



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**World Trade Center Health Program; Petition 006—Primary Biliary Cirrhosis; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

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

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**SUMMARY:** On October 20, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition to add primary biliary cirrhosis (Petition 006) to the List of WTC-Related Health Conditions (List). The Administrator has not found sufficient scientific evidence to conduct an analysis of whether to add primary biliary cirrhosis to the List. 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 THE FEDERAL REGISTER]

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

**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 XXXIII<sup>1</sup> 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 60 calendar days after receipt of a

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<sup>1</sup> 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.

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 006

On October 20, 2014, the Administrator received a petition to add primary biliary cirrhosis to the List (Petition 006).<sup>2</sup> The petition was submitted by a Salvation Army responder who worked at Ground Zero in the aftermath of the September 11, 2001, terrorist attacks. The petitioner stated that she had been diagnosed with primary biliary cirrhosis and shared letters from her personal physicians confirming the diagnosis. The petition offered as evidence a number of articles identifying potential associations between primary biliary cirrhosis and other autoimmune diseases to various environmental exposures, including polycyclic aromatic hydrocarbons, xenobiotics, asbestos, and silicon.<sup>3</sup>

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<sup>2</sup> See Petition 006. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

<sup>3</sup> Smyk D, Mytilinaiou MG, Rigopoulou EI, Bogdanos DP [2010]. PBC triggers in water reservoirs, coal mining areas and waste disposal sites: from Newcastle to New York. *Disease Markers* 29:337-344; Pleil JD, Vette AF, Johnson BA, Rappaport SM [2004]. Air levels of carcinogenic polycyclic aromatic hydrocarbons after the World Trade Center disaster. *PNAS* 101(32):11685-11688; Dronamraju D, Odin J, Bach N [2010]. Primary biliary cirrhosis: environmental risk factors. *Disease Markers* 29:323-328; Selmi C, De Santis M, Cavaciocchi F, Gershwin ME [2010]. Infectious agents and xenobiotics in the etiology of primary biliary

### C. Administrator's Determination on Petition 006

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions.<sup>4</sup> First, the Administrator determines whether published, peer-reviewed studies about the health condition among 9/11-exposed populations are available to assess evidence for a causal relationship and provide a basis for a decision on whether to add the condition to the List. If the studies provide sufficient evidence for analysis, the Administrator proceeds with an assessment of the information. A health condition may be added to the List if published, peer-reviewed direct observational or epidemiologic studies provide substantial support<sup>5</sup> for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If only epidemiologic studies are available and they provide only modest support<sup>6</sup> 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.<sup>7</sup> If that

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cirrhosis. Disease Markers 29:287-299; September 11th Worker Protection Task Force. Interim Report. March 4, 2008; Walsh N [2014]. Asbestos revisited: a new autoimmune disease? MedPage Today at <http://www.medpagetoday.com/Rheumatology/GeneralRheumatology/46972>; Speck-Hernandez CA and Montoya-Ortiz G [2012]. Silicon, a possible link between environmental exposure and autoimmune diseases: the case of rheumatoid arthritis. Arthritis at <http://dx.doi.org/10.1155/2012/604187>.

<sup>4</sup> This methodology, "Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions," revised October 21, 2014, is available on the WTC Health Program website, at <http://www.cdc.gov/wtc/policies.html>.

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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 either the New York City disaster area, the Pentagon site, or in Shanksville, Pennsylvania site as defined in 42 CFR Part 88.

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.

In accordance with section 3312(a)(6)(B) of the PHS Act and 42 CFR 88.17, described above, the Administrator has reviewed the evidence presented in Petition 006. None of the articles presented with the petition provide sufficient evidence of a causal relationship between primary biliary cirrhosis and 9/11 exposures to establish a basis for a decision on whether to add primary biliary cirrhosis to the List. Although some of the articles identify potential associations between specific 9/11 agents and primary biliary cirrhosis or autoimmune disease in general, none of the articles are peer-reviewed direct observational or epidemiologic studies of 9/11 populations, as required by the methodology described above.

In addition to reviewing the evidence provided in Petition 006, the Administrator also conducted a search of the existing scientific/medical literature for evidence that could establish a causal relationship between 9/11 exposures and primary biliary cirrhosis. He did not find any peer-reviewed, published direct observational or epidemiologic studies of 9/11-exposed populations which would support such a relationship.

Because neither the evidence submitted by the Petitioner nor a search of published scientific/medical literature provided information regarding the occurrence of primary biliary cirrhosis

among 9/11-exposed populations, the Administrator has 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. In prior actions, the Administrator requested a recommendation from the STAC when he determined that it would assist his evaluation; such as when, for example, the Administrator is in need of an interpretation of conflicting or inconclusive published scientific evidence.

Similarly, the Administrator has determined that insufficient evidence exists to take further action, including either proposing the addition of primary biliary cirrhosis 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)). In order to publish such a proposed addition or a determination not to propose a rule, the Administrator would first need to find that enough scientific evidence is available to analyze whether 9/11 exposures are associated with the health condition. Since the Administrator is unable to identify sufficient evidence to conduct an analysis of whether to add the health condition, the Administrator (pursuant to PHS Act, section 3312(a)(6)(B)(iv) and 42 CFR 88.17(a)(2)(iv)) is publishing a determination that he cannot take any of the other statutory and regulatory actions.

For the reasons discussed above, the request made in Petition 006 to add primary biliary cirrhosis to the List of WTC-Related Health Conditions is denied.

John Howard, M.D.

Dated: December 10, 2014.

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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