



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[NIOSH Docket 094]

World Trade Center Health Program; Petitions 032, 033, and 068—Peripheral Neuropathy; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

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

SUMMARY: The Administrator of the World Trade Center (WTC) Health Program has received three petitions (Petitions 032, 033, and 068) to add “peripheral neuropathy” to the List of WTC-Related Health Conditions. Upon reviewing the scientific and medical literature, including information provided by the petitioners, the Administrator has determined that there is insufficient evidence available to support taking further action at this time regarding peripheral neuropathy. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee, publish a proposed rule, or publish a determination not to publish a proposed rule.

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

ADDRESSES: Visit the WTC Health Program website at <https://www.cdc.gov/wtc/received.html> to review Petitions 032, 033, and 068.

FOR FURTHER INFORMATION CONTACT:

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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, Pub. L. 116-59, Pub. L. 117-328, Pub. L. 118-31, and Pub. L. 119-75), 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 for health conditions on the List of WTC-Related Health Conditions (List)² 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). The Program also provides benefits 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 area³ (survivors).

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-64. 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.

² The List of WTC-Related Health Conditions is established in 42 U.S.C. 300mm-22(a)(3)–(4) and 300mm-32(b); additional conditions may be added through rulemaking and the complete list is provided in WTC Health Program regulations at 42 CFR 88.15.

³ See 42 U.S.C. 300mm-5(8); 42 CFR 88.1.

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

In accordance with 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. Within 90 days after receipt of a valid 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) of the PHS Act and § 88.16(a)(2) of the WTC Health Program regulations: (1) Request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (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.

More information about the WTC Health Program, including the List and the petition process, is available at www.cdc.gov/wtc/.

B. Procedures for Evaluating a Petition

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,⁴ as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.⁵

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 and Procedures for Handling Submissions*

⁴ See WTC Health Program [2026], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*, January 22, 2026,

https://www.cdc.gov/wtc/pdfs/policies/PP_SubmissionsPetitions%20_20260122-508.pdf.

⁵ See WTC Health Program [2024], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, October 18, 2024,

https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancer_Health_Conditions_20241018.pdf.

and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions,⁶ reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.⁷ Studies linking 9/11 agents or hazards⁸ to the petitioned health condition may also provide sufficient medical basis for a valid petition.⁹ 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 for the association between 9/11 exposures and the condition to be added. A new medical basis is evidence not previously reviewed by the Administrator.

After the Program has determined that a petition is valid, and in accordance with the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions (Policy and Procedures)*, the Administrator directs the WTC Health Program Science Team (Science Team) to conduct a review of the scientific literature. The literature review is a keyword search of relevant scientific databases intended to identify peer-reviewed, published, epidemiologic studies about the health condition among 9/11-exposed populations.

The Science Team evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search using validity indicators described in the *Policy and Procedures*.¹⁰ Studies exhibiting sufficient validity indicators have the potential to provide a basis for deciding whether to

⁶ *Supra* note 4.

⁷ *Id.* at 7.

⁸ 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. See WTC Health Program [2018], *Development of the Inventory of 9/11 Agents*, July 17, 2018, https://www.n.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.

⁹ *Supra* note 4 at 7.

¹⁰ *Supra* note 5 at 7–8.

propose adding the health condition to the List and are considered “high-quality” studies. The Science Team then evaluates the identified high-quality studies, individually and together, to characterize the evidence of a causal association between 9/11 exposures and the health condition. As part of this evaluation, the Science Team considers the Bradford Hill weight of evidence criteria,¹¹ study limitations, and whether the studies are representative of the 9/11-exposed population of responders and survivors. After evaluating the totality of the evidence, the Science Team assesses the degree to which the evidence supports a causal association between 9/11 exposures and the health condition and assigns the evidence to one of the following five categories:

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|--------------|---------------------------------------------------------------------------|
| Category I | Evidence supports substantial likelihood of causal association |
| Category II | Evidence supports high likelihood of causal association |
| Category III | Evidence supports limited likelihood of causal association |
| Category IV | Evidence does not support causal association |
| Category V | Evidence is inadequate to determine the likelihood of causal association. |

The Science Team provides the outcome of its evaluation to the Administrator. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that there is a substantial likelihood of a causal association between 9/11 exposures and the health condition (Category I).¹² If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations shows a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition (Category II),¹³ then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents in non-9/11 exposure scenarios. If that additional assessment

¹¹ Hill AB [1965], *The Environment and Disease: Association or Causation?* Proc R Soc Med 58(5):295–300. According to the *Policy and Procedures*, the Bradford Hill criteria are a leading weight of evidence framework “which comprises nine aspects of association. These aspects comprise strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy.” See *supra* note 5 at 9–10 and discussion of Bradford Hill analysis at footnote 21.

