

**Dragon, Karen E. (CDC/NIOSH/EID)**

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**From:** Rob Spencer [osart@covad.net]  
**Sent:** Friday, April 29, 2011 11:19 PM  
**To:** NIOSH Docket Office (CDC); Bilics, Jessica (CDC/NIOSH/OD)  
**Cc:** Kimberly Flynn  
**Subject:** NIOSH DOCKET 226: WTC EHC Community Advisory Committee Comments on Zadroga Act Implementation  
**Attachments:** WTC EHC CAC Comments Zadroga Act Implementation.pdf

Attached as a pdf file are comments submitted by the WTC EHC Community Advisory Committee on implementation of the James Zadroga 9/11 Health and Compensation Act for NIOSH Docket 226. Thank you.



# Community Advisory Committee

c/o Robert Spencer  
Director of Media Services  
Organization of Staff Analysts  
220 East 23<sup>rd</sup> Street, Suite 707  
New York, NY 10010

## Community Advisory Committee Members

105 Duane Street Residents  
125 Cedar Street Residents  
9/11 Environmental Action  
Beyond Ground Zero Network  
Civil Service Employees Association  
Communication Workers of America, District 1  
Concerned Stuyvesant Community District Council 37, AFSCME  
Ecuadorian International Center, Inc.  
Good Old Lower East Side (GOLES)  
Henry Street Settlement  
Independence Plaza North Tenants' Association  
Manhattan Community Board 1  
Manhattan Community Board 2  
Manhattan Community Board 3  
New York Committee for Occupational Safety and Health  
New York From the Ground Up  
New York State Laborers' Union  
New York State Public Employees Federation  
The Organization of Staff Analysts  
Rebuild.Downtown.Our.Town  
Rebuild with a Spotlight on the Poor  
Southbridge Parent and Youth Association  
StuyHealth  
United Jewish Council of the East Side  
University Settlement  
WTC Community Labor Coalition  
World Trade Center Residents Coalition

April 29, 2011

John Howard, MD. M.P.H., Director  
National Institute of Occupational Safety and Health (NIOSH)  
Patriots Plaza Building  
395 E Street SW Suite 9200  
Washington DC 20201

Re: Comments on NIOSH Implementation of the James Zadroga 9/11 Health and Compensation Act of 2010.

Dear Dr. Howard:

We write on behalf of the World Trade Center Environmental Health Center Community Advisory Committee (CAC) to express our appreciation for your ongoing commitment -- and that of NIOSH -- to addressing the health needs of those affected by the terrorist attacks on the World Trade Center and for your solicitation of input from affected communities as NIOSH moves forward on implementing the Zadroga Act. The Act will provide much needed and long-overdue regular federal funding for the healthcare needs of so many within the responder and survivor communities.

As you know, the World Trade Center Environmental Health Center (WTC EHC) is the World Trade Center clinical center of excellence that presently serves the health care needs of residents, students and area workers impacted by 9/11. Known as the survivor program in the Zadroga Act, WTC EHC comprises three sites operated by the New York City Health and Hospitals Corporation at Bellevue, Gouverneur and Elmhurst hospitals. The WTC EHC currently cares for a patient population totaling more than 5,200.

The WTC EHC CAC meets monthly to provide advice and support to the WTC EHC and outreach to the communities the WTC EHC serves. The CAC is comprised of representatives of dozens of groups serving non-responders whose health was adversely affected by exposure to the World Trade Center disaster and its environmental aftermath. Members of the CAC include representatives of community-based organizations, advocacy groups, labor unions and three New York City Community Boards, as well as individual WTC EHC patients and other affected downtown residents and local workers.

In the weeks and months after 9/11, residents, school parents, and area workers were left to struggle on their own, to protect themselves and their children as best they could from unprecedented toxic exposures. It is also the case that, as people became sick from those exposures, they had no access to accurate environmental health information, effective and timely testing or cleanups of their homes, schools or offices, appropriate public health guidance, or proper medical evaluation or care.

The negligence of the federal Environmental Protection Agency as well as other federal, state and local agencies constitutes a massive failure of our government to take legally prescribed actions that would have protected the very people who had come under attack from suffering still more harm from the health hazards released by that attack.

