

beneficiaries regarding grandfathered status? If not, how could the disclosure be improved?

### *B. General Information About Grandfathered Group Health Plans and Group Health Insurance Coverage*

1. Other than the Kaiser Family Foundation's "Employer Health Benefits Annual Survey," and the MEPS-IC survey, what data resources are available to help the Departments better understand how many group health plans and group health insurance policies are considered grandfathered and how many participants and beneficiaries are enrolled in such plans and coverage?

2. What are the characteristics (for example, plan size, geographic areas, or industries) of grandfathered group health plans and the plan sponsors and group health insurance issuers that have chosen to retain the grandfathered status of their plans or coverage? Do grandfathered group health plans or the plan sponsors and group health insurance issuers that have chosen to retain the grandfathered status of their plans or coverage share common characteristics?

3. Do group health plan sponsors and group health insurance issuers that have chosen to retain grandfathered status for certain plans, benefit packages, or policies also offer other plans, benefit packages, or policies that are not grandfathered? If so, why?

4. What are the typical differences in benefits, cost-sharing, and premiums (including employer contributions, employee organization contributions, and employee contributions) associated with grandfathered group health plans and grandfathered group health insurance coverage compared to non-grandfathered group health plans?

5. How many group health plan sponsors and group health insurance issuers are considering making changes to their plans or coverage over the next few years that are likely to cause loss of grandfathered status under the November 2015 final rules? How many individuals would be affected?

6. What impact do grandfathered group health plans and grandfathered group health insurance coverage have on the individual and small group market risk pools?

### **III. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, section II of this document does contain a general solicitation of

comments in the form of a request for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

Signed at Washington, DC, this 13th day of February 2019.

**Victoria Judson,**

*Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), Internal Revenue Service, Department of the Treasury.*

Signed at Washington, DC, this 19th day of February, 2019.

**Carol Weiser,**

*Acting Benefits Tax Counsel, Department of the Treasury.*

Signed at Washington, DC, this 13th day of February 2019.

**Preston Rutledge,**

*Assistant Secretary, Employee Benefits Security Administration, Department of Labor.*

Dated: February 13, 2019.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: February 13, 2019.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

#### **42 CFR Part 88**

**[NIOSH Docket 094]**

### **World Trade Center Health Program; Petition 020—Stroke; Finding of Insufficient Evidence**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

**SUMMARY:** On August 26, 2018, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 020) to add "two forms of stroke, both ischemic and non-aneurysmal hemorrhagic," to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add stroke to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of February 25, 2019.

**ADDRESSES:** Visit the WTC Health Program website at <https://www.cdc.gov/wtc/received.html> to review Petition 020.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

#### **SUPPLEMENTARY INFORMATION:**

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#### **A. WTC Health Program Statutory Authority**

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113), added Title XXXIII to the Public Health Service (PHS) Act,<sup>1</sup> establishing the WTC Health Program within the Department of Health and

<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the James Zadroga 9/11 Health and Compensation Act of 2010 found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.15. Within 90 days after receipt of a valid petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) of the PHS Act and § 88.16(a)(2) of the Program regulations: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the **Federal Register** to add such health condition; (3) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (1) through (3) above.

## B. Procedures for Evaluating a Petition

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the review of submissions and petitions,<sup>2</sup> as well as the analysis of evidence supporting the potential addition of a non-cancer health condition to the List.<sup>3</sup>

A valid petition must include sufficient medical basis for the association between the September 11, 2001, terrorist attacks and the health condition to be added; in accordance with WTC Health Program policy,

<sup>2</sup> See WTC Health Program [2014], *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions*, May 14, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHEPPPPetitionHandlingProcedures14May2014.pdf>.

<sup>3</sup> See WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017, [https://www.cdc.gov/wtc/pdfs/policies/WTCHEPP\\_PP\\_Adding\\_NonCancers\\_14\\_February\\_2017-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHEPP_PP_Adding_NonCancers_14_February_2017-508.pdf).

reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors may demonstrate the required medical basis.<sup>4</sup> Studies linking 9/11 agents<sup>5</sup> to the petitioned health condition may also provide sufficient medical basis for a valid petition.

