



**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention**

**[NIOSH Docket 094]**

**World Trade Center (WTC) Health Program; Petition 026—Anti-Glomerular Basement Membrane (Anti-GBM) Glomerulonephritis; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, Department of Health and Human Services.

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

**SUMMARY:** The Administrator of the WTC Health Program received a petition (Petition 026) to add “Anti GBM Disease Glomerulonephritis (Anti-Glomerular Basement Membrane Disease)” to the List of WTC-Related Health Conditions. Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that there is insufficient evidence available to support taking further action at this time regarding anti-GBM glomerulonephritis. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee, publish a proposed rule, or 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 026.

**FOR FURTHER INFORMATION CONTACT:**

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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, Pub. L. 116-59, Pub. L. 117-328, Pub. L. 118-31, and Pub. L. 119-75), 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 for health conditions on the List of WTC-Related Health Conditions (List)<sup>2</sup> 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). The Program also provides benefits 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<sup>3</sup> (survivors).

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.

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<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-64. 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.

<sup>2</sup> The List of WTC-Related Health Conditions is established in 42 U.S.C. 300mm-22(a)(3)-(4) and 300mm-32(b); additional conditions may be added through rulemaking and the complete list is provided in WTC Health Program regulations at 42 CFR 88.15.

<sup>3</sup> See 42 U.S.C. 300mm-5(8); 42 CFR 88.1.

In accordance with 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 WTC Health Program regulations: (1) Request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (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.

More information about the WTC Health Program, including the List and the petition process, is available at [www.cdc.gov/wtc/](http://www.cdc.gov/wtc/).

## **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>4</sup> as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.<sup>5</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 and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*,<sup>6</sup> reference to a peer-reviewed, published, epidemiologic study about the health condition

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<sup>4</sup> See WTC Health Program [2026], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*, January 22, 2026, [https://www.cdc.gov/wtc/pdfs/policies/PPN\\_SubmissionsPetitions%20\\_20260122-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/PPN_SubmissionsPetitions%20_20260122-508.pdf).

<sup>5</sup> See WTC Health Program [2024], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, October 18, 2024, [https://www.cdc.gov/wtc/pdfs/policies/WTCHP\\_PP\\_Adding\\_NonCancer\\_Health\\_Conditions\\_20241018.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancer_Health_Conditions_20241018.pdf).

<sup>6</sup> *Supra* note 4.

among 9/11-exposed populations or clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.<sup>7</sup> Studies linking 9/11 agents or hazards<sup>8</sup> to the petitioned health condition may also provide sufficient medical basis for a valid petition.<sup>9</sup> In accordance with 42 CFR 88.16(a)(5), the Administrator is required to consider a new petition for a previously evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis for the association between 9/11 exposures and the condition to be added. A new medical basis is evidence not previously reviewed by the Administrator.

After the Program has determined that a petition is valid, and in accordance with the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions (Policy and Procedures)*, the Administrator directs the WTC Health Program Science Team (Science Team) to conduct a review of the scientific literature. The literature review is a keyword search of relevant scientific databases intended to identify peer-reviewed, published, epidemiologic studies about the health condition among 9/11-exposed populations.

The Science Team evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search using validity indicators described in the *Policy and Procedures*.<sup>10</sup> Studies exhibiting sufficient validity indicators have the potential to provide a basis for deciding whether to propose adding the health condition to the List and are considered “high-quality” studies. The Science Team then evaluates the identified high-quality studies, individually and

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<sup>7</sup> *Id.* at 7.

<sup>8</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. See WTC Health Program [2018], *Development of the Inventory of 9/11 Agents*, July 17, 2018, [https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://wwwn.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf).

<sup>9</sup> *Supra* note 4 at 7.

<sup>10</sup> *Supra* note 5 at 7.

together, to characterize the evidence of a causal association between 9/11 exposures and the health condition. As part of this evaluation, the Science Team considers the Bradford Hill weight of evidence criteria,<sup>11</sup> study limitations, and whether the studies are representative of the 9/11-exposed population of responders and survivors. After evaluating the totality of the evidence, the Science Team assesses the degree to which the evidence supports a causal association between 9/11 exposures and the health condition and assigns the evidence to one of the following five categories:

- Category I Evidence supports substantial likelihood of causal association
- Category II Evidence supports high likelihood of causal association
- Category III Evidence supports limited likelihood of causal association
- Category IV Evidence does not support causal association
- Category V Evidence is inadequate to determine the likelihood of causal association.

The Science Team provides the outcome of its evaluation to the Administrator. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that there is a substantial likelihood of a causal association between the health condition and 9/11 exposures (Category I).<sup>12</sup> If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations shows a high, but not substantial, likelihood of a causal association between the 9/11 exposures and the health condition (Category II),<sup>13</sup> then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents in non-9/11 exposure scenarios. If that additional assessment establishes that there is now sufficient evidence to support the conclusion that a causal association between the 9/11 exposures and the health condition is substantially likely

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<sup>11</sup> Hill AB [1965], *The Environment and Disease: Association or Causation?* Proc R Soc Med 58(5):295–300.

