



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

**World Trade Center Health Program; Petition 004--Cardiovascular
Disease; Finding of Insufficient Evidence**

AGENCY: Centers for Disease Control and Prevention, HHS.

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

SUMMARY: On March 7, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 004) to add "heart attack," which the Administrator has interpreted to mean "cardiovascular disease," 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 cardiovascular disease to the List. 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 THE FEDERAL REGISTER]

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SUPPLEMENTARY INFORMATION:

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII¹ 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 (responders) who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible persons (survivors) who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

school, childcare, or adult daycare in the New York City disaster area.

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 60 calendar days after receipt of a 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) and 42 CFR 88.17: (i) request a recommendation of the STAC; (ii) publish a proposed rule in the Federal Register to add such health condition; (iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the Federal Register a determination that insufficient evidence exists to take action under (i) through (iii) above.

B. Petition 004

On March 7, 2014, the Administrator received a petition to add "heart attack" to the List (Petition 004).² The petition was submitted by a WTC Health Program member who responded to the September 11, 2001 terrorist attacks in New York City. The petitioner indicated

² See Petition 004. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

that he has been diagnosed with a number of WTC-related health conditions, and has suffered a heart attack. Also included in his petition was a press release published by the New York City Department of Health and Mental Hygiene describing a WTC Health Registry study authored by Hannah T. Jordan et al. and published in the Journal of the American Heart Association on October 24, 2013.³

C. Administrator's Determination on Petition 004

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions.⁴ A health condition may be added to the List if published, peer-reviewed epidemiologic evidence provides substantial support for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations.⁵ If the epidemiologic evidence provides modest support for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate studies of associations between the health condition and 9/11 agents in similarly-exposed populations.⁶ If that additional assessment establishes substantial support for a

³ Jordan HT, Stellman SD, Morabia A, Miller-Archie SA, Alper H, Laskaris Z, Brackbill RM, and Cone JE [2013] Cardiovascular disease hospitalizations in relation to exposure to the September 11, 2001 World Trade Center disaster and posttraumatic stress disorder. *Journal of the American Heart Association* 2(5).

⁴ This methodology, "Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions," is available on the WTC Health Program website, at <http://www.cdc.gov/wtc/policies.html>.

⁵ 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 findings regarding a causal association between the 9/11 exposure(s) and the health condition.

⁶ 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.

causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

In accordance with section 3312(a)(6)(B) of the PHS Act, 42 CFR 88.17, and the methodology for the addition of non-cancer health conditions, the Administrator reviewed the evidence presented in Petition 004. Although the petitioner requested the addition of "heart attack," the Administrator determined that the more appropriate health condition is "cardiovascular disease," which includes heart attack, acute or chronic coronary artery disease, cardiac arrhythmia, angina, and any other heart condition. The Administrator then selected a team under the direction of the WTC Health Program Associate Director for Science (ADS) to perform a systematic literature search and provide input on whether the available scientific and medical information has the potential to provide a basis for a decision on whether to add the health condition to the List. The ADS conducted a search of the existing scientific/medical literature for epidemiologic evidence of a causal relationship between 9/11 exposures and cardiovascular disease. Among the studies identified by the literature search, four were found to be published, peer-reviewed epidemiologic studies of 9/11-exposed populations.⁷ However, when reviewed by the ADS for relevance,

⁷ Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011]. Mortality among survivors of the Sept 11, 2001, World Trade Center disaster: results from the World Trade Center Health Registry cohort. *The Lancet* 378: 879-87; Jordan HT, Miller-Archie SA, Cone JE, Morabia A, Stellman SD [2011]. Heart disease among adults exposed to the September 11, 2001 World Trade Center disaster: Results from the World Trade Center Health Registry. *Preventive Medicine* 53:370-376; 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*; Brackbill RM, Cone JE, Farfel MR, Stellman SD [2014]. Chronic Physical Health Consequences

quantity, and quality, each of the four published, peer-reviewed epidemiologic studies of 9/11-exposed populations were found to have significant limitations, both individually and in combination. Limitations of the four studies included selection, recall, and confounding bias;⁸ poor generalizability among all exposed groups; and lack of consistency among the associations reported between 9/11 exposures and cardiovascular disease between studies. Thus, the ADS concluded that the available information did not have the potential to form the basis for a decision on whether to propose adding cardiovascular disease to the List.

The findings described above led the Administrator to determine that insufficient evidence exists to take further action, including either proposing the addition of cardiovascular disease to the List (pursuant to PHS Act, section 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, section 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, section 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

of Being Injured During the Terrorist Attacks on World Trade Center on September 11, 2001. American Journal of Epidemiology. Advance Access published February 20, 2014.

⁸ In this case, "selection bias" refers to study populations that include individuals who were self-identified as heart patients but whose reported illness was not independently verified; "recall bias" refers to the inaccuracies or incompleteness inherent in the self-reporting of 9/11-related health conditions years after the event; and "confounding bias" refers to the existence of risk factors for cardiovascular disease that have not been accounted for by study authors.

For the reasons discussed above, the request made in Petition 004 to add cardiovascular disease to the List of WTC-Related Health Conditions is denied.

Dated: May 1, 2014.

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