After the Program has determined that a petition is valid, the Administrator must direct the Program to conduct 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 health condition to the List.<sup>6</sup> The literature review is a keyword search of relevant scientific databases; peer-reviewed, published, epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations are then identified from the initial search results. The Program evaluates the scientific quality of each peer-reviewed, published, epidemiologic study of the health condition identified in the literature search; the Program then compiles the scientific results of each study to assess whether a causal relationship between 9/11 exposures and the health condition is supported, and evaluates whether the results of the studies are representative of the 9/11-exposed population of responders and survivors. A health condition may be added to the List if peer-reviewed, published, epidemiologic studies provide support that the health condition is substantially likely<sup>7</sup> to be causally associated with 9/11 exposures. If the evaluation of evidence provided in peer-reviewed, published, epidemiologic studies of the health condition in 9/11 populations demonstrates a high, but not substantial,

<sup>4</sup> See *supra* note 2.

<sup>5</sup> 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, 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 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. See WTC Health Program [2018], *Development of the Inventory of 9/11 Agents*, July 17, 2018, [https://www.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://www.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf).

<sup>6</sup> See *supra* note 3.

<sup>7</sup> The “substantially likely” standard is met when the scientific evidence, taken as a whole, demonstrates a strong relationship between the 9/11 exposures and the health condition.

likelihood of a causal association between the 9/11 exposures and the health condition, then the Administrator may consider additional highly relevant scientific evidence regarding exposures to 9/11 agents from sources using non-9/11-exposed populations. If that additional assessment establishes that the health condition is substantially likely to be causally associated with 9/11 exposures among 9/11-exposed populations, the health condition may be added to the List.

## C. Petition 020

On August 26, 2018, the Administrator received a petition (Petition 020) from a WTC survivor who resided near Ground Zero, requesting the addition of “two forms of stroke, both ischemic and non-aneurysmal hemorrhagic,” to the List.<sup>8</sup> The petition included eight scientific articles, three of which provided sufficient medical basis for the petition to be evaluated because they are scientific sources that demonstrate a potential link between 9/11 exposure and stroke:<sup>9</sup> a 2006 study by Brackbill *et al.*,<sup>10</sup> a 2013 study by Jordan *et al.*,<sup>11</sup> and a 2018 study by Yu *et al.*<sup>12</sup>

<sup>8</sup> See Petition 020, *WTC Health Program: Petitions Received*, <http://www.cdc.gov/wtc/received.html>.

<sup>9</sup> Five of the studies referenced in Petition 020 were insufficient to provide medical basis because they were not conducted in 9/11 populations nor did they demonstrate an association between any 9/11 agents and stroke; these five studies include the following: Truelsen T, Prescott E, Lange P, Schnohr P, Boysen G [2001], *Lung Function and Risk of Fatal and Non-Fatal Stroke, The Copenhagen City Heart Study*, *Int J Epidemiol* 30(1):145–151; Soderholm M, Zia E, Hedblad B, Engstrom G [2012], *Lung Function as a Risk Factor for Subarachnoid Hemorrhage*, *Stroke* 43(10):2598–2603; Chen MH, Pan TL, Li CT, Lin WC, Chen YS, Lee YC, Tsai SJ, Hsu JW, Huang KL, Tsai CF, Chang WH, Chen TJ, Su TP, Bai YM [2015], *Risk of Stroke Among Patients with Post-Traumatic Stress Disorder: Nationwide Longitudinal Study*, *Br J Psychiatry* 206(4):302–307; Austin V, Crack PJ, Bozinovski S, Miller AA, Vlahos R [2016], *COPD and Stroke: Are Systemic Inflammation and Oxidative Stress the Missing Links?* *Clin Sci (Lond)*, 130(13):1039–1050; and Lekoubou A, Ovbiagele B [2017], *Prevalence and Influence of Chronic Obstructive Pulmonary Disease on Stroke Outcomes in Hospitalized Stroke Patients*, *eNeurologicalSci* 6:21–24.

<sup>10</sup> Brackbill RM, Thorpe LE, DiGrande L, Perrin M, Sapp JH, 2nd, Wu D, Campolucci S, Walker DJ, Cone J, Pulliam P, Thalji L, Farfel MR, Thomas P [2006], *Surveillance for World Trade Center Disaster Health Effects among Survivors of Collapsed and Damaged Buildings*, *MMWR Surveill Summ* 55: 1–18.

<sup>11</sup> Jordan HT, Stellman SD, Morabia A, Miller-Archie SA, Alper H, Laskaris Z, Brackbill RM, Cone JE [2013], *Cardiovascular Disease Hospitalizations in Relation to Exposure to the September 11, 2001 World Trade Center Disaster and Posttraumatic Stress Disorder*, *J Am Heart Assoc* 2(5):e000431.

