



National Institute for
Occupational Safety and Health
Centers for Disease Control
and Prevention (CDC)
200 Independence Avenue, SW
Washington, DC 20201

September 7, 2006

The Honorable Carolyn Maloney
United States House of Representatives
Congress of the United States
Washington, D.C. 20515

Dear Ms. Maloney:

Thank you for your letter of July 11, 2006, co-signed by Mr. Fossella, and for your kind words regarding my assignment as Coordinator of US Department of Health and Human Services ("HHS") World Trade Center ("WTC") Programs.

As you know, Michael O. Leavitt, HHS Secretary, in a February 27, 2006 letter to each of you, stated that:

"there is a critical need to ensure that programs addressing the health of WTC responders and nearby residents are well-coordinated and that I have asked Dr. John Howard, Director of the National Institute for Occupational Safety and Health (NIOSH) to play the lead role in this effort."

Since then, I have made seven trips to New York City ("NYC")¹ to engage in a dialogue with members of the affected WTC responder communities, affected nearby WTC communities in Lower Manhattan and Chinatown, and with those programs funded by HHS, and by other public and private entities, which are providing medical care or support services to WTC affected populations. During those meetings, I have been working to coordinate programs for WTC-affected populations that are specifically funded through HHS.

In addition, I have been stressing the importance of reporting in the medical and scientific literature the experience to date of every program serving WTC-affected populations (whether federally-funded or not) in order to provide a better understanding of the health effects arising from the WTC disaster. These types of reports aid in improving treatment options by diagnosing health effects at an earlier stage. Scientific reporting of the health effects being experienced by WTC-affected populations also informs policymakers about the frequency and

¹My trips to NYC have occurred on the following dates: April 5-7; April 25-28; May 10-12; May 18; May 31-June 1; June 27-30; and July 24-28.

severity of WTC health effects and assists them in understanding the scope of any unmet health needs of WTC-affected populations.

The primary goal of my assignment as WTC HHS Programs Coordinator is programs coordination. Since I am doing coordination in a milieu of evolving circumstances, I do not have plans to issue a formal report, particularly since it would become quickly out of date, but I am pleased to provide you an update of my primary tasks (1) coordinating existing programs; (2) promoting scientific reporting of health issues and effects; and (3) identifying unmet needs.

Specific Questions Regarding Coordinating Existing Programs:

To provide better service for former federal responders, the National Institute for Occupational Safety and Health (NIOSH) is actively exploring with Association of Occupational and Environmental Clinics (AOEC) their interest in administering the monitoring of former federal workers on a national basis. Our goal, then, is to have a national network of clinics available to former federal workers administered by the AOEC. This proposal frees the WTC Clinical Consortium to concentrate their administrative resources on the responders who reside in the NYC Metropolitan Area. AOEC would then perform medical monitoring of all eligible former federal WTC responders nationwide through the network of AOEC clinics.

1. What is the projected date for the availability of treatment funding?

Treatment is currently available for WTC responders and volunteers. Supported by funding from the American Red Cross (ARC),² treatment programs for responders are administered by the WTC Clinical Consortium, the Fire Department of New York City (FDNY), and AOEC.

Beginning August 11, 2006, the ARC funds will be gradually replaced by funds from the FY 2006 Congressional appropriation to the Centers for Disease Control and Prevention ("CDC"), e.g., \$1.5 million in appropriations will be made available to FDNY for mental health treatment and additional funds will be added to the Mt. Sinai Medical Monitoring Program for expanded monitoring and treatment.

Support from the ARC, as administered by the Rockefeller Philanthropy Advisors is critical to ensuring a smooth transition in funding treatment of WTC responders and volunteers. Through a Memorandum of Understanding between NIOSH and the ARC, NIOSH has been able to harmonize differences in requirements between ARC-funded treatment and NIOSH-funded treatment which will allow NIOSH to utilize the current

² Current federal workers access treatment through employer-funded health insurance.

ARC funds to exhaustion, thereby augmenting the amount Congress appropriated for treatment in FY 2006.

