STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

STEVEN E. CHESTER
DIRECTOR

October 20, 2009

David H. Garabrant, M.D., MPH
Emeritus Professor of Occupational
Medicine & Epidemiology
Department of Environmental Health Sciences
School of Public Health
The University of Michigan
109 South Observatory Street
Ann Arbor, Michigan 48109-2029

Alfred Franzblau, M.D.
Professor of Occupational Medicine
Department of Environmental Health Sciences
School of Public Health
The University of Michigan
109 South Observatory Street
Ann Arbor, Michigan 48109-2029

Dear Drs. Garabrant and Franzblau:

SUBJECT: Information on the Michigan Department of Environmental Quality (MDEQ) Web Site Regarding The University of Michigan (UM) Dioxin Exposure Study (DES)

Thank you for your letter of September 25, 2009, to Director Steven E. Chester, MDEQ, requesting the correction of information regarding the State of Michigan's review of the UM DES on the MDEQ Web site. Director Chester has referred your letter to me for response.

The MDEQ has committed to working with the UM DES team and The Dow Chemical Company (Dow) to obtain further evaluations and interpretation of the data from the study as a more productive approach than back-and-forth responses to the concerns raised by Dr. John Kern's March 2009 Report (Report). Although it is taking a considerable amount of time to complete this collaborative work, you and your team have expressed to us, and agreed, that these further evaluations are desirable for a better understanding and interpretation of the data. We are continuing to work with you to complete the rest of the analyses and define the range of conditions/parameters to which they apply prior to updating the Report and discussing any interpretations of the data with the public.

As you are aware, the MDEQ identified many of the key issues and brought them to your team's attention in 2004, during the study design phase. The MDEQ is prepared to complete the ongoing evaluations to address the concerns raised in the Report. Once the collaborative evaluations are completed, the MDEQ will provide an updated Report to replace the current Report on our Web site.

You stated in your letter that the questions raised by Dr. Kern were addressed by the UM by July 10, 2009. Although a few of the concerns raised about the base model have been addressed, the most critical concerns related to risk management decisions still require

additional information and analyses. As indicated in my e-mail response to you of July 22, 2009 (enclosed), those that still have not been completely addressed include:

- Evaluation of more recent exposure with short half-life congeners

- Providing numbers and levels for participants included in the model related to exposure variables, such as:

    - Fish consumption;
    - Game consumption;
    - Soil concentration and soil exposure related activities; and
    - Waterfront property owners.

    This information should be provided in a simple spreadsheet to save preparation time.

- Evaluations that link exposure to contaminant concentrations (e.g., game consumption and game concentrations, fish consumption and fish concentration, and years gardening and soil concentration).

Although progress has been made in resolving some fundamental concerns with the base model, the MDEQ does not agree that these key issues have been fully resolved. Until they have been fully resolved, we plan to leave the Kern Report on our Web site. We will continue to work with your team to resolve the above key issues, as well as any emerging issues. All of this information is critical to allow the MDEQ to evaluate how the study results may apply to the regulatory requirements associated with the contamination (e.g., reasonable maximum exposures).

Examples of some of the preliminary results from the ongoing evaluations include:

- Ongoing hunting on the Tittabawassee River floodplain, fish consumption from the Saginaw River and Bay, and soil concentrations are all associated with significantly higher serum levels for 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF) (a short half-life congener highly elevated from historic releases from Dow). This means that ongoing exposures related to historic releases from Dow may be important. This is in direct contradiction to the UM DES findings published in the *Environmental Health Perspectives* article that stated, "There was little contribution from exposures since 1980 in Midland and Saginaw Counties to serum dioxins." Additional work was identified by the UM, MDEQ, and Dow teams for this and other short half-life congeners to further evaluate ongoing exposures.

- The conclusions of the UM DES that the main exposure in the Midland/Saginaw area occurred during the 1960s and 1970s are suspect. The participants in the UM DES who lived in the Midland/Saginaw area during the 1960s and 1970s also lived in the Midland/Saginaw area through the "after 1980" time period. The UM DES was not able to include participants that lived in the Midland/Saginaw area only during the 1960s and 1970s. This makes it difficult to determine if the effect is due to the time of exposure (1960s and 1970s) OR a longer duration of residence in the Midland/Saginaw area (from the 1960s and 70s through the time of serum collection in 2005-2006).

