



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

#### **[NIOSH Docket 094]**

#### **World Trade Center Health Program; Petitions 029, 034, 035, and 062—Hepatic Steatosis; 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 World Trade Center (WTC) Health Program has received several petitions (Petitions 029, 034, 035, and 062) to add “hepatic steatosis” or “fatty liver disease” to the List of WTC-Related Health Conditions. Upon reviewing the scientific and medical literature, including information provided by the petitioners, the Administrator has determined that there is insufficient evidence available to support taking further action at this time regarding hepatic steatosis. 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 these petitions 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 Petitions 029, 034, 035, and 062.

**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).

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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.

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.

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

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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).

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 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 includes 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

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

<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://www.cdc.gov/wtc/pdfs/policies/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://www.cdc.gov/wtc/pdfs/policies/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 7–8.

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 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

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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 id.* at 9–10 and footnotes 21–30, discussion of Bradford Hill analysis.

<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.

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

### **C. Petitions 029, 034, 035, and 062**

On November 12, 2020, the Administrator received a petition (Petition 029) requesting the addition of several conditions, including “hepatotoxic injury—fatty liver disease” to the List.<sup>14</sup> The petition’s validity was established by references to one peer-reviewed, published, epidemiologic study that provided a medical basis for the association between 9/11 exposures and hepatotoxic injury—fatty liver disease. The referenced study establishing a medical basis is:

- *Elevated Prevalence of Moderate-to-Severe Hepatic Steatosis in World Trade Center General Responder Cohort in a Program of CT Lung Screening*, by Chen et al. [2020],<sup>15</sup> a peer-reviewed, published cross-sectional study of WTC responders designed to compare hepatic steatosis in 9/11-exposed WTC responders compared with non-9/11-exposed lung cancer screening participants.

This study suggests a potential association between exposure to 9/11 agents and hepatotoxic injury—fatty liver disease, and thus provided a sufficient medical basis to consider the submission a valid petition.

On August 4, 2021, the Administrator received a petition (Petition 034) requesting the addition of “Hepatic Steatosis (also known as Fatty Liver Disease or Non-Alcoholic Liver Disease)” to the List.<sup>16</sup> The petition’s validity was established by

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<sup>14</sup> See Petition 029, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

<sup>15</sup> Chen X, Ma T, Yip R, Perumalswami PV, Branch AD, Lewis S, Crane M, Yankelevitz DF, Henschke CI [2020], *Elevated Prevalence of Moderate-to-Severe Hepatic Steatosis in World Trade Center General Responder Cohort in a Program of CT Lung Screening*, *Clin Imaging* 60(2):237–243.

<sup>16</sup> See Petition 034, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

reference to two peer-reviewed, published, epidemiologic studies that provided a medical basis for the association between 9/11 exposures and hepatic steatosis. The referenced studies each individually establishing a medical basis were the study by Chen et al. [2020], described above, and:

- *Dose-Response Relationship between World Trade Center Dust Exposure and Hepatic Steatosis*, by Jirapatnakul et al. [2021],<sup>17</sup> peer-reviewed, published cross-sectional study to evaluate the existence of a dose-response relationship between the intensity of 9/11 exposures and hepatic steatosis prevalence in WTC responders.

These two studies suggest a potential association between exposure to 9/11 agents and hepatic steatosis, and thus provided sufficient medical basis to consider the submission a valid petition.

On November 15, 2021, the Administrator received a petition (Petition 035) requesting the addition of “Hepatic Steatosis/Cirrhosis” to the List.<sup>18</sup> The petition’s validity was established by reference to one peer-reviewed, published, epidemiologic study that demonstrates a positive association between 9/11 exposures and hepatic steatosis. The referenced study establishing a medical basis is the study by Jirapatnakul et al. [2021],<sup>19</sup> described above. This study suggests a potential association between exposure to 9/11 agents (specifically WTC dust) and hepatic steatosis, and thus provided a sufficient medical basis to consider the submission a valid petition.

Finally, on May 14, 2025, the Administrator received a petition (Petition 062) requesting the addition of “Hepatic Steatosis (Fatty Liver Disease)” to the List.<sup>20</sup> The petition’s validity was also established by reference to Jirapatnakul et al. [2021],<sup>21</sup> described above.

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<sup>17</sup> Jirapatnakul A, Yip R, Branch AD, Lewis S, Crane M, Yankelevitz DF, Henschke CI [2021], *Dose-Response Relationship between World Trade Center Dust Exposure and Hepatic Steatosis*, *Am J Ind Med* 64(10):837–844.

