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COMMENTARY

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The World Trade Center Health Program: Petitions for adding qualifying health conditions

Robert D. Daniels PhD[1] | Tania Carreón PhD, MS[1] | Jessica A. Bilics MPH[1] | Dori B. Reissman MD[1] | John Howard MD[2]

[1]World Trade Center Health Program (WTCHP), Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Washington, DC, USA

[2]National Institute for Occupational Safety and Health (NIOSH), Washington, DC, USA

Correspondence
Robert D. Daniels, 1090 Tusculum Ave, Mailstop MS R-12, Cincinnati, OH 45226, USA.
Email: rtd2@cdc.gov

Abstract

The federally mandated World Trade Center Health Program provides limited health benefits for qualifying health conditions related to the 9/11 terrorist attacks. A qualifying health condition is an illness or health condition for which the member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the 9/11 terrorist attacks is considered substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition. These qualifying health conditions are listed in federal regulations. The regulations also provide a process for amending this list. This commentary describes the methods developed for adding health conditions to the list of qualifying health conditions and discusses changes to the list that have occurred during the Program's 2011–2020 period.

1 | INTRODUCTION

In 2011, the James Zadroga 9/11 Health and Compensation Act of 2010 (Act) was enacted, establishing the World Trade Center (WTC) Health Program to medically monitor and treat the population affected by the terrorist attacks on September 11, 2001.[1] The Program enrolls persons who responded to the attacks in lower Manhattan, New York, at the Pentagon in Arlington Virginia, and near Shanksville, Pennsylvania (e.g., firefighters, police, rescue, and recovery workers), as well as nearby survivors who were impacted and adversely affected (e.g., residents, building occupants, and other affected workers) within the New York City disaster area. The WTC Health Program is housed under the U.S. Department of Health and Human Services and is administered by the Director, National Institute for Occupational Safety and Health (NIOSH). Authorization extends through 2090.

WTC Health Program member benefits include periodic medical monitoring, diagnosis, and treatment for qualifying health conditions. According to federal regulations, a qualifying health condition refers to a diagnosed illness or health condition (including mental health conditions) for which a member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the 9/11 terrorist attacks is *substantially likely to be a significant factor* in aggravating, contributing to, or causing the illness or health condition (42 CFR §88.1).[2] These conditions, also known as "WTC-related health conditions," comprise a heterogeneous group of aerodigestive disorders, mental health conditions, musculoskeletal disorders, cancers, and acute traumatic injuries that have been linked to the terrorist attacks. The list of health conditions is codified in 42 CFR §88.15 (i.e., the List of WTC-Related Health Conditions, henceforth known as the List) and is summarized in Table 1. The top 10 certified health conditions for 2020 are shown in Table 2.

The list was carefully crafted given available evidence on potential health risks obtained from health surveillance and research. Nonetheless, information is likely incomplete for some health conditions, and new conditions manifesting years after exposure might be discovered (e.g., late sequelae or a health condition not initially observed due to disease

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TABLE 1 WTC-related health conditions (42 CFR §88.15)

Group	Health condition
Aerodigestive disorders	Interstitial lung diseases
	Chronic respiratory disorder–fumes/vapors
	Asthma
	Reactive airways dysfunction syndrome
	WTC-exacerbated and new-onset chronic obstructive pulmonary disease
	Chronic cough syndrome
	Upper airway hyperreactivity
	Chronic rhinosinusitis
	Chronic nasopharyngitis
	Chronic laryngitis
	Gastroesophageal reflux disorder
	Sleep apnea exacerbated by or related to an aerodigestive disorder described above
Mental health conditions	Posttraumatic stress disorder
	Major depressive disorder
	Panic disorder
	Generalized anxiety disorder
	Anxiety disorder (not otherwise specified)
	Depression (not otherwise specified)
	Acute stress disorder
	Dysthymic disorder
	Adjustment disorder
	Substance abuse
Musculoskeletal disorders[a]	Low back pain
	Carpal tunnel syndrome
	Other musculoskeletal disorders
Cancers	Malignant neoplasms of the lip; tongue; salivary gland; floor of mouth; gum and other mouth; tonsil; oropharynx; hypopharynx; and other oral cavity and pharynx
	Malignant neoplasm of the nasopharynx
	Malignant neoplasms of the nose; nasal cavity; middle ear; and accessory sinuses
	Malignant neoplasm of the larynx
	Malignant neoplasm of the esophagus
	Malignant neoplasm of the stomach
	Malignant neoplasms of the colon and rectum
	Malignant neoplasms of the liver and intrahepatic bile duct
	Malignant neoplasms of the retroperitoneum and peritoneum; omentum; and mesentery
	Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs
	Mesothelioma
	Malignant neoplasms of the peripheral nerves and autonomic nervous system; and other connective and soft tissue
	Malignant neoplasms of the skin (melanoma and nonmelanoma), including scrotal cancer
	Malignant neoplasm of the female breast
	Malignant neoplasm of the ovary
	Malignant neoplasm of the prostate
	Malignant neoplasm of the urinary bladder
	Malignant neoplasm of the kidney
	Malignant neoplasms of the renal pelvis; ureter; and other urinary organs
	Malignant neoplasms of the eye and orbit
	Malignant neoplasm of the thyroid
	Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma)
	Childhood cancers: any type of cancer diagnosed in a person less than 20 years of age
	Rare cancers: any type of cancer that occurs in less than 15 cases per 100,000 persons per year in the United States
Acute traumatic injuries[b]	Eye injury
	Burn
	Head trauma
	Fracture
	Tendon tear
	Complex sprain
	Other similar acute traumatic injuries

