U.S. House of Representatives Committee on Science & Technology Subcommittee on Investigations & Oversight

HEARING CHARTER

"Toxic Trailers: Have the Centers for Disease Control Failed to Protect Public Health?"

Tuesday, April 1, 2008 9:30 a.m. – 1:00 p.m. 2318 Rayburn House Office Building

Overview

The mission of the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of the Centers for Disease Control and Prevention (CDC), "is to 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 to toxic substances." Unfortunately, the agency failed to meet any of those objectives when it produced a Health Consultation on Formaldehyde Sampling of FEMA Temporary-Housing Trailers in February 2007. In almost every respect ATSDR failed to fulfill its mission to protect the public from exposure to formaldehyde at levels known to cause illhealth effects. The agency's handling of this issue and their inability to quickly and effectively correct it was the direct result of a collapse of senior management and leadership at the very top of the agency. The agency failed to translate scientific findings and facts into appropriate public health actions which would have resulted in properly informing and warning tens of thousands of Hurricanes Katrina and Rita survivors living in FEMA-provided trailers and mobile homes of the potential health risks they faced. The agency should have pushed to remove them from this circumstance as early as possible. Instead, they did virtually nothing.

The Health Consultation, which was conducted at the request of the Federal Emergency Management Agency's (FEMA) Office of General Counsel was scientifically flawed and omitted critical health information. The report provided an illusion of safety that was used to drive FEMA policy of maintaining tens of thousands of Hurricanes Katrina and Rita families in FEMA-provided travel trailers. Rather than clearly warning occupants of the full-extent of potential health effects they could be exposed to the report determined that opening windows and vents would reduce the concentrations of formaldehyde in the trailers below levels of health concern.

Opening windows and vents did substantially reduce the level of formaldehyde in the trailers, but the Health Consultation inappropriately relied on a "level of concern"

regarding the health risks of formaldehyde of 0.3 parts per million (ppm), ten times higher than ATSDR's own Minimal Risk Level of up to one year of exposure (0.03 ppm) and three times higher than the level of exposure widely accepted by other federal agencies to cause health effects (0.1 ppm). It also neglected to mention the potential long-term effects of exposure to formaldehyde and possible cancer risks.

Purpose

The Subcommittee hearing will review how and why the nation's public health agency failed to protect the public's health. The hearing will examine the direct involvement of the Director and Deputy Director of ATSDR in reviewing, vetting and approving the release of the agency's February 2007 Health Consultation on formaldehyde which was scientifically unsound and quickly dismissed by the agency's chief toxicologist after it had been forwarded to FEMA. Dr. Christopher De Rosa, ATSDR's chief toxicologist and then-Director of the Division of Toxicology and Environmental Medicine, immediately drafted a swift, sharp letter to FEMA pointing out many of the scientific faults with the report and said to release it as it was would be "perhaps misleading." The Director of ATSDR finally had the letter sent to Mr. Rick Preston from FEMA's Office of General Counsel, who had requested the report in the first place, from a separate ATSDR office on March 17, 2007. Amazingly, Mr. Preston acknowledged in interviews with Subcommittee staff that he simply placed the letter in a file drawer and never shared it with anyone else.

Without knowledge of the March letter, the February Health Consultation by itself led senior FEMA officials to believe that concentrations of formaldehyde in FEMA-provided temporary housing units did not present a public health hazard. That interpretation of ATSDR's Health Consultation and the astonishingly lackluster effort by ATSDR officials to correct public mis-statements by FEMA officials or to immediately revise their own flawed report in the Spring of 2007 led FEMA to maintain the *status quo* and keep tens of thousands of Hurricane Katrina and Rita survivors living in potentially formaldehyde-laden toxic trailers for at least one year longer than necessary or warranted. Apart from the March 17th letter ATSDR had no response at all. If they had, perhaps more than 30,000 families would not remain in these temporary housing units today.

