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UIC University of Illinois
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December 20, 2007

Howard Frumkin, M.D., D.P.H.
Director,
Thomas Sinks, Ph.D.
Deputy Director
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry
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Dear Drs. Frumkin and Sinks:

I apologize for the long delay in response to your letter of September 12, 2007 concerning the ATSDR Report on *Public Health Implications of Great Lakes Areas of Concern*. This has been a difficult letter to get to. While I helped with the production of the International Joint Commission's letter to you on this topic, I do owe one of my own as I was an external reviewer of the manuscript. This will be a straight forward, and I am afraid, critical letter. Therefore, let me say at the outset that I write this with the outmost respect for both of you as scientists and advocates for our environment and reductions in threats to human health.

As you recall, for many years environmental researchers, physicians, and advocates have been asking that the Federal Government organize existing health and environmental data bases into a form that can be correlated and compared. This call was made with full knowledge of the deficits of the individual data bases and the difficulty in gleaning anything useful from their interconnection. Despite these problems, we were and are convinced that these correlations will raise interesting hypotheses of possible concern about potential interactions of environmental toxins in an area and health conditions of the public.

Historically such hypotheses were raised by scientists, physicians, and most importantly by the public at large have been the driving force in securing public and private funds for research to assess the accuracy of these evidence based speculations. This engine has enabled elected officials on both sides of the aisle to secure funding for research, and needed interventions if the hypotheses have proven to represent a true human health impact of environmental toxins.

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I recall a Congressman in your area some years ago who had entered the Congress at the head of a "revolution" to reduce Government spending. When presented with a situation in his district was a great supporter of ATSDR and its full assessment of an environmental exposure which was raised as a potential hazard by his constituents. Without this engine little attention would be directed toward these seemingly invisible dangers.

With this in mind, I was most gratified some years ago that, at the request of the IJC, ATSDR agreed to undertake a significant review of available information to produce the first systematic evaluation of the contribution of hazardous waste sites to the environmental chemical contaminant burden and their potential impacts on public health in Great Lakes' Areas of Concern. Your agency agreed to focus on the 11 Critical Pollutants identified by the IJC that have been described as immediate priorities, targeted for virtual elimination; and banned from production and/or highly toxic substances that have been commonly associated with specific health outcomes observed at one or more AOC sites. The report was projected to include data covering over 100 hazardous waste sites in the 26 U.S. IJC designated Areas Of Concern. This report was projected as part of the US responsibilities under Annex 2 of the Great Lakes Water Quality Agreement (GLWQA).

Your agency agreed that this approach of utilizing environmental and public health information in the 26 U.S. AOCs, is a part of its role under the U.S. Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) to assess health hazards at designated hazardous waste sites.

The agency hired the Syracuse Research Corporation to produce a first draft and assigned senior staffer Dr. Annette E. Ashizawa, (now a member of IJC Health Professionals Task Force) as Project Manager. Further, the obvious difficulty inherent in developing this report was underlined when Toxicology Division Chief Dr. Christopher T. De Rosa gave much of his personal attention to this project. These steps were particularly gratifying as I have been impressed by the high quality, well balanced, work of these agency scientists in the past. I have utilized the Toxicologic Profiles of ATSDR as teaching and reference tools for well over a decade. I had seen these scientists handle the complex issues of association without causation and precautionary approaches to preventing harm, with a calm reliance on science and data when economic and political winds swirled around them.

I note that this report, which has taken years in production, was subjected to independent expert review by the IJC's Health Professionals Task Force and other Boards, over 20 EPA scientists, state agency scientists from New York and Minnesota, 3 academics (including myself), and multiple reviews within ATSDR. As such, this is perhaps the most extensively critiqued report, internally and externally, that I have heard of. It was exciting therefore to hear from the IJC that a joint release was planned for last spring and disappointing to hear that ATSDR delayed this release.

It is with this background that I read of your last minute concerns with this report contained in the letter that you sent on September 12, 2007. In response, I should like to restate my impression formed during my more careful review of the draft as an

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external reviewer last fall. This is a well done useful piece of work that raises a series of interesting questions that should stimulate further evaluation.

The authors clearly and amply note the limitations of the study and specifically say that this report "does not attempt" to demonstrate "links between specific exposures and corresponding health effects". In fact, they conclude:

"Thus, this report should be considered only an overview of patterns of exposure and general health measures in the Great Lakes region... It does not accomplish the goal of defining the threat to human health posed by pollutants in the Great Lakes region.... Perhaps the major conclusion that can be drawn from this Report is that far more science needs to be done in order to reach a more complete understanding of the health effects of chemical exposures in the Great Lakes."

As such this report is exactly what I had originally expected. It will permit the educated lay public to form hypotheses based on available data. I should add that the exciting use of GIS mapping modalities will help the public understand the correlations and their limitations. I believe it is of utmost importance that the public be allowed to see the information that the government has available without spin or obfuscation. It will stimulate interest and a research agenda for subsequent years.

I believe I have answered your question concerning whether the report "falls very far short of achieving its purpose" and that "perhaps it should not be issued." I would only add a more general note that all surveillance data is available to multiple interpretations which it should be and this should never lead to misguided attempts to protect the public from available data. I would add that this is frequently a problem of full epidemiologic studies as well and has been used by those with secondary gain to keep the public in the dark about important information.

In response to the statement in the next paragraph that this report does not include "other approaches to assessing human exposures" and questions whether the "existing approach to assessing exposure is sufficient and valid?" After all the discussion in this report of its limitations, this straw man borders on the ridiculous. Of course, as the authors have said, it is not in and of itself sufficient and valid – but unfortunately it is probably necessary for the creation of further efforts that may come closer to sufficiency.

As to "The value of the health outcome data" which you observe was not subjected to an analysis utilizing a 90th percentile criterion to identify those counties that have elevated rates due to real causative factors rather than by chance alone. You both well know that a 90th percentile criteria is quite specific and allows the identification of those outlier counties that have a 9 in 10 chance of a real causative factor in their elevated rates (the low end not as relevant for these purposes). Yet you also know that this causes you to over look those counties which have an 8 in 10, 7 in 10, 6 in 10 chance that the differences seen have statistically non random reasons for existing. After the caveats in this report about not implying causation, why not leave it up to the public to

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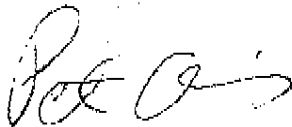
decide whether their rate of a particular disease is above average by chance or necessitates further investigation.

The repeated recitation of the deficiencies of the data available on the next page of your letter and the anguish about the lack of causative information is merely a repetition of the cautions in the report itself. Finally, as if repeating the criticisms once again, whose answers have delayed the production of this report over the years and now have caused you to delay it another half a year after its promised release, you raise the issue of the age of the data itself. This even without an argument that that the intervening years have seen such a major shift in health status or exposures as to invalidate these data that the agency has been messaging for so long. If you hurry you could start on edition 2 of this report with new data just in time to respond to questions from the covered communities as to what are the time trends of both exposure and health data.

Let me then conclude again with a strongly worded endorsement of this report, with all of its blemishes, and the wisdom of the public to utilize this information to define hypotheses about the frequently invisible effects of the environment on human health. In an era when less and less health and environmental data is collected, what does exist should not be hidden in a government vault or warehouse popularized in the first Indiana Jones movie as the resting place for the Arc of the Covenant.

All of my best to you both and your families in this holiday season. Thank you for the opportunity to comment upon this report again. Of course, I am available to discuss this further at any time you may find it useful.

Sincerely,



Peter Orris, MD, MPH

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