Form Approved
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Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

General Instructions

Any interested party may petition the WTC Program Administrator to add a condition to the List of WTC-Related Health Conditions (List) in 42 C.F.R. Part 88 (see http://www.cdc.gov/wtc/faq.html#hlthcond for the complete list).

Please use this form to petition the Administrator to add a health condition (any recognized medical condition requiring treatment or medication) to the List. Please use a separate form for each health condition.

Use of this petition *form* is voluntary, but any petition must include all of the information identified below, as required by 42 C.F.R. Part 88. Petitions that do not provide the required information will not be considered by the WTC Program Administrator. Additional supporting materials may be submitted and are encouraged.

Please note, however, the petition and all supporting materials submitted to the WTC Health Program are part of the public record and may be subject to public disclosure. Personal information will be redacted prior to public disclosure.

Please TYPE or PRINT all information clearly on the form.

If you need more space to provide the required information, please attach additional pages to this form.

Mail or email this form to: World Trade Center Health Program
395 E. Street, S.W., Suite 9200
Washington, D.C. 20201
WTC@cdc.gov

A. Interested Party Information

A1. Do you represent an organization (are you submitting this petition on behalf of an organization)?
☐ Yes (Go to A2) ☒ No (Go to A3)

A2. Organization Information:

Name of organization

A3. Name of Individual Petitioner or Organization Representative:

[redacted]

First name Last name

Position, if representative of organization

A4. Mailing Address:

[redacted]

Street

[redacted]

City State Zip code

A5. Telephone Number: [redacted]

A6. Email Address [redacted]

B. Proposed WTC-Related Health Condition Information

B1. Health Condition Information:

Peripheral Neuropathy

Name of health condition you wish to petition to add to the List of covered conditions

If the name of the condition is not known, please provide a description of the condition or the name of the diagnosis provided by a physician or other healthcare provider.

C. Basis for Proposing that the Condition Be Added to the List of WTC-Related Health Conditions

C1. Describe the reasons the WTC Program Administrator should consider the addition of this health condition. Explain how the health condition you are proposing relates to the exposures that may have occurred from the September 11, 2001, terrorist attacks. Your explanation must include a medical basis for the relationship/association between the 9/11 exposure and the proposed health condition. The medical basis may be demonstrated by 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. First-hand accounts or anecdotal evidence may not be sufficient to establish medical basis. If you need more space, please attach additional pages to this form.

Please see attached

In the previous petition, these two studies were referenced.

1. Analysis of short term effects of world trade center dust on rat sciatic nerve – Stecker, Mark MD, PhD; Segelnick, Jacqueline; Wilkenfeld, Marc MD. 2014.

   Nerve action potentials were recorded in nerves exposed to dust from the WTC and control nerves. The results showed that there was a statistically significant reduction in conduction velocity of nerves exposed to dust from the WTC compared with controls. This study provided a model for biologic plausibility of a causative effect between WTC dust exposure and increased risk of neuropathy.

2. Neuropathic symptoms in world trade center survivors and responders -Wilkenfeld, Marc MD; Fazzari, Melissa PhD; Segelnick, Jacqueline BA, MA; Stecker, Mark MD, PhD. 2016.

   Neuropathic symptoms were surveyed in patients who were and were not exposed at the WTC based on the Michigan Neuropathy Screening Instrument (MNSI). There were 255 complete surveys that were subjected to analysis. WTC exposed patients had higher MNSI neuropathy scores indicating they endorsed more neuropathic symptoms. Patients exposed at the WTC also had a higher rate of abnormal EMG studies than those not exposed. This study suggests WTC dust exposure results in an increased risk of neuropathy in responders and survivors of the WTC.

The previous petition was rejected due to insufficient evidence linking WTC exposure with increased risk of peripheral neuropathy. The following are new studies adding more evidence to the link between WTC and peripheral neuropathy. I've included four studies linking WTC dust particles and toxins to peripheral neuropathy and four epidemiological studies linking WTC exposure to peripheral neuropathy.

WTC dust particles and peripheral neuropathy:

1. Lioy PJ, Weisel CP, Millette JR, Eisenreich S, Vallero D, Offenberg 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. 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. Environ Health Perspect. 2002 Jul;110(7):703-14. doi: 10.1289/ehp.02110703. PMID: 12117648; PMCID: PMC1240917.

