



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[NIOSH Docket 094]

**World Trade Center Health Program; Petition 015--Neuropathy;
Finding of Insufficient Evidence**

AGENCY: Centers for Disease Control and Prevention, HHS.

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

SUMMARY: On November 25, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 015) to add 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 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 **FEDERAL REGISTER**].

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A. WTC Health Program Statutory Authority

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

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

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 88.15 (2017). Within 90 days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.16(a)(2): (1) Request a recommendation of the STAC; (2) publish a proposed rule in the Federal Register to add such health condition; (3) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the Federal Register a determination that insufficient evidence exists to take action under (1) through (3) above. However, in accordance with 42 CFR 88.16(a)(5), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis -- evidence not previously reviewed by the Administrator -- for the association between 9/11 exposures and the condition to be added.

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,² as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.³ In accordance with the aforementioned non-cancer health condition addition 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 health condition to the List. A literature review includes a search for peer-reviewed, published epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations; such studies are considered "relevant." Relevant studies identified in the literature search are further reviewed for their 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

² See WTC Health Program [2014], Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions, May 14, <http://www.cdc.gov/wtc/pdfs/WTCHPPPpetitionHandlingProcedures14May2014.pdf>.

³ See WTC Health Program [2016], Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, May 11, http://www.cdc.gov/wtc/pdfs/WTCHP_PP Adding NonCancer Conditions Revision 11 May 2016.pdf. Since the date of receipt of Petition 015, the Administrator has revised the policy and procedures for addition of non-cancer health conditions. Petition 015 was evaluated using the May 11, 2016 version of the policy and procedures in place at the time of receipt of the petition.

health condition may be added to the List if peer-reviewed, published, direct observational or epidemiologic studies provide substantial support⁴ for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If the evidence assessment provides only modest support⁵ for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate additional peer-reviewed, published epidemiologic studies, conducted among non-9/11-exposed populations, evaluating associations between the health condition of interest and 9/11 agents.⁶ If that additional 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.

B. Petition 015

On November 25, 2016, the Administrator received a petition from a New York City Police Department (NYPD) responder who worked at Ground Zero, requesting the addition of neuropathy to the List. The petition referenced studies conducted by researchers from Winthrop University which, according to the petitioner, found that 9/11 exposures led to nerve damage.⁷

⁴ 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.

⁵ 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.

⁶ 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.

⁷ See Petition 015, WTC Health Program: Petitions Received, <http://www.cdc.gov/wtc/received.html>.

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy, reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.⁸ Based on the information provided by the petitioner, who referred to “medical studies by Winthrop University doctors” concerning 9/11 exposure and nerve damage, the Program identified three studies by Winthrop University researchers concerning 9/11 exposure and nerve damage (neuropathy). The first reference, “Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve,” by Stecker et al. [2014]⁹ investigated the short-term effects of WTC dust on the sciatic nerve in laboratory rats. “Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders,” by Wilkenfeld et al. [2016],¹⁰ investigated whether neuropathic symptoms were more prevalent in 9/11-exposed patients than non-exposed patients; and “Neurologic Evaluations of Patients Exposed to the World Trade Center Disaster,” by Stecker et al. [2016], looked for objective evidence of neurologic injury in 9/11-exposed patients.¹¹ These three studies suggested a potential association between 9/11 exposures and

⁸ See supra note 2.

⁹ Stecker M, Segelnick J, Wilkenfeld M [2014], Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve, JOEM 56(10):1024-1028.

¹⁰ Wilkenfeld M, Fazzari M, Segelnick J, and Stecker M [2016], Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders, JOEM 58(1):83-86.

¹¹ Stecker M, Yu H, Barlev R, et al. [2016], Neurologic Evaluations of Patients Exposed to the World Trade Center Disaster, JOEM 58(11):1150-1154.

neuropathy and were thus considered to establish a sufficient medical basis to consider the submission a valid petition.

