

April 3, 2004

Dr. David Garabrant, MD, MPH
Professor of Occupational Medicine and Epidemiology
University of Michigan School of Public Health

Dear Dr. Garabrant and UM exposure investigation team,

Thank you for the opportunity to again comment on the process and content of the proposed Dow-funded University of Michigan

Dioxin Exposure Study (UMDES). These comments are in response to a powerpoint presentation of the study (we have not yet

seen a study protocol), a letter dated March 22, 2004 and a phone conference held on March 23, 2004 when input on the study

was discussed.

Our comments are submitted on behalf of two of the original petitioners to the ATSDR urging a review of the potential threat

to the health of residents as a result of dioxin contamination in the region.

Our groups continue to believe that a cleanup of dioxin must be the number one priority in the region, and must be expedited

to protect the health of residents.

Our initial request to ATSDR resulted in two public health consultations that are not yet finalized. Those draft

consultations suggested that further information was necessary to evaluate risks to health. Subsequently, significant

additional testing has been conducted further confirming major contamination in the floodplain. More testing is ongoing.

There was also an evaluation of risks to wildlife in the region, which determined the risks to be significant. Also

subsequent to the release of the draft consultation, the Michigan Department of Community Health announced plans to conduct a

pilot exposure investigation to test the blood of residents living in the contaminated floodplain, with the possibility of an

expanded study in the future.

It is in this context that Dow Chemical approached the University of Michigan to conduct an exposure study of residents in

the area. We have detailed our concerns about this in an earlier letter, and believe those concerns have not been adequately

addressed.

We are providing this additional input to further detail our concerns:

* Independence of Scientific Advisory Panel (SAP)

An independent Scientific Advisory Panel is critical to provide a level of assurance to the public that the source of funding

for this study will not influence study design and interpretation. As currently configured, the SAP is chosen by the

University of Michigan, and reports to the University of Michigan. Because the University is receiving money from Dow

Chemical (which has a significant interest at stake), an additional level of scrutiny and independence is warranted. ATSDR

and MDCH suggested the SAP could be convened by the Michigan Public Health Institute. UM researchers argued that this entity

is conflicted due to the source of some portion of its funding - the Michigan Department of Community Health. We believe

this argument is flawed. Based on the discussion during the last call, it is our understanding the MPHI is an entity

supported by taxpayer dollars. The taxpayers of Michigan do not have a direct economic interest in this matter, nor does the

Michigan Department of Community Health. UM researchers further argued that MDCH is conflicted because they are conducting

their own study of residents of the floodplain. This however, does not qualify as a conflict of interest. We support an

independent entity as the convener of the Scientific Advisory Panel, and believe the MPHI could serve this role well.

UM researchers suggested an alternative to MPHI: UM would appoint members to the SAP, but would allow the ATSDR to veto

nominations. This proposal raises numerous questions and concerns. What is the role of the ATSDR in this study? What level

of input does ATSDR have in the design and interpretation of this study? The proposal seems to offer a very passive role in

the process, yet is supposed to provide a measure of independence and oversight. This proposal does not fully address the

closed loop between UM researchers and the UM SAP. Also, who decides within ATSDR? Using what criteria? How will these

criteria be developed? What is the public input for that process? What is the precedent for this? How does this increase

community confidence in the SAP?

We appreciate the University's willingness to be "diligent both in appearance and in fact" in providing independence. We do

not believe that standard has yet been met.

We want to reiterate our position that it is important to designate some portion of the substantial Dow funding to provide

compensation for an expert to serve on the SAP on behalf of community/environmental interests.

* Timing of the Convening of the Scientific Advisory Panel

The discussion about the independence of the SAP may be moot given the expedited timeline of the study. It is our

understanding that the protocol for the UM Dioxin Exposure Investigation will be submitted to the UM Internal Review Board

for approval on April 8. Community groups, the public, ATSDR, MDCH and other stakeholders will not have an opportunity to

review any study protocol before it is submitted to the IRB. It is also our understanding that the UM intends to begin the

study in the Spring, or soon after approval. UM researchers have indicated that further input in study design could result

in changes, and that those changes would need to go before the IRB as amendments. Our groups are greatly concerned by this timeline. If the SAP is not involved in basic study design questions, one of its primary functions will not be fulfilled. In fact, we believe that this

is a fatal flaw. As you know, one of the most important roles of the SAP is to have meaningful input into study design.

Submitting the design to the IRB before the SAP is even constituted and convened is a clear indication that the SAP is to be

relegated to the margins and will not serve a substantive purpose except perhaps to provide the appearance of oversight.

Relatedly, why is the study timeline so accelerated? Given the result is to sacrifice real input from an independent panel

of scientists, what is the rationale for such an aggressive timeline?

* Role and Representation on the Community Advisory Panel (CAP) We remain concerned about the role and representation of the

CAP, as outlined thus far (although the outline and discussion have been vague). UM researchers seemed to indicate on the

last phone conference that they intend to recruit their own Community Advisory Panel that they deem representative of the

community. Dr. Garabrant indicated they intended to talk with community and religious leaders among others. This proposal

will be met with considerable suspicion and hostility. Again, this proposal must be seen in the context of a highly

contentious and political community struggle for public health protection and cleanup. The University of Michigan, funded by

Dow, will not be seen as a neutral party in forming a CAP. We are strongly opposed to this proposal.

