Center for Health, Environment & Justice
P.O. Box 6806 • Falls Church, VA 22040 • Phone: 703.237.2249 • Fax: 703.237.8389 • www.chej.org

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Hearing on
Preventing Harm – Protecting Health: Reforming CDC's Environmental Public Health Practices

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Stephen Lester, Science Director
Center for Health, Environment & Justice

Mister Chairman, distinguished Members of the Subcommittee, thank you for this opportunity to testify on the policies and procedures used by the Centers for Disease Control and Prevention and its National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR) to assess, validate and release public health documents. My name is Stephen Lester and I am the Science Director for the Center for Health, Environment & Justice (CHEJ). CHEJ is a national environmental health organization founded in 1981 by Love Canal community leader Lois Gibbs. We assist people to fight for justice, empower them to protect their communities, and lead national environmental health campaigns.

I would like to address five issues in my testimony.

1) I will provide some background on past efforts taken by CHEJ to reform the way ATSDR investigates and responds to potential public health hazards.

2) I will provide a brief description of how ATSDR‘s inadequate or flawed public health investigations have impacted local communities that have been exposed to environmental contamination.

3) I will briefly discuss my impression as a participant of the agency’s initiative called the National Conversation on Public Health and Chemical Exposures.

4) I will provide brief comments on why ATSDR has failed to adequately protect the public in the past and has been unable to address the issues that have led to these failures for the past two decades.

5) I will provide specific recommendations that I believe are important to help reform ATSDR and help ensure that its future public health products are based on sound science, address critical aspects of potential human health effects of environmental contamination and assist local communities exposed to toxic substances.

By way of background, I have master's degrees in toxicology from the Harvard University School of Public Health, and in environmental health from the New York University Institute of Environmental Medicine. I have been involved in evaluating health studies and health problems in communities since I was hired in 1978 by the New York State Department of Health to be the Science Advisor to the residents at Love Canal in Niagara Falls, NY. I joined the Center for Health, Environment & Justice in 1983 where I have been the Science Director since. One of my main responsibilities has been to provide scientific assistance and understanding to grassroots community organizations across the country. A key component of this work has been to evaluate both completed and proposed health studies conducted by state or federal agencies in response to requests from communities to address perceived increases in adverse health problems in their community. Over the 27 years that I have been doing this work I have easily reviewed many hundreds of health studies, health assessments, and health investigations, including many conducted by ATSDR. It is with this background and experience that I offer this testimony.

First, I want to make it clear that under no circumstances should the responsibility for evaluating health problems in communities be taken away from ATSDR. It is critically important that a federal agency be available to respond to concerns and questions raised by community organizations. While ATSDR has not done this well in the past, the solution is not to throw the baby out with the bath water but to fix the problem and reform the agency so that it does its work well. I will offer several recommendations later on how this may be done.

I. CHEJ's Efforts to Work with ATSDR

CHEJ (then as the Citizens Clearinghouse for Hazardous Waste or CCHW) spent several years, from 1990 to 1992, working closely with ATSDR to help reform the agency. We took on this task after Barry Johnson who was then the Director of ATSDR came to our office to meet with Lois Gibbs, CHEJ's Executive Director, and myself in early 1990. This meeting occurred at a time when ATSDR was feeling a great deal of

pressure about the quality and effectiveness of its work. The U.S. General Accounting Office (GAO) had begun an investigation into the quality of the Public Health Assessments being conducted by the agency and several leading agency officials were called before Congress to address these concerns.

ATSDR was required by the Superfund Amendments and Reauthorization Act of 1986 to complete by December 1988 Public Health Assessments at all 951 Superfund sites that existed at that time. In response to this mandate, ATSDR made a poor decision that Barry Johnson would later acknowledge was a major mistake. The agency chose to sacrifice quality for quantity. ATSDR also acknowledged at the time that the use of data generated by EPA to evaluate the extent of contamination at a Superfund site was often inadequate to evaluate the public health risks posed by the contamination at a site, but they used it anyway. GAO released its final report on the ATSDR's Public Heath Assessments in 1991.

One had to ask why Barry Johnson came to CHEJ at that time in 1990. Was he looking to divert some of the pressure the agency was feeling and show that things were different now? In his own words, Barry Johnson told Ms. Gibbs and I that the agency was "turning over a new leaf."

