



Elizabeth Ward, Ph.D.
Chair, Scientific/Technical Advisory Committee
World Trade Center Health Program
10 Sunset Terrace
Asheville, NC 28801

FEB 14 2017

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
395 E Street, S.W.
Suite 9200, Patriots Plaza 1
Washington, D.C. 20201
PHONE: (202) 245-0625
FAX: (202) 245-0628


Re: June 2016 Scientific/Technical Advisory Committee Recommendations

Dear Dr. Ward:

On behalf of the World Trade Center (WTC) Health Program, I want to express my appreciation to the members of the WTC Health Program's Scientific/Technical Advisory Committee (STAC) for twelve thoughtful recommendations on the two issues arising from provisions of the James Zadroga 9/11 Health and Compensation Reauthorization Act that I charged the Committee to consider. The first issue related to independent peer review¹ and identification of individuals conducting independent peer review.² The second issue related to a review and evaluation of the *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* and the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*.³

Please find enclosed with this letter my consideration of each of the twelve recommendations provided by the STAC along with a final revised *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* which takes into account the Committee's recommendations. The *Policy and Procedures for Adding Types of Cancer to the List of WTC-Related Health Conditions* remains the same as the version previously provided to the STAC.

Sincerely,



John Howard, M.D.
Administrator

¹ 42 U.S.C. § 300mm-22(a)(6)(F)—INDEPENDENT PEER REVIEWS. Prior to issuing a final rule to add a health condition to the list in paragraph (3), the WTC Program Administrator shall provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.

² 42 U.S.C. § 300mm-22(a)(6)(G)(ii)—IDENTIFICATION OF INDIVIDUALS CONDUCTING INDEPENDENT PEER REVIEWS.—Not later than 1 year after the date of enactment of the James Zadroga 9/11 Health and Compensation Reauthorization Act and not less than every 2 years thereafter, the WTC Program Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct the independent peer reviews under subparagraph (F).

³ 42 U.S.C. § 300mm-22(a)(6)(G)(i)—ADDITIONAL ADVISORY COMMITTEE RECOMMENDATIONS.—(i) PROGRAM POLICIES.—(I) EXISTING POLICIES.—Not later than 1 year after the date of enactment of the James Zadroga 9/11 Health and Compensation Reauthorization Act, the WTC Program Administrator shall request the Advisory Committee to review and evaluate the policies and procedures, in effect at the time of the review and evaluation, that are used to determine whether sufficient evidence exists to support adding a health condition to the list in paragraph (3). (II) SUBSEQUENT POLICIES.—Prior to establishing any substantive new policy or procedure used to make the determination described in subclause (I) or prior to making any substantive amendment to any policy or procedure described in such subclause, the WTC Program Administrator shall request the Advisory Committee to review and evaluate such substantive policy, procedure, or amendment.

Recommendations of the Scientific/Technical Advisory Committee Adopted on November 3, 2016

Recommendation 1. The peer review and public comment should be sequential so the public commenters have access to the peer review comments.

Recommendation 2. For any condition for which the Administrator determines there is modest or substantial support for adding it as a WTC covered condition the Administrator should secure external peer review of the determination.

Recommendation 3. Any written peer reviews should be made public whether or not the Administrator determines to propose rulemaking.

Recommendation 4. To the extent feasible, the Administrator and peer reviewers should consider scientific evidence beyond 9/11 studies including epidemiologic, toxicologic, and mechanistic studies when relevant.

Recommendation 5. The Administrator should develop and implement a process to solicit from the public recommendations of scientific experts to perform peer review.

Recommendation 6. A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a peer review is required. This could be done by an open solicitation by which persons could be nominated, a process that could be repeated periodically. Peer reviewers should be individuals with background and experience in relevant occupational and environment research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to WTC health effects and hazards, disasters, and other relevant exposures. In forming this pool, we advise that no exclusionary criteria be applied. Other persons could be chosen as peer reviewers based on their expertise if appropriate peer reviewers are not found in the pool.