Among the key questions:

- Why did the leadership of ATSDR take such halfhearted actions after the flawed report was issued and after they were informed and agreed that the report was fundamentally flawed and would be misleading if it was released?
- Why did top officials of ATSDR fail to either publicly or privately correct misstatements by the FEMA Administrator that formaldehyde in the trailers did not pose a threat to the inhabitants?
- The preparation and dissemination of the February Health Consultation to FEMA was managed by the Office of the Director. The Director of ATSDR, Dr. Howard

Frumkin, reviewed and commented on the report and his Deputy, Dr. Tom Sinks, reviewed, edited and approved the release of the report. Given their intimate involvement in the preparation of this report, why did Drs. Frumkin and Sinks both take concerted actions in the fall of 2007 to publicly scold the two authors of the report, reprimand their branch chief who was unaware of the report and demote and retaliate against Dr. Chris De Rosa, the agency's chief toxicologist, who appeared to be the one individual who repeatedly pushed the agency to do more and be more assertive in its response to the formaldehyde issue?

• How can the public and Congress trust an agency to protect the public's health that treated one of the most important public health issues of the agency's recent past so wantonly, with so little urgency, insight, sound scientific advise or concern?

Background

Formaldehyde is a colorless, strong-smelling gas that is widely used in the building industry, as an adhesive in many consumer products, including plywood, particle board, carpet and upholstery. Travel trailers are widely composed of these products. Because of the materials used in their construction, mobile homes and travel trailers have long been known to contain higher levels of formaldehyde, particularly when they are new, and there is a lot of "off-gassing" of formaldehyde. Over time the levels of formaldehyde in these products normally decrease as "off-gassing" occurs. Still, some trailers have shown elevated levels of formaldehyde even after years of "off-gassing."

Hurricane Katrina made landfall on August 29, 2005. Less than one month later on September 24, 2005 Hurricane Rita struck the Gulf Coast. These hurricanes left tens of thousands of individuals and families homeless. In response, FEMA provided more than 140,000 mobile homes and travel trailers known as temporary housing units, to individuals and families across the Gulf Coast, but the potential threat of exposure to high levels of formaldehyde from this housing was soon recognized by at least some federal agencies. High levels of formaldehyde in the manufactured homes industry was no secret. Several health studies in the 1980s documented adverse health effects from individuals living in travel trailers and mobile homes. By October 2005, concerned about the health consequences of formaldehyde exposures to FEMA workers, the Occupational Safety and Health Administration (OSHA) began testing for formaldehyde in FEMA temporary housing staging areas and discovered high levels of formaldehyde. But no agencies conducted testing on the actual trailers families and individuals would be living in for extended periods of time.

In November 2005, Dr. Howard Frumkin, who took over as Director of the Agency for Toxic Substances and Disease Registry (ATSDR) two months earlier, seemingly recognized the health risks from the toxic chemicals being unleashed into the environment in the wake of Hurricane Katrina, including formaldehyde. But Dr. Frumkin did not link the formaldehyde to trailers at the time, but said as a result of Hurricane Katrina people faced a number of environmental health risk factors. "In many ways," Dr. Frumkin told the Knight Ridder Newspapers, "this is the major environmental health disaster of our lifetime."¹ Yet, the issue of formaldehyde exposure in travel trailers never seemed to galvanize or sustain Dr. Frumkin's attention or interest.

In April 2006, after hearing of a high level of formaldehyde in one trailer, the Sierra Club began testing other FEMA trailers. It conducted 52 tests between April and August, 2006 and found that 45 of the trailers it tested had levels of formaldehyde above 0.1 parts per million, the level at which potential health effects may begin to occur. In June 2006, a Louisiana man living in a trailer who had complained of formaldehyde died. This, in combination with the Sierra Club tests and the fact that FEMA was concerned about litigation regarding the presence of elevated levels of formaldehyde in these trailers, spurred FEMA to initiate environmental testing of the trailers for formaldehyde.

In June 2006, FEMA and the Environmental Protection Agency (EPA) began developing protocols for the testing of trailers. Since the immediate aftermath of Hurricane Katrina the EPA had been working with ATSDR on emergency public health incidents, including oil fires and potentially contaminated sediment. Dr. Frumkin had implemented a streamlined procedure to respond to these sorts of emergency public health calls. Federal or state agencies would contact ATSDR's Office of Terrorism Preparedness and Emergency Response (OTPER) within the Office of the Director who would assign the specific tasks to subject matter experts within ATSDR or very often to the Emergency Response Team within the Division of Toxicology and Environmental Medicine (DTEM). In this instance, Sam Coleman, Director of EPA's Region 6 Superfund Division, who had worked in the past with the Emergency Response Team contacted Scott Wright, a member of the team about assisting FEMA in testing travel trailers for formaldehyde.