2. What is the decision-making process for determining what medical conditions and services will be covered by the treatment program?

Implicit in the scope of coverage issue is another more difficult question-- which physical and mental health effects seen in responders and volunteers are results of their WTC exposures and which have no relation, other than temporal, with their WTC exposures? This is a difficult question to answer with scientific certainty even five years after the WTC disaster.

Nevertheless, this issue must be confronted in order to implement a WTC treatment program that is consistent with the purposes of the appropriation. A starting point for addressing this aspect of the scope of coverage issue is to review the clinical experience accumulated to date on the approximately 30,000 responders and volunteers who have been examined in the WTC Medical Monitoring Program administered by the FDNY,, the WTC Clinical Consortium³ as well as other sources of medical information on health effects in the responder population.

Medical monitoring experience to date demonstrates that a number of conditions are occurring in the responder population with some frequency, e.g., upper and lower respiratory system conditions of an inflammatory nature,⁴ post-traumatic stress disorder⁵ and other conditions reported with

³ The "WTC Clinical Consortium" is composed of the following institutions: (1) New York University Occupational and Environmental Medical Clinic; (2) Mount Sinai School of Medicine; (3) Stony Brook School of Medicine; (4) Center for Biology of Natural Systems, Queens College; and (5) UMDNJ-Robert Wood Johnson Medical School.

⁴ See, for example, the following reports: Rom et al., *Acute Eosinophilic Pneumonia in a New York City firefighter exposed to World Trade Center Dust*, Am J Respir Crit Care Med, Vol. 166, pp.797-800, 2002; Prezant et al., *Cough and Bronchial Responsiveness in Firefighters at the World Trade Center Site*, New England Journal of Medicine, 347:806-815, 2002; Safirstein et al., *Granulomatous pneumonitis following Exposure to the World Trade Center Collapse*, Chest, 123:301-304, 2003; Banauch et al., *Persistent hyperactivity and Reactive Airway Dysfunction in Firefighters at the World Trade Center*, Am J Respir Crit Care Med, Vol. 168:54-62, 2003; Skloot et al., *Respiratory Symptoms and Physiologic Assessment of Ironworkers at the World Trade Center Disaster Site*, Chest, Vol. 125:1248-1255, 2004; Salzmann et al., *Early Respiratory Abnormalities in Emergency Services Police Officers at the World Trade Center Site*, J. Occup Environ Med, Vol. 46(2):113-122, 2004; Payne et al., *Effects of Airborne World Trade Center Dust on Cytokine Release by Primary Human Lung Cells in Vitro*, J Occup Environ Med, Vol. 46(5):420-427, 2004; *Physical Health Status of World Trade Center Rescue and Recovery Workers and Volunteers--New York City, July 2002-August 2004*, MMWR, Vol. 53(35):807-812, 2004; Fireman et al., *Induced Sputum Assessment in New York City Firefighters Exposed to World Trade Center Dust*, Environmental Health Perspectives, Vol. 112:1564-1569, November, 2004; Feldman et al., *Symptoms, Respiratory Use and Pulmonary Function Changes Among New York City Firefighters Responding to the World Trade Center Disaster*, Vol. 125:1256-1264, 2004; Mann et al., *World Trade Center Dyspnea: Bronchiolitis Obliterans with Functional Improvement: A Case Report*, Am. Journal of Industrial Medicine, Vol. 48:225-229, 2005;

some frequency in the scientific literature. Using this five-year accumulated clinical experience as a start, flexibility can be built into the scope of coverage for treatment as our scientific understanding of late-onset medical conditions increases.

3. Will treatment funding cover inpatient care?

Yes, in some cases inpatient care may be covered. The appropriations language in question does not provide specific language with regard to how treatment is to be made available, i.e., in an inpatient or an outpatient setting. In the absence of any language explicitly limiting the scope of treatment, basing treatment for WTC-related conditions on medical need seems consistent with the WTC-related purposes of the appropriation.

