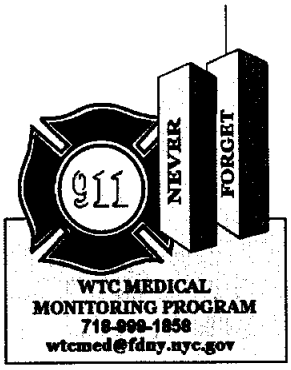

FIRE DEPARTMENT

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June 21, 2011

John Howard, MD
Director, National Institute of Occupational Safety and Health
World Trade Center program Administrator
National Institute of Occupational Safety and Health
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Dear Dr. Howard:

On June 3, 2011, you requested that the Principal Investigators for the National Institute of Occupational Safety and Health (NIOSH) funded World Trade Center (WTC) Health Programs submit by June 22, 2011 any information that might prove important for the required [Zadroga Act - Section 3312(a)(5)(A)] periodic review by the WTC Program Administrator on WTC-related cancer risk. Your request specified the need for: "(1) any clinically observed findings, including trends, that are unpublished, but which you believe are important clinical observations pertaining to cancer; (2) any planned data analysis or research efforts pertaining to cancer; or (3) any findings pertaining to cancer that are being prepared by you for publication, with an estimate when such paper(s) are expected to be published."

NIOSH's interest in WTC-related cancer risks has also been long-standing as highlighted by the initial request for information in the March 29, 2011 edition of the Federal Register, the Broad Agency Announcement (2011-Q-13340) issued in April 2011 and in meetings you have had with NIOSH-funded WTC Principal Investigators starting in 2005 or early 2006.

FDNY researchers, in collaboration with the FDNY WTC Clinical Center of Excellence and the FDNY WTC Data Center, are in a unique position to study health outcomes, such as cancer, as we are able to estimate pre- and post-9/11 cancer rates in non-WTC exposed rescue workers, both those retired prior to and those hired after closure of the WTC site as a comparison for WTC-exposed workers. We are able to do this because we continue to follow virtually the entire WTC-exposed and non-WTC exposed cohorts through matches with various state cancer

registries. Furthermore, by having two occupational groups (Fire and EMS) with well-documented but quite different exposures, we have high and low exposed groups for comparison studies. Inasmuch as FDNY Bureau of Health Services (BHS) cares for both these groups using the same surveillance protocols and each group has identical access to healthcare, comparisons of cancer rates between these groups should limit the potential for surveillance bias.

FDNY has developed a cancer database that collects and documents cases of cancer reported: 1) in the annual monitoring questionnaires; 2) in the FDNY electronic medical record during any treatment visit; and, 3) via matches with state cancer registries. This has led to a nearly complete dataset for both pre- and post-9/11 cancers. In this study, follow-up began in 1996 because this is when cancer data from the New York State cancer registry reached high levels of completeness (>97%).

We have just completed our first cancer study in this cohort – examining cancers occurring within the first seven years post-9/11/2001 in ~10,000 FDNY firefighters. We were hoping to receive permission from *The LANCET* to include a summary of these findings but we have been informed that protocol prohibits this. This does not preclude you from contacting them directly.

Additional research is needed as the time interval since 9/11 is still short for cancer outcome studies. As in any observational study, it is also difficult to rule out the effect of surveillance bias or potential unmeasured confounders. Furthermore, FDNY firefighters experienced uniquely intense WTC exposures and therefore our findings need to be reproduced in other groups with different but equally well-documented exposures and similar access to healthcare. Our FDNY EMS workers are a perfect group for this comparison analysis.

To fund this additional research, we have recently submitted to NIOSH a research application that would allow us to continue our study of cancer rates of incident (first cancers) and multiple primary tumors, in separate cohorts of firefighters and EMS workers. This future research, if funded, will build upon the knowledge and analytic experience our team gained from this initial study by extending the study to include additional years of follow-up for firefighters, and for the first time, by studying our EMS population. Continuing this research by leveraging the existing infrastructure and the established trust that the FDNY clinical and data centers have built with this cohort will provide an effective path to reach this important scientific objective.

This research would benefit the WTC program and the cohort it serves. If cancer rates are increased, then a screening and treatment program can be tailored to the specific-sites or organs that are affected and the cohort can receive targeted education on strategies to prevent and find new cancers. In contrast, if these analyses show that cancer is not increased in the two different groups (Fire and EMS) with well-documented but different exposures and similar access to healthcare (e.g., similar case surveillance issues), then this information can be communicated to the cohort in a responsible fashion, emphasizing that longer-term studies are needed, but that until there is evidence to the contrary, limited healthcare dollars should be directed otherwise.

Sincerely,

David Prezant, MD, FDNY
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Co-Director, FDNY WTC Medical Monitoring & Treatment Programs

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