The WTC EHC was formed in direct response to grassroots community and labor group activism, outreach and advocacy. In the face of virtually universal denial by government at all levels of the health impacts of 9/11 on non-responders, the survivor community brought its unmet health needs to Dr. Joan Reibman at the Bellevue Hospital Asthma Clinic. Bellevue responded to the survivor community's needs when no one else would.

From the beginning, the WTC EHC has recognized the importance of a patient-centered approach and a close partnership with the diverse community and labor groups representing the affected neighborhoods and populations in order to ensure that the WTC EHC's 9/11 health services are finely tuned to meet the needs of the populations it serves.

The WTC EHC rests on the foundation of New York City's municipal hospital system. Patients receive environmental and mental health treatment from an interdisciplinary, highly skilled team of specialists with established expertise in WTC illness.

In addition, and crucially, translation services, benefits counseling and other critical services are offered, enabling patients to access care easily. The close relationship between the WTC EHC and the CAC helps to ensure that the services the WTC EHC provides closely fit the evolving health needs of the diverse affected populations in the community.

The overriding goal of this collaborative work between the EHC and the CAC has always been improving health outcomes for affected lower Manhattan residents, students and area workers.

#### Areas of Concern

As NIOSH drafts regulations to implement the provisions of the Zadroga Act, we wish to emphasize that the framing of all regulations should be formulated in such a way as to strengthen the WTC EHC as the New York City survivor Center of Excellence under the Act and to maintain the ease of access to care and the standards of effectiveness that the WTC EHC currently provides to its patients.

#### Contracting Out of Services

We understand that NIOSH is considering contracting out a wide range of administrative functions and responsibilities for the WTC Health Program to information technology contractors such as Northrop-Grumman, who are on a list of pre-approved Centers for Disease Control contractors. We would appreciate clarification on which functions are being considered for outsourcing and what the rationale is for outsourcing these functions. As you know, in its present form, the Zadroga Act provides a far smaller pool of health care funding than had been originally requested at the start of the legislative process. These scarce resources for medical care must be carefully marshaled since there is no separate pool of money earmarked for administrative services. While we believe solid administrative oversight is necessary and required, we hope that this does not lead to open-ended and disproportionate expenditure on costs other than clinical services, data gathering or research.

Historically, the effectiveness of the WTC EHC has depended on the close relationship between administrators and clinicians and between the program as a whole and representatives of the populations served.

We are therefore concerned that the outsourcing of key administrative functions may in some fashion disrupt the delivery of services, the development of community and labor-based outreach techniques, and the establishment of a data center that operates on a community-based participatory research model.

We also are concerned that the introduction of a new layer of administrative bureaucracy may impede the ability of the affected communities to directly communicate concerns with NIOSH. The transparency of that relationship has thus far helped to ensure the program's effectiveness.

### Cooperative Agreements Instead of Contracts

We support the preference stated in comments by the Executive and Medical Directors of the WTC EHC for a cooperative agreement as opposed to a contract as the basis for the provision of survivor health care under the Zadroga Act. We agree that the medical needs of survivors should continue to be the driving force of the partnership between the WTC EHC and NIOSH, and for the delivery of services by the WTC EHC. The use of cooperative agreements by NIOSH has enabled the WTC EHC to have the necessary flexibility to respond to the sometimes rapidly evolving medical needs of the patient populations it serves. Operating under a contract, with a 'fee for service' model and a fixed set of deliverables, will likely limit the options of providers working to understand and develop treatments for the established and emergent health effects resulting from the unprecedented exposures to the WTC disaster.

Additionally, EHC leadership notes that cooperative agreements are allowed under Zadroga and cites precedents where NIOSH and other health programs have utilized similar approaches to health care service delivery. We ask that NIOSH seriously re-consider this model which has proven effectiveness in the delivery of WTC-specialized care, in implementing the Zadroga Act.

### Terrorist Watch List Review Process

The WTC EHC CAC would like to express our strongest possible concern with the proposed procedure for checking patient names and other identifying information against the "Terrorist Watch List."

While we understand that the "Terrorist Watch List" review requirement is part of the Zadroga Act as enacted, we urge that every effort be made to limit the impact of this provision. Based on the experiences of CAC members with the survivor population, we have grave concerns that such an intrusion into privacy may have a chilling effect and thus serve as a barrier to care for many.

