most of them -- are persistent. They'll be carried for long distance by prevailing winds and they can be magnified in the food chain. Radioactive agents are a good example of this, which is a concern.

And, again, I have concerns about the large degree of judgmental and discretionary power which is allowed to EPA in these instances. Your resources are very limited and it really puts you at the

mercy of claims and data submitted to you by the regulated industries themselves.

For example, the large role reserved for economic and other non-health considerations in various decision-making note points in this policy, I think, are ominous. They are an open invitation for those industries to pressure and manipulate the data and the agency itself -- for example, in deciding what is going to be best available technology -- and I'd feel much more comfortable if EPA's latitude in making these decisions on the basis of non-health matters were considerably narrowed.

Again, let me thank you for coming here to Boston for those of us who find it difficult, since we are testifying as individuals and are not being paid by any other concern to come and testify, to come here to us so that we can give our views and I feel confident that this process of public participation will improve the proposed policy, and it's a policy which I think is sound in essence.

And I'd be glad to answer any questions.

MR. HOHMAN: Thank you Dr. Ozonoff. Bob Kellam?

MR. KELLAM: I just have one question, Dr. Ozonoff. You mentioned earlier in your testimony

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that at least one of the pieces of evidence that could lead us to believe that air pollution may contribute to human cancer have been the studies by the National Cancer Institute in their mortality atlas and the fact that cancer rates appear to be elevated in some parts of the country as opposed to others.

One of the previous witnesses at the Washington hearing presented some information which compared three cities which are largely heavily industrial with three other cities which I guess can be characterized as having rather light industry. And his conclusion based on the mortality from these six cities was that there did not appear to be an increase in cancer incidence in the industrialized cities as opposed to those which were not industrialized.

Would you have any comments on the relevance of the use of cancer mortality in reaching this kind of conclusion?

DR. OZONOFF: Well, of course, cancer mortality is not a measure of cancer incidence. I mean, this is another aspect of using epidemiological studies. Even if they were any good, even if they were sensitive enough and even if we didn't have to deal with a lag period, we simply don't have the tools to practice good epidemiology for cancer in this country because, for the

most part, we don't have cancer registries. In this state of Massachusetts, for example, where there is no cancer registry, we don't really have any decent idea how much cancer there is, who's getting it, where they're getting, how often they're getting it, what kind of cancer it is, and the best data available from the third national cancer survey was a ten percent sample of which Massachusetts is not included at all, so although we are attempting to get a cancer registry here, we have no idea and the relationship between mortality and cancer incidence is unknown.

Second of all, studies which purport to show relationships between some ecological variable like industrialization and cancer mortality, even without the problems I mentioned, really aren't any damned good because you don't know what you're looking at. You don't know what the pollutants are, you don't know how long they've been there, you don't know what kind of cancers you should be looking for against what kind of background.

And with respect to your question about the cancer atlas, that when you do begin to see suggestive patterns, I think that's very frightening. If you don't see patterns, I don't think that's surprising at all. If you do see them, I think that's enough to scare

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the pants of almost anyone. If you look in their latest American Journal of Public Health, which arrived yesterday, there's a suggestion that people who live around oil refineries and smelters may have increased rates of cancer of the pancreas. They are only suggestive, but things that suggest things through epidemiological studies, I think are much more frightening that other kinds of evidence and negative kinds of evidence like the kind you cite just don't amount to a hill of beans as far as what's really going on there.

Dr. Albert actually mentioned -- asked Tony about the rules of the game for risk benefit analysis. I just want to make a quick comment on that.

I don't know who set the rules for that game which says that we consider the risk to some people and the benefits for others, but let me point out that the rules are stacked against certain environments and against some and for others, that the risks and benefits are not randomly distributed throughout our population.

The people in Somerville are more likely to suffer the risks and the people who live out in the suburbs are more likely to get the benefits, and I think that's a serious question about risk benefit analysis which hasn't been addressed.

MR. HOHMAN: Todd?

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MR. JOSEPH: Dr. Ozonoff, just one question. As an epidemiologist, do you think that the evidence exists today by which we could know through epidemiology whether industrial air pollution might be resulting in one of two thousand cancers per year in the United States?

DR. OZONOFF: No, I don't believe that that evidence exists. I think it's possible to use all sorts of data to make all sorts of plausible estimates. I think the very low estimates as plausible and I think the very high estimates are plausible and the ones in between are plausible.

I doubt that we're every likely to get the data that's going to enable us to make those, and I think that the judgments have to be made on other grounds if there's a great deal of scientific evidence to indicate that these chemical and physical agents cause cancer, that there are synergisms in promoting interactions that occur in the environment and that a prudent and plausible thing to do would be to reduce exposures to a minimum. That data about how much it's going to cost to reduce each one of these exposures -- the cost data usually comes from the industry and as we know in the vinyl chloride case, their first estimate of what it was going to cost vinyl chloride exposures

in the workplace were not only inflated, but they were inflated to an extent that one suspects fraudulent motives on the part of coming up with those estimates. I mean, it was just astronomical, the cost, and turned out to be much, much lower than they estimated.

I don't have any good reason to believe most of the cost estimates involved.

MR. JOSEPH: Is there any way for you to estimate how many cancers per year there would have to be as a result of industrial air pollution for us to be relatively confident of seeing through that epidemiology?

DR. OZONOFF: Well, if one accepts the lowest excess that's been detected epidemiologically and applies it to the bladder cancer case, we're talking now about fifteen to twenty thousand cancers in the Greater Boston area. It's a lot of cancer and bladder cancer is not the most common kind. It's a lot of cancer.

MR. JOSEPH: Thank you.

MR. ALBERT: Speaking for the Carcinogen Assessment Group, I want to comment that on the fact that in relationship to your testimony that the agency has regarded epidemiology as a blunt tool, although a powerful one when it does demonstrate positive relationships,

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but it has never allowed negative epidemiologic data to cancel out positive epidemiologic data that's solid or positive animal data.

Negative epidemiologic data has been used in quantitative risk assessment in terms of putting upper limits of risk where the judgment that an agent is carcinogenic is based on the animal data and the negative epidemiologic data has been used, as I say, to set upper limits of risk, but we certainly appreciate your expression of this position.

DR. OZONOFF: Well, I came not only to give my opinion but to recommend that you make this explicit in the final policy. The OSHA generic standards, for example, have made it explicit and state the conditions under which such evidence and other kinds of evidence will be used and I recommend that to you as a policy.

MR. HOHMAN: Okay, thank you very much. Charlotte Ploss?

MS. PLOSS: Hello. My name is Charlotte Ploss. I live at --

MR. HOHMAN: (Interrupting) Excuse me. I've been asked to ask the speakers to speak more directly into the microphone.

MS. PLOSS: Oh. Is this better?

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MR. HOHMAN: I guess. Who's the judge?

MS. PLOSS: Okay? Can everybody hear?

MR. HOHMAN: Can't we raise the microphone?

MS. PLOSS: I don't -- I'm not mechanically minded.

MR. HOHMAN: Go ahead.

MS. PLOSS: My name is Charlotte Ploss. I live at 12 Cherokee Street in Mission Hill. I am here representing the Mission Hill Planning Commission.

Mission Hill is a neighborhood in Boston. It is a congested, overpopulated, residential urban area. Many if not most of Mission Hill's residents are low income and/or elderly, or very young, and/or suffering from a chronic illness - all of the criteria to make us a community at high risk. Yet, we are the one neighborhood in Boston, if not the country, which shouldn't be at risk.

Our community is host to a wide and varied range of the finest medical institutions in the world - Harvard Medical School and Dental School; Harvard School of Public Health and Harvard's many affiliated teaching hospitals, Peter Bent Brigham, Children's Medical Center and a dozen more renowned names, all of which are clustered in a one-mile square area at the

foot of Mission Hill. It is that medical industry surrounding us, crowding us, swallowing our land and our homes which in 1973 began to covet our air as well.

That medical industry which prides itself for producing the healers, promoting the teachers of the healers and for spawning Nobel Prize winners has given birth to another offspring - the medical area total energy plant.

Now, about now, some of you must be wondering what I'm doing here. I did not intend to give any scientific information. I do not intend to offer detailed comments on individual or collective particulates, effluents or chemicals from any source stationary or otherwise. My credentials are my four children, my granddaughter, my love for my community, my active concern for its wellbeing and my consumer, taxpayer status.

What I am here to do is give, quote, public testimony on the proposed policy and procedure of the Environmental Protection Agency, unquote. And, again, you wonder what I could possibly know about environmental rules and regulations. Nothing until 1974. At that time, Harvard University issued an environmental impact report, describing an oil-fed, diesel-powered energy plant which would supply thirteen

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medical and educational institutions with electricity, heat, hot water and air conditioning, enough power to serve a city of 30,000. And they called this miracle of co-generation the Medical Area Total Energy Plant, further known as MATEP, and MATEP was to be constructed in Mission Hill amid the medical institutions it was to serve.

The EIR was not issued on April Fool's Day, but it might as well have been. The neighborhood considered it a joke, the scientific community considered it a joke and even the local utility company guffawed. Even though I and most of my neighbors were rank amateurs when it came to environmental impact reports, we were able to spot the numerous inadequacies, weaknesses and inconsistencies in that one. And the very fact that Harvard had to do this environment report and because it was so shabbily and cavalierly done, we were falsely reassured.

We thought the project would never get off the ground. After all we learned, the air in Mission Hill was already too dirty to meet federal standards then. The rules and laws would stop Harvard from pumping any more pollution in it. Moreover, Mission Hill was included and cited in the study of Boston's infamous death zone - God's waiting room, they called

it - because of our having one of the highest infant mortality rates in the country and the highest respiratory illness incidence. There were rules to protect the sick people.

Further, within a three-mile radius of the proposed plant site are concentrated more people over the age of fifty-five than in all of St. Petersburg, Florida, a retirement community. Harvard can't build a plant like that. The law would never allow it. There are rules against that sort of thing.

But that's Harvard and Harvard has its own golden rule: Them that got the gold make the rules. I dare say that the same model hangs high on the executive boardroom rules of Exxon, Mobil, General Motors, Ford, et al. And Harvard's gold was everywhere. The wooden soldiers began toppling.

First, City Planning Agency okayed the project before the ink was dry on the EIR. Next, sixty-day eviction notices to tenants in the then-97 apartments on the plant site were issued and enforced. An in-lieu-of-tax-payment status was granted to the plant, saving Harvard millions in property taxes. The plant secured exemptions from all fire, health, safety and zoning codes. The plant was granted a 24-hour variance from noise pollution control limits. And all this was before

the state's Environmental Secretary had finished reading the title and/or the author on this draft environmental impact report which was subsequently disapproved, amended, disapproved and amended three times.

The variances, the exemptions, waivers, special case allowances went on and on and on, and our community went to court. What chance did our rag tag band of volunteers have against the well-armed legal might of Harvard, especially when Harvard's lawyer is president of the Mass. Bar Association, calls the Judge by his college nickname and plans in court to meet him on the 13th hole. But, we continued to inform and organize other groups in the adjacent neighborhoods about the MATEP issues. It was at that time we learned of the Department of Environmental Quality Engineering, DEQE, and the Division of Air and Hazardous Materials and other lights at the end of the tunnel and other tunnels where there were no lights.

The MATEP controversy was over three years old and this would be the first opportunity we had had, my community had, to address an agency about the health effects and dangers of the proposed power plant. But first, we had to slog through the morass of rules and regulations and procedures. And each time we finally got to understand one of the rules and regu-

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lations, Harvard already changed it and got a variance.

Whoever could not be bought was inundated with paperwork, lawyers, scientists, experts, Harvard alumni and special effects men.

Harvard had approached DEQE with, "Listen, this is what we want to build, show us how to build it." The community wanted the same consideration. "This is what we want to stop, show us how to stop it."

The community needed information, guarantees and support and what we got was entertainment provided by Harvard's special effects team. One instance. A solid four days of public hearings. Six hundred community homemakers, job holders yawned and fidgeted through slide show fantasies, feats of engineering marvals, mathematical meandering and rhetoric delivered with religious furvor. Masters of understatement, experts in half truth and apostles of insurance and assurance blanketed the audience with such good news as -- and I quote -- "Oh, don't worry about the three hundred and fifteen foot smokestack. We're going to paint it so it blends in with the sky." And, "The adjacent nursing home is safe, don't worry. In fact, the environment of the home will be improved because we're going to totally enclose the back yard with a hundred and twenty foot wall which just happens to house

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the six diesel generators behind it." And, as a special social amenity because we've all been so good, "We've reduced the number of diesel trucks delivering fuel to the plant by increasing the size of the trucks. Moreover so the trucks won't tie up traffic, we've secured a right-of-way through the back yard of the nursing home - a safe thirty feet away from their back door, of course."

Community calculations showed a diesel truck unloading fuel at MATEP every fifty-seven minutes every day, every week of the year, three hundred and sixty-five days. Harvard solved further objections. They tore down the nursing home.

Time and again, at very meeting, hearing, conference, coffee-klatch, the community was reassured that MATEP would meet all city, state and federal standards and would employ best available technology. It's now 1980. Harvard kept talking and kept pouring concrete. Even though the Department of Environmental Quality Engineering has disapproved the MATEP diesel three times, the power plant is almost completed. And Harvard is sliding in a fourth set of plans under the Department's door.

Mission Hill is grateful that DEQE has held out against the Harvard bullion almost as long as the community and we would welcome them in our community

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as volunteers and if their budget gets cut again this year, they probably will be soon.

Most Americans assume that their participation and contribution in their community consists of paying their taxes and curbing their dogs. When we write out our checks to pay property, income, entertainment and all other taxes, it is more or less done with blind trust to create and fund agencies which we trust to protect the public health.

The agency should not bite the hand that feeds it. I should not have to be here today. I should not have had to read thousands of pages of environmental and legal texts, testimony, theories, calculations, projections, worst-case estimates, building plans, regulations, rules, et cetera, et cetera. I should not have had to sit through endless meetings, hearings and court sessions listening to NO_2, SO_2 and too bad for you.

What I should be able to do is believe and trust that an agency with the moniker, "Environmental Protection," does just that - protects the public's environment.

Most consumers do not expect nor do they wish industry to shut down. We're grateful to industry for giving us cars, perma-press clothes and garbage disposals. We do expect industry, however, to ply their

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wares with the least amount of damage to our health and our environment and our economy.

I'm here today representing my community to first recommend that the proposed rules and regulations be translated to language other than that understood by only environmental experts and lawyers. Industry understands risk avoidance criteria and presumptive national emission standards. The average consumer only knows that whatever that means, industry has a means to get around it.

Secondly, some of the proposed rules and regulations set forth one policy let leave a loophole large enough to drive a diesel truck through. We understand that agencies such as yours suffer from chronic low-budgetitis and cannot continually compete with the multi-million dollar corporations and their resources, and it's just that imbalanced that makes the strictest possible controls and rules and regulations absolutely necessary.

Because the corporations are going to find loopholes, they're going to find the back doors anyway no matter what you do -- they're going to find them. They have people who do that all day long. That's their job all day long. They have the time, they have the money, the motivation, the lawyers, the soothsayers

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and all other special effects people.

My grandmother once told me -- she made it a proverb to me -- and she said, "It is harder for a rich man to pass through the gates of heaven than for a camel to pass through the eye of a needle." Let me assure you, Harvard not only got a two-humped camel through, an entire caravan led by Lawrence of Arabia, and all using applicable rules and regulations.

Thank you.

MR. HOHMAN: Thank you. (Applause) Are there any questions from the panel?

(No response)

MS. PLOSS: Okay.

MR. HOHMAN: Thank you very much for coming. The next speaker is Ed Calabrese.

DR. CALABRESE: My name is Ed Calabrese and I'm on the faculty in the Division of Public Health at the University of Massachusetts at Amherst.

I strongly endorse the attempt by EPA to develop a comprehensive and rational methodology for reducing the exposure of the general public to airborne carcinogens from stationary sources. In an effort to provide the agency with my recommendations for improving their proposed methodology, I offer the following comments.

The use of a "single well-conducted ani-

mal study" may be sufficient to establish if exposure to an environmental agent results in a significant human cancer risk. However, this depends on how closely the animal model simulates the human condition. Concern for only research design, statistical appropriateness and proper laboratory procedures, while critically important for the reliability of any animal model study, is incomplete without careful concern for the appropriateness of the animal model to predict human responses.

Thus, positive or negative findings must be interpreted in light of the adequacy of the model to simulate the human condition. While much uncertainty does exist as to the efficacy of specific models to predict human responses, great progress has been made in recent years in the area of comparative biochemistry and this has led to general guidelines for the selection of animal models for toxicity and carcinogenicity testing.

It is very clear that all animal models are not equal in their ability to predict human responses from carcinogen exposures. For example, guindea pigs are refractory to the development of aromatic amine induced bladder and/or liver cancer presumably because of a lack of ability to bioactive such compounds via N-hydroxylation. Yet, since 1938, dogs have been generally con-

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sidered an effective model to predice human susceptibility to aromatic amine induced bladder cancer because both species, that is, the human and dog, metabolize aromatic amines in a similar manner. More recently, several rodent models have also been found to accurately predict human susceptibility to several aromatic amines.

Not to take the appropriateness of the animal model into consideration may marketly enhance the occurrence of either false positives or false negatives with respect to predicting the occurrence of chemically-induced human cancer.

While EPA may not be able to effectively deal with the issue of false negatives, the occurrence of false positives will often result in not only the smug and self-righteous conclusion of erring on the side of safety, but also in the inappropriate assessment of resources and priorities which ultimately compromise human health.

Even though the knowledge of how accurately animal models simulate the human responses to chemical carcinogens remains imperfect, EPA should encorporate its information, when appropriate, into the process of how chemicals are assigned into priority groupings. While the knowledge contributed from animal models at the present state of the art would be undoubtedly minor,

this should not lead EPA to ignore potentially valuable contributions.

Second, the EPA carcinogen prioritization scheme should be commended for taking into consideration most of the important factors in the determination of quantitative risk assessment including characterization of carcinogen levels, numbers of people exposed, and potency of the carcinogen, amongst others. However, one additional rea that should be considered for inclusion within this process is that of further characterization of the population with respect to risk factors, and I think that was pointed out very nicely by the previous speaker, when you take a look at the potential high-risk groups within certain sub-areas of any region. Back to the text, however.

However, one additional area -- Just knowing how many people may be exposed, which is one of the components of EPA's policy, okay? Just knowing how many people may be exposed, while an important factor in the development of risk assessments, does not provide decision makers with an indication of whether those exposed populations may have a higher than expected proportion of individuals with enhanced risk to the agents considered.

Dr. Richard Wadden of the University of

of Illinois, School of Public Health, has utilized the concept of increased susceptibility in environmental planning for possible highway constructions routes within Illinois. For example, several potential routes for an interstate highway differed markedly in their potential air pollution health problems since one route came into close proximity with several hospitals, elderly housing units and elementary schools. Since the very young and old are known to be at enhanced risk to the respiratory effects of automobile pollutants such as carbon monoxide, nitrogen dioxide and sulfate, it was clear that the highway route which affected the lower number of high risk persons and not just the total number of people was a better choice.

The same principle can be applied with respect to carcinogens as well. Genetic susceptibility to chemical carcinogenesis is very well documented and in several instances the underlying causes are also known. For example, it has been postulated that humans with a low ability to acetylate aromatic amines may be at enhanced risk to developing bladder cancer. This trait is genetically transmitted via simple Mendelion ratios.

Consequently, if the population were to be exposed to carcinogenic aromatic amines and a sizeable

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number of that group were slow acetylators, this should cause greater concern that if the population was uniformly fast acetylators. Knowledge of genetic and nutritional factors which enhance susceptibility to environmental carcinogens is rapidly progressing. Such knowledge, although limited, should be used by EPA to further assist in the ranking of carcinogenic agents scheduled for regulation.

A third point. While Section 112 of the Clean Air Act which pertains to the National Emission Standards for Hazardous Air Pollutants provides for the listing of pollutants which cause or contribute -- that's cause or contribute -- to irreversible illness, that is cancer, it is odd that the EPA proposed carcinogen policy does not provide a methodology for dealing with co-carcinogens or promoters. Since certain promoters may enhance the carcinogenic outcome within selected studies by several orders of magnitude, this is not an issue to take lightly. Clearly, carcinogenesis is a two stage process - that of initiation and promotion. Since EPA procedures are not designed to eliminate exposures to initiators, there must be continued concern to reduce exposure to promoters as well.

As indicated in my opening sentence, I support the attempt by EPA to deal with the airborne

carcinogen problem. However, since the intention is to reduce not just the theoretical risk of developing environmentally induced cancer but the actual occurrence of such cancers, how is EPA to know if all this planning, study, and financial expense to consumers is really worth it?

While any program designed to reduce the occurrence of cancer will meet with psychological approval, how does EPA plan to evaluate the success of its program? Just lowering the levels of suspected carcinogens is not truly sufficient - although it is an important goal to achieve. For the goal to be achieved, EPA's program must prevent the occurrence of at least some cancers the Agency claims are being caused, in part, by airborne carcinogens from stationary sources.

While the ultimate answers may await the outcome of epidemiologic investigations some 30 to 40 years from now, isn't there some way to evaluate interim potential benefits of such a program? For example, why not survey with proper epidemiological methodology the occurrence of chromosomal breaks in circulating lymphocytes of humans in the risk areas of concern? This methodology is used by industrial hygiene programs within industry and there is no reason why it could not be adopted here. Clearly, EPA must be accountable and here

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is an interim way that it could evaluate its own program.

In conclusion, it is my opinion that EPA should re-evaluate their priority scheme for evaluating chemical carcinogens by encorporating (1) the knowledge of the appropriateness of animal models in simulating the response of humans to carcinogenic agents and (2) the concept of increased risk within the population to carcinogenic agents.

In addition, the carcinogen policy, while dealing exclusively with initiators, should also include promoters. Finally, EPA should attempt to evaluate how effectively their program is on an interim basis by developing a population monitoring scheme possibly concerned with assessing changes in the chromosome aberration load.

I'd be happy to entertain any questions from the panel.

MR. HOHMAN: Thank you, Dr. Calabrese. Roy?

MR. ALBERT: I believe that your recommendations are sound if theoretical, and probably applicable more in the future than now. For example, although you recommend that we take into account knowledge of the appropriateness of animal models, I think you would have

to agree that faced with bio-assay results at the present time, it's very difficult to pass judgment on the extent to which the responsiveness of a given strain or species of animal is indeed appropriate.

DR. CALABRESE: I wholeheartedly agree with your comment and my point with that particular item was to indicate that in limited cases, there are better than -- you know, you can rank a model. It may not give you the precise information you may be looking for and it is preliminary in the sense of the state of the art. But I think in terms of writing into a methodology, I think it's important to take that into consideration. I don't think it's wise to assume that all are equal. Yet we may not have enough information to differentiate among those which are better than others at this present time.