The continuum of coverage based on medical need for WTC-related conditions would include outpatient care, outpatient diagnostic testing and imaging, and pharmaceutical and other outpatient therapies. In some cases, though, I anticipate that inpatient care for WTC-related conditions may be medically indicated.

The scope of coverage issues you ask about in Questions 2 and 3 are currently being actively considered by the members of the WTC Medical Monitoring Steering Committee.

4. What will be the governance of the treatment program and how will you ensure that the designated labor representatives of the current monitoring program continue to have a say in the development and implementation of the treatment program?

When the NIOSH Request for Applications (RFA) was initially published in 2002 to implement the medical screening program, the RFA contained language establishing a committee composed of representatives of responders and volunteers, and those providing medical screening to

Banauch et al., *Pulmonary Disease in Rescue Workers at the World Trade Center Site*, *Current Opinions in Pulmonary Medicine*, Vol. 11:160-168, 2005; Banauch et al., *Bronchial hyperreactivity and other inhalation lung injuries in rescue/recovery workers after the World Trade Center Collapse*; *Crit Care Med*, Vol.33(1):S102-S106, 2005; Banauch et al., *Pulmonary function after exposure to the World Trade Center in the New York City Fire Department*, *Am J Respir Crit Care Med*, article in press, published on April 27, 2006 as doi:10/1164/rccm.200511-1736OC.

⁵ See, for example, the following reports: Boscarino et al., *Psychiatric medication use among Manhattan Residents Following the World Trade Center Disaster*, *Journal of Traumatic Stress*, Vol. 16(3):301-306, 2003; Cancro, R., *Mental health impact of September 11*, *Molecular Psychiatry*, Vol. 9:1055-1056, 2004; Tapp et al., *Physical and Mental Health Symptoms Among NYC Transit Workers Seven and One-Half Months After WTC Attacks*, *Am J Industrial Medicine*, Vol.47:475-483, 2005; and Adams and Boscarino, *Stress and Well-Being in the aftermath of the World Trade Center Attack: The Continuing Effects of a Communitywide Disaster*, *Journal of Community Psychology*, Vol.33(2):175-190, 2005.

responders and volunteers, together with NIOSH representatives. Since then, the WTC Medical Monitoring Program has successfully utilized what has come to be known as the "WTC Medical Monitoring Program Steering Committee." Serving on the WTC Steering Committee since its inception have been several representatives of bargaining units with members in the affected WTC responder community who continue to provide valuable input.

5. What plans are being developed to care for patients outside of the New York Metropolitan Area and when will they be up and running?

Enrollees in the WTC Medical Monitoring Program who need medical outpatient treatment, but who are located in regions of the nation outside of NYC Metropolitan Area, can be seen in any one of the network of AOEC clinics nearby their place of residence under the ARC funding. Since its founding in 1987, AOEC has grown to a network of more than 60 clinics and more than 250 individuals committed to improving the practice of occupational and environmental medicine through information sharing and collaborative research.

To date, AOEC clinics have seen over 650 responders who reside outside of the NYC Metropolitan Area. These responders have been seen both in the NIOSH-funded medical monitoring program and the ARC-funded treatment program.

I am working with AOEC to develop a seamless program across all clinical locations where responders can receive federally-funded medical monitoring and treatment.

6. What progress has been made with the medical screening program for federal employees?

The WTC Federal Responder Screening Program provides medical screening for all federal employees who were involved in rescue, recovery, or cleanup operations. The medical screening is strictly voluntary and all medical screening information is kept private and confidential. The examination is provided at no cost. Specifically, all current federal workers who were involved in rescue, recovery, or cleanup operations at the WTC site or at the debris handling operations on Staten Island for at least one shift any time between September 11, 2001 and September 10, 2002 are eligible. Current federal employees receive medical screening through the Federal Occupational Health (FOH), which has clinic locations in areas where large numbers of federal workers are employed. A total of 975 federal workers have been screened to date.

7. What has been done to incorporate federal employees who have left federal service into existing medical monitoring programs?

