Janet Olszewski
Director
Michigan Department of Community Health

Henry Falk, MD, MPH
Director, National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry
Atlanta, Georgia 30333

Tracey Easthope, MPH
Director, Environmental Health Project
Ecology Center
117 N. Division
Ann Arbor, MI 48104

Michelle Hurd Riddick
Lone Tree Council

C. Michael Krecek, RS, MPH
Director/Health Office
Midland County Department of Public Health

March 22, 2004

Dear Sirs:

We are pleased to respond to the comments regarding the University of Michigan Dioxin Exposure Study (UMDES) submitted by the Agency for Toxic Substances and Disease Registry (ATSDR) and the Michigan Department of Community Health (MDCH) (submitted by Janet Olszewski and Henry Falk); Ecology Center of Ann Arbor and the Lone Tree Council (submitted by Tracey Easthope and Michelle Hurd Riddick); and the Midland County Department of Public Health (submitted by Michael Krecek). We have given careful consideration to each comment and we endorse many of the themes that are suggested.

A. RESPONSES TO THE COMMENTS OF THE ATSDR/MDCH

The potential role of the Michigan Public Health Institute (MPHI) deserves thoughtful consideration. The implications of its involvement in the University of Michigan Dioxin

Exposure Study are considerable and must be fully anticipated before it can have a relationship to the UMDES. Janet Olszewski, Director of the MDCH, and Henry Falk, Director of the National Center for Environmental Health/ATSDR, have suggested the MPHI should serve in multiple capacities, including:

- Facilitation of recruitment, review, selection, and retention of participants in the Scientific Advisory Panel (SAP)
- Develop a data center that will collect, archive, collate, prepare, and release data sets for analysis
- Oversee the formation of the Community Advisory Panel (CAP)

We have fully considered these proposals and the appropriateness of having the MPHI fulfill these responsibilities. In doing so, we have reviewed the mission statement and authorizing legislation of the MPHI.

The MPHI was created by an act of the Michigan Legislature in 1989, which authorized the Michigan Public Health Department (which was reorganized into the Michigan Department of Community Health in 1996) to "establish a nonprofit corporation… the purpose of the corporation shall be to plan, promote, and coordinate health services research with a public university or a consortium of public universities within the state." The annual appropriations bill for the MDCH authorizes MPHI as a pre-approved provider for the design and implementation of projects and for other public health related activities. Each year a "master contract agreement is signed between MPHI and the MDCH, with each project made a task order under the umbrella agreement". On July 19, 1990 the articles of incorporation were filed with the Michigan Department of Commerce to establish MPHI as a 501(c)3 nonprofit research organization. The founding partners in this new organization were the former Michigan Department of Public Health, Michigan State University, the University of Michigan, and Wayne State University. The corporate filing included this statement of the new institute's purpose: "The Corporation shall provide a scientific and experimental basis for the action of government to meet changing health conditions… The Corporation must maintain a scholarly atmosphere of freedom of inquiry and promote the protection of human subjects in pursuit of the solution of public health problems."

The following facts make participation of the MPHI in the UMDES inappropriate:

1. The MPHI is not independent of the MDCH.
    - MPHI's funding is closely tied to the MDCH through an annual "master" contract agreement.
    - The Director of the MDCH, Janet Olszewski, is the President of the MPHI. Insofar as her own department is conducting a similar study of the dioxin contamination of the Tittabawassee River, she has an apparent conflict of interest in monitoring the University of Michigan study. She has an interest in the outcome of the study being conducted in her own department.

- MDCH appoints six of the twelve members of the Board of Directors of the MPHI. Thus, the MPHI is largely governed by appointees of the MDCH.

2. MPHI is not independent of the University of Michigan.
   - Two members of the Board of Directors of the MPHI are University of Michigan faculty and administrators. One of these, Professor James Vincent, is the Chair of the Department of Environmental Health Sciences. This is the academic home of Professor Garabrant's appointment and is the department through which the grant from the Dow Chemical Company will be administered. This creates an apparent conflict of interest for Professor Vincent (a conflict which is identical to that of Dr. Olszewski of the MDCH, insofar as he has an interest in the outcome of the study done within his own department).