¹² *Substantial likelihood of causal association* means that the association is strongly supported by evidence from high-quality, peer-reviewed, published epidemiologic studies of the health condition in 9/11-exposed populations and there is high confidence that the association cannot be explained by chance, bias, confounding, or any other alternative explanation. See *supra* note 5 at 12.

¹³ *High likelihood of causal association* means that the scientific evidence, taken as a whole, demonstrates that the likelihood of a causal association is less than substantial, but definitively more than limited. Therefore, there is some meaningful likelihood that the association can be explained by chance, bias, confounding, or another alternative explanation. See *supra* note 5 at 12.

establishes that there is now sufficient evidence to support the conclusion that a causal association between the 9/11 exposures and the health condition is substantially likely among 9/11-exposed populations (Category I), then the Administrator may propose the health condition for addition to the List.

C. Petitions 032, 033, and 068

On July 29, 2021, the Administrator received a petition (Petition 032) requesting the addition of “neuropathy and paresthesias” to the List.¹⁴ Because paresthesia is a symptom of sensory neuropathy, the Program considered the petitioned health condition to be neuropathy. The petition’s validity was established by reference to one peer-reviewed, published, epidemiologic study demonstrating a positive association between 9/11 exposures and peripheral neuropathy: *Case-Control Study of Paresthesia Among World Trade Center-Exposed Community Members*, by Marmor M, et al. [2020],¹⁵ a peer-reviewed, published case-control study. The study found “increased prevalence of clinical and laboratory-test abnormalities indicative of neuropathy among individuals with WTC exposure and paresthesia of the lower extremities.”

On September 2, 2021, the Administrator received a second petition (Petition 033) requesting the addition of peripheral neuropathy to the List.¹⁶ The petition’s validity was established by reference to five peer-reviewed, published, epidemiologic studies demonstrating a positive association between 9/11 exposures and peripheral neuropathy. The following referenced publications each individually establish a medical basis:

- *Case-Control Study of Paresthesia Among World Trade Center-Exposed Community Members*, by Marmor M et al. [2020], discussed above.
- *Post-9/11 Peripheral Neuropathy Symptoms among World Trade Center-Exposed Firefighters and Emergency Medical Service Workers*, by Colbeth

¹⁴ See Petition 032, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

¹⁵ Marmor M, Thawani S, Cotrina ML, Shao Y, Wong ES, Stecker MM, Wang B, Allen A, Wilkenfeld M, Vinik EJ, Vinik AI, Reibman J [2020], *Case-Control Study of Paresthesia among World Trade Center-Exposed Community Members*, *J Occup Environ Med* 62(4):307–316.

¹⁶ See Petition 033, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

HL et al. [2019],¹⁷ a peer-reviewed, published cross-sectional study which found increased reporting of peripheral neuropathy symptoms among 9/11-exposed responders.

- *Peripheral Neuropathy Due to Vitamin Deficiency, Toxins, and Medications*, by Staff NP and Windebank AJ, [2014],¹⁸ a peer-reviewed, published systematic review which described positive associations between 9/11 agents identified in the *Inventory of 9/11 Agents*,¹⁹ including heavy metals, and peripheral neuropathy.
- *Increased Risk of Sensory Neuropathy in Workers with Chloracne after Exposure to 2,3,7,8-Polychlorinated Dioxins and Furans*, by Thömke F et al. [1999],²⁰ a peer-reviewed, published cross sectional study which found a positive association between exposure to polychlorinated dioxins and furans (PCDD/F), 9/11 agents identified in the *Inventory of 9/11 Agents*, and neuropathy in pesticide plant workers.
- *Neurological Studies on Polychlorinated Biphenyl (PCB)-Poisoned Patients*, by Chia LG and Chu FL [1984],²¹ a peer-reviewed, published epidemiologic study, which found a positive association between exposure to polychlorinated biphenyl (PCB), a 9/11 agent identified in the *Inventory of 9/11 Agents*, and peripheral neuropathy in Taiwan residents.

Finally, the Administrator received Petition 068, requesting the addition of “bilateral neuropathy” to the List, on September 3, 2025.²² Petition validity was established by reference to the study by Colbeth et al. [2019], described above.

The five studies submitted by the petitioners described above provided sufficient medical basis suggest a positive association between exposures to 9/11 agents and peripheral neuropathy and thus provided a sufficient medical basis to consider the submissions valid petitions.

The WTC Health Program previously evaluated the available scientific literature regarding peripheral neuropathy in response to Petitions 010 and 015 and found that the literature did not have the potential to provide a basis on whether to add the health

¹⁷ Colbeth HL, Zeig-Owens R, Webber MP, Goldfarb DG, Schwartz TM, Hall CB, Prezant DJ [2019], *Post-9/11 Peripheral Neuropathy Symptoms among World Trade Center-Exposed Firefighters and Emergency Medical Service Workers*, Int J Environ Res Public Health 16(10):1727.