Abbreviation: WTC, World Trade Center.

[a]A WTC-related musculoskeletal disorder is a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. For a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003.

[b]WTC-related acute traumatic injury is physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. For a WTC responder or screening-eligible or certified-eligible survivors who received any medical treatment for a WTC-related acute traumatic injury on or before September 11, 2003.

TABLE 2 Top 10 certified health conditions by World Trade Center (WTC) Health Program population[a]

Certified health condition[b]	Responder	Survivor
Chronic rhinosinusitis	26,559	5783
Gastroesophageal reflux disease	24,138	4839
Cancers	13,278	7931
Asthma	13,082	4710
Sleep apnea	13,999	1294
Posttraumatic stress disorder	8491	3438
Chronic respiratory disorder—fumes/vapors	7463	1177
WTC-exacerbated chronic obstructive pulmonary disease	3205	774
Anxiety disorder (not otherwise specified)	2501	903
Major depressive disorder	2436	798

[a]Data current as of December 31, 2020. Individual members might have certifications in more than one health condition category.

[b]As defined in 42 CFR §88.1, certification means WTC Health Program review of a health condition in a particular WTC Health Program member for the purpose of identification and approval of a WTC-related health condition, as defined in this section and included on the List of WTC-Related Health Conditions in 42 CFR §88.15, or a health condition medically associated with a WTC-related health condition.

latency). The Act includes provisions for researching new health conditions and the authority to amend the List when provided new evidence of a causal association between the health condition and 9/11 exposure. In this commentary, we describe the methods developed for adding health conditions to the List and discuss additions made using these methods through 2020.

2 | HOW PETITIONS ARE REVIEWED

The methods used for adding health conditions are described in detail in three NIOSH policies and procedures documents that are available online (https://www.cdc.gov/wtc/policies.html).[3–5] Briefly, a health condition may be added to the List only through rulemaking. Rulemaking can be initiated at the discretion of the Administrator of the WTC Health Program or in response to a valid petition by an interested party. This commentary only focuses on those health conditions considered via the petition process. Once initiated, there are some differences in the processes for adding cancer[5] and non-cancer[4] conditions to the List. Nonetheless, in every case, the process requires a thorough science evaluation to assess the evidence on whether the proposed health condition is WTC-related. Upon considering this evidence, and within 90 calendar days of receiving a valid petition, a decision is made to either seek recommendations from the Scientific/Technical Advisory Committee (STAC), publish a proposed rule in the Federal Register to add the health condition, publish a decision and basis for not publishing a proposed rule, or publish a decision that insufficient evidence is available to take any of the actions previously listed. The STAC members comprise scientists, clinicians, and responder/survivor representatives who, if requested, review scientific and medical evidence, and offer recommendations on WTC Health Program eligibility criteria, and adding WTC-related health conditions. The STAC has 90 days to respond following a review request, but this can be extended to 180 days. Upon receipt of STAC recommendations and Program deliberation, a decision on whether to publish in the federal register a proposed rule adding a health condition usually occurs within 90 days. After the publication of a proposed rule, interested parties are provided no less than 45 calendar days to submit written comments. In the event a health condition is proposed to be added to the list, an independent peer review of the scientific and technical evidence supporting a rule is conducted concurrently with the first 30 calendar days of public comment.

