



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[NIOSH Docket 094]**

**World Trade Center Health Program; Petition 048a—Peripheral Artery Disease;
Finding of Insufficient Evidence**

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

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

SUMMARY: The Administrator of the World Trade Center (WTC) Health Program has received a petition (Petition 048a) to add “peripheral vascular disease” (referred to herein as “peripheral artery disease”) to the List of WTC-Related Health Conditions. Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that there is insufficient evidence available to support taking further action at this time regarding peripheral artery disease. 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 this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Visit the WTC Health Program website at <https://www.cdc.gov/wtc/received.html> to review Petition 048a.

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).

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

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.

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 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

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/PPN_SubmissionsPetitions%20_20260122-508.pdf.

⁵ See WTC Health Program [2026], *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*, May 14, 2026, https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancer_Health_Conditions_20260514.pdf.

⁶ *Supra* note 4.

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 Health 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 includes 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 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

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.cdc.gov/wtc/pdfs/policies/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.

⁹ *Supra* note 4 at 7.

¹⁰ *Supra* note 5 at 7–8.

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:

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 the health condition and 9/11 exposures (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 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

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 footnotes 21–30, discussion of Bradford Hill analysis.

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.

among 9/11-exposed populations (Category I), then the Administrator may propose the addition of the health condition to the List.

C. Petition 048a

On September 3, 2023, the Administrator received a submission (Petition 048a) requesting the addition of several cardiovascular conditions, including “peripheral vascular disease” to the List.¹⁴ The Administrator understands the term “peripheral vascular disease” to mean the health condition commonly known as “peripheral artery disease” (PAD). The petition’s validity was established by references to seven peer-reviewed, published, epidemiologic studies that provided a medical basis for the association between 9/11 exposures and PAD. The referenced studies establishing a medical basis are as follows:

- *Particulate Matter Air Pollution and Cardiovascular Disease: An Update to the Scientific Statement from the American Heart Association*, by Brook et al. [2010],¹⁵ an updated scientific statement concluding that modest epidemiologic evidence supports a causal relationship between exposure to particulate matter (PM) <2.5 micrometers (µm) in diameter (PM_{2.5}) and increased PAD morbidity.
- *Expert Position Paper on Air Pollution and Cardiovascular Disease*, by Newby et al. [2015],¹⁶ a scientific review and consensus document by the European Society of Cardiology that evaluated the evidence linking air pollution (comprising the 9/11 agents PM_{2.5} and PM ≤ 10 µm (PM₁₀), ozone, nitrogen dioxide (NO₂), volatile organic compounds (including benzene), carbon monoxide (CO), and sulfur dioxide (SO₂)) to cardiovascular disease (CVD) outcomes including PAD.

¹⁴ See Petition 048a, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>. The submission received on September 3, 2023, requested the addition of three discrete health condition groupings: (1) “myocardial infarction (*sic*), unstable angina, obstructive coronary artery disease, ischemic cardiomyopathy, ischemic congestive heart failure, arrhythmias (due to any of the above);” (2) “stroke;” and (3) “peripheral vascular disease.” Because the submission was found to be valid for each group of health conditions, the Administrator exercised his discretion to separate the conditions into three separate petitions and evaluations. Group (1) health conditions were evaluated as “ischemic heart disease” under Petition 047, addressed in a *Federal Register* notice published on June 30, 2026 (91 FR 39616). The second condition, stroke, was evaluated under Petition 048, and is addressed in a *Federal Register* notice published in this issue. The third condition, peripheral vascular disease (commonly referred to as peripheral artery disease, “PAD”), is assessed in the current evaluation under Petition 048a.

¹⁵ Brook RD, Rajagopalan S, Pope CA, Brook JR, Bhatnagar A, Diez-Roux AV, Holguin F, Hong Y, Luepker RV, Mittleman MA, Peters A, Siscovick D, Smith SC, Whitsel L, Kaufman JD, and on behalf of the American Heart Association Council on Epidemiology and Prevention, Council on the Kidney in Cardiovascular Disease, and Council on Nutrition, Physical Activity and Metabolism [2010], *Particulate Matter Air Pollution and Cardiovascular Disease: An Update to the Scientific Statement from the American Heart Association*, *Circulation* 121(21):2331–2378.

