



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 014--Autoimmune Diseases; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

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

SUMMARY: On September 29, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition to add autoimmune diseases, including rheumatoid arthritis, to the List of WTC-Related Health Conditions (List). Upon reviewing the information provided by the petitioner, the Administrator has determined that Petition 014 is not substantially different from Petitions 007, 008, 009, 011, and 013, which also requested the addition of autoimmune diseases, including various subtypes. The Administrator has published responses to the five previous petitions in the Federal Register and has determined that Petition 014 does not provide additional evidence of a causal relationship between 9/11 exposures and autoimmune diseases, including

rheumatoid arthritis. 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

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.

health condition to the List in 42 CFR 88.15. Within 90 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 88.16: (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 88.16(a)(5), the Administrator is required to consider a new submission for a previously-evaluated health condition determined not to qualify for addition to the List as a valid new petition only if the submission 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.²

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review

² 42 CFR 88.16(a)(5) further allows that a "submission that provides no new medical basis and is received after the publication of a response in the Federal Register to a petition requesting the addition of the same health condition will not be considered a valid petition and will not be answered in a Federal Register notice.... The interested party will be informed of the ... decision in writing."

of submissions and petitions³ and the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.⁴ In accordance with the non-cancer health condition 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

³ 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>.

⁴ See WTC Health Program [2016], Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, May 11, <http://www.cdc.gov/wtc/pdfs/WTCPP Adding Non-Cancer Conditions Revision 11 May 2016.pdf>.

be added to the List if peer-reviewed, published epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) provide substantial support⁵ for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If the evidence assessment provides only modest support⁶ 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.⁷ If that additional assessment adds enough support for the Administrator to determine there is substantial support⁸ 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 014

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.

⁷ 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.

⁸ See supra note 5.

On September 29, 2016, the Administrator received a petition from a WTC Health Program member to add "autoimmune conditions like Rheumatoid Arthritis" to the List, considered Petition 014.⁹ This is the sixth petition to the Administrator requesting the addition of autoimmune diseases, including various subtypes, to the List; each of the first five autoimmune disease petitions were denied due to insufficient evidence, as described in respective Federal Register notices (FRNs).¹⁰ Petition 014 was received prior to recent amendments to WTC Health Program regulations regarding petitions for additions to the List taking effect.¹¹ The Petition was evaluated pursuant to the regulations and policies in effect at the time of its receipt¹² and, therefore, Petition 014 was considered valid. Future such submissions requesting the addition of autoimmune diseases to the List and providing the same peer-reviewed, published, epidemiologic evidence, however, may not be considered valid in accordance with 42 CFR 88.16(a)(5), as amended.

⁹ See Petition 014, WTC Health Program: Petitions Received, <http://www.cdc.gov/wtc/received.html>.

¹⁰ "World Trade Center Health Program; Petition 007-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 32333 (June 8, 2015); "World Trade Center Health Program; Petition 008-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 39720 (July 10, 2015); "World Trade Center Health Program; Petition 009-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 65980 (Oct. 28, 2015); "World Trade Center Health Program; Petition 011-Autoimmune Diseases; Finding of Insufficient Evidence," 81 FR 24047 (April 25, 2016); and "World Trade Center Health Program; Petition 013--Autoimmune Disease; Finding of Insufficient Evidence," 81 FR 60329 (Sept. 1, 2016).

¹¹ See "World Trade Center Health Program; Amendments to Definitions, Appeals, and Other Requirements; Final Rule," 81 FR 90926 (Dec. 15, 2016), effective Jan. 17, 2017.

¹² See 42 CFR 88.17 (2016); see also 77 FR 24628 (Apr. 25, 2012).

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.¹³ Petition 014 presented an online news article¹⁴ announcing the online publication of a study published by Webber et al. [2015], entitled "Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers."¹⁵ Because Webber et al. [2015] is a peer-reviewed, published epidemiologic study of autoimmune diseases among 9/11-exposed responders and survivors, the petition was considered valid. Accordingly, the Program conducted a review of available scientific information regarding the causal association between 9/11 exposure and autoimmune diseases, including rheumatoid arthritis.