MR. ALBERT: And also, I would take the same tack in commenting on your discussion of including the concept of sub-populations with increased risk. In principle, I think this is fine, and presumably knowledge in this area will develop, but it's awfully difficult to make this a -- convert this into a concrete approach from a regulatory standpoint at the present time.

DR. CALABRESE: I agree with you.

MR. ALBERT: Also, I believe that the

notion of monitoring populations for changes ascribe to improvement in pollution is fine. I'm not sure that the study of chromosomal abnormalities is going to be of sufficient sensitivity to do it, but there are other possibilities on the horizon such as as looking at carcinogenic adducts bound to hemoglobin proteins, but this is a methodology which is still in the emerging stage.

DR. CALABRESE: Right. I posed that just as one of many examples that could be considered by EPA.

MR. ALBERT: You say it is odd that the policy doesn't consider co-carcinogens and promoters. I think one of the reasons for that is that the scientific basis for characterizing promotion and co-carcinogenisis and knowing whether indeed it is applicable to the human situation is at a pretty thin stage at the present time.

For example, we don't have any good characterization of dose response relationships even for co-carcinogens and promoters. So, I think the absence of this in the policy reflects the scientific status of the field more than any oversight.

Finally, I want to -- I didn't understand one point that you made here, and that is that you say

carcinogenesis is a two-stage process - that of initiation and promotion, and since EPA procedures are not designed to eliminate exposure to initiators --

DR. CALABRESE: (Interrupting) Did I say, "not?"

MR. ALBERT: Yes.

DR. CALABRESE: Yes.

MR. ALBERT: Well, that's an error then. Obviously they're designed to eliminate or to reduce initiators.

MR. ALBERT: Yeah, I see. So --

DR. CALABRESE: Well, they're not designed to eliminate initiators. They're designed, at least as I read it, they address only initiators but they're not designed to eliminate all exposure necessarily to these compounds.

MR. ALBERT: I see. That's all.

MR. HOHMAN: Okay. Bob?

MR. KELLAM: Dr. Calabrese, you mentioned that genetic susceptibility could be one factor which would increase -- might increase the risk of cancer for specific sub-populations. Are you aware of other factors, environmental in nature or otherwise, which might increase the population's sensitivity to the induction of cancer?

DR. CALABRESE: Yes. There is a wealth

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of information which has accumulated at least with respect to animal studies, taking a look at the influence of nutritional status on susceptibility to a wide variety of carcinogenic agents. For example, the amazing work which is coming out of NCI and Michael Sporen's (phonetically) group with respect to Vitamin A susceptibility - and low levels of Vitamin A in the diet and susceptibility to -- well, it could be any type of benzo-a-pyrene like (phonetically) compound affecting epithelial cancers. That's clearly well known.

There is the long-term association of the azo dyes inversely with certain B Vitamins. The documentation for dietary factors enhancing the susceptibility to -- or diminishing the susceptibility to agents - for example, there is some concern in Boston air and apparently other air with respect to nitrosamines (phonetically) and although there has been a recent study published in Nature and a follow-up one by a fellow by the name of Gutenplan (phonetically), who has shown that at least in an animal model that ascorbic acid, given in sufficient doses, can prevent the occurrence nitrosamine-induced bladder cancer.

Now, usually the ascorbic acid is thought to prevent the occurrence or the formation of nitrosamine in the gastrointestinal tract and that's clearly well

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known from a dietary point of view, but Gutenplan's work was the first that I knew that took a look at the influence of a dietary factor affecting -- at least ascorbic acid affecting the occurrence of nitro mine-induced bladder cancer.

There's tremendous work from the group of researchers at MIT, Paul Newburn's group, dealing with marginal lipotropes with respect to a number of carcinogens including aflatoxins and nitrosamine and several others.

From a dietary point of view, nutritional status point of view, there's a wealth of information on that. Genetic factors are becoming more well known and more investigated. The work associating the ability to induce aerohydrocarbon hydroxyles activity and susceptibility to lung cancer is at least in animal models and some suggestive clinical studies in humans indicates some differential susceptibility. I think that's in its early stages of evaluation, but I think that clearly nutritional status markedly enhances our retired susceptibility to a wide range of chemical carcinogens.

MR. KELLAM: One other question. Several witnesses who have testified before this hearing in Washington have addressed the issue of whether or not thresholds may exist for carcinogens. Do you have any

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comments on whether or not for such things as environmen-
carcinogens there are indeed thresholds, levels in the environment below which individuals would not be exposed to a risk of cancer?

DR. CALABRESE: I feel very convinced that there are definite thresholds at the individual level and I think that there are no thresholds when you take a look at the population. Let me elaborate on that just a little bit.

I think if you take a look at any individual and you try to do some type of pharmacokinetics with respect to a carcinogen and you follow that carcinogen from the point of entry into the body from distribution, protein binding, detoxification, excretion and so forth, you'll find -- and getting into, ultimately, the body has the capacity to not absorb the material, number one, to bind it in a place where it may not reach a critical site of action. If it does reach a critical site of action, it may come into contact with DNA and cause a change in a non-critical site within the DNA. If it does cause a change in a critical site and does initiate a particular alteration which may possibly result in the occurrence of a cancer, we certain do know that there are highly evolved mechanisms of DNA repair and so forth and I think that you can certainly

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overwhelm these repair mechanisms and there may be some error-prone occurrences as well.

But, I think that each individual has their limit with respect to -- or their threshold with regard to any particular agent. However, if you take a look at the population as a whole, you'll find that in our heterogeneous grouping in the United States, that there is a broad range of genetic susceptibilities going from people who have highly efficient DNA repair mechanisms, detoxification mechanisms, to the spectrum way to the left where these people are genetically impaired with respect to their ability to repair damaged DNA. There's a whole broad spectrum there.

If you take a look at our dietary status within this country, you'll find we go from the vitamin pill-popping crowd to those who have the most inappropriate nutritional status that one could imagine, and what we have also are people coming from different cultures where they will have either different proportions of relative enzymes and so forth based upon their own genetic capability.

For example, some work that I do is with susceptibility to oxident stresses in the environment on red blood cells and we know that there is a tremendous variability in susceptibility to oxident-

induced stresses on red blood cells depending upon the genetic make-up and nutritional status of the individual.

And so, it's my feeling that if you look at the whole population, you're going to have people that are the very weak to the very strong, most of us being in the middle, and there's going to be no single threshold. There's going to be an adverse effect sometime, somewhere within this heterogeneous population. Whereas I think every individual has a threshold, collectively as a group, there is no threshold.

It's going to be affecting some percentage of the portion at some particular time. The big question is what percentage of the population is being affected? Can they be identified? Can you deal with this in a special administrative manner?

I think if you know more about the risk factors involved, then you can begin to get a handle on it. And this is -- when you talk about a risk factor of one in a million, it's my feeling that that risk factor -- or one in ten thousand -- I think that this suggests to me that there are some unique, relatively rare occurrences, genetic occurrences or -- we'll say genetic in this particular sense -- that may predispose an individual.

I don't believe the risk is randomly distributed. The risk is there by biological or cultural design and it's a matter of identifying that risk.

MR. HOHMAN: Okay, thank you very much. I that's all the time we have right now. Peter Fairchild?

MR. FAIRCHILD: My name is Peter Fairchild. I'm the Executive Director of NESCAUM, which is the Northeast States for Coordinated Air Use Management. We are the official regional air quality planning organization for the northeast formed under the auspices of the New England Governors' Conference. The membership consists of the state air pollution control agencies from the six New England states, New York and New Jersey.

Several of the states have commented or will be commenting directly to you on the specifics of the proposal and we have not formed NESCAUM or group consensus on the policy because of the individual states' comments, but we have discussed it among ourselves.

Bob Kellam came to one of our recent meetings and discussed the proposed policy and there have been several issues that have come up in these discussions that I would like to pass along to you. These are strictly from the regulatory agency point of view. I'm not capable of commenting on some of the scientific basis for the proposal.

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But there are three basic issues that we are concerned about and one of the greatest benefits that we as regulatory agencies see from the policy and the work you're doing is the scientific data on risks and controls that will be developed during the process of identification, assessment and evaluation.

This information will assist us in responding to the increasing number of questions coming to our agencies regarding cancer risks, and it will also provide us with the basis for state regulations, if they become appropriate. Obvious, the state's role in regulating carcinogens will be expanding, but we don't have the staff or the scientific expertise to be developing all this information ourselves. We will have to continue to rely on EPA, and by that, I also mean the other agencies working with the EPA and the assessment groups. We will have to rely on the federal expertise to provide this information.

Along this line, we would recommend strongly that you consider establishing a mechanism for routine transfer of information to the state regulatory agencies of not just final listings and final determinations, but even your preliminary assessments. In thinking about this, this may also be a benefit for you too. As sister regulatory agencies, we may be able to respond and

input into some of these difficult trade-offs you'll be making from our perspective, so I think the benefits go both ways to some routine back-and-forth trading of information even on preliminary assessments that you make.

The determinations of the appropriate degree of control and ample margin of safety in the proposed policy allow considerable judgment, and consideration of economic and social impacts. This has been mentioned by several speakers this morning. While we don't feel that this is totally inappropriate, it does raise a concern.

The effects of carcinogen exposures are usually localized around a source or within some identifiable distance from the source, while significant benefits may accrue nationally or at least regionally. The obvious inequity between the distribution of benefits and the concentration of risks must be handled fairly and as responsibly as possible. It's essential that the affected state and local areas have direct input into this decision and evaluation process.

And it occurs to me from listening to Dr. Ozonoff's comments, the same is true in discussing the time distribution, the latency period. The detrimental effects may occur over a long period of time

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while the benefits can be shown to occur very -- in a short period of time, very immediate, and it is not fair to trade off those immediate benefits for long-term effects which are nevertheless real.

Speaking strictly for myself and not on behalf of NESCAUM, it seems fair and obvious to me that it's prudent as regulatory agencies that we try to, as much as possible, relate the benefits and risks on comparable scales and comparable timeframes. That seems the only fair way to approach the problem.

The last point is the new source requirements. The new source requirements in the proposal are of also great concern to us. They don't require, but they tend to discourage industrial growth in densely populated areas such as the northeast, while favoring other regions of the country. The potential economic impacts to the northeast must be given careful consideration in the final policy. And, as a related concern, unpopulated areas may seem like the ideal locations for you to encourage siting of potential sources of carcinogens, they also are areas likely to encourage new commercial and residential growth.

And it's a Catch-22 situation. This industrial and residential growth are receptors of the carcinogens that may be emitted from the plant you've

located in that area, and we don't have the means to control residential and commercial development to the same degree as we do a potential source of carcinogens, so we may be allowing receptors to come into an area at a later time and posing as real a health problem as if you located the potential carcinogen-emitting facility in a populated area at the time.

So, there is a contradiction and, as I say, a Catch-22 kind of concern that we urge you to consider. Obviously we're not only concerned with economic impacts, but as regulatory agencies, we work in a political environment and we have to be able to support policies that are not insensitive to economic development, and from the northeast point of view, we are concerned with the new source regulations -- the requirements.

I appreciate the opportunity to comment. I'll try to answer any questions if there are any.

MR. HOHMAN: Thank you. Does anyone have any questions?

(No response)

MR. HOHMAN: Thank you for speaking.

MR. FAIRCHILD: Okay, thank you.

MR. HOHMAN: Mr. John Groopman?

DR. GROOPMAN: My name is John Groopman.

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I'm a toxicologist at the Massachusetts Institute of Technology.

The EPA emission standards for identifying and assessing and regulating airborne substances that initiate or promote carcinogenesis is a significant step towards cancer prevention. These regulations have far-reaching implications since the vast majority of chemical carcinogens are low-molecular weight compounds which are either intrinsically volatile or else easily complexed or absorbed by particulate matter.

Therefore, once these chemicals are constituents of air, they can readily contaminate water and soil and ultimately all living organisms. The scientific basis of these regulations are that a majority of human cancer is initiated by environmentally present chemical compounds. The issue of whether these compounds are synthesized by plants, microorganisms or in an organic chemistry lab is moot since once they are disseminated in the environment, they pose potential carcinogenic risk.

Since these agents are environmentally occurring, hence controllable, many scientists have come to the logical conclusion that the majority of human cancer is potentially preventable. Historically, many forms of chronic human disease such as malaria, yellow

fever and tuberculosis have been controlled through the use of preventative health measures. In fact, in the 1890's cholera was eradicated here in the City of Boston, not through the understanding of the molecular biology of how cholera toxin worked, but through the realization that if you had an uncontaminated water supply, people would not get the disease.

Therefore, we only need to know the ideology of cause and not necessarily the mechanism of action to eliminate the human suffering caused by these diseases. An analogous case now exists with respect to chemical carcinogens. The realization is that if an individual is not exposed to these agents, that person will have a miniscule probability of getting cancer. As I'll be discussing in greater detail the precise mechanisms controlling each stage of malignant transformation have yet been delineated. However, research and experimental carcinogenesis has given us much insight into the basic mechanisms of how these agents initiate cancer.

These unifying concepts form a paradigm for the molecular action of these agents and also serves as the basis for the mutagenesis screening assays. Despite the substantial efforts on the part of the medical community over the last fifty years, treatment

of cancer following clinical diagnosis works in only a minority of instances. If one uses the five-year survival rate as a guideline, in the 1930's, twenty percent of all cancer patients lived longer than five years. During the next twenty years, this was increased to a third of all cases. However, since 1960, the five-year survival for the vast majority of human cancers - lung, breast, colon and stomach - have not changed.

We must not promulgate the misconception by people who believe that they can afford the luxury of getting cancer rather than preventing it -- the scientific literatures replete with research which provides insight into the basic mechanism of initiation of cancer by chemical carcinogens.

These compounds first enter a cell by diffusion or active transport across the cell membrane. Most chemical carcinogens are inherently inert and need to be metabolically activated or chemically changed to react as species in this proximate or ultimate carcinogenic form, and given the genetic nature of cancer, interacts with nuclear macromolecules forming the lesion. The nuclear macromolecules comprising the genetic apparatus are DNA, which includes all potential phenotypes; nuclear proteins which direct the expression of genes and DNA; and some RNA.

Damage to these macromolecules, and specific with DNA, can be repaired or not and following DNA replication, these unrepaired lesions can be fixed as mutations. Eventually this transformed cell can express its new phenotype and experimentally we have found that cancers generally found to be monoclonal in origin -- that is, that tumors arise as a result of changes in a single sell and its progeny.

After this, there is a multiplicity of of steps where agents such as promoting chemical compounds can potentiate the malignancy. One lesson of this process is that many cell generations will have occurred before the clinical manifestation of that single transformed cell is seen, and we are all cognizant that this is already too late.

The postulates that I have just outlined are widely accepted and are the products of classical, conservative interpretations of properly-designed experments. For the sake of completion, I wish to briefly discuss these experimental models.

The phenomena of initiative and promotion was discovered using mouse skin carcinogenesis studies. The mechanism of action of compounds such as aromatic amines and N-nitrosamines have been studied in rodents where they are patocarcinogens (phonetically). Inhala-

tion of vinyl chloride in laboratory animals produces apatoangiosarcomas (phonetically) of the same type that occurs in humans.

Bronchiogenicarcinomas, again of the same cell type seen in humans are found in experimental models for lung carcinogenesis in mice, rats, hamsters and dogs. Indeed, mammary cancer in rats, by injections using N-methyl N-nitroceurea mimics its human counterpart in that it metastasizes to bone and produces hypercalcemia.

Colon cancer models in mice and rats can be produced by a number of chemical carcinogens. Pancreatic cancer can be induced in rats, guinea pigs and hamsters. Other organ sites for which animal models exist include cervix, endometrium, esophagus, kidney, brain, hematological tumors and bladder. With the possible exception of prostate cancer, there is an animal model which mimics its mammalian cousin, the human.

It is therefore shallow argument or hypocritical to say that scientists can experiment with these animals to understand the molecular mechanisms of cancer and be honored with prizes and awards, but at the same time state that these model systems cannot be used to assess the carcinogenic potency of a chemical compound.

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However, there is always the argument of the extrapolation of data from experimental animals to humans. Here too there are experimental models in the form of explant human tissues in organ culture that have been shown to have the same initiation reactions as many chemical carcinogens in animals.

To date, these models include tissues such as bronchus, breast, esophagus, pancreatic, and colon.

In summation, basic scientific research has resulted in a general understanding of the biology of carcinogenesis in the molecular biology of malignant transformation using animal and organ explant human tissue models.

In order to prevent cancer, an obligatory first step in public awareness is that we are dealing with a preventable disease. This is defeated by the active cultivation in the public's mind that, quote, everything causes cancer.

The National Cancer Institute, having looked at seven thousand likely chemical carcinogens in the survey of compounds which have been tested for carcinogenic activity have found that less than fifteen percent or one thousand were positive. Out of the four million known chemical compounds with about fifty

thousand in use today, only a fraction of these are carcinogenic.

It serves no end to admit futility when we are dealing with a technologically, analytically and conceptually manageable situation.

Finally, due to the generational latent period of cancer from initiation to clinical manifestation, we are seeing today the results of our ignorance, both active and passive, about cancer in the 1940's and 50's. The agents responsible for the cancers of the early 21st century are already present in our environment.

So, how arrogant must we be to allow one after another generation to be condemned to the misery of this disease?

MR. HOHMAN: Thank you. Are there any questions from the panel? Bob?

MR. KELLAM: Dr. Groopman, I'd just like to ask you the same question that I asked Dr. Calabrese, and that is, with regard to thresholds for carcinogens, do you feel that -- I guess there are three possibilities that there are thresholds for some carcinogens for some individuals, that there are not generally thresholds for carcinogins --

DR. GROOPMAN: Well, it depends what you

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want to talk about. If you want to talk about an experimental model in a laboratory where you have the luxury of using, let's say, ten million animals so you can use extremely low doses to see if you can get a significant number producing a tumor. Then you could do the fine, mathematical extrapolation to find out if you have the answer to the question, "Is there a threshold at this level."

But, if you're out in the environment where you're dealing with a whole number of compounds working synergistically, antagonistically and otherwise together, I just fail to grasp the comment about threshold. They're two different things.

If you want to talk in the laboratory situation, it's one thing. If you want to talk about policy, I think it's a totally different question.

MR. KELLAM: Let, let's just address the laboratory situation.

DR. GROOPMAN: Well, in my understanding, there have been mega-mouse experiments where people have used ten-to-the-eighth mice in order to test the -- excuse me, the proposals to do this -- in order to look at a threshold level down to extremely low doses. But you're talking about the type of experiments that are expensive, time-consuming, and only looks at one parti-

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cular compound when you could be using those resources to look at a whole series of compounds.

MR. KELLAM: Do you personally believe though that there may be thresholds, that what's commonly called the one-hit model, that a single molecule of a carcinogen can induce a cancer is valid or invalid?

DR. GROOPMAN: Well, I think at the laboratory level, in a quantitative mutogenesis assay that you would do in either mammalian cell culture or in bacterial reversion assays, that if you calculate how many hits you needed in that geno in order to get a mutation that you can measure, it's on the order of five to seven hits per geno . Whether you can extrapolate that out to anything else is something I certainly would never do.

MR. KELLAM: Thank you.

MR. HOHMAN: Okay, thank you very much. Our next speaker is Helena Brown.

MS. BROWN: My name is Helena Brown and I'm a researcher in the cancer area at MIT.

Presently, there are fifty thousand synthetic chemicals used on the market in large quantities every day and about one thousand new ones are introduced every year. Many of these chemicals find their

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way into the environment in the form of air pollution. There is a good reason, therefore, to be concerned about the potential of proving carcinogenic activity of these compounds to humans.

Most carcinogens are in effect pro-carcinogens, which means that once entering a living cell, they have to be metabolized by similar enzymes before they can act. It is now well known that the metabolism transforms most pro-carcinogens to electrofilic reactants which in turn bind covalantly to cellular macromolecules, including proteins, DNA and RNA.

It is now believed that binding to DNA, the somatic mutation is in most cases the first necessary, although not sufficient, stop in a complex chain of events which leads ultimately to cancer. Somatic mutation gives rise to cancer by changing the normal cellular mechanisms coded foreign DNA that control and prevent self-multiplication.

Now, there are three fundamental types of evidence used at the present time by scientists to determine the carcinogenic activity of an agent with respect to humans -- epidemiological data, animal testing and short-term screening assays. Epidemiological evidence was addressed fairly well by David Ozonoff and I will not elaborate on that issue. Suffice it to say that although

this kind of evidence is absolutely essential in determination of environmental causes of human cancer, it has a number of limitations.

One of its very serious problems is the fact that people have already been exposed to a carcinogen for decades by the time a particular cause of cancer was identified. The reason for that is that it takes anywhere between ten and thirty years from the initial assault on the human body to the actual appearance of cancer in humans, so it's a very serious limitation of the epidemiological evidence.

At the present time, the key method for detecting potential human carcinogens is the animal bio-assay, usually done with rats and mice. The weakness of this technique very commonly stressed by those who do not want to accept the data emerging from such experiments are, and I list the two main ones.

First, there are wide differences in response between species, so extrapolation of results obtained with animals to human cancer is open to question. And secondly, lack of correlation between high doses administered to animals in a laboratory situation and low doses in ambiant air relevant to everyday human exposure is also open to question.

Now, I would like to address those weak-

nesses which are sometimes discussed. All the animal testing, even when done properly, perhaps not an ideal method to determine risk to human health, there are some basic facts about it.

First, metabolism of many carcinogens in human and rodent cells follows the same pathways and it doesn't always hold true, but it has been shown over and over again with many polycyclic aromatics and other carcinogenic compounds, that there are identical or very similar metabolic pathways involved.

Secondly, recent work by Bruce Ames (phonetically) showed that the potency of the carcinogen does not actually vary significantly between sexes and between rats and mice.

Thirdly, that a very recently published -- actually, it's the last month's issue of Cancer Research -- published by the International Agency for Research on Cancer showed that among twenty-three compounds positively identified as human carcinogens, twenty-one were also carcinogenic to test animals, so there is a pretty good correlation between the data with humans which is already proven and the animal testing data.

And lastly, as to the relevance of the extrapolation of high experimental doses in animals to low level environmental human exposure, there is a very

good reason for that. It is illustrated as follows. An environment carcinogen causing cancer in only one percent of a hundred million people would result in a million new cases of cancer. We're talking about weak carcinogens, one percent. Detection of cancer in animal tests at one percent level would require ten thousand rats and involve astronomical expenses.

For example, an average experiment involves fifty animals in each group and the cost of an experiment like that can go up to a half a million dollars as it is. Therefore, instead of increasing the number of animals, the researchers simply increase the dose.

Now, well documented positive linear relationships between the dose of a carcinogen and the tumor incidence makes this extrapolation valid. Based on the data collected there is a good scientific evidence pointing to the relevance of animal testing data to human situations.

Now, briefly, the third alternative for screening the chemicals is a battery of fast, inexpensive, short-term assays, the best known of which is a bacterial mutation test, Ames' assay. Here again, no single assay is perfect because each system detects a few carcinogens which others do not. The idea of a

battery of short-term tests is now favored by many investigators.

