



Shanksville



New York City



Pentagon

Overview of Policy and Procedures to Add Cancer Conditions

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Pathways To Add A Cancer Condition To The List:

http://www.cdc.gov/wtc/pdfs/WTCHPPPAdditionofCancerPolicy_Revision_11_May_2016.pdf

1. The Administrator of the WTC Health Program initiates the process at his own discretion.
 2. The Administrator initiates the process after receiving a petition by an interested party.
 - “Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions” (http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures_14May2014.pdf) and determines whether the submission meets the requirements for a petition specified in 42 C.F.R. § 88.17(a)(1).
- A health condition may only be added to the List by rulemaking.

P&P Cancer – Literature Review

- The Program Science Team leads a review of the scientific literature:
 - Systematic Literature Search
 - Studies regarding the type of cancer among 9/11-exposed populations;
 - Studies regarding potential causal association between that cancer and a condition already on the List; and
 - The most recent classifications of the World Health Organization’s International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) *Report on Carcinogens*.
 - Literature Evidence Review:
 - Information is determined to be relevant if it is presented in peer-reviewed, published, epidemiologic studies of the cancer in 9/11-exposed populations;
 - Quantity and quality of relevant studies are then reviewed for their potential to provide a basis for deciding whether to propose adding the type of cancer to the List.
 - Findings of the review, including any information about IARC classifications and the NTP *Report on Carcinogens*, are documented and discussed with the Administrator.

P&P Cancer - Administrator Determination

1. If the evidence does not provide a sufficient basis for a decision:
 - Evaluation is documented and archived.
 - If initiated by a petition, determination published in the *Federal Register* and petitioner is notified in writing.

2. If the available evidence has the potential to provide a basis for a decision, the Administrator may:
 - Direct the Science Team to assess the scientific and medical evidence.
 - Request advice from the STAC.

P&P Cancer - Assessment of Information

- Science Team conducts an assessment of the available evidence under four methods. At least one of the methods must be fulfilled:
 - Method 1. Epidemiologic Studies of September 11, 2001 Exposed Populations.
 - Method 2. Established Causal Associations with a Health Condition Already on the List of WTC-Related Health Conditions.
 - Method 3. Review of Evaluations of Carcinogenicity in Humans.
 - Method 4. Review of Information Provided by the STAC upon Request by the Administrator.
- Science team ensures that the results of the assessment are documented and discussed with the Administrator.

P&P Cancer – Method 1

- Peer-reviewed, published, epidemiologic studies of 9/11-exposed populations are assessed by applying criteria extrapolated from the Bradford Hill criteria:
 - Strength of the association between a 9/11 exposure and the health condition, including the precision of the risk estimate.
 - Consistency of the findings across multiple studies.
 - Biological gradient, or dose-response relationships between 9/11 exposures and the health condition.
 - Plausibility and coherence with known facts about the biology of the health condition.
- No cancers have been added under Method 1 to date, but several epidemiologic studies of cancer in 9/11-exposed populations beginning in 2011 have been suggestive of a causal association between 9/11 agents and various cancers.

P&P Cancer – Method 2

- A type of cancer may be added to the List of WTC-Related Health Conditions 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.
- Example: Adenocarcinoma of the esophagus that progresses from gastroesophageal reflux disease.

P&P Cancer – Method 3

Both of the following criteria must be satisfied:

- 9/11 agents were reported in a published, peer-reviewed, exposure assessment study of responders or survivors present in the New York City disaster area, or at the Pentagon, or in Shanksville, Pennsylvania.
- The National Toxicology Program (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 the International Agency for Research on Cancer (IARC) has determined there is sufficient or limited evidence that the 9/11 agent causes a type of cancer.
- Example: Mesothelioma and ovarian cancer.

P&P Cancer – Method 4

- A type of cancer may be added to the List of WTC-Related Health Conditions if the STAC has provided a reasonable basis for adding a type of cancer.
- Example: Childhood cancers.

P&P Cancer - Administrator Actions

- If the assessment was performed in response to a petition:
 - The Administrator publishes a NPRM in the *Federal Register* if at least one of the four methods is fulfilled;
 - The Administrator publishes a determination not to propose a rule and the basis for such determination in the *Federal Register* if none of the four methods are fulfilled and evidence demonstrates that 9/11 exposures are not causally related to the type of cancer; or
 - The Administrator publishes a determination in the *Federal Register* that the review of the evidence indicates the information is insufficient to take either of these actions.
- If the assessment was initiated by the Administrator, the Administrator may take one of the actions described above.

P&P Cancer – Rulemaking to Add a Type of Cancer

- **NPRM**
 - Proposed addition is published in the *Federal Register*.
 - Public Comments are solicited.
 - Peer reviewers are identified with consideration of STAC’s input to conduct an independent peer review.
- **Final Rule**
 - WTC Health Program considers and responds to comments by peer reviewers and the public.
 - Administrator determines whether evidence continues to support addition of health condition to the List of WTC-Related Health Conditions.