<sup>12</sup> Yu S, Alper HE, Nguyen AM, Brackbill RM [2018], *Risk of Stroke Among Survivors of the September 11, 2001 World Trade Center Disaster*, *J Occup Environ Med* 60(8):e371–e376.

#### D. Review of Scientific and Medical Information and Administrator Determination

The Program policy on the addition of non-cancer health conditions to the List directs the Program to conduct a literature review on the health condition(s) petitioned.<sup>13</sup> Petition 020 requested the addition of ischemic and non-aneurysmal hemorrhagic stroke. Stroke is defined as an acute brain injury resulting from either too little blood to supply an adequate amount of oxygen to the affected part of the brain or too much blood within the cranial cavity.<sup>14</sup> An ischemic stroke occurs when there is an inadequate supply of oxygen-rich blood to the brain, such as may occur due to thrombosis, embolism, or systemic hypoperfusion. A hemorrhagic stroke occurs when blood builds up and leaks in the brain, such as may occur due to an intracerebral or subarachnoid hemorrhage, or an aneurysm (a balloon-like bulge in an artery that can stretch and burst). A transient ischemic attack, also called a TIA or “mini-stroke,” is similar to a stroke; it occurs if blood flow to a portion of the brain is blocked only for a short time, producing a transient episode of neurologic dysfunction without acute infarction or death of brain tissue.

In response to Petition 020, the Program conducted a review of the scientific literature on stroke, including both ischemic and non-aneurysmal hemorrhagic, as well as transient ischemic attack.<sup>15</sup> In total, this initial literature review identified 12 studies appearing to potentially meet the Program’s criteria for further evaluation. Three of the studies identified<sup>16</sup> were peer-reviewed, published, epidemiologic studies of stroke in the 9/11-exposed population eligible, in accordance with the Program’s policy,<sup>17</sup> for further evaluation. The nine remaining studies identified in the

literature review did not meet the Program’s criteria for further evaluation.<sup>18</sup>

#### *Evaluation of Three Published, Peer-Reviewed Epidemiologic Studies of Stroke in the 9/11 Population*

As discussed above, the Program determined that of the 12 studies identified in the literature review that appeared to potentially meet the criteria for evaluation, only 3 could be fully evaluated because they are peer-reviewed, published, epidemiologic studies of stroke in the 9/11 population: Brackbill *et al.* [2006] and Yu *et al.* [2018], which were referenced in Petition 020, and Remch *et al.* [2018].<sup>19</sup>

#### Study Summaries

1. Brackbill *et al.* conducted a cross-sectional study<sup>20</sup> designed to assess the physical and mental health conditions and symptoms reported by survivors of the WTC towers and nearby buildings between September 5, 2003 and November 20, 2004, and to examine the relationship between their reported 9/11 exposures and health and mental health outcomes. The study used WTC Health Registry data from baseline interviews conducted with 8,418 adult survivors who had been occupants of collapsed or damaged buildings. Exposure data were evaluated and exposures were sorted by location and time proximity to exposure events according to whether the participant was present in the WTC dust cloud; occupied a collapsed versus damaged building; or evacuated before or after the collapse of the first tower. Health histories were also collected from Registry interview data, including self-reports of physician-diagnosed stroke subsequent to September 11, 2001. The rate of stroke among adult

survivors of collapsed and damaged buildings was adjusted for sex and mode of recruitment (physical and mental health symptoms tended to be higher among Registry members who self-identified than among those identified from a list of building survivors with security badges). Brackbill *et al.* found a statistically significant association for stroke among survivors exposed to the WTC dust cloud compared to those not exposed to the WTC dust cloud [adjusted odds ratio (aOR) = 5.6, 95% CI 1.3–24.4]; however, the prevalence of stroke among survivors who evacuated before versus after the collapse of the first WTC tower and among those who evacuated from collapsed buildings versus damaged buildings was not significantly different [aOR = 0.6, 95% CI 0.1–4.5, and aOR = 1.5, 95% CI 0.6–4.0, respectively]. According to the authors, this indicated a “potential relation” between WTC dust exposure and stroke; this finding was considered preliminary, however, meriting continued monitoring, because the small sample size and cross-sectional design limits the interpretation and generalizability of findings. The cross-sectional design of this study is a major limitation because it fails to establish a temporal relationship between 9/11 exposure and reported stroke. Finally, the study did not differentiate between hemorrhagic and ischemic stroke, which have different risk factors.