At the center of rulemaking is a critical appraisal of the causal association between the health condition and exposure to hazardous agents or other stressors stemming from the 9/11 attacks. This appraisal relies heavily on a rigorous systematic review of the published, peer-reviewed epidemiologic literature. In general, the review follows five key steps to (1) define questions and develop criteria for study selection; (2) develop a literature search protocol and conduct the search; (3) review, identify, and select the relevant information from available studies; (4) evaluate and integrate the evidence across studies; and (5) synthesize and interpret findings.[6,7] The evaluation considers viewpoints first introduced by Sir Austin Bradford Hill (1965), who proposed several defining aspects of causal associations, including the strength of association, consistency among studies, dose–response relationships, and the plausibility and coherence with known facts about the exposure and the biology of the outcome, among others.[8] Study quality is also assessed, including an evaluation of limitations (e.g., representativeness, random error, bias, and confounding) that could adversely affect both internal and external validity. Internal validity refers to the degree in which study findings are free from bias. External validity refers to the degree to which findings can be extrapolated to the population or groups of interests.[7] In summary, the appraisal assesses the nature and strength of the evidence on causation or relatedness and uses this assessment as a scientific basis for deciding whether to add a health condition to the List.

In practice, most available evidence stems from analytic observational studies of health effects among those persons at risk from the 9/11 attacks. Since 2011, these studies have been mostly funded by the WTC Health Program. Detailed information on WTC Health Program research is available online (https://wwwn.cdc.gov/ResearchGateway) and elsewhere.[9] Briefly, WTC Health Program-funded research examines a wide array of physical and mental health conditions to reduce diagnostic and treatment uncertainty among Program members, uncover new information on listed health conditions, and identify and characterize emerging health conditions that may be related to 9/11 exposures. NIOSH manages the WTC Health Program research agenda through grants and cooperative agreements using a National Institutes of Health framework for solicitation and award. Research solicitations (announcements) are periodically published that address program priorities, including research that targets emerging health conditions. Nearly $130M

has been awarded by the WTC Health Program for research. Nearly a thousand publications on health effects from the 9/11 attacks are now available for review and synthesis to inform decisions about adding new health conditions.

3 | OUTCOME OF COMPLETED PETITIONS

There have been 24 valid petitions submitted with decisions rendered between the period 2011–2020 (Table 3). More information is available online (https://www.cdc.gov/wtc/received.html). Among these, STAC recommendations were sought once (Petition 001). Rulemaking related to Petition 001 was finalized on October 12, 2012 and established 24 cancer types (over 50 cancers), broadly described by body organ or region, including rare cancers and childhood cancers, as WTC-related health conditions. A year later, a second petition (Petition 002) and subsequent rulemaking added prostate cancer to the list based primarily on new scientific evidence obtained since the first petition. In 2014, the WTC Health Program more clearly defined the category of rare cancers, which modified the list to include cancers of the brain, pancreas, cervix uterine, and testis, among others that have an incidence rate <15 cases per 100,000 persons per year (based on age-adjusted 2005–2009 average annual data).[10]

The remaining 22 petitions with decisions did not result in changes to the List. In all cases, it was determined that the available evidence was insufficient to request STAC recommendations, publish a proposed rule, or publish a determination not to publish a proposed rule. Of those petitions denied, most addressed nonmalignant health conditions, including six petitions on autoimmune diseases, such as lupus erythematosus, rheumatoid arthritis, and multiple sclerosis (Petitions 007–009, 011, 013, 014). Other groupings include five petitions involving circulatory system diseases (Petitions 004, 012, 018, 020, and 021), three on Parkinson's disease and parkinsonism (Petitions 016, 017, and 025), and two on neuropathies (Petitions 010 and 015). The remainder included four nonmalignant health conditions (i.e., Petition 003, kidney disease; Petition 005, acoustic neuroma; Petition 006, primary biliary cirrhosis; and Petition 019, irritable bowel syndrome), and two conditions grouped as cancer or precancerous outcomes (Petitions 022 and 023).

At the time of this review, there are three petitions (Petitions 024, 026, and 027) that are under consideration. These involve cardiovascular disease, anti-glomerular basement membrane disease, and psoriatic arthritis/psoriasis, respectively. WTC Health Program scientists are now evaluating the evidence supporting these petitions; therefore, decisions on each are anticipated soon.

4 | DISCUSSION

The first petitions prompted a series of rule changes adding cancers to the list shortly after enacting the WTC Health Program. Cancer ranks third in the number of certified health conditions among the affected population and first among survivors (Table 2); therefore, this rulemaking effort has had a profound programmatic effect.