<sup>18</sup> See Petition 035, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

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

<sup>20</sup> See Petition 062, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

<sup>21</sup> See *supra* note 17.

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

In response to Petitions 029, 034, 035, and 062 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 hepatic steatosis among 9/11-exposed populations. Identified studies were assessed for quality; those studies determined to be high-quality were then evaluated to determine if they provide evidence to support a likelihood of a causal association between 9/11 exposure and the health condition under consideration. The Science Team provided the Administrator with a paper describing its findings, *Evaluation of Scientific Evidence Supporting the Addition of Hepatic Steatosis to the List of WTC-Related Health Conditions*. This paper is available in the docket for this activity<sup>22</sup> and on the Program's website.<sup>23</sup>

The literature search conducted by the WTC Health Program identified two peer-reviewed, published, epidemiologic studies of hepatic steatosis in 9/11-exposed populations: Chen et al. [2020] and Jirapatnakul et al. [2021], discussed above. These two studies were determined to have sufficient validity indicators to be considered high-quality studies eligible for further evaluation in accordance with the Program's *Policy and Procedures*.<sup>24</sup> The Science Team conducted an evaluation, separately and together, of the two studies to determine the likelihood of a causal association between 9/11 exposures and the petitioned health condition. The systematic literature search, the Science Team's evaluation and synthesis of the available literature, and the Science Team's conclusions regarding the association between 9/11 exposure and hepatic steatosis are described in full in the Science Team's *Evaluation of Scientific Evidence*

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<sup>22</sup> <https://www.cdc.gov/niosh/docket/archive/docket094.html>.

<sup>23</sup> <https://www.cdc.gov/wtc/received.html>.

<sup>24</sup> See *supra* note 5 at 7–8.

## *Supporting the Addition of Hepatic Steatosis to the List of WTC-Related Health*

### *Conditions.*

In accordance with the *Policy and Procedures*,<sup>25</sup> the WTC Health Program uses the following Bradford Hill criteria to evaluate studies of 9/11-exposed populations: strength of association,<sup>26</sup> precision of the risk estimate,<sup>27</sup> consistency of associations,<sup>28</sup> temporality,<sup>29</sup> biological gradient,<sup>30</sup> biological plausibility,<sup>31</sup> coherence,<sup>32</sup> and analogy.<sup>33</sup> As discussed in full in the *Evaluation of Scientific Evidence Supporting the Addition of Hepatic Steatosis to the List of WTC-Related Health Conditions*, the Science Team assessed each criterion as follows:

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<b>Aspect of Associative Causal Inference</b>	<b>Evaluation Findings</b>
Strength of Association	Two high-quality studies were available for evaluation [Chen et al. 2020; Jirapatnakul et al. 2021]. Both studies reported statistically significant estimates of increased prevalence of hepatic steatosis in the 9/11 responder population. Chen et al. [2020] found that the prevalence of moderate-to-severe hepatic steatosis was more than 3-fold higher in the WTC-participant group compared with non-WTC participants, while the linear regression estimates reported by Jirapatnakul et al. [2021] for liver attenuation were lower among those with earlier arrival dates, suggesting an exposure-response of more hepatic steatosis among those with higher 9/11 exposures (liver attenuation is inversely related to hepatic steatosis, meaning that lower liver attenuation demonstrates higher amounts of hepatic steatosis).

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<sup>25</sup> *Supra* note 5 at 9–10.

<sup>26</sup> It is generally thought that strong associations are more likely to be causal than weak associations; however, a weak association does not rule out a causal relationship.

<sup>27</sup> Precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is expressed as a confidence interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size, and a wider interval indicates greater uncertainty. While precision is not a Bradford Hill criterion, the Science Team takes it into consideration to evaluate the existence of random error in a study.

<sup>28</sup> Consistent findings are demonstrated when they have been repeatedly reported by multiple studies.

<sup>29</sup> Temporality is the condition that the 9/11 exposure must precede the health condition of interest and is typically assessed when considering aspects of exposure in the study design.

<sup>30</sup> Studies establish an exposure-response relationship by demonstrating that increases in exposure (i.e., exposures of greater intensity and/or longer duration) are associated with a greater incidence of disease. A thorough evaluation of exposure-response requires analysis of multiple levels of exposure such that the investigator can demonstrate that the risk increases with increasing levels of exposure.

