E 4163-18-P

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

World Trade Center Health Program; Petitions 048 and 051a—Stroke; 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 two petitions (Petitions 048 and 051a) to add "stroke" 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 regarding stroke at this time. 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 048 and 051a.

FOR FURTHER INFORMATION CONTACT:

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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 (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 area[3] (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 90 days after receipt of a valid petition to add a condition to the List, the Administrator

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[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.

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 responders or survivors may demonstrate the required medical basis.[7] Studies linking

[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/PNP_SubmissionsPetitions%20_20260122-508.pdf.
[5] *See* WTC Health Program [2026], *Policy and Procedures for Adding Non-Cancer 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.
[7] *Id.* at 7.

9/11 agents or hazards[8] 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 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 the health condition. As part of this evaluation, the Science Team considers the Bradford

[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.

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

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[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.

C. Petitions 048 and 051a

On September 3, 2023, the Administrator received a submission (Petition 048) requesting the addition of several cardiovascular conditions, including "stroke" to the List.[14] The petition's validity was established by references to 10 peer-reviewed, published, epidemiologic studies that provided a medical basis for the association between 9/11 exposures and stroke. 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 the available evidence supports a causal relationship between exposure to particulate matter (PM) <2.5 micrometers (μm) in diameter ($PM_{2.5}$) and increased stroke morbidity and mortality. The paper also briefly discussed other 9/11 agents such as nitrogen oxide and dioxide (NO_x), carbon monoxide (CO), and ozone (O_3), associated with cardiovascular diseases (CVD), including ischemic stroke.

- *Expert Position Paper on Air Pollution and Cardiovascular Disease*, by Newby et al. [2015],[16] a scientific review and consensus document that evaluated the evidence linking air pollution (comprising the 9/11 agents $PM_{2.5}$ and PM ≤ 10 μm (PM_{10}), ozone, nitrogen dioxide (NO_2), volatile organic compounds (including benzene), carbon monoxide (CO), and sulfur dioxide (SO_2)) to stroke and other types of CVD. The authors concluded that air pollution increases the risk of stroke morbidity and mortality, outlined potential biological mechanisms underlying this relationship and determined that air pollution should be considered a modifiable risk factor for CVD, including stroke.

- *Estimates and 25-Year Trends of the Global Burden of Disease Attributable to Ambient Air Pollution: An Analysis of Data from the Global Burden of Diseases*

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[14] *See* Petition 048, *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 infraction (*sic*), unstable angina, obstructive coronary artery disease, ischemic cardiomyopathy, ischemic congestive heart failure, arrythmias (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, is assessed in the current evaluation under a new ordinal number as Petition 048. The third condition, peripheral vascular disease (commonly referred to as peripheral artery disease, PAD), has been evaluated separately under a new ordinal number Petition 048a, and is addressed in a *Federal Register* notice published in this issue.

[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.

Study 2015, by Cohen et al. [2017],[17] which examined trends in morbidity and mortality, including increased stroke, related to ambient air pollution ($PM_{2.5}$) from 1990 to 2015. The authors found that ambient $PM_{2.5}$ was the fifth-ranked risk factor for global deaths in 2015, with CVD, including stroke, accounting for most of those deaths.

- *A Joint ERS/ATS Policy Statement: What Constitutes an Adverse Health Effect of Air Pollution? An Analytical Framework*, by Thurston et al. [2017],[18] 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. The statement defines ischemic stroke as an adverse effect of air pollution. It also provides references to papers that describe increased risks for stroke 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],[19] a non-systematic review on CVD outcomes, including stroke, associated with air pollution. The review reported that $PM_{2.5}$ is associated with increased cerebrovascular events.

- *Long-Term Cardiovascular Disease Risk among Firefighters after the World Trade Center Disaster*, by Cohen et al. [2019],[20] a peer-reviewed, published longitudinal cohort study designed to assess whether 9/11 exposures were associated with elevated CVD risk, including stroke, in Fire Department of New York (FDNY) firefighters. The study found that positive associations were observed between CVD 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],[21] a detailed integrated science assessment that examined the impact of PM, including $PM_{2.5}$, on CVD outcomes including stroke. The assessment concluded that there is some evidence that long-term (one month to years) exposure to $PM_{2.5}$ increases stroke risk.

- *Cardiopulmonary Impact of Particulate Air Pollution in High-Risk Populations: JACC State-of-the-Art Review*, by Newman et al. [2020], a Journal of the American College of Cardiology (JACC) state-of-the-art review of the cardiopulmonary impact of PM in high-risk populations. It recognized that air pollution, including $PM_{2.5}$, poses ischemic stroke and other CVD risks.