2. Yu *et al.* conducted a cohort study to investigate the risk of stroke among 42,527 WTC responders and survivors who experienced PTSD and who had intense exposure to WTC dust. Self-reports of WTC dust exposure and stroke diagnosis subsequent to September 11, 2001 were obtained from WTC Health Registry surveys collected from 2003 to 2016. Intense exposure was defined as having been in the WTC dust cloud and reporting at least one of the following: Inability to see more than a few feet; difficulty walking; difficulty finding shelter; being covered with dust; or loss of hearing. Minimal or no-exposure was defined as being in the WTC dust but without experiencing intense exposure, or no WTC dust exposure at all. After adjusting for sociodemographic characteristics, risk factors for stroke (smoking and history of hypertension and/or diabetes), and PTSD, the study found that WTC dust cloud exposure was independently associated with an increased risk for stroke among WTC responders and survivors [aHR = 1.2, 95% CI 1.0–1.4]. The study has numerous strengths, including the longitudinal design,

<sup>18</sup> Four of the nine studies, including Jordan *et al.* which was submitted as medical basis for the petition, contained limited findings regarding an association between 9/11 exposure and stroke that the Program determined warranted additional review. Those four studies are summarized in the docket, as “background information,” to illustrate their inability to provide dispositive information about an association between 9/11 exposure and stroke.

<sup>19</sup> Remch M, Laskaris Z, Flory J, Mora-McLaughlin C, Morabia A [2018], *Post-Traumatic Stress Disorder and Cardiovascular Diseases: A Cohort Study of Men and Women Involved in Cleaning the Debris of the World Trade Center Complex*, *Circ Cardiovasc Qual Outcomes* 11(7):e004572.

<sup>20</sup> A cross-sectional study is a type of observational study that evaluates a sample of persons from a specific population and measures the sample’s exposures and health outcomes simultaneously. Because the presence of disease and the determination of exposure are conducted at the same specific point in time, the temporal sequence of cause and effect (*i.e.* did the disease appear before or after exposure) generally cannot be determined.

<sup>13</sup> *Supra* note 3.

<sup>14</sup> See generally National Heart, Lung, and Blood Institute (NHBLI), *Health Topics: Stroke*, <https://www.nhlbi.nih.gov/health-topics/stroke> (last accessed on Dec. 12, 2018).

<sup>15</sup> Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health & Safety, PsycINFO, PubMed, Scopus, and Toxicology Abstracts/TOXLINE. Studies were also identified using the WTC Health Program Research Compendium. Keywords used to conduct the search include: Stroke, cerebrovascular accident, transient ischemic attack, intracerebral hemorrhage, cerebral hemorrhage, subarachnoid hemorrhage, brain ischemia, brain infarction, cerebral infarction. The literature search was conducted in English-language journals on September 26, 2018.

<sup>16</sup> Two of these three studies, Brackbill *et al.* and Yu *et al.*, were also included as medical basis with the petition.

<sup>17</sup> See *supra* note 3.

adequate control of confounding and a large number of participants with small loss to follow up. Limitations included that stroke was self-reported and the authors did not distinguish between hemorrhagic and ischemic stroke.

3. Remch *et al.* conducted a cohort study to determine whether PTSD is a risk factor for myocardial infarction and stroke. The study used data collected between January 2012 and June 2013 from World Trade Center (WTC)-Heart, a WTC Health Program Research Program-funded cohort study of 6,481 Program members who were non-firefighter workers and volunteers engaged in rescue, recovery, restoration of services, cleanup, or other support work on or after September 11, 2001. Exposure was reported in a self-administered questionnaire, which asked participants about when they started to work at Ground Zero, whether they were in the dust cloud, whether they worked on or near the pile or the pit (the remains of the WTC towers), and whether a respiratory protective device was worn. Stroke was self-reported and tentatively confirmed by additional personal interviews conducted by phone. Approximately 60 percent of self-reported stroke cases were confirmed by medical records documenting typical stroke symptoms and either supportive medical imaging or sonographic signs. Cases of stroke were also identified in the New York State Department of Health's, Statewide Planning and Research Cooperative System (SPARCS) database by searching for hospitalized cohort members with a discharge diagnosis of stroke. However, the study did not report whether the participants who experienced recurrent strokes (of the 53 reported strokes, 15 were recurrent) had their first stroke before September 11, 2001, and whether the first stroke may have been the cause of subsequent recurrent strokes. Based on their analysis, Remch *et al.* concluded that none of the 9/11 exposure variables (*i.e.*, timing and intensity of WTC dust and dust cloud exposure, use of respiratory protection) were independently associated with subsequent stroke. It should be noted, however, that detailed data to support these findings were not presented in the article apart from the finding that the risk of stroke was not significantly reduced by the use of a respirator [aHR = 0.8, 95% CI 0.4–1.8]. The study also concluded that PTSD was an independent determinant of stroke in both men and women, before and after controlling for use of a respirator during debris cleanup, cardiovascular risk factors, and depression. Remch *et al.* has