Recommendation 7. NIOSH should develop a transparent, written [Conflict of Interest] COI policy for selection of peer reviewers, to ensure that bias can be minimized in the peer review process and the outcome of the review achieves maximum credibility. The identity of the peer reviewers and their areas of expertise should be made available to the public after the review is completed along with written review comments and the Program's responses with attribution of specific comments to specific reviewers.

Recommendation 8. The WTC administrator should be responsible for ensuring that the peer review process and reviewers are balanced and expected to give an unbiased scientific review. The selection of the peer reviewers should be made by NIOSH with consideration of the subject matter relevant to the petition. The peer review pool may also be useful to NIOSH to identify consultants to assist NIOSH with their initial scientific review of the evidence supporting the addition of a condition. NIOSH may consider, if needed, the retention of an outside contractor (with specific guidelines developed by NIOSH) to select the peer reviewers and coordinate the review.

Recommendation 9. NIOSH Science Team should seek input of expert consultants when needed in definition of a proposed WTC-related health condition including symptoms, clinical findings, imaging and laboratory findings.

Recommendation 10. The NIOSH Science team, when evaluating a petition, should include experts with a range of relevant expertise, including, at a minimum, clinical medicine, epidemiology, exposure assessment (preferably including but not limited to WTC exposures), and industrial hygiene. These are the core disciplines that are needed to address elements of the specified policy and procedures for adding conditions to the list of WTC-related health conditions, including biological gradient, plausibility, coherence and exposure qualifications. If possible, NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH Science team in the review of additional proposed conditions, including psychiatry, cardiology, rheumatology, and others if needed.

Recommendation 11. The program should consider whether the mechanism of a STAC teleconference or other mechanism could be used to solicit external comments when a petition is likely to advance to the WTCHP Science Team assessment phase. We see this as distinct from a formal request by the Administrator for the STAC to make a recommendation on a petition and as a mechanism to allow opportunity for public comment and benefit from the scientific expertise and knowledge base of the STAC.

Recommendation 12. The Policy and Procedures for Non-Cancer Conditions describes three potential phases of the NIOSH Science team review of scientific evidence: 1) initial review (p. 2); 2) a fuller assessment (p. 3-4); and 3) if “modest support” is found, a supplemental assessment of additional scientific literature (p. 5). This supplemental assessment is limited to epidemiologic studies of 9/11 agents with special emphasis on the relevance of exposure conditions. It would be important to give the NIOSH Science team some flexibility in the range of scientific studies they review by adding at the end of Section IV.B.1.d.i. (p. 5, line 9) the phrase “and additional knowledge based on peer-reviewed scientific studies that they deem highly relevant.”

Responses by Administrator to STAC Recommendations⁴

I. Identifying Independent Peer Reviewers

A. Public Solicitation

STAC Recommendation 5. The Administrator should develop and implement a process to solicit from the public recommendations of scientific experts to perform peer review.

Administrator Response. The Administrator agrees and will include a Federal Register notice to solicit public input for consideration in the process of identifying potential peer reviewers for the WTC Health Program.

Reference to Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions (P&P). See Section VI.B. Independent Peer Review.

STAC Recommendation 6.a. A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a peer review is required. This could be done by an open solicitation by which persons could be nominated, a process that could be repeated periodically.

Administrator Response. The Administrator agrees and will include a Federal Register notice to solicit public input for consideration in the process of identifying potential peer reviewers for the WTC Health Program.

Reference to P&P. See Section VI.B. Independent Peer Review.

B. Selection

1. Qualifications

STAC Recommendations 6.b. Peer reviewers should be individuals with background and experience in relevant occupational and environmental research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to WTC health effects and hazards, disasters, and other relevant exposures. In forming this pool, we advise that no exclusionary criteria be applied. Other

⁴The STAC Recommendations are categorized by topic area, and in some cases were subdivided to provide more precise responses. Where appropriate, references to specific sections of the *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* are also provided.

persons could be chosen as peer reviewers based on their expertise if appropriate peer reviewers are not found in the pool.

Administrator Response. The Administrator agrees and will include these types of expertise qualifications in the solicitation for potential peer reviewers for the WTC Health Program.

Reference to P&P. See Section VI.B.1. Selection of Peer Reviewers.