3. ATSDR/MDCH are "concerned that there may be perceived conflicts of interest if the UM… retains oversight of the SAP". The involvement of the MPHI does not remedy this concern. It simply adds new conflicts of interest without explaining how this oversight benefits the University of Michigan study by protecting against conflict of interest.

4. The activities proposed for the MPHI are not consistent with its corporate charter and legislative authority. It is explicit in the MPHI charter that its purpose is to plan, promote, and coordinate health services research … The University of Michigan Dioxin Exposure Study is not health services research. Moreover, the proposed role of the MPHI has nothing to do with planning, promoting, or coordinating health services research.

Scientific Advisory Panel (SAP)

We agree with many of the themes suggested by the ATSDR/MDCH regarding the Scientific Advisory Panel. We agree to create a Scientific Advisory Panel to provide expert advice in the conduct of the exposure investigations in Midland and Saginaw Counties.

- The purpose of the SAP is to oversee the conduct of the University of Michigan study. It is redundant to create an oversight panel over this oversight panel. There is no rationale for how this will improve the conduct of the study, nor do the ATSDR/MDCH comments indicate how such an oversight function will reduce perceived conflicts of interest. As we have pointed out above, the involvement of the MPHI will likely add to the perception of conflict of interest, not reduce it.
- We are not aware that the MDCH study being conducted in the Tittabawassee River flood plain has created any oversight panel for their study such as they suggest for the University of Michigan study. We question why a redundant layer of oversight will be of benefit to the University of Michigan, yet has not been incorporated into the MDCH study. This appears to be a double standard.
- We agree that the Dow Chemical Company should not be involved in the conduct of the scientific study.

- We welcome the development of selection criteria for members of the SAP. We have already proposed selection criteria that include independence, scientific expertise relevant to dioxin studies, and stature in the scientific community. We are surprised that ATSDR/MDCH have neither endorsed these criteria nor suggested alternative criteria. We are pleased to have the opportunity to develop criteria in a cooperative manner with both ATSDR and MDCH. We have proposed our selection criteria. We welcome input from ATSDR/MDCH for establishing criteria for the SAP.
- We welcome nominations to the SAP by stakeholder groups including the involved State of Michigan agencies, NCEH/ATSDR, local health departments, environmental groups, private citizens, and professional organizations.
- We agree that SAP meetings should be held in Michigan. We agree that the SAP meetings should be attended by a liaison from the Community Action Panel (CAP). We also propose that NCEH/ATSDR appoint an ex officio (non-voting) representative with appropriate scientific credentials (an advanced degree and experience relevant to dioxin studies) who will attend SAP meetings.
- We believe that cooperation between MDCH/MDEQ and the University of Michigan is an essential element in enhancing the credibility of the dioxin studies being conducted by both groups in the Tittabawassee River flood plain. In a spirit of collegiality and increased cooperation we endorse the concept of ex-officio (non-voting) members of the SAP from the MDCH and MDEQ, provided that identical status be given to a member of the University of Michigan Dioxin Exposure Study research team on the MDCH and MDEQ studies.
- We agree that the SAP should convene to comment and approve 1) the study protocol; 2) the analysis plan prior to data analysis; 3) provide needed expert advice while the study is ongoing; 4) review study reports before they are made final and released to the public.
- We do not believe it is feasible to have a liaison from the SAP to the Community Advisory Panel. It is unlikely that the members of the SAP will be residents of Michigan and it is extremely unlikely that scientists of national stature will agree to commit the time to fulfill such a role. We suggest as an alternative that a member of the CAP attend the SAP meetings and that this person will communicate SAP findings and reports to the CAP. This person will also convey technical questions and answers between the CAP and the SAP.