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[17] Cohen AJ, Brauer M, Burnett R, Anderson R, Frostad J, Estep K, Balakrishnan K, Brunekreef B, Dandona L, Dandona R, Feigin V, Freedman G, Hubbell B, Jobling A, Kan H, Knibbs L, Liu Y, Martin R, Morawska L, Pope A, FOrouzanfar MH [2017], *Estimates and 25-Year Trends of the Global Burden of Disease Attributable to Ambient Air Pollution: An Analysis of Data from the Global Burden of Diseases Study 2015*, The Lancet 389(10082):1907–1918.

[18] 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.

[19] 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.

[20] 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.

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

- *Cardiovascular Disease in the World Trade Center Health Program General Responder Cohort*, by Sloan et al. [2021],[22] a peer-reviewed, published prospective cohort study designed to examine the annual and cumulative incidence of CVD, including stroke, among the WTC Health Program general responder cohort (GRC). The study reported increased CVD risk in males and females exposed to the WTC dust cloud compared to those who were not exposed to the dust cloud (i.e., arrived on or after September 12, 2021).

- *Stroke Hospitalizations, Posttraumatic Stress Disorder, and 9/11-Related Dust Exposure: Results from the World Trade Center Health Registry*, by Yu et al. [2021],[23] a longitudinal study that examined the risk of stroke among WTC Health Registry enrollees. The study found that WTC dust exposure is a possible risk factor for ischemic stroke but not for hemorrhagic strokes.

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

On November 1, 2023, the Administrator received a submission (Petition 051a) requesting the addition of cardiovascular diseases, including, among other conditions, "stroke" to the List.[24] The petition's validity was established by reference to two peer-reviewed, published, epidemiologic studies that provided a medical basis for the association between 9/11 exposures and stroke. The referenced studies (Cohen et al. [2019] and Sloan et al. [2021]) each individually establish a medical basis and are described above. These two studies suggest a potential association between exposure to 9/11 agents and stroke and thus provided sufficient medical basis to consider the submission a valid petition.

Together, the two petitions requested the addition of stroke, including both ischemic and hemorrhagic types. Of the 10 studies that provided sufficient medical basis, 4 distinguish between the two types of stroke and provide sufficient medical basis for both ischemic and hemorrhagic stroke [Brook et al. 2010; Newby et al. 2015; EPA 2019;

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[22] Sloan NL, Shapiro MZ, Sabra A, Dasaro CR, Crane MA, Harrison DJ, Luft BJ, Moline JM, Udasin IG, Todd AC, Teitelbaum SL [2021], *Cardiovascular Disease in the World Trade Center Health Program General Responder Cohort*, Am J Ind Med 64:97–107.
[23] Yu S, Alper HE, Nguyen A-M, Maqsood J, Brackbill RM [2021], *Stroke Hospitalizations, Posttraumatic Stress Disorder, and 9/11-Related Dust Exposure: Results from the World Trade Center Health Registry*, Am J Ind Med 64(10):827–836.
[24] *See* Petition 051a, *WTC Health Program: Petitions Received,* http://www.cdc.gov/wtc/received.html. The submission received on November 1, 2023, was found to be valid for both cardiovascular diseases and stroke. The Administrator exercised his discretion to separate the health conditions into two petitions and evaluations. Cardiovascular diseases were evaluated as "ischemic heart disease" under Petition 051, addressed *Federal Register* notice published on June 30, 2026 (91 FR 39616). Stroke is assessed in the current evaluation under a new ordinal number Petition 051a.

Yu et al. 2021]. The other six studies do not distinguish between the two types of stroke [Cohen et al. 2017; Thurston et al. 2017; Casio and Long 2018, Cohen et al. 2019; Newman et al. 2020; Sloan et al. 2021]. The Administrator determined that the evaluation of scientific evidence should address both ischemic and hemorrhagic stroke.

D. Evaluation of Scientific Evidence: Findings and Conclusion

In response to Petitions 048 and 051a 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 stroke among 9/11-exposed populations. Identified studies were assessed for quality; those studies determined to be high-quality were then 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 Ischemic and Hemorrhagic Stroke to the List of WTC-Related Health Conditions*. This paper, which builds on previous evaluations of atherosclerosis and stroke conducted in response to Petitions 012 and 020, respectively, is available in the docket for this activity[25] and on the Program's website.[26]

The literature search conducted by the WTC Health Program identified 18 peer-reviewed, published, epidemiologic studies of stroke in 9/11-exposed populations. Of those, nine studies were found not to demonstrate sufficient validity indicators to be considered high-quality studies and were not evaluated further.[27] The remaining nine