¹⁶ Newby DE, Mannucci PM, Tell GS, Baccarelli AA, Brook RD, Donaldson K, Forastiere F, Franchini M, Franco OH, Graham I, Hoek G, Hoffmann B, Hoylaerts MF, Künzli N, Mills N, Pekkanen J, Peters A, Piepoli MF, Rajagopalan S, Storey RF, on behalf of ESC Working Group on Thrombosis, European Association for Cardiovascular Prevention and Rehabilitation and ESC Heart Failure Association [2014], *Expert Position Paper on Air Pollution and Cardiovascular Disease*, *Eur Heart J* 36(2):83–93.

- *A Joint ERS/ATS Policy Statement: What Constitutes an Adverse Health Effect of Air Pollution? An Analytical Framework*, by Thurston et al. [2017],¹⁷ a joint European Respiratory Society/American Thoracic Society policy statement on what constitutes an adverse health effect of air pollution. It provides an analytical framework for interpreting scientific evidence on the health effects of air pollution for risk management purposes and references to papers that describe increased risks of impaired vascular function—a manifestation of PAD—and increased carotid artery stenosis from PM_{2.5} exposure.
- *Ambient Air Quality and Cardiovascular Health: Translation of Environmental Research for Public Health and Clinical Care*, by Cascio and Long [2018],¹⁸ a non-systematic review on CVD outcomes, including PAD, associated with air pollution. The review reported that residential proximity to major roads is associated with increased PAD risk. Traffic-related air pollution includes several 9/11 agents, e.g., PM_{2.5}, PM₁₀, nitrogen oxides, sulfur dioxide, and carbon monoxide.
- *Long-Term Cardiovascular Disease Risk among Firefighters after the World Trade Center Disaster*, by Cohen et al. [2019],¹⁹ a peer-reviewed, published longitudinal cohort study of Fire Department of New York (FDNY) firefighters designed to assess whether 9/11 exposures were associated with elevated CVD risk, including a composite outcome variable. Among firefighters with the composite outcome, very few had PAD, however, the study found positive associations between this composite cardiovascular outcome and 9/11 exposures related to time of arrival and length of response.
- *Integrated Science Assessment (ISA) for Particulate Matter*, by EPA's Center for Public Health and Environmental Assessment [2019],²⁰ a detailed integrated science assessment that examined the impact of PM, including PM_{2.5}, on CVD outcomes including PAD. The assessment summarized several studies that found increased PAD risk associated with PM_{2.5} exposure.
- *Environmental Pollution and Peripheral Artery Disease*, by Serra et al. [2021],²¹ provided a review of environmental pollutant exposures associated with PAD. This study provided evidence supporting an association between exposure to PM₁₀ and increased PAD risk.

These studies suggest a potential association between exposure to 9/11 agents and PAD and thus provided sufficient medical basis to consider the submission a valid petition.

¹⁷ Thurston GD, Kipen H, Annesi-Maesano I, Balmes J, Brook RD, Cromar K, DeMatteis S, Forastiere F, Forsberg B, Frampton MW, Grigg J, Heederik D, Kelly FJ, Kuenzli N, Laumbach R, Peters A, Rajagopalan ST, Rich D, Ritz B, Samet JM, Sandstrom T, Sigsgaard T, Sunyer J, Brunekreef B [2017], *A Joint ERS/ATS Policy Statement: What Constitutes an Adverse Health Effect of Air Pollution? An Analytical Framework*, Eur Respir J 49(1):1600419.

¹⁸ Cascio WE, Long TC [2018], *Ambient Air Quality and Cardiovascular Health: Translation of Environmental Research for Public Health and Clinical Care*, NC Med J 79(5):306–312.

¹⁹ Cohen HW, Zeig-Owens R, Joe C, Hall CB, Webber MP, Weiden MD, Cleven KL, Jaber N, Skerker M, Yip J, Schwartz T, Prezant DJ [2019], *Long-Term Cardiovascular Disease Risk among Firefighters after the World Trade Center Disaster*, JAMA Netw Open 2(9):e199775.

²⁰ EPA [2019], *Integrated Science Assessment (ISA) for Particulate Matter (Final Report, Dec 2019)*, EPA/600/R-19/188.

²¹ Serra R, Abramo A, Ielapi N, Procopio S, Marino P [2021], *Environmental Pollution and Peripheral Artery Disease*, Risk Manag Healthc Policy 14:2181–2190.