We believe an obvious solution is to designate the existing, open and thus far, democratic Community Advisory Panel -- which

was convened to address the ongoing contamination issues, and includes a broad cross section of the interested community --

as the group for discussion and consideration of this study. This group has been the place where other studies have been discussed including the wildlife and pilot exposure investigation studies. Of course, this must be with

the advice and consent of the CAP and the organizers of that group.

* Communication Plan

We would like some additional information on the communications plan regarding this study. Thus far, we haven't seen a draft

of a plan. For instance, does the UM plan to communicate with the community through the CAP, or through press releases or

community meetings, etc? Are there particular benchmarks during the study that will trigger communication with the

community? Will the UM consult with the MDCH on any communications with the public that may be interpreted as providing

public health advice related to the contamination? Will the SAP review communication related to the study and study results?

How will communications with Dow be handled? Will Dow receive draft communications for review prior to their release to the

public?

* Security of data

Will UM data and samples be open to subpoena in a court case? Does the UM anticipate conducting additional studies with the

samples collected?

* Purpose of the study

We are still unclear about the purpose of the proposed study. The response to our letter was inadequate. The purpose of a

study is not a description of study design, but instead should provide the broader framework and intent or aim of the study.

We also remain unclear about the specific null hypotheses being forwarded. Again, the response to our last inquiry did not

adequately address this question. Finally, we remain concerned that the study design will not have adequate power to result

in findings useful to the protection of public health.

One null hypothesis, as we understand it, is that dioxin blood levels are not associated with levels of dioxin in the dust

and soil, or to proximity or duration of residence to Dow's sources of contamination, or to consumption of fish/game, past

occupations, and other factors (or some variation of this). Based on a review of the literature, understanding the

relationship between dust and soil and serum dioxin levels, for instance, is complex. Also, given the overwhelming

importance of diet to serum dioxin levels, you are unlikely to learn more about the relationship between these other factors

without carefully controlling for dietary sources and habits. How do you intend to do that? As currently proposed, we fail

to see how this study design will contribute to understanding this complex problem. The likely results could muddy, not

clarify, the picture for residents.

Further, is there any intention of trying to identify people in the floodplain or the surrounding counties who may have

elevated levels of dioxin in their blood, if they exist? If so, then one would want to design the study to figure out what

factors tend to cause elevated levels, and then oversample based on that information.

A second null hypothesis, although this appears to be shifting, is: residents living in the contaminated floodplain do not

have elevated levels of dioxin in blood serum when compared to a control group. We have previously and continue to assert

that residents of Midland and Saginaw counties outside of the floodplain are clearly not an uncontaminated control group.

These residents are likely to have a range of exposures which will be hard to characterize and not representative of

background levels. Generally characterizing exposure through a random sample may be interesting, but again we would assert

that this information is not the most critical when considering public health protections -- it is more important to learn

about those most likely to be at risk, and those most likely to be more heavily exposed -- in order to protect those

groups.

* Role of plaintiffs in the study

We are concerned that the large group of people who may become plaintiffs in the class action lawsuit with Dow (and who will

likely represent the vast majority of those living along the contaminated floodplain) can participate in the study by having their blood tested and replying to a survey, yet weren't involved in

community meetings convened about the UM study, and aren't able to have input into study design and interpretation because

they are excluded from the UM-convened CAP.

* Source of Quote

In our previous letter, we quoted your powerpoint presentation that the statistical analysis proposes to "characterize the

distribution of dioxin blood levels in the region of the Tittabawassee River outside the flood plain." You wondered about

the source of that quote. It is a direct quote from slide 24 of your powerpoint presentation of 2/19/04.

* Risk Communication

In our earlier letter, we asked whether a risk communication plan had been developed for reporting results to participants.

Your response indicated you thought it premature to work on this, and further you didn't expect any messages specific to

those most exposed. We believe this answer is inadequate. It is not too early to prepare for risk communication to

subjects. Elevated levels of dioxin, particularly in women of child bearing age, may suggest an intervention to test thyroid

levels, for instance. Thyroid hormone levels or function could be affected by exposure to dioxin. Normal thyroid hormone

function is critical to fetal development. There may be other interventions that are important to consider. A review of the

literature and a detailed consultation with experts seems the absolute minimum to address this issue.

* Indoor dust sampling

Based on our quick review of the literature, there has been a significant amount of work lately on reviewing the

effectiveness of various dust sampling protocols. The one outlined by UM does not appear

to represent the latest thinking. We continue to believe that dust sampling procedures and protocols are critically important for a valid study.

We continue to have significant concerns about this study. Thank you for the opportunity to comment.

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Ecology Center

Dave Dempsey
Michigan Environmental Council

Petitioners to ATSDR

And
Michelle Hurd Riddick
Lone Tree Council

CC:
MDEQ
MDCH

ATSDR
SPH
Elected representatives