[25] https://www.cdc.gov/niosh/docket/archive/docket094.html.
[26] https://www.cdc.gov/wtc/received.html.
[27] Brackbill RM, Thorpe LE, DiGrande L, Perrin M, Sapp JH, Wu D, Campolucci S, Walker DJ, Cone J, Pulliam P, Thalji L, Farfel MR, Thomas P [2006], *Surveillance for World Trade Center Disaster Health Effects Among Survivors of Collapsed and Damaged Buildings*, MMWR Surveill Summ 55(2):1–18; 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

studies were determined to have sufficient validity indicators to be considered high-quality studies eligible for further evaluation in accordance with the Program's *Policy and Procedures*.[28] Three of the high-quality studies were previously evaluated in the Program's response to Petition 020:

- Jordan HT, Stellman SD, Morabia A, Miller-Archie SA, Alper H, Laskaris Z, Brackbill RM, Cone JE [2013], *Cardiovascular Disease Hospitalizations in Relation to Exposure to the September 11, 2001 World Trade Center Disaster and Posttraumatic Stress Disorder*, J Am Heart Assoc 2(5):e000431.

- Yu S, Alper HE, Nguyen AM, Brackbill RM [2018], *Risk of Stroke Among Survivors of the September 11, 2001, World Trade Center Disaster*, J Occup Environ Med 60(8):e371–e376.

- Remch M, Laskaris Z, Flory J, Mora-McLaughlin C, Morabia A [2018], *Post-Traumatic Stress Disorder and Cardiovascular Diseases: A Cohort Study of Men and Women Involved in Cleaning the Debris of the World Trade Center Complex*, Circ Cardiovasc Qual Outcomes 11(7):e004572.

The six newly-identified high-quality studies were:

- 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.

- Sloan NL, Shapiro MZ, Sabra A, Dasaro CR, Crane MA, Harrison DJ, Luft BJ, Moline JM, Udasin IG, Todd AC, Teitelbaum SL [2021], *Cardiovascular Disease in the World Trade Center Health Program General Responder Cohort*, Am J Ind Med 64(2):97–107.

- Yu S, Alper HE, Nguyen A-M, Maqsood J, Brackbill RM [2021], *Stroke Hospitalizations, Posttraumatic Stress Disorder, and 9/11-Related Dust Exposure: Results from the World Trade Center Health Registry*, Am J Ind Med 64(10):827–836.

RG, Holden WL [2016], *Mortality Among World Trade Center Rescue and Recovery Workers, 2002–2011*, Am J Ind Med 59(2):87–95; Wilkenfeld M, Fazzari M, Segelnick J, Stecker M [2016], *Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders*, J Occup Environ Med 58(1):83–86; 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; 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 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.

[28] *See supra* note 5 at 7–8.

- Alper HE, Brite J, Cone JE, Brackbill RM [2021], *Comparison of Prevalence and Exposure-Disease Associations Using Self-Report and Hospitalization Data Among Enrollees of the World Trade Center Health Registry*, BMC Med Res Methodol 21(162).

- Mueller AK, Cohen H, Singh A, Webber MP, Hall CB, Prezant DJ, Zeig-Owens R [2024], *Self-Reported Cardiovascular Disease in Career Firefighters With and Without World Trade Center Exposure*, J Occup Environ Med 66(2):135–140.

The Science Team conducted an evaluation, separately and together, of the nine studies to determine the likelihood of a causal association between 9/11 exposures and the petitioned health condition. The systematic literature search, the Science Team's evaluation and synthesis of the available literature, and the Science Team's conclusions regarding the association between 9/11 exposure and stroke are described in full in the Science Team's *Evaluation of Scientific Evidence Supporting the Addition of Ischemic and Hemorrhagic Stroke to the List of WTC-Related Health Conditions*.

In accordance with the *Policy and Procedures*,[29] the WTC Health Program uses the following Bradford Hill criteria to evaluate studies of 9/11-exposed populations: strength of association,[30] precision of the risk estimate,[31] consistency of associations,[32] temporality,[33] biological gradient,[34] and biological plausibility,[35] coherence,[36] and analogy.[37] The Science Team also considered the limitations of the evaluated evidence and whether the evidence is representative of the complete 9/11-exposed population of

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[29] *Supra* note 5 at 9–10.
[30] It is generally thought that strong associations are more likely to be causal than weak associations; however, a weak association does not rule out a causal relationship.
[31] Precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is expressed as a confidence interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size, and a wider interval indicates greater uncertainty. While precision is not a Bradford Hill criterion, the Science Team takes it into consideration to evaluate the existence of random error in a study.
[32] Consistent findings are demonstrated when they have been repeatedly reported by multiple studies.
[33] Temporality is the condition that the 9/11 exposure must precede the health condition of interest and is typically assessed when considering aspects of exposure in the study design.
[34] Studies establish an exposure-response relationship by demonstrating that increases in exposure (i.e., exposures of greater intensity and/or longer duration) are associated with a greater incidence of disease. A thorough evaluation of exposure-response requires analysis of multiple levels of exposure such that the investigator can demonstrate that the risk increases with increasing levels of exposure.
[35] Study findings demonstrate a basis in scientific theory that supports the relationship between the exposure and the health effect and do not conflict with known facts about the biology of the health condition.
[36] Coherence implies that the interpretation of a causal association agrees with known disease etiology.
[37] Analogy is used to inform on biological plausibility and coherence by contrasting the evidence on the suspected causal association with that from an established association between similar (analogous) causes or effects.