According to the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, the Bradford Hill criteria are a leading weight of evidence framework “which comprises nine aspects of association. These aspects comprise strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy.” See *supra* note 5 at 9, discussion of Bradford Hill analysis in footnote 21.

<sup>12</sup> *Substantial likelihood of causal association* means that the association is strongly supported by evidence from high-quality, peer-reviewed, published epidemiologic studies of the health condition in 9/11-exposed populations and there is high confidence that the association cannot be explained by chance, bias, confounding, or any other alternative explanation. See *supra* note 5 at 12.

<sup>13</sup> *High likelihood of causal association* means that the scientific evidence, taken as a whole, demonstrates that the likelihood of a causal association is less than substantial, but definitively more than limited. Therefore, there is some meaningful likelihood that the association can be explained by chance, bias, confounding, or another alternative explanation. See *supra* note 5 at 12.

among 9/11-exposed populations (Category I), then the Administrator may propose the health condition for addition to the List.

### **C. Petition 026**

On March 12, 2020, the Administrator received a petition (Petition 026) requesting the addition of “Anti GBM Disease Glomerulonephritis (Anti-Glomerular Basement Membrane Disease)” to the List.<sup>14</sup> The petition’s validity was established by references to two peer-reviewed, published studies that provide a medical basis for the association between anti-GBM glomerulonephritis—a type of kidney disease—and hydrocarbon exposure. Several hydrocarbons (including organic solvents and fuels such as pristane, phytane, and benzo(a)pyrene) are identified as 9/11 agents. The following referenced studies (a literature review and a case study) each individually establish a medical basis:

- *Hydrocarbon Exposure May Cause Glomerulonephritis and Worsen Renal Function: Evidence Based on Hill’s Criteria for Causality*, by Ravnskov [2000],<sup>15</sup> is a peer-reviewed, published literature review discussing the role of hydrocarbons in causing glomerulonephritis and end-stage renal failure.
- *Anti-Glomerular Basement Membrane Disease*, by Pusey [2003],<sup>16</sup> is a peer-reviewed, published case review discussing the role of hydrocarbons in anti-GBM disease.

These two studies suggest a potential association between exposure to 9/11 agents (specific hydrocarbons) and anti-GBM glomerulonephritis and thus provided a sufficient medical basis to consider the submission a valid petition.

### **D. Evaluation of Scientific Evidence: Findings and Conclusion**

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<sup>14</sup> See Petition 026, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

<sup>15</sup> Ravnskov U [2000], *Hydrocarbon Exposure May Cause Glomerulonephritis and Worsen Renal Function: Evidence Based on Hill’s Criteria for Causality*, *Q J Med* 93(8):551–556.

<sup>16</sup> Pusey CD [2003], *Anti-Glomerular Basement Membrane Disease*, *Kidney Int* 64(4):1535–1550.

In response to Petition 026, and pursuant to the *Policy and Procedures*, the Administrator of the WTC Health Program directed the Science Team to conduct a systematic search of the scientific literature to identify all peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis among 9/11-exposed populations. These types of studies are evaluated to determine if they provide evidence to support the likelihood of a causal association between 9/11 exposure and the health condition under consideration. The Science Team provided a paper to the Administrator describing its findings, *Evaluation of Scientific Evidence Supporting the Addition of Anti-Glomerular Basement Membrane Disease (Anti-GBM) Glomerulonephritis to the List of WTC-Related Health Conditions*. This paper is available in the docket for this activity<sup>17</sup> and on the Program's website.<sup>18</sup>

Neither the systematic literature search nor the references provided in the petition, including those described above, identified any peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis in 9/11-exposed populations. In accordance with the WTC Health Program's *Policy and Procedures*, because no such peer-reviewed, published, epidemiologic studies of anti-GBM glomerulonephritis in 9/11-exposed populations were found, the Program was unable to conduct an evaluation of scientific evidence to determine the likelihood of a causal association between 9/11 exposures and the petitioned health condition.

Upon finding no evidence available in peer-reviewed, published, epidemiological studies regarding anti-GBM glomerulonephritis among 9/11-exposed populations, the Science Team concluded that there is inadequate evidence to determine the likelihood of a causal association<sup>19</sup> between 9/11 exposures and anti-GBM glomerulonephritis (Category V).

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<sup>17</sup> <https://www.cdc.gov/niosh/docket/archive/docket094.html>.

<sup>18</sup> <https://www.cdc.gov/wtc/received.html>

<sup>19</sup> See *supra* note 5 at 17.

### **E. Administrator’s Final Decision on Whether to Propose the Addition of Anti-GBM Glomerulonephritis to the List**

Pursuant to the PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), and in accordance with Sec. VIII.B. of the *Policy and Procedures*, the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of anti-GBM glomerulonephritis to the List (pursuant to the 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 the PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator also determined that requesting a recommendation from the STAC (pursuant to the 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 026 request to add “Anti GBM Disease Glomerulonephritis (Anti-Glomerular Basement Membrane Disease)” 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. Acting CDC Director Jay Bhattacharya, MD, PhD, approved this document for publication on March 11, 2026.

**John J. 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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