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May 19, 2023

Dear Dr. Ward,

Thank you for your letter dated February 17, 2023, conveying recommendations of the World Trade Center (WTC) Health Program Scientific/Technical Advisory Committee (STAC) in response to the Administrator's charge to the STAC at their meeting on February 9, 2023. The STAC provided four recommendations regarding the WTC Health Program's proposed revisions to the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*. The Administrator reviewed the STAC's recommendations and provides the following responses to each of STAC's four recommendations:

STAC Recommendation 1:

In the Policy & Procedure for adding non-cancer conditions, with respect to the consideration of health conditions for which a high or limited likelihood of causal association is being assessed, the Science Team [should] consider studies that go beyond peer-reviewed and published epidemiologic studies of 9/11-exposed populations and US Government authoritative scientific publications, to the extent feasible. This is to include peer-reviewed clinical, mechanistic, toxicologic, biomedical, and mental health literature that are relevant to the 9/11 exposures.

RESPONSE: The Administrator partially agrees with the recommendation. To address the STAC's recommendation, the discretionary secondary evaluation procedures outlined in Section V.B.1., for use when the evidence supports a *High Likelihood of Causal Association*, were revised. The revised discretionary secondary evaluation procedure allows the Science Team to, at its discretion, supplement its review of U.S. government sources with additional highly relevant, peer-reviewed, published scientific information, if each of the following three factors are satisfied: Factor 1—The information available in the U.S. government sources referenced in the Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions is outdated or inconclusive; Factor 2—The supplemental scientific information was published more recently than the afore-referenced U.S. government sources; and Factor 3—The supplemental scientific information uses data that is expected to be included in future updates to the afore-referenced U.S. government sources. This expansion of the discretionary literature review was not extended to the *Limited Likelihood of Causal Association* category (Section V.C.). The Administrator declined to extend the expanded review beyond the *High Likelihood* category. While the consideration of additional highly relevant, peer-reviewed, published scientific information may be sufficient to move the categorization of a finding from *High Likelihood of Causal Association* to *Substantial Likelihood of Causal Association*, the Administrator believes that it is much less likely that consideration of such additional information would achieve the *Substantial Likelihood* standard if the initial evaluation found only a *Limited Likelihood of Causal Association*. Moreover, such consideration of additional sources for *Limited Likelihood* finding would result in considerable delay in publishing a petition decision in the Federal Register.

STAC Recommendation 2:

In IV.B.1.a. [the STAC recommends] revis[ing] the highlighted phrase in the first sentence from “Substantial likelihood of causal association means that “the scientific evidence demonstrates that a causal association exists” to “the association is strongly supported by peer-reviewed evidence in 9/11-exposed populations” [sic] and there is high confidence that the association cannot be explained by chance, bias, confounding, or any other alternative explanation.”

RESPONSE: The Administrator concurs with this recommendation and has revised the sentence for clarity. The sentence now reads – “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.”

STAC Recommendation 3:

The Committee recommends that the Program develop and add to the Policy and Procedures a table [flowchart] that clearly delineates the categories that will be used at various stages of the review process.

RESPONSE: The Administrator carefully considered the recommendation but declines to add a table or flowchart to the *Policy and Procedures* document. However, the Administrator will develop a flowchart as a job aid and communications tool separate from the *Policy and Procedures* document. The Administrator determined that a table or flowchart may not fully capture all requirements documented in the highly detailed *Policy and Procedures* text, which could lead to misinterpreting Program requirements. However, since a flowchart may be useful for training and communication purposes, the Program will develop a flowchart for illustrative purposes only; this flowchart will not supplant requirements documented in the approved *Policy and Procedure*.

STAC Recommendation 4 [Motion 4]:

The Committee endorses the use of five weight-of-evidence categories and recommends that these five mutually exclusive categories be maintained in all sections of the Policy and Procedures, as appropriate.

RESPONSE: The Administrator agrees with this recommendation and the *Policy and Procedure* was revised to clarify and maintain the five mutually exclusive categories throughout. These categories are: (1) substantial likelihood of causal association, (2) high likelihood of causal association, (3) limited likelihood of causal association, (4) no likelihood of causal association, and (5) inadequate evidence to determine the likelihood of causal association (see Section IV A.).

Thank you to the Committee and to you personally for your thoughtful recommendations and your commitment to the WTC Health Program.

Sincerely,

John Howard, M.D.
Director