It is important to consider that this population is predisposed to mistrusting the federal government. In the aftermath of 9/11, the United States failed to acknowledge the risks to the community from WTC exposures and to provide a proper cleanup. The federal government also delayed in providing specialized care to those who are sick as a result of the disaster and the poor federal response.

In recent weeks, we have seen the revelation of the Terror Watch List provision spark public anger and resentment among the responder population. They have been furious, and rightly so, at the implication that the thousands of public servants and private individuals who came to the WTC site to engage in rescue and recovery work, at great risk, must now prove they are not terrorists.

Likewise, those in the survivor community, many of whom have suffered the long term physical and mental health effects of 9/11, are gravely offended by and concerned about the Terror Watch List. We have already spoken with some residents and area workers who may not seek care at EHC or may even withdraw from the program because this unseemly, inapposite requirement raises suspicions that the government will improperly collect and share their private information for other purposes.

The Terrorist Watch List has been roundly criticized for its arbitrariness, breadth, and inaccuracy. However, its application to a healthcare scenario is even more troubling than in other circumstances: there is simply no reason why a security check must be tied to accessing health treatment. Even in settings where security is a real concern, government officials have taken steps to limit the List's impact and to provide opportunities for redress where individuals are mistakenly identified as being on the List—whether due to name duplication or some other pitfall.

With respect to the Zadroga Act, it is imperative that:

- 1) HHS/NIOSH and the WTC medical program providers covered by the Act clarify to the public and the patient population that the Terror Watch List check is for a limited purpose and will not, as a matter of course, lead to information-sharing across federal agencies. HHS/NIOSH should

reassess whether the extensive patient information specified in its April 20, 2011 correspondence to the World Trade Center Environmental Health Center is necessary for purposes of the Zadroga Act. Moreover, the proposed “Model Notification Letter” should be rewritten in collaboration with community-based groups familiar with the patient population to better explain the Terror Watch List requirement and reassure the public of its limited application.

- 2) HHS/NIOSH, in creating a new database pursuant to the Zadroga Act’s Terror Watch List provision, codify the limited purpose of this name check in its System of Records Notice; and
- 3) HHS/NIOSH develop an adequate redress procedure for patients mistakenly identified as belonging to or erroneously appearing on the Terror Watch List. HHS should also become a signatory to the 2007 “Memorandum of Understanding on Terrorist Watchlist Redress Procedures,” to which then Secretaries of State, Treasury, Defense, and Homeland Security; then Attorney General; and then Directors of National Intelligence, Federal Bureau of Investigation, National Counterterrorism Center, Central Intelligence Agency, and Terrorist Screening Center were all signatories.

#### Members of the Scientific/Technical Advisory Committee

Section 3302 of the Zadroga Act mandates the creation of a WTC Health Program Scientific/Technical Advisory Committee and two Steering Committees. The purpose of the Advisory Committee is “to review scientific and medical evidence and to make recommendations to the Administrator on additional WTC Program eligibility criteria and on additional WTC-related health conditions.” Among the Advisory Committee members to be appointed by the WTC Program Administrator are at least two representatives of WTC responders and two representatives of certified-eligible WTC survivors.

At the same time, the law creates a Responders Steering Committee and a Survivors Steering Committee “for the purpose of receiving input from affected stakeholders and facilitating the coordination of monitoring and treatment programs for the respective communities and initial health evaluations for the Survivor program.”

We believe the Program Administrator should designate the respective Steering Committees as the proper nominating bodies for the responder and survivor community members of the Advisory Committee. This will ensure accountability to the affected communities and effective, informed input from those communities in the work of the Advisory Committee.

In addition, the Program Administrator should create a mechanism through which the affected communities may nominate, for his or her consideration, appropriately qualified individuals to serve in other roles on the Advisory Committee. As those who have worked on these issues for a decade know, there are a tremendous number of highly qualified experts who might make an effective contribution to the Advisory Committee.