   Lioy et al 2002 collected dust and smoke samples from the WTC and analyzed each sample and identified metals, radionuclides, ionic species, asbestos, polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs), polychlorinated dibenzodioxins, polychlorinated dibenzofurans, pesticides, phthalate esters, brominated diphenyl ethers, and other hydrocarbons. We are able to make connections between the metals and particles found at the WTC site and causes of peripheral neuropathy based on the below studies.

2. Chia LG, Chu FL. Neurological studies on polychlorinated biphenyl (PCB)-poisoned patients. Am J Ind Med. 1984;5(1-2):117-26. PMID: 6422742.

   Chia et al 1984 conducted neurological studies on polychlorinated biphenyl (PCB) poisoned patients. 35 patients out of 2000 PCB poisoned cases in Taiwan were neurologically studied and peripheral neuropathy occurred in 2/3 cases. PCBs were found at the WTC disaster site.

3. Thömke F, Jung D, Besser R, Röder R, Konietzko J, Hopf HC. Increased risk of sensory neuropathy in workers with chloracne after exposure to 2,3,7,8-polychlorinated dioxins and furans. Acta Neurol Scand. 1999 Jul;100(1):1-5. doi: 10.1111/j.1600-0404.1999.tb00716.x. PMID: 10416505.

   Thomke et al 1999 investigated the development of sensory neuropathy in workers with chloracne after exposure to polychlorinated dioxins and furans. Motor conduction and sensory conduction tests were done in 156 exposed workers from a pesticide producing plant. Workers with a higher exposure to dioxins complained of sensory neuropathy restricted to the legs and had more neurophysiologic abnormalities. Polychlorinated dioxins and furans were found in the dust and smoke at the WTC site according to Lioy et al 2001.

4. Staff NP, Windebank AJ. Peripheral neuropathy due to vitamin deficiency, toxins, and medications. *Continuum (Minneap Minn)*. 2014;20(5 Peripheral Nervous System Disorders):1293-1306. doi:10.1212/01.CON.0000455880.06675.5a

   Staff et al 2014 conducted a systematic review investigating peripheral neuropathy causes due to toxins, vitamin deficiency, and medications. They found that heavy metals such as lead, arsenic, thallium, mercury as well as hexacarbons and organophosphates can lead to peripheral neuropathy. Lead, hexacarbons and organophosphates were all found at the WTC site according to Lioy et al 2001 and provide the link between toxins found in WTC dust and peripheral neuropathy.

Epidemiological studies:

1. Stecker MM, Yu H, Barlev R, Marmor M, Wilkenfeld M. Neurologic Evaluations of Patients Exposed to the World Trade Center Disaster. J Occup Environ Med. 2016 Nov;58(11):1150-1154. doi: 10.1097/JOM.0000000000000889. PMID: 27820766.

   Stecker et al 2016 conducted a cohort study to determine whether those exposed at the WTC had evidence of neurologic injury. 16 patients agreed to have their clinical information evaluated and underwent a neurological exam. The control population were patients referred for an outpatient EMG at Winthrop University Hospital and consisted of 209 patients. WTC patients were eliminated from this group and there were 174 patients left with a clear neurophysiologic diagnosis. Each patient filled out the MNSI and EMG and nerve conduction studies were done. 56% of referred patients had neuropathy that could not be explained by other factors such as Lyme disease, B12 deficiency, or diabetes

and could be candidates for neuropathy related to WTC exposure. Relative risk in WTC exposed patients was 1.9 times more likely to have neuropathy than the group of non-WTC exposed patients referred for EMGs.

2. Marmor M, Shao Y, Bhatt DH, et al. Paresthesias Among Community Members Exposed to the World Trade Center Disaster. *J Occup Environ Med*. 2017;59(4):389-396. doi:10.1097/JOM.0000000000000966

   Marmor et al 2017 analyzed data from 3,141 community members exposed to the WTC disaster. At enrollment, patients underwent venipuncture for CBC and blood chemistries. They estimated severity of exposure to the dust clouds according to responses to a question asking about the amount of dust on a person's body, clothes, and hair. 56% of patients reported paresthesias at enrollment 7-15 years following the WTC.

