

Memorandum

AN6204

To : Julie Nauman
Chief Deputy Director
Department of Housing and Community Development

Date : September 9, 1988

Subject: Pipe study protocol

From : Jon Rosenberg
Chief
Hazard Evaluation System and Information Service

Along with other members of the Department of Health Services (DHS) staff and of the plastic pipe study team, I have reviewed the August 30, 1988 letter to you from Tom Adams. In summary, we believe that some of the objections to our protocol raised by Mr. Adams in his letter may represent sincere concerns that certain categories of potentially hazardous exposures are given insufficient attention in our study as planned. However, many of the specific criticisms in the letter are inaccurate in both substance and detail. Mr. Adams suggestions for revising the protocol, made at our August 29 meeting, do not reflect adequate understanding of either the hazards associated with plastic pipe installation or the methods appropriate for studying those hazards. We recommend that the study proceed as specified in the protocol. We further recommend that constructive dialog take place between DHS and Mr. Adams, in hopes that some of his concerns might be addressed by minor modifications, within the flexibility offered by our protocol.

Points of Disagreement

In his letter, Mr. Adams made several incorrect statements about the Department of Health Services (DHS) protocol for the plastic pipe worker exposure study. In the interest of clarifying the most important issues, we review below the relevant scientific background and explain the reasoning behind decisions made by DHS in the development of the protocol.

Adams' substantive criticisms can be summarized as:

1) "the proposed protocol will not provide HCD with the kind of information required to identify significant effects," because the study "admittedly is not intended to characterize exposures under worst case conditions;"

2) "the study would not provide any specific measurements of workers exposed to a combination of high exposure conditions" such as hot weather and confined spaces; therefore, "HCD will have no information about the maximum exposure risk to a plumber working in a confined space in hot weather;"

3) "the study team acknowledges that the limited scope of the sampling will result in a tremendous amount of unexplained variation in the exposure data;"

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4) "the number of samples specified are merely goals;" and

5) "the study team has clearly stated that it had no knowledge of CEQA and did not design the protocol with CEQA in mind;"

Mr. Adams, at the end of his letter, further states, "The failure of this study to 'prove' that mitigation measures are needed will be misused to claim that the product is safe, rather than to acknowledge that the study was defective." We understand that Mr. Adams has a responsibility to represent his client's interests by seeking the best possible study protocol, and that this responsibility may ultimately include attacking inappropriate uses of its results. However, we believe that a discussion about our conclusions and their validity should wait until the data have been collected and those conclusions have been reached. Mr. Adams may think that he already knows the outcome of our study; we do not.

DHS Positions

With respect to these issues, we believe that HCD should be cognizant of the following information. The numbers correspond to numbered criticisms above.

1) Our study is designed to provide estimates of exposures that are likely to occur under a variety of circumstances, not only worst-case.

This profile will include several types of information: the average exposures expected under normal working conditions, the factors that contribute to higher exposures, and the frequency and severity of exposures that approach worst-case. We believe that this information will greatly assist HCD in assessing the impact on workers of expanded plastic pipe use.

We considered, and ultimately rejected, conducting a study that focussed exclusively on monitoring supposed worst-case exposures. Our reasons for rejecting such a study design include:

a. The circumstances under which the most significant exposures occur are not presently known. Here, it is important to keep in mind that the most significant exposures are those that are most likely to cause adverse health impact. Adams refers in his letter to hot weather and confined spaces as conditions that lead to high exposures. For the volatile solvents MEK and THF, temperature and enclosure may indeed be important contributing factors, but in our review of the toxicology of these substances we found little evidence of toxic effects in humans. Reversible central nervous system depression has been documented, but only at extremely high exposure levels. Short-term eye, nose, and throat irritation is frequently reported, but is more a matter of comfort than health. (Methyl ethyl ketone is also known to potentiate the toxicity of chemicals such as n-hexane that are not used in plastic pipe installation.)

For DMF, the picture is quite different. It is known to cause liver damage in humans, even after relatively brief exposures, and several investigators have identified a possible link between DMF exposure and testicular cancer. For DMF, the factors most likely to influence exposure levels include: the DMF content of the cements and primers used, the extent

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of skin contact, and the number of joints glued in a day. Hot weather and enclosure may produce high instantaneous exposure levels, but they might also indirectly decrease full shift exposures because workers typically complete fewer joints in hot weather and in enclosed spaces, and because the effects of temperature on skin absorption of DMF are unknown.

With so many factors influencing DMF exposure levels, how is it possible to know which of these is most important, and thus which should be targeted for worst-case sampling? Our answer is that current data is insufficient to make even an educated guess about the relative importance of the variables. The only way to begin to rank them is to collect data under a wide variety of exposure conditions and then determine which of the variables correlates most closely with DMF exposure.

Additionally, we believe that the notion of finding the "worst case" and then measuring its severity, while it may seem attractive, is ultimately illusory. Irrespective of how the search for worst cases is conducted, the results of the search can never be considered, with confidence, to truly represent the worst case that will occur.

b. A study in which monitoring were conducted exclusively in worst-case conditions (assuming that the factors creating worst-case conditions were known) would be incapable of providing data on the frequency with which the measured exposures occur; we believe that frequency information is critical to the EIR process. For this reason we have insisted that a degree of randomization be included in the site-selection process, so that the proportion of high exposures measured in our study will be reflective of their proportion in the industry as a whole.

c. While the small number of plumbers who work under worst-case conditions may be at highest risk for work-related illness, the exposures of the large number plumbers who work under more typical conditions cannot be overlooked as a possible source of "significant effects." This observation is based on the principal that the number of occupational illness cases that can be expected in any group is dependant on both the exposure levels of the group and the number of people exposed. A large group is more likely to include individuals with heightened susceptibility to any particular agent.