    The MDEQ raised further concerns with these conclusions based on the results of July 2009 follow-up analyses related to blood serum levels for a short half-life congener. Elevated blood serum levels were associated in the UM DES with behavioral activities that

occurred in the 1960s and 1970s. However, these elevated serum levels of this short half-life congener could not be caused by exposures during that specific time frame (2,3,7,8-TCDF has a half-life of about one year in the human body). This further evaluation identified that exposures that occurred in the 1960s and 1970s cannot be separated from ongoing and current exposures as asserted in the Report.

It should be noted that many of these key issues were also raised as concerns by the U.S. Environmental Protection Agency (U.S. EPA) in their recent review (released September 30, 2009). An additional concern raised by the U.S. EPA and MDEQ is that the study does not include children (especially those living on properties with elevated soil concentrations). We expect the additional information and evaluations will also help address some of the U.S. EPA's concerns.

It is important to note that the MDEQ Web site does contain the April 2, 2009, letter committing the MDEQ to the collaborative evaluations, and we added a statement regarding the ongoing evaluations as committed to in our July 22, 2009, e-mail communication. Since resolution of MDEQ concerns is taking longer than anticipated, we plan to add a note indicating that people can contact Dr. Deb MacKenzie-Taylor, Waste and Hazardous Materials Division (WHMD), MDEQ, for updates on the ongoing review and for other communications associated with this review.

With respect to your assertion that the Michigan Department of Community Health (MDCH) studies should have been reviewed by Dr. Kern, those studies do not rely on complex statistics such as those used in the UM DES. Furthermore, the MDCH studies have not been used by the MDEQ at this point to make regulatory decisions. The MDCH also has its own mandates for protection of public health, separate from the MDEQ.

We understand you are continuing to present results of the UM DES to local community groups. We requested copies of your presentation materials on June 11, 2009, July 17, 2009, and July 22, 2009. You committed to provide them to us in your e-mail of June 11, 2009; however, we have not yet received these materials and would appreciate receiving them from you at your earliest convenience.

If you should have any questions regarding this letter or require further information, please contact Mr. George W. Bruchmann, Chief, WHMD, at 517-373-9523; or you may contact Dr. MacKenzie-Taylor at 517-335-4715; or you may contact me.

Sincerely,

Jim Sygo

Jim Sygo
Deputy Director
517-241-7394

Enclosure

cc: United States Representative David Camp
Governor Jennifer M. Granholm
Senator Jim Barcia
Senator Roger Kahn
Senator Tony Stamas
Representative Andy Coulouris
Representative Kenneth Horn
Representative Jim Stamas
Dr. Mary Sue Coleman, President, UM
Dr. Linda Birnbaum, National Institute for Environmental Health and Science
Dr. Marie Haring Sweeney, National Institute for Occupational Safety and Health
Dr. Ronald Hites, Indiana University
Dr. Paolo Boffetta, International Agency for Research on Cancer
Dr. James Collins, Dow
Dr. John Kern, Kern Statistical Services, Inc.
Mr. Jeff Frithsen, U.S. EPA
Ms. Mary Logan, U.S. EPA, Region 5
Mr. Mario Mangino, U.S. EPA, Region 5
Ms. Genna Gent, Governor's Washington Office
Dr. Donald Patterson
Dr. Linda Dykema, MDCH
Mr. Steven E. Chester, Director, MDEQ
Ms. Carol Linteau, Legislative Director, MDEQ
Mr. Frank Ruswick Jr., Senior Policy Advisor, MDEQ
Mr. George W. Bruchmann, MDEQ
Ms. De Montgomery, MDEQ
Mr. Steve Buda, MDEQ
Mr. Terry Walkington/Ms. Trisha Confer, MDEQ
Ms. Cheryl Howe/Dr. Deb MacKenzie-Taylor/Mr. Al Taylor, MDEQ
Corrective Action File

From: Sygo, Jim (DEQ)
Sent: Wednesday, July 22, 2009 1:12 PM
To: 'Garabrant, David'
Cc: Franzblau, Alfred; birnbaumls@niehs.nih.gov; Hites, Ronald A.; Sweeney, Marie (CDC/NIOSH/DSHEFS); boffetta
Subject: RE: July 9-10 Workshop

David,

I appreciate your team's efforts to work with the MDEQ to address the concerns raised by the Kern review and the time it is taking to complete the collaborative evaluations.