Scott Wright, following the normal procedure established by Dr. Frumkin, contacted Don Benken who was then Acting Director of OTPER. The first of a long series of conference calls took place in late June between FEMA, EPA and ATSDR regarding the testing of FEMA trailers. Don Benken was present on the call as well as Scott Wright and Joseph Little, from the Emergency Response Team. The calls were normally directed by Rick Preston, a trial attorney from FEMA's Office of General Counsel who was handling FEMA's litigation on the formaldehyde issue.

After this first call Don Benken says that he physically walked into Dr. Tom Sinks' office and informed him that FEMA arranged the call partly because they were concerned about litigation. Dr. Sinks said that they should offer assistance in any way that they could. In the end, the test protocols called for testing 96 "unoccupied" trailers for levels of formaldehyde. Testing "occupied trailers" was deemed too difficult because of confounding lifestyle issues, such as smoking. Tobacco contains formaldehyde and could have skewed the test results, some of the participants argued.

¹ Seth Borenstein and Chris Adams, "Health problems abound months after Katrina roared ashore," Knight Ridder Washington Bureau, 30 November 2005.

In the tests, the EPA collected environmental samples in 96 new <u>unoccupied</u> travel trailers in order to access the levels of formaldehyde in closed trailers and under two ventilation methods: by running the air conditioning with the bathroom vents open and by opening the windows and vents. The tests were conducted in October 2006 and the data was provided to FEMA attorney Rick Preston, who provided a CD of the test results to Scott Wright at ATSDR in November.

In the letter, received by Wright in early December, Preston said: "Please review the data and provide to us a written report of your analysis of the results of these tests and any conclusions or recommendations that can be derived therefrom." Preston also asked that the information and their analysis be kept confidential. The role of ATSDR was to interpret and analyze the data, make recommendations regarding the best methods to reduce formaldehyde in the trailers and determine potential health implications.

February 2007 Health Consultation

On December 1, 2006, Sam Coleman from the EPA sent an e-mail to Joseph Little and Scott Wright at ATSDR and cc'd Dr. Frumkin and others at EPA on the e-mail. The e-mail thanked Joe and Scott for all of their help, but then warned: "We at EPA are concerned that FEMA might not be properly interpreting the data. We urge CDC to complete its review as soon as possible to provide appropriate advice to FEMA."

Dr. Frumkin sent an e-mail to Joe and Scott the following day saying "I didn't know this was happening" and asked who at ATSDR was handling this issue. Dr. Frumkin appeared so concerned about this issue at the time that he telephoned Scott Wright on his cell phone on Wright's day off. On December 4th, Joe Little sent an e-mail to Dr. Frumkin, Dr. Sinks, and others, including Dr. De Rosa, that clearly mentions they are working with Rick Preston from FEMA's Office of General Council.

Scott and Joe's evaluation looked simply at ventilation methods to reduce formaldehyde in the trailers. Opening windows and vents did substantially reduce the level of formaldehyde in the trailers, but the Health Consultation also relied on a "level of concern" regarding the health risks of formaldehyde of 0.3 parts per million (ppm), ten times higher than ATSDR's own Minimal Risk Level of up to one year of exposure (0.03 ppm) and three times higher than the level of exposure widely accepted by other federal agencies, including EPA, OSHA and the Consumer Products Safety Commission and international organizations to cause health effects (0.1 ppm). These health effects can include irritation of the respiratory tract, watery eyes, burning sensations in the eyes, nose and throat, nausea, coughing, chest tightness, wheezing, skin rashes, and allergic reactions. Over the long term exposure to elevated levels of formaldehyde may be linked to cancers of the nasal sinuses, brain and leukemia.