Independent data center

The justification for the proposed independent data center is based on concerns expressed by MDCH/ATSDR about data confidentiality and security at the University of Michigan. The University of Michigan School of Public Health has a long history of providing data security and confidentiality. There is no basis for this concern. There is no reason to believe that another entity such as MPHI can provide better security or confidentiality than can the University of Michigan.

Moreover, the University of Michigan is an independent scientific institution that is fully qualified to collect, archive, prepare, and analyze data and prepare reports. Such activities are a central function of the mission of the University of Michigan and the University of Michigan is fully qualified to do this. The University of Michigan has a long and successful history of insuring the confidentiality and security of data in human research. The IRB function at the

University of Michigan is highly regarded as a part of this effort and is fully compliant with all applicable Federal regulations.

Furthermore, for the reasons stated above, the involvement of the MPHI in the data collection, archiving, collating, preparation, and releasing of data sets will neither reduce concerns about data confidentiality nor provide any definable benefit to the conduct of the University of Michigan study.

Instead, we propose the following actions be incorporated into the University of Michigan study protocol.

- NCEH/ATSDR will appoint a qualified professional from its staff to perform periodic audits of the University of Michigan data. This auditor will be given access to all survey instruments, raw data, analytic programs, created data sets, and analyses collected or performed by the University of Michigan in the conduct of the University of Michigan Dioxin Exposure Study.
- The audits performed by the NCEH/ATSDR will follow a protocol that will include measures to insure the confidentiality of the data, methods to be followed by the auditor, involvement of the University of Michigan investigators in the audit, written results of the audits, and procedures for the University of Michigan investigators to resolve questions and errors.

Certificate of Confidentiality

We appreciate the suggestion of seeking a Certificate of Confidentiality and we have already initiated the process of seeking such a certificate. We agree that such extra protection is warranted for this study given the sensitive nature of the study and the possibility of negative consequence if personal blood, soil or house dust results are ever divulged publicly. We believe that the MDCH/MDEQ should also seek a Certificate of Confidentiality for their study.

In light of this suggestion it is surprising that the MDCH/MDEQ have posted the personally identifiable soil results of their study participants on the web, including complete street addresses and soil concentrations. Furthermore, it is our understanding that residents at these locations will be solicited to provide blood samples, so, in effect, blood donors in the MDCH/MDEQ study have also been publicly identified. Posting information on the web in this manner violates the terms of a Certificate of Confidentiality.

In light of our responsibility to assure the data confidentiality, the extensive resources and polices of the University of Michigan that are designed to provide such assurance, and our concern that the MDCH/MDEQ study has not followed the same level of security and protection of the identity of human subjects used in their research (and the potential for adverse consequence to their study subjects as a result of their research procedures), we do not feel that release of the UM data to an entity outside of our research team is appropriate.

Comparison of UM Results with MDCH's Pilot Exposure Investigation (PEI)

It is not true that comparison of the PEI results to those from the UM study will be uninformative. Such comparisons are essential to the interpretation of the dioxin levels found in

the MDCH/MDEQ study. MDCH has stated its intention to compare their results to the NHANES data. What justifies the intended MDCH/MDEQ comparison to the NHANES data (which has a high limit of detection and which is derived from the US population broadly, not Michigan) when a comparison to a local Michigan population is believed by MDCH to be uninformative? If the MDCH does not wish to make such comparisons they should explain the scientific basis for why such comparisons would not be informative.

- The MDCH has provided no scientific justification for the assertion that our Phase 1 study is not an appropriate comparison for people living in the flood plain.
- We propose that MDCH and the University of Michigan work cooperatively to identify ways in which data from the two studies can be compared appropriately. We suggest that such a comparison may involve stratification by age, sex, location of residence, duration of residence in Midland and Saginaw counties, and other factors. We believe that cooperative interaction in this area would greatly enhance the value of both data sets.
- We propose to work cooperatively with the MDCH to identify a subset of our study participants that do not reside downwind of the Dow facilities or in or near the flood plains of the Tittabawassee, Shiawassee, or Saginaw rivers, and who are believed to be representative of the population that has had no identifiable contact with either the Dow Chemical Company or emissions from Dow's manufacturing operations. The proper choice of this data subset can be assured through the data audit function described above.