Current federal employees receive medical screening through the Federal Occupational Health ("FOH"), a component agency of the HHS. Screening of former federal workers⁶ was previously performed by FOH until it was determined that FOH could not provide such service to former federal workers under their current scope of responsibility. An interruption in monitoring of former federal workers occurred, but in February of 2006, NIOSH and the HHS OPHEP signed a Memorandum of Understanding to facilitate monitoring of former federal workers through the WTC Clinical Consortium.

In June of 2006, Mt. Sinai received their official Notice of Grant Award to screen former federal WTC responders. Since then, Mt. Sinai has been working diligently to develop and execute contracts and business associate agreements with national clinic partners across the country to better serve former federal workers since the vast majority of former federal WTC responders do not live in the NYC Metropolitan Area. Executing such agreements is institutionally challenging. Despite these challenges, Mt. Sinai School of Medicine has screened 26 former federal WTC responders since resumption of the former federal responder program out of approximately 270 former federal workers from 42 states and 227 cities who have expressed an interest in participating in the program by registering on the website for screening.

Also, I am actively exploring with AOEC their interest in administering the monitoring of former federal workers on a national basis. These clinics will perform medical monitoring of all eligible former federal WTC responders--both in the NYC Metropolitan Area through the WTC Clinical Consortium and nationwide through the network of AOEC clinics.

8. How will all of these programs coordinate with each other so that we have a uniform standard for monitoring and treatment?

I have asked the Acting FOH Administrative Director and the FOH Medical Director to join with me and the Mt. Sinai WTC Health Effects Treatment Program Medical Director, the Mt. Sinai Medical Monitoring Program Data and Coordination Center Principal Investigator and the Executive Director of the AOEC to participate in coordination meetings to ensure that medical

⁶ The term "former federal workers" include those who have federal service (retired or changed jobs) as well as short term employees of the federal government for the purposes of response to the WTC disaster, e.g., disaster medical assistance team (DMAT) members, who were "temporary federal employees" during the WTC disaster.

screening for current and former federal WTC responders is uniform across programs.

9. Are there operational or medical justifications for having separate programs [for Federal WTC responders who are current Federal employees vs. former Federal workers] or should they be merged?

All current Federal workers have the option of receiving their occupational health services from FOH, including screening for health effects arising from their work as a WTC responder at locations at or nearby where they work. Requiring those workers to receive health services relating specifically to WTC work exposures in another program--perhaps in another city--might interrupt continuity of care for existing federal workers.

Currently, employment status does determine from which source screening services are obtained by current and former federal workers. I believe that it is vitally important to achieve close coordination between FOH and the national monitoring and treatment programs to ensure that current and former federal workers who responded to the WTC disaster receive the same high quality standard of care.

Ensuring Scientific Reporting

Clinical Guidelines from NYC Department of Health and Mental Hygiene

An early set of *Clinical Guidelines* was developed in January of 2002. The NYC Department of Health and Mental Hygiene (DOHMH) released updated guidelines on August 31, 2006. The updated *Guidelines* are being sent to physicians throughout NYC and will aid them in diagnosing and treating persons affected by the WTC disaster. NYC DOHMH anticipates posting them on the WTC Health Registry's home page as well as on the NYC DOHMH home page at <http://www.nyc.gov/html/doh/html/home/home.shtml>.

Development of the update was performed with the assistance of clinicians throughout the NYC Metropolitan Area who are seeing responders in the WTC Medical Monitoring and Treatment Program. I believe that the finalization and posting of the *Guidelines* will greatly assist physicians outside of the WTC Medical Monitoring and Treatment Program in providing state-of-the-art diagnosis and treatment of prevalent WTC conditions to responders they encounter in their practice. I plan to link the *Guidelines* to the HHS website to increase national awareness of prevalent WTC conditions. In addition, clinicians from the federally-funded clinical centers within the WTC monitoring programs are being asked to be available to provide consultation to other clinical providers throughout the NYC Metropolitan Area and nationwide.