On January 8, 2007, Mike Allred, Associate Director of the OTPER presented the "draft" Health Consultation at Director Frumkin's normal weekly Issues Management Meeting. Dr. Frumkin told Allred that he wanted an executive summary and some conclusions. Dr. Sinks recalls seeing and editing the document at least once, although

Scott and Joe say the document went through four revisions with the Director's office. Mike Allred physically carried the document from Joe and Scott to Dr. Sinks for edits. Dr. Sinks does not recall making any significant changes or corrections to the document. On February 1, 2007, the Health Consultation was completed and sent to Rick Preston, the FEMA trial attorney. The transmittal letter to the Health Consultation said: "In summary, the opening of windows and vents was effective in reducing formaldehyde concentrations below levels of health concern."

On February 27, 2007, the Director of ATSDR's Division of Toxicology and Environmental Medicine, Dr. Chris De Rosa became aware of the report for the first time. He immediately informed the director of ATSDR and his deputy that the report was fundamentally flawed and he drafted – on his own volition – a letter to FEMA's Rick Preston that said the February Health Consultation failed to undergo "a policy review by our senior technical staff" and neglected to mention that formaldehyde was a "probable" carcinogen, that there was no safe levels of exposure and it omitted any reference to long term exposure or cancer risks. It concluded: "Failure to communicate this issue is possibly misleading, and a threat to public health."

On Monday, March 5, 2007, "Formaldehyde in FEMA trailers" was one of the topics of discussion at the Director's Issues Management Meeting. These meetings are not attended by Division Directors, such as Dr. De Rosa.

On March 8th, Dr. De Rosa sent a second e-mail to Dr. Sinks and Dr. Frumkin, since he had not heard anything from them on his Feb. 27th e-mail, and told them that he planned to send the letter to FEMA the following day if he received no objections from them. On Friday, March 9th, Dr. Frumkin did respond to Dr. De Rosa and said he agreed with his concerns but wanted the response to FEMA coming from the same ATSDR office that originated the initial health consultation to respond. On March 17, 2007, ATSDR finally sent a letter drafted by Dr. De Rosa, but signed by the new Associate Director of the OTPER, Dr. Mark Keim, to Rick Preston at FEMA. Rick Preston told Subcommittee staff that he simply took the letter and filed it away because he believed everyone at FEMA was well aware of the risks noted in the March letter. The letter, according to Preston, was never shared with anyone else.

From March onward, Dr. De Rosa continued to raise the formaldehyde issue internally. He repeatedly pushed and prodded the agency to do more and to alert the residents of the trailers, the public and Congress to the true risks of formaldehyde exposure. At the same time, FEMA was publicly using the February Health Consultation to justify maintaining the *status quo* and keeping people in trailers. At a Congressional hearing in mid-May 2007, FEMA Administrator David Paulison said, referring to the February Health Consultation, "We've been told that the formaldehyde does not present a health hazard." During the same time-frame the media was reporting on formaldehyde linked health problems in children and others living in trailers on the Gulf Coast.

Yet, the leadership of ATSDR remained silent. They did not publicly or privately correct the record, seek a "revised" Health Consultation or take other appropriate actions.

Both Dr. Frumkin and Dr. Sinks told Subcommittee staff that they were simply unaware of media, congressional or other attention to this issue between March and the summer of 2007. They say that they wish they had done more sooner. Yet, documents obtained by the Subcommittee show that the formaldehyde issue was brought up at the Director's Issues Management Meetings at least two other times after the March 17th letter was mailed. Once on March 21st and again on May 21st in response to a CBS News report on the formaldehyde issue in FEMA trailers.

Meanwhile Dr. Chris De Rosa, continued to push the agency to become more engaged on the formaldehyde issue. On June 1, 2007, Dr. De Rosa again sends an e-mail to Director Frumkin, Deputy Director Sinks and others regarding the formaldehyde issue, warning them that there is no "safe" level of exposure to formaldehyde. Only after a second Congressional hearing on this topic in July 2007 and a severe public critique of ATSDR's February Health Consultation did ATSDR begin to respond. Even as the agency began to respond, Chris De Rosa kept pushing to do more.