With this approach, there is a very good correlation, anywhere between eighty and ninety percent -- there is a controversy among scientists here -- but it's a very good correlation between mutagenic activity of a compound and its demonstrated carcinogenicity to animals.

In short, there is a good reason to believe that compounds shown to be positive either in short-term screening assays or in animal testing studies or both are potentially carcinogenic to humans and should be strictly regulated.

MR. HOHMAN: Thank you. Any questions?

MS. ANDERSON: I just have a --

MR. HOHMAN: Betty?

MS. ANDERSON: It seems to me your statement is pretty much an endorsement, at least on the scientific side, of how the EPA has approached the risk assessments with carcinogens.

MS. BROWN: That's correct.

MS. ANDERSON: I wondered if you were suggesting that we do something that we are not doing currently or you are endorsing what we are currently doing.

MS. BROWN: Well, one thing I can stress is the time factor involved. From reading the EPA register, I understand that the period of time between, I guess, first naming the prospective chemical and actually coming out with regulations is about three years. If there is any possibility of shortening that period of time -- but in general, I endorse the EPA's approach.

MR. HOHMAN: Okay, thank you.

MS. BROWN: Thank you.

MR. HOHMAN: Let me reminate here for a minute. We have a number of speakers -- about twenty, I think. My thought is that we will stop at some convenient time around twelve-thirty for about a forty-five minute break, after which we will get back to work again and move through the afternoon.

If the average time is of the order of fifteen minutes or so per speaker, I think we can handle this pretty well. So, I will call the next speaker or two and then around twelve-thirty or so we'll take a break for about forty-five minutes.

Herb Northrop is next, I believe.

MR. JAESCHKE: Dr. Northrop is here and he's available to answer medical questions that might arise from my testimony. I'm Wayne Jaeschke, Vice President of Environmental Services for Stauffer and then Mr.

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Ronan, our counsel, wishes to make some comments on the pertinent legal deficiencies of EPA's proposal.

I the position that I held in Stauffer, I'm responsible for the activities of over 200 professionals and other employees devoted to toxicology, health research, occupational medicine, product safety and environmental regulations which affect our chemical production throughout the United States. I'm also a member of the Environmental Management Committee of the Chemical Manufacturers Association, a member of the board of directors of Chemical Industry Institute of Toxicology. I'm also a parent, a taxpayer and certainly as concerned as anyone in this room with the issues of cancer and the air that we all breathe.

I wish to discuss several of the policy issues relative to EPA's proposal. I'm deeply concerned that EPA's proposal is completely unnecessary, scientifically unsound and will add yet another layer of bureaucratic procedure and counterproductive controls. It will divert necessary and finite and limited resources away from much more fruitful research and production of essential goods. Anyone who has observed the ravaging and dehumanizing effects of human cancer as I have and I'm sure that many in this room have, particular in its terminal stages, cannot help but be moved and moti-

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vated to seek a constructive action to alleviate suffering of future generations from cancer.

On the other hand, I feel a sense of outrage towards nonscientific and simply bureaucratic procedures and controls which will needlessly and additionally burden essential productive capacity without any rational demonstration of human benefit.

I certainly think we should have a moratorium on such potentially counterproductive regulatory activity until such time as there is scientific understanding of the subject proposed to be regulated and a clera demonstration of need. Our energies and resources should be focused instead on the scientific research and information which must be carried out in order to predict whether, and at what levels, humans are at increased risk of cancer from any type of environmental contamination.

Over the past ten years, Congress has enacted many new laws and agencies have written hundreds of thousands of pages of regulations, guidelines and orders about environmental and toxic substance control. My company and our industry have recognized the need and support such actions where such a need has been clearly demonstrated. Industry as a whole has spent billions of capital dollars, and my company alone over two hundred

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million dollars, to control environmental pollution. Stauffer spends about fifty million dollars annually to operate facilities for pollution control and testing for products for biological safety. We recently built a new environmental health center in Farmington, of large production, to carry out animal, Ames' and other types of testing.

Rules and regulations have grown from those few which are basic and essential to a huge number of conflicting, overlapping ones containing many serious technical and legal flaws. In many cases, highly skilled doctors, lawyers and engineers cannot adequately understand or cope with this bureaucratic maze. The simple hamburger, for example, according to recent U.S. News and World Report, is the subject of no less than 41,000 regulations.

Now, the Clean Air Act and regulations provide ample room already for case-by-case regulation of airborne pollutants. For example, EPA has already regulated the suspect carcinogens asbestos and vinyl chloride, as well as others, under Section 112 of the Clean Air Act. There is no reason for adding more regulations which will overlap and most likely conflict with the existing ones. Dealing with this overlapping layer simply diverts our resources from projects which have a

high probability of human benefit.

Now, I'd like to deal with the proposed policy. I feel there is no evidence of a connection between general air pollution and cancer, as much of the testimony in Washington demonstrated. I feel that prudent public policy as well as the law demand a clear demonstration of need and benefit prior to implementing a regulation of potentially huge impact. EPA is unable to demonstrate that the present proposal is necessary or likely to reduce cancer mortality in the general population. I find several facts particularly impressive in this regard in support of the conclusion that general air pollution does not impact the incidence of cancer.

National Cancer Institute, NCI, cancer statistics, when adjusted for smoking, show the cancer mortality among women has decreased slightly while mortality among men has increased slightly for the period 1970 to 1977, although, presumably, men and women are exposed equally to the general environment. And it is my understanding that NCI will soon publish a manuscript now in preparation that will state essentially the same relationships and the decline of incidence rates as well.

Cancer mortality in certain heavily polluted cities is less than in comparable relatively clean cities, which has been amply testified to by Dr.

Dimopolous (phonetically) in the Washington hearings.

The general population has been exposed to low levels of airborne pollutants over the last thirty to forty years, yet no correlation exists with increased cancer mortality.

There is no firm evidence to support the hypothesis that the general air pollution increases the risk of lung cancer.

Epidemiology, while I think all agree is a blunt tool, it is sufficiently sensitive to flat significantly increased human risks, as demonstrated by liver cancer studies of aflatoxin in various African states and the remarkable correlations of cancer and smoking shown in both sexes by NCI statistics.

I feel it's totally improper to set regulatory policy on the basis of speculation in the absence of scientific data. We should bear in mind that the purpose of EPA's proposal is to regulate agents, which if present in the general ambient environment at all are at levels measurable in parts per billion. Rules under this proposal might, for example, result in the reduction of a chemical agent in the environment from, say, 200 parts per billion to, let's say, 50 parts per billion by expenditure of millions of dollars.

Prudent public policy, certainly, requires

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a strong showing in such a case that there is a reasonable probability, based on some scientific data, that such a miniscule change in the overall makeup of the environment will reduce cancer incidence.

I think it's shocking to find this type of regulation being strongly pushed and considered since there is simply no scientific understanding of low dose effects, even at the levels of low parts per million, let alone parts per billion and trillion. There is an absolute lack of scientific information concerning the difference in biological impact on live animal organisms, for example, when ambient exposure is changed from high parts per billion to low.

EPA's argument for regulation must, therefore, be based solely on speculation and philosophy. Private and public resources would be spent more productively, for example, on scientific research on the effects of such ambient levels rather than on counterproductive controls.

The speculation about potential synergistic effects at parts per billion levels has even less scientific basis. Indeed, one could speculate about the antagonistic effects equally as well. Either effect is certainly extremely highly improbable in view of the rarity of collisions amongst molecules present at parts

per billion levels. Scientific data, not speculation, must be the basis for prudent regulation.

Now I'd like to address the question of criteria because as has been said over and over again, concerning goals of reducing carcinogens in the environment, is an important goal. And I think we might all agree as to that. The real question is how does one, absent epidemiological data, how do you spot those things that might reasonably be considered to be a human carcinogen based on some form of predictive animal or other data.

The establishment of criteria which would enable EPA to regulate a substance as an airborne carcinogen, based on positive results on a single animal species, without more, is not supportable, in my view, from a scientific point of view. Establishment of this type of arbitrary criteria for the convenience of the agency is certainly improper in this area where scientific measurement and judgment of all of the facts are essential in order to properly assess whether any substance should be considered for regulation as an airborne carcinogen in the general environment.

At the outset, scientific judgment is required to determine whether there actually exists an increased risk of exposure of the experimental animal

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subject to massive doses of the agent or whether increased tumor formation might be due to other factors such as metabolic overloads, dietary deficiencies, or poor animal health caused by overexposure.

If a significant risk is established in one of the species under test, then additional measurement and scientific judgment certainly seem to be required to extrapolate these findings to other species and ultimately to man.

In the Dry Color Manufacturers case, the court wisely recognized a need for evidence linking effects in animals with risk to man. And I think there has been testimony on that here this morning. In that case, the chemical DCB induced tumors in rats as well as in mice. The action was attributed, however, to a metabolite produced in the rodents. Experiments with dogs which appear to handle DCB in a way metabolically similar to man, showed that the dogs failed to produce the carcinogenic metabolite and were resistant to tumors. In that case, the agency's application for emergency action was denied by the court.

There are numerous other examples of differential tumor susceptibility of species by reason of differing metabolism, including 2-acetylaminofluorine which induces cancer in rodents but not in guinea pigs,

and 2-naphthylamine, which is carcinogenic in dogs, monkeys and hamsters, but not in rats and rabbits.

Recent research by the Chemical Industry Institute of Toxicology revealed that under the same exposure conditions, rats are susceptible to squamous cell nasal carcinomas whilc mice are not susceptible. This further demonstrates the futility of condemining highly useful products on the basis solely of a single positive test. Fortunately, this finding has caused leading comparative biologists -- for example at Rockefeller University -- to more vigorously explore the scientific bases for the extrapolation of risk from species to species.

It has further stipulated scientific thinking as to the potential significanc of differences in enzymes, hormones and other biochemical factors which might be important in cancer risk assessment. Research by Dr. David Sachs at the National Institute of Health on the relationship between surgical transplantation of kidneys and tumor immunity suggests the necessity of understanding the role of the immune system in predicting the risk of human cancer promotion in relation to animal models.

There are numerous other examples of species specific carcinogens, including a wide range of

chlorinated hydrocarbon solvents and pesticides. Also, while phenobarbital is known to produce cancer in rats, it has been used safely by thousands of human beings for many, many years - long past the latency period.

While this subject has not been thoroughly researched, species specific carcinogens are probably the rule rather than the exception. Therefore, the basis for indictment of any specific agent based solely on one mouse study, for example, at massive doses, is fundamentally without scientific merit.

Finally, scientific judgment and measuremen are essential requirements for the assessment of the meaning of "no observable effect levels" in animal models and consideration of "safe" levels of airborne substances. There are numerous examples of chemicals such as selenium, estrogen, both endogenous and exogenous chemicals of all kinds, which are essential components of human survival at low levels, yet they induce tumors in animals at high dose levels.

Dr. Henry Pitot, who is Director of the McArdle Laboratory for Cancer Research -- and certainly one of the leading cancer scientists in the United States -- recently said, "The determination of a threshold effect of a carcinogenic agent should be carried out for a number of known exogenous and endogenous carcino-

gens at low doses utilizing the extrapolation of 'time to tumor'. Thus far, studies have almost exclusively been carried out looking only at the incidence of cancer which statistically becomes meaningless very rapidly as the dose approaches zero. Thus the 'effective threshold' should be sought rather than the 'absolute threshold'."

The FDA, for example, has even set a safe level or "tolerance" for the presence of the naturally occurring, extremely potent carcinogen, aflatoxin, in peanut butter, by established risk assessment procedures. The subject of effective or practical thresholds must be given more attention particularly in view of the extremely low levels which would be the subject of regulation under EPA's proposal.

The foregoing discussion and examples of risk factors clearly illustrate the futility of trying to properly assess the carcinogenic risk to man, based on arbitrary criteria alone in this area, where the causal factors are not understood and cannot yet be rationalized as a set of guiding principles.

Given our present lack of fundamental understanding, meaningful risk assessment and extrapolation can only be made by thorough scientific appraisal of the data. A Science Panel, such as proposed by AIHC, would be most useful for this purpose, and I urge the EPA to

support creation of such a panel in the public interest.

There is a high priority need for a greatly increased level of mechanistic research on tumor effects in animals, for research on effects at low doses found in the general environment, research on the principles of comparative toxicity amongst species, and the value and limitations of toxicological procedures in general as predictors of risk to man. There is no need for more regulation until the scientific back up is in hand. There is adequate mechanism under Section 112 for regulating on a case-by-case basis.

These facts are beginning to gain recognition, for example, by the chairman of the President's Cancer Panel and by other independent scientists, including the Nobel laureate scientists who helped form the American Business Cancer Research Foundation for the purpose of catalyzing such research.

EPA should recognize and support this critical scientific endeavor since this is far more likely to alleviate future human suffering than counter-productive and needless added regulation. Thank you.

MR. HOHMAN: Thank you. Roy?

MR. ALBERT: I have a couple of comments and then a question. I believe the points that you make in quoting Dimopolous on Page 4 were dealt with in the

Washington hearings and are on the record, the objections to his assertions.

I think your use of aflatoxin as an example of epidemiology as a sensitive tool to flag significantly increased human risks is a poor choice because in the areas that you're talking about, in Africa, liver cancer is not only the leading cause of cancer, it's a leading cause of death. And so, you practically don't need epidemiology at all to pick that out.

Also, your objections to the use of single -- responses in single species is applicable to the aflatoxin situation because if one were to apply it to aflatoxin, aflatoxin would not be identified for regulatory action because it would only show up as positive in routine bio-assays in the rat, not the mouse.

I think your objection to the induction of squamous cancers in the nose of rats is not particularly well founded because this was the prime response that identified bischloromethyl ether as a carcinogen and subsequently demonstrated to be a human carcinogen, not of the nose, but of the bronchial tree.

Your reference to Pitot's recommendation of using temporal thresholds I think is an opinion of

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his and I'm sure he would be the first to recognize that there are sharp differences in opinions about -- or at least a major uncertainty about the temporal characterization of tumor responses, and that there are two different models that equally well fit the data at the present time, one of which would support a temporal threshold and the other wouldn't.

Now, finally, in terms of your recommendation on Page 9 about the Science Panel, it seemed to me that the entire thrust of your testimony is that there is no scientific basis for estimating carcinogenic risks whatsoever at the present time in humans and yet you seem to call for the -- well, at least you state that, "... meaningful risk assessment and extrapolation can only be made through scientific appraisal of data," when you went through a litany which seemed to indicate that you couldn't do this. And then you call for the creation of a Science Panel to do essentially what you've called an impossibility.

I find this a contradiction in terms of the thrust of your testimony. I wonder if you would respond to that.

MR. JAESCHKE: Well, which of the long litany of questions would you like me to respond to first?

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MR. ALBERT: The last.

MR. JAESCHKE: Because I disagree essentially with the thrust of each and every one of the comments --

MR. ALBERT: (Interrupting) I thought you would. (Laughter)

MR. JAESCHKE: -- or discussions that you made. I find no contradiction in the statement that a Science Panel is needed. The position that's quite clearly stated here is not that any rule-making should not go on in cases -- indeed, rule-making has gone down in vinyl chloride, beryllium, asbestos. It's adequate regulation, legislation which enables EPA to get on with the business of regulating where regulation is necessary.

The argument, and the fundamental argument is that the one mouse criteria that EPA has set up is totally unsound, that this is a matter where there are no rationalized clear-cut principles. That's been made abundantly clear by the litany of testimony here on metabolism and other factors, and it certainly seems to me that this is a matter of scientific judgment and that's quite consistent with our position.

You must have the best scientific judgment. We're not saying that categorically -- or I'm not saying

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categorically, and no one is -- that in a case where you simply have a rodent bio-assay that you can connect by appropriate linking evidence, whether it's metabolism or something else that might be appropriate to raise a presumption of carcinogenicity in man, that regulations shouldn't take place. But as a categorical rule, that's not scientific at all. So, it's quite consistent.

MS. ANDERSON: I have just a follow-up question.

MR. HOHMAN: All right, go ahead.

MS. ANDERSON: That makes me wonder if indeed the tests which are now being reported from formaldehyde studies indicating a positive result on nasal squamous cell carcinoma in the rat, but a negative result in the mouse, turn out indeed to be quite corrective, that you would think that the agency should --

MR. JAESCHKE: Which one would turn out to be correct?

MS. ANDERSON: That the results are preliminary. The study is now at eighteen months.

MR. JAESCHKE: Right.

MS. ANDERSON: If indeed the results do turn out as they certainly appear they will, that there is an overwhelming positive response in the rats, a negative response in the mouse, and you're seeing the kind

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of tumors that were first identified from bischloromethyl ether, would you think the agency should ignore that?

MR. JAESCHKE: I think that the actions that are going on are epidemiology in human beings and the class of individuals that have been heavily exposed to formaldehyde, namely morticians, that action at industry's behest has been undertaken. A great number of people have expressed the indication that one ought to find out what the biological factors are behind -- what's the reason for the difference, is it some sort of hormonal or enzymatic excretion in one species that does not happen in a second species or does not happen in man? After all, formaldehyde has been around for many, many years. EPA has not taken any action. It's not the government, in this case, that is promoting action but industry.

MS. ANDERSON: I wasn't asking about action or inaction, I was just asking what you would do with these kinds of results.

MR. JAESCHKE: I would certainly try to find out why they were so. That's the whole point.

MS. ANDERSON: Suppose you can't get that answer. How long do you think the agency should just hold data like this without regarding it as some signal that should trigger some regulatory action?

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MR. JAESCHKE: Well, the agency has sat on formaldehyde for the last forty years. I suspect - and has done nothing until industry has done the testing. I suspect that reasonable prudence would say that one ought to find out whether there is some reason to believe that this is a human affect before he does something.

There's no reason to suspect that in this case, but because of the intervention of industry and the strong research that we've sponsored, perhaps we will have the answers. At the point where there is some reasonable link with human carcinogenesis, I would say the agency should move forthwith, but not until.

MS. ANDERSON: In the absence of some link with human studies, then you would think the agency should not move?

MR. JAESCHKE: I would absolutely think the agency should have some rational scientific underpinning for any action that it takes. That's a sine qua non of the law and a reasonably prudent public policy.

MS. ANDERSON: At the extreme, I understand you're saying that can come from positive epidemiology studies. Do you think there are other ways, other sources of information to buttress this kind of data?

MR. JAESCHKE: I think that all evidence needs to be considered and I think that's a very impor-

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tant point in these hearings, that no evidence -- I'm most dismayed to hear people calling for arbitrary exclusion of evidence, telling the EPA in effect that it is not intelligent enough to assess the data, as I heard earlier this morning. I think all data, whether this is done by a Science Panel or whether it's done by the EPA, certainly all of the data ought to be considered by the professional toxicologists, medical people, as well as the regulatory policy-makers in coming to their conclusions, and therefore would strongly urge that you not write, or eliminate from these regulations, anything to the contrary. I think it's totally wrong.

MS. ANDERSON: EPA has had the interim guidelines for assessing carcinogenesis for three and a half years now. The thrust of the guideline and the weight of evidence approaches to consider all data in the aggregate and make statements on a case-by-case basis about the likely risk. This activity has been carried on by an internal group, the EPA's Carcinogen Assessment Group.

I wondered what fault you might find with what that group is doing that would make you think the agency should endorse an external panel to do the same thing.

MR. JAESCHKE: We complimented the agency

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in 1976 when it came out with guidelines because I think that in the adoption of public policy, it's most important that the agency communicate with the public what it is doing, but guidelines are one thing. The rigidity of criteria written into a regulation, particularly with arbitrary rules as to exclusion or inclusion of data, is just plain wrong.

Now, I think the thrust of your question was, what's the benefit of a Science Panel. Is that --

MS. ANDERSON: Yes, since the agency has an internal group that is doing what I think you're proposing that an external group do. I wondered where you saw the need for the agency to endorse an external group as opposed to this internal --

MR. JAESCHKE: Well, the USCPA is but one of a number of co-equal agencies of the federal government which has a strong interest and need in carcinogen regulation. Certainly I see no need to squander the taxpayers' money on doing this job in what I consider to be less than totally efficient way, spread amongst a nuber of agencies.

I would think that the public interest demands that we have one group, the best group of scientists available as an independent group, make the assessment of whether something is in fact a carcinogen

that places humans at risk. To do that at the outset and then feed that finding to the EPA, to OSHA, to FDA, or to any other state, local -- whatever regulatory actions are interested in it, so there's an area of efficiency and I think if you can put emphasis on that at the front end of the process, you're much more likely to get a better group of scientists who can concentrate their efforts --

MS. ANDERSON: Yes. I just wondered if this stemmed from efficiency or a central criticism of the Carcinogen Assessment Group within EPA. I see that it's the efficiency, so --

MR. HOHMAN: Todd, do you have anything?

MR. JOSEPH: I have just a few questions. First, let me clarify what seems to be a misunderstanding. These regulations are not intended as anything more than a decision framework and set of principles to guide case-by-case regulation. They are not intended in lieu of case-by-case regulation. They're just intended --

MR. JAESCHKE: Well, let me just say something. I am a lawyer admitted to the New York Bar. I've studied engineering at Cornell University, I've been vice president of Stauffer Chemical for sometime, I'm on a number of boards, and I'll tell you, I am certainly confused by the statement that you're making.

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I'm delighted to hear it, but I don't agree that that's the rational interpretation of what you're doing. If it is and if the regulations are written clearly, that all that's intended is a case-by-case evaluation on the merits, taking into account all scientific and other available data, and dealing with controls on a case-by-case basis, then we heartily endorse it.

MR. JOSEPH: Well, as I said, one thing that the proposed regulations contain is certain principles that we're trying to resolve in this proceeding. We will certainly -- we have certainly seen in these hearings to date the need to clarify what it is we're trying to do, and it may be of some comfort to you that a uniform comment of various environmental in the Washington hearing was that these regulations were deficient in that they really didn't commit EPA to doing anything about any particular chemicals, but merely said what EPA would do when it decided to do something about a chemical or how it would decide to do something about a chemical.

But let me ask you some more specific questions, if I may. At a couple of points in your statement you mentioned EPA's vinyl chloride regulation under Section 112 in the context of case-by-case regulation. Are you -- I wasn't quite clear whether what you

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were saying is that is a sort of a generally, reasonable approach, more or less, without asking you to endorse exactly that regulation?

MR. JAESCHKE: Let me say that the case-by-case approach is necessary, it's essential. We're not saying that where something is appropriate when the evidence is at hand that the EPA should not act. I should point out, however, that there is no evidence whatsoever in the case of vinyl chloride of the low-dose effects on man.

MR. JOSEPH: So, do you think we should or should not have acted in the case of vinyl chloride?