There was insufficient evidence to support rulemaking for the remainder of petitioned outcomes. The threshold for inclusion requires that the available evidence supports a conclusion that the health condition is causally associated with 9/11 exposures. Clearly, this standard represents a significant challenge for researchers to conduct epidemiologic research that is sufficient, both in quality and quantity, to support a change to the list. Meeting this standard generally requires several high-quality large studies of persons in different subpopulations; additionally, for most rare, chronic, and late-emerging diseases it requires observation over long periods. These studies must also tackle many limitations common to most observational studies, such as incomplete information on outcome and exposure, the potential for unmeasured confounding, selection bias, and other important sources of study bias (e.g., model misspecification, healthy worker effects, random error). These challenges, coupled with a developing research agenda, help explain the current pattern of decisions on petitions. Interestingly, there are multiple petitions for certain outcomes (e.g., cardiovascular diseases, autoimmune diseases) among those that were denied and those currently in review. This acknowledges that decisions on health conditions can always be revisited, and future research might eventually yield sufficient evidence to support changes to the list.

High-quality epidemiologic research directly examining the at-risk population is the preferred source of evidence supporting decisions on the list. As shown in this special issue, research examining the at-risk population exposed on 9/11 is ongoing. Some of the studies included in this issue add to the literature on new outcomes and outcomes previously assessed as having insufficient information for rulemaking. It is also noteworthy that the WTC Health Program has awarded nearly $130M for grants and cooperative agreements for health effects research between 2011 and 2020, and will continue these awards well into the foreseeable future.[9] Researchers are encouraged to participate in future funding calls by the WTC Health Program, including proposals for studies that might better inform on causal relationships between 9/11 exposures and outcomes that are not currently listed as a WTC-related health condition.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

DISCLOSURE BY AJIM EDITOR OF RECORD

Steven Markowitz declares that he has no conflict of interest in the review and publication decision regarding this article.

AUTHOR CONTRIBUTIONS

Robert D. Daniels participated in all aspects of the work, including: conception, interpretation, writing, and critical revisions for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

TABLE 3 Petitions with decisions rendered (2011–2020)

Petition no.	Health condition(s)	Received	Exercise option for STAC response?	Decision	Date of proposed rule or decision	Date of the final rule	Federal Register Notice(s)
001	Malignant neoplasms of the lip, tongue, salivary gland, floor of the mouth, gum and other mouth, tonsil, oropharynx, hypopharynx, and other oral cavity and pharynx; nasopharynx, nose, nasal cavity, middle ear, and accessory sinuses; larynx; esophagus; stomach; colon and rectum; liver and intrahepatic bile duct; retroperitoneum and peritoneum, omentum, and mesentery; trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory; Mesothelioma; soft tissues (sarcomas); skin (melanoma and non-melanoma), including scrotal cancer; breast; ovary; urinary bladder; kidney; renal pelvis, ureter and other urinary organs; eye and orbit; thyroid; blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma); childhood cancers, and rare cancers[a]	September 7, 2011	Yes	Approved	June 13, 2012	September 12, 2012	77 (177): 56,138–56,168 September 12, 2012; 77 (198): 62,167–62,176 October 12, 2012
002	Prostate cancer	May 2, 2013	No	Approved	July 2, 2013	September 19, 2013	78 (182): 57,505–57,523 September 19, 2013
003	Chronic kidney damage/disease	January 22, 2014	No	Denied (finding of insufficient evidence)	March 31, 2014	NA	79 (61): 17,972–17,973 March 31, 2014
004	Cardiovascular disease	March 7, 2014	No	Denied (finding of insufficient evidence)	May 6, 2014	NA	79 (87): 25,766–25,767 May 6, 2014
005	Acoustic neuroma and related conditions, such as l as the related conditions acoustic neurinoma, acoustic neurilemoma, or vestibular schwannoma	September 2, 2014	No	Denied (finding of insufficient evidence)	November 4, 2014	NA	79 (213): 65,369–65,371 November 4, 2014
006	Primary biliary cirrhosis	October 20, 2014	No	Denied (finding of insufficient evidence)	December 18, 2014	NA	79 (243): 75,528–75,529 December 18, 2014
007	Certain autoimmune diseases, including rheumatoid arthritis and connective tissues diseases	April 6, 2015	No	Denied (finding of insufficient evidence)	June 8, 2015	NA	80 (109): 32,333–32,334 June 8, 2015

(Continues)

TABLE 3 (Continued)