multiple strengths, including the cohort-study design, active follow-up, validation of stroke using SPARCS, and adjustment for cardiovascular risk factors, including smoking and depression. Limitations include PTSD being self-reported, as well as the lack of distinction between hemorrhagic and ischemic stroke and the failure to clarify whether pre-September 11, 2001 and recurrent strokes were appropriately analyzed. Moreover, the study focused on assessing whether those with PTSD are at increased risk of myocardial infarction or stroke; determining the effect of WTC dust exposure on those outcomes was of secondary importance. Finally, the authors did not provide detailed findings using exposure data, apart from reporting on respirator use and non-use; even where respirator use was reported, however, information on frequency and time of use was not provided.

#### Evaluation of Studies Using Select Bradford Hill Criteria

Together, the three studies by Brackbill *et al.*, Yu *et al.*, and Remch *et al.* were assessed to determine whether a causal relationship between 9/11 exposures and stroke is supported.<sup>21</sup> As described in the policy on the addition of non-cancer health conditions to the List,<sup>22</sup> the WTC Health Program uses the following Bradford Hill criteria to evaluate studies of 9/11-exposed populations: strength of association, precision of the risk estimate, consistency of association, biological gradient, and plausibility and coherence.

**Strength of association:**<sup>23</sup> Of the three studies, Brackbill *et al.* reported a strong association between exposure to WTC dust and the risk of stroke in WTC survivors; Yu *et al.* reported a moderate association between WTC dust exposure and stroke in WTC responders and survivors; and Remch *et al.* reported no association between WTC dust exposure and risk of stroke in WTC responders.

**Precision of risk estimate:**<sup>24</sup> Although both Brackbill *et al.* and Yu *et al.* were

<sup>21</sup> Although the Brackbill *et al.* and Yu *et al.* studies were both conducted in the WTC Health Registry population, the Yu *et al.* study is not a follow-up to the Brackbill *et al.* study and each was evaluated independently in this action.

<sup>22</sup> WTC Health Program [2017], *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, February 14, 2017 at 3–4, [https://www.cdc.gov/wtc/pdfs/policies/WTCHP\\_PP\\_Adding\\_NonCancers\\_14\\_February\\_2017-508.pdf](https://www.cdc.gov/wtc/pdfs/policies/WTCHP_PP_Adding_NonCancers_14_February_2017-508.pdf).

<sup>23</sup> It is generally thought that strong associations are more likely to be causal than weak associations; however, a weak association does not rule out a causal relationship.

<sup>24</sup> The uncertainty inherent in estimating the strength of association between exposure and health

conducted using WTC Health Registry data, the more recent study by Yu is more precise because the sample size is larger; in contrast, Brackbill reported very wide confidence intervals. Remch *et al.* studied a cohort of responders in the WTC Health Program; despite reporting a relatively large number of stroke cases, the precision of the study findings could not be evaluated because detailed findings (*i.e.*, number of stroke cases associated with different levels of 9/11 exposure, risk estimates, and confidence intervals) regarding possible association between 9/11 exposure and stroke were not reported.

**Consistency of association:**<sup>25</sup> The findings were not consistent across the three studies: The WTC Health Registry studies showed increased risk of stroke with exposure to the WTC dust cloud; Remch *et al.* did not find an association between intermediate or high exposure and the risk of stroke.

