



## **Policy and Procedures for Adding Non-Cancer Conditions To the List of WTC-Related Health Conditions**

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### **I. Authority**

The *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions* is based on the James Zadroga 9/11 Health and Compensation Act of 2010 (“Act”)<sup>1</sup> and the World Trade Center (WTC) Health Program regulations.<sup>2</sup>

### **II. Introduction**

The Act provides two pathways to initiate the process of deciding whether to propose adding a health condition to the List of WTC-Related Health Conditions (“List”). These pathways are: (1) the Administrator of the WTC Health Program may initiate the process at the Administrator’s own discretion;<sup>3</sup> or (2) the Administrator initiates the process after receiving a petition<sup>4</sup> by an interested party.<sup>5</sup> A health condition may only be added to the List by rulemaking.

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<sup>1</sup> 42 U.S.C. § 300mm et seq.

<sup>2</sup> 42 C.F.R. Part 88.

<sup>3</sup> 42 U.S.C. § 300mm-22(a)(6)(A).

<sup>4</sup> When the Administrator receives a submission from an interested party to add a health condition to the List of WTC-related health conditions (List) he follows the steps outlined in the “Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions” (available at: <http://www.cdc.gov/wtc/policies.html>) and determines whether it meets the requirements for a petition specified in 42 C.F.R. § 88.17(a)(1).

<sup>5</sup> 42 U.S.C. § 300mm-22(a)(6)(B).

### **III. Review of Scientific and Medical Information and Administrator Determination**

Once the process of determining whether to propose adding a health condition to the List is initiated, the WTC Health Program's Associate Director for Science (ADS) will lead 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 condition to the List.

#### **A. Systematic Literature Search**

Information will be obtained about the health condition among 9/11-exposed populations by performing a systematic literature search.

#### **B. Literature Evidence Review**

1. For health conditions, such as injuries, for which direct observational evidence<sup>6</sup> may establish causation,<sup>7</sup> the available peer-reviewed, published, direct observational studies of 9/11-exposed populations are reviewed for their relevance, quantity, and quality to provide a basis for deciding whether to propose adding the health condition to the List.
2. For health conditions, such as diseases, for which epidemiologic evidence is needed to establish causation,<sup>8</sup> the available peer-reviewed, published, epidemiologic studies of 9/11-exposed populations are reviewed for their relevance, quantity, and quality of evidence for a causal relationship relative to its potential to provide a basis for deciding whether to propose adding the health condition to the List.

The findings of the review are documented and discussed with the Administrator.

#### **C. Administrator Determination**

The Administrator determines whether the evidence for a causal relationship available in peer-reviewed, published studies about the health condition among 9/11-exposed populations has the potential to provide a basis for a decision on whether to add the health condition and whether to proceed with an assessment of that information.

1. Where the Administrator determines that the evidence does not provide a sufficient basis for a decision:

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<sup>6</sup> Direct observational evidence may be found, in studies such as surveillance or on-site reports.

<sup>7</sup> Examples of health conditions for which direct observational evidence may establish a causal relationship with 9/11 exposures include, but are not limited to, acute injuries such as fractures, burns, and dislocations. Such types of health conditions have an immediate and observable cause and effect which is known to have occurred at a site of the September 11, 2001, terrorist attacks.

<sup>8</sup> Examples of health conditions for which epidemiologic studies are needed to establish a causal relationship with 9/11 exposures include, but are not limited to, diseases such as cardiovascular disease, respiratory disease, and kidney disease. Such types of health conditions do not have an immediate and observable cause and effect and the condition may have causes other than exposures at a site of the September 11, 2001, terrorist attacks.

