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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**World Trade Center Health Program; Petition 005--Acoustic Neuroma;  
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 September 2, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition to add acoustic neuroma (Petition 005) 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 acoustic neuroma 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, 4674 Columbia Parkway, 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 005

On September 2, 2014, the Administrator received a petition to add acoustic neuroma to the List (Petition 005).<sup>2</sup> The petition was submitted by a New York City police sergeant who worked at Ground Zero in the aftermath of the September 11, 2001, terrorist attacks. The petitioner stated that he had been diagnosed with acoustic neuroma and shared letters from his personal physicians confirming the diagnosis. The petition offered as evidence an article published in the International Journal of Adolescent Medicine and Health (IJAMH) linking exposure to toxic molds to "acoustic mycotic neuroma,"<sup>3</sup> and a link to an Occupational Safety and Health Administration (OSHA) web page, linking benzene exposure to acoustic neuroma.<sup>4</sup>

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<sup>2</sup> See Petition 005. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

<sup>3</sup> Anyanwu E, Campbell AW, High W [2002]. Brainstem auditory evoked response in adolescents with acoustic mycotic neuroma due to environmental exposure to toxic molds. *Int J Adolesc Med Health* 14(1):67-76.

<sup>4</sup> OSHA, [https://www.osha.gov/dts/chemicalsampling/data/CH\\_220100.html](https://www.osha.gov/dts/chemicalsampling/data/CH_220100.html).

### C. Administrator's Determination on Petition 005

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions.<sup>5</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>6</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>7</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>8</sup> If that additional assessment establishes substantial support for a causal

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<sup>5</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>6</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>7</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>8</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.

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 005. Neither the IJAMH article nor the OSHA information on benzene provide sufficient evidence of a causal relationship between acoustic neuroma and 9/11 exposures to establish a basis for a decision on whether to add acoustic neuroma to the List. The IJAMH article concerns a study population that is not related to the September 11, 2001, terrorist attacks. Moreover, the study related to the development of acoustic neuroma among adolescents exposed to toxic mold; toxic mold is not considered a 9/11 agent. With regard to the second reference provided by the petitioner, although the OSHA web page includes a reference to another published study suggesting an association between occupational exposures to benzene (a recognized 9/11 agent) and acoustic neuroma,<sup>9</sup> the study population was not 9/11-exposed.

In addition to reviewing the evidence provided in Petition 005, 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 acoustic neuroma, as well as the related conditions acoustic neurinoma, acoustic neurilemoma or vestibular schwannoma. He did not find any peer-

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<sup>9</sup> Prochazka M, Feychting M, Ahlbom A, Edwards CG, Nise G, Plato N, Schwartzbaum JA, Forssén UM [2010]. Occupational exposures and risk of acoustic neuroma. *Occup Environ Med.* 2010 Nov;67(11):766-71.

reviewed, published 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 acoustic neuroma 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 acoustic neuroma 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 005 to add acoustic neuroma to the List of WTC-Related Health Conditions is denied.

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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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