We agree with Mr. Adams that the highest exposures pose the greatest concern and may, depending upon their severity, need mitigation measures. However, we believe that average exposures that occur under normal conditions in a large number of worksites must also be considered. Only a broader study such as ours is capable of assessing those exposures. In our meetings before protocol development began, Mr. Adams had many opportunities in which he could have stipulated that worker exposures during routine plastic pipe installation were insignificant. He did not do so, probably because the exposure levels have not been adequately characterized.

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2) We have consistently maintained that the study team is highly likely to collect samples in enclosed spaces in hot weather; however, we have declined to provide any guarantee because both the weather and working conditions are beyond our control.

The counties in which most of our monitoring will be conducted (Los Angeles, Orange, San Diego, San Bernardino, Riverside, Contra Costa, Sacramento, Santa Clara, Alameda, and Ventura) all have a large percentage of hot days between August 15th and October 15th, the scheduled monitoring period. At the sites selected for monitoring, workers exposed in enclosed spaces during hot days will be monitored.

During the hottest monitoring days, the slight possibility exists that no plumbers will be working in enclosed areas at the sites selected. Even this occurrence would not leave the study devoid of useful information about this combination of conditions. With data on the independent effects of temperature and enclosure, exposure levels when the two are combined can be predicted. Thus, Adams' assertion that the study will produce no information about this combination of conditions is based on unfounded assumptions.

Of course, the more actual data that are available for any type of exposure, a higher level of confidence can be attached to any conclusions drawn from the data. However, we continue to believe that by characterizing the range of exposures and their expected frequency, and by identifying the factors that most strongly influence exposure levels, our study will make a major contribution towards assessing the likelihood that installation of plastic pipe poses a worker health risk.

3) We have stated that the exposure data to be collected according to our protocol will, in addition to showing the effects of the most significant determinant factors, contain a large amount of unexplained variability.

This comes as no surprise, since virtually all data sets reflecting workplace exposure contain a large amount of unexplained variability. What makes our study unusual is that it will have any explained variability at all and that it will honestly state the extent to which some variability is unexplained; most workplace exposure studies do not even attempt to address this issue. Any suggestion that a workplace exposure study of any design, executed with any level of resources, would not contain substantial unexplained variability is either uninformed or disingenuous.

However, the issue of uncertainty is important in considering the implications of this study. We believe that the greatest uncertainties, by far, will lie not in interpreting our data but in using it to project the exposures that will occur in California if plastic pipe installations increase. Even with inclusion of out-of-state monitoring in areas where CPVC is commonly installed for distribution of water supply in residences, our study cannot provide a definitive view of conditions that will exist in California at some future time.

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4) In our protocol, we have explicitly stated minimum numbers of sites to be evaluated, we have described the types of sites to be included, and we have specified the types of samples to be collected at the selected sites.

This approach is built on the best industrial hygiene practices currently available, and reflects the fact that in any real-world study, it is more realistic to specify the methods to be used for selecting sampling periods than to specify in advance the conditions that will prevail during those periods. Since the study team has no control over the various exposure variables (such as the number of joints glued in any time interval, or the amount of work in enclosed spaces), we could not guarantee the number of monitoring periods that would fall into various categories for any finite study.

In our meeting of August 29th, 1988, Mr. Adams expressed particular dissatisfaction that the numbers of samples in the various short-term exposure categories are estimates rather than firm commitments (see the table on page 13 of our protocol, draft 3, enclosed). When considering this issue, two important points should be kept in mind. First, these exposure categories pertain only to the monitoring for MEK, THF, and cyclohexanone, and are not relevant to monitoring for DMF, which we consider to be more significant toxicologically. Second, these categories were defined according to factors that could be readily identified in the field to guide our sampling, but we continue to believe that the factors that are most likely to produce significant health effects are currently unknown.

5) We have kept the needs of the EIR process in mind at every step of protocol development.

We are not experts on the legal details of CEQA, as we have stated on numerous occasions. However, I have participated for many years, along with HCD and representatives of the Attorney General's office, in defining the requirements of CEQA that must be addressed in a worker health study. We have reviewed the relevant sections of the preliminary Environmental Review Document, and have tailored our study towards filling the data gaps identified in that document.

Conclusions

Mr. Adams criticisms have highlighted two important points that HCD must recognize as it considers this worker exposure study.

First, the exposures that are of most concern (the "worst cases") are hardest to study, because they occur infrequently. Adams' suggestion for dealing with this situation, presented at our August 29 meeting, is that the protocol include guarantees that minimum numbers of samples be collected under specified temperature and enclosure conditions. We believe that the most significant exposures will occur under conditions that cannot now be predicted, and we have designed our protocol to idedveloping the developing the developing the ntify those conditions that are most important.

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Second, the results of our study will include substantial uncertainty. We will not be able to state with scientific certainty whether plastic pipe installation is "safe" or whether the possible health impacts are "significant". This would also be the case if we adopted Mr. Adams' suggestions. The fact remains that major opportunities for disagreement will still exist, not only about the exposure data generated by our study, but about its application to possible changes in California plumbing practices and even about the toxicity of the substances whose workplace concentrations we will measure. HCD will have to make important policy decisions based upon data that are valid and useful, but not conclusive.

We continue to believe that our protocol is appropriate method for assessing worker exposures associated with plastic pipe installation, and that the data produced will be both valid and useful to HCD in the EIR process. Further, we believe that at this point in the sampling period, it is unrealistic to consider substantial changes in the study approach or protocol. We are prepared to discuss with Mr. Adams minor modifications that can be made within the existing protocol.

cc: Richard J. Jackson, M.D., M.P.H., Chief
Office of Environmental Health Hazard Assessment (OEHHHA)

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