I have encouraged the broadest expert peer review--and also labor and community input--of the updated *Clinical Guidelines*, to ensure both scientific soundness as well as to prevent any conflicts of interest from influencing sound medical judgment. Robust external review is the key to developing a set of *Clinical Guidelines* that would withstand any criticism with regard to any internal organizational reviews. I am pleased to note that drafts of the *Guidelines* were shared with key stakeholder labor and community groups and their feedback has been important in developing the final set of *Guidelines*. I understand that the NYC DOHMH also shared the *Guidelines* with community clinicians to obtain their feedback on usefulness and clarity.

Specific Questions Regarding Ensuring Scientific Reporting:

- 1. What is the status of the release of the clinical guidelines for 9/11 related illnesses by the New York City Department of Health and Mental Hygiene?**

The NYC DOHMH disseminated the updated *Clinical Guidelines* on August 31, 2006.

- 2. What is the review process for the clinical guidelines?**

This question is best addressed directly by the NYC DOHMH. They were responsible for carrying out the review.

- 3. What is the review process for 9/11-related research and/or presentations produced by the NYC DOHMH?**

For scientific research products funded by the Agency for Toxic Substances Disease Registry ("ATSDR"), in addition to any review conducted by the NYC DOHMH, ATSDR conducts its own scientific peer review of the research products prior to approving them for publication.

The ATSDR review process follows the policies and procedures established by the CDC, e.g., (1) "Peer Review of Research" (CDC, September 27, 2002) and "Clearance of Information Products Disseminated Outside CDC for Public Use" (CDC, July 22, 2005).

- 4. Is it unusual to have a legal review of a medical protocol before it is released?**

The occurrence of a legal review may vary with the particular governmental or non-governmental entity and with the nature of the research or public health practice topic that is the subject of the publication.

5. Is there careful monitoring to ensure there are no potential conflicts of interest between the requirement to provide the best health advice and the City's desire to protect itself from liability?

The most effective means of preventing any potential conflict of interest from affecting the dissemination of scientific information of an influential or highly influential nature is robust peer review.⁷

6. Once the clinical guidelines are disseminated, what plans are being developed, if any, to collect information from physicians on the incidence of potential 9/11-related deaths?

The current focus of federally funded programs is on collecting information on illness in living WTC populations. The collection and reporting of information on the occurrence of illnesses in WTC responders and volunteers, *as well as fatalities*, is an important aspect of the current medical monitoring programs and has not been dependent on dissemination of the *Clinical Guidelines* from the NYC DOHMH.

As a part of ensuring scientific reporting from the medical monitoring program, HHS funds two data coordination centers (DCCs)--one at FDNY and the other at the Mt. Sinai School of Medicine--for the purpose of collecting information about symptoms and conditions seen in living WTC responders and volunteers who participate in the medical monitoring program. In 2004, the WTC Worker and Volunteer Medical Screening Program at the Mt. Sinai School of Medicine published their first report on the prevalence of symptomatology in responders and volunteers.⁸ A more expansive case series is under development now which will describe the WTC Clinical Consortium scientific experience monitoring responders and volunteers to date.

With regard to collecting information on possible WTC-related fatalities, I believe that it is very important to gather information from physicians in the NYC Metropolitan Area on their experience with the *Clinical Guidelines* and any patient that they have seen who has a possible WTC-related condition or any patient who they suspect may have died from a WTC-related condition. The purpose of the *Guidelines* is to improve recognition of possible WTC conditions and to foster early intervention to ensure effective treatment. It is hoped that widespread use of the 2006 Clinical Guidelines and subsequent revisions will prevent fatalities. Additionally, I am working with the NYC DOHMH to develop a fatality investigations

⁷ OIRA/OMB, "Final Information Quality Bulletin for Peer Review," 70 Fed. Reg. 2664-2677, January 14, 2005.

⁸ *Physical health status of world trade center rescue and recovery workers and volunteers--New York City, July 2002-August 2004*, MMWR, Vol.53(35);807-812, 2004.

program to capture possible WTC-related deaths. See response to Question 7 below.