MR. JAESCHKE: I think it's a moot question. I think you did act and I think I've said that there certainly may be other cases where EPA would more productively spend its time than by trying to enunciate principles of science that are not here yet. But, I don't see the point of --

MR. JOSEPH: Well, it's not clear from your statement just what it is you think EPA should know before acting, and that's why I am asking you to apply your analysis to the vinyl chloride case.

MR. JAESCHKE: Yes, well, what I'm saying is that if EPA -- what EPA should do is to strongly endorse a Science Panel of some type that would enable

professional doctors, toxicologists, and so forth, to review data on a case-by-case basis and recommend to EPA and the other agencies whether there are data that is sufficiently suggestive of human risk in order to initiate action. That's what EPA needs to know.

You need to have a good, scientifically based risk assessment of both the qualitative and quantitative aspects before you can energize the regulatory process.

MR. JOSEPH: But it's not very helpful to us for you to just tell us that we need to know whether there is enough information to act. We need to know what constitutes enough information to act.

MR. JAESCHKE: Well, certainly, I've said very plainly in my testimony that there are cases where one might find a positive bio-assay, you might find that that positive bio-assay was not due to some extraneous factor. At least reasonable toxicologists could draw the conclusion that the effect is related to the compound being administered, and there may be evidence which could be a second bio-assay in a second species or there may be some linking evidence such as we talked about in the Dry Colors Manufacturers case where the metabolic patterns of the animals, it was determined that the animal from a metabolic standpoint,

for example, was a good surrogate for man.

It certainly seems to me that that's at least a rational basis for raising some form of presumption. Absent some sort of confirmation or linking evidence, merely to say that because it's positive in one animal species, I don't think is adequate because as I say, I think that species specificity is the rule rather than the exception. I think that's well borne out.

MR. JOSEPH: Thank you.

MR. HOHMAN: Thank you. We have time for one more question. Roy?

MR. ALBERT: Yes. Isn't it true that the main thrust in the AIHC's and your proposal for an outside scientific panel to do assessments is the hope that such a panel would develop criteria that would set a higher threshold for the acceptance of evidence of human carcinogenecities than now exists in the EPA?

MR. JAESCHKE: I'm dismayed by that question from the point of view that since all of us are susceptible of getting cancer at one stage of our life or another, it seems to me that we all share the very same common interest in understanding the basic fundamental principles of cancer causation rather than going on witch hunts and trying to damn everything in site, and I think that that type of behavior isn't going

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to get us very far.

This type of proposal of the one mouse criter doesn't advance science one little bit, so I don't think that any of us wants anything more than scientific understanding so that we know the factors which place us at risk and might take adequate steps to remove them from the environment or may take adequate steps to protect ourselves in whatever regulatory or personal way is available.

So, the answer is clearly, absolutely no to your question.

MR. HOHMAN: I have another question from Betty.

MS. ANDERSON: It's mainly a comment. I think that the thrust of your testimony has left some confusion when you say, "the one mouse criteria." There is no such thing --

MR. JAESCHKE: (Interrupting) Excuse me, that's a matter of characterization.

MS. ANDERSON: Yeah, but I think it's very important to note that the whole thrust of the EPA policy is to take all the data in the aggregate. There is no one mouse criteria or one rat criteria or anything of the kind. There is an earnest effort on the part of the scientists in the agency doing this work to look at

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all of the available data, certainly looking at negative studies as well as positive studies. Any information we have about mechanisms of action, short-term test data, all of the information is put together to see what sense we can make of the entire picture, so there is no search in a haystack for one study that happens to show a positive signal and then just action going straight ahead on that basis.

I think to leave that impression is unfortunate and I just wanted to try to correct that.

MR. JAESCHKE: All right. Let me see if I understand you correctly. You're saying that it is the agency's intent, which will be a matter of record from these proceedings, that all data concerning carcinogenesis of the species and compounds and so forth, the compound under consideration, will be considered? There is absolutely no arbitrary criteria such as the ruling out of some negative data or any other data, that one will look at -- that the EPA scientists and regulators will look at all of the metabolic, hormonal or whatever data on an unbiased and impartial way, and that that is the sense of this commission, that's the sense of this regulation? Is that right?

MS. ANDERSON: The guidelines that were adopted by the agency, the interim guidelines for judging

carcinogenecity that were published in May of 1976 made that statement in more than one way. The agency has been proceeding on that basis now for three and a half years. The current air cancer policy for regulatory action under Section 112 excerpts that statement and lists it in the Federal Register notice.

I see no reason to think that the agency is going to start doing anything on a different basis.

MR. JAESCHKE: Well, I'm delighted to hear that you agree with my testimony. Thank you. I'm sorry, are there further questions?

MR. HOHMAN: No, I think not. Thank you. I understand that there's a cafeteria on the third floor and I think probably that would be a prime candidate. I think we'll adjourn now until one-thirty.

(Whereupon the hearing adjourned)

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AFTERNOON SESSION

THE CHAIRMAN. I might say to the assembled group, we do have a tighter and tighter scheduling problem as the day wears on, and so I think we can get through okay, but I'll have to pay fairly close attention to it.

MR. RONAN: Good afternoon, distinguished members of the Panel. My name is John Ronan, I am Legal Counsel for Stauffer Chemical Company.

Stauffer Chemical Company endorses the comments of the American Industrial Health Counsel, AIHC, relating to the proposed U.S. EPA Policy and Procedure For Regulating Airborne Carcinogens.

The proposed EPA Regulation for Airborne Carcinogens fails to meet the statutory requirements of Section 112 of the Clean Air Act.

Further, the proposed regulation is unsound as a matter of Regulatory Policy.

We endorse and recommend for EPA's consideration, the Proposal for an Alternative Regulation, which AIHC has submitted to the EPA in Formal Comments.

Section 307 of the Clean Air Act requires that a Notice of Proposed Rulemaking shall be accompanied by a statement of its basis and purpose and shall include a summary of the factual data on which the

Proposed Rule is based, and the methodology used in obtaining the data and in analyzing the data.

EPA has failed to present evidence demonstrating a need for the Proposed National Policy.

The Agency has cited 37 references in support of the Proposed Regulation, some of which show a remarkable correlations between cigarette consumption levels and lung cancer rates.

EPA, however, has utterly failed to show any correlation between air pollution and increases in lung cancer mortality.

To the contrary, the most recent authoritative study by E. C. Hammond and L. Garfunkel, "General Air Pollution and Cancer in the United States," states that the authors concluded that there was no firm evidence to support the hypothesis that general urban air pollution increases the risk of lung cancer to an important degree, if at all.

Data from our studies support that conclusion and we are unaware of any evidence that convincingly leads to a contrary conclusion.

Instead of a massive cancer epidemic, age-adjusted U.S. cancer data indicates that except for lung cancer, cancer rates have remained stable, or have decreased over the past fifty years.

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Ninety per cent or more of the lung cancer rate is attributable to pandemic cigarette smoking. In contrast, there is no clear evidence linking lung cancer to air pollution.

I refer the EPA to the AIHC comments, particularly Appendix A to the comments on legal issues, which analyzes the references cited by EPA.

Executive Order 12044 requires that meaningful alternatives are to be considered and analyzed before a regulation is issued, and that compliance costs and other burdens on the public should be minimized.

Agencies are directed to insure that alternative approaches have been considered, and the least burdensome of the acceptable alternatives has been chosen.

Detailed Regulatory Analyses are required for major regulations with potentially significant economic consequences. The Regulatory Analysis is required on all regulations, which will result in an annual effect on the economy of 1 million dollars or more.

A Cost Impact Study, by Arthur D. Little, Inc., included in the AIHC comments, demonstrates that the very significant cost impact of the proposed rule would substantially exceed this criteria.

For benzyne alone, the initial cost of

compliance with BAT requirements and the draft generic standards, are estimated to be 82 million dollars, and the annual costs are estimated to be 68 million, assuming gasoline handling is not controlled.

Similarly, for perchloroethylene, compliance with the draft Generic Standards, and BAT Requirements would cost 213 million dollars, initially, with an annual cost of 103 million dollars.

These highly conservative estimates concern only two of the multiplicity of compounds, which would be subject to regulation.

Despite the very significant potential impact of the Proposed Regulation, EPA has failed to conduct an economic and Regulatory assessment.

The EPA Proposal has been criticized by the Regulatory Analysis Review Group on many of the same grounds that have been outlined in the AIHC Comments.

Significantly, RARG has stated that the Proposed Regulation might allow an unwarranted low hurdle, which may result in listing substances for which it later appears that controls that the levels required are unjustified.

Considering the major Regulatory and economic impacts, it would appear that the Propose Rule should have received a more careful review by EPA, prior to

proposal.

A detailed legal analysis of the Proposed Regulation has been submitted in the AIHC Comments on Legal Issues. I will, therefore, broadly outline key aspects in which the Proposed Rule exceeds the Statutory Authority of Section 112.

Section 112 of the Clean Air Act is not intended for the regulation of a large number of carcinogens. The legislative history clearly demonstrates that Section 112 is concerned with only a few extraordinary toxic pollutants within that narrow category of substances, which pose an especially grave threat to human health.

Section 112 is simply inappropriate for the massive regulation of a large number of substances.

The Proposed Regulations fails to conform to the substantive requirements of Section 112, for listing. Section 112 requires that a determination to list a substance as a hazardous air pollutant must be based upon a reasoned weighing of all relevant evidence.

The Proposed Rule, however, would preclude relevant scientific evidence from consideration in the development of specific standards.

The two key criteria for listing a substance as a hazardous air pollutant, create an unreasonably

low hurdle for Regulatory action.

The first criteria is triggered when the Administrator judges that there is a high probability the substance is a human carcinogen, which could be based upon a single animal test demonstrating the induction of malignant tumors with or without additional evidence, which could be inconclusive by itself.

This criteria would ignore scientific evidence relating to dose response, metabolic overdose, comparative metabolism, threshhold effects and species sensitivity.

For reasons explained in the AIHC Comments, and additional testimony presented at these Hearings, this criteria is scientifically unsound.

The second criteria is triggered where there is evidence of significant public exposure via the ambient air from stationery sources based upon a qualitative of preliminary estimate of the population exposed.

This criteria fails to relate ambient levels of exposure to levels of risk, which would be provided by a definitive, quantitative risk assessment. A quantitative risk assessment would define whether ambient air levels exceed an ample margin of safety, and would, therefore, require Regulatory action.

A quantitative risk assessment, therefore, should be a prerequisite to statutory listing.

Although Section 112 provides a mechanism for delisting of a compound, there is no provision for delisting in the Proposed Rule. EPA has essentially proposed a low-hurdle scheme for listing a large number of compounds with a non-existent or impossibly high hurdle for delisting, that is totally at odds with the Regulatory approach envisioned under Section 112.

The establishment of interim design standards under the Proposed Rule would clearly exceed the Agency's statutory authority.

Section 112 of the Clean Air Act does not authorize the two-phased approach to standard setting, which would immediately propose and adopt BAT generic controls on substances when listed with subsequent more owner control, based upon a quantative risk assessment.

The Regulatory options to be employed in setting final standards, likewise, exceed statutory authority granted to EPA under Section 112 in a number of respects.

To be specific, Section 112 does not provide for didfferent standards for new and existing sources. Section 112 does not authorize the Administrator to consider the availability of substitutes in setting

emission standards.

Section 112 does not provide for an emissions offset policy.

Congress established an Inter-Agency Task Force on Environmental Cancer, Heart and Lung Disease. The Task Force, chaired by the EPA Administrator, is specifically directed to recommend a comprehensive research program to determine and quantify the relationship between environmental pollution and human cancer, and to recommend comprehensive strategies to reduce or eliminate the risks of cancer or such other decisions associated with environmental pollution.

The Administrator, however, has not proceed as Congress directed, but has prematurely proposed a sweeping and costly generic control strategy without a proper scientific foundation.

The EPA has proposed a regulation that would attempt to change the basic structure and requirements of Section 112 of the Clean Air Act as enacted by Congress to support a scheme for the wholesale generic regulation of a very large number of chemical compounds.

This would exceed the statutory authority granted to EPA.

The Proposed Regulation is unsound as a matter of regulatory policy. More importantly, the

Proposed Regulation is scientifically unsound. The Agency has not undertaken the Regulatory Analysis before proposing regulation required by Executive Order 12044.

The Proposed Regulation should be withdrawn and reconsidered. We endorse and recommend for EPA's review the proposed alternative offered by the American Industrial Health Council, which we believe offers, scientifically and methodologically, sound recommendations for determining whether substances should be regulated and suggest legally sound procedures for regulation.

We urge EPA's serious consideration of this Proposal.

Thank you.

THE CHAIRMAN: I'd like to limit this to one question.

Todd?

MR. JOSEPH: I'll ask one question and make one clarification.

The clarification is that the Proposal for Generic Standards is not associated with BAT. BAT is not an element of that. The Generic Standard Proposal which, at this point, is only an Advanced Notice of Proposed Rulemaking, is a Fugitive Emission and Leak Control Program, and nothing more.

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The question is, I would appreciate it if you could specify where, in the Proposed Rule, there is stated any intention to preclude the consideration of any evidence in deciding whether a particular compound may be carcinogenic.

MR. RONAN: I'd like to refer you to page 58656 of the Federal Register Announcement, and I'd like to read -- I believe this begins at the top of the Column No. 3, the righthand column:

"EPA considers well-conducted, single-species tests and single test results substantial evidence of carcinogenicity. Such tests are widely used in industry and government laboratories. In light of available evidence delaying the implementation of controls for three or more years, etc."

It seems to me this is a pretty clear endorsement of regulation based upon single-species, single-test evidence. I think that's pretty clear.

Now, as Mr. Jasky has stated earlier, if indeed, the EPA is not intending to regulate on single-species tests, if you are going to consider all of the evidence, if you are going to consider all of the relevant scientific evidence, such as a battery of bio-assay testing, consider questions such as threshhold dose response, species sensitivity, comparative metabolism,

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I would appreciate you clarifying that at this point.

I also would appreciate you clarifying the statement made earlier, that this is simply a guideline. This is, in fact, a mechanism for massive regulation.

The Proposal is to adopt a number of generic standards, a number of class performance standards or source category standards, for very rapid regulation, which would be immediately proposed and immediately adopted upon listing of a compound with very little in the way of scientific assessment, with very little in the way of risk analysis.

So, we're disabused if indeed you are willing to accept a very broad range of scientific evidence, if your approach is far more cautioned than envisioned, I think it would be useful to elucidate on that.

DR. ANDERSON: I would like to point out that the sentence that you have read is taken, I think, somewhat out of context on page 58656, in that it's taken out of the middle of a paragraph where different kinds of evidence is set out in contrast -- that is, human epidemiology, and then it mentions the animal test and then surmises that short-term tests are not sufficiently developed to serve as a basis.

But it concludes by saying that EPA feels that, given the available scientific evidence, protection of

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public health requires the use of the criteria outlined in the interim guidelines.

And then if you go back to the beginning of the policy on page 58647, there is an excerpt from the interim guidelines, which says judgements about the weight of evidence involved, considerations of the quality and adequacy of the data and the kinds of responses induced by the suspect carcinogen, and then goes through all types of data that would be considered.

And I think, furthermore, the entire statement in the interim guidelines emphasizes the nature of the exercise, that is to consider all of the data in the aggregate.

MR. RONAN: Well, if this is so, this certainly is progress.

DR. ALBERT: But I think, nevertheless, it still does hold that the Agency has taken the position for essentially the last four years that a single response that is a response of a single species can form the basis of a judgement of substantial likelihood that an agent is a ----

MR. RONAN: (Interrupting.) That's what we're saying. That is exactly what we're concerned about ----

DR. ALBERT: (Interrupting.) This is something that we've been doing now for four years.

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MR. RONAN: ---- and we have called this into very serious question as to scientific probity.

DR. ALBERT: Well, we'd like to hear the evidence that it's a judgement that's a mistake. It doesn't do much good, I don't think, to simply say, that's not good enough, when we say it is good enough. What's the evidence that it's not good enough?

MR. RONAN: I would like to refer you to a very detailed AIHC Comments on this point. I think you would find it useful.

MR. JOSEPH: There does seem to be some misunderstanding, however, as to whether a particular piece of evidence is automatically, automatically means something. Any evidence and all evidence that we can find we want and we consider in every case.

We may conclude that in a particular instance with a particular chemical, the presence of one positive animal test, if it's appropriately conducted, does provide substantial evidence, enough evidence to consider it carcinogenic for Regulatory purposes.

On the other hand, we may not. We may consider that there is, that other of the evidence leads us to not make that kind of conclusion at that point.

What has to be understood is that it is not automatic in any way, that it's based on a weighing,

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in every case, of all the evidence we can get and, of course, it bears emphasizing that determinations made by EPA staff are reviewed by an independent Advisory Committee, the Science Advisory Board.

Of course, that is open to -- those are meetings open to the public, announced in the Federal Register, and with an opportunity for the public to submit comments in advance.

MR. RONAN: Well, of course, what we are seeking is a careful consideration of all relevant evidence and to the extent that the EPA is implementing that approach, of course we are gratified.

DR. ALBERT: Could you direct me to where in this Comment there is a discussion of the non-validity of facing a judgement of human carcinogenicity on a single species?

UNIDENTIFIED SPEAKER: It would be in the Section 1 on Procedures and Comments, not in Section 2, which is the Legal Comments, Dr. Albert. I can't cite you the exact page, but it is in there.

DR. ALBERT: Okay, thank you.

MR. RONAN: Thank you.

THE CHAIRMAN: Alonzo Plough?

Is Alonzo Plough in the audience?

(No response.)

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Sheldon Krimsky.

MR. KRIMSKY: Good afternoon, my name is Sheldon Krimsky and I am Assistant Professor in the Department of Urban and Environmental Policy at Tufts University. I'm particularly interested in Public Policy and Environmental Issues.

The Proposed Emission Standards are a small but important step in dealing with the larger issue of environmental carcinogenesis, and I'm not going to use my time to comment on the many positive features of the standards. Instead, I shall raise some questions where items are not sufficiently clear, or where I believe there are some deficiencies.

My first comment is on the question of the chemical by chemical approach to regulation. One of the major difficulties I find with the standards is that they would regulate on a chemical by chemical basis -- unless I am mistaken, and I would hope that the Panel would please clarify this -- we already have the experience of the failure of this approach through OSHA.

So, I wonder how EPA is going to make any progress is regulating the known chemical carcinogens released into the air, much less those pollutants which have not as yet been identified.

EPA has, it seems to me, a mandate to regulate

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the airborne carcinogens in a reasonable period of time. A goal of zero exposure should be sought for all such carcinogens, to be consistent with EPA's own position that carcinogens be considered, for Regulatory purposes, to pose some finite risk of cancer at any exposure level above zero.

It seems to me that one should choose a period of time in which to insure the regulation of carcinogens, and one reasonable period of time would be a decade. And it seems to me this implies two things.

First, a systematic carcinogen screening program for all pollutants should be instituted immediately.

And, second, a sufficient number of carcinogens should be regulated per year to exhaust the list by the end of the decade, otherwise, at least in terms of the public confidence, there is going to be a question of how long it will take before one gets through a formidable preliminary list at least.

Chemicals that their close family resemblances to known carcinogens should be presumed suspect until proven safe.

Chemicals that appear often in the same process stream can be considered as one entry in the Regulatory process, given that there are enough industrial processes

for which groups of chemicals are used in the same stream.

The second comment has to do with information sources and scientific expertise. As in many issues pertaining to environmental health, our knowledge of the role of airborne carcinogens, the role that they play in the onset of human cancer is still quite in its infancy.

But even so, my own feeling is the references cited in the Proposed Rules indicate that EPA has not taken sufficient advantage of the available expertise from the National Cancer Institute and the National Institute of Environmental Health Sciences.

Without demonstrable epidemiological evidence that the air pollution factor in carcinogenesis is negligible, the prudent course to take is zero exposure to carcinogens from air pollutants.

Again, and I'm sure you've heard this many times, but as somebody who is not representing a particular constituency, it seems -- and also as an individual who has a background, my doctorate is in philosophy and I deal with a lot of value issues and a lot of ethical issues -- it seems to me that the burden should be placed on the industrial sector to show that they cannot achieve zero emissions and that they

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are, in fact, operating with the best available technology.

In addition, on the question of the so-called BAT, EPA should not settle for the best technology presently on the market, or, in fact, in some operational mode, it should rather set the appropriate level of BAT at the state of the art, and maybe that's already assumed or indicated in some of your documents, but I didn't see it, and I hope it would be taken into consideration.

The third point, I'd like to say something about risk balancing. And this has become a question of considerable controversy and debate.

It seems to me important from an ethical and social welfare standpoint, that EPA use its finite resources to protect the quality of as many laws as possible.

This is a categorical imperative. It alone can justify quantitative risk assessment. It is morally indefensible, it seems to me, to trade off lives for jobs or lives for contributions to the GNP.

If anyone doubts the efficacy of this imperative, then I simply ask you to perform a simple thought experiment. Would you support a policy that raised economic output, or increased the number of

jobs, if the overall effect of that policy meant an increase in human mortality -- that is, sometime in the future.

If the answer is in the affirmative, then this nation should actively pursue policies that raise the average quality of life, while at the same time sacrificing the lives of small groups of people. If the answer is in the negative, then there is no more justification in supporting a status quo of human sacrifice. Jobs and economic goods are renewable and replaceable and human lives are not.

The last point I want to make has to do with new chemicals entering production. While the standards do not address new chemicals entering production process much more cautious standards must be used for potential carcinogens.

I assume TOSCA will handle this aspect of the problem. Every effort, it seems to me, must be made to ensure that carcinogens do not escape screening and assessment and therefore enter the production system. Any new substances even suspected as carcinogens should be severely restricted, far more restricted than the restrictions placed on the substances that are already in the sphere of economic activity, since, as is obvious to everybody, it is a lot easier to regulate

substances before the enter the economic sphere, than after they enter the economic sphere.

That is the completion of my comments.

THE CHAIRMAN: Thank you.

Are there questions?

(No response.)

Thank you.

Ken Nelson.

MR. NELSON: Panel members, ladies and gentlemen, I am Kenneth W. Nelson, Vice President for Environmental Affairs of ASARCO Incorporated.

My purpose in appearing here today is to emphasize certain concerns ASARCO has about the EPA's Proposed Policy for Regulating Airborne Carcinogens.

I want to add at this point, that I'm not going to read the statement which you have, nor any part of, or only small parts of the attached documents, but I hope you will take the time, and can take the time to read everything that I have passed out.

ASARCO operates a number of major nonferrous smelters in this country. Nonferrous ores of metals such as copper, lead and zinc, contain small amounts and traces of quite a large number of different elements, which in various chemical combinations become volatilized during the smelting process. One of these, arsenic,

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and indeed it is a volatile element, may be considered for listing under the proposed new carcinogen policy.

Now, the points in the next few paragraphs have been made by the speakers from Stauffer. I will skip over to near the bottom of page 2.

Now, arsenic, of course, is a natural substance. It occurs everywhere. We haven't analyzed any soil or any living thing without finding it. And Dr. Leonard Goldwater, who is a widely respected toxicologist and a Professor of Medicine at Duke University and the University of North Carolina, has reviewed the collective evidence about arsenic and given his opinion of its carcinogenic properties, and its threat in ambient air, in the statement which you have.

And I'll quote him to this effect: "The ubiquity of arsenic must be taken into account in any discussion of environmental control."

Because of this ubiquity, the human body apparently has adapted to arsenic over the eons, developing its "own mechanism for converting the arsenic it receives from nature into forms which it can use and which can be excreted if too much is taken in."

As a result, Dr. Goldwater says: "a threshold for arsenic that must be exceeded -- there is a threshold for arsenic that must be exceeded before the

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body's defenses are overwhelmed."

Now, indeed, we have to consider the possible essentially of arsenic. The traces of it may be necessary for life.

Three investigators in different part of the world have shown by their experiments that arsenic may be an essential element for rats, for chicks, and I believe it's for goats.

Drs. Schwartz, Nielson and Onkey are the three investigators.

EPA, in viewing animal experimentation with arsenic, would find that the attempts to produce cancer in animals with arsenic have not been notably successful. EPA, I think, should consider these findings of the three investigators that I mentioned, that arsenic may indeed be essential for human life.

Dr. Goldwater has concluded that the most probably explanation of all the available evidence is that there is a safe threshold for exposure to arsenic not only in our food and drink, but also in the air we breathe, and that arsenic at levels found in the ambient air does not represent a danger to the public health.

New evidence is being developed almost daily about arsenic. Dr. Enterline's current work on the mortality of Tacoma smelter employees--our smelter, by

the way -- promises to produce significant new information. Indeed, it already has. In your packet is a preliminary report by Dr. Enterline on his latest study.

And if you will turn to the last page of that preliminary report, you will see in Table 4, standardized mortality rates among workmen, retired workmen, from the Tacoma smelter, derived from an old study in which 527 people were involved, and the standardized mortality rates from a new study in which there were 597.

Now, the two studies were very similar, except that more people were found in the new study, people that had escaped notice in the first study.

Also, in the old study, exposures were estimated on the basis of 1973 measurements of arsenic in urine. The new study uses measurements and extrapolations of measurements of urine arsenic made between 1948 and 1952.

You will note that in the first three exposure groups of the new study, there is shown no statistically significant excess mortality rate, due to lung cancer.

This, to me, and I think to almost anyone, suggsts a threshold, that there is indeed a threshold for inhaled arsenic, as well as that ingested.

In addition, Dr. Enterline and Dr. Milham of the State of Washington, are studying persons who attended the school adjacent to the Tacoma smelter, to

determine if the higher levels of ambient arsenic prevailing in the past have effected those people. To date, the findings have been negative, but the study is still continuing.

The smelter Environmental Research Association has funded an independent study of mortality in smelter counties, the results of which are scheduled to be announced this month. And just yesterday, I received from Dr. Rohm (phonetic), at the University of Utah, a copy of the paper which he proposes to give near the end of this month at a conference in Utah, and let me quote the last sentence of this report:

"In summary, the data evaluated did not establish an association between community air pollution due to smelter effluence and the incidents of lung cancer in communities surrounding nonferrous smelters."

You don't have this study. I'm sorry, there wasn't time to make copies of it, but I can get them to you if you wish.

There is a study going on in Fallor, Nevada, by Dr. Vig. He is looking at the population there, which has been exposed to a high concentration of arsenic in its drinking water for, I believe, several generations.

We will try to keep EPA informed of all of

the studies as they are completed. And you may have other sources which we don't know about. I hope you will consider all the evidence.

But so far as we can determine at this point, trace amounts of arsenic in the ambient air do not endanger the public health. A policy that would foreclose EPA from considering such evidence, or any relevant evidence, with respect to any substance that might become a candidate for listing and regulation is indefensible, legally, scientifically, and as a matter of prudent public health policy.

I'm going to skip over, in my statement, now, to page 6, at the bottom. Putting aside the specifics of various studies, we believe EPA should be free to make a reasoned judgment, on the basis of all the available evidence, about the health effects of smelter arsenic emission at the time it makes a listing decision or any decisions as to appropriate emission standards.

Rules which restrict EPA's ability to make such a reasoned judgment may make EPA's job easier, but they do not serve the public interest and are not what the Congress intended.

EPA must act in the real world. It is a world in which resources are scarce. EPA's proposed rule would increase inflation and reduce productivity. It

certainly should not be adopted unless it can be demonstrated that it addresses a real public need, that is that air pollution contributes measurably to cancer rates in this country.

EPA, we believe, should withdraw the Proposal or at least substantially revise it, in accordance with AIHC suggestions. Quantitative risk assessments derived from all the available evidence, including of thresholds and best scientific judgment, should be relied upon at all stages of decision-making.

That's all I have.

THE CHAIRMAN: Thank you, Ken.

MR. JOSEPH: I have one question, if I may.

Mr. Nelson, do you think that it's likely that assuming the existence of a threshold for carcinogenesis of arsenic in any given individual, do you think it's likely that the level of these thresholds may vary by some fair amount, from person to person?

MR. NELSON: Yes, I think that's evidence from the standardized mortality rates we had from the various levels of exposure.

THE CHAIRMAN: I wanted to ask what rules you are referring to that restrict EPA's ability to make judgments?

MR. NELSON: I'm not an attorney, as you well

know. But I recall one statement that bothered me very much and that was that negative epidemiological studies should not be given much credence or no credence at all.

I can't quite understand that, that foreclosure which it seems to be.

DR. ANDERSON: Just to correct, I don't think that's -- if it came across that way, it's not what's intended because I think the statement in here is that EPA feels that while negative epidemiologic evidence can sometimes provide upper bounds on possible risk, that it's normally not sensitive enough to provide the sole justification for ignoring other types of responses.

But I think it's important to point out that the negative epidemiology evidence has been used by the Carcinogen Assessment Group to set upper bounds. So, it certainly is not ignored.

MR. NELSON: I'm glad to hear that.

THE CHAIRMAN: Anything else?

MR. NELSON: Not really, except my concern is that because of certain set procedures and policies, a number will emerge with which we cannot comply, and that means shutdown to an enterprise and losses of jobs and so on.

DR. ALBERT: I'm not sure of the logic of

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what you said about the existence of a threshold in arsenic on Table 4, the new study. Although the three lower doses do show elevated standard mortality ratios, albeit they are not statistically significant.

That data is not evidence of a threshold, and Enterline didn't say anything about that either, and I think you're reading too much into that data.

MR. NELSON: He didn't say anything in it -- Well, you can interpret it your way and I'll interpret it my way.

To me, this suggests a threshold, strongly suggests it, and Dr. Enterline made a similar statement in his appearance before OSHA, when the matter of arsenic was considered.

DR. ALBERT: But the SMR's are elevated at all theree of the lower doses.

MR. NELSON: How can you get any -- What can you do with one? I mean, it depends on the number of people you have. You observe one lung cancer case. The SMR might be 142 or it might be 42, it depends on the number of people.

DR. ALBERT: Well, put all three lower doses together.

MR. NELSON: I am.

DR. ANDERSON: Well, I've wondered about the

same thing, and I was trying to recall some of the exposure levels, but when you have these numbers of people, you could have a reasonably high exposure level, say an increased risk of 10^{-2} or something, and really not be able to pick it up.

In other words, the sensitivity down there wouldn't show this kind of increase.

MR. NELSON: That's a possibility, but I believe we have to operate on the basis of evidence we have not speculation, not maybe, might, perhaps.

DR. ANDERSON: But I'm saying, you really wouldn't expect to see it if your dose response holds at all, I don't believe, but I can't remember the exposure levels.

MR. NELSON: But if there is a threshold, if, as I said, arsenic is a natural substance, it's been around for eons, we all have it, isn't that also evidence of a threshold, and isn't that some comfort -- and I would apply the same reasoning to any naturally occurring substance, selenium, tolurium, cobalt, whatever.

THE CHAIRMAN: Ken, another question. You make a statement that the case is not proved that air pollution contributes measurably to cancer rates in this country, so I take it that you don't lend credence to some of the studies of specific chemicals or specific emissions

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such as coke oven emissions or pollutants such as that which ----

MR. NELSON: Were there neighborhood elevations and lung cancer from coke oven emissions, to your knowledge? I'm not aware of any study that showed that.

The Asbestos Study, by Selikoff and, I think, Hammond, the neighborhood study of a plant in New Jersey, showed no elevation of lung cancer rates. And one would expect it, possibly, from asbestos.

THE CHAIRMAN: Roy, you had a question?

DR. ALBERT: Well, I think you've given the answer to my question, and that is that if you take Dr. Goldwater's position literally, it means that any natural carcinogen automatically has a threshold, so that if we assumed it to be the case for arsenic, then we would have to assume that it's the case for ionizing radiation ----

MR. NELSON: (Interrupting.) Perhaps so.

DR. ALBERT: Paraphlatoxin, and polycyclic-aromatic hydrocarbons?

MR. NELSON: Perhaps so, indeed.

DR. ALBERT: You don't grant that one could simply develop a fairly resistant strain, namely humans to these things, so that the time required to develop cancer is so long that it doesn't affect the reproductive

period, so in effect it becomes inocuous from an evolutionary standpoint. Is that not possible?

MR. NELSON: Almost anything is possible, Dr. Albert. I can't fault that statement.

But I'm saying when it comes to regulating, when it comes to making the decisions which affect the lives of people at work, in an enterprise, if a rule based on speculation and not solid evidence is proposed and adopted, it puts that enterprise out of business, I think that's wrong.

THE CHAIRMAN: Any other questions.

(No response.)

Thank you, Ken.

John Barr.

MR. BARR: Mr. Chairman, ladies and gentlemen of the Panel, my name is John T. Barr, I'm employed by Air Products and Chemicals, whom I represent here today.

You should have in front of you a copy which contains most of what I'm going to say. I will see that you get a conformed copy of the complete presentation within a few days.

Air Products and Chemicas has submitted detailed written comments on the Proposed Airborne Carcinogen Policy. The purpose of this statement is to summarize our written comments in the perspective

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of the comments of others on this proposal, and to reply to some of the statements made at the hearing held in Washington earlier this week. We urge that you conisder both of these statements in connection with your review of this proposal.

The heart of the Agency policy is given in the proposed principle that the presence of airborne carcinogens in relatively low ambient concentrations warrants regulatory action.

As is the case for so many other critical terms in this proposal, no definition is provided for the meanin of "relatively low".

However, from the recent Agency action in the case of the trihalomethanes in drinking water, and the listing of radiation as a hazardous substance under Section 112 of the Clean Air Act, we can deduce that this is meant to include substantially any measurable concentration.

Thuse, the Agency appears to be taking the position that the mere presence of measurable amounts of suspect animal carcinogens requires listing under Stection 112 and regulation to at least Best Available Technology.

This position is unsupportable on at least three counts:

First, there has been no showing that the presence of industrially-related suspect or proven carcinogens at any concentration has caused or contributed to death or illness in the general population, despite many serious attempts to demonstrate such a relationship.

Every effort to measure the effects of airborne carcinogens in the ambient air has yielded negative results. An early major study was may by this Agency for vinyl chloride, and the Agency has stated that it "produced no evidence that living around the vinyl chloride-handling plants is a risk factor."

A later study of all the recorded national cases of angiosarcoma for a ten-year peirod confirmed these findings.

There was discussion at Washington on Tuesday, of a report by Brady and coworkers on angiosarcoma cases in New York. This study found that five of nineteen non-occupational, or non-medical cases lived closer to PVC operations than did their controls.

This speaker did not mention that four of these five plants were PVC fabrication plants and not production units. This Agency has investigated the emissions from this class of operations and found them not to be significant, and these operations were not regulated under the vinyl chloride standard.

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Considering the many small fabricating plants in this state, it appears to be only coincidental that these relationships appeared and the author has concluded after a discussion of the shortcomings of their study, only that this study lends some indirect support to the supposition that there could be an association between place of residence and that disease.

Hammond, Selikoff and Nicholson examined long-term residents of a town with a large asbestos-producing plant, and reported no significant difference in the mortality rates from cancer, between this town and another similar town used as the control.

Pike and coworkers performed a case-control study of south central Los Angeles County to determine if long-term residence in this area of high air pollution was associated with the excess of male lung cancer found there.

They had found earlier that there was no correlation between residence and female lung cancer.

Their conclusion was that the evidence from this study does not support the hypothesis that air pollution is the explanation for the regional excess of lung cancer.

A study was performed by this Agency, in which the trends and the type and number of cancer deaths were

examined, in which the trends and the type and number of cancer deaths were examined, and eight of the fifteen towns in this country containing copper smelters, and which therefore are suspected of having higher arsenic emissions.

It also looked at comparable cities with steel and coal mining activities. The conclusions of the authors were that abusive alcohol is a probably cause of excessive digestive diseases, including cancer in copper smelting communities, and that further study is required to provide conclusive evidence of the industry-disease relationship for the steel and coal-mining industries.

Lung cancer, which is usually assumed to be the mark of disease for arsenic exposure, was not elevated in these eight towns.

Our written comments contain many other references to more generalized attempts to associate ambient pollution with cancer death. All were negative.

A recent conference on air pollution and cancer, which was sponsored by the American Health Foundation was summarized by Hammond and Garfinkle, who wrote: "We conclude the general air pollution at present has very little effect, if any, on the lung cancer rate."

The references cited by the Agency in the

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preamble to its proposal policy provide no support for the adoption of the so-called principle that any concentration warrants regulation, other than to reiterate the presumption that there is no absolutely safe exposure. Even the proponents of this assumption present no supporting data, but offer it as an article of faith.

These hearings, I've received comments from several scientist who do not believe that this presumption is correct.

We have reviewed all of the public comments which were available in the docket, two weeks after closing of the comment period, and of the dozen or so which were supportive to any degree of this proposal, only one, that of the EDF/NRDC, purported to provide any factual data.

None of the references cited there contained any acceptable scientific evidence that industrially related air pollution can be related to cancer in a genera population, and all such studies have been refuted by more recent studies.

We did not hear any new evidence at the Washington hearing, nor have we heard any factual data today, which support the connection between industrial air pollution and cancer.

Therefore, neither the Agency, nor the

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proponents of this proposal, have made a reasonable case for the need for the Agency of any authority beyond that which it now has.

The second reason that the position taken by the Agency is unsupportable is that its quantitative features are based on inappropriate data. The Agency has relied on Type I risk assessments by the Carcinogen Assessment Group to arrive at quantitative estimates of the effect on the human population from animal test results.

These Type I preliminary tests were never intended for this purpose, and the Agency has recognized this in the past. The purpose of Type I estimates has been stated by the Agency as follows:

"The Type I study is one whereby we would ask CAG for a preliminary assessment based perhaps on only one health study (such as an NCI study). We would ask CAG to make an estimate as to whether the compound is a carcinogen, based on this study. Following this, we would ask CAG to develop a preliminary unit risk value for a 70-year exposure at 1 ug/m3. We would use this risk value with our exposure data to develop a preliminary risk assessment to aid us in determining whether to proceed to a Type II study."

Notwithstanding this intention for a Type I

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study to be no more than a screening test to examine the need for a more definitive study, the Agency has used these results to support a claim of significant risk to the general public.

The National Academy of Scient recently recommended that the Agency stop all preparation of these estimates because of their misuse by the Agency, and the EDF has demanded that the Agency not use risk assesments in the implementation of its policies.

We believe that this would be a serious mistake, for there is a place for such preliminary studies, such as in determining priorities, and because we very badly need to develop our presently incomplete knowledge of extrapolation methods, which can only be done by use.

We do not agree with the use of only the simplistic linear extrapolation method, nor the uncritical acceptance of animal data of unknown quality, nor the choice of the highest response point from the most sensitive species, and we certainly do not agree with the use of these preliminary studies as substantiation of the need for regulatory action, but properly developed quantitative risk assessment should be an important part of the regulatory process.

Apparently there are those in the Agency who agree with this, for we have been told by official in

CAG that the Type I estimate is to be upgraded to make it suitable for listing decisions under Section 112 of the Clean Air Act.

The preamble to the proposed policy spoke of some forty substances on the Agency priority list which were to have been screened by the preparation of Type I estimates by last December. This task has not been completed, but we have been able to obtain a few of these documents.

In our written comments we show that this method, that is the linear method, overestimates the risk by about a factor of three orders of magnitude, wherever a comparison can be made with actual human experience.

Nevertheless, and despite a total lack of demonstration of credibility of this procedure, the Agency has relied on these preliminary estimates for regulatory decision-making in the air, water, and pesticide programs.

The Agency can provide no basis for reliance on these estimates as support for the need of regulating pollution, which may be present in trace quantities in the environment, and should not attempt to do so.

A third reason for the inability of the Agency to rely on a presumption of need for regulation of these

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compounds is that it is contrary to law and to its own administrative policy. The recent court decisions of Bean versus CPSC and Monsanto versus Kennedy have in both cases held that a regulation may not depend on an assumption that a need may exist, but must demonstrate that a risk is present, and that the proposed action will reduce that risk.

Neither of those conditions is met by this proposal.

Executive Order 12044 states, "after it has been determined that a chemical substance is likely to be a carcinogen, the next step in regulatory decision-making is to assess the risk that people face..."

This Agency has prepared a program for compliance with this order, but it has failed in several instances to comply with its own rules and in the proposal of this policy. With one notable exception, it has prevented public participation in the development of this proposal, rather than encourage full public debate on the need for or the wisdom of its actions, and it gave no public notice of the forthcoming proposal until after it had been published.

It has failed to prepare either the Notification Form, a development plan, or a decision package, all of which are required by its own rules, and it has

has refused to prepare a regulatory analysis.

Thus, the present proposal is in conflict with established legal and policy principles in both its basic assumptions and in the formulation of the proposal, and the Agency must not proceed until these conflicts have been resolved.

The one exception to the Agency's closed door policy was the Environmental Defense Fund, which initiated the movement to develop this policy, and which has had considerable influence and the final form of the proposal.

That group has now announced that it has a list of several hundred substances from which the Agency must regulate at least twenty per year, to attone for its past deficiencies.

This action underscores the point which we made in our written comments that the Agency will lose control of its own future if it persists in promulgating these rigid and unscientific rules.

We believe that these defects could best be repaired if the Agency were to deem this proposal an Advanced Notice of Proposed Regulations and to repropose it only after careful consideration of the public comments which it will receive.

This reproposal should contain three

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major factors:

The first, a procedural rule for internal Agency guidance in the steps leading up to the decision for lifting. This would include the screening and evaluation stages, the establishment of priorities among the candidate substances, a detailed quantitative risk assessment for determining the extend of regulation necessary and the consideration of alternative control strategies.

The Agency has said in the preamble that a major reason for this proposal is for administrative convenience, and it is appropriate for the Agency to formalize the procedural process. This is the only rule that should be promulgated now.

Second, a revised critera for risk assessment should be presented for publi comment, as the second point. The Agency recognized the preliminary nature of the Interim Guidelines when they were published in 1976, but it has taken no action in this proposal to revise this document, in the light of current science, nor has there ever been an opportunity for full public comment.

Both the Interim Guidelines and the risk assessment methodology used by the Carcinogen Assessment Group should be opened for public comment and possible

revision.

And we would add, here, that the Carcinogen Assessment Group ought to made a formal part of the Agency, in some way, rather than being the informal organization that it is now.

And third, it is important that the Agency assure that a true weight-of-the-evidence evaluation be applied to all scientific considerations, and that the Agency not impose artificial limitations on the examination of this evidence, nor should it intermingle these considerations with socioeconomic decisions in the overall regulatory process.

It is not at all clear why, if the Agency merely intends to continue its present policy, it did not simply say so, rather than present the lengthy list of limitations on the evidence which would be acceptable.

To assume this, we urge the adoption of the Alternative Proposal made by the American Industrial Health Council, which calls for establishment of an Independent Scientific Panel to work closely with the Agency during the development of regulations to provide the best available scientific basis for its actions. This action will assist the Agency in rapid and responsible response to any potential hazard.

We need very badly the "balanced approach to

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to the questions of protecting the environment within a regulatory framework" of which the Administrator spoke recents, and we believe that the steps recommended above will be of major assistance in that direction.

In addition, the Agency must place the various areas of its responsibility in proper perspective, both as seen within the Agency, and on a national basis.

Potential problems should be allocated resources on the basis of their relative seriousness on a national scale. Despite the preliminary efforts of the Regulatory Council and the National Toxicology Program to take a broader view of our nation's needs in the health area, individual agencies are still concentrating on extremely narrow segments of the overall picture.

We urge that the federal agencies adopt a rational and coherent approach to the control of airborne health hazards that will provide proper emphasis on the more significant problems.

We do not believe that the evidence supports a presumption that cancer due to industrial pollutants is a significant problem, nor that the present proposal will produce any significant benefit to the public health.

We believe that the steps which we have recommended will enable the Agency to attack those problems which may exist in this segment of its

responsibilities in an efficient and orderly manner, utilizing its existing authority.

We urge the adoption of our recommendations and offer our assistance in developing the details of such an action.

Thank you for your attention. I'll be glad to try to answer any questions.

DR. ALBERT: You mentioned that on a couple of the evaluations that the CAG has done, you have tested them against epidemiologic data and found that they are off by three orders of magnitude.

I would like to point out that it's been our policy in the CAG, where we do risk assessments based on animal data to look around to see if we can qualify these assessments based on data available from human populations that have been exposed; even if the results are negative, these type of data serves a very useful function of qualifying the assessments based on animal data alone.

So that if you have found that by testing assessments based on animal data against epidemilogic data, that we have been off by several orders of magnitude. You have done something which we should have done, and apparently didn't do.

Could you identify which agents you found this

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to be the case?

MR. BARR: I'd be happy to.

It's all spelled out clearly in my written comments, which has been in now for about a month and a half, but I'll go through it again.

It's an even simpler test than epidemiology. It's something that any schoolboy could have done. In three water cases, I took the risk which CAG developed. I multiplied it by the figure in the Water-Quality Criteria document, for the average concentration in this country, to get an incidence.

In the case of arsenic, the answer came out to be something between 18 and 64 million cases of skin cancer a year.

Now, you don't need epidemiology to tell you whether or not you have 64 million cases of skin cancer a year in this country.

In the second case, for the PAH's, the answer came out to be 2 million cases of cancer a year. Again, you don't need epidemiology to tell you where two million people are dying a year of cancer.

For asbestos, the answer came out to be 2,000 cases of mesiothelioma. This would be non-occupational, naturally, from drinking water, and so would occur in areas where the mesiothelioma, which we see does not

occur. Selikoff says he sees a handful of cases a year.

Those are three examples.

DR. ALBERT: Well, somebody's arithmetic is wrong because we've done the same thing. We'll have to look into it.

MR. BARR: Well, I'm glad you looked at my written comments.

MR. KELLAM: Just one question, Mr. Barr, you mentioned that with one notable exception, there essentially was no public participation in the development of this policy. could you clarify that exception?

MR. BARR: Once again, let me refer you to my written comments, which have been in for a month and a half.

There is a chronology given, which spells out in great detail, the number of attempts which industry, individuals and trade association made to participate.

If you want to take the time to go through it, when we found out in October of 1978, that you were working on this, we visited you, Mr. Padgett, Mr. Patrick, and others, and Robert Durham, and asked you for a copy of the draft, and we were refused.

We visited later on, we asked again. We were

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refused.

A copy of a draft dated December 8, was given to the Environmental Defense Fund and they wrote a letter to you dated February 22, which was about 20 pages long, which contained a number of demands.

They had then met with you and discussed that memorandum. After that, you changed from a Proposed Policy to a Rule.

MR. KELLAM: Excuse me, my question was, though, you mentioned there was a notable exception ----

MR. BARR: I told you about that in the next paragraph. The notable exception was the Environmental Defense Fund. Those were the ones who were permitted to participate in this.

MR. KELLAM: And the first time that you learned of the development of the policy was in October of 1978?

MR. BARR: That's correct.

MR. KELLAM: In spite of the fact that in March of that year, we held a public meeting, which specific purpose was to solicit comments on the development of an Airborne Carcinogen Policy and to solicit comments on the petition by the Environmental Defense Fund.

MR. BARR: The record shows that we participated at a March 23, 1978, meeting. What we learned about was that you were then actually working on it and that

you actually had a policy being developed and we, as I told you, asked on several occasions to obtain a draft of that policy, to discuss the contents with you, to have it explained to us. It was refused to us on every occasion, and this full chronology is in our written comments.

THE CHAIRMAN: Betty, you had a comment?

DR. ANDERSON: Yes, some of this is a matter of clarification.

In your statement, the first thing, you say that in the policy there is the adoption of a principal that any concentration warrants regulation. I wasn't aware that that was in the policy, that any concentration -- perhaps later on, you could submit for the record, if you cited, I'm not sure we need to take the time right now, but I didn't think that was the thrust of the policy.

MR. BARR: I have a quotation of page one of my comments, in which the reference is cited.

DR. ANDERSON: Okay, we'll go back to that.

The second thing, you said that in reviewing all the public comments you had found no acceptable scientific evidence that industrially related air pollution can be related to cancer in the general population.

This morning, Dr. Wilson presented some numbers

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and he says he will give us the benefit of his calculations later. I wonder if you had seen his calculations since he said that for the chemical industry alone, he thinks that about at least ten cases per year can be attributed to air pollution.

MR. BARR: I'm afraid there has been a communication problem here. Perhaps Dr. Wilson's accent made it difficult for you to understand him. I think if you will examine his written comments, he didn't say that he thought the chemical industry caused ten cases a year.

What he said was that by calculation using your methods, it could possibly be extrapolated to that figure. But he also very carefully said that he had no absolute data at all indicating that these cases had occurred. This was merely a postulate, a speculation that these cases could occur, based on your extrapolation methods.

DR. ANDERSON: Well, to take it one step further I think, again, one thing that has been solicited in these hearings is opinions about the nature of the airborne cancer problem.

MR. BARR: Yes, ma'am.

DR. ANDERSON: Are you then saying that you think there is no problem at all?

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MR. BARR: Ma'am, what I said, in my written comments, and my spoken comments today is that I have examined the 31 references which EPA put into the document, and I was appalled by the poor quality of the research going on there, but they show no connection whatsoever.

I have examined the 161 written comments in the docket which were available to us. Only one of those purported even to cite a reference, and that was EDF and EDF cited six or seven references in the front part of that which was written by Joe Wagner, and we have reviewed those references, one of which was the Brady paper that I discussed now. And there are a few others.

And I will submit a written discussion of those in our rebuttal comments. But none of those, and none of the authors of those claim to have shown a firm relationship, contrary to how they are quoted in the EDF document. But if you will read what the authors say -----

DR. ANDERSON: (Interrupting.) So, in your opinion, then ----

MR. BARR: (Interrupting.) In my opinion, there are no scientifically acceptable data which demonstrates a connection between industrially-related air pollution and cancer death in the general population.

DR. ANDERSON: I thought that was what you were saying, but I was not entirely sure.

The next thing, you mentioned the Type I, EPA Report. You were quite correct that they were commenced with one purpose in mind, they will be reissued.

Just a brief comment. I think you will see that the basis, at least on the evaluation of the carcinogenesis data will include a document that's submitted for public review, it will be reviewed by the Science Advisory Board, which will include a complete discussion of metabolic pathways, mutagenesis data, the toxicity data, epidemiology, both positive and negative where it's available, animal bio-assay data, both positive and negative where it's available, and also some indication of potency.

So, I thought, just for the record, that you and other witnesses who have commented on this should know that there will be this type of backup documentation.

MR. BARR: We are very happy to hear that you are going to start doing that soon. I'm sure that it will have a very beneficial effect on the value of those documents.

DR. ANDERSON: Well, it's really something we have been doing.

MR. BARR: I have no seen any of those yet.

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I have them -- on record, it hasn't asked for every one you prepared, and I would be glad to have one if I could.

DR. ANDERSON: One other important point, I think you indicated that the existence of the Agency's Carcinogen Assessment Group was an informal organization, not a part of the Agency.

MR. BARR: No, I didn't say that. Not a part of this Proposal.

DR. ANDERSON: The Carcinogen Assessment Group is a formal part of the Agency, and I thought it was certainly a formal part of this Proposal.

MR. BARR: This is one of our many problems that we have with this. We have a very verbose preamble which says all sorts of things various ways, but if you read the Proposed Regulation, itself, it says, "We currently will evaluate these by our 1976 Interim Policy."

That implies a temporary status, that Interim Policy. It does not mention CAG, it does not say who will do the evaluation or how it will be done. It is totally omitted from the Proposed Regulation itself.

DR. ANDERSON: Well, the CAG is mentioned, certainly, in the Regulations and in the ----

MR. BARR: (Interrupting.) In the preamble, it is, but not in the Regulations.

DR. ANDERSON: Well, I thought I heard you

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say that it was time for the CAG to become a part of the Agency, and I wondered about that.

MR. BARR: Well, that too, perhaps, but for the conversation here, today, it is time for it to become a part of the Proposal.

We are very much in favor of risk assessment, and one of the things we are concerned about here is that risk assessment is not properly formalized in the Proposal, that way it's put out.

And, therefore -- You see, CAG has never been established by any sort of a formal rule that binds the Agency to maintain CAG. The Administrator could abolish CAG tomorrow if he cared to.

We would like to see CAG and the Policies and Rules and Procedures formalized in such a way that they are subject to public comment, that they are subject to peer view, and that they cannot be wiped out by someone's whim.

DR. ANDERSON: Well, for that matter, I believe the Administrator could wipe out any part of the organization if he wanted to. I don't think ----

MR. BARR: (Interrupting.) Not if it's a Formal Rule, he can't. It would have to at least have a rulemaking procedure.

DR. ANDERSON: But I don't think that -- In

short, I think that the CAG certainly isn't the Agency. It's a part of the Agency and ----

MR. BARR: (Interrupting.) That, we understand.

DR. ANDERSON: Okay. And then the other thing was, you seemed to think that you had not had adequate opportunity to comment on the Interim Guidelines, and I just wanted to say that they have been published, they were published for public comment. One reason they were not revised was because the comment was largely favorable.

The AIHC has submitted comment. We certainly invite your comment. It's not too late to comment. So, I just didn't want you to feel that you could not comment on the Agency's policy here.

MR. BARR: Well, I wouldn't want you to feel you are left out either, so why don't you take our comments to IRLG and the Regulatory Council, and on this proposal, all these parts are comments on the Interim Procedure because they all deal with the same.

The reason that the Interim Guideline did not get much attention in 1976 is that they were published under FIFRA.

DR. ANDERSON: No, they weren't.

MR. BARR: Pardon?

DR. ANDERSON: They certainly were not.

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MR. BARR: If you will look at it, it says: "We will use these for doing the Proposal for FIFRA," and then down at the footnote it says, "and other things too."

DR. ANDERSON: That's absolutely wrong. I helped write them, and there is a whole procedure in the very front part of the guildelines that, certainly at the time, the Pesticide Act was a key act under which the guidelines were needed, but other acts are mentioned as well.

MR. BARR: I understand, but as I say, at the time, it attracted attention of the FIFRA people, and not unfortunately, of the general industry people, which it should have.

I agree with you, we have been derelict in not commenting, but I think we have given you some comments in the last few weeks.

THE CHAIRMAN: I think we had best go on.

Do you have anything else?

(No response.)

Okay, thank you very much.

MR. BARR: Thank you.

THE CHAIRMAN: Bill Cavellini.

I'm sorry for the misprint on the organization, that's the Cambridge Port Alliance. I'm sorry that we

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got that wrong.

MR. CAVELLINI: My comments will be very brief.

I'm here today with two other residents of the Cambridge Port Community from Cambridge, Mass., and we were, in 1977, beset with a problem of airborne styrene pollution from the Advent Corporation's manufacture of widescreen televisions.

The main point I want to make today is that if styrene had been recognized as a carcinogen in 1976, there should have been a way that the EPA could have acted to help us, instead of us, the people of Cambridge Port having to rely solely on the State and our own devices.

Styrene is a toxic substance that up until last year was suspected to being a carcinogen. Styrene is highly irritating to the skin, eyes, nose, throat and respiratory tract. The fumes can cause headache, nausea and dizziness.

In high concentrations, styrene can damage the liver and cause blood disorders and eventually effect the central nervous system.

Workers at Advent used to get so much styrene fumes that they had to wear masks and workers were often seen being carried out on stretchers and taken to the hospital.

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To correct this, a year after their operation opened on Emily Street in Cambridge, they vented the fumes outside. Immediately, residents began to complain of the odor, of dizziness, of nausea, and skin irritations.

But it was to take almost three years because residents could breathe the air without inhaling styrene fumes.

First, in 1977, the residents went to the City Council. The Council directed them to go to the State Air Quality Control Division of the Department of Environmental Quality Engineering.

First, DEQE suggested that Advent cover the odor, cover the odor with a banana scented masking agent. And they did that.

Well, they did that, and the community continued to complain. Air Quality officials began negotiating with the company to install a carbon filter. These negotiations lasted nine months. And amidst claims that the filter had actually been installed, the fumes continued to pour out of the plant.

Calls to EPA by our group got the same answer, twice -- go to the State. Well, we were already there, and they weren't doing such a good job. They didn't even have the equipment to test for airborne styrene.

Finally, after over a year of public protest, on August 11, 1978, the Attorney General of Massachusetts filed a Civil Complaint charging Advent with violation of the State Air Pollution Control Regulations.

Before resolution of this court case, the Advent Corporation announced abruptly that it was leaving Cambridge, leaving Massachusetts, for the State of New Hampshire.

This did solve our air pollution problem. But it also took 600 jobs.

There was some talk about th leaving having something to do with our fight to clean up the air pollution. This view was spread primarily by officials of the company, and it didn't stop until newspapers revealed that the company had been looking for sites outside Massachusetts for a year prior to the time when we started the fight against the pollution.

Why didn't Advent want to leave Cambridge, it was running away from an organizing work force. It was seeking lower taxes in New Hampshire. But it was not trying to get away from installing a $15,000 filter in a company that grossed $200 million a year.

We have some suggestions, as people who were and still are affected by airborne pollutions, suggestions for these rules. They, perhaps, are not as sophisticated

encouched in scientific language as some of the previous speakers, but we are the people that are affected by the companies that are adjacent to where we live.

We ask you that when you consider the benefits and costs of controlling airborne pollutants, that you take into account the long-term affects of low level concentrations of the pollutant on the human body.

When we were informing ourselves about the affects of styrene, we found that a lot of the literature and much of the research, I might say, was done in Japan and Russia, and very little here.

We found that it was the long-term affects of low-level concentrations that could be almost as frightful in their effects as high concentrations that workers would be exposed to.

And second, we ask you to consider the psychological effects on people who know that they are being exposed to a suspected carcinogen, and what that does to the way they approach their lives and their daily tasks.

And third, we ask you to consider, in your Cost Benefit Analysis, the disruption of community and neighborhood that results from the panic that sets in, such as the panic that set in in Rutherford, New Jersey, and here in Cambridge Port, when we saw this article

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on the first page of the Boston Globe: "Outbreak of Cancer Scares Town." And the two substances that were cited were benzene and styrene.

We ask you to take into consideration that disruption that a town like Rutherford, New Jersey, faces and what it does when families move out, when friendships are severed, when children are pulled out of schools, when workers leave jobs, when they must go on unemployment because they can't find another job in the new community they move to.

And this disruption happens when people are worried about an environment that is unhealthy and unclean.

We ask that the potential for polluting should be measured before a company moves into an area, that levels of pollution should be monitored during its first year of operation, particularly with a substance that is suspected ot being a carcinogen.

So, generally, we ask that you value human life and health as much, if not more, than the almighty dollar, that you ask residents and workers in the effected area what they want. Let them make the choice, if there is one to be made, between health and potential economic hardship.

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participation through hearings, where expert testimony and the opinions of all affected parties can be hears.

Thank you.

THE CHAIRMAN: Thank you.

Are there questions?

(No response.)

Thank you very much.

Is Gregor McGregor here or not?

(No response.)

The next speaker after Gregor McGregor is someone from Friends of the Earth? I don't have a name. Is someone here from Friends of the Earth?

(No response.)

Richard Thompson?

MR. THOMPSON: The Sierra Club welcomes and appreciates the opportunity to speak before the EPA on its Proposed Air Carcinogen Policy.

My name is Richard Thompson. I have a Bachelor' Degree in the Natural Resources Program at the University of Massachusetts in Amherst, and I have been an active member and volunteer in the Sierra Club for the past two months.

The Sierra Club has been involved in the cancer problem for a number of years. It was through our organization that Samuel Epstein, author of the well-know

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book, "Politics of Cancer", was able to publish his work.

We have expressed our concern avoer the use of a number of known or suspected carcinogens. Most recently, we have sent in written testimony in support of the Cancer Registry in the State of Massachusetts.

As a non-profit, environmental advocacy organization, we are concerned with carcinogens at the human level as well as the role carcinogens play in natural ecosystems and in the food chain. We have consistently maintained that reduction of carcinogens in the ambient air, the water, the workplace, and food, and in the general environment is of vital importance.

This is a wholistic approach that takes into account the synergistic qualities that carcinogens often have. We strongly believe that Federal legislation and efforts should be coordinated and spearheaded in this direction.

We have been led to this general concern about cancer and specifically here to the hearings, for two reasons. The first is that 60 per cent to 90 per cent of human cancers can be traced to environmental causes. Of these causes, viruses evidently play an insignificant role. This leaves us with radiation, industrial chemicals and chemical agents as causal examples.

John Cairns, a researcher at the Mill Hill

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Laboratories of the Imperial Cancer Research Fund in London, states in a Scientific American article, and I quote:

"...most of the common kinds of cancer seem to be caused in large part by environmental factors; because we can alter the environment, those cancers are potentially avoidable."

Coupled with this is the almost epidemic proportions that cancer has grown to in the United States. Cancer is the second leading cause of death, here in Massachusetts, as well as in the nation as a whole. Over 1,000 people die every day from this disease, as I am sure you well know. It is expected that one out of four people will contract some form of the disease, while one out of five people will die from it in our lifetime.

The Sierrra Club feels that the bulk of the environmentally produced cancers are avoidable. For many years, our country has energetically poured millions of dollars into research for a cancer cure. Our consideratic with cancer has been largely after the fact. We have ignored the potential of controling our environmental exposures to carcinogens, thus reducing the cancers that are caused by them.

The EPA Air Carcinogen Policy is an important

large scale attempt at a preventative approach. This policy acknowledges the exogenous factors inherent in many of the cancers occurging today, and attempts to deal with some of them at their source.

Sierra Club would like strongly to support this policy as a single facet in what will hopefully become a multi-faceted program of cancer prevention and control.

We realize that not all cancers are cause by exporsures to carcinogens in the ambient air. But it is important to stress at this point that Sierra Club agrees with the National Academy of Sciences and a majority of the scientific community. These people have proclaimed that because of statistical difficulties inherent in conducting laboratory and epidemiological studies, there has been no demonstration of a safe dose level to any known carcinogens.

In other words, any dose from a carcinogen above zero will produce cancers. There are some segments of industry that would have us believe that the dose response is not linear, but is a curve which rises up beyond a certain, predictable and measurable threshold. Even if this were true, what of biological concentration and magnification?

Can it be expected and guaranteed that as long

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as the dose is under the stipulated amount at each exposure, it will not accumulate over time?

We urge that the EPA uphold its position of an ample margin of safety with regard to public health under Section 112. Erring to the detriment of the health of even a fraction of a per cent of the population would translate itself into the death and suffering of thousands of people.

There have even been questions raised as to how a potential or suspect carcinogen will be positively or negatively proven. Industry has been quick to ask for an epidemiological study to determine carcinogenicity. Sierra Club feels that this is only a tactic designed to prolong the outcome of regulation. Epidemiology studie hold flaws that are difficult to control when dealing with single chemicals or compounds.

Requirements of effectiveness are overwhelmed by the multiple variables of the study.

Some of these requirements include the need to identify the population that has been exposed at the time of exposure. Also, what was the exposure in quantity?

It is obviously difficult to determine how much of the suspect carcinogen was absorbed. We may need a gradation of exposures to show the effectiveness

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of the cancer. To weed out the possibility that it could have been caused by a number of other carcinogens acting alone, or carcinogens and promoters together, or carcinogens acting synergistically.

Finally, can we ethically or even economically justify using a highly suspect carcinogen on hundreds of thousands of people, while waiting for a cancer latency period of up to thirty years? Could we truly expect the epidemiology study to make a positive identification of the particular substance?

We advocate a well-designed animal study to determine the high to low probability carcinogens. The study should be performed immediately in the case of significant exposure to the public. If industry is serious about epidemiological studies, we challenge them to conduct well-designed studies. The results might then be used to aftect subsequent legislation in the long term, but could in no way be expected to halt regulation up till that time.

Because of the adverse affect on public health, potentially carcinogenic substances must be found guilty until proven innocent. Shifting of the burden of proof will cause industry to react quickly with studies which can be reviewed by the EPA.

Compliance costs have been stated by industry

as a major factor in opposing the Policy. But it may be shown that the average consumer would be willing to exchange a slightly higher price in return for an environment subjecting them to lower amounts of carcinogens, especially through the medium of ambient air where the person has no choice in deciding to take the substance in.

The costs must also be weighed against the incredible costs of cancer. Your own Agency estimates the hospital care costs of cancer patients alone as 1.8 billion dollars per year. Add to this, the tens of millions of dollars spent on research, facilities, supplies, time, personnel and the figure is enormous.

The estimated 1.8 million workyears lost, along with the lost productivity must also be considered. This does not include the immeasurable human suffering and degeneration of a society wracked by cancer. These are the costs easily hidden and intangible to the economic system we have.

Industry can often express their increased costs with hard figures and estimates. This does not mean that the public health affects are any less important We at Sierra Club feel that any cost/benefit ratio of a particular substance will hopefully consider some of the public health costs, intangible as they may seem

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st first glance.

The Sierra Club must also express its concern about EPA's desire to locate new sources in unpopulated area. Part of our underlying philosophy is the protection of natural areas. We ask if consideration has been made of the impacts on wildlife and the foodchain. Rural residents may also be negatively impacted by the new source siting. We hope that EPA may come up with a policy that doesn't simply switch the problem and the burden to rural area.

The EPA Air Carcinogen Policy is an excellent first step in attaining a preventative approach to carcinogens. It is greatly desired if we are to begin to combat carcinogens and their presence in our environment.

This policy deals with the ambient air, but Federal, State, private and public organizations and concerned citizens must work towards the control of human carcinogens in water, our food, the workplace and in the general environment.

Sierra Club advocates and supports a strong policy directed at the identification, assessment and effective regulation of airborne carcinogens.

Thank you for your time.

MR. HOHMAN: Thank you.

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Are there any questions?

(No response.)

I just wondered if you -- You mentioned the new source siting, briefly, toward the end. I just wondered if you had any suggestions on how that might be handled?

MR. THOMPSON: That's something, I'm not a scientist and I wouldn't -- I was just concerned about it because of our philosophy, the basic philosophy of natural ecosystem protection.

THE CHAIRMAN: Thank you.

MR. THOMPSON: Thank you.

THE CHAIRMAN: William Mendez.

MR. MENDEZ: Good afternoon. My name is William Mendez. I'm a Research Associate at the Center for Policy Alternatives at the Massachusetts Institute of Technology. I have a Doctorate in Biochemistry from the University of Chicago and am currently a part-time student in the Public Policy Program at the Kennedy School of Government at Harvard.

During the past two years, I have been conducti research concerning public health policies related to the control and regulation of toxic substances exposure in the workplace and in the general environment.

The views I am going to express are solely

my own and do not represent the position of the Massachusetts Institute of Technology or the Center for Policy Alternatives.

The first issue that I would like to address is the nature and magnitude of the airborne carcinogen problem. There are several lines of evidence that suggest to me that the EPA could accomplish a great deal, in terms of improved public health, by adopting a program for the rapid and efficient control of atmospheric emission of carcinogenic substances.

A number of recent epidemiological studies, and they are given in the reference list, have found not only that high cancer rates are often associated with urban development, but also that the geographical patterns of incidence for a number of varieties of cancer are strongly associated with the location of specific industries.

For example, it has been found that the rate for long cancer for men in the U.S. counties where paper, chemical, petroleum and transportation industries are located were significantly elevated compared to those counties where no such facilities exist.

Similarly, elevated rates for cancer of the lung, nasal cavity, liver and skin were found in counties where the petroleum industry was highly concentrated.

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In addition, statistically significant elevations of cancer rates, for a number of other organs have been found to occur in counties where specific chemical manufacturing activities are performed, for example, dye manufacturing.

It is possible that a large proportion of these increases may be due to chemical exposures which occur in the workplace, rather than to the general population. It should be noted, however, that the findings of elevated cancer rates in women, as well as men, in two of these studies, strongly suggest that general population exposure to carcinogenic substances arising from industrial activity is an important public health problem.

Partially, in response to some comments that were made earlier, I'm going to deviate for just a second, from my statement.

The first think I would like to do is call the attention of the Panel to a study by William Weiss of Urban Air Pollution in Philadelphia. This appeared in the American Journal of Public Health in August of 1978.

Dr. Weiss compared death rates due to lung cancer, in the ten publich health districts in Philadelphi in 1970, to measures of particulate air pollution that occurred ten years previously.

His hypothesis was that if there was in fact a ten-year induction period, or some kind of lag period, that these two variables should be correlated. He did, in fact, find that there was a very strong correlation between levels of particulate air pollution and cancer rates in the public health districts in Philadelphia.

The magnitude of the effects that we're talking about is such that the highly-polluted districts had rates that were increased almost two-fold, over the lightly polluted districts.

The second thing I would like to do is to address the issue that was raised previously of time patterns of cancer incidence in the general population.

The first point I would like to make is that all of the data that I have seen has indicated that age adjusted cancer incidence rates, as compared to mortality rates, for most kinds of cancer are increasing in the United States. Sources for this data include the three national cancer surveys, taken by the National Cancer Institute and the Sear data, which has just recently become available.

An excellent discussion of this data can be found in testimony by Marvin Schneiderman, who is the Assistant Director for Science Policy of the NCI, that was given in front of a Senate Sub-Committee last April.

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The second point I'd like to make is that the attribution of 90 per cent of lung cancer to smoking, and thus and then separating out the rest of cancer rates, is spurious in the presence of other multiple exposures that could also contribute to lung cancer, for example, many occupational exposures are known to contribute to lung cancer as well.

The third thing I would like to point out is that stable and decreasing aggregate cancer rates include great contributions from large decreases in stomach cancer in men and women, and uterine cancer in women, which can be ascribed to dietary and life-style factors.

And, in fact, as I say, incidence, age-adjusted incidence rates for most kinds of cancer in most age groups is increasing in the United States.

The last point I would like to make is that a recent paper given, again by Marvin Schneiderman, presented at the Society for Occupational and Epidemiologic -- the SOEH Conference in December of 1979, studied, found that types of cancer for which there are well-established occupational associations, cancers that are known to be associated with various industrial activities are uniformly increasing in the United States.

It is quite possible that the existing

epidemiological data, in fact, understand the degree of risk posed by airborne carcinogens. The practical problems involved in conducting adequate epidemiological studies are well know. Most substances have not and could not be studied epidemiologically, since significant human exposure has occurred only recently.

Since as many as 1,000 new chemical substances are produced in significant amounts per year, and many of these are found to be carcinogenic in animal tests and mutagenic and in vitro tests, and since the volume of organic chemicals produced has doubled every seven to eight years in the United States, since World War II, it is likely that both the number and level of known exposures to airborne carcinogens will increase unless vigorous attempts to control emissions are made.

EPA's initiative in this area is appropriate and timely and could produce substantial benefits in terms of reduced cancer incidence.

The general structure of the policy proposed by EPA is well-suited to the control of the relatively large numbers of substances and source categories that would need to be regulated as posing serious carcinogenic risks to the public. The automatic imposition of generic standards immediately upon the agency listing of a substance as carcinogenic could greatly reduce the magnitude of

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exposure to most substances at relatively little cost to firms without the expense and delay of protracted regulatory proceedings.

Regardless of whether the control measures under the applicable generic standards reduce emissions to the point where the remaining emissions constitute a reasonable residual risk, it is likely that, as long as generic standards are in place, the initial reduction of emissions upon the listing of a substance as a Section 112 carcinogen would result in significant reduction in emissions.

For example, EPA could list a relatively large number of substances as carcinogens, and achieve a 50, 75 or 90 per cent reduction in emissions of each substance, while conserving regulatory resources to expend on those substances where exposures are high or inexpensive control measures are not available and where further analyses and regulatory action are required to reduce residual risks to acceptable levels.

In order for the generic approach to accomplish these goals, however, it is necessary that the generic standards developed are sufficiently broad to apply to a large number of source classes and substances, yet flexible enough so that meaningful exposure reductions can be achieved for specific source classes without

major tailoring and without imposing unreasonable compliance costs. These goals are realistic and achievable and the draft generic standards in the EPA Proposal, such as housekeeping, leak detection procedures and storage practices, are a good first step in controlling airborne carcinogens.

The last issue that I'd like to talk about is the use of quantitative risk assessment techniques envisioned by the EPA Proposal. Under the Proposal, rough risk assessment based on rough estimates of carcinogenic potency and exposure, could be used to aid decisions about whether to classify substances as a Section 112 carcinogen, while exhaustive, detailed risk assessments would be used to establish priorities for regulation among source categories and in determining the degree of control required in setting emissions standards.

In my opinion, the use of the rough assessments, consisting mainly of a finding that given substance is a carcinogen and that significant exposure occurs, or based on a single, simple linear extrapolation, as a guide for deciding whether a substance should be listed as a Section 112 carcinogen is fully justified.

Great care must be taken, however, in using the results of quantitative risk analyses for setting

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priorities for regulation among source classes, and in setting permissible exposure limits.

In attempting to set priorities for regulation, it is likely that the results of detailed risk assessment will not be able to distinguish, with any degree of statistical significance, between similar source categories.

Priorities for regulating different source categories for the same pollutant are liable to depend to a large extent on particular analytical or modeling assumptions, and different, equally reasonable modeling assumptions could easily lead to a different set of priorities.

Unless modeling and analysis procedures are rather rigidly standardized, risk assessments for source categories emitting different pollutants are likely to incorporate different assumptions and use different techniques and thus are not likely to be easily comparable.

The point I'm trying to make is that as far as priority setting is concerned, detailed risk assessment are likely to be able to divide source categories into a few very broadly defined classes and are not likely to be useful in deciding close calls.

Perhaps it would be better not to expend the resources necessary to conduct a full-scale risk assessment if the only aim is to set priorities for

regulation among source categories.

The use of quantitative risk assessments in setting emissions standards again is likely to require great care. The EPA was wise to refuse to limit itself to a specific set of decision rules, such as cost-benefit or cost-effectiveness analysis, and instead to reserve to itself the right to make fully-informed policy choices.

The Agency seems to have recognized most of the practical and theoretical problems inherent in using highly imprecise risk estimates in making policy. Again, it is not likely that quantitative risk assessments be accurate enough to help much with close calls.

It does not appear, however, that the EPA has adopted any consistent policy to deal with the large degree of uncertainty that would be encountered in performing and using quantitative carcinogenic risk assessments. Developing such a policy toward uncertainty in risk estimates could help the EPA to more effectively obtain and utilize information of this nature.

Such a policy would have to be developed carefully and reevaluated continuously, but would probably consist of two major elements:

First, a procedure should be developed to assure that at every stage of risk analysis, as much information about uncertainty be developed and transmitted as possible.

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Too often, at each stage of such analyses, such as estimation of emission factors, dispersion modelin and so on, information about uncertainties surrounding preceding steps in the analyses are lost, or the analysts themselves are afraid to commit themselves to quantitative estimates of the likely magnitude of error surrounding their analyses.

This leaves the people who have to conduct the final rsik assessment, usually the Carcinogenicity Assessment Group, with the Herculean task of trying to construct reasonable confidence intervals about the final risk estimates from little or no data and produces a situation where decision makers attempting to use risk estimates are most unlikely to be aware of the magnitude and sources of uncertainty associated with these estimates.

The development of such a procedure for assurin that sources of uncertainty are considered and included in every stage of the analysis could probably best be designed by those charged with conducting the final risk analyses, the Carcinogenicity Assessment Group.

Second, the EPA should develop an explicit risk posture with regard to the use of quantitative risk assessments for setting emission standards. That is, decisions should be made about whether, in setting

standards, the Agency is going to use the man value generated by the best, most accurate analytic method, or whether they wish to be risk-averse, for instance, by using upper confidence intervals associated with risk estimates.

It seems to me that the EPA might want to be somewhat risk-averse in interpreting quantitative risk assessments for the purpose of setting standards. Doing so would be totally consistent with the Agency's statutory mandate to set standards with an ample margin of safety.

This does not mean that I favor the use of analytical techniques that are, themselves, conservative, that is, which tend to overstate risk. It is important that accurate, unbiased analyses be conducted. If desired, these then can be interpreted in a manner tha, although it may involve an explicity risk-averse attitude, also assures that no impotant analytical assumptions or sources of error are concealed.

In this manner, fully-informed decision-making could be greatly facilitated.

Thank you.

THE CHAIRMAN: Thank you.

Roy?

DR. ALBERT: I'd like to compliment Dr. Mendez for a very thoughtful statement.

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DR. ANDERSON: I just have one other comment, and that is for the first time somebody did bring up, in these hearings, the importance of the exposure assessment work, and I just wanted to say that the Agency is aware of this and currently has an effort under way to try to establish mor econsistent ways of expressing exposure assessments.

THE CHAIRMAN: Thank you.

Our next speaker will be Nancy Anderson.

(No response.)

Okay, Barbara Fegan?

MS. FEGAN: Thank you very much.

I have two hats, if you will. I am Barbara Fegan, President of the League of Women Voters, of Massachusetts, and I am very happy to have presented you a telegram rather than a speech, and I am a generalist here.

I would like to quote the Jr. Senator from New York, and say, "The world is a dangerous place."

For many years, the League of Women Voters has pursued the dual goals of environmental enhancement and wise economic development. We were present at the birth of the Environmental Protection Agency and have supported its development as an efficient, competent and strong federal regulatory body to set and enforce

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environmental standards that protect the health and well-being of our citizens.

And as you heard before -- I think I, perhaps, will be telling you a lot of things that you already know, and if it's so, forgive me.

Of the three major causes of death in the United States, heart disease and stroke rates are decreasing while the cancer death rate is increasing. And since exposure to carcinogens is a significant health and life threat, the League of Women Voters believes that such exposure must be prevented.

The League supports a strong air carcinogen policy implemented by the Environmental Protection Agency to eliminate air borne carcinogens.

A prudent public policy must consider all of the costs of environmental pollution control. The reduction in the rate of cancer cases means more productive worker time and days. That is a benefit. Pollution control is a cost of doing business. Citizens and taxpayers expect some of the cost to be passed on to them, but they should not be expected to underwrite only a change in profitability.

In order to maintain competition among businesses, small businesses should have financial assistance to enable them to purchase control equipment

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and develop substitute products. And that is singularly important for we in New England because so many of our manufacturing firms are small firms.

The fact that some areas of the country have, quote, "cleaner" air than others should not be considered a license to pollute. New facilities in cleaner areas should be prevented from contributing to the deterioratio of air quality.

We look to the timely implementation of this policy. Since listing of a carcinogen triggers general housekeeping rules in a state with an approved implementation plan, we cannot see a need for lengthy epidemiologic studies.

The League has supported, and always will support, the right of citizens to participate in the decisions that affect their lives and encourage the continued effort of regulatory agencies to involve not only the special interests but the public at learge.

I'd be happy to answer any questions on that very specific, scientific document.

(Laughter.)

THE CHAIRMAN: Any questions?

MS. FEGAN: One thing I did leave out was the matter of the burden of proof, and that has been a cardinal rule in the League's positions on environmental

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quality that the burden of proof rests with the person who would change the environment for the worse, so that we would expect industry to come up and say that they are really not doing a bad job.

I also chair a Sub-Committee of the Regional Cancer Control Committee that is involved with environmental and occupational health. And I'll put that hat on, if I may, to use up the rest of the time.

The Regional Cancer Control Committee strongly supports the Environmental Protection Agency's Proposed Policies and Procedures for identifying, assessing and regulating airborne substances, which pose a risk of cancer.

I think what is important here is the Regional Cancer Control Committee is composed of thirteen agencies and organizations and includes Boston's four major cancer treatment centers.

One of our goals is to reduce the incidence of cancer in Massachusetts. We were among the people who filed the legislation and are supporting the legislation for an incidence of cancer registry in Massachusetts.

Cancer is the second leading cause of death in Massachusetts and in the United States. During 1977, 22.4 per cent of deaths in Massachusetts were caused

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by cancer. And despite significant improvement in the treatment of many types of cancer, the treatment of lung cancer has reamined a serious problem. Cure rates are low. Lung cancer is presently the leading type of cancer in males, and its incidence in females is rising.

Nationwide, there has been a twenty-fold increase in lung cancer in males during the last forty years.

Statistics cannot paint a gloomier picture. Our lungs are those organs readily exposed to noxious substances, and with few exceptions, we have little choice as to the presence of these substances in the air we breathe.

Establishment of a policy to limit those substances to which we are exposed, is one that we certainly can support.

Nationwide, it has been estimated that between 50 and 90 per cent of all cancer is associated with environmental conditions. The Council on Environmental Quality had that data in their first paragraph of their yearbook published in 1976, and I do think that that particular phrase comes back to haunt all of us.

We know, depending upon what you are looking at, you are either looking at the small end of 60 per cent, or the large end, the 90 per cent, when you are

dealing with carcinogens.

At the same time, it is estimated that one-fourth to one-third of all cancer deaths in the United States are avoidable, through prevention or early diagnosis, which is probably the more telling statistic.

The Regional Cancer Control Committee and other organizations involved in cancer control deal with the entire spectrum of cancer interventions, and it should be noted that we are planning an increasing emphasis on prevention.

Certain important airborne substances that cause cancer have already been identified, and one of these is asbestos. Fortunately its use has come under intense scrutiny and regulations have been written. Whether they are fully enforceable for every small business and service organizations is uncertain. The EPA may need to focus on regulations for removal of dangerous asbestos from schools and other public buildings.

It's interesting to note that we already have some evidence that Congress is recognizing this as a public health issue in the amendment to provide money for just this procedure.

A second airborne carcinogen is cigarette smoke, which is one way of blaming the victim, in terms of public policy. However, we do know that cigarette

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smoking has a symbiotic relationship with some of the airborne carcinogens.

The third important area to which EPA should direct its attention is a large group of substances that have uncertain cancer risks and need further study and classification.

Since cancer treatment is never as effective as prevention, more of our health dollars should be expended on prevention. For example, lung cancer is preventable, yet payment to hospitals for treatment by lung and bronchial patients reached 368.3 million dollars.

Health care costs are escalating annually. In 1979, they accounted for 9.1 per cent of the gross national produce and predicted to be 10.2 per cent of the gross national product in 1984.

Cancer alone exerts a tremendous economic impact on patients, familiies and society as a whole. In terms of assessing health benefits, medical care costs and wage loss can be measured. Estimates for the total cost of cancer, including direct costs for care and treatment, as weall as the indirect costs, such as the loss of earning power and productivity of patients, range from $13.7 billion to $22.7 billion annually.

The cost of controls used in cancer prevention

measures is an important issue and should be carefully considered. The EPA has addressed many components of a cost-effectiveness paradigm. We would like to emphasize the necessity for including health care costs in considering this issue. The objective of such a cost effectiveness paradign is to achieve the greatest possible health benefit for the amount of resources expended on controls and regulation.

Looking to the users of a health care system, cancer patients are unique due to the process of their disease. Most cancer patients need both hospital-based services and continuing care services. In addition, the nature of the disease often results in patient's readmission to acute care institutions years after diagnosis and the use of services for monitoring and continuing care.

Our assessment of health benefits comes to a standstill when we try to put a price on human suffering and loss of function. There is no way to estimate the value of one life, let along the sixteen year average reduction in the life expectancy of the cancer patient.

EPA's proposed Air Carcinogen Policy is an important step in the prevention of cancer and its resulting social and medical costs. The Regional Cancer Control Committee supports EPA's Proposed Policy on National

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Emission Standards for Hazardous Air Pollutants.

We have appended a list of the members of the Regional Cancer Control Committee and a description of who we are and how we go about our business.

THE CHAIRMAN: Okay, thank you.

Any questions on that testimony?

(No response.)

Thank you.

Before our next speaker, I would like to declare a ten-minute recess, so we will start again in ten minutes, at quarter of four.

(Whereupon a ten-minute recess was taken.)

THE CHAIRMAN: John Hermos?

MR. HERMOS: My name is Dr. John Hermos, I'm a resident of Brookline, Massachusetts. I'm an internist and gastroenterologist at the Boston Veterans Administration Medical Center and Assistant Professor of Medicine at Boston Univeristy School of Medicine.

Today I am representing a group known as Brookline Citizens to Protect the Environment. We are a citizens group opposing Harvard University's proposed Medical Area Total Energy Plant, or MATEP. This is a large, diesel-powered cogeneration plant situated in an urban and residential area on the Boston and Brookline line.

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Our group is a member of a larger organization of neighborhood groups from Brookline and Boston, the NO MATEP Coalition. And in concert with the Town of Brookline, we have provided extensive testimony to the Commonwealth on the potential adverse health and environmental impact of MATEP's diesel engine emissions.

Today, I'm here to urge that EPA adopt an air carcinogen policy that is conservative, that allows for the worst case analysis and that is enforcable. And we take that stand for very personal reasons. Having been engaged in literally a life or death struggle with Harvard University for the last three years, we are horrified to thing that we or any other community might have to live under the constant threat of cancer from an unavoidable source -- not unavoidable that it can't be disapproved, but unavoidable that it would be in the air -- source such as a large stationary source of air pollution in a residential area.

For this hearing, it may be important for you to know that we are a single issue group, that is we are opposing one proposed diesel facility. Thus, we are not an established environmental group. And I make that distinction only because our membership is comprised of people with a wide range of philosophies on this issue, and as a whole, we would probably take a very balanced

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balanced view between the alleged conflicting issues of industrial growth and environmental protection.

Also, we are not using this form to argue the risks of the MATEP proposal because we have been doing that very effectively in front of the Commonwealth, and thus far, the Commonwealth and an independent hearing office have already disapproved MATEP's diesle engines in three previous rulings on the basis of their NOX emissions.

However, as the MATEP application is still viable, and since the serious issue of carcinogenesis from diesel exhaust has been raised by scientists and by federal officials, we are very deeply troubles by the potential effects this could have on our communities.

I'll leave my text for a moment. I understand from one of my colleagues that the issue of diesel emissi particulates has not been raised at this hearing. I don't know if it's particularly relevant to that, but I'd be willing to answer any questions that you might have on that.

I think it's fair to say that -- Let me say one thing, in our research of it, which has been very extensive, virtually all the work has been done on mobile sources, yet with stationary sources, and one as large as the power plant we're fighting, we have a potential

emission of fine particulates that would be equivalent to 261 million car miles -- that's on a .2 gram, fine particulate emission standard, which has been proposed. That's from one source.

So, one can sense the importance of a stationary source and how that might effect a community. And, tragically, very little work has been done in this area, and we look on that as a very important gap in our knowledge. We are having a very difficult time trying to extrapolate what is known about smaller engines, both light and heavey-duty, towards a large, stationary source.

But, again, a lot of particulates from this one source.

Returning to my text, I think it's fair to say that we are scared, and that we are not certain to whom we can turn and who we can trust. Cancer can be a devastating illness, as you know, and very little progress has been made, if any, in either the palliation or the cure of lung cancer.

More than 90 per cent of all patients with carcinoma of the lung either have non-resectable disease at diagnosis or recurrent lesions after surgey. And five-year survivals are still only about 5 per cent.

As no familiy is immune to this potential risk, and where some families may be even more susceptible

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than others to all cancers, this threat is very real to all of us.

We feel it is essential that EPA and the federal government do not backslide or equivocate on this issue. The intent of the Clean Air Act is clearly to protect public health, and in doing so, must necessarily be technology-forcing in its effect.

There are two statements I'd like to read which articulate this mission.

This is from John Bonine, in the Environment Reporter, in 1975: "A recent survey of the Act and its interpretation in court said: 'Although the Act was not the first federal statutory attempt to control air quality, its perspective was unique; rather than regulate from the standpoint of what was technically feasible, it started from a point of determining what air standards were necessary to protect the public health and it required technology to meet those standards."

Senator Muskie stated in 1970: "Predictions of technological impossibility or infeasibility are not sufficient as reasons to avoid tough standards and deadlines, and thus to compromise the public health... Only a clear cut and tough public policy can generate the needed effort."

We feel very strongly that when human cancer

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is the issue, following this mandate is prudent and absolutely necessary.

We further suggest that it would be sound public policy to be especially conservative in determining the cancer risks from new, major sources of potential airborne carcinogens. As in many aspects of life and of law, it is usually greatly beneficial to have established the ground rules for behavior before the event, so that everyone will know them, and know what the consequences are for not abiding by them.

Form our experiences, the proponents of a polluting sources are not accountable to the public by simply saying "trust us." We know, and you know that if a new sources is approved, it is the economic factors and not the environmental factors that will govern the operation of the source by either the owners or the users.

In this regard, EPA has some very difficult problems with which to contend with existing sources of dangerous air pollutants. Conversely, with new sources of air pollutants, you have an exciting challenge to prevent costly errors before they become irretrievable.

In the case of diesel engines, whether they be mobile or stationary, it would be a tragedy for the country to become economically and emotionally hooked to this type of energy production. Then, 10, 20, 30

years later, discover the health consequences, including cancer, that the scientific data of the 1970's indicated.

At the present time, due to this country's real vulnerability in obtaining energy sources, this quick fix of diesel engine seems quite attractive.

However, just as it is with cigarette smokers, once hooked, it is very difficult to break the habit, despite well-known and serious health consequences.

I believe that the industrial proponents of a lax airbonrne carcinogen policy are asking the government to get us hooked now and worry about the consequences later when they occur. This does not representa prudent policy for the government to follow.

An additional reason for setting a strict and conservative policy for airborne carcinogens is the large population put at risk by air pollutants.

For example, even if a carcinogen produced only a 2:1 increment in lung cancer risk, when applied to a large population, the absolute number of cases would be substantil.

Further, when the exposure to this large popula tion involves nor more than the obligatory process of breathing, and in no way involves free choice, EPA should show special concern in establishing its policy. I think that the enormous response generated by the revelation

of asbestos shields in hair dryers indicates how very seriously the majority of the population considers the problem of unwarranted exposure to potential and real carcinogens.

Conclusions: As a representative of many people suddenly faced with the possibility that a major new source of potential airborne carcinogens will be introduced into the air that we breathe, I want to convey to you that we are scared. As a doctor, who has seen far too many deaths from cancer, the goal of prevention is mandatory.

As a tired, but experienced opponent of a developer of a plant, that will necessarily pollute the air because of its engines and modes of operation, I do not believe that energy producers, in general, can be trusted with the health of the population.

Therefore, we turn to EPA and ask that you act with foresight and prudence in establishing the country's policy for airborne carcinogens.

We urge that the decision or decisions that you reach be appropriately conservative -- and again by conservative, I mean, taking the worst case into consideration -- in a policy that allows for the many unfavorable variables associated with widespread air pollutants, and especially that the policy reflect

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the concerns of the people in the country who would be most severely affected.

Thank you.

MR. JOSEPH: Dr. Hermos, I think we would appreciate it if you could submit for our record, some time in the next month or so, any information you might have on emissions from stationary sources of diesels and constituants of the emissions and the exposures.

DR. HERMOS: That sounds like the question that I've been calling up everyone in EPA that I know, asking you people for it.

MR. JOSEPH: Well, anything that you have gathered, would be helpful.

DR. HERMOS: Surely.

THE CHAIRMAN: Any other questions?

(No response.)

Robert Dubrow? Is Robert Dubrow in the audience?

(No response.)

Fred Krupp?

MR. KRUPP: My name is Fred Krupp. I am the General Counsel of the Connecticut Fund for the Environment, a non-profit, public interest, state level, environmental legal group. In the two years since we have been established, we have attracted over 1,000

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members in the State of Connecticut, and even some publicity in the State of Rhode Island.