ATSDR/MDCH have suggested that the first phase of the University of Michigan study should focus on the population living outside Midland and Saginaw Counties. The rationale for this change is apparently that ATSDR/MDCH believe a population outside the Midland/Saginaw area would be representative of "background" dioxin levels.

- We believe that this concern can be fully addressed through the approach outlined above and that the MDCH should support this plan. The population of the Tittabawassee River flood plain will have concern regarding their blood dioxin levels when the MDCH study results are reported and the University of Michigan data will be informative to them. Our intent is to insure that appropriate comparisons are made between the MDCH data and the University of Michigan data. We have no interest in making inappropriate or misleading comparisons and we will not participate in doing so.
- It is not logistically feasible for the University of Michigan study to incorporate the additional referent population in Phase 1 as suggested by ATSDR/MDCH. Given the lack of a rationale for this change in our scientific protocol and the availability of a procedure for insuring the relevance of the data collected in Midland and Saginaw Counties, we do not believe that there is any identifiable benefit to changing our protocol.
- Furthermore, this suggestion by ATSDR/MDCH is not a "process" issue, but is a scientific consideration.

Community Advisory Panel (CAP)

We fully endorse the principle that the CAP should be formed to ensure meaningful participation of the community and without perceived bias. Given the perceived bias of the MPHI, we do not believe that MPHI is an appropriate entity to provide such assurance. We believe the CAP is the oversight panel for the community to monitor the conduct of the study

and that an additional oversight body over the oversight body is both redundant and unnecessary. Furthermore, the MDCH/MDEQ study has no such oversight body over its CAP and they apparently did not (and do not) feel the need for such oversight in the conduct of their study. This inconsistency between their assumptions that they (or MPHI) can assure impartiality and that we cannot is not credible. Furthermore, if they believe additional oversight is necessary, it should be in their study, too.

Communications plan

The MDCH suggests a communication system that prohibits the University of Michigan from directly communicating with stakeholders, but that requires the University of Michigan to filter communications through the MPHI. We believe that the proper role of the CAP is to facilitate communications between the University of Michigan and the community, and that it alone is the appropriate entity for doing so. We do not agree that the University of Michigan needs an interface between it and the CAP, the SAB, or any of the stakeholders. The University of Michigan, including the School of Public Health and the Institute for Social Research, have a long and successful history of conducting community-based research and has high credibility in this arena.

We do not agree that the MPHI has the appropriate expertise to evaluate and edit information from the University of Michigan study. Such a function also would violate the University of Michigan's academic freedom to conduct and report scientific research findings in the scientific and lay press. The University of Michigan reserves this right in all contracts under which research is performed and this function is an essential element in maintaining the integrity and independence of university-based research.

Scientific Content Versus Study Process

There are many comments in the ATDR/MDCH comments that are unrelated to process and are intended to change the scientific content and procedures in the UM study. We welcome such scientific comments and wish to simply clarify that the ATSDR/MDCH documents are intended to provide input on the scientific conduct of the UM study, and not just process.

B. RESPONSES TO COMMENTS FROM THE MIDLAND COUNTY HEALTH DEPARTMENT

We appreciate the comments from the Midland County Health Department which recognize the qualifications of the University of Michigan investigators, the high reputation of the University of Michigan as an academic and research institution, and the potential value of the proposed research study. We concur that the proposed study will move the "community and state agencies one step closer to making informed decisions". We believe that the Midland County Health Department correctly recognizes that the University of Michigan study can possibly provide outcomes that are in parallel with the MDCH study.