- a. The evaluation will be documented and archived according to document management requirements; and
  - b. If the evaluation was initiated by a petition, the Administrator will:
    - i. Publish a determination in the *Federal Register* explaining that the available information is insufficient to take action;<sup>9</sup> and
    - ii. Notify the petitioner in writing of the decision simultaneously with the publication of the determination in the *Federal Register*.
2. Where the Administrator determines that the available evidence has the potential to provide a basis for a decision, the Administrator may:
- a. Direct the ADS to lead an assessment of the scientific and medical evidence and provide input on whether the available information supports a causal relationship between 9/11 exposures and the health condition [see Section IV.A.], and/or
  - b. Request advice from the WTC Health Program Scientific/Technical Advisory Committee (STAC) [see Section IV.B.].

## **IV. Assessment of Scientific and Medical Information**

### **A. Assessment Process**

#### **1. Review Criteria**

##### **a. Direct Observational Studies**

For health conditions, such as injuries, for which direct observational evidence may establish causation, published, peer-reviewed studies of the health condition in populations with 9/11 exposures will be assessed with consideration given to the relevance, quality, and quantity of that evidence.<sup>10</sup>

##### **b. Epidemiologic Studies**

For health conditions, such as diseases, for which the evidence of causation is provided in epidemiologic studies, the relevance, quality, bias, and confounding of the peer-reviewed, published, epidemiologic studies of 9/11 exposed populations will be assessed applying the following criteria extrapolated from the Bradford Hill criteria:

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<sup>9</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

<sup>10</sup> For health conditions which have an immediate and observable cause and effect that are known to be potentially directly caused by exposures that occurred during the September 11, 2001, terrorist attacks and subsequent response and recovery, direct observational studies (such as surveillance studies, rather than epidemiologic studies) which document that the outcomes occurred because of those 9/11 exposures may be reviewed to assess whether to add the health condition to the List.

- i. Strength of the association between a 9/11 exposure and a health condition (including the magnitude of the effect and statistical significance);
- ii. Consistency of the findings across multiple studies. If only a single published epidemiologic study is available for assessment, the consistency of findings cannot be evaluated and strength of association will necessarily place greater emphasis on statistical significance than on the magnitude of the effect;
- iii. Biological gradient, or dose-response relationships between 9/11 exposures and the health condition; and
- iv. Plausibility and coherence with known facts about the biology of the health condition.

## 2. Discussion with Administrator

The ADS will ensure that the results of the assessment are documented and discussed with the Administrator.

### B. Administrator Actions

If the assessment was performed in response to a petition, the Administrator will take one of the following actions.

1. For a health condition for which the evidence of causation is provided in direct observational studies:
  - a. If the evidence provides substantial<sup>11</sup> support for a causal relationship between the health condition and 9/11 exposures, the Administrator will publish in the *Federal Register* a notice of proposed rulemaking (NPRM) to add the health condition to the List;<sup>12</sup> or
  - b. If the evidence provides substantial support that 9/11 exposures are not causally related to the health condition, the Administrator then publishes in the *Federal Register* a determination not to propose a rule and the basis for such determination;<sup>13</sup> or
  - c. If the evidence is insufficient to take either of the actions in IV.B.1.a. or b., above, the Administrator then publishes that determination in the *Federal Register*;<sup>14</sup>

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<sup>11</sup> The substantial evidence standard is met when the WTC Health 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>12</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(ii).

<sup>13</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iii).