Recognizing the importance of the work of ATSDR, CHEJ decided to work with the agency and we proposed in a letter to Barry Johnson a series of workshops involving community leaders from sites where ATSDR had conducted either a health study, health assessment, or some health investigation, and key agency staff. The initial concerns that CHEJ had with ATSDR and the proposed plan to conduct the workshops are described in a memo written to Barry Johnson on January 10, 1990. A copy of this memo is included as Attachment 1.

The first meeting was held on June 30, 1990. The purpose of that meeting was to provide communities with the opportunity to express their needs and concerns directly to ATSDR; to provide the agency with the opportunity to explain what the agency does

and plans to do in the future; to look at how well ATSDR addresses the needs and concerns identified by the community representatives; and to look at ways the agency and communities can work together to address these needs and concerns. A summary of the meeting is included as Attachment 2.

The participants of this meeting generated a list of concerns/problems that community representatives had with ATSDR; a list of needs identified by the representatives; a list of issues that needed to be addressed, and a series of recommendations. The recommendations included:

- Change ATSDR's Congressional mandate to better and more directly serve community needs;
- Work with local community groups to help get relocation or medical care for those who need it;
- Increase citizen's role in health studies, health assessments, or health investigations - involve groups from the beginning – set up a process that allows for true public input.
- Consider community needs in establishing programs and setting priorities – meet with people/ask them what their needs are;
- Conduct a health study, health assessment, or health investigation that uses objective measures of health damage - stop using risk assessment, especially those that focus on cancer alone;
- Stop doing health assessments that measure only risks based on exposure data; instead conduct studies that answer the question "Is my health affected?"
- Educate family physicians and health care providers about the consequences of chemical exposures.

A second meeting was held in May 1991. A larger number of community representatives participated in this meeting as well as a number of scientists and agency staff. A summary of this meeting is included as Attachment 3. Barry Johnson made a number of commitments at this meeting, some of which were kept, but others

were not. This began the deterioration of the working relationship not only between CHEJ and ATSDR, but between many community leaders and the agency. Community leaders expected to see changes in how a health study, health assessment, or health investigation was conducted by ATSDR. Instead, they saw few changes. They wanted another meeting, but ATDSR, who had paid for the first two meetings, wanted to limit a third meeting to 8 to10 people and to limit the conversation to the agency's draft public participation plan that they were developing. People did not agree with this agenda and refused to participate in a third meeting.

I would summarize this experience this way. ATSDR learned what people wanted and adopted the language of the people they had met with. They used this language in their literature to make it sound like they were doing the right thing while they continued to do what they had always been doing – using inadequate or inappropriate methods to assess health problems in communities. In my opinion, ATSDR used this experience to sharpen its image at the expense of meeting community needs. In the words of Dr. Nicholas Ashford, Professor of Technology and Policy at the Massachusetts Institute of Technology and a participant in the second meeting, "ATSDR became primarily concerned with public relations and not in developing public relationships."

Ms. Gibbs and I also had a meeting in January of 2009 with Dr. Howard Frumkin, then director of ATSDR that had a very similar feeling to the meeting in 1990 with Dr. Barry Johnson. Dr. Frumkin came to our office to seek CHEJ's participation in what was described as a National Conversation that would among other issues seek to improve the effectiveness of ATSDR in addressing health problems in communities. We shared with Dr. Frumkin our previous experience with ATSDR and suggested that he skip the national conversation and begin by looking back at the recommendations that came out of the work we did with ATSDR from 1990 to 1992. Most of those recommendations were never implemented by the agency and they are still applicable today. Copies of the same materials found in Attachments 1-3 were sent to Howard Frumkin following our meeting, but we never heard back from him about these recommendations. If the agency had listened to the community leaders who attended the two CHEJ meetings

back in 1990-91 and had implemented the recommendations offered at that time, then it's very likely there would be no need for today's hearing.

II. How the Studies, Assessments, and Investigations Conducted by ATSDR have Impacted Local Communities

Over the years, we have seen many examples of ATSDR's inadequate or flawed health studies, health assessments and health investigations. The impact of these studies is quite significant in the communities where these studies are conducted. Most importantly, decisions are made as a result of these studies that affect people's lives and well being. These decisions might include whether to require additional cleanup, provide supplemental drinking water, relocate people, or take other steps to reduce exposures. None of these or other similar actions are taken when an ATSDR health study, health assessment, or health investigation finds no relationship between exposure and health outcomes, or if it is inconclusive.