Our responses to specific comments are as follows:

- We reaffirm that the Dow Chemical Company will have no right to edit or alter in any way the analyses, interpretation, or reporting of the result of this research study.

- The timeline for implementation of the study has been altered such that field work will begin in May of 2004.
- We appreciate the suggestion that we may wish to consider two control communities, one for Midland County and one for Saginaw County. We are in the process of investigating appropriate referent communities to be included in phase 2 of or our study. We take seriously comments such as this and will solicit input from stakeholder groups regarding the selection of appropriate referent communities.
- We intend to include local public health officials in the CAP and agree that they meet the criteria described in the study design.
- We agree that the county health departments in Midland, Saginaw, and Bay counties have a vested interest in the outcome of the University of Michigan study (and the MDCH/ MDEQ study), and that their interest is in the community, as is ours.

C. RESPONSES TO COMMENTS FROM THE ECOLOGY CENTER OF ANN ARBOR AND THE LONE TREE COUNCIL

We will address the comments regarding both the process and the content of the University of Michigan study by page and paragraph number.

Concerns about the genesis of the study. (Pages 2-3)

We agree that the University of Michigan must be diligent both in appearance and in fact in providing the independence that we claim to have. As stated above, the Dow Chemical Company will have no right to edit or alter in any way the analyses, interpretation, or reporting of the result of this research study.

There are no other questions or suggestions posed.

Advisory panels (Pages 3-4)

We agree that the independence of the Scientific Advisory Board is essential to the conduct of the University of Michigan study. We are pleased to consider nominations for SAP membership from qualified people external to the University of Michigan, including stakeholder groups such as the involved State of Michigan agencies, NCEH/ATSDR, local health departments, environmental groups, private citizens, and professional organizations. The Dow Chemical Company will not be involved in choosing the members of the SAP beyond suggesting nominees. The SAP will report to the Community Advisory Panel through a liaison who will attend both groups' meetings. The SAP will also report to the public through its reports on conduct of the study. The 'independence' of Board members is intended to mean not having a conflict of interest and not having any financial relationship to any entity that would benefit from or be adversely affected by the results of the University of Michigan study. Such entities would include the Dow Chemical Company, the MDCH/MDEQ, and parties involved in litigation over dioxin contamination in Saginaw, Bay, and Midland Counties.

The qualifications for membership on the Community Advisory Panel that were stated during the February 19 presentation were independence, representation of community groups, and stature and respect in the community. This would include people who live in a contaminated

area. It would not include litigants (neither defendants nor plaintiffs) since they potentially stand to benefit from the outcome of the study and are not viewed as independent.

We are impressed by the technical expertise of the people who are already available to the community. We are aware through the websites and public comments of the Ecology Center, the Lone Tree Council, and the Tittabawassee River Watch that some members of the community are quite knowledgeable about technical issues regarding study design.

ATSDR and MDCH have been asked for input into the study design and we are asking them to provide ongoing input (see response above to ATSDR/MDCH comments).

We do not understand what is meant by "the narrow definition of the community employed by the University thus far". We disagree with your characterization of our statements.

The role of the Community Advisory Panel is to facilitate communication between the University of Michigan investigators, the Scientific Advisory Panel, and the community. It includes providing feedback to the investigators regarding the concerns of the community and informing the community about the conduct and progress of the study. Comments on study design from the CAP will be welcomed.

The formation of the CAP and SAP and their roles are being developed. Comments such as yours, those from ATSDR/MDCH, and the community health departments are important in our planning for how the CAP and SAP will be formed and what roles they will play.

We are not aware that the University of Michigan School of Public Health has a mission statement specific to sites of environmental contamination. The mission of the University of Michigan School of Public Health is

> "to create and disseminate knowledge with the aim to prevent disease and promote the health of populations in the United States and worldwide. We are especially concerned with the poor, often minority populations, who suffer disproportionately from illness and disability. The generation of knowledge derives from the school's research enterprise, presentation and publication of research findings, instruction of professional and graduate students, and service activities conducted in collaboration with the public health practice community. The school employs integrated approaches to solving public health problems, and teaches and promotes the ethical practice of public health."