STAC Recommendations 8.a.2. The selection of the peer reviewers should be made by NIOSH with consideration of the subject matter relevant to the petition.

Administrator Response. The Administrator agrees and will consider qualifications such as those identified in Recommendation 6.b. and their relevance to the petition when selecting peer reviewers.

Reference to P&P. See Section VI.B.1. Selection of Peer Reviewers.

2. Conflict of Interest (COI) and Balance

STAC Recommendation 7.a. NIOSH should develop a transparent, written COI policy for selection of peer reviewers, to ensure that bias can be minimized in the peer review process and the outcome of the review achieves maximum credibility.

Administrator Response. The Administrator will apply Federal science agency conflict or bias prevention methods to ensure that peer review outcomes are credible.

Reference to P&P. See Section VI.B.1. Selection of Peer Reviewers.

STAC Recommendation 8.a.1. The WTC administrator should be responsible for ensuring that the peer review process and reviewers are balanced and expected to give an unbiased scientific review.

Administrator Response. The Administrator agrees and will ensure that the peer review process and peer reviewers are balanced to the extent possible.

Reference to P&P. See Section VI.B.1. Selection of Peer Reviewers.

3. Use of Contractor

STAC Recommendation 8.b.2. NIOSH may consider, if needed, the retention of an outside contractor (with specific guidelines developed by NIOSH) to select the peer reviewers and coordinate the review.

Administrator Response. The Administrator appreciates the potential value of using a contractor to select peer reviewers and/or conduct the peer review process, but is concerned about potential unnecessary delay or costs to the WTC Health Program. At this time, the Administrator has decided that the selection of peer reviewers and coordination of peer review will continue to be conducted by the WTC Health Program.

II. Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

A. Process of Evaluating a Health Condition for Addition to the List

1. Definition of a Health Condition

STAC Recommendation 9. NIOSH Science Team should seek input of expert consultants when needed in definition of a proposed WTC-related health condition including symptoms, clinical findings, imaging and laboratory findings.

Administrator Response. Subject matter experts within the WTC Health Program, NIOSH, and/or other Federal science agencies, may be consulted as needed about the definitions of health conditions.

Reference to P&P. See Section III.A. Petition Review.

2. STAC Input

STAC Recommendation 11. The program should consider whether the mechanism of a STAC teleconference or other mechanism could be used to solicit external comments when a petition is likely to advance to the WTCHP Science Team assessment phase. We see this as distinct from a formal request by the Administrator for the STAC to make a recommendation on a petition and as a mechanism to allow opportunity for public comment and benefit from the scientific expertise and knowledge base of the STAC.

Administrator Response. The Administrator considered the feasibility of using the STAC to provide comments when a petition is likely to advance to the assessment phase, and understands the potential value of obtaining outside perspectives early in the evaluation process. However, such use of

the STAC would trigger the Federal Advisory Committee Act (FACA) and associated regulations and is not feasible given the time constraints associated with use of the STAC pursuant to the Zadroga Act and FACA requirements.

3. Make-up of Science Team

STAC Recommendation 10.a. The NIOSH Science team, when evaluating a petition, should include experts with a range of relevant expertise, including, at a minimum, clinical medicine, epidemiology, exposure assessment (preferably including but not limited to WTC exposures), and industrial hygiene. These are the core disciplines that are needed to address elements of the specified policy and procedures for adding conditions to the list of WTC-related health conditions, including biological gradient, plausibility, coherence and exposure qualifications.

Administrator Response. The Administrator agrees that various core scientific disciplines may be needed to evaluate and assess the evidence provided in the scientific literature to determine if support exists to add a condition to the List of WTC-Related Health Conditions. The Administrator will ensure that relevant scientific expertise is available to provide a thorough analysis of the scientific evidence.

Reference to P&P. See Section III.A. Petition Review.

STAC Recommendation 10.b. If possible, NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH Science team in the review of additional proposed conditions, including psychiatry, cardiology, rheumatology, and others if needed.

Administrator Response. The Administrator agrees that discipline-specific experts may provide valuable insights and perspectives that could aid in the assessment of a petition. The Administrator will identify such experts from within the WTC Health Program, NIOSH, and/or other Federal science agencies as needed.

