



**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 88**

**[NIOSH Docket 094]**

**World Trade Center Health Program; Petition 019—Irritable Bowel Syndrome; Finding of Insufficient Evidence**

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

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

**SUMMARY:** On May 17, 2018, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 019) to add irritable bowel syndrome (IBS) 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 IBS to the List. The Administrator also 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**].

**ADDRESSES:** Visit the WTC Health Program website at <https://www.cdc.gov/wtc/received.html> to review Petition 019.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090

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**SUPPLEMENTARY INFORMATION:**

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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,<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).

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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 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.

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his 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 88.15. Within 90 days after receipt of a valid 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) of the PHS Act and § 88.16(a)(2) of the Program regulations: (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.

## **B. Procedures for Evaluating a Petition**

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,<sup>2</sup> as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.<sup>3</sup>

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy, 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 may demonstrate the required medical basis.<sup>4</sup> Studies

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<sup>2</sup> 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, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPpetitionHandlingProcedures14May2014.pdf>.

<sup>3</sup> See WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017, [https://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_Adding\\_NonCancers\\_14\\_February\\_2017.pdf](https://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_14_February_2017.pdf).

<sup>4</sup> See *supra* note 2.

linking 9/11 agents to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the 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.<sup>5</sup> The 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. The Program evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search; the Program then compiles the scientific results of each study to assess whether a causal relationship between 9/11 exposures and the health condition is supported, and evaluates whether the results of the studies are representative of the 9/11-exposed population of responders and survivors. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that the health condition is substantially likely<sup>6</sup> to be causally associated with 9/11 exposures. If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations demonstrates a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition, then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents<sup>7</sup> from sources using non-9/11-exposed populations. If that additional assessment establishes that the health condition is substantially likely to be causally associated with 9/11 exposures among 9/11-exposed populations, the health condition may be added to the List.

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<sup>5</sup> See *supra* note 3.

<sup>6</sup> The “substantially likely” standard is met when the scientific evidence, taken as a whole, demonstrates a strong relationship between the 9/11 exposures and the health condition.

<sup>7</sup> 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites.

### C. Petition 019

On May 17, 2018, the Administrator received a petition (Petition 019) from a WTC survivor who was caught in the dust cloud near Ground Zero, requesting the addition of “irritable bowel syndrome (IBS)” to the List.<sup>8</sup> The petition included one scientific article, by Marynowski *et al.* [2015],<sup>9</sup> reviewing the findings of peer-reviewed, published epidemiologic studies concerning the association of IBS with environmental pollution (including particulate matter, a 9/11 agent). Although the Marynowski article on its own did not provide a sufficient medical basis for the submission to be considered a valid petition, the article referenced a peer-reviewed, published study by Kaplan *et al.* [2012]<sup>10</sup> regarding IBS symptoms in non-9/11-exposed populations. Kaplan *et al.* conducted an epidemiologic study to evaluate the association between daily concentrations of air pollutants, including particulate matter, with emergency department visits for non-specific abdominal pain, a symptom necessary for a diagnosis of IBS. The inclusion of a reference to this study provides sufficient medical basis for the submission to be considered a valid petition.

### D. Review of Scientific and Medical Information and Administrator Determination

In response to Petition 019, and pursuant to the Program policy on the addition of non-cancer health conditions to the List,<sup>11</sup> the Program conducted a review of the scientific literature on IBS.<sup>12</sup> The Program was unable to identify any references to the petitioned health condition, IBS, in 9/11-exposed populations for further scientific evaluation based on the literature search. Since Kaplan *et al.* [2012] is not an epidemiologic study of IBS in 9/11-exposed populations, it

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<sup>8</sup> See Petition 019, WTC Health Program: Petitions Received, <http://www.cdc.gov/wtc/received.html>.

<sup>9</sup> Marynowski M, Likońska A, Zatorski H, Fichna J [2015], *Role of Environmental Pollution in Irritable Bowel Syndrome*, *World J Gastroentero* 21(40):11371–11378.

<sup>10</sup> Kaplan GG, Szyszkowicz M, Fichna J, Rowe BH, Porada E, Vincent R, Madsen K, Ghosh S, Storr M [2012], *Non-Specific Abdominal Pain and Air Pollution: A Novel Association*, *PLOS ONE* 7(10).

<sup>11</sup> *Supra* note 3.

<sup>12</sup> Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health & Safety, PsycINFO, PubMed, Scopus, and Toxicology Abstracts/TOXLINE.

does not meet the threshold for evaluation established in Program policy; therefore, the article was not further reviewed.

**E. Administrator’s Final Decision on Whether to Propose the Addition of IBS to the List**

The Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of IBS 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.

For the reasons discussed above, the Petition 019 request to add IBS to the List of WTC-Related Health Conditions is denied.

**F. Approval to Submit Document to the Office of the Federal Register**

The Secretary, HHS, or 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. Robert Redfield M.D., Director, CDC, and Administrator, ATSDR, approved this document for publication on August 10, 2018.

Dated: August 10, 2018.

Frank J. Hearl,  
Chief of Staff, National Institute for Occupational Safety and Health,

Delegated the duties of the 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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