#### Importance of Participation by Community and Labor Organizations in WTC Health Program Outreach

In Section 3303, the Zadroga Act mandates “the WTC Program Administrator shall institute a program that provides education and outreach on the existence and availability of services under the WTC Program. The outreach and education program -- (1) shall include -- (A) the establishment of a public Web site with information about the WTC Program; (B) meetings with potentially eligible populations; (C) development and dissemination of outreach materials informing people about the program; and (D) the establishment of phone information services; and (2) shall be conducted in a manner intended -- (A) to reach all affected populations; and (B) to include materials for culturally and linguistically diverse populations.”



We believe that there is some latitude in how the Health Program can achieve these goals. We especially urge the WTC Program Administrator to implement techniques that partner with existing community and labor organizations serving affected populations.

The WTC EHC has employed a range of outreach techniques for reaching its target populations within the survivor community over the past few years, among them: traditional radio, television and print advertising, extensive advertising in subway cars, partnership with the NYC Department of Health's World Trade Center Health Registry, linking WTCHR enrollees with care, and organizing annual WTC health forums. Most importantly, the EHC funded a series of successful outreach projects in which community and labor-based organizations partnered directly with the WTC EHC to reach affected populations with information about the program and its services.

Based on WTC EHC data, this community-based outreach has been highly effective in linking individuals with care, more so than traditional media mechanisms, with the possible exception of full-car subway advertising. In large measure, this is due to pre-existing established trust relationships that these groups have with the populations they serve. In addition, these groups often have unique awareness of special needs of the affected populations and have worked closely with those populations to both promote awareness and as problem solvers when patients run into obstacles or barriers in achieving care.

NIOSH should ensure the continuance of the EHC's outreach, including the community and labor-based outreach programs which have demonstrated deep reach into the diversity of the affected populations. Without exception, these programs used face-to-face outreach that has been especially effective in overcoming a variety of psychological or cultural barriers to care.

We also hope that NIOSH will be able to provide a mechanism to fund community and labor-based outreach so that groups can seize the ideal opportunity presented by the 10th anniversary of 9/11 to raise awareness of health impacts and the availability of care.

Finally, as we explained at the meeting the EHC-funded community and labor-based groups held with NIOSH communications specialist Max Lum, many organizations and institutions possess lists of affected individuals – volunteers and students, for example - who do not yet know that they have access to WTC-specialized care. We ask that NIOSH facilitate attempts by the EHC and organizations doing outreach to provide that information.

#### Need For Survivor Population Surveillance In The Form of a Data Coordinating Center

For many years, the survivor community has called for the creation of a program to conduct population surveillance of WTC-related health conditions among survivors, comparable to the Data Coordinating Center (DCC) maintained by the Mount Sinai WTC Medical Monitoring and Treatment Program (WTC MMTP).

Until now, only survivors with current symptoms potentially linked to 9/11 have been eligible for screening at the WTC EHC. The Zadroga Act permits, and NIOSH should foster, the creation of a survivor DCC to conduct proper surveillance for WTC health impacts on downtown residents, area workers and students, over the long term.

The DCC should be established with the WTC EHC as its corresponding clinical center. A fully funded and staffed DCC should be well-integrated with the work of the EHC, i.e., it would collect all screening, monitoring and treatment data gathered by the EHC, would have the capacity to aggregate and analyze data, and would serve the EHC as a means for generating diagnostic, prognostic and treatment hypotheses for further exploration.

Like the WTC Health Registry, it would also provide a platform for research studies. Unlike the Registry, the DCC would have access to data from medical screening and monitoring exams, as well as a wealth of other clinical information generated by its coordinating clinical center.

Optimally, the DCC would incorporate data from screening exams for all screening-eligible survivors with 9/11 exposures, whether or not they are currently experiencing symptoms.

In addition, a fully operational DCC for survivors is essential because it will address important gaps in the data currently being collected:

- The WTC Health Registry has excluded from eligibility people exposed in geographic areas where EHC patient data show that exposures had the potential to cause serious health effects. In addition, the Registry only has 3000 enrollees who were under the age of 18 on 9/11, out of a population of more than 30,000 eligible children.
- WTC MMTP is monitoring a population of responders that is overwhelmingly adult, white and male. The survivor program, which serves a far more heterogeneous population in terms of gender, age and ethnicity, provides the opportunity to monitor the impact of 9/11 exposures on everyone else.
- WTC MMTP is collecting data on a responder population which, in general, was subjected to high level exposures on the pile, at the landfill, and at the debris barges. Protective public health policy requires an understanding of impacts along the full dose-response continuum and also seeks to learn how little exposure it takes to cause harm, especially for more vulnerable populations.