¹⁸ Staff NP and Windebank AJ [2014], *Peripheral Neuropathy Due to Vitamin Deficiency, Toxins, and Medications*, Continuum (Minneapolis, Minn.) 20(5):1293–1306.

¹⁹ 9/11 agents are listed in the *Development of the Inventory of 9/11 Agents*. See *supra* note 8.

²⁰ Thömke F, Jung D, Besser R, Roder R, Konietzko J, Hopf HC [1999], *Increased Risk of Sensory Neuropathy in Workers with Chloracne after Exposure to 2,3,7,8-Polychlorinated Dioxins and Furans*, Acta Neurol Scand 100(1):1–5.

²¹ Chia LG, Chu FL [1984], *Neurological Studies on Polychlorinated Biphenyl (PCB)-Poisoned Patients*, Am J Ind Med 5(1-2):117–126.

²² See Petition 068, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

condition to the List. A *Federal Register* notice denying Petition 010 was published on April 4, 2016 (81 FR 19108), and a notice denying Petition 015 was published on May 11, 2017 (82 FR 22004). The studies by Marmor M et al. [2020]; Colbeth HL et al. [2019], Staff NP and Windebank AJ [2014], Thömke F et al. [1999], and Chia LG and Chu FL [1984], discussed above, provided a new medical basis for the petitions reviewed in this notice.

D. Evaluation of Scientific Evidence: Findings and Conclusion

In response to Petitions 032, 033, and 068, and pursuant to the *Policy and Procedures*, the Administrator of the WTC Health Program directed the Science Team to conduct a systematic literature search to identify all peer-reviewed, published, epidemiologic studies of peripheral neuropathy among 9/11-exposed populations. Identified studies were assessed for quality; any studies determined to be high-quality would then be evaluated to determine if they provide evidence to support a likelihood of a causal association between 9/11 exposure and the health condition under consideration. The Science Team provided the Administrator with a paper describing its findings, *Evaluation of Scientific Evidence Supporting the Addition of Peripheral Neuropathy to the List of WTC-Related Health Conditions*. This paper is available in the docket for this activity²³ and on the Program's website.²⁴

The literature search conducted by the Science Team identified six peer-reviewed, published, epidemiologic studies of peripheral neuropathy in 9/11-exposed populations. Three of the identified studies were previously reviewed in support of already-evaluated Petitions 010 and 015 and found to be inadequate to provide a basis for a causal association between exposure to 9/11 agents and peripheral neuropathy.²⁵ The remaining

²³ <https://www.cdc.gov/niosh/docket/archive/docket094.html>.

²⁴ <https://www.cdc.gov/wtc/received.html>.

²⁵ Stecker MM, Yu H, Barlev R, Marmor M, Wilkenfeld M [2016], *Neurologic Evaluations of Patients Exposed to the World Trade Center Disaster*, JOEM 58(11):1150–1154; Wilkenfeld M, Fazzari M, Segelnick J, Stecker M [2016], *Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders*, JOEM 58(1):83–86; Marmor M, Shao Y, Bhatt DH, Stecker M, Berger K, Goldring R, Rosen R, Caplan-Shaw C, Kazeros A, Pradhan D, Wilkenfeld M, Reibman J [2017], *Paresthesias Among Community Members Exposed to the World Trade Center Disaster*, JOEM 59(4):389–396.

three studies identified by the literature search²⁶ were determined not to have sufficient validity indicators to be considered high-quality studies, and thus were not found eligible for further evaluation in accordance the Program's *Policy and Procedures*.²⁷ Accordingly, the Science Team did not conduct further evaluation of the three new studies described above.

Upon review of the evidence available in peer-reviewed, published, epidemiologic studies regarding peripheral neuropathy among 9/11-exposed populations, the Science Team found that there is inadequate evidence to determine a causal association²⁸ between 9/11 exposures and peripheral neuropathy (Category V).

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

Pursuant to the PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), and in accordance with Sec. VIII.B. of the *Policy and Procedures*, the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of peripheral neuropathy to the List (pursuant to the 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 the 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 the PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request in Petitions 032, 033, and 068 to add peripheral neuropathy to the List of WTC-Related Health Conditions is denied.

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

²⁶ Colbeth et al. [2019], *supra* note 17; Marmor et al. [2020], *supra* note 15; and Thawani S, Wang B, Shao Y, Reibman J, Marmor M [2019], *Time to Onset of Paresthesia Among Community Members Exposed to the World Trade Center Disaster*, Int J Environ Res Public Health 16(8):1429.

²⁷ See *supra* note 5 at 7–8.

²⁸ See *supra* note 5 at Sec. V.E.—Evidence is Inadequate to Determine a Causal Association.

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. Jay Bhattacharya MD, PhD, Senior Official Carrying out the Delegable Duties of the CDC Director, approved this document for publication on May 1, 2026.

John J. 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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