The MDEQ will be pleased to provide an updated report once the collaborative evaluations are completed. It is my understanding that while some of the concerns raised have been addressed, completion of the additional analyses and information requests is essential to address the issues most critical to risk management decisions as follows:

- Evaluations more directly related to current exposure
- Information on contamination related exposure variables of participants included in the model such as
    - fish consumption;
    - game consumption;
    - soil concentration and soil exposure related activities; and
    - waterfront property owners
- Evaluations that include exposure related activity and contaminant concentrations (e.g., game consumption and game concentrations, fish consumption and fish concentration, years gardening and soil concentration). This information can be provided in a simple spreadsheet to save preparation time.
- Applicability of the study results to the regulatory requirements associated with the contamination (e.g., reasonable maximum exposures).

As you are aware, these are key issue for the agency in the review of the UM DES and have been communicated to the team from the study design phase. It is not our impression that these have been resolved to date. Although we agree that progress has been made in resolving some fundamental concerns with the base model, the above, key issues have yet to be fully resolved. Until those issues are resolved, we plan to leave the Kern review on our website with the statement suggested in Deb MacKenzie-Taylor's July 17, 2009 e-mail, as follows:

> Evaluation of additional information and analyses is ongoing in a further collaborative review with the MDEQ, the UMDES team and Dow to address issues raised in the March 2009, Kern Statistical Services, Inc. Review of UMDES Statistical Modeling Methods, Analysis, and Interpretation. This collaborative review is expected to be completed during 2009.

In the meantime, we remain encouraged that the above key issues, as well as any emerging issues, may be resolved or better understood and communicated with the further analyses and information that your team has agreed to complete this year.

I noticed in Deb MacKenzie-Taylor's e-mail reference to presentation materials from your recent public presentations. I, too, would appreciate receiving a copy of that information.

Thank you.

From: Garabrant, David [mailto:dhg@umich.edu]
Sent: Friday, July 17, 2009 3:58 PM
To: Sygo, Jim (DEQ)
Cc: Franzblau, Alfred; birnbaumls@niehs.nih.gov; Hites, Ronald A.; Sweeney, Marie (CDC/NIOSH/DSHEFS); boffetta
Subject: FW: July 9-10 Workshop

Jim,
We request that MDEQ remove the John Kern comments regarding the UMDES from its website. The comments are wrong, your staff knows they are wrong, and they are creating misunderstandings about the UMDES.

It is not appropriate for MDEQ to publicize inaccurate statements about our research long after your agency has been apprised of the inaccuracies in those statements. We have worked extensively with your consultant Dr. Kern to address his concerns. Every analysis he has requested has either been completed or we have agreed to complete in the next few months.

The statement that Deb Mackenzie Taylor has suggested below is not an adequate response in part because it continues to allow misleading statements to be publicly available on your website.

With warmest regards.

David H. Garabrant, MD, MPH
Emeritus Professor of Occupational Medicine and Epidemiology
The University of Michigan
1420 Washington Heights
Ann Arbor, MI 48109-2029
e-mail: dhg@umich.edu
phone: 734-936-0753

From: MacKenzie-Taylor, Deb (DEQ) [mailto:MACKENZIE-TAYLORD@michigan.gov]
Sent: Friday, July 17, 2009 3:14 PM
To: Garabrant, David; Franzblau, Alfred; Jolliet, Olivier; Gillespie, Brenda
Cc: John Kern; birnbaumls@niehs.nih.gov; Hites, Ronald A.; Sweeney, Marie (CDC/NIOSH/DSHEFS); boffetta; Price, Paul (S); Lesa Aylward
Subject: July 9-10 Workshop

David et al,

I would like to thank you for hosting the meetings last week and all the work your team has done for this collaborative process. I think we are making progress and understand the time limitations you have had for completing the additional analyses.

Please send us a copy of the latest revision to the meeting notes document and attachments. We were unable to download these documents at the conclusion of the meeting on Friday.

In response to your request to remove the March 2009 document from our website, we expect to replace the document once our collaborative review has been completed. We agree that a summary document and technical detail attachment will be appropriate. We are willing to add the statement to the website in the meantime as follows:

> Evaluation of additional information and analyses is ongoing in a further collaborative review with the MDEQ, the UMDES team and Dow to address issues raised in the March 2009, Kern Statistical Services, Inc. Review of UMDES Statistical Modeling Methods, Analysis, and Interpretation. This collaborative review is expected to be completed during 2009.