Finally, patients in both the responder and survivor medical programs are already facing increasingly complex and debilitating health problems. Some are dying or have died.

In order for emerging health conditions to be added for coverage under the Zadroga Act, it is essential that all clinical centers and DCCs begin to gather information on conditions not currently linked to WTC exposures. Appearance of new symptoms or reports of new diagnoses must be captured in a systematic and uniform way at all WTC medical and monitoring visits. Such data must be analyzed by the DCC at regular intervals for higher disease rates or for unexpected disease patterns. Only then will we begin to have a foundation for the kind of medical and epidemiological vigilance which affected responders and survivors need and deserve.

It is essential that the affected stakeholders partner with the CCEs and the DCCs under a Community Based Participatory Research (CBPR) process to ensure that the collection and analysis of data most fully addresses the unmet health needs of responders and survivors.

#### Research Funded by the Zadroga Act Should Operate as a Community Based Participatory Research Process

The 9/11 community of responders and survivors has an undeniable stake in the nature and scope of the research that is done under the Zadroga Act and is entitled to a genuine partnership in the research process. We believe that 9/11 community stakeholders should play an important and ongoing role in shaping the research agenda that will affect their health. Furthermore, we believe that NIOSH should give priority to researchers committed to engaging in collaboration with responder and survivor stakeholders using a Community Based Participatory Research (CBPR) model for all phases of their studies. According to the Harvard Clinical Translational and Science Center, CBPR is an emerging approach to scientific inquiry that equitably “includes community members in all aspects of research including the conception, design, analysis and dissemination of the research.”

[See: <http://catalyst.harvard.edu/programs/communityengagement/cbpr.html>]

The benefits of the CBPR model are well established. In our experience, an extremely productive dialogue can emerge where a sharing of perspectives, information and expertise has the outcome of strengthening the quality of the research.

#### The 9/11-Related Health Needs of Those Exposed as Children Must Be Met

The WTC disaster exposed more than 30,000 children who lived or went to school downtown to toxic smoke and dust. Even though it is well-established fact that children are more susceptible to harm from toxic environmental exposures, the government expressly denied the risks to children starting within the first days following the attacks. In a declaration that flew in the face of a growing body of evidence highlighting the hazards of prenatal exposures to pollution breathed by the mother, the NY City Health Department falsely assured pregnant women that there was no cause for concern.

For many years following 9/11, parents and pediatricians had no access to accurate information about 9/11-related health risks or health impacts to the area's children. Scientifically sound public health guidance on children's environmental health impacts was non-existent until 2009 and the WTC Pediatric Program, created by the City of New York at Bellevue Hospital, was not fully operational until 2008. Prior to that time, there was no WTC specialized treatment available to children.

Although a small number of studies have found that children have developed respiratory illnesses, post-traumatic stress and other conditions from their 9/11 exposures, children's 9/11-related medical problems are the least studied of any exposed population. The official silence surrounding pediatric impacts was so pervasive that the WTC Health Registry managed to enroll only 3000 children.

Beginning in 2004, a series of studies conducted by the Columbia Center for Children's Environmental Health of babies born to mothers in the months after 9/11 show that in-utero WTC-related exposures resulted in reduced fetal growth, which is associated with cognitive deficits and future health risks. Later, researchers released additional findings on this cohort showing higher levels of BP-DNA adducts, a marker of genetic damage that may increase cancer risks, in the blood of pregnant mothers and babies in the WTC cohort.

In 2008, the WTC Health Registry published a study based on its "child survey," finding that children under five who had been attending school or living in lower Manhattan were getting asthma at twice the already high rate for the northeastern U.S.

Currently, a dwindling number of studies focus on affected children as they get older, documenting mental health impacts for a range of ages, including increased post-9/11 alcohol or substance abuse among WTC-exposed adolescents.

In addition, the population of affected adolescents and young adults has become widely dispersed, creating even greater health tracking challenges.

The federal government failed to protect children and families by refusing to issue truthful risk communications and to provide proper cleanup, literally leaving them in the toxic dust. It is imperative that NIOSH make sure that those who experienced 9/11 as children do not continue to pay the price for the unconscionably long delay in government recognition of and response to WTC pediatric health effects.