Reference to P&P. See Section III.A. Petition Review.

STAC Recommendation 8.b.1. The peer review pool may also be useful to NIOSH to identify consultants to assist NIOSH with their initial scientific review of the evidence supporting the addition of a condition.

Administrator Response. The Administrator considered the feasibility of using consultants to assist the WTC Health Program with the initial scientific review of evidence provided in the scientific literature to

determine if support exists to add a condition to the List of WTC-Related Health Conditions and understands the potential value of obtaining outside perspectives. However, the core disciplines needed are already available in the WTC Health Program, NIOSH, and/or other Federal science agencies. Identifying and contracting with consultants who have specific expertise for conditions before it is known what conditions will be petitioned is not feasible because of constraints associated with the petition review process. Moreover, the Administrator is concerned about potential unnecessary delay or costs to the WTC Health Program associated with contracting with such consultants.

Reference to P&P. See Section III.A. Petition Review.

4. Evaluation of Scientific Evidence

a. Timing of Independent Peer Review

STAC Recommendation 2. For any condition for which the Administrator determines there is modest or substantial support for adding it as a WTC covered condition, the Administrator should secure external peer review of the determination.

Administrator Response. The Administrator will conduct external peer reviews on proposed rulemaking as required by the James Zadroga Act 9/11 Health and Compensation Reauthorization Act.

Reference to P&P. See Section VI.B. Independent Peer Review.

b. Type of Scientific Evidence

STAC Recommendation 4. To the extent feasible, the Administrator and peer reviewers should consider scientific evidence beyond 9/11 studies including epidemiologic, toxicologic, and mechanistic studies when relevant.

Administrator Response. The Administrator agrees that in certain situations there may be value in including scientific evidence beyond epidemiologic studies of 9/11-exposed populations in the assessment to determine whether a health condition should be added to the List of WTC-Related Health Conditions.

Reference to P&P. See Section III.B.2. Science Evidence from Sources Using Non-9/11-Exposed Populations.

STAC Recommendation 12. The Administrator should add at the end of Section IV.B.1.d. (p. 5, line 9) of the Policy and Procedures for

Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, the phrase “and additional knowledge based on peer-reviewed scientific studies that they [*sic: science team*] deem highly relevant.”

Administrator Response. The Administrator agrees that in certain situations there may be value in including scientific evidence beyond epidemiologic studies of 9/11-exposed populations in the assessment to determine whether a health condition should be added to the List of WTC-Related Health Conditions.

Reference to P&P. See Section III.B.2.a.

5. Disclosure of Independent Peer Reviewer Comments

STAC Recommendation 3. Any written peer reviews should be made public whether or not the Administrator determines to propose rulemaking.

Administrator Response. All written comments made during the required peer reviews on proposed rulemaking will be made public.

Reference to P&P. See Section VI.B.2.b.

STAC Recommendation 1. The peer review and public comment should be sequential so the public commenters have access to the peer review comments.

Administrator Response. The Administrator agrees that peer review comments should be available to public commenters. To accomplish this, the peer review comments will be requested within 30 days after publication of the proposed rule in the Federal Register. Peer review comments will be published in the NIOSH Docket. To permit public commenters time to consider peer review comments, public comment will remain open no less than 45 days after publication of the proposed rule in the Federal Register.

Reference to P&P. See Section VI.C. Public Comments.

STAC Recommendation 7.b. The identity of the peer reviewers and their areas of expertise should be made available to the public after the review is completed along with written review comments and the Program’s responses with attribution of specific comments to specific reviewers.

Administrator Response. The Administrator agrees that the names of peer reviewers and their areas of expertise should be made available to the public after the peer review is completed. The Administrator also agrees that the written peer review comments should be made available to the public. However, while the Administrator understands the value of transparency in attributing specific comments to specific reviewers, the Administrator is concerned that such attribution of peer review comments may make it more difficult to obtain qualified peer reviewers. At this time, the Administrator has decided to post comments to the NIOSH Docket without attribution of specific comments to specific reviewers.

Reference to P&P. See Section VI.B.2.b.