The recent report by the President's Cancer Panel also found that "weak, flawed and uncorroborated studies" are a barrier to taking steps to reduce exposures and protect the public. "Efforts to identify, quantify and control environmental exposures that raise cancer risk ... have been complicated by the use of different measures, exposure limits, assessment procedures, and classification structures across agencies. In addition, efforts have been compromised by a lack of effective measurement methods and tools; delay in adopting available newer technologies; inadequate computational models; and weak, flawed or uncorroborated studies."[1]

Negative or inconclusive findings would logically follow if the design of a study was capable of providing a reasonably accurate evaluation of the potential health risks and health problems occurring in the study population. Unfortunately, this is not usually the case. Instead, studies conducted by ATSDR have consistently asked the wrong

[1] *Reducing Environmental Cancer Risk What We Can Do Now*, President's Cancer Panel, 2008-2009 Annual Report, Bethesda, Maryland, April 2010, Executive Summary, Page ii.

questions (Yukon, PA; Pensacola, FL), used inappropriate study design (Elmira, NY; Fort Hall, ID), dilute exposed populations with unexposed populations (Hopewell Junction, NY), suffered from omissions and scientific inaccuracies (Camp Lejeune, NC; Jacksonville, FL), used incomplete and or inadequate information (Midlothian, TX, Frederick, MD), and used other ill-conceived scientific methods that lead to irrelevant or inconclusive results.

Consequently, there have been hundreds of studies in hundreds of communities where the results are inconclusive by design, leading to a complete lack of trust and confidence in ATSDR and in government in general.[2] And as result, people who live in these contaminated communities are not getting the information and assistance they need to protect themselves and their children from the chemical exposures that they suffer. They are also are not getting the medical treatment they need to address their health problems. ATSDR's conclusions also tend to discourage both the individual and the local family physician from further evaluating their health problems.

III. The National Conversation

ATSDR has partnered with the U.S. Environmental Protection Agency (EPA) and the National Institute for Environmental Health Sciences (NIEHS) to create an initiative called the "National Conversation on Public Health and Chemical Exposures."[3] This project is intended to convene a wide range of stakeholders, including community groups, industry, environmental groups and public health groups to develop an "action agenda for revitalizing the public health approach to chemical exposures."

I am an appointed participant to the Scientific Understand Work Group (one of six contributing work groups) of this National Conversation. This process began in June of 2009 when Howard Frumkin was still director of ATSDR. The project is expected to

[2] See *Inconclusive by Design, Waste, Fraud, and Abuse in Federal Environmental Heath Resea*rch, Environmental Health Network, National Toxics Campaign, May 1992 and *Centers for Disease Control: Cover-up, Deceit and Confusion*, Citizens Clearinghouse for Hazardous Waste, 1988.
[3] See http://www.atsdr.cdc.gov/nationalconversation/index.html.

continue until some time in mid 2011. There are some very good people involved in this effort (there are more than 180 participants in the 6 work groups plus another 30 or so on the leadership council) and at this point it would be premature to evaluate the process and its effectiveness. I will say however, that since Dr Frumkin left the project, there has been a noticeable leadership void for the project (no permanent replacement has yet to be named) and many of the participants including myself have raised questions about how the work product of the group will be used and who is the target audience of the final work product. These and related questions are being addressed by the addition of an implementation meeting to the end of the project period. This meeting was not part of the originally plan and there is concern that there is no funding to hold this meeting.

Another observation about the National Conversation is that we have been directed in our work groups to make our recommendations generic and not focused on a specific agency such as ATSDR, even though I and others have raised specific issues to address weaknesses at ATSDR. If this process holds true, I would expect the good work that comes out of this process will not be specifically targeted or necessarily taken up by ATSDR.

IV. ATSDR's Failure to Adequately Protect the Public and Address the Issues that have Led to these Failures for the Past Two Decades.