7. How will the federal government collect information about potential 9/11-related deaths?

As stated in the response to Question 6 above, the federally funded Data Coordination Centers are the primary means for collecting information about both ante-mortem conditions in responders as well as potential WTC-related responder fatalities. As seen in recent print media reports, though, there are responder fatalities that are occurring outside of the medical monitoring programs.

When the responder is not enrolled in the federally-funded WTC Medical Monitoring and Treatment Program, their death is more difficult to understand from a scientific point of view since the attending physician may not be trained in environmental or occupational medicine. For instance, without obtaining an adequate exposure history, without consistent medical monitoring records for specific agents, and without a scientifically rigorous post-mortem examination very near the time of death, it is often quite difficult to establish a scientific linkage between WTC exposure and death.

Therefore, a more comprehensive system for collecting information about potential WTC fatalities is needed to ensure that responder fatalities occurring outside of the federally funded monitoring and treatment programs are systematically captured and reviewed.

WTC Fatality Investigations

I have been working with the NYC DOHMH, the Center for Environmental Health at the New York State Department of Health, and other partners to develop a program that will aid in collecting information about potential WTC-related fatalities. For example, a WTC Fatalities Investigation Program would collect information on all responder and volunteer deaths and analyze each case to determine the existence of patterns of disease and any possible linkages with exposure to WTC toxic agents. The WTC Fatalities Investigation Program would provide a consistent approach to the evaluation of the cause of death of WTC responders and volunteers.

The WTC Fatalities Investigation Program would be guided scientifically by an expert medical panel comprised of independent and impartial experts in the subspecialties of medicine and pathology. Appropriate confidentiality protections, and adherence to institutional and governmental regulations about medical information, will need to be addressed to allow for the sharing of medical information.

Uniform Guidelines for the Examination of Tissues from WTC Cases

An important adjunct to consistent evaluation of responder fatalities is the uniform preparation and examination of tissues from WTC cases. The proposed WTC fatality investigations expert medical panel could be used to generate a standardized approach to the ante-mortem and post-mortem examination of tissue, specifying the types of tissues to be sampled and studies to be performed. This activity would include developing standardized guidelines for evaluating autopsy and other information (such as medical records and exposure information) to ascertain causation of pathology and death by WTC-related exposures.

8. What will be the role of the federal government in making determinations regarding causality for deaths potentially related to work at Ground Zero?

Cause of death determinations are generally made by the physician who attends the patient at the time of death or, in some cases, by a hospital-based anatomic pathologist or a local governmental forensic pathologist. Cause of death determinations for WTC-related conditions will be a matter of some sophistication as there is quite a bit of scientific uncertainty with regard to the association of WTC exposures and any particular condition. Linking particular occupational exposures to specific causes of death is a complex task both on the individual level and on a population-based level. Until the current scientific uncertainty surrounding WTC deaths is resolved, cause of death determinations for WTC deaths belong properly to specialists in pathology, epidemiology and other disciplines at academic medical centers.

Under the proposed WTC fatality investigation program, the role of the Federal government would be as a grantor in facilitating cause-of-death determinations by a grantee academic institution who would impanel experts from the fields of medicine and pathology.

9. What will be done to aggregate data recording recent deaths and future deaths that may have been caused by 9/11 related exposures when multiple jurisdictions and/or states are involved?

Although most of the responder population currently resided in New York State or adjoining states, it is important to capture all cases of responder fatalities to ensure that we have a complete picture of the pattern of disease in responders. Our goal would be to link case data from deaths arising in different states.

10. Are there any reports that link cancers to exposure from 9/11 toxins? If any reports exist, is HHS investigating them and does HHS have an opinion regarding their findings?

There are no scientific reports linking WTC exposures to cancer. However, a number of print media accounts have described responders who have developed cancer subsequent to September 11, 2001. What is not certain from a scientific perspective is whether the reported *temporal* association is a *causal* one also. At this time--only five years following the WTC disaster--it is difficult to draw scientifically sound causal connections between the cancers that are occurring in the responder population now and their previous WTC exposures.