D. Evaluation of Scientific Evidence: Findings and Conclusion

In response to Petition 048a and pursuant to the *Policy and Procedures*, the Administrator of the WTC Health Program directed the Science Team to conduct a systematic search of the scientific literature to identify all peer-reviewed, published, epidemiologic studies of PAD 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 Artery Disease to the List of WTC-Related Health Conditions*. This evaluation builds on a previous evaluation of atherosclerosis, an antecedent health condition leading to the development of PAD, conducted in response to Petition 012. The current evaluation for Petition 048a is available in the docket for this activity²² and on the Program’s website.²³

The literature search conducted by the WTC Health Program identified nine peer-reviewed, published, epidemiologic studies of PAD in 9/11-exposed populations (including one study by Mani et al. [2013] that was reviewed in the Petition 012 evaluation). None of the nine identified studies, however, demonstrate sufficient validity indicators to be considered high-quality studies.²⁴ Accordingly, the Science Team did not

²² <https://www.cdc.gov/niosh/docket/archive/docket094.html>.

²³ <https://www.cdc.gov/wtc/received.html>.

²⁴ Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011a], *Mortality Among Survivors of the Sept 11, 2001, World Trade Center Disaster: Results from the World Trade Center Health Registry Cohort*, *Lancet* 378(9794):879–887; Mani V, Wong SK, Sawitt ST, Calcagno C, Maceda C, Ramachandran S, Fayad ZA, Moline J, McLaughlin MA [2013], *Relationship Between Particulate Matter Exposure and Atherogenic Profile in “Ground Zero” Workers as Shown by Dynamic Contrast Enhanced MR Imaging*, *Int J Cardiovasc Imaging* 29:827–833; Stein CR, Wallenstein S, Shapiro M, Hashim D, Moline JM, Udasin I, Crane MA, Luft BJ, Lucchini RG, Holden WL [2016], *Mortality Among World Trade Center Rescue and Recovery Workers, 2002–2011*, *Am J Ind Med* 59(2):87–95; Jordan HT, Stein CR, Li J, Cone JE, Stayner L, Hadler JL, Brackbill RM, Farfel MR [2018], *Mortality Among Rescue and Recovery Workers and Community Members Exposed to the September 11, 2001 World Trade Center Terrorist Attacks, 2003–2014*, *Environ Res* 163:270–279; Cohen HW, Zeig-Owens R, Joe C, Hall CB, Webber MP, Weiden MD, Cleven KL, Jaber N, Skerker M, Yip J, Schwartz T, Prezant DJ [2019], *Long-Term Cardiovascular Disease Risk among Firefighters after the World Trade Center Disaster*, *JAMA Netw Open* 2(9):e199775; Colbeth HL, Zeig-Owens R, Hall CB, Webber MP, Schwartz TM, Prezant DJ [2020], *Mortality Among Fire Department of the City of New York Rescue and Recovery Workers Exposed to the World Trade Center Disaster, 2001–2017*, *Int J Environ Res Public Health* 17(17):6266; Li J, Hall CB, Yung J, Kehm RD, Zeig-Owens R, Singh A, Cone JE, Brackbill RM, Farfel MR, Qiao B, Schymura MJ, Shapiro MZ, Dasaro CR, Todd AC, Prezant DJ, Boffetta P [2023], *A 15-Year Follow-Up Study of Mortality in a Pooled Cohort of World Trade Center Rescue and Recovery Workers*, *Environ Res* 219:115116; Singh A, Zeig-Owens R, Cannon M, Webber MP, Goldfarb DG, Daniels RD, Prezant DJ, Boffetta P, Hall CB [2023], *All-Cause and Cause-Specific Mortality in a Cohort*

conduct further evaluation of the studies identified in the literature search described above.

Upon review of the evidence available in peer-reviewed, published, epidemiologic studies regarding PAD among 9/11-exposed populations, the Science Team found that there is inadequate evidence to determine a causal association²⁵ between 9/11 exposures and PAD (Category V).

E. Administrator's Final Decision on Whether to Propose the Addition of Peripheral Artery Disease 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 PAD 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 Petition 048a to add PAD to the List of WTC-Related Health Conditions is denied.

F. 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

of WTC-Exposed and Non-WTC-Exposed Firefighters, Occup Environ Med 80(6):297–303; Parvin A, Kehm RD, Qiao B, Cone JE, Farfel MR, Zeig-Owens R, Goldfarb DG, Shapiro MZ, Todd AC, Insaf T, Hall CB, Boffetta P, Li J [2026], *Effect of World Trade Center Health Program on Mortality Among 9/11 Responders*, Ann Epidemiol 115:8-14.

²⁵ See *supra* note 5 at Sec. V.E.—Evidence is Inadequate to Determine a Causal Association.

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. Erica Schwartz, MD, MPH, JD, RADM, USPHS (ret), Director, CDC, and Administrator, ATSDR, approved this document for publication on September 8, 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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