It is difficult to say why ATSDR has acted as is has over a period of more than 20 years. Obviously some staff will have turned over during this time and some staff will have remained. I do feel, however, that much of their behavior can be traced to a lack of respect and interest in listening to and working with impacted communities. Perhaps it is arrogance and disdain for those with less education and perceived knowledge as Barry Johnson, Director of ATSDR from 1986 to 1998, warned a roomful of his staff and peers, "We may carry with us the presumption of education. It is evident in our language – in phrases such as "self- reported" or "anecdotal evidence" – and in our

dealings with the non-toxicologists, non-physicians, non-epidemiologists, and non-engineers who live around sites." [4]

Johnson closed his presentation by telling the audience that they should "not discount their experience [the community leaders]. They are our guides, and we should hear them." Good advice. Ironically, this is exactly what ATSDR needed to do then and unfortunately, still needs to do today. ATDSR needs to recognize that in order to solve community health problems caused by exposures to toxic chemicals they need to partner with the impacted community, understand its needs and concerns, and develop a response that meets those needs. Together with the community, ATSDR should define the questions that people want the agency to address. In response, the agency needs to be honest and straightforward with the community in presenting the limitations of the scientific methods available to respond to these concerns and questions. Furthermore, the role and availability of resources needs to be addressed early in the site assessment process. If the most promising study design requires a labor intensive collection of information which will cost an inordinate amount of money, then this needs to be addressed right up front with the community.

ATSDR also needs to avoid the cookie-cutter one size fits all approach to evaluating health risk at a site that has been so popular with agency. This approach is favored because it is safe and helps address the many uncertainties inherent in evaluating the health impact from exposure to toxic chemicals. These uncertainties include specifics about exposure including the level and length of exposure, the susceptibility and vulnerability of the individual, cumulative effects overtime and due to exposure to multiple chemicals, and the special vulnerabilities of children. But these uncertainties should not be used to avoid taking action to reduce exposures and protect public health. As pointed out by the President's Cancer Panel, despite many uncertainties, "in a great many instances, we know enough to act." [5]

[4] Division of Heath Assessments and Consultations (DHAC) and Cooperative Agreement States Workshop, San Antonio, Texas, March 7, 1990.
[5] Reducing Environmental Cancer Risk What We Can Do Now, President's Cancer Panel, 2008-2009 Annual Report, Bethesda, Maryland, April 2010, Executive Summary, Page vi.

The agency has also been strapped by legislative language that frames its work and restricts its responsibilities and authority. For example, Congress said that the agency must conduct a health assessment for every Superfund site in the nation. This seems logical at face value, but the legislation provided little guidance on what should be included in this assessment or how it should be conducted. When most community leaders learn that ATSDR is going to do a health assessment, they immediately think that the agency is going to evaluate or assess some measure of the health of the people who are exposed in the impacted community. In most cases, these leaders are shocked to find out that this is not what happens. Instead, ATSDR's health assessment is little more than an assessment of the risks based on available exposure data. Barry Johnson described the health assessment as the agency's "principle statements on health risk" and that "health assessments are qualitative risk assessments."[6]

When CHEJ meet with Johnson and asked him to change the term "health assessment" because it was inaccurate and misleading, he refused, arguing that he could not change what Congress had mandated ATSDR to do. Consequently, the announcement that a health assessment will be done in a community immediately raises the expectations, and hopes, of the community. When they learn how the health assessment is actually conducted, they are disappointed, often angry and frustrated, which quickly leads to distrust of the agency and of government in general.

Another statute limitation is that EPA is not required to act on the results of an ATSDR health assessment unless the assessment concludes that a site poses a "significant" risk.[7] In these instances, EPA is legally required to take steps to reduce exposures and eliminate or mitigate the risk, though how it does this is not defined. In 1991, when GAO first evaluated the effectiveness of ATSDR's Health Assessments, they found that only 13 of 951 posed a significant risk, a number that is extremely low.[8] It is unclear

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[6] Barry Johnson, "Quantitative Risk Assessment – Experiences and Lessons in Effective Risk Communication," V.T. Covello et al, Plenum Press,1989, pp. 63-66.
[7] U.S. General Accounting Office, *Superfund Public Health Assessments Incomplete and of Questionable Value*, GAO/RCED-91-178, August, 1991.
[8] Ibid.

what criteria ATSDR uses to define this critical legal threshold. It is clear, however, that recommendations to take action at sites that do not meet this threshold are not likely followed by the agency. This may lead to frustration of ATSDR staff and a lack of enthusiasm to research and identify ways to reduce or eliminate exposures if the agency does not have the authority to carry out its recommendations.

