



BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 021—Deep Vein Thrombosis and Pulmonary Embolism; 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 28, 2018, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 021) to add “multiple deep vein thrombosis and pulmonary embolism” 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 deep vein thrombosis or pulmonary embolism to the List. The Administrator also 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**].

ADDRESSES: Visit the WTC Health Program website at <https://www.cdc.gov/wtc/received.html> to review Petition 021.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- A. WTC Health Program Statutory Authority
- B. Procedures for Evaluating a Petition
- C. Petition 021
- D. Review of Scientific and Medical Information and Administrator Determination
- E. Administrator's Final Decision on Whether to Propose the Addition of Deep Vein Thrombosis and/or Pulmonary Embolism to the List
- F. Approval to Submit Document to the Office of the Federal Register

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 for health conditions on the List to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or

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.

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 document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his 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. 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 Program regulations: (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.

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,² as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.³

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

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, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPpetitionHandlingProcedures14May2014.pdf>.

³ See WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017, https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancers_14_February_2017-508.pdf.

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.⁴ Studies linking 9/11 agents or hazards⁵ to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the 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.⁶ The literature review is a keyword search of relevant scientific databases; 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 are then identified from the initial search results. The Program evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search; the Program then compiles the scientific results of each study to assess whether a causal relationship between 9/11 exposures and the health condition is supported, and evaluates whether the results of the studies are representative of the 9/11-exposed population of responders and survivors. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that the health condition is substantially

⁴ See *supra* note 2.

⁵ 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/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.

⁶ See *supra* note 3.

likely⁷ to be causally associated with 9/11 exposures. If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations demonstrates a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition, then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents from sources using non-9/11-exposed populations. If that additional assessment establishes that the health condition is substantially likely to be causally associated with 9/11 exposures among 9/11-exposed populations, the health condition may be added to the List.

C. Petition 021

On November 28, 2018, the Administrator received a petition (Petition 021) requesting the addition of “multiple deep vein thrombosis and pulmonary embolism” to the List.⁸ The petition referenced two scientific articles which provided sufficient medical basis for the petition to be considered valid because they are scientific sources that demonstrate a potential link between exposure to a 9/11 hazard (particulate matter)⁹ and deep vein thrombosis and/or pulmonary embolism: a 2008 study by Baccarelli *et al.*,¹⁰ and a publication by Franchini *et al.*¹¹

⁷ The “substantially likely” standard is met when the scientific evidence, taken as a whole, demonstrates a strong relationship between the 9/11 exposures and the health condition.

⁸ See Petition 021, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

⁹ The 9/11 hazard identified by the petitioner was “particulate matter,” whereas the WTC Health Program *Inventory of 9/11 Agents* identifies particulate matter more precisely as WTC Dust: Glass shards, WTC Dust: PM₁₀, WTC Dust: PM_{2.5}, WTC Dust: Particles >2 μm, and WTC Dust: Particles >5 μm. See *supra* note 5.

¹⁰ Baccarelli A, Martinelli I, Zanobetti A, Grillo P, Hou LF, Bertazzi PA, Mannucci PM, Schwartz J [2008], *Exposure to Particulate Air Pollution and Risk of Deep Vein Thrombosis*, *Arch Intern Med* 12;168(9).

¹¹ The petitioner stated that the “European Journal of Medicine published a report and concluded that exposure to high level of pollutants lead to a high risk of developing DVTs and PEs. Massimo Franchini, dept [*sic*] of Transfusion and Hematology.” However, the Program was unable to identify a publication that met those criteria, and instead identified two publications which the petitioner may have intended to reference -- a 2016 study and a 2017 letter to the editor. Because it was not possible to determine which one was intended by the petitioner, the Program determined both would be considered and that, together, both met the medical basis

Because Baccarelli *et al.* and the two Franchini *et al.* publications described in footnote 11 are not epidemiologic studies of deep vein thrombosis or pulmonary embolism in 9/11-exposed populations, they do not meet the threshold for inclusion in the evidence evaluation established in Program policy, as described above, even though they qualify as sufficient medical basis for the petition to be considered valid. Therefore, based on Program policy, these articles were not further reviewed.

D. Review of Scientific and Medical Information and Administrator Determination

The Program policy on the addition of non-cancer health conditions to the List directs the Program to conduct a literature review on the health condition(s) petitioned.¹² Petition 021 requested the addition of deep vein thrombosis and pulmonary embolism. Deep vein thrombosis occurs when a blood clot forms in a deep vein, usually in the legs or pelvis; a pulmonary embolism occurs when a clot breaks loose and travels through the bloodstream to an artery in the lungs, causing a blockage.¹³

In response to Petition 021, the Program conducted a review of the scientific literature on deep vein thrombosis and pulmonary embolism to identify peer-reviewed, published studies of the health conditions in the 9/11-exposed population.¹⁴ No studies meeting the Program's criteria for further evaluation were identified in this literature review.

requirement. Franchini M, Mengoli C, Cruciani M, Bonfanti C, Mannucci PM [2016], *Association Between Particulate Air Pollution and Venous Thromboembolism: A Systematic Literature Review*, *Eur J Intern Med* 27:10-13; Franchini M, Mannucci PM [2017], *Letter to the Editor: More on Air Pollution and Venous Thromboembolism*, *Eur J Intern Med* 37(2017):e1 1.

¹² *Supra* note 3.

¹³ See <https://www.cdc.gov/ncbddd/dvt/facts.html>; <https://www.nhlbi.nih.gov/health-topics/venous-thromboembolism#Signs,-Symptoms,-and-Complications>.

¹⁴ Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health & Safety, PsycINFO, Ovid MEDLINE, Scopus, Toxicology Abstracts/TOXLINE, and WTC Health Program Bibliographic Database. Keywords used to conduct the search include: deep vein thrombosis, venous thromboembolism, venous thrombosis, phlebitis, thrombophlebitis, venous thrombotic event, pulmonary embolism, pulmonary infarction, pulmonary thromboembolism, and pulmonary thrombosis. The literature search was conducted in English-language journals on January 22, 2019.

E. Administrator's Final Decision on Whether to Propose the Addition of Deep Vein Thrombosis and/or Pulmonary Embolism to the List

Pursuant to PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of deep vein thrombosis and/or pulmonary embolism 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 021 request to add deep vein thrombosis and pulmonary embolism 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. Robert Redfield M.D.,

Director, CDC, and Administrator, ATSDR, approved this document for publication on March 19, 2019.

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.

[FR Doc. 2019-05690 Filed: 3/25/2019 8:45 am; Publication Date: 3/26/2019]