**Biological gradient:**<sup>26</sup> None of the three studies reported exposure-response. Although Brackbill *et al.* and Yu *et al.* each found a positive association between 9/11 exposure and stroke, they both conducted limited, binary evaluations of exposure variables: Brackbill *et al.* sorted exposures according to location and temporal proximity to the WTC dust and dust cloud, and Yu *et al.* sorted exposures by determining if study subjects were intensely exposed to the dust and dust cloud. Neither study fully analyzed stroke in the context of a full exposure-response assessment. Remch *et al.*, which did not find a positive association between 9/11 exposure and stroke, also did not report exposure-response.

**Plausibility and coherence:**<sup>27</sup> Brackbill *et al.* and Yu *et al.* each mentioned that other studies have found an association between stroke and air pollution, which primarily comprises

effect (effect size) from observational data is expressed as a confidence interval, illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty. See *supra* note 22.

<sup>25</sup> Consistent findings are demonstrated when they have been repeatedly reported by multiple studies.

<sup>26</sup> Studies establish an exposure-response relationship by demonstrating that increases in exposure (*i.e.*, exposures of greater intensity and/or longer duration) are associated with a greater incidence of disease. A thorough evaluation of exposure-response requires analysis of multiple levels of exposure such that the investigator can demonstrate that the risk increases with increasing levels of exposure.

<sup>27</sup> Study findings demonstrate a basis in scientific theory that supports the relationship between the exposure and the health effect, and do not conflict with known facts about the biology of the health condition.

small particulate matter (PM<sub>2.5</sub>). Both Brackbill *et al.* and Yu *et al.* also noted that the WTC dust and dust cloud contained a unique mixture of construction debris and combustion products,<sup>28</sup> including small particulate matter (PM<sub>2.5</sub>) as well as large particulate matter (>PM<sub>10</sub>) not typically found in air pollution.<sup>29</sup> Although the comparison of air pollution to WTC dust is imperfect because of the high concentration of >PM<sub>10</sub> in WTC dust and dust cloud samples, it is nevertheless instructive due to the documented health effects of PM<sub>2.5</sub> exposure, including stroke.<sup>30</sup> While the association between WTC dust and stroke seems plausible because of the presence of PM<sub>2.5</sub>, the underlying biological mechanisms through which small particulate matter exerts its effect on the vascular system is still an area of study.

#### Evaluation of Representativeness of Studies

Finally, the three studies were reviewed to determine whether both the WTC responder and survivor cohorts studied are representative of the entire 9/11-exposed population, and whether the results can be extrapolated. The cohort studied by Brackbill *et al.* consisted of survivors enrolled in the WTC Health Registry; the population studied by Yu *et al.* included responders and survivors enrolled in the WTC Health Registry; the population studied by Remch *et al.* only included non-

firefighter responders who were members of the WTC-Heart cohort within the WTC Health Program. Although Brackbill *et al.* and Yu *et al.* consisted of Registry members, the former only included 8,418 adult survivors of collapsed buildings and buildings with major or moderate damage, while the latter included 42,527 survivors and responders of the WTC attack.<sup>31</sup> According to an assessment of the WTC Health Registry by Kim *et al.* [2018],<sup>32</sup> although enrollment was voluntary, extensive outreach efforts show that selection bias is unlikely for this cohort. The cohort studied by Remch *et al.* is nested within the WTC Health Program and appears to be representative of the population served by the clinics where recruitment took place. As a result, the Program determined that the results of the three evaluated studies can be extrapolated to the entire 9/11-exposed population.

#### Summary of Evaluation

Although the studies described and evaluated above provide evidence that suggests a possible association between 9/11 exposure and stroke, the evidence is insufficient to conclude that stroke is either substantially likely<sup>33</sup> or highly likely<sup>34</sup> to be causally associated with 9/11 exposures among 9/11-exposed populations. The evidence provided by the three studies is insufficient to support an addition to the List for several reasons. Most importantly, the results of the three studies lacked consistency: Two studies found a positive association between 9/11 exposure and stroke (Brackbill *et al.* and Yu *et al.*), and one did not (Remch *et al.*). The two studies that found a positive association between 9/11 exposure and stroke relied on self-reported stroke, which may be prone to recall bias and the imperfections of human memory. In contrast, Remch *et al.* confirmed the presence of stroke using medical records and SPARCS data, but failed to find an association between 9/11 exposure and stroke. Another limitation common to all three studies was the lack of differentiation

between hemorrhagic and ischemic stroke; these two variants have different pathophysiology and causes, and therefore it is not clear if the reported incidence of stroke refers to one or both types of stroke. Finally, the absence of an exposure-response analysis in all of the studies means that the biological gradient is not adequately assessed. In conclusion, when all three studies are considered together, their limitations and lack of consistent findings do not provide adequate evidence to propose the addition of stroke to the List. Without significant positive findings from studies with sufficient sample size, objective confirmation of stroke, and an assessment of exposure-response, the available evidence does not demonstrate that stroke is either substantially likely or highly likely to be causally associated with 9/11 exposures among 9/11-exposed populations.