C. Review of Scientific and Medical Information and Administrator Determination

¹³ See supra note 2.

¹⁴ Boynes-Shuck A [2015], Why Rheumatoid Arthritis Is Plaguing 9/11 First Responders, Healthline News, <http://www.healthline.com/health-news/why-rheumatoid-arthritis-is-plaguing-9-11-first-responders-040415#1>.

¹⁵ Webber M, Moir W, Zeig-Owens R, et al. [2015], Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers, *Arthritis Rheumatol* 67(5):1369-1376.

A literature search conducted in response to Petition 007¹⁶ included all of the autoimmune conditions in the 2015 Webber study; the Program conducted updates of that literature search in response to Petition 011 and Petition 013, looking for relevant studies published since the date of the previous literature search.¹⁷ In reviewing Petition 014, the Program conducted a search¹⁸ to update the results of the previous literature review for all of the types of autoimmune diseases identified in the 2015 Webber et al. study.¹⁹ The Program identified one new reference since the publication of the Petition 013 FRN in September 2016, a conference abstract regarding sarcoidosis in 9/11-exposed firefighters.²⁰ Upon review, the abstract was determined not to be relevant because it is not a published epidemiologic study in a peer-reviewed scientific journal.

The literature review did not identify any newly-published, relevant studies of autoimmune diseases, including rheumatoid arthritis, in the 9/11-exposed

¹⁶ 80 FR 32333 (June 8, 2015).

¹⁷ See 81 FR 24047 (April 25, 2016) and 81 FR 60329 (Sept. 1, 2016), respectively.

¹⁸ Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health and Safety Science Abstracts, PubMed, Scopus, Toxicology Abstracts, and TOXLINE.

¹⁹ Rheumatoid arthritis; spondyloarthritis; inflammatory myositis (polymyositis and dermatomyositis); systemic lupus erythematosus; systemic sclerosis (scleroderma); Sjogren's syndrome; antiphospholipid syndrome; granulomatosis with polyangiitis (Wegener's); and eosinophilic granulomatosis with polyangiitis (Churg-Strauss).

²⁰ Hena K, Yip J, Jaber N, et al. [2016], Clinical Characteristics of Sarcoidosis in World Trade Center (WTC) Exposed Fire Department of the City of New York (FDNY) Firefighters, Chest 150(4S):514A.

population.²¹ Therefore, in accordance with the Program policy discussed above, the Program was unable to further evaluate Petition 014.

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

Finding no newly-published, relevant studies with regard to Petition 014, the Administrator has accordingly determined that insufficient evidence is available to take further action at this time, including either proposing the addition of autoimmune diseases, including rheumatoid arthritis, 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.

²¹ Two relevant studies identified in previous FRNs, Webber *et al.* [2015] and Webber M, Moir W, Crowson C, *et al.* [2016], Post-September 11, 2001, Incidence of Systemic Autoimmune Diseases in World Trade Center-Exposed Firefighters and Emergency Medical Service Workers, *Mayo Clin Proc* 2016;91(1):23-32, were reviewed in the Petition 011 and Petition 013 FRNs and found not to have the potential to provide a basis for a decision on whether to propose adding autoimmune diseases to the List. These studies are not further discussed in this notice; discussions of the Administrator's findings with regard to these studies may be found in previous notices for Petition 011, 81 FR 24047 (April 25, 2016) and Petition 013, 81 FR 60329 (Sept. 1, 2016).

For the reasons discussed above, the Petition 014 request to add autoimmune diseases, including rheumatoid arthritis, to the List of WTC-Related Health Conditions is denied.

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

The Secretary, HHS, or her/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. Anne Schuchat, M.D., Acting Director, CDC, and Acting Administrator, ATSDR, approved this document for publication on February 9, 2017.

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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