3. Colbeth HL, Zeig-Owens R, Webber MP, Goldfarb DG, Schwartz TM, Hall CB, Prezant DJ. Post-9/11 Peripheral Neuropathy Symptoms among World Trade Center-Exposed Firefighters and Emergency Medical Service Workers. Int J Environ Res Public Health. 2019 May 16;16(10):1727. doi: 10.3390/ijerph16101727. PMID: 31100846; PMCID: PMC6572143.

   Colbeth et al 2019 investigated peripheral neuropathy symptoms among WTC exposed firefighters and EMS workers by analyzing questionnaire data. The final study cohort was 9239 people who were moderately exposed to the WTC disaster, grouped into an indicated group with conditions associated with paresthesia and a non-indicated group without conditions associated. Data included non-WTC individuals who participated in the survey for a comparison and the prevalence of peripheral neuropathy was calculated among each group. The prevalence of scoring positive on the Diabetic Neuropathy Symptom survey among the indicated group was 30.6% while the non-indicated group scored 23.8%. Logistic regression models used the following outcomes: positive on the DNS and often/almost continuously experiencing paresthesia in the legs or feet, in the arms or hands, or in both. Those with highest exposure to the WTC were more likely to score positive on the DNS than in the lowest exposure group. Trend tests between WTC exposure level and paresthesias of the arms and extremities were significant.

4. Marmor M, Thawani S, Cotrina ML, Shao Y, Wong ES, Stecker MM, Wang B, Allen A, Wilkenfeld M, Vinik EJ, Vinik AI, Reibman J. Case-Control Study of Paresthesia Among World Trade Center-Exposed Community Members. J Occup Environ Med. 2020 Apr;62(4):307-316. doi: 10.1097/JOM.0000000000001828. PMID: 32049876; PMCID: PMC7113112.

   Marmor et al 2020 conducted a case control study of paresthesia among WTC exposed community members. The study compared WTC exposed paresthesia cases with clinic controls (WTC exposed without paresthesia's) and community controls (WTC unexposed persons). Questionnaire explored WTC exposures and a history of exposure to potential neurotoxins during work. Nerve fiber densities were below normal in 47% of cases and sural to radial sensory nerve amplitude ratios were less than 0.4 in 29.4%. Epidermal and

sweat gland nerve fiber densities were significantly reduced among cases compared to controls and remained significant after adjusting for age and gender. The odds ratio for paresthesia with being heavily exposed to WTC dust was 2.3. Blood tests did not reveal any other association with non-WTC related disease, metabolic or toxic etiologies of peripheral neuropathy.

These studies provide strong evidence and establish a causal link between World Trade Center dust and nerve damage. Many first responders, citizens, and survivors were exposed to the WTC site and have developed peripheral neuropathy as a result and are suffering. This petition lists undeniable evidence that there is a link between WTC exposure and peripheral neuropathy. We ask that peripheral neuropathy be added to the list of conditions covered under the WTC Health Program.

D. Signature of Petitioner

Sign your name below to indicate that you are petitioning the WTC Program Administrator to consider adding [redacted] itions identified in 42 C.F.R. Part 88.

[redacted] 9/1/21

Signature Date

Privacy Act Statement

In accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a), you are hereby notified of the following:

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. Sections 3311, 3312, and 3321 of Title XXXIII of the PHS Act require that the WTC Program Administrator develop regulations to implement portions of the WTC Health Program established within the Department of Health and Human Services (HHS). The WTC Health Program is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC). The information provided with this form and supporting documentation will be used by the WTC Program Administrator to consider the disposition of a petitioned-for health condition. Disclosure of this information is voluntary.

Records containing information in identifiable form become part of an existing NIOSH system of records under the Privacy Act, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH." These records are treated in a confidential manner, unless otherwise compelled by law.

Information submitted to WTC Health Program which may be considered "protected health information" pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191; 42 U.S.C. § 1320d) and the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164) will be maintained in accordance with all applicable laws.

NIOSH may disclose information in identifiable form only insofar as such disclosure is permitted pursuant to the HIPAA Privacy Rule; this may include disclosure to the WTC Health Program Scientific/Technical Advisory Committee (STAC), which may be asked to consider the petition and issue a recommendation to the WTC Program Administrator. Information in identifiable form will be redacted from submitted petition forms and supporting documentation that become a part of the public record (e.g. in conjunction with STAC consideration or a rulemaking).