#### E. Administrator's Final Decision on Whether To Propose the Addition of Stroke to the List

Pursuant to PHS Act, § 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of stroke to the List (pursuant to PHS Act, § 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, § 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, § 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 020 request to add stroke to the List of WTC-Related Health Conditions is denied.

#### F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Robert Redfield M.D., Director, CDC, and Administrator, ATSDR, approved

<sup>28</sup> The WTC Health Program's *Inventory of 9/11 Agents* (available at [https://www.cdc.gov/ResearchGateway/Content/pdfs/Development\\_of\\_the\\_Inventory\\_of\\_9-11\\_Agents\\_20180717.pdf](https://www.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf)) identifies chemical, physical, biologic, and other hazards as having been present at any of the three disaster sites. Of the 352 chemical 9/11 agents identified from air and settled dust sampling studies and from biological monitoring studies, five are types of WTC dust, including: WTC Dust: Glass shards, WTC Dust: PM<sub>10</sub>, WTC Dust: PM<sub>2.5</sub>, WTC Dust: Particles >2 µm, and WTC Dust: Particles >5 µm. The remaining 347 chemicals are identified by name. See *supra* note 5.

<sup>29</sup> Brackbill *et al.* [2006] *supra* note 10 at 12; Yu *et al.* [2018] *supra* note 11 at e375, and Lioy PJ, Weisel CP, Millette JR, Eisenreich S, Vallero D, Offenber J, Buckley B, Turpin B, Zhong M, Cohen MD, Prophete C, Yang I, Stiles R, Chee G, Johnson W, Porcja R, Alimokhtari S, Hale RC, Weschler C, Chen LC [2002], *Characterization of the dust/smoke aerosol that settled east of the World Trade Center (WTC) in Lower Manhattan after the collapse of the WTC 11 September 2001*, *Env Health Perspect* 110:703–714.

<sup>30</sup> Feigin VL, Roth GA, Naghavi M, Parmar P, Krishnamurthi R, Chugh S, Mensah GA, Norrving B, Shiu I, Ng M, Estep K, Cercy K, Murray CJL, Forouzanfar MH [2016], *Global Burden of Stroke and Risk Factors in 188 Countries, During 1990–2013: A Systematic Analysis for the Global Burden of Disease Study 2013*, *Lancet Neurol* 15(9):913–924; Béjot Y, Reis J, Giroud M, Feigin V [2018], *A Review of Epidemiological Research on Stroke and Dementia and Exposure to Air Pollution*, *Int J Stroke* 13(7):687–695.

<sup>31</sup> For more information on the WTC Health Registry cohort and recruitment methods, see: Farfel M, DiGrande L, Brackbill R, Prann A, Cone J, Friedman S, Walker DJ, Pezeski G, Thomas P, Galea S, Williamson D, Frieden TR, Thorpe L [2008], *An Overview of 9/11 Experiences and Respiratory and Mental Health Conditions among World Trade Center Health Registry Enrollees*, *J Urban Health* 85(6):880–909.

<sup>32</sup> Kim H, Baidwan NK, Kriebel D, Cifuentes M, Baron S [2018], *Asthma among World Trade Center First Responders: A Qualitative Synthesis and Bias Assessment*, *Int J Environ Res Public Health* 15(6):1053.

<sup>33</sup> See *supra* note 3 at sec. III.B.1.c.(1).

<sup>34</sup> See *supra* note 3 at sec. III.B.1.c.(2).

this document for publication on February 14, 2019.

**John J. Howard,**

*Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 216

RIN 0648-XG809

#### Notification of Receipt of a Petition To Ban Imports of All Fish and Fish Products From New Zealand That Do Not Satisfy the Marine Mammal Protection Act

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Receipt of petition to ban imports through emergency rulemaking; request for information and comments.

