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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**[NIOSH Docket 094]**

**World Trade Center Health Program; Petition 010--Peripheral Neuropathy; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

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**SUMMARY:** On January 5, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 010) to add peripheral neuropathy to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add peripheral neuropathy to the List. The Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) Public Law 111-347, as amended by Public Law 114-113, added Title XXXIII to the Public Health Service Act (PHS Act)<sup>1</sup> establishing the WTC Health Program within the Department of Health and Human

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<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. After receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in PHS Act, section 3312(a)(6)(B) and 42 CFR 88.17: (i) request a recommendation of the STAC; (ii) publish a proposed rule in the Federal Register to add such health condition; (iii) publish in the Federal Register the Administrator's determination not to publish such a

proposed rule and the basis for such determination; or (iv) publish in the Federal Register a determination that insufficient evidence exists to take action under (i) through (iii) above.

B. Approval to Submit Document to the Office of the Federal Register

The Secretary, HHS, or her designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Thomas R. Frieden, M.D., M.P.H., Director, CDC, and Administrator, ATSDR, approved this document on March 24, 2016, for publication.

C. Petition 010

On January 5, 2016, the Administrator received a petition to add "peripheral neuropathy" to the List (Petition 010).<sup>2</sup> The petition was submitted by a Fire Department of New York member who responded to the September 11, 2001, terrorist attacks in New York City. The petitioner indicated that he was diagnosed with peripheral

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<sup>2</sup> See Petition 010, WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

neuropathy shortly after the incident. The petitioner described two studies as the medical basis for his petition: a study of the short-term effects of WTC dust on the sciatic nerve of laboratory rats, and another concerning neuropathic symptoms in WTC responders and survivors. Both studies, as well as an initial literature search conducted by the WTC Health Program, are described below.

#### D. Administrator's Determination on Petition 010

The Administrator has established a policy for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program website.<sup>3</sup> In accordance with the policy, the Administrator directs the WTC Health Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. The literature review includes published, peer-reviewed epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition

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<sup>3</sup> John Howard MD, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, October 21, 2014. [http://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_Adding\\_NonCancers\\_21\\_Oct\\_2014.pdf](http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf).

among 9/11-exposed populations. The studies are reviewed for their relevance, quantity, and quality to provide a basis for deciding whether to propose adding the health condition to the List. Where the available evidence has the potential to provide a basis for a decision, the scientific and medical evidence is further assessed to determine whether a causal relationship between 9/11 exposures and the health condition is supported. A health condition may be added to the List if published, peer-reviewed, direct observational or epidemiologic studies, as appropriate, provide substantial support<sup>4</sup> for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If the evidence assessment provides only modest support<sup>5</sup> for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate additional published, peer-reviewed, epidemiologic studies, conducted among non-9/11-exposed populations, evaluating associations between the health condition of interest and 9/11 agents.<sup>6</sup> If that additional

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<sup>4</sup> The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>5</sup> The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>6</sup> 9/11 agents are chemical, physical, biological, or other agents or hazards reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area, at the Pentagon site, or at the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1.

assessment establishes substantial support for a causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

In accordance with section 3312(a)(6)(B) of the PHS Act, 42 CFR 88.17, and the policy for the addition of non-cancer health conditions to the List, the Administrator reviewed the evidence presented in Petition 010. The WTC Health Program conducted a systematic literature search of the published scientific and medical literature<sup>7</sup> for evidence of a causal relationship between 9/11 exposures and peripheral neuropathy and reviewed both studies submitted in the petition.

The first study cited by the petitioner, "Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve," by Stecker et al.<sup>8</sup> investigated the short-term effects of WTC dust on the sciatic nerve in laboratory rats. This study was not identified in the literature search. Because this study does not meet the policy's requirement that the decision to add a health condition to the List must be based on epidemiologic studies of 9/11-exposed populations, it was not further considered.

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<sup>7</sup> Databases searched include: PubMed, Health & Safety Science Abstracts, Toxicology Abstracts, Toxline, Scopus, Embase, and NIOSHTIC-2.

<sup>8</sup> Mark Stecker, Jacqueline Segelnick, Marc Wilkenfeld, Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve, JOEM 56(10):1024-1028, October 2014.

The systematic literature search identified only one epidemiologic study regarding peripheral neuropathy in 9/11-exposed populations, which was the second study cited by the petitioner, "Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders," by Wilkenfeld et al.<sup>9</sup> Upon review of the study's relevance, quantity, and quality, the paper was found to have numerous limitations, including a small sample size; exclusive use of subjective self-reported outcome and exposure data; lack of information about comparability among the groups; lack of objective measurements to confirm the presence of peripheral neuropathy; and absence of control for key confounders other than the comorbidities studied. Each of these limitations affect the strength of the study results, and thus the Wilkenfeld et al. study is not sufficient to provide the Administrator with a potential basis for deciding whether to propose adding peripheral neuropathy to the List.

Due to the substantial limitations inherent in the only available study, the Administrator has concluded that the available evidence does not have the potential to

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<sup>9</sup> Marc Wilkenfeld, Melissa Fazzari, Jacqueline Segelnick, and Mark Stecker, Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders, JOEM 58(1):83-86, January 2016.

provide a basis for a decision on whether to add peripheral neuropathy to the List.

The findings described above led the Administrator to determine that insufficient evidence exists to take further action, including either proposing the addition of peripheral neuropathy to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 010 to add peripheral neuropathy to the List of WTC-Related Health Conditions is denied.

Dated: March 28, 2016

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John Howard,

Administrator, World Trade Center Health Program and  
Director, National Institute for Occupational Safety and  
Health, Centers for Disease Control and Prevention,  
Department of Health and Human Services  
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