Control of data samples (Page 4)

The University of Michigan investigators will have control over the data and samples. The data and samples will be stored in the School of Public Health, ISR, and in the College of Engineering under appropriate conditions to insure their preservation over time. The Dow Chemical Company will have no access to the samples or to the data. The University of Michigan owns the data. Only the research team will have access to the data. The study participants will be informed of who will have access to their data and in what form.

Public communication (Page 4)

The University of Michigan will be responsible for communication to the public about the study. We have no knowledge of the intentions of the Dow Chemical Company regarding communications about the study, nor do we have any plans to assist them.

Purpose of the study (Page 4)

The purposes of the study were presented on February 19 during a videoconference which you attended. They are:

1. To select random samples of three populations:
   - Residents of the Tittabawassee River flood plain between the Dow facility in Midland and the Center Street bridge (approx.) in Saginaw.
   - Residents of Saginaw and Midland counties who do not reside in the flood plains of the Tittabawassee or Saginaw Rivers or the confluence flood plain of the Shiawassee River.
   - Residents of Michigan outside of Saginaw and Midland counties.
2. To collect the following data from each participant:
   - Responses to a 1-hour personal interview
   - Measurements of 17 specific congeners of dioxins, furans, and co-planar PCBs in
     - –Serum
     - –House dust
     - –Soil
3. To explain the variability in serum dioxins (both specific congeners and TEQ) as a function of:
   - Soil dioxin concentrations
   - House dust dioxin concentrations
   - Proximity and duration of residence to
     - The Tittabawassee River
     - The Dow facilities in Midland
   - Consumption of fish and game from the Tittabawassee River and flood plain
   - Past occupations
   - Other factors (age, sex, race, diet, etc.)

Your statement that "the statistical analysis proposes to 'characterize the distribution of dioxin blood levels in the region of the Tittabawassee River outside of the flood plain'" is not what was presented on February 19. Please tell us the source of this quotation and we will try to reconstruct the context of the statement. The correct goals of the statistical analysis are summarized in goal 3, above.

The overall study will serve the public health by explaining the sources of variability in serum dioxin levels, whatever they are. The population of Saginaw and Midland counties, including those who live in the Tittabawassee River flood plain, need to know whether they have elevated serum dioxin levels and the factors that predict high levels and low levels (and that explain variation in serum dioxin levels). This will serve the public health by informing people about their exposures to dioxins in their environment and what the likely sources of exposure are. The study will not compare medians only, it will also compare upper tails of the distributions.

Soil and dust samples are not being archived for one year. We are developing plans for the analysis of the soil and dust samples and it is clear to us that it will take a substantial amount of time to process samples. Processing and analysis will begin as soon as soil collection is completed. It is anticipated that the analyses of phase 1 samples will take close to a year. The study is designed to oversample the residents of the Tittabawassee River flood plain, who we believe are the most likely group to have high soil levels.

The study will advance the public health of the residents that live on the flood plain or in contaminated areas by informing them about their exposures to dioxins in their environment and what the likely sources of exposure are. We will interpret the correlations between soil and blood levels when we have the ability to see the entire pattern of results. We are not prepared at this time to draw any conclusions about what the results may mean. That would be premature insofar as we have not yet completed the study design, data collection, or data analysis.

The rationale for phasing the study is based on logistics, availability of people and resources, and seasons. We plan to study Midland and Saginaw County residents outside of the flood plain first because the concerns over dioxin are focused in these counties and we believe this is an appropriate population for the startup of our study while we finalize our field methods.

Study populations (Pages 6-7)

The sampling of the residents living in the contaminated flood plain ends at the Center Street bridge because we believe this is the approximate location where backflow up the Tittabawassee River ends during floods. The flood plain below this may be contaminated by sediments from the Shiawassee River, while the flood plain above this is believed to have sediments only from the Tittabawassee River.