<sup>31</sup> Study findings demonstrate a basis in scientific theory that supports the relationship between the exposure and the health effect and do not conflict with known facts about the biology of the health condition.

<sup>32</sup> Coherence implies that the interpretation of a causal association agrees with known disease etiology.

<sup>33</sup> Analogy is used to inform on biological plausibility and coherence by contrasting the evidence on the suspected causal association with that from an established association between similar (analogous) causes or effects.

Aspect of Associative Causal Inference	Evaluation Findings
Precision of the Risk Estimate	The confidence interval for the risk estimate in the Chen et al. [2020] study is wide but does not include the null value. Likewise, the multivariable regression estimates in the Jirapatnakul et al. [2021] study were above the statistical significance level of 0.05, except for the exposure category of those arriving on or after September 14, 2001.
Consistency of Associations	The findings are consistent among both studies, but the study by Chen et al. [2020] includes only a small sample of heavy smokers. Further studies, particularly among other 9/11 populations (e.g., survivors, responders from the Fire Department of the City of New York [FDNY]), are needed to confirm the findings reported by Jirapatnakul et al. [2021].
Temporality	Both studies were cross-sectional; therefore, information on temporality was limited. It is unclear in either study whether occupational and environmental exposures occurring prior to 9/11 or unmeasured exposures after 9/11 may have contributed to the observed health conditions.
Biological Gradient	The study by Jirapatnakul et al. [2021] suggests a trend of increasing hepatic steatosis prevalence with earlier arrival dates. However, no such gradient was found among those who arrived on 9/11 and had extensive dust cloud exposure versus those who arrived on 9/11 but did not have extensive dust cloud exposure [Jirapatnakul et al. 2021]. The study by Chen et al. [2020] did not report biological gradient findings.
Plausibility, Coherence, and Analogy	An association between 9/11 agents such as trichloroethylene, tetrachloroethylene, trichloroethane, carbon tetrachloride, polychlorinated biphenyls, arsenic, thallium, phosphorus, dioxin, lead, and chloroform, and hepatic steatosis satisfies these criteria and agrees with the available evidence.
Representativeness	The two studies examined persons in the General Responder Cohort. There were no studies of hepatic steatosis in the survivor population nor from the FDNY, Pentagon, or Shanksville responder cohorts. The findings of the evaluated studies might not be generalizable to other 9/11-exposed groups.

As summarized above, the Science Team evaluated the studies by Chen et al. [2020] and Jirapatnakul et al. [2021] using the Bradford Hill criteria to determine whether a causal association between 9/11 exposures and hepatic steatosis is supported. The Science Team concluded that the information available in these studies is insufficient to support a claim for causation using these criteria.

Only the study by Jirapatnakul et al. [2021] reported an exposure-response gradient with hepatic steatosis prevalence. However, Jirapatnakul et al. [2021] found no such gradient among those who arrived on 9/11 and had extensive dust cloud exposure versus those who arrived on 9/11 but did not have extensive dust cloud exposure. Even though both studies showed positive associations, the risk estimate in the study by Chen et al. [2020] lacked precision and is subject to potential selection bias. Both studies controlled for some, but not all, important confounders, and misclassification of exposure and outcome is possible. Consequently, chance, bias, and confounding could not be ruled out with reasonable confidence for either study. The known information on mechanisms of action supports an association between certain 9/11 agents and hepatic steatosis. However, given the significant limitations discussed above, the Science Team concluded that the available evidence is inadequate to determine the likelihood of a causal association between 9/11 exposures and hepatic steatosis.

Upon review of the evidence available in high-quality studies regarding hepatic steatosis among 9/11-exposed populations, the Science Team concluded that there is inadequate evidence to determine the likelihood of a causal association between 9/11 exposures and hepatic steatosis (Category V).<sup>34</sup>

#### **E. Administrator's Final Decision on Whether to Propose the Addition of Hepatic Steatosis 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 hepatic steatosis 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

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<sup>34</sup> See *Policy and Procedures supra* note 5 at Sec. V.E.—Evidence is Inadequate to Determine a Causal Association.

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 has 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 request in Petitions 029, 034, 035, and 062 to add hepatic steatosis 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. Jay Bhattacharya, MD, PhD, Senior Official Carrying out the Delegable Duties of the CDC Director, approved this document for publication on April 2, 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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