We also agree that once this collaborative evaluation has been completed, we should present the results to the public. We will have to determine the appropriate meeting venue, once the evaluation is complete.

I am also reminding you of the request for a copy of the presentation materials from the June 12, 2009 Midland Chamber of Commerce meeting. We would like a copy a schedule of the meetings you mentioned on July 9 and if there will be revisions to the presentation materials for the upcoming meetings, a copy of the revised presentation materials.

Thank you again for your time and assistance on these issues.

Deb

Please note that the offices of the Michigan Department of Environmental Quality are to be closed on June 19, July 6 and 24, August 7 and 21, and September 4, 2009, due to the furlough of state government employees. These unpaid temporary layoff days are to help eliminate a shortfall in the 2009 state budget.

Deborah R. MacKenzie-Taylor, Ph.D.
Toxicology Specialist
Hazardous Waste Technical Support Unit
Waste and Hazardous Materials Division
Michigan Department of Environmental Quality
P.O. Box 30241
525 W. Allegan St. (for overnight deliveries)
Lansing, MI 48909
517-335-4715
mackenzie-taylord@michigan.gov

From: David Garabrant [mailto:dhg@umich.edu]
Sent: Thursday, June 11, 2009 6:12 PM
To: MacKenzie-Taylor, Deb (DEQ)
Cc: 'John Kern'; 'Alfred Franzblau 1'; birnbaumls@niehs.nih.gov; 'Hites, Ronald A.'; 'Sweeney, Marie (CDC/NIOSH/DSHEFS)'; 'boffetta'
Subject: RE: response to UMDES meeting notes from April 28-29 and May 4

Deb and John,
Thanks very much. It is clear you and John have put a huge amount of time into this. We are grateful. We will get working on the analyses and your requests for supporting outputs ASAP.

I will be happy to keep you informed of my public outreach activities and will provide you with my powerpoints.

I would also appreciate two things that you could do for us:

- I have tried to be included in the MDEQ remediation meetings since last fall and repeatedly have been denied an opportunity to speak. Once we come to agreement on the UMDES results I think it is appropriate that I have a chance to address the meeting, or we could do a joint address regarding the UMDES findings. Perhaps you could mention this to your colleagues who set the agenda.

- We are concerned about the EPA's announcement that they will review the UMDES and provide a written critique by Sept 30. Given that no one at EPA has engaged meaningfully with us in the past 5 years, we are appropriately concerned that this review may not be rigorous or accurate. Our real concern is that they will reiterate John Kern's March 2009 comments as a basis for saying that the UMDES is unreliable and irrelevant. This would be an injustice that we would seek to correct. It would be a great help if MDEQ and Dr. Kern would publicly state that we have made substantial cooperative progress since his initial comments and that they no longer reflect your opinions about the UMDES. If you could say positive things, like you believe the data collection and analytic approaches are reliable and appropriate, this would be even better. You could point out the areas where additional work is needed in order to finalize the interpretation of the data. I think your comments on the meeting notes spell this out well. This should be made known to the EPA promptly, since a Sept 30 deadline means they have probably already written their draft evaluation.

Thanks and best wishes.

David H. Garabrant, MD, MPH
Emeritus Professor of Occupational Medicine and Epidemiology
The University of Michigan
1420 Washington Heights
Ann Arbor, MI 48109-2029
e-mail: dhg@umich.edu
phone: 734-936-0753

From: MacKenzie-Taylor, Deb (DEQ) [mailto:MACKENZIE-TAYLORD@michigan.gov]
Sent: Thursday, June 11, 2009 5:19 PM
To: MacKenzie-Taylor, Deb (DEQ); David Garabrant; John Kern
Cc: Biling Hong; Xiaohui Jiang; birnbaumls@niehs.nih.gov; Hites, Ronald A.; boffetta; Sweeney, Marie (CDC/NIOSH/DSHEFS); Gillespie, Brenda; Alfred Franzblau 1; Price, Paul (S); Budinsky, Robert (RA); Howe, Cheryl (DEQ); Taylor, Al (DEQ); Montgomery, Delores (DEQ); logan.mary@epa.gov; clark.milt@epa.gov; rudloff.gregory@epa.gov; mangino.mario@epa.gov
Subject: RE: response to UMDES meeting notes from April 28-29 and May 4

Attachment

Please note that the offices of the Michigan Department of Environmental Quality are to be closed on June 19, July 6 and 24, August 7 and 21, and September 4, 2009, due to the furlough of state government employees. These unpaid temporary layoff days are to help eliminate a shortfall in the 2009 state budget.