The sample of people living within the flood plain will include all adult residents who have resided there for 5 or more years. It is my understanding that plaintiffs were not invited to meetings because Dow sent the invitations and they must obey a court order that prohibits them from contact with plaintiffs.

Plaintiffs are not excluded from participating as subjects in the study.

Five years of residence was chosen to be consistent with the selection criterion used in the MDCH study.

Once we have identified the Michigan regions from which we intend to sample, we will use a two stage sampling design similar to the one we are using in Midland and Saginaw counties. The sample is meant to be a random sample of the population and the serum dioxin levels will be regarded as representative of the distribution in residents from the areas that are sampled. We have no current plans regarding the utility of the data with respect to national background levels.

We believe that comparison of the phase 1 results to the MDCH results is valuable, as is comparison of the phase 1 and phase 2 results. Both will occur. See also our response to questions regarding the comparison to the MDCH results, above.

A referent group is a group to which a group of interest is compared, typically with respect to a variable (or variables) of interest. In this setting one of the variables of interest is living in the Tittabawassee River flood plain. The study group lives in the Tittabawassee River flood plain and the referent group does not live in the Tittabawassee River flood plain. We are not sure what you are referring to in your question about the definition of a control group in this study. Please clarify this.

The study is designed, in part, to estimate the association between age and serum dioxin levels in the populations we will study.

Fish consumption (Page 7)

We will ask about sport fish consumption from all sources. We will use a quantitative variable for fish consumption, to reflect the number of fish meals per month of each type of sport fish eaten. Our fish consumption protocol will be at least as comprehensive as that used by MDCH.

Labs and sampling protocols (Page 7)

We have not selected laboratories for the soil and dust analyses. We intend that the blood samples will be analyzed in the NCEH laboratories at CDC in Atlanta. We believe that the detection limits for the blood samples are in the range of 1 ppt in that laboratory. We intend to measure all the components of the TEQ, including dioxins, furans, and coplanar PCBs, and mono-ortho-substituted PCBs. We will also measure serum lipid levels. We will consider weight change, breast feeding, and parity in our analyses of dioxin levels.

Risk communication (Page 7)

We have not developed our communications plan for reporting results to participants. We intend to tell participants how their serum dioxin levels compare to other subjects in the study. It is not clear what you mean by advice that we would give the most heavily exposed. The interpretation of the results that we provide to individual study participants will depend largely on what the results of the study show. It is premature to decide what, if any, interventions we will propose until after we have the results of the study.

Indoor dust sampling (Pages 7-8)

We do not understand the first question. We intend to take dust samples from soft surfaces (carpets) and from hard surfaces (floors, horizontal surfaces). We do not think that data on housecleaning practices and the age of the carpet is likely to be interpretable.

The soil and dust samples are not being archived for a year. Sample preparation and analysis will begin shortly after sample collection is completed.

Miscellaneous (Page 8)

We do not know what the implications of this study are for the class action lawsuit. We do not have any opinion on how this study might be used for setting cleanup standards.

Questions such as this cannot be answered meaningfully until the results have been interpreted. This study has no relationship to the ongoing characterization and cleanup efforts. We have no knowledge of those activities. We have no knowledge of any risk assessment activities.

The plume from Dow's activities will be modeled by Dow because they have the input data for the models. We will use these models if they appear to be valid in our professional judgment. We will consider all data that we can collect that allows us to infer exposure to dioxins. We recognize that there are limitations to some types of data, such as people's limited knowledge of whether they have fill dirt in their yard and where the fill dirt came from.

We appreciate having the opportunity to consider and benefit from the thoughtful comments and suggestions of each of the groups above. We recognize that the preparation of these comments took considerable time, effort, and expertise.

Sincerely,

David H. Garabrant, MD, MPH
Professor of Occupational Medicine and Epidemiology