In August, Dr. Frumkin placed Dr. De Rosa in charge of re-writing the February Health Consultation. He was removed from this role in September. On September 21, 2007, Dr. De Rosa wrote a blistering letter to ATSDR Director Dr. Frumkin raising his concerns that ATSDR was failing to protect the public's health on the formaldehyde and other issues. The following month, as part of his annual review, Dr. De Rosa received an "unsatisfactory" performance evaluation and was removed as Director of the Division of Toxicology, a post he had held with distinction for the previous 16 years. The Subcommittee considers Dr. De Rosa a whistleblower.

The agency did finally publish a "revised" (much more complete) Health Consultation in October 2007. But the fundamental failings of the agency revealed as a result of their work on the formaldehyde issue remains a serious issue of concern. Rather than articulating a clear, concise and scientifically sound response to the formaldehyde issue from the beginning ATSDR seems to be an agency marred by confusion, lack of clear guidance and poor science from the very top of the leadership pyramid to the bottom. In February 2007, an internal ATSDR summary of the February Health Consultation said: "In summary, the opening of windows and vents was effective in reducing formaldehyde concentrations below levels of health concern." In April 2007, the Director of ATSDR, Dr. Howard Frumkin sent out a personal newsletter to all staff that mentioned ATSDR's role in accessing environmental samples of formaldehyde levels in trailers that resulted in the February report. "These data indicate that in trailers with closed windows, formaldehyde levels are similar to those found in new conventional housing," he wrote. The day after Congressional hearings in July 2007 on this issue, one of the two primary authors of the February report wrote: "ATSDR emphatically stated in the conclusions that the levels of formaldehyde seen in trailers was of a Health Concern!" It appears clear that the agency's overall "conclusions" were not based in scientific fact, but seemed to wax and wane with the public and congressional interest in this matter.

In February 2008, a full year after ATSDR completed its initial Health Consultation on formaldehyde, Dr. Julie Gerberding, the Director of the CDC held a press conference to announce the results of new formaldehyde tests on occupied trailers. Dr. Gerberding said the tests provided a snapshot of formaldehyde levels in FEMA trailers that helped the CDC "understand and confirm what we suspected all along," she said, "that in some of these situations the formaldehyde levels are high enough where there could be a health hazard to the people who are living there." Because formaldehyde levels are likely to rise in the summer as the heat and humidity increase the CDC made that those in trailers "be relocated to safer, permanent housing as quickly as possible, and certainly before the warm summer months arrive, because we want people to be as safe as they can possibly be." At the same news conference, FEMA administrator David Paulison said, "The real issue is not what it will cost but how fast we can move people out."

Remarkably, seven months earlier, on July 24, 1007, Dr. De Rosa sent an e-mail addressed to "colleagues" at ATSDR, including Drs. Frumkin and Sinks and 15 other employees regarding FEMA's announcement that it intended to conduct formaldehyde testing in trailers. "Colleagues," wrote De Rosa, "While testing may be warranted, what immediate interventions are being pursued thru appropriate channels to interdict exposures? Or to mitigate health impacts? I am concerned that the reported clinical signs are the harbinger of a[n] impending public health disaster." But no one seemed to listen.

Witnesses

Panel I:

- Dr. Heidi Sinclair, Assistant Professor of Pediatrics, Louisiana State University, Medical Director, Baton Rouge Children's Health Program
- Mrs. Lindsay Huckabee, *Resident of FEMA-provided mobile home in Kiln, Mississippi from October 2005-to-present, along with her husband and five children.*
- Ms. Becky Gillette, Formaldehyde Campaign Director, Sierra Club Gulf Coast Environmental Restoration Task Force

Panel II:

- Dr. Christopher DeRosa, Former Director, Division of Toxicology and Environment Medicine, Agency for Toxic Substances and Disease Registry (ATSDR)
- Dr. Meryl Karol, Professor Emerita, University of Pittsburgh, Department of Environmental & Occupational Health

Panel III:

- Dr. Howard Frumkin, Director, Agency for Toxic Substances and Disease Registry (ATSDR) and National Center for Environmental Health, (NCEH)
- Dr. Tom Sinks, Deputy Director, Agency for Toxic Substances and Disease Registry (ATSDR) and National Center for Environmental Health, (NCEH)

• Vice Admiral (ret.) Harvey E. Johnson, Jr., Deputy Administrator, Federal Emergency Management Agency (FEMA