Deborah R. MacKenzie-Taylor, Ph.D.
Toxicology Specialist
Hazardous Waste Technical Support Unit
Waste and Hazardous Materials Division
Michigan Department of Environmental Quality

P.O. Box 30241
525 W. Allegan St. (for overnight deliveries)
Lansing, MI 48909
517-335-4715
mackenzie-taylord@michigan.gov

From: MacKenzie-Taylor, Deb (DEQ)
Sent: Thursday, June 11, 2009 5:18 PM
To: 'David Garabrant'; 'John Kern'
Cc: 'Biling Hong'; 'Xiaohui Jiang'; birnbaumls@niehs.nih.gov; 'Hites, Ronald A.'; 'boffetta'; 'Sweeney, Marie (CDC/NIOSH/DSHEFS)'; 'Gillespie, Brenda'; 'Alfred Franzblau 1'; 'Price, Paul (S)'; 'Budinsky, Robert (RA)'; Howe, Cheryl (DEQ); Taylor, Al (DEQ); Montgomery, Delores (DEQ); 'logan.mary@epa.gov'; 'clark.milt@epa.gov'; 'rudloff.gregory@epa.gov'; 'mangino.mario@epa.gov'
Subject: RE: response to UMDES meeting notes from April 28-29 and May 4

David,

We apologize for not getting this to you sooner. Both John and the MDEQ staff have had many competing priorities.

We realize your team has probably completed many of the "to be done" items. We are also requesting copies of the outputs from the analyses complete April 28 and 29 and those to be conducted, so the basis of these evaluations and interpretations is transparent.

We have been working on the fish and game data, but the data that was provided involved the individual congener data values combined with codes. Extracting the values from the codes is taking some time. We may need for Dow to provide the data in a different format for both of us to use in combining with the state's fish contaminant monitoring data and developing congener specific summary statistics to use for both fish and game. I will send the MDEQ's fish contaminant monitoring data. We will want to evaluate the three sets of fish filet data and two sets of wild game edible tissue data. Other topics to discuss include:

- Exclusion of upstream and/or control data
- Whether to treat data in same manner as consumption advisories data
    - Type of filet
    - Values below the detection limit
- Averaging of duplicates and/or lab replicates
- Consumption proportions or ratios for species combinations
- Other issues to be identified

We agree with Olivier that we need to discuss this soon and get the data summarized for your team to complete the fish and game models. The proposed June 19 date is not available due to it being a state mandatory furlough day.

We have also received two inquiries regarding a presentation you are giving to the Midland Chamber of Commerce tomorrow. We would appreciate a copy of your presentation materials (or they could be placed on your website). We would also appreciate you letting us know of other public outreach that you are conducting related to the results of the study.

We also know we need to schedule another meeting soon. John and I are available the following dates:

- June 22
- June 29 - 30
- July 9-10
- July 13-17
- July 20-23

Thank you for your patience and assistance in this process.

Deb

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Lansing, MI 48909
517-335-4715
mackenzie-taylord@michigan.gov

From: David Garabrant [mailto:dhg@umich.edu]
Sent: Tuesday, May 19, 2009 4:56 PM
To: MacKenzie-Taylor, Deb (DEQ); 'John Kern'
Cc: 'Biling Hong'; 'Xiaohui Jiang'; birnbaumls@niehs.nih.gov; 'Hites, Ronald A.'; 'boffetta'; 'Sweeney, Marie (CDC/NIOSH/DSHEFS)'; 'Gillespie, Brenda'; 'Alfred Franzblau 1'; 'Price, Paul (S)'; 'Budinsky, Robert (RA)'
Subject: response to UMDES meeting notes from April 28-29 and May 4

Deb and John,
We would appreciate your comments and revisions to the meeting notes I sent you after the UMDES SAB meeting. We are trying to get the analyses done and want to be sure that we captured the discussion, recommendations, and conclusions accurately. Could we get your response by this Friday May 22.

Thanks and best wishes.

David H. Garabrant, MD, MPH
Emeritus Professor of Occupational Medicine and Epidemiology
The University of Michigan
1420 Washington Heights
Ann Arbor, MI 48109-2029
e-mail: dhg@umich.edu
phone: 734-936-0753