Identifying Unmet Health Needs

For the three large WTC-affected population groupings, responders and volunteers,⁹ residents¹⁰ and workers in buildings affected by the WTC disaster,¹¹ there currently exists three HHS-funded programs: (1) for non-federal and former federal responders and volunteers, there is the *WTC Medical Monitoring & Treatment Program*; (2) for Federal WTC responders, there is the *Federal Responder Screening Program*; and (3) for all other groups, including all responders, residents, schoolchildren and other affected populations, there is the *WTC Health Registry*.

In the scientific literature, there are reports about health effects in affected residents and building occupants¹² which mirror those seen in the responder

⁹"Responders" refer to all workers (federal and non-federal) and volunteers (from the American Red Cross and other entities) who performed any of the following activities: rescue of survivors; recovery of bodies; removal of debris or dust; or restoration of essential services.

¹⁰"Residents" refers to those persons residing in Lower Manhattan, Chinatown and parts of western Brooklyn impacted by debris, dust and/or smoke from the WTC disaster.

¹¹"Workers in buildings affected by the WTC Disaster" refer to workers and others (such as schoolchildren) who worked or attended school in buildings surrounding the WTC at the time of the WTC disaster or who reoccupied buildings affected by debris, dust and/or smoke from the WTC disaster.

¹² See, for example, the following reports: Trout et al., *Health Effects and Occupational Exposures Among Office Workers near the World Trade Center Disaster Site*, J Occup Environ Med, Vol. 44:601-605, 2002; Fagan et al., *Relationship of self-reported asthma severity and urgent health care Utilization to Psychological Sequelae of the September 11, 2001 Terrorist Attacks on the World Trade Center Among New York City Area Residents*, Psychosomatic Medicine, Vol. 65:993-996, 2003; Landrigan et al., *Health and Environmental Consequences of the World Trade Center Disaster*, Environ. Health Perspectives, Vol. 112 (6), May, 2004; Szema et al., *Clinical Deterioration in pediatric asthma patients after September 11, 2001*, J Allergy Clin Immunol, Vol. 113(3), March, 2004; Lin et al., *Upper Respiratory Symptoms and Other Health Effects among Residents Living Near the World Trade Center Site after September 11, 2001*, Am. J. Epidemiology, Vol. 162(6), September, 2005; Reibman et al., *The World Trade Center Residents' Respiratory Health Study: New-Onset Respiratory Symptoms and Pulmonary Function*, Environ

population, e.g., upper and lower respiratory conditions, and mental health conditions.

Specific Questions Regarding Identifying Unmet Health Needs:

1. When do you anticipate releasing a report that identifies the unmet health needs?

There are several scientific reports noting the onset of new or worsened health conditions in affected residents and building occupants. These reports, supplemented by my own dialogue with residents seeking care at the Bellevue Hospital, provide a basis for assessing the needs in the resident population of Lower Manhattan and Chinatown. I anticipate that the follow-up survey being conducted now by the WTC Health Registry will provide us a more current basis for understanding whether the symptomatology seen in residents and building occupants early after September 11, 2001 has ameliorated, persisted or worsened in the ensuing five years.

2. Will these findings take into account the needs of residents, area workers and schoolchildren who were also exposed to the toxins of Ground Zero, but are not currently eligible for any federal program for monitoring or treatment?

Identifying unmet health needs among non-responder WTC-affected populations is very important given the level of symptomatology seen in residents following the WTC disaster. Even though there is no *medical* monitoring for non-responder populations, their health status is being monitored by the WTC Health Registry.

It is important that this population of 71,000 registrants (including more than 14,000 residents and 2,000 school children in Lower Manhattan) is followed through time in order to inform policymakers about the need for monitoring and treatment of the non-responder populations. The WTC Health Registry can also be a platform to launch medical monitoring studies. For instance, the NYC DOHMH has informed me of their current efforts to develop an in-depth respiratory health study of residents in collaboration with the Bellevue Hospital that includes clinical testing as well as a "pathway to care" for residents.