C. Review of Scientific and Medical Information and Administrator Determination

In response to Petition 015, and pursuant to the Program policy on addition of non-cancer health conditions to the List,¹² the Program conducted a review of the scientific literature on neuropathy to determine if the available evidence has the potential to provide a basis for a decision on whether to add neuropathy to the List.¹³

The literature search identified two relevant citations for neuropathy, the studies by Wilkenfeld et al. [2016] and Stecker et al. [2016] referenced by the petitioner. The third study referenced by the petitioner, Stecker et al. [2014], does not meet the policy's relevance requirement of being an epidemiologic study of a 9/11-exposed population, because it was an in vitro study conducted in rat tissues;¹⁴ therefore, it was not further considered. The Program also identified a study by Marmor et al. [2017]¹⁵ which reported on the prevalence and risk factors for paresthesia, a condition related to and at times a symptom of neuropathy, among community members who attended the WTC Environmental Health Center for treatment of health outcomes

¹² Supra note 3.

¹³ Databases searched include: Embase, NIOSHTIC-2, ProQuest Health & Safety, PubMed, Scopus, Toxicology Abstracts, and TOXLINE.

¹⁴ Only epidemiologic studies of the health condition in human 9/11-exposed populations are considered relevant.

¹⁵ Marmor M, Shao Y, Bhatt DH, et al. [2017], Paresthesias among Community Members Exposed to the World Trade Center Disaster, JOEM article in press.

resulting from 9/11 exposures. Since the Marmor et al. [2017] study concerns paresthesia rather than neuropathy, it is not considered "relevant" and, per Program policy,¹⁶ cannot provide potential support for deciding whether to propose adding neuropathy to the List.¹⁷

The Wilkenfeld et al. study was previously reviewed for quality as part of the Program's evaluation of Petition 010, which requested the addition of peripheral neuropathy to the List. As discussed in the Federal Register notice regarding Petition 010, the Wilkenfeld et al. [2016] study was found to have numerous limitations preventing further evaluation.¹⁸

Upon review, the Stecker et al. [2016] study also exhibited significant limitations, including flawed study design and selection bias. Similar to the study by Wilkenfeld et al. [2016], the Stecker et al. [2016] study was cross-sectional and did not include appropriate population sampling criteria. Although Stecker et al. [2016] used an objective measure of neuropathy, the comparison group was inadequate. The small exposure group and multiple statistical tests may have limited the study power. Neither the Wilkenfeld et al. [2016] nor the Stecker et al. [2016] study addressed potential exposures to toxins outside of

¹⁶ See supra note 3 and Section A.

¹⁷ Paresthesia refers to abnormal sensations such as prickling, tingling, itching, burning or cold, skin crawling or impaired sensations. Although paresthesia symptoms could arise from nerve damage, including neuropathy, other conditions can also produce paresthesia, such as anxiety, metabolic derangements, and certain infectious diseases such as Lyme disease. Because paresthesia is not exclusively associated with neuropathy, paresthesia is not a proxy for neuropathy.

¹⁸ See 81 FR 19108 (April 4, 2016).

9/11 exposures and other confounders that could explain the findings.

The studies by Wilkenfeld et al. [2016] and Stecker et al. [2016] exhibited many significant limitations and were found, individually and together, not to provide a basis for deciding whether to propose adding neuropathy to the List.

D. Administrator's Final Decision on Whether to Propose the Addition of Neuropathy to the List

In accordance with the review and determination discussed above, the Administrator has concluded that the available evidence does not have the potential to provide a basis for a decision on whether to add neuropathy to the List. Accordingly, the Administrator has determined that insufficient evidence is available to take further action at this time, including either proposing the addition of neuropathy to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(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 88.16(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 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 015 request to add neuropathy to the List of WTC-Related Health Conditions is denied.

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

The Secretary, HHS, or his 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. Anne Schuchat, M.D., Acting Director, CDC, and Acting Administrator, ATSDR, approved this document for publication on May 2, 2017.

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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