Petition no.	Health condition(s)	Received	Exercise option for STAC response?	Decision	Date of proposed rule or decision	Date of the final rule	Federal Register Notice(s)
008	Autoimmune disease—encephalitis of the brain	May 11, 2015	No	Denied (finding of insufficient evidence)	July 10, 2015	NA	80 (132): 39,720–39,722 July 10, 2015
009	Autoimmune disease multiple sclerosis	September 14, 2015	No	Denied (finding of insufficient evidence)	October 28, 2015	NA	80 (208): 65,980–65,982 October 28, 2015
010	Peripheral neuropathy	January 5, 2016	No	Denied (finding of insufficient evidence)	April 4, 2016	NA	81 (64): 19,108–19,110 April 4, 2016
011	Autoimmune disease, lupus, and rheumatoid arthritis	January 25, 2016	No	Denied (finding of insufficient evidence)	April 25, 2016	NA	81 (79): 24,047–24,050 April 25, 2016
012	Atherosclerosis	April 11, 2016	No	Denied (finding of insufficient evidence)	December 14, 2016	NA	81 (240): 90,295–90,297 December 14, 2016
013	Relapsing-remitting multiple sclerosis (autoimmune)	April 4, 2016	No	Denied (finding of insufficient evidence)	9/1/2016	NA	81 (170): 60,329–60,332 September 1, 2016
014	Autoimmune diseases, including rheumatoid arthritis	September 29, 2016	No	Denied (finding of insufficient evidence)	February 21, 2017	NA	82 (33): 11,164–11,166 February 21, 2017
015	Neuropathy	November 25, 2016	No	Denied (finding of insufficient evidence)	May 11, 2017	NA	82 (90): 22,004–22,006 May 11, 2017
016 and 017	Parkinson's disease and parkinsonism, including manganese-induced parkinsonism	February 22, 2017 and May 10, 2017	No	Denied (finding of insufficient evidence)	July 13, 2017	NA	82 (133): 32,312–32,315 July 13, 2017
018	Hypertension	January 5, 2018	No	Denied (finding of insufficient evidence)	April 24, 2018	NA	83 (79): 17,783–17,787 April 24, 2018
019	Irritable bowel syndrome	May 17, 2018	No	Denied (finding of insufficient evidence)	August 17, 2018	NA	83 (160): 41,039–41,041 August 17, 2018

TABLE 3 (Continued)

Petition no.	Health condition(s)	Received	Exercise option for STAC response?	Decision	Date of proposed rule or decision	Date of the final rule	Federal Register Notice(s)
020	Ischemic and nonaneurysmal hemorrhagic stroke	August 26, 2018	No	Denied (finding of insufficient evidence)	February 25, 2019	NA	84 (37): 5972–5977 February 25, 2019
021	Deep vein thrombosis and/or pulmonary embolism	November 28, 2018	No	Denied (finding of insufficient evidence)	March 26, 2019	NA	84 (58): 11,267–11,268 March 26, 2019
022	Monoclonal gammopathy of undetermined significance	March 11, 2019	No	Denied (finding of insufficient evidence)	August 6, 2019	NA	84 (151): 38,177–38,180 August 6, 2019
023	Uterine cancer, including endometrial cancer	April 23, 2019	No	Denied (finding of insufficient evidence)	September 24, 2019	NA	84 (185): 49,954–49,959 September 24, 2019
025	Parkinson's disease and parkinsonism, including heavy metal-induced parkinsonism	October 15, 2019	No	Denied (finding of insufficient evidence)	February 20, 2020	NA	85 (33): 9441–9444 February 20, 2020

Abbreviations: NA, not applicable; STAC, Scientific/Technical Advisory Committee.

[a]A cancer that occurs in less than 15 cases per 100,000 persons per year in the United States based on 2005–2009 average annual data age-adjusted to the 2000 US population (42 CFR §88.15(*d*)(24)).

of any part of the work are appropriately investigated and resolved. Tania Carreón and Jessica A. Bilics participated in interpretation, writing, and critical revisions for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Dori B. Reissman and John Howard participated in critical revisions for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DATA ACCESSIBILITY

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

ETHICS APPROVAL AND INFORMED CONSENT

This study was conducted by US government employees of the National Institute for Occupational Safety and Health, which is part of the Centers for Disease Control and Prevention (CDC) under the United States Department of Health and Human Services. No contact was made with study participants. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy. This activity does not constitute human subjects research as defined by 45 CFR §102(l). Ethics review and approval and informed consent were not required.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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