



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

**World Trade Center Health Program; Petition 012--
Atherosclerosis; Finding of Insufficient Evidence**

AGENCY: Centers for Disease Control and Prevention, HHS.

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

SUMMARY: On April 11, 2016, the Administrator of the World Trade Center (WTC) Health Program received two petitions (combined into Petition 012) to add atherosclerosis to the List of WTC-Related Health Conditions (List). The Program conducted a literature search for the term in response to the Petition and found no relevant studies regarding atherosclerosis among 9/11-exposed populations. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

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

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by

Pub. L. 114-113), added Title XXXIII to the Public Health Service (PHS) Act,¹ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

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

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 90 days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four

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.

actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the Federal Register to add such health condition; (3) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the Federal Register a determination that insufficient evidence exists to take action under (1) through (3) above. However, in accordance with 42 CFR 88.17(a)(4), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis -- evidence not previously reviewed by the Administrator -- for the association between 9/11 exposures and the condition to be added.

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions² and the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.³ In accordance with the

² See WTC Health Program [2014], Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions, May 14, <http://www.cdc.gov/wtc/pdfs/WTCPPPPetitionHandlingProcedures14May2014.pdf>.

³ See WTC Health Program [2016], Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, May 11,

aforementioned non-cancer health condition addition policy, the Administrator directs the WTC Health Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the health condition to the List. A literature review includes a search for peer-reviewed, published epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations; such studies are considered "relevant." Relevant studies identified in the literature search are further reviewed for their quantity and quality to provide a basis for deciding whether to propose adding the health condition to the List. Where the available evidence has the potential to provide a basis for a decision, the scientific and medical evidence is further assessed to determine whether a causal relationship between 9/11 exposures and the health condition is supported. A health condition may be added to the List if peer-reviewed, published, direct observational or epidemiologic studies provide substantial support⁴ for a causal relationship

http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf

⁴ The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its

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

B. Petition 012

On April 11, 2016, the Administrator received a petition from a New York City Police Department (NYPD) responder who worked at Ground Zero, and a second, related petition which requested the addition of "atherosclerosis (plaque in arteries)," and "atherosclerosis -- arterial plaque," respectively, to the List; the petitions provided references to the same medical basis, a study by Mani et

findings regarding a causal association between the 9/11 exposure(s) and the health condition.

⁵ The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

⁶ 9/11 agents are chemical, physical, biological, or other agents or hazards reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area, at the Pentagon site, or at the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1.

al. [2013]. The petitions together are considered Petition 012 as permitted by 42 CFR 88.17(a)(3).⁷

In accordance with WTC Health Program policy, the medical basis for a potential addition to the List may be demonstrated by 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.⁸ Both of the submissions considered in the current petition, Petition 012, presented the same single reference to support the request to add "Atherosclerosis (plaque in arteries)" to the List. The reference, a study by Mani et al. [2013],⁹ is a pilot study of the ability of diagnostic imaging to evaluate differences in atherosclerosis profiles in WTC responders exposed to high levels (as found in the initial dust cloud) and low levels (found after September 13, 2001) of particulate matter. The study evaluated the feasibility of using dynamic contrast enhanced MRI, a relatively new imaging method, to evaluate atherosclerosis among 31 law enforcement personnel who responded at Ground Zero (19 with self-reported high exposures and 12 with self-reported low

⁷ See Petition 012, WTC Health Program: Petitions Received, <http://www.cdc.gov/wtc/received.html>.

⁸ See supra note 2.

⁹ Mani V, Wong S, Sawit S, et al. [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.

exposures). The study population examined in Mani et al. [2013] is small and is not fully representative of the greater 9/11 population, including other non-law enforcement responders and survivors. Although the study has attributes of an epidemiologic study, the small subset of law enforcement personnel sampled and the non-random manner in which the sample was obtained prevent extrapolation of the findings of Mani et al. [2013] to the whole 9/11-exposed population. Moreover, the study does not investigate the causal link between 9/11 exposures and atherosclerosis. Therefore, the Administrator has determined that while the inclusion of this peer-reviewed and published study in the submissions provides sufficient medical basis to be considered a valid petition, Mani et al. [2013] is not an epidemiologic study, cannot be considered relevant, and is not further reviewed below.

C. Review of Scientific and Medical Information and Administrator Determination

In response to Petition 012, and pursuant to Program policy,¹⁰ the Program conducted a review of the scientific literature on atherosclerosis to determine if the available evidence has the potential to provide a basis for a

¹⁰ Supra note 3.

decision on whether to add atherosclerosis to the List.¹¹ The literature search identified one citation for atherosclerosis;¹² upon review, however, it was found not to be relevant because it was not a study of atherosclerosis among the 9/11-exposed population.

Since the literature review did not identify any relevant studies of atherosclerosis in the 9/11-exposed population, in accordance with the Program policy discussed above, the Program was unable to further evaluate Petition 012.

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

Finding no relevant studies with regard to Petition 012, the Administrator has accordingly determined that insufficient evidence is available to take further action at this time, including either proposing the addition of atherosclerosis to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, sec.

¹¹ Databases searched include: CINAHL, Embase, PsycINFO, PubMed, and Scopus.

¹² Landrigan PJ, Wright RO, Cordero JF, et al. [2015], The NIEHS Superfund Research Program: 25 Years of Translational Research for Public Health, Environ Health Perspect 123(10):909-918. This manuscript describes the successes of the Superfund Research Program; although the key terms "atherosclerosis" and "World Trade Center" are both mentioned, they are not discussed in relation to each other.

3312(a)(6)(B)(iii) and 42 CFR 88.17(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 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 012 to add atherosclerosis to the List of WTC-Related Health Conditions is denied.

Studies have not yet demonstrated whether 9/11 exposures, including inhalational dust/debris exposures or psychological exposures of the duration and magnitude experienced on and in the aftermath of September 11, 2001, could cause the development of atherosclerosis in an individual WTC responder or survivor several years later. The Administrator looks forward to more definitive studies that directly evaluate the causal association between 9/11 exposures, especially inhalational dust exposures, and atherosclerosis.

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

The Secretary, HHS, or her 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. Thomas R. Frieden, M.D., M.P.H., Director, CDC, and Administrator, ATSDR, approved this document for publication on December 2, 2016.

Dated: December 8, 2016. .

John Howard,
Administrator, World Trade Center Health Program and
Director, National Institute for Occupational Safety and
Health, Centers for Disease Control and Prevention,
Department of Health and Human Services.

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