July 31. 2026

To: Dr. John Howard, WTC Health Program Administrator

From: The WTC Clinical Centers of Excellence and Data Centers, Submitted Unanimously

Re: PETITION TO RECONSIDER ISCHEMIC CARDIOVASCULAR DISEASE AS A WORLD TRADE CENTER (WTC) HEALTH PROGRAM COVERED CONDITION

I. Introduction

Pursuant to 42 C.F.R. § 88.15 and § 88.16, this petition respectfully requests that Dