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Organization Resources Counselors Inc.

Memorandum

February 21, 1984

TO: ORC Asbestos Task Force

From: Darrell K. Mattheis

Subject: Report of February 9, 1984 Task Force Meeting and Announcment of the next Task Force Meeting

Next Task Force Meeting

The next meeting of the Asbestos Task Force will be on March 26, 1984 at ORC Offices in Washington D.C. The meeting will begin at 1:00 pm and last to approximately 5:00 p.m.

Purpose of the February 9, 1984 Meeting

The Task Force met to decide what kind of a response should be made to the OSHA Notice of Proposed Rulemaking (Draft) that had previously been distributed.

Defining OSHA's Intent

The draft NPR is so vaguely worded that it is difficult to determine just what OSHA has in mind. The NPR rather than outlining what OSHA intends to do, asks for comments at every critical juncture, and says that final action will depend on the comments that it receives! This format gives the agency almost complete freedom of action to do what ever it wishes, since in addition to the comments that they already have, they will receive additional arguments on both sides of every question asked. This will enable OSHA to shape its response to meet the demands of the moment, rather than be locked into a clearly outlined position.

Given the fact that OSHA's risk assessment was developed with the assistance of Dr. Selikoff's group at Mount Sinai, and that labor, NIOSH and some environmental groups have pushed very hard for a PEL of 0.1 fibers/cc, it seems possible that with appropriate pressure, OSHA could be persuaded to lower the PEL to 0.1 fibers/cc.

NPR At OMB (EARLY MARCH PUBLICATION POSSIBLE)

At the moment, OSHA seems to be committed to a PEL of 0.5 fibers/cc with reasonable flexibility allowed for the use of respirators. OSHA sent an asbestos NPR to OMB on February 10, 1984, and it is said to be very similar to the early draft released to the Construction Advisory Committee. The draft sent to OMB discussed 0.5, 0.2 and . 0.1 fibers per/cc as a possible PEL. It is possible that the NPR will be published by the begining of March 1984, as OMB has seen it already, and it is being handled on an "expedited" basis.

What Should Our Strategy Be?

To be most effective, we must be positive in our comments. If we wish OSHA to continue to support a PEL of 0.5 fibers /cc, it is important that we give the agency positive comments designed to strengthen the 0.5 PEL.

This does not mean that we cannot be critical of the risk assessment or other assumptions made in the document. Indeed, it is imperative that we take care to point out (in a positive way) that because of the very conservative assumptions made in the risk estimate, the number of actual cases of disease that may result from exposure to asbestos fibers in the modern working environment is likely to be significantly smaller than those in OSHA's risk estimate.

The Task Force should concentrate on those elements of the NPR where we have good data, or where we know that OSHA is weak. This means that we need to respond to individual elements of the risk estimate as well as many of the specific questions that OSHA is asking.

Responding To The Risk Estimate

The first thing we need to do here is to carefully read the OSHA ETS, because it contains a much more detailed discussion of their risk estimate than the NPR. Additionally, I will obtain a copy of the risk estimate that OSHA entered into the record and make this available to those who request it.

Several elements of the risk estimate lend themselves to immediate analysis: (1) The assumption of 45 years of exposure, and (2) The assumed exposure to a given level of asbestos fibers, 8 hours a day, 5 days a week. The 45 year assumption, which is key, can be attacked on a number of basis, including the known turn-over-rate in a number of major industries. (3) The number of workers exposed to asbestos fibers at concentrations above 2 fibers/cc is small (found mainly in businesses making asbestos products) and rapidly declining. (4) The great majority of those occupationally exposed to asbestos fibers have quite low, intermittant exposure. (5) The number of industrial plants with significant amounts of installed asbestos is steadily declining with time.

We need to collect data on the turnover rate in individual jobs or industries, on the known exposures, the amount of disease that actually has resulted, and critiques of the studies that were used as the basis for OSHA's risk estimate, and the number of industrial plants remaining with significant amounts of installed asbestos, as well as their rate of removal.

A useful tool for our comments on the OSHA risk estimate is an affidavit of Dr. Kenny Sherman Crump concerning the OSHA ETS. I am including that document with this report.

Another area of concern is that of friction products, since one of the major remaining uses of asbestos is in the production, installation, repair and replacement of brake linings and clutch facings. We need to collect as much as possible of the pertinent data published in this area, and where it is available, unpublished data that would assist us in making our case.

Preparing Our Response

We should re-submit to OSHA, and wherever possible in our comments answer by reference to, the ORC Recommended Revision of 1910.1001.

In our comments to OSHA we need to present data showing that the actual, as opposed to calculated, hazard at 0.5 fibers/cc is small, and that with appropriate measures, personal exposure levels should be much lower than 0.5.

The comments should emphasize that in general industry, where most of the potential exposure to asbestos fibers exists, exposures are low, intermittent, often not feasible to engineer out, and that in any case the individual is protected through the use of personal protective equipment.

We need to make the point that in a practical sense, the quality of the protection received by the employee depends more on the quality of the safety and health program and its enforcement, than it does on setting a low PEL.

We need to find data to back up the point that for a high percentage of general industry exposure, the nature of the work being done makes the use of engineering controls almost impossible. Thus, most of the employees doing work where there is a potential for the release of asbestos fibers, will use a combination of work practices and respirators to prevent exposure to dangerous levels of asbestos fibers.

We need to make it clear that while we would like to keep the ambient levels of asbestos fibers as low as possible, it is often difficult to keep them below 0.5 while a job is being done. Thus the use of fit-tested, efficient respirators can and does reduce employee exposure far below 0.5 fibers/cc. We need to emphasize that it does not make sense to equate ambient air concentrations with employee exposure, and present data to back up that contention.

We need to comment on fiber type and industrial process as important determinents in the kind and amount of disease found among those exposed.

Our Time Is Limited!

We need to carefully read OSHA's ETS and NPR; Dr. Kenny Crump's affidavit, and we should look over the OTA paper. Then, as individuals, determine which of OSHA's questions we can best answer. We should begin this reading and selection process as early as possible, since once the NPR is published, we are only going to have 45 days to prepare and submit our written response.

What I Am Requesting

I would like to request that as you read over the questions that OSHA has asked, or as you contemplate the larger questions involved, you select a question or questions that you would feel comfortable answering, and write up your thoughts and bring them to the March 26 meeting of the task force. Once you have chosen a topic or question if you would give me a call to let me know what you have selected I would appreciate it. That way I can coordinate things so we have the most complete coverage of the questions.

OSHA's Questions

Begining on page 7 in the draft copy of their NPR OSHA lists 19 questions that cover, in a general way, the areas where they want some answers. These questions do not necessarily match those that OSHA asks in the course of the discussion. Thus it is important to carefully examine both sets of questions to determine what the agency really wants.

I have reproduced the initial 19 questions, (attached) and in the following, I list the questions OSHA asks in the course of the NPR discussion and the page they are on. I urge all to read the whole discussion however, because the intent of the questions becomes clearer in context.

Definitions

Page 28: "OSHA requests comments on how the nonasbestiforms or varieties of the mineral should be regulated. A change in definition would mean that the mineral fibers that are now regulated as asbestos under the OSHA standard would no longer be specifically regulated, but would rther fall into the nuisance dust category. OShA requests and encourages public coments on whether the mineralogic definition of asbestos fibers should be used in OSHA's definition for protecting worker health. OSHA requests comments on how mineral fibers that are not asbestos in the mineralogic sense should be regulated.

page 28: "Another issue concerning the definition of asbestos is whether asbestos which has been chemically treated or altered should be regulated the same as untreated or unaltered asbestos."

Page 29: "Public comment is requested regarding whether asbestos that has been chemically treated and/or altered should be regulated to the same extent as other forms of asbestos."

PERMISSIBLE EXPOSURE LEVELS

Page 32: "OSHA belives however, that a PEL lower than 0.5 fibers/cc maybe desirable to reduce risk for any fiber type if measurable, and OSHA is encouraged that the British appear to have had success with the 0.2 f/cc limits for certain fiber types. OSHA requests comments on whether the scientific evidence is sufficient to support differences in the asbestos standard for some fiber types and whether such differences are feasible."

ACTION LEVEL

Page 37: "Also, although OSHA recognizes the potential uncertainty of asbestos measurements at air concentrations below the proposed PEL, OSHA seeks comments on the question of whether measurement unreliability limits OSHA's ability to adopt an action level, and if so, how. Greater uncertainty may be tolerated at the action level than at the PEL. OSHA seeks comments on this issue." "OSHA requests comments on whether an action level should be adopted, and if so, what requirements it should trigger."

EXPOSURE MONITORING

Page 38 "OSHA requests data, information and comments concerning any changes that should be made in the monitoring provisions of the current asbestos standard. "

REGULATED AREAS

Page 39: "OSHA anticipates that the regulated areas may be established at the action level. OSHA requests comments on whether this is appropriate, and what additional activities should be required or prohibited in the regulated area."

METHODS OF COMPLIANCE

Page 41: "OSHA solicits comments concerning the methods of compliance. The agency is particularly interested in receiving comments, information, data and other evidence concerning the extent to which respirators may provide effective protection against asbestos exposure and may be relied upon as a substitute for engineering or work practice controls."

Page 42: As an alternative to proposing a flexible compliance requirement for all asbestos workplaces, OSHA is considering a limited exemption from an engineering control requirement for intermittent exposure situations." "OSHA requests comments regarding the application of an exemption from engineering controls for intermittent exposures to asbestos and how it can be applied to the types of exposures in the affected industries." " In any case OSHA intends to maintain the existing requirement for engineering controls to reduce exposures to 2 f/cc. This will prevent massive release of asbestos fiber in the working environment."

PERSONAL PROTECTIVE EQUIPMENT

Page 44-45: "OSHA believes that advances in work practices since 1972 have reduced exposure levels in these operations

and therefore always requiring Type "C" supplied air respirators may no longer be necessary in all cases. OSHA is also considering whether other types of respirators should be required for this type of work. For example, powered air purifying respirators have become widely available since 1972 and may suffice under present conditions in the workplace. OSHA recognizes, also, that a reduction in the PEL will result in requiring improved respirator types at lower ambient air levels. OSHA requests information and comments regarding this issue and, in particular, whether it is practical to require the use of supplied air respirators.

MEDICAL SURVEILLANCE PROGRAM

Page 47: "Although the current standard lacks clarity, by administrative interpretation and judicial decision, the medical surveillance provisions are not triggered at the 0.1 f/cc level. Included for discussion are whether:"

(a) "The action level concept is appropriate for medical surveillance and what action level should apply;

(b) The frequency of chest x-ray examinations should be decreased for young employees or employees with short duration exposures.

(c) There should be a clarification of the time within which the employer must conduct preplacement examinations after hiring employees;

(d) There should be any additional tests or procedures (such as use of questionnaires) for the purposes of early diagnosis of any disease, including asbestosis; and

(e) There should be screening tests for colo-rectal cancer such as tests for occult blood in the feces; and (f) Only "B readers" should interpret x-rays.

METHODS OF MEASUREMENT

Page 49-50: "One issue raised in the record to date is whether phase contrast microscopy analysis is capable of reliable measuring airborne concentrations of 0.5 fibers/cc and less." " It may be possible that phase contrast microscopy errors can be reduced if improved and standardized procedures are followed, perhaps by adding requirements to the standard."

"In revisions to the permanent asbestos standard, OSHA may, therefore, mandate technical training, laboratory certification, and laboratory participation in a round robin testing program. OSHA may require that laboratories receive passing grades in the program. Finally, OSHA is considering adopting verbatim or with modifications, the NIOSH analytical procedure (Ex. 84-62), the procedures recommended by the AIA (Ex. 86-002), or procedures of the kind described by Chatfield (Ex. 84-319)."

"Comments on this issue and on regulatory language to be used in these provisions are requested. OSHA also requests technical comments on which analytical procedure provides the best results and whether OSHA should specify the procedure in the revised asbestos standard."

Page 51-53: "OSHA also has considered whether other analytical methods, in particular electron microscope analysis, should replace phase contrast microscopy as the required method for measuring airborne concentrations of asbestos. At this time, OSHA believes that it is not practical or necessary to modify its standard to require electron microscopy analysis instead of phase contrast light microscopy."

"OSHA requests information relating to the relative merits of the electron microscopy and phase contrast microscope methods, and to the feasibility and appropriateness of other methods of measurement for airborne asbestos fibers. OSHA also requests data on the statistical limits of measurements at the 0.5 f/cc, 0.2 f/cc and 0.1 f/cc levels and comments on whether OSHA should choose an action level which is more uncertain in terms of measurement than the PEL."

CLOSING COMMENTS:

These are the main questions OSHA is asking in the body of its DRAFT NPR. These questions, plus those listed initially represent a lot of work if we try to answer all of them, but I do not think we can answer them all in the time available. Again I want to remind you that we may see the NPR published by the beginning of March 1984.

Darrell K. Matthies

DKM/dm

005497

CONFIDENTIAL

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

In re EMERGENCY TEMPORARY STANDARD FOR OCCUPATIONAL EXPOSURE TO ASBESTOS	OSHA Docket No. H-033C

AFFIDAVIT OF DR. KENNY SHERMAN CRUMP

Kenny Sherman Crump, being first duly sworn deposes and says:

1. I am an expert in biostatistics and quantitative risk assessment. As further detailed in my attached curriculum vitae (Attachment 1), I have extensive education and experience in critiquing and performing quantitative risk assessments. I earned a Ph.D. in mathematics from Montana State University in 1968, and was a Professor of Mathematics from 1966 to 1980 at Louisiana Tech University. In 1974 and 1975 I was a visting scientist at the National Institute of Environmental Health Sciences (NIEHS). Since 1978, I have been the President of Science Research Systems, Inc., in Ruston, Louisiana.

2. Since 1968 I have authored numerous articles in refereed scientific publications, as listed in my curriculum

vitae, particularly on issues relating to quantitative risk assessment. I have consulted for and prepared reports for many Government agencies, including NIEHS, the Environmental Protection Agency, the Council on Environmental Quality, and the Congressional Office of Technology Assessment, as well as for a number of private industry groups. I have been a member of National Academy of Science panels, including the panel that earlier this year issued the report, "Risk Assessment in the Federal Government: Managing the Process" (OSHA Ex. 84-322).

3. Most recently, I have developed several quantitative risk assessments for the Occupational Safety and Health Administration (OSHA). I conducted a risk assessment for OSHA on workplace arsenic exposure in 1982 and testified for OSHA at its hearings conducted as part of its rulemaking to establish an arsenic standard. I performed a comparable role for OSHA in its 1983 proceedings to regulate ethylene oxide.

4. I have become thoroughly acquainted with the evidence on health risks associated with asbestos exposures over the past four years. As a result of my review of the animal and human studies of asbestos exposures, I was asked by the Asbestos Information Association/North America (AIA/NA) to testify on quantitative risk assessment of asbestos in August 1981 before the Royal Commission on Asbestos of the province of Ontario, Canada (OSHA Ex. 85-22).

5. I have reviewed OSHA's asbestos ETS Federal Register notice and its underlying quantitative risk assessments (OSHA Exs. 84-1, 84-349, 84-392), as well as other asbestos risk assessments made for the government of the United Kingdom (OSHA Exs. 84-216 and 84-243) and the Consumer Product Safety Commission (Ex. 84-256).

I. The Nature of Quantitative Risk Assessment

6. Quantitative risk assessment is inherently uncertain. As the NAS Committee on Risk Assessment on which I served wrote: "The dominant analytic difficulty of [risk assessment] is pervasive uncertainty." (OSHA Ex. 84-322, at 11).

7. In describing the many uncertainties of quantitative risk assessment, the NAS Committee listed a number of assumptions that are particularly relevant to risk assesments of asbestos. For example, in dose-response assessment, the NAS Committee lists the need to determine, inter alia, (a) "what dose-response models should be used to extrapolate from observed doses to relevant doses," (b) "how should exposures to other carcinogens, such as cigarette smoke, be taken into consideration," and (c) "how should one deal with different temporal exposure patterns in the study population and in the population for which risk estimates are required." (OSHA Ex. 84-322, at 31). An additional crucial determination

is what were the levels of exposure in the study populations. In assessing current exposures, the same crucial determination must be made, namely, as phrased in the NAS report, "how should one estimate the size and nature of the populations likely to be exposed." (OSHA Ex. 84-322, at 32).

8. The uncertainties inherent in quantitative risk assessment are particularly severe when one attempts to assess the risk of a small segment of total human exposure. For example, quantitative estimates of the risk to individuals from a lifetime of smoking cigarettes involve uncertainties, but even greater uncertainty exists if one attempts to assess the risk of smoking one cigarette, or the change in overall lifetime smoking risks for abstaining from smoking for a short period. Similarly, numerous uncertainties exist in assessing risks from lifetime exposure to asbestos; even greater uncertainty exists in estimating the risk of the contribution of one six month's asbestos exposure during a working lifetime, or the change in overall lifetime risks from reducing asbestos exposures during any given six month period.

9. Because of the many uncertainties in quantitative risk assessment, the NAS Panel on which I served recommended any "agency's risk assessment should be reviewed by an independent science advisory panel before any major regulatory action or decision not to regulate." (OSHA Ex. 84-322, at 156).

10. The NAS Committee envisioned that the public would be given an opportunity to nominate persons to serve on such a panel and that the panel would then subject the assessment to "such scrutiny as the members find necessary to satisfy themselves that it i . . as complete and objective as available data permit." The panel then "should provide a written evaluation of the agency's risk assessment." (OSHA Ex. 84-322, at 157-58). The NAS report further recommends that the agency "should discuss any important criticisms of its [risk] assessment in its proposed regulatory action . . ." (OSHA Ex 84-322, at 159).

11. In the absence of an independent peer review panel's scrutiny of agency risk assessments, as called for by the NAS Committee, some aspects of quantitative risk assessment can be explored effectively through rulemaking and hearing procedures conducted after an agency proposal is made. For example, determination of exposures of workers both in the studied populations, and among current workers, can often be effectively assessed through reports from and testimony of the scientists who conducted the studies of past exposures and of industrial hygiene personnel who are familiar with current exposure levels in the workplace. Absent a peer review panel as envisioned by the NAS Committee, these review procedures can be effected through agency hearings.

III. The Assumptions in OSHA's Asbestos Quantitative Risk Assessment

12. In estimating health risks from exposure to asbestos fibers, OSHA makes a number of assumptions which are open to question. These include:

(a) OSHA assumes that there is a linear relationship between asbestos exposures (in terms of both intensity and duration) and health effects at exposure levels as low as 2 fibers/cc for as short a time as six months.

(b) OSHA assumes that estimates of exposures in two of the studies on which OSHA relies are valid even though no exposure information was collected on the workers whose health effects were examined in those studies (i.e., the Selikoff and Seidman studies, OSHA Exs. 84-90 and 84-87). OSHA estimates exposures for the workers studied by Seidman, who were in a plant in Paterson, New Jersey, during World War II, based on measurements in two other plants, which OSHA states "manufactured the same products with similar fiber and machinery," which measurements were made 21 to 31 years later at these other plants in Texas and Pennsylvania (Ex. 84-392, at 26-27). I know of no other instance in which regulators have relied on quantitative risk assessment based on studies for

which exposures among the studied workers are equated to exposures in other plants 25 or more years later.

(c) OSHA assumes that estimated exposures in the remaining studies on which OSHA relied are accurate despite being based upon very limited data, and despite numerous changes in the exposure measurement techniques which have occurred over the years. As OSHA itself states: "Exposure data frequently are not available for workers exposed before 1970. Where historical exposure data are available, the data often have such limitations as having been collected and analyzed using industrial hygiene techniques no longer in use or having been collected in only some areas of the worksite or having been collected on only a few occasions. Therefore, of necessity, estimates of dose-response based on epidemiologic studies will have a fairly broad range of uncertainty." (48 Fed. Reg. at 51100). Prior to the 1960's most asbestos measurements were in terms of particles (of any substance) rather than in terms of fibers. The graticule grid method of counting fibers used today gives different fiber counts than the previously used whole field counting method. Also, many of the older fiber counts were made using samplers fixed

in place and those measurements can be quite different from those obtained from personal samplers, which OSHA will use to enforce the ETS (Ex. 84-216). Consequently, both the very limited amount of exposure data available from early periods (when exposures were highest) plus the changes in measurement techniques imply that there is considerable uncertainty associated with the exposure estimates used by OSHA to derive quantitative risk estimated.

(d) OSHA assumes that no distinctions in risk should be made for different types of asbestos or different types of asbestos operations.

(e) OSHA assumes that each of the eleven studies relied upon in OSHA's risk assessment should be accorded equal reliability and weight in determining a best estimate of quantitative risk.

(f) OSHA assumes that the eleven studies upon which OSHA relies to predict lung cancer risks are the appropriate studies upon which to rely in estimating asbestos lung cancer risks.

(g) OSHA assumes that the four studies upon which OSHA relies to predict mesothelioma risks are the appropriate studies upon which to rely in estimating mesothelioma asbestos risks.

(h) OSHA assumes that risks estimated from historical populations are extrapolatable to modern

workers despite differences in lifestyle, smoking habits, etc.

Each of these assumptions is subject to considerable dispute in the scientific community. Were any of these assumptions altered, they could significantly affect OSHA's quantitative risk assessment and thus its prediction of the benefits of the emergency standard. The following two paragraphs contain examples of two of many assumptions made by OSHA which have been called into question, and which could have a significant impact upon their risk estimate.

13. OSHA's predictions of mesothelioma risk are derived from only 4 of the 11 studies used to develop lung cancer risks. In the remaining 7 studies very few mesotheliomas were observed. Consequently, OSHA's estimates for mesothelioma come only from studies that show relatively high risks. Although OSHA made an adjustment to account for this bias, it is by no means clear that this adjustment was adequate. In the Dement study (Ex. 84-35) which OSHA did not use to estimate mesothelioma risk, 19.5 excess lung cancers were discovered and only 1 mesothelioma. By way of contrast, in the Selikoff et al. study, (Ex. 84-90) which OSHA did use, there were 323 excess lung cancers and 104 mesotheliomas, based upon death certificate data. This suggests that the fibers in the Dement study were only (1/19.5)/(104/323) = 0.16 as potent in producing mesotheliomas as in producing lung

cancers, relative to the fibers in the Selikoff study. Since the carcinogenic potencies for lung cancer estimated by OSHA were $K_L = 0.020$ for the Selikoff study and $K_L = 0.042$ for the Dement study and the potency for mesothelioma from the Selikoff study was $K_M = 1.5 \times 10^{-8}$, this suggests a potency for mesothelioma in the Dement study of $K_M = (0.16)(0.042)/(0.020)(1.5 \times 10^{-8}) = 5.0 \times 10^{-9}$. This value is smaller than any of the four potencies for mesothelioma estimated by OSHA and is one-half the K_M value used in OSHA's risk assessment to predict mesothelioma deaths.

14. There are also many assumptions used in analyzing the individual studies which could be questioned. For example, for the Peto study (Ex. 84-169), OSHA calculated values of K_L of 0.0076 and 0.00091 for pre-1950 and post-1950 groups, respectively (Ex. 84-392). However, rather than combining these estimates, OSHA took the larger value of 0.0076 as their estimate of K_L (48 Fed. Reg. at 51127), which is about eight times larger than the post-1951 group value.

15. OSHA makes a significant omission in its risk assessment by failing to distinguish lung cancer risks for workers who do and do not smoke. OSHA acknowledges the association between smoking and lung cancer among asbestos workers and notes that risks from asbestos exposure are approximately ten times higher for smokers than for non-smokers, 48 Fed. Reg. at 51108. However, OSHA's quantitative risk assessment does not calculate the resultant

ten-fold difference in lung cancer risks for smokers and non-smokers.

III. Comparisons with Risks Predicted by OSHA in Other Proceedings Where Emergency Standards Have Not Issued

16. I am familiar with, indeed I myself developed in some cases, quantitative risk assessments upon which OSHA has relied in regulatory proceedings on other substances. In several of those proceedings, OSHA's estimates of the risks at the then-existing permissible exposure levels for each substance have been significantly higher than its estimates of risk for asbestos at the existing 2 fiber/cc standard. Yet, in none of these cases has OSHA issued an emergency temporary standard.

17. OSHA's best estimate of lifetime cancer risks for asbestos workers exposed to 2 fibers/cc is 64/1000, 48 Fed. Reg. at 51089. By contrast, OSHA followed its normal rule-making procedures with respect to arsenic despite a best estimate of lifetime lung cancer risk at the existing 500 $\mu g/m^3$ standard of 375 to 465/1000. See the arsenic preamble, 44 Fed. Reg. at 15360 (April 9, 1982).

18. Likewise, in its advanced notice of proposed rulemaking on ethylene dibromide, a substance for which OSHA denied an ETS request (OSHA Ex. 84-282), OSHA noted that an excess cancer risk of 400/1000 had been predicted at the existing permissible exposure level. 46 Fed. Reg. at 61674

(Dec. 18, 1981). This risk is nearly seven times higher than the risks OSHA estimates for asbestos exposure at the current standard.

19. Similarly, OSHA denied a petition to issue an ETS for ethylene oxide (OSHA Ex. 84-283), even though it estimated an excess cancer risk of from 63/1000 to 152/1000 from lifetime occupational exposure at the then-existing OSHA standard of 50 ppm. 48 Fed. Reg. at 17293. The population exposed to ethylene oxide is comparable in size to that OSHA estimates to be exposed to asbestos. OSHA estimated 80,000 workers directly exposed, and 144,000 indirectly exposed to ethylene oxide, 48 Fed. 17297, as compared to 375,399 exposed to asbestos with only 48,644 exposed above the ETS of 0.5 fibers/cc, 48 Fed. Reg. at 51094.

IV. The Absence of New Evidence in OSHA's Asbestos Risk Agreement

20. Besides estimating risks lower than on other substances where an ETS was rejected, OSHA's asbestos risk assessment does not rely on any new data.

21. As is typical of most assessments of asbestos that seek to determine the quantitative risks of various exposures (in terms of both intensity and duration), OSHA's risk assessment is based on the findings of a number of worker mortality epidemiology studies (i.e., studies that compare

the mortality experience among groups of workers exposed to asbestos to the mortality experience among some segment of the general population).

22. All eleven of the epidemiology studies on which OSHA relies in its quantitative risk assessment, as listed at 48 Fed. Reg. 51124, have been available for review for more than two years. Several, although more recently updated, were first published in the 1960's and early 1970's (e.g., the Selikoff, Ex. 84-90; McDonald-Liddell, Ex. 84-65; and Enterline, Ex. 84-48 studies). Most of the eleven studies were published between 1975 and 1980. The results of only three of the eleven studies relied on by OSHA (i.e., the Finkelstein, Ex. 84-240, Dement, Ex. 84-35, and Berry and Newhouse, Ex. 84-21, studies) were published since 1980, but each of those study's results were widely circulated in scientific and regulatory circles by the summer of 1981.

23. In sum, the risks predicted by OSHA are not premised on new evidence; rather, the results of all the studies have been available for review and quantitative risk assessment for more than two years.

V. The Absence of Direct Evidence that OSHA's ETS Will Provide Health Benefits

24. In its Federal Register notice, OSHA asserts that health benefits will be achieved if exposures to asbestos are lowered over the next six months, because of its emergency

standard, from 2.0 to 0.5 fibers/cubic centimeter (cc), 48 Fed. Reg. at 51089-90. OSHA's assertion is premised on a number of assumptions, as enumerated in ¶ 12. None of the studies on which it relies found increased risks of asbestos-related deaths among workers exposed at such low levels for such a short period of time.

25. As OSHA itself notes (48 Fed. Reg. at 51100), in each of the eleven studies upon what it relies workers were exposed to asbestos at levels considerably above the current standard of 2 fibers/cc. For example, OSHA estimates that exposures in the Selikoff study of asbestos insulators ranged from 10 to 40 fibers/cc (Ex. 84-392, at 25), and exposure of amosite insulation manufacturers in the Seidman study averaged 35 fibers/cc (Ex. 84-392, at 28). Although lower average exposures were estimated for some workers in other studies, none of the studies provide OSHA with risk estimates based on workers exposed at levels of 2 fibers/cc or less.

26. OSHA assumes, in its prediction that benefits will be achieved by lowering the permissible exposure level, that cumulative exposures achieved at the low exposure levels prevalent in the workplace today are equal to cumulative exposures of workers obtained at much higher fiber concentrations in the past. It appears that it is not possible to verify directly this assumption. As OSHA states, 48 Fed.

Reg. at 51101: "At this time, it does not appear possible to determine whether intensity of exposure has an effect on disease separate from that of cumulative exposure."

27. In other words, OSHA has found no evidence on which to rely in supporting its assumption that cumulative exposures, from exposure at 1 fiber/cc for twenty years pose as much risk as exposures in the past to 20 fibers/cc for one year. None of the studies on which OSHA says it relies demonstrate directly that there is increased risk for workers who would be exposed to 1 fiber/cc-year, the cumulative exposure that would be achieved over the next six months at average exposures of 2.0 fibers/cc.

VI. An Apparent Miscalculation in OSHA's Risk Assessment

28. I have reviewed Tables 1, 3, 4 and 11 in OSHA's ETS notice, 48 Fed. Reg. at 51093-94, 51096, 51097, 51129. Table 4 is labeled "Cancer Deaths Avoided with a 0.5 ETS Assuming Compliance with the 2 f/cc Standard." This table assumes that all workers are currently exposed at no more than the 2.0 fibers/cc standard. It thus determines what additional benefits OSHA calculates would be gained by reducing all worker exposures to the 0.5 fibers/cc ETS level.

29. Table 4 is based on OSHA's estimates of current exposure levels in Table 1 and its estimates of cancer risks

for various exposure levels and durations of exposures in Table 11.

30. Based on Tables 1 and 11, I am able to calculate the same numbers in Table 4 as does OSHA, except for the category construction workers. That is, OSHA calculates, in the first column of Table 4, that 57 construction worker lives will be saved by reducing exposures for six months from 2.0 fibers/cc to 0.5 fibers/cc. Using the same method of calculation I used to reconstruct the Table 4 numbers for other worker categories, I calculated that the number of construction worker lives saved over 6 months is 17, rather than 57 as reported by OSHA. I performed the following calculations for the three categories of construction workers currently said by OSHA to be exposed above 0.5 fibers/cc:

A/C pipe workers:	[5,458 workers] x [.5 years] x [the one year risk at 1 f/cc minus the one year risk at 0.5 f/cc, namely (111-74)/100,000] = 1.0 life.
A/C sheet workers:	[1,765 workers] x [.5 years] x [the one year risk at 2 f/cc minus the one year risk at 0.5 f/cc, namely (296-74)/ 100,000] = 1.9 lives.
Drywall removal, demolition, and renovation workers:	[12,955 workers] x [.5 years] x [the one year risk at 2.0 f/cc minus the one year risk at 0.5 f/cc, namely (297-74)/ 100,000] = 14.3 lives.

Thus, 1.0 + 1.9 + 14.3 = 17.2, or rounded off, 17.

31. Similar errors appear to exist in OSHA's calculation in Table 4 of construction workers lives saved for 1 year, 20 year, and 45 year exposure reductions from 2.0 to 0.5 fibers/cc.

32. After correcting OSHA's apparent error in the number of lives saved among construction workers by reducing exposures from 2.0 fibers/cc to 0.5 fibers/cc (i.e., 17 lives rather than OSHA's 57), the assumptions used by OSHA imply that the total number of lives saved in Table 4 over a six-month period is 40, rather than the 80 reported at the bottom of the first column of that Table by OSHA.

33. Although even the figure of 40 lives is subject to doubt because of the doubtful assumptions used in deriving it, finding of this apparent error reinforces the premise that the OSHA risk assessment could benefit from careful review such as might be obtained in a formal OSHA hearing.

34. In Table 3, OSHA calculates that 210 lives would be saved over a six-month period if all worker exposures were lowered from their current levels to the 0.5 ETS level. As determined in paragraph 32 above, 40 of those 210 lives are the lives saved by reducing exposures from 2.0 fibers/cc to 0.5 fibers/cc. Therefore, 170 of the 210 predicted saved lives (210-40), or 81% of OSHA's claimed benefits of reducing the standard to 0.5 fibers/cc, would be achieved if all workers' exposures were in compliance with the pre-existing 2.0 fiber standard.

Ruston

Louisiana

Dr. Kenny S. Crump, being first duly sworn, deposes and says that all facts contained in the foregoing affidavit are true and correct to the best of his knowledge, information and belief.

Kenny S. Crump
Kenny S. Crump

Subscribed and sworn before me
this 11th day of November, 1983

M. L. VanHeusen
Notary Public

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CONFIDENTIAL

CURRICULUM VITAE

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Date of Birth	October 13, 1939
Place of Birth	Haynesville, Louisiana
Marital Status	Married
Children	Three

Education

1961	B.S. Electrical Engineering	Louisiana Tech University
1963	M.A. Mathematics	University of Denver
1968	Ph.D. Mathematics	Montana State University

Honors

B.S. cum laude, Omicron Delta Kappa, Phi Kappa Phi, Tau Beta Pi, Eta Kappa Nu, Who's Who in American Colleges and Universities, Engineering Honor Freshman, Louisiana Tech Sigma Xi Research Award-1977, Sigma Pi Sigma.

Research Interests

Application of statistics and stochastic processes to problems in biology and health.
Methodology for assessment of effects upon human health from environmental exposures.

Professional Society Memberships

American Association for the Advancement of Science
American Statistical Association
Biometric Society
Institute of Mathematical Statistics
Sigma Xi, The Scientific Research Society of North America
Society for Epidemiologic Research
Society for Risk Analysis
Society for Mathematical Biology

Professional Experience

1961-1963	Research Associate, Denver Research Institute
1963-1966	Instructor of Mathematics, Montana State University
1966-1980	Professor of Mathematics and Statistics, Louisiana Tech University
1967-1968	Research Associate, Department of Statistics, State University of New York at Buffalo (on leave)

Professional Experience (continued)

1969 (summer)	Research participant, Statistics group, Mathematics Section, Oak Ridge National Laboratory, Tennessee
1974-1975	Visiting Scientist, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina (on leave)
1978-present	President, Science Research Systems, Inc. Ruston, Louisiana

Committees and Offices

1976-1979 Officer, Louisiana Chapter American Statistical Association

Secretary-Treasurer	1976-1977
Vice-President	1977-1978
President	1978-1979

1978-1979 United States Congress Office of Technology Assessment; member of Tolerance Advisory Panel-Environmental Contaminants in Food.

1979-1980 National Academy of Sciences; member of Diesel Impacts Study Committee and Panel on the Health Effects of Diesel Emissions.

1980-1983 American Statistical Association; member of Committee on Statistics and the Environment

1981-1982 National Academy of Sciences; member of Committee on Institutional Means for the Assessment of Risks to Public Health

Selected Testimony

Royal Commission on Matters of Health and Safety Arising From the Use of Asbestos in Ontario August 13, 1981 (presented findings resulting from review of asbestos health effect literature, critiques of risk assessments carried out by other investigators, and independent risk calculations.)

Congress of the United States, House of Representatives, Committee on Science and Technology May 20, 1982 (reviewed EPA's carcinogenic risk assessment on formaldehyde.)

Occupational Safety and Health Administration Hearing on Exposure to Inorganic Arsenic, June 18, 1982 (critiqued quantitative risk assessments and presented independent findings.)

Areas of Consulting Experience

Environmental Statistics
Bioassay Statistical Design and Analysis
Environmental Epidemiology
Cancer Epidemiology
Health Risk Assessment (especially cancer)

Publications in Refereed Journals

1. Crump, K. S. and Mode, C. J. (1968). A general age-dependent branching process I. Journal of Mathematical Analysis and Applications 24, 494-508.

2. Crump, K. S. and Mode, C. J. (1969). A general age-dependent branching process II. Journal of Mathematical Analysis and Application 25, No. 1, 8-17.

3. Crump, K. S. and Mode, C. J. (1969). A branching process with correlations among siblings. Journal of Applied Probability 6, 205-210.

4. Crump, K. S. (1970). On systems of renewal equations. Journal of Mathematical Analysis and Applications 30, No. 2., 425-434.

5. Crump, K. S. (1970). On systems at renewal equations: The reducible case. Journal of Mathematical Analysis and Applications 30, No. 3, 517-528.

6. Crump, K. S. (1970). Migratory populations in branching processes. Journal of Applied Probability 7, 565-572.

7. Crump, K. S. and Hoel, D. G. (1970). Some applications for renewal theory on the whole line. Journal of Applied Probability 7, 734-746.

8. Crump, K. S. and Howe, R. B. (1972). Nonparametric estimation of the age of a Galton-Watson branching process. Biometrika 59, 533-538.

9. Hoel, D. G. and Crump, K. S. (1974). Estimating the generation-time of an age-dependent branching process. Biometrics 30, 125-235.

10. Crump, K. S. and Hoel, D. G. (1974). Mathematical models for estimating mutation rates in cell populations. Biometrika 61, 237-252.

11. Crump, K. S. and Howe, R. B. (1974). Estimation of the age of a Bellman-Harris branching process. Mathematical Biosciences 19, 175-184.

12. Crump, K. S. (1975). On point processes having an order statistic structure. Sankhya 37, Series A, 396-404.

13. Crump, K. S. (1976). Numerical inversion of Laplace transforms using a Fourier series approximation. Journal of the Association for Computing Machinery 23, 89-96.

14. Crump, K. S., Hoel, D. G., Langley, C. H. and Peto, R. (1976). Fundamental carcinogenic processes and their implications to low dose risk assessment. Cancer Research 36, 2973-2979.

15. Crump, K. S. and Gillespie, J. H. (1976). The dispersion of a neutral allele considered as a branching process. Journal of Applied Probability 13, 208-218.

Publications in Refereed Journals (continued)

16. Crump, K. S. (1976). A birth-death-migration solution to the geographical distribution of a neutral allele in a continuous finite habitat. Mathematical Biosciences 30, 159-167.

17. Guess, H. A. and Crump, K. S. (1976). Low-dose extrapolation of data from animal carcinogenesis experiments--analysis of a new statistical technique. Mathematical Biosciences 32, 15-36.

18. Crump, K. S. (1977). Mathematical models for mutations in cultures of diploid cells. Mathematical Biosciences 33, 177-188.

19. Crump, K. S., Guess, H. A. and Deal, K. L. (1977). Confidence intervals and tests of hypotheses inferred from animal carcinogenicity data. Biometrics 33, No. 2, 437-451.

20. Crump, K. S. and Gillespie, J. H. (1977). The geographical distribution of a neutral allele. Theoretical Population Biology 12, 10-20.

21. Guess, H. A., Crump, K. S. and Peto, R. (1977). Uncertainty estimates for low-dose extrapolations of animal carcinogenicity data. Cancer Research 37, 3475-3483.

22. Guess, H. A. and Crump, K. S. (1978). Maximum likelihood estimation of dose-response functions subject to absolutely monotonic constraints. Annals of Statistics 6, No. 1, 101-111.

23. Garner, J. B., Crump, K. S., and Stephenson, J. L. (1978). Transient behavior to the single loop solute cycling model of the renal medulla. Bulletin of Mathematical Biology 40, 273-300.

24. Crump, K. S. (1977). Open Query: Theoretical Problems in the modified Mantel-Bryan procedure. Biometrics 33, 752-755.

25. Crump, K. S. and O'Young, W. C. (1979). Some stochastic features of bacterial constant growth apparatus. Bulletin of Mathematical Biology 41, 56-66.

26. Crump, K. S. (1978). Low-dose extrapolations of animal carcinogenicity data (reply to the letter of Nathan Mantel). Cancer Research 38, (June issue).

27. Crump, K. S. (1978). Models for carcinogenic risk assessment (Technical Comment), Science 202, 1106.

28. Crump, K. S. (1979). Dose response problems in carcinogenesis. Biometrics 35, 157-168.

29. Daffer, P. Z., Crump, K. S., and Masterman. M. D. (1980). Asymptotic theory for analyzing dose response survival data with application to the low-dose extrapolation problem. Mathematical Biosciences 50, 207-230.

Publications in Refereed Journals (continued)

30. Crump, K. S. (1981). An improved procedure for low-dose carcinogenic risk assessment from animal data. Journal of Environmental Pathology and Toxocology, Vol. 5, No. 2, 675-684.

31. Crump, K. S. (1982). Designs for discriminating between binary dose response models with applications to animal carcinogenicity experiments. Communications in Statistics, 11(4), 375-393.

32. Crump, K. S. and Sims, S. E. (1982). The quantitative effect of migration upon geographic studies. (submitted).

33. Krewski, D., Crump, K. S., Farmer, J., Gaylor, D. W., Howe, R. B., Portier, C., Salsburg, D., Sielken, R. L., and Van Ryzin, J. (1982). A comparison of statistical methods for low-dose extrapolation utilizing time-to-tumour data. Fundamental and Applied Toxicology (Proceedings of the Workshop on Biological and Statistical Implications of the ED_{01} Study and Related Data Bases) (to appear).

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35. Crump, K. S. (1983). Ranking carcinogens for regulation (letter to the editor). Science, 219:4582, 236-238.

36. Crump, K. S. and Howe, R. B. (1983). The multistage model with a time-dependent dose pattern: Applications to carcinogenic risk assessment. (submitted)

Other Publications, Reports, Etc.

1. Johnson, A. M. and Crump, K. S. (1976). Transient solution of a solute cycling model of the renal medulla using Laplace transforms. Proceedings of the 1976 Summer Simulation Conference, 460-463.

2. Guess, H. A. and Crump, K. S. (1977). Best-estimate low-dose extrapolation of carcinogenicity data. Environmental Health Perspectives 22, 149-152.

3. Guess, H. A. and Crump, K. S. (1977). Can we use animal experiments to estimate 'safe' doses for chemical carcinogens? Environmental Health: Quantitative Methods: 13-30. SIAM, Philadelphia (ed. by Alice Whittmore).

4. Langley, C. H. and Crump, K. S. (1977). Possible advantages and disadvantages of nontransmitted single-cell human mutagenesis assays. Zentrallaboratarium fur Mutagenitatsprufung (Conference on population monitoring methods for detecting increased mutation rates, 1976), 83-85.

5. Crump, K. S. (1978). Estimates of Risks to Humans from Chemical Residues in Meat. Prepared for the United States Congress Office of Technology Assessment.

6. Crump, K. S. (1978). Estimation of Mean Pesticide Concentrations When Observations are Detected Below the Quantification Limit. Prepared for Food and Drug Administration.

7. Crump, K. S. (1977). Experimental Design. Proceedings of the Conference on TSCA Carcinogenicity Testing Methods, 140-141 (sponsored by National Center for Toxicological Research) Little Rock, Ark., Aug. 22-23.

8. Cohen, A. C. and Crump, K. S. (1978). Statistical Analysis of Radionuclide Levels in Food Commodities. Prepared for the Food and Drug Administration.

9. Crump, K. S. and Masterman, M. D. (1979). Assessment of Carcinogenic Risks from PCBs in Food. Prepared for the United States Congress Office of Technology Assessment. In: Environmental Contaminants in Food, Vol. II - Working Papers (available from NTIS).

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16. Crump, K. S. (1980). Evaluation of Uncertainties in the Estimation of Carcinogenic Risks. Prepared for the American Petroleum Institute, 46 pages.

17. Crump, K. S. and Howe, R. B. (1980). Carcinogenic, Mutagenic and Teratogenic Risk Assessment: An Annotated Bibliography. Prepared for the Environmental Protection Agency under Contract 68-01-5975, 30 pages.

18. Crump, K. S. and Howe, R. B. (1980). Approaches to Carcinogenic, Mutagenic and Teratogenic Risk Assessment. U. S. Environmental Protection Agency, Contract No. 68-01-5975, Task A, Subtask NO. 5 Summary Report, 169 pages.

19. Crump, K. S. (1980). Carcinogen-based Criteria: Assessment of Uncertainties. Proceedings of Symposium on the Development, Use and Value of Water Quality Criteria and Standards, George Washington University, June 23-25, 1980, 18 pages.

20. Crump, K. S. and Guess, H. A. (1980). Drinking Water and Cancer: Review of Recent Findings and Assessment of Risks. Executive Office of the President, Council on Environmental Quality, Washington, D. C. Contract No. EQ10AC018, 109 pages.

21. Nisbet, I. C. T., Crump, K. S., Paxton, M. B. and Turim, J. (1980). Carcinogenic Risk Assessment for Hexachlorobenzene. Prepared for the U. S. Environmental Protection Agency, Contract No. 68-01-5824, 87 pages.

22. Crump, K. S. and Guess, H. A. (1982). Drinking water and cancer. In: (L. Breslow, J. E. Fielding and L. B. Lave, eds.) Annual Review of Public Health Vol. 3, pp. 339-357.

23. Ricci, P. F., Crouch, E. A. C., and Crump, K. S. (1982). Sourcebook on Technological Risk Assessment (in preparation).

Other Publications, Reports, Etc. (continued)

24. Crump, K. S. and Howe, R. B. (1980). A Small Sample Study of Some Multivariate and Dose Response Permutation Tests for Use with Teratogenesis or Carcinogenesis Data. Prepared for the Food and Drug Administration under contract to Ebon Research Systems, 34 pages.

25. Crump, K. S. (1981). Statistical aspects of linear extrapolation. In: (ed. C. R. Richmond, P. J. Walsh, and D. Copenhaver). Proceedings of the Third Life Sciences Symposium, Health Risk Analysis, Gatlinburg, Tennessee, October, 1980, pp.381-392.

26. Crump, K. S. (1981). Issues related to carcinogenic risk assessment from animal data. Presented at the International School of Technological Risk Assessment, a NATO Advanced Study Institute, Erice, Italy. (in press)

27. Crump, K. S. (1981). Chlorinated drinking water and cancer: The strength of the epidemiologic evidence. In: (ed. R. L. Jolley, et al.) Water Chlorination: Environmental Impact and Health Effects, Volume 4, Book 2, Environment, Health, and Risk, Ann Arbor Science Publishers, pp. 1481-1491.

28. Crump, K. S. and Howe R. B. (1982). Examination of Options for Calculating Daily Intake Levels (DILS). Prepared for the Environmental Protection Agency, Order No. C2171NAST, 56 pages.

29. Crump, K. S. (1982). Implications of the Multistage Model to Risks from Partial Lifetime Exposure. Prepared for the Environmental Protection Agency, Order No. C2171NASR, 26 pages.

30. Crump, K. S. (1982). The Scientific Basis for Health Risk Assessment. Presented at the seminar sponsored by George Washington University Graduate Program in Science, Technology, and Public Policy and by the U. S. Environmental Protection Agency, Washington, D. C. March 2, 29 pages.

31. Howe, R. B., and Crump, K. S. (1982). GLOBAL 82: A Computer Program to Extrapolate Quantal Animal Toxicity Data to Low Doses. Prepared for the Office of Carcinogen Standards, OSHA, U.S. Department of Labor, Contract 41USC252C3.

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33. Crump, K. S. (1982). Quantitative Assessment of Human Risk from Exposure to Carcinogens with Special Reference to Vinyl Chloride. Prepared for the Ontario Ministry of Labour, Occupational Safety and Health Division.