responder and survivors, including those exposed in the New York City disaster area as well as the Pentagon and Shanksville, Pennsylvania sites. The nine high-quality studies are discussed in full in the Science Team's Evaluation; a summary of the evidence synthesis is found in Table 11, reproduced here:

Aspect of Associative Causal Inference	**Evaluation Findings**
Strength of the Association (and estimate of precision)	Modest positive associations were evident in some studies that were suggestive of a causal association. One earlier study of self-reported stroke reported a modest but statistically significant association with WTC-dust exposure [Yu et al. 2018]. However, statistically significant estimates of exposure-related stroke were not reported by any study published since the evaluation for Petition 020 was published. Two studies of responders reported significant positive associations between 9/11 exposure and a composite outcome in which cerebrovascular disease was a minor contributor [Cohen et al. 2019; Sloan et al. 2021]. Objective measures of stroke events and stroke risk were limited to three studies published since the previous evaluation [Alper et al. 2021; Yu et al. 2021; Mueller et al. 2024], and none of those studies found significant risk elevations in those objective stroke measures from 9/11 exposures.
Consistency of Associations	Findings among studies were inconsistent, ranging from strong deficits in mortality [Colbeth et al. 2020] to modest, but statistically significant increases in incidence in four studies [Yu et al. 2018; Cohen et el. 2019; Alper et al. 2021; Sloan et al. 2021]. In general, the inconsistency may be attributable to large differences in outcome definition and study designs. For example, large differences in risk estimates were observed in one study using both self-reported stroke and stroke ascertained from medical records [Mueller et al. 2024]. In another study using both self-reported stroke and stroke ascertained from medical records, risk estimates were statistically significant only for self-reported stroke [Alper et al. 2021]. Only one study differentiated between ischemic and hemorrhagic stroke subtypes [Yu et al. 2021]. That study reported a modest but imprecise estimate of an association between 9/11 exposure and ischemic stroke, and no evidence of an association with hemorrhagic stroke. Despite ischemic and hemorrhagic stroke having similar risk factors, Yu et al. [2021] did not report findings for all types of stroke combined.
Temporality	Longitudinal study designs reduced the potential for errors from preexisting conditions. Researchers attempted to exclude persons with previous stroke. However, given potentially long latency, stroke and related health conditions may have manifested prior to 9/11. Analyses examining temporal effects (e.g., latency and persistence) were not conducted.

Aspect of Associative Causal Inference	Evaluation Findings
Biological Gradient	Mueller et al. [2024] was the only study that used a specific stroke outcome and also examined biological gradient. It found evidence suggestive of modestly increasing stroke risk across increasing categories of 9/11 exposure, but the trend was not statistically significant.
Plausibility, Coherence, and Analogy	An association between WTC dust exposure and stroke is coherent with the available evidence. There is large uncertainty in an analogy comparing a proposed causal association between WTC dust exposure and stroke and the possible relationship between $PM_{2.5}$ in air pollution and stroke. The latter is supported by evidence linking long-term exposure to ambient air pollution to increased stroke risk. Chronic exposure to $PM_{2.5}$ in air pollution and acute exposure to WTC dusts are largely dissimilar. There is sparse evidence available on the relevant etiologic period for late cardiovascular effects from $PM_{2.5}$ exposure; therefore, the biological plausibility of these effects remains largely uncertain.
Representativeness	There was representation of all groups of 9/11-exposed populations.

Upon review of the evidence available in high-quality studies regarding stroke among 9/11-exposed populations, the Science Team found that the current evidence is insufficient to support a finding of *substantial* or *high likelihood* of a causal association. Based on weight of evidence, the Science Team has concluded that: (1) the available evidence of a causal association between 9/11 exposures and ischemic stroke is *limited* (Category III);[38] and (2) the available evidence of a causal association between 9/11 exposures and hemorrhagic stroke or a transient ischemic attack is *inadequate* (Category V).[39]

E. Administrator's Final Decision on Whether to Propose the Addition of Stroke 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

[38] *See Policy and Procedures supra* note 5 at Section V.C. Category III—Evidence Supports Limited Likelihood of Causal Association.
[39] *See Policy and Procedures supra* note 5 at Section V.E. Category V—Evidence is Inadequate to Determine a Causal Association.

determined that insufficient evidence is available to take further action at this time, including proposing the addition of stroke 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 048 and 051a to add stroke 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 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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