<sup>14</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

2. For a health condition for which the evidence of causation is provided in epidemiologic studies:
  - a. If the evidence provides substantial<sup>10</sup> support for a causal relationship between 9/11 exposures and the health condition, the Administrator will publish in the *Federal Register* a notice of proposed rulemaking (NPRM) to add the health condition to the List;<sup>15</sup> or
  - b. If the evidence provides substantial support that 9/11 exposures are not causally related to the health condition, the Administrator then publishes in the *Federal Register* a determination not to propose a rule and the basis for such determination;<sup>16</sup> or
  - c. If the evidence is insufficient to take either of the actions in IV.B.2.a. or b., above, the Administrator then publishes that determination in the *Federal Register*;<sup>17</sup> or
  - d. If the epidemiologic evidence provides only modest<sup>18</sup> support for a causal relationship between 9/11 exposures and the health condition, the Administrator will request additional assessment of whether a causal relationship is supported by other published, peer-reviewed, epidemiologic studies of associations between 9/11 agents<sup>19</sup> and the health condition.
    - i. The evaluation of these other studies must include an assessment of the similarity of the exposure conditions documented in the epidemiologic studies and the exposure conditions that occurred as a result of the 9/11 terrorist attacks and cleanup. Similarity of exposure conditions includes factors such as magnitude, route of exposure, physical form (e.g., particulate, gas, fume, vapor, or solute), duration, and timing. Consideration will be given to health outcomes from acute and subchronic exposures.<sup>20</sup>
    - ii. For outcomes from subchronic exposures, the consistency of the presence of the 9/11 agent during the response and recovery should be assessed.
    - iii. If the additional assessment adds enough support for the Administrator to determine that there is substantial<sup>7</sup> support for a causal relationship between 9/11

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<sup>15</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(ii).

<sup>16</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iii).

<sup>17</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

<sup>18</sup> The modest evidence standard is met when the WTC Health 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>19</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 as defined in 42 C.F.R. Part 88, or at the Pentagon site, or in Shanksville, Pennsylvania site as defined in 42 C.F.R. § 88.1.

<sup>20</sup> Toxicity is a function of both exposure concentration and duration. Exposure must have been substantially likely to have been a significant factor to elicit a toxic response resulting in a health condition.

exposures and the health condition, the Administrator will publish in the *Federal Register* an NPRM to add the health condition to the List. In the absence of substantial support for a causal relationship, the Administrator determines the evidence is insufficient to take action and then publishes that determination in the *Federal Register*.

3. If the assessment was initiated by the Administrator, the Administrator may take one of the actions described in Section IV.B.

## V. WTC Health Program Scientific/Technical Advisory Committee (STAC)

### A. Convening the STAC

The Administrator may convene the STAC if he determines that its advice would be helpful. For example, where there is need of an interpretation of conflicting or inconclusive published scientific evidence, the Administrator may convene the STAC.

### B. Meeting Procedures

If the Administrator decides to request a recommendation from the STAC regarding a health condition, the Administrator provides a charge to the STAC, and the Designated Federal Official (DFO) works with the STAC to schedule meetings and assemble information needed to develop recommendations on whether 9/11 exposures have a causal relationship with the health condition.

### C. Time Limits

1. If a petition has been received, then within 60 days of receipt of the petition to add a health condition to the List the Administrator may send a letter to the STAC Chair requesting advice on whether to add the petitioned health condition. The Administrator establishes a time period, up to 180 days, for the committee to provide recommendations and the scientific and medical basis for those recommendations.
2. If a petition has not been received, the Administrator establishes a time period for the STAC to provide recommendations and a report on the scientific or medical basis for those recommendations.
3. After receiving the report and recommendations from the STAC, the Administrator will evaluate the STAC's advice and will take appropriate action under Section IV.B.

**Exception:** The options found in Section IV.B.1.c. and B.2.c. above are not available to the Administrator when advice has been requested from the STAC in response to a petition.

## **VI. Rulemaking**

### **A. NPRM**

If the Administrator decides to publish an NPRM in the *Federal Register* to add the health condition, following receipt and review of public comments he will again review the available evidence and any new scientific and medical information provided by commenters.

### **B. Final Rule**

After reviewing the public comments, the Administrator will determine whether the rationale discussed in the NPRM is changed by the information supplied by commenters. If the evidence continues to support the addition of the health condition:

1. A final rule is developed and published in the *Federal Register*;
2. The condition is added to the List of WTC-Related Health Conditions; and
3. Implementation procedures will be developed, including establishing coverage conditions such as:
  - a. Exposure qualifications;
  - b. Time intervals; and
  - c. Other procedures as appropriate to the particular health condition.

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