Since June of 1979, CFE has been involved as one of its cases, and an instance of a residential community being inundated by airborne pollution spewn into it from synthetic organic chemical plant.

The situation exists in North Haven and Hampden, Connecticut. The manufacturer is the internationally famous Upjohn Company. The residents complain of odors, headaches, tearing eyes, abrupt awakenings in the night and sleepless nights.

The company, through legal efforts, is resisting even a court order that we have obtained to supply data necessary to determine the chemical constituency of the fumes which waft their ways into the neighbors homes.

Given this lack of data, we know very little. One thing we do know is that benzene is one of the substances released into the air by Upjohn. Benzene is, as you are well aware, is one of the four airborne carcinogens now regulated under Section 112.

At the outset, let me express my sincere hope that EPA will be ever cognizant of the dynamics present when it schedules a public hearing, whenever it makes a rule or regulation, or calls for public input.

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A small segment of the public has an economic incentive to develop highly funded testimony. Needless to say, this is the segment of our society which stands to profit from the continued absence of effective regulation of chemical carcinogens. Unfortunately, despite the fact that the interests of the huge majority will suffer from the continued absence of effective regulation of chemical carcinogens, no one individual can martial the information or hire the resources to put together this similarly funded rebutting testimony.

Thus, the large majority of the public is left with a serious handicap in presenting its views to the EPA. I hope EPA will not only recognize this, but take necessary action to rectify the imbalance of testimony which will undoubtedly result from hearings such as these.

It is not good enough for you to view yourselves as mediators between the public interest and the well-funded special interests, between the well-funded special interests and a few public interest groups trying to address the panoply of issues. The public interest is just diffused over too many individuals to be martialed as effectively as the private interest. And this is so even in this case of considering airborne carcinogens, even though we already know the contribution

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that environmental factors play in increasing the cancer rate.

Now, as I have indicated previously, my statement today stems from the real world experience of representing a large number of people -- over 2,000 people in North Haven and Hampden have expressed their displeasure at what is going into their air -- who are being involuntarily held captives of chemical pollution. The lives of these people are being placed at risk.

Our knowledge is far from perfect, and although no threshold level for benzene has been shown, these people, today, must endure the risks of involuntarily being exposed to low ambient levels of the leukemogen benzene.

I might add that although the tests today, taken by EPA in our state, Connecticut State DEP, have been very poor in methodology, and there have only been two or three of them, we have found levels next to the acres of lagoons, open-air, chemical lagoons, levels of up to 2.7 parts per million, and we don't at all assume that that is the worst case. They may be significantly higher than that.

Those are ambient open-air levels.

Now, the situation in North Haven, not only with benzene, but will all the other chemicals that are

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smelled and sensed in the air, gives rise to some questions. Will children be affected more than adults? Will the sick be affected more than the strong? How about pregnant women?

These are the awesome questions posed by the deplorable situation. The chemicals Upjohn emits to the adjacent residential neighborhood are very odorous, causing considerable discomfort to joggers, high school students during their outdoor recreation periods, as well as neighbors in their homes, even in the winter, even with their windows closed.

Moreover, there are physical health effects, as I've mentioned, which may merely be the traces of a much larger underlying problem.

Now, despite the high level of public concern that exists now in Connecticut, the managers of the plant have been far less than forthcoming with the data necessary from which citizens and scientists, alike, could evaluate the safety or hazards of these fumes. Some of these chemicals are released through open air stacks and some of the unknown chemicals volatilize from acres of waste treatment lagoons.

The citizens are so stymied by the moneyed company that they have yet even to gain the facts. Recently, as I mentioned, the state court ordered Upjohn

to yield the data, but the company has appealed this order, rather than comply with it.

What we do know is that Congress instructed the EPA, through the Clean Air Act, to have its Administrator, within 90 days from December 31, 1970, publish a list which includes each hazardous air pollutant for which he intends to establish an emissions standard under this Section.

Despite this mandate ten years ago, only four chemicals have been listed under this Section. Now, we know there are many, many more chemicals, some of which are synthetic creations that are known to have the ability to mutate genes, cause cancer, and other diseases.

Furthermore, we know from analogous studies of other toxic agents which work in part by destroying or segmenting DNA that threshold levels have not been shown and seem not to exist for radiation in many cancer causing chemicals, that we know of.

Thus, when Congress instructed EPA to provide an ample margin of safety for these hazardous air pollutants, it is doubtful that what Congress had in mind was the marked lack of progress with which EPA has proceeded in the last ten years.

It is doubtful that Congress could have

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conceived that benzene, the only chemical known to man capable of inducing leukemia, would be visited upon citizens years after its powers were known, and even after it had been listed under Section 112.

I suspect that the situation in North Haven where benzene is among the maze of chemicals permeating the community, and where a company refuses to even say what is in the fumes which it spews off, would not have been tolerated by a Congress whose legislation reflected the judgment of the American public that it should not be exposed to chemicals with effects as awesome as adding to the increasing cancer rate.

Yet, today, there are still no EPA regulations concerning even the already listed chemical benzene. No standards which in any way protect the North Haven citizens afflicted by this among other unknown chemicals. Today there are no EPA regulations under Section 112 which place on industry the burden of even discloing what chemicals it is releasing, and of controlling these emissions.

How then are we to judge what type of program is needed on behalf of the Federal Government to regulate cancer causing chemicals. Having recognized that the need is great, and that the probably number of chemicals which must be controlled is very large, it seems as

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though the program which the government must implement is one which will quickoy place ceilings and caps on the vents, valves, tanks and lagoons, from which these cancer causing chemicals are escaping.

If there can ever be an excuse for the emission of these synthetic poisons whose power is that to wreck the fundamental basis of life itself, then the burden of developing such a rationale in each instance ought fairly to be placed on those who seek to profit by such air dumping.

No one knows better than those who work at EPA that the burden on the regulators is already huge. It seems as though the program which EPA develops, its cancer policy, must, by necessity, and in response to a fundamental notion of justice, place a share of the burden on those whose activities give rise to the problem, on those who have the best information necessary to control the problem.

EPA's regulations proposed, and before us, today, however, unfortunately, for reasons that I really don't understand, give EPA itself the lion's share of the information gathering and evaluation burden. The burden is placed on EPA to come up with methods and resources to aleviate the emission of carcinogens.

For example, on page 58, 650 of the Federal

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Register, a brief quote: "EPA will perform detailed analyses to identify alternative, technologically feasible control options and the economic, energy and environmental impacts that would result from their application. Where substitution is determined to be a feasible option, the benefits of continued use of the substance or process will be considered. These analyses will rely primarily on the procedures and techniques..." etcetera.

It seems that this system gives industry itself no incentive to regulate and rectify the problem itself. There are many responsible businessmen who would voluntarily limit the risks associated with their activity. But they will be put at a competitive disadvantage unless there is an incentive for all their competitors, some of which may be less scrupulous to do likewise.

A program which set proposed limits and a proposed time table would assure that industries which emit these substances will make their own economic and technological decisions as to the feasibility of continued operations. In addition, such limits and timetables would require industry, having gathered that information to either implement the solution or present a convincing, compelling case that such a

solution should be delayed or is totally impractical.

To implement these regulations, as they stand now, and thus place on EPA an impossible burden, I think guarantees that the program will be a failure.

Thus, I concur with the comments made by the Natural Resources Defense Council, that a minimum number of pollutants should be screened and regulated each year. A candidate list should be drawn, and EPA ought to take 20 chemicals off the list each year, listing them as hazardous air pollutants.

I think the number 20 is minimal, in view of the fact that the scope of the problem is so large that quick and dramatic action is needed to solve it. Similarly, a testing list should be established so that chemicals for which more information is needed could be prioritized and channeled into the testing programs of EPA, other agencies, and private industry.

I also want to concur with the concept of setting a zero standard for carcinogens, which would go into effect one year after their listing. The presumption, given the discussion in EPA's proposed regulations, and the extensive literature and testimony upon which it is based, should be that we can achieve zero through control measures and process changes.

Let us not underestimate the power of

American technology. There could be an interim standard which could be set during the year prior to when the zero level would be achieved.

Inasmuch as economic dislocation is not anyone's desire, it seems as though there could be some flexibility for an extension of the zero standard, delaying it for even more than a year. Here is where, however, the burden must be placed on industry to show that there are good reasons for such an extension. Exemptions should be determined by individual source. This is the scheme which seems to have been envisioned by the Act itself.

Perhaps the criteria identified in the proposed cancer policy could serve as guidelines for the type of arguments which industry could make for an extension. However, I must add my own extreme reluctance at relying on quantitative risk assessments which are often based upon data that is extremely sketchy, such that the conclusions are extremely qualified and that the theory is often verified by the data from which it was induced.

Quite simply, it is an impossible problem to test low level dangers and we must always bear in mind that the lower the exposure level, the longer the period which one would have to endure in order to establish either the safety or the danger of the chemical involved.

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Placing the emphasis on quantitative risk assessments which EPA does in the regulations by necessity, lets the threshold concept sneak in the back door, despite EPA's redudiation of it, in the preamble. It's almost like creating a scientific fiction, similar to the legal fiction we lawyers have to deal with, and I wouldn't recommend it.

Similarly, given the uncertainties of these risk assessments, it risks the serious danger of having the pseudo threshold, which the risk assessments establish, be set at too high a level.

By establishing the timetable I've proposed, finally, there would be an incentive on industry to come forward and do the research which it is best capable of doing, to cooperate and attempt to achieve the zero standard.

EPA, I think, has been too quick to jump to the conclusion that a zero standard for cancer causing chemicals is impossible to achieve. I think it would make more sense to require an industry showing of what difficulties it is having, for which sources, for which processes of emissions, for which chemicals.

In addition, as implied above, I think it is essential that the regulations under Section 112 require industries to completely disclose the names of all

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chemicals released into the air, and make reasonable efforts to disclose information on the quantities released. The public has a right to know what goes into the community air. Such disclosure could increase pressure on industry to develop closed systems and thereby ease EPA's burden.

The regulations make clear that once a chemical is listed, the emission controls will be applicable to only certain designated source categories. Given the wide range of ways in wich chemicals can and are used, it seems dangerous to limit the applicability of the implace of a carcinogen listing under Section 112 to only particular source categories.

Let's go back for a second to my own experience in North Haven, where benzene in part is being emitted from open-air lagoons which are acres in size. In fact, one of the large lagoons is aerated, which increases the volitalization of benzene and the other chemicals as yet unknown.

Some of the other peaks, by the way, have shown up on our Mass spec tests, although we haven't identifie them.

Yet although benzene is listed as a hazardous chemical, as an airborne carcinogen, this particular source type is not one which is now regulated, or which

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the regulators even contemplate addressing from their own North Carolina think tanks.

Thus, it seems that the consequences of listing a chemical as a hazardous air pollutant should also trigger a ceiving on the amount of the toxin which can be released by any facility by whatever process it uses.

In this way, EPA, or citizens afflicted by a problem, could spot and have some leverage to solve the problem. One way to decide which source categories should be addressed, might be to have the generic standard applicable across the board and place the burden of exempting specific source categories on those who seek to spew the dangerous chemicals into the community's air.

Even though there may be only one particular source which utilizes benzene in a way, maybe we have the only lagoon source in the country, it seems as though the national regulations, could, without high burden on the federal regulators, establish interim and final ceiling limits on how much of a chemical could be emitted across the board.

Naturally, concurrent with the broadening of source categories, I have already suggested that the zero level be implemented one year from this listing

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unless industry has sustained their burden of making a convincing case for delay in the attainment of that standard.

EPA's proposal of a cancer policy is a step forward. Unfortunately, however, adoption of this policy, with the burden wrongly placed on the regulator, and with an absence of timetables and incentives, will not allow our society to effectively come to grips with the airborne carcinogen problem.

America has expressed its faith in technology and its risk adverse posture to carcinogens through Congressional action. Let us pray that EPA will implement this collective decision and properly protect us from this invidious threat.

THE CHAIRMAN: Any questions for Mr. Krupp?

DR. ALBERT: In listening to your story about the pollution in this valley, the question comes to my mind as to whether or not there are any resources that exist at the present time for dealing with a situation like this, which is clearly not low-level pollution, but high-level pollution.

It's obviously a nusiance in the area. It reminds me of the situation that existed in Hopewell, Virginia, where both the EPA looked into the Life Sciences Company, as well as OSHA, and neither did

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anything, but action was taken when a physician who examined one of the workers that had neurological disorders there, called the State Health Department and the State Health Department came and looked at the plant and shut it down the next day.

Can't they come in and do something about this?

MR. KRUPP: Rest assured that CFE, on behalf of the citizens, and the citizens themselves, have contacted the Municipal Planning and Zoning Commission, the Wetlands Commission, the Town Health Officer, the State -- I've visited with Commissioner Douglas Lloyd from the State Department of Health, who claims not to have regulatory power, as well as, we are not involved in extended proceedings before the Connecticut State Department of Environmental Protection, concerning the NPDES Permit, which allows a water discharge, but concomitant with the water discharge is where these chemicals are volitlizing from, at least in part.

And, unfortunately, the regulators, despite the public outcry, are not willing, have not yet shown a willingness to take the steps necessary, in my opinion, to abate the hazard.

DR. ALBERT: But don't you think there is something sick about the situation when a local problem like this, which clearly needs rectification, can't be

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coped with by the local authorities. It's kind of pathetic, isn't it, to rely on a federal agency to carry out ----

MR. KRUPP: (Interrupting.) Well, Dr. Albert, let me -- I wish you could be with me at the hearing -- but let me explain to you what the state authorities tell me. Today I met with the head of the State Air Pollution Program, Len Brugman. He had proposed that there be limits set on airborne carcinogens, not only for the Upjohn plant, but across the board in the state because there is no regulatory handles that they have on the state level.

And he met with such fierce opposition, he explained to me today, from industry, that it's his sentiment that there is no way that Connecticut can step out ahead of the rest of the nation until the federal government takes action.

So, the local and the state regulators are waiting for the feds to take action because Connecticut as other states, don't want to put themselves at a competitive disadvantage, can't afford to have rules for the Upjohn Company here, that would be different if they moved to Massachusetts, or New Hampshire.

And so, they are waiting for the feds, and that is what I hear again and again, at the local and

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state levels.

I hope you are able to add your name and credibility to our efforts.

THE CHAIRMAN: Let me ask you, have you talked to Merrill Hohman, who started out as Chairman here this morning, from Region I? Have you talked with him at all? Or have you talked with anyone in Region I, EPA?

MR. KRUPP: We have begun discussions with people in Region I. We have had -- there's a file.

THE CHAIRMAN: I think that's probably your first step, and I'll talk to Mel also and make sure this is brought to his attention.

DR. ANDERSON: I have just one quick comment, and this has to do with your dismissal of quantitative risk assessment. Before you dismiss it, I thought that in light of the fact that we certainly do know that chemicals vary in potency as much as a million-fold or more, and as an example, if saccharin or cigarette smoke were as potent as aplotoxin or dioxin, we would have a major tragedy on our hands.

And I just wondered if, before you discard it, if you don't think that it makes some sense to take this into account in some fashion, and this policy that is proposed to take a look at this, to set priorities,

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to try to take regulatory actions to solve the greatest helath problems first, and to look at residual risk to see just how bad the circumstance might be after application of best available technology.

MR. KRUPP: I think it does make some sense. I'm familiar with the Ames scale of toxicity and the other indications of potency, but I think it does make sense that risk assessments be used to prioritize which chemicals should be listed first, but to try to use them and the preamble, I might say is, I think, well written, and disclaims that risk assessments will be used for detailed decisions, but I think the regulations themselves are at variance with the preamble. I think the regulations themselves use risk assessments not only for setting the initial priorities, but also in determining what levels will be acceptable.

Maybe I'm misreading the regulations, but I really don't think so. In other words, It hink the regulations put far too much emphasis on risk assessments.

THE CHAIRMAN: Okay, thank you.

DR. HERMOS: I'd like to say something in response to your question on differences or similarities between large and small diesels, we did do extensive research in this area using as best we could, EPA consultants and Dr. William Balgore (phonetic), from

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Environmental Resources Technology, from Connecticut, and others as well, and as far as anyone would testify, there is no intrinsic differences between small and large diesels, light or heavy-duty, as far as their fine particulate emissions and their poly-cyclic organic compounds, which are the mutagenic and carcinogenic compounds, in that it may be the fuel properties, the higher residual fuels and the higher, with the higher aromatic content, that would have the greater mutagenicity, and this was work that came out of EPA lab in North Carolina. Husing (phonetic), I believe, was the lead author, and Bradow (phonetic) was one of the collaborators in that study.

So, at this point, no one has demonstrated any intrinsic differences between large or small diesel engines, as far as their carcinogenic, or mutagenic emissions.

THE CHAIRMAN: Thank you.

No one is here from the Physicians for Social Responsibility, I gather.

(No response.)

Ed Loechler?

MR. LOECHLER: I'd first like to say I appreciate the opportunity to appear at this EPA hearing, on this important subject.

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My name is Dr. Edward L. Loechler, and I'm a Research Fellow in the Biology Department of the Massachusetts Institute of Technology, and my research interests lie in the area of the molecular mechanisms of toxicity. My concern for the environment has led me to testify here today in support, general support of your EPA Ambient Air Generic Carcinogen Standards.

Now, I have a testimony here that I'm going to forego a large part of it, in lieu of the time. What's basically in there are things that I think you are well aware of at this point.

I was going to support your efforts to use animal studies that are applicable to the human situation, and by and large, the evidence that I cite in here says that the animal studies are applicable to the human situation.

And, primarily, I refer to work by Tomatis at the IARC Working Group, for example. And, as a matter of fact, also, some of Dr. Albert's work, preliminary work on potencies in humans versus animals.

In summary, I'd like to say that in spite of the complications that have been alluded to between extrapolation between animals and humans -- for example, pharmacal-kinetic difference and metabolic differences. Animals seems to do pretty well as a model for the human

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situation.

I'll pick up on page 3. In summary, the results I've cited above suggest to me that animal experiments are efficaciously serving as human surrogates in cancer tests. It is true that in detail vast differences can exist between the response of animals and humans to carcinogens.

However, to answer the question, "does this chemical pose a human cancer risk," animal experiments are reliable.

The IARC Working Group recommended that in the absence of adequate data in humans it is reasonable, for practical purposes, to regard chemicals for which there is sufficienc evidence of carcinogenicity in animals, as if they presented a carcinogenic risk for humans.

Tomatis, himself, said, "There is really no justification to wait for the proof that a chemical causes cancer in man before measures to avoid exposure are taken.."

One lesson from history accentuates the need to consider animal studies in evaluating cancer causing substances.

In 1941, both diethylstilbesterol and 2-acetylaminofluorene were shown to be carcinogenic

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in animals. 2-AAF, developed as a pesticide, was banned based on this single animal experiment.

Although we will never know how many lives were saved or what benefits were lost from this ban, I think the general concensus was that the correct choice was made.

Diethylstilbesterol, on the other hand, wasn't banned. The result has been untold misery for many young women. In this case, the animal experiment was disregarded. And I think the concensus today would have been that the wrong choice was made as far as the animal experiments go.

I would also like to support your decision to require evidence from only a single well-conducted animal study. One positive study sufficiently demonstrate a chemical's carcinogenic potential. The delays involved in further confirmatory studies do seem unwarranted to me.

A comment about this, appropros of something that was mentioned earlier -- For example, something like formaldehyde is positive in rats and negative in mice, imagine a situation where in rats, let's say, in your hundred animals, you had 20 that showed some signs of getting cancer, and let's imagine that the potency is five-fold less in mice. You would get maybe

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four, and four is not statistically significant, so it would be scored as a negative, and yet it could very well be that formaldehyde was carcinogenic to mice, but you just couldn't pick it up.

So, this whole idea of negative results as meaning it isn't carcinogenic, it may very well just mean that the carcinogen is less potent in that particular species.

And for that reason, I think then, that you can say that perhaps the carcinogen is less potent or not the same potency in all species, but the rat data shows you that it is really, has the potential for being a carcinogen in humans.

This work, of course, has been done quite extensively by Bruce Ames and Kim Hooper.

I would like to make two additional brief comments. I also support your use of short-term tests, such as the Ames Test to help prioritize chemicals for animal tests and to help confirm the hazards suggested by animal tests.

In addition, I urge you to consider the issue other than cancer, raised by the Ames Test, namely the problem of exposure to environmental mutagens. Any chemical shown to be positive in the Ames Test and to which humans are exposed, should not be treated lightly,

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whether it is carcinogenic or not.

Finally, I support your desire to include the public in the process of controlling ambient air quality. In this regard, I believe community groups and/or citizens in an affected area should be notified when a potential problem is identified. This will allow them to evaluate for themselves how they are being affected and given them the opportunity to respond to the problem.

I know community groups may sometimes seem like they are a pain in the neck, but I think it's very important that they have the opportunity to decide for themselves if they feel like they are being exposed to an undue risk, and since it really is that group of people that you are trying to protect, I think that they have the right to participate in that decision.

I would say that I hope, in general, that these rules are passed, and that they are used prudently and I think that there should be rules of this sort in the EPA's docket to address these problems, if need be.

That's the end of my statement. I'll be happy to take questions.

THE CHAIRMAN: Any questions.

DR. ANDERSON: I have just one comment, just quickly, and this is along the same lines as the comment I made in response to earlier testimony, and

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that is, I think that it's incorrect to say the EPA is only requiring a single animal test. I think you would have bio-assay requirements under the Toxic Substances Act and the Pesticide Act. It's clear the Agency would like to see more evidence than that.

In the Interim Guidelines, we certainly consider everything we know about the chemical. On the other hand, if there is the single convincing animal study, and we don't know anything else, then that's certainly a conceivable basis.

But I just didn't want this to come across, again, as a single criteria, go look as hard as you can for one single test in the absence of any other consideration. It's just not the way we do business.

DR. LOECHLER: Right, but what I was supporting was, if somebody does a lousy mouse study, and somebody does a good rat study, you shouldn't regard the mice study very heavily, as I'm sure you won't.

DR. ANDERSON: Yes, I understand.

THE CHAIRMAN: Anything else?

(No response.)

Thank you, Dr. Loechler.

Is there anyone else who was listed as a speaker whom I failed to call?

If not, then, the meeting will be -- Oh, yes,

the Hearing record will remain open for thirty days from tomorrow, the 14th.

With no further speakers, then, I declare the meeting adjourned. We will hold a session in Houston tomorrow, to complete the public testimony on this proposed rule.

The meeting is adjourned.

(Whereupon the meeting was adjourned.)

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C E R T I F I C A T E

UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

This is to certify that the attached proceedings before the Environmental Protection Agency, RE: PROPOSED POLICY FOR REGULATING AIRBORNE CARCINOGENS held at Boston, Massachusetts, on Wednesday, March 12, 1980 consisting of 281 pages was held as herein appears and that this is tne original transcript thereof for the file of the Department.

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