The first follow-up survey of all 71,000 registrants is expected to begin this month and will be conducted by the NYC DOHMH's WTC Health Registry and will include questions about new and worsening physical and mental

Health Perspectives, Vol. 113(4), April 2005; and, *Surveillance for World Trade Center Disaster Health Effects Among Survivors of Collapsed and Damaged Buildings*, MMWR; Vol. 55, April 7, 2006.

health symptoms and conditions as well as unmet needs that might be related to the WTC disaster. The results of this follow-up survey will add important information to the developing scientific base of information about the health effects of the WTC disaster on the resident and school children populations.

- 3. What is HHS' estimate of the total amount of funding needed over the next two years for medical monitoring and treatment for everybody currently enrolled in a federally-funded monitoring program?**

HHS will evaluate the funding experience as it implements the statute.

- 4. What is HHS' estimate over the next twenty years?**

Generating an estimate through time would require adjusting an accurate annual expenditure estimate (and the response to Question 3 indicates, HHS does not have such an estimate) by the rate of health care expenditure growth over the period of time of the estimate.

- 5. What is HHS' estimate of individuals who should be a part of a medical monitoring program, but are not eligible since no program exists for them (i.e., residents, area workers, area schoolchildren)?**

Any estimate of residents, area workers and schoolchildren would depend on how you characterize exposure from the WTC disaster. If you use the most generous exposure characterization, e.g., "caught in the plume" approach, such an approach would yield a very large estimate of eligible persons. Utilizing a "nearby residents, building occupants and schoolchildren" approach would yield a much lower estimate. For example, schoolchildren present on September 11, 2001 in "nearby schools" would include schoolchildren attending the four elementary schools situated about 4 to 6 blocks immediately north and northwest of the north tower of the WTC, and three public high schools near the site--two about 150 feet south of south tower, and one, Stuyvesant High School, about five blocks north. The total number of schoolchildren in this estimate is 8,950.¹³

- 6. What is the estimated two-year cost for medical monitoring and treatment for individuals who are not eligible, but should be monitored based upon exposure?**

This figure would be difficult to determine since the Federal government has had no experience with costs for medical monitoring and treatment for

¹³Bartlett S. & Patrarca, J. *Schools of Ground Zero: Early lessons learned in children's environmental health*. Joint Publication of the American Public Health Association and Healthy Schools Network, Inc., Albany, New York; 2002, p.1.

the non-responder population. Importantly, a non-responder population may be a less fit population before exposure and, as a result, exhibit a different profile of medical and psychological response than a more uniformly fit responder population, e.g., firefighters. Taking this fact into consideration suggests that monitoring and treatment costs for a non-responder population may be greater. However, at the present time, it is difficult to make a realistic cost estimate.

7. What is the estimated cost over twenty years?

No estimate can be projected at this time because of the uncertainties involved in making such a cost projection.

8. Does HHS have an estimate for the total number of individuals who were exposed to the toxins of 9/11?

NIOSH projects there may be up to 50,000 or more responders & volunteers eligible for medical monitoring and treatment (this population includes both non-federal and federal responders). Estimates for the number of individuals who experienced any exposure to dust or debris from the WTC disaster would greatly exceed that figure and would be dependent on how you define "WTC exposure."

9. Will you or the Department of Health and Human Services make any budget recommendations to fulfill these unmet needs?

The Department's plan is to spend the \$75 million no-year emergency funding appropriated in FY 2006 to monitor and treat World Trade Center responders; and as the projects are implemented the Department will evaluate future funding.

I hope that the foregoing information assists you in understanding the current status of my assignment and is responsive to the questions posed in your letter. I would be pleased to brief you in person at anytime. A copy of this response will also be provided to Mr. Fossella, who co-signed your letter.

Sincerely,



John Howard, M.D.
Director