NIOSH should:

- Make the study of children's and adolescents' unmet 9/11 mental and physical health needs a research priority and address the major gaps in understanding those impacts. The complete pediatric cohort should be studied, including children who were directly exposed, children who experienced 'take home' exposures, children who were exposed in-utero, and children at risk for 'reproductive impacts' as a result of paternal exposures



- Fully support a pediatric program that meets the standard of care and provides the comprehensive services necessary and expected within a Pediatric Center of Excellence. We join the request by WTC EHC leadership that NIOSH allow the needed latitude in administering the program so that the Bellevue WTC pediatric program can continue to maintain its interdisciplinary team of pediatric specialists.
- Lay the groundwork in the first five years of the Zadroga Act for the long-term monitoring of the cohort of people exposed to the World Trade Center disaster as children. Because children have much of their lifetimes ahead of them, it is critically important that this population be monitored and, if needed, linked with care many years into the future, so the trends and emergent diseases can be recognized, studied and, of foremost importance, treated as quickly as possible.

### Survivor Eligibility Boundary

Historically, the geographic catchment area for eligibility for the WTC EHC has included the area north of Houston Street and South of 14<sup>th</sup> Street. The Zadroga Act largely excludes people exposed in this area from eligibility. However, it does permit the Program Administrator to establish modified eligibility criteria “after consultation with the Data Centers described in section 3305 and the WTC Scientific/Technical Advisory Committee and WTC Health Program Steering Committees under section 3302.”

We urge that such modified eligibility criteria be established in such a way that barriers to care are avoided. NIOSH should preserve the ready access to care for the diverse community of survivors. At least one study has demonstrated that individuals exposed in the area between Houston and 14<sup>th</sup> Street are experiencing the same WTC-related illnesses as those in lower Manhattan below Houston Street. We therefore believe the WTC Program Administrator should include individuals in that geographic area found to have 9/11-related illnesses by the WTC EHC's clinicians.

### The Importance of Being Inclusive When Adding New Covered Conditions

We echo many other responder and survivor stakeholders when we call for an expedited and inclusive process for adding new conditions to the list of covered conditions under the Zadroga Act. It is essential that the statutory language be interpreted broadly, that the evidence required for adding conditions be inclusive of any relevant body of research, including research on health effects resulting from other disasters, research on animals, and research in occupational or community contexts.

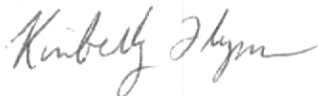
In fulfilling the Act's mandates, the Program Administrator and the Advisory Committee must recognize that due to the unprecedented nature of 9/11 as an environmental disaster, we are in somewhat uncharted territory when it comes applying our current knowledge base to the progression of exposure-related disease or the emergence of new exposure-related conditions.

We would point to the study conducted by Jacqueline Moline, et al., at Mount Sinai, “Multiple Myeloma in World Trade Center Responders: A Case Series.” In August 2009, Mount Sinai-based clinical researchers reported higher than expected cases of a bone marrow cancer, multiple myeloma, in WTC first-responders, with an unusual number of cases in police officers under 45 years of age. An additional eight cases in WTC first-responders are in the process of being verified. Researchers point to the potential for unprecedented exposures to result in unexpected patterns of disease: “The exact nature of the complex mixture of toxins released into the air on September 11th, 2001 and consequently the extent and precise nature of the exposures sustained by workers and volunteers will never be fully known. However, based on extensive analysis of dust samples collected from sites around Lower Manhattan after 9/11, it is certain that the air contained many known carcinogens. The combined effects of all the substances present at Ground Zero could interact to have new and unexpected health effects.”

To wait to reach the gold standard of epidemiological certainty before adding a condition would have catastrophic results, ensuring that care and compensation will come too late for too many.

In closing, we would like to thank you for this opportunity to provide comments to NIOSH as it undertakes the enormous task of implementing the Zadroga Act. The communities the WTC EHC CAC represents are depending on NIOSH's ability to do so in an effective, inclusive and equitable fashion.

Sincerely yours,



Kimberly Flynn  
Community Co-Chair



Robert Spencer  
Labor Co-Chair