**SUMMARY:** NMFS announces receipt of a petition for emergency rulemaking under the Administrative Procedure Act. Sea Shepherd Legal, Sea Shepherd New Zealand Ltd., and Sea Shepherd Conservation Society petitioned the U.S. Department of Commerce and other relevant Departments to initiate emergency rulemaking under the Marine Mammal Protection Act (“MMPA”), to ban importation of commercial fish or products from fish that have been caught with commercial fishing technology that results in incidental mortality or serious injury of Māui dolphin in excess of United States standards.

**DATES:** Written comments must be received by 5 p.m. Eastern Time on March 27, 2019.

**ADDRESSES:** You may submit comments on this document, identified by NOAA-NMFS-2019-0013, by either of the following methods:

1. *Electronic Submissions:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0013](http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0013), click the “Comment Now!” icon, complete the required fields and enter or attach your comments.

2. *Mail:* Submit written comments to: Director, Office of International Affairs

and Seafood Inspection, Attn: MMPA Petition, NMFS, F/IASI, 1315 East-West Highway, Silver Spring, MD 20910.

**Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on <http://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe portable document file (PDF) formats only. The complete text of the petition is available via the internet at the following web address: <http://www.nmfs.noaa.gov/ia/>. In addition, copies of this petition may be obtained by contacting NMFS at the above address.

**FOR FURTHER INFORMATION CONTACT:**

Nina Young, NMFS F/IASI at [Nina.Young@noaa.gov](mailto:Nina.Young@noaa.gov) or 301-427-8383.

**SUPPLEMENTARY INFORMATION:**

#### Background

Section 101(a)(2) of the Marine Mammal Protection Act (MMPA), 16 U.S.C. 1371(a)(2), states that: “The Secretary of the Treasury shall ban the importation of commercial fish or products from fish which have been caught with commercial fishing technology which results in the incidental kill or incidental serious injury of ocean mammals in excess of United States standards.” In August 2016, NMFS published a final rule (81 FR 54390; August 15, 2016) implementing the fish and fish product import provisions in section 101(a)(2) of the MMPA. This rule established conditions for evaluating a harvesting nation’s regulatory programs to address incidental and intentional mortality and serious injury of marine mammals in fisheries operated by nations that export fish and fish products to the United States. In that rule’s preamble, NMFS stated that it may consider emergency rulemaking to ban imports of fish and fish products from an export or exempt fishery having or likely to have an immediate and significant adverse impact on a marine mammal stock.

#### Information in the Petition

NMFS received the petition on February 6, 2019. The petition alleges that the Secretaries of Commerce and other relevant federal Departments are required to carry out non-discretionary duties under section 101(a)(2) of the MMPA (16 U.S.C. 1371(a)(2)), to “ban the importation of commercial fish or products from fish” sourced in a manner that “results in the incidental kill or incidental serious injury” of Māui dolphin “in excess of United States standards.” The petition requested that the relevant Secretary ban the importation of all fish and fish products caught in set nets or trawls inside the Māui dolphin’s range and from either the west coast of New Zealand’s North Island or the Cook Strait, unless affirmatively identified as having been caught with a gear type other than set nets or trawls or affirmatively identified as caught outside the Māui dolphin’s range.

As support for the need for this action, the petition cites several reports and studies noting various estimates of decline. The petitioners assert that for the Māui dolphin, set net and trawl bycatch has driven the species from a population of approximately 2,000 individuals in 1971, to 111 in 2004, to 55 in 2011. Further, the petition notes that in 2018 the Scientific Committee of the International Whaling Commission reported an abundance estimate of 57 individuals, with a 95% confidence interval of 44 to 75 individuals, which equates to an average decline of 2% every year and a total decline of 59% over the 31-year period from 1985 to 2016.

The petitioners maintain that any fishery using set nets, trawls, or gillnets in the Māui dolphin range along the west coast of New Zealand’s North Island violates U.S. standards under the MMPA. The petitioners provide a list of 11 fish species harvested within the Māui dolphin range by set nets, trawls, or gillnets that are potentially imported into the U.S. as fish or fish products.

As noted in the petition, New Zealand has attempted to address the bycatch problem by (1) restricting set nets and trawls in certain areas, and (2) increasing observer coverage and other monitoring mechanisms. In the case of gear and area/seasonal restrictions, trawling has been banned in approximately 5% of the habitat of Māui dolphin, while gillnets are banned in an additional 14% of that habitat. In addition, New Zealand’s Hector’s and Māui dolphin Threat Management Plan is currently under review for updates, with decision documents scheduled to