



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

John Howard, M.D., Administrator  
World Trade Center Health Program

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### I. Authority

The *Policy and Procedures for Adding Types of Cancer 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> the Final Rule, “*World Trade Center Health Program: Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions*”<sup>2</sup> and the World Trade Center (WTC) Health Program regulations.<sup>3</sup>

### II. Introduction

The Act provides two pathways to initiate the process of deciding whether to propose adding a health condition, including types of cancer, 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>4</sup> or (2) the Administrator initiates the process after receiving a petition<sup>5</sup> by an interested party.<sup>6</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> 77 Fed. Reg. 56138 (Sept 12, 2012). See <http://www.gpo.gov/fdsys/pkg/FR-2012-09-12/pdf/2012-22304.pdf>

<sup>3</sup> 42 C.F.R. Part 88.

<sup>4</sup> 42 U.S.C. § 300mm-22(a)(6)(A).

<sup>5</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>6</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 type of cancer 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 type of cancer to the List.

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

Information will be obtained about the type of cancer among 9/11-exposed populations and potential causal association between that cancer and a condition already on the List by performing a systematic literature search. The classifications of the World Health Organization's International Agency for Research on Cancer (IARC) and the most recent National Toxicology Program (NTP) *Report on Carcinogens* will also be reviewed.

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

The relevance, quantity, and quality of the evidence available in peer-reviewed, published, epidemiologic studies of 9/11-exposed populations and possible causal association between that cancer and a condition already on the List will be reviewed relative to their potential to provide a basis for deciding whether to propose adding the type of cancer to the List. The findings of the review will be documented and discussed with the Administrator.

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

The Administrator determines whether the evidence available in peer-reviewed, published, epidemiologic studies about the type of cancer among 9/11-exposed populations has the potential to provide a basis for a decision on whether to add the type of cancer 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:
  - a. The evaluation will be documented and archived according to document management requirements; and
  - b. If the evaluation was initiated by a petition, then the Administrator will:
    - i. Publish a determination in the *Federal Register* that the available information is insufficient to take action;<sup>7</sup> and
    - ii. Notify the petitioner in writing of the decision simultaneously to the determination being published in the *Federal Register*.

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<sup>7</sup> 42 U.S.C. § 300mm-22 (a)(6)(B)(iv).

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 type of cancer [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**

The ADS will lead an assessment of the available evidence in the following hierarchy of methods for determining whether to add a type of cancer to the List. In determining whether to propose that a type of a cancer be included on the List, a review of the evidence must demonstrate fulfillment of at least one of the following four methods:

##### ***Method 1. Epidemiologic Studies of September 11, 2001 Exposed Populations.***

A type of cancer may be added to the List if published, peer-reviewed epidemiologic evidence supports a causal association between 9/11 exposures and the cancer type. The following criteria extrapolated from the Bradford Hill criteria will be used to evaluate the evidence of the exposure-cancer relationship:

- a. Strength of the association between a 9/11 exposure and a type of cancer (including the magnitude of the effect and statistical significance);
- b. 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;
- c. Biological gradient, or dose-response relationships between 9/11 exposures and the type of cancer; and
- d. Plausibility and coherence with known facts about the biology of the type of cancer.

**Method 2. Established Causal Associations.**

A type of cancer may be added to the List if there is well-established scientific support published in multiple epidemiologic studies for a causal association between that cancer and a condition already on the List of WTC-Related Health Conditions.

**Method 3. Review of Evaluations of Carcinogenicity in Humans.**

A type of cancer may be added to the List only if both of the following criteria for Method 3 are satisfied:

**3A. Published Exposure Assessment Information.** 9/11 agents<sup>8</sup> were 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 CFR 88.1, or at the Pentagon, or in Shanksville, Pennsylvania<sup>9</sup>; and

**3B. Evaluation of Carcinogenicity in Humans from Scientific Studies.** NTP has determined that the 9/11 agent is *known to be a human carcinogen* or is *reasonably anticipated to be a human carcinogen*, and IARC has determined there is *sufficient* or *limited* evidence that the 9/11 agent causes a type of cancer.

**Method 4. Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee.**

A type of cancer may be added to the List if the STAC has provided a reasonable basis for adding a type of cancer and the basis for inclusion does not meet the criteria for Method 1, Method 2, or Method 3.

**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. If a review of the evidence demonstrates fulfillment of at least one of the four methods described in IV.A. above, the Administrator will publish in the *Federal*

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<sup>8</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 the New York City disaster area or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 C.F.R. § 88.1.

<sup>9</sup> Definitions of these locations are provided in 42 C.F.R. § 88.1.

*Register* a notice of proposed rulemaking (NPRM) to add the type of cancer to the List;<sup>10</sup> or

2. If a review of the evidence does not demonstrate fulfillment of at least one of the four methods described in IV.A. above and does demonstrate that 9/11 exposures are not causally related to the type of cancer, the Administrator will publish in the *Federal Register* a determination not to propose a rule and the basis for such determination;<sup>11</sup> or
3. If a review of the evidence indicates the information is insufficient to take either of the actions in IV.B.1. or 2., above the Administrator will publish that determination in the *Federal Register*.<sup>12</sup>
4. 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 type of cancer, 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 type of cancer.

**C. Time Limits**

1. If a petition has been received, then within 60 days of receipt of the petition to add a type of cancer to the List the Administrator may send a letter to the STAC Chair requesting advice on whether to add the petitioned type of cancer. 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.

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<sup>10</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(ii).

<sup>11</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iii).

<sup>12</sup> 42 U.S.C. § 300mm-22(a)(6)(B)(iv).

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 option found in Section IV.B.3. above is not an option for 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 type of cancer, 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 then 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 type of cancer:

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 type of cancer.

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