There is also a lack of leadership at the top of the agency, not just because there is no current full-time director, but over the years, the agency has lacked a director with vision and a commitment to protecting the health of the public. The agency needs a champion who is willing to fully accept and carry out its mission to "serve the public by using the best science, taking responsive public health action, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances."

To the extent that Congress can take steps to remove barriers to carrying out this mission, then I would welcome and encourage these changes.

V. Recommendations for Reforming ATSDR

1) ATSDR needs to meet with and include the community early on before it decides how to respond to the questions and concerns raised by the community. How it responds should be tailored to address the concerns and questions raised by the community. ATDSR should consider the community its partner and jointly develop the scope of work to be done at the site. A similar recommendation was made in 1990.

   Before beginning any work at a site, ATSDR should include members of the affected community in the design and development of any protocol for conducting a health study, heath assessment or health investigation that the agency is considering in response to a request or concerns raised by a community. This same recommendation was made in 1990.

2) ATSDR should consider providing financial resources to communities so that they can participate as partners in the design and development of the study/assessment. Perhaps a Health Assessment Grant, comparable to EPA's Technical Assistance Grant could be made available to community organizations. This same recommendation was made in 1990.

3) ATSDR needs to acknowledge that the scientific methods and procedures currently used to respond to questions and concerns about increased health problems in a community are limited and rarely can provided accurate and useful information about the health problems in a community. Research is needed to critique the scientific methods and procedures currently used to respond to questions about increased health problems in a community.

   ATSDR should overhaul its health study, health assessment, and cluster investigation methods and procedures. The fundamental direction of such studies should be to aid local communities in applying precautionary principles to end potentially harmful exposures. The local community should have the right to veto the undertaking of a health evaluation/investigation. This right should be codified explicitly in federal legislation. A similar recommendation was made in 1990.

4) ATSDR should be given the authority it needs to achieve its mission which is "serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances." ATSDR should have the authority to order the relocation of residents exposed to levels of toxic chemicals that pose an unacceptable health risk and to take appropriate actions to reduce or avoid public health exposures.

ATSDR has the authority to declare and respond to urgent public health concerns, and to require EPA to take action on significant risks, but the agency has little if any authority to take action at sites where the risks are not as well characterized or defined, which likely include more that 90% of the sites that ATSDR is involved in. The agency needs to be given the authority to follow through with steps to reduce or eliminate exposures especially in situations where data is lacking or where uncertainty about the risks exists.

5) ATSDR should take a precautionary approach to environmental health. The primary role of a federal health agency should be to identify precautionary measures that could be taken to reduce public exposure to toxic substances. Clear thresholds should be established and adhered to that recommend actions such as relocation or providing alternative water supplies.

6) ATSDR should have its own budget for testing to collect and analyze environmental samples. The agency is too dependent upon data and information generated by EPA that is collected to define the degree and extent of contamination at a site, not necessarily to evaluate the health risks and health impacts posed by a site. With its own budget for testing, the agency would be able to address data quality concerns and to fill in data gaps and inconsistencies. The agency should also be empowered to challenge EPA when it identifies data of poor quality, data gaps, or data inconsistencies. It may also be helpful if ATSDR got involved earlier in the site investigation process in order to have input into the design of the data collection process as part of the Remedial Investigation/Feasibility Study (RI/FS).

7) ATSDR should review and perhaps alter its criteria for establishing if a significant risk exists at a site. It currently appears to have an overly stringent requirement for data to prove past or current significant health risks. A different framework is needed to allow ATSDR to use limited and incomplete data, which will always be the case, to reach conclusions on the basis of the weight of the evidence. It

needs to focus more on qualitative information rather than on the kinds of data used by EPA in risk assessments.

8) In considering options to address the community's concerns and questions, ATSDR should be flexible and more creative and consider alternatives such conducting a pilot study to gather information rather than limit their options to a health assessment or other typical response. A pilot study might include conducting specific medical tests to help determine who has been exposed and how severely, collecting blood from a targeted group of residents, or conducting a disease or symptom prevalence study which could provide valuable information to the community and which could be the basis for further study and action. A similar recommendation was made in 1990.

9) There should be independent and timely expert peer review of ATSDR health studies, health assessments, and health investigations. The peer review members should include community representatives as well as scientists.

Thank you for your time and the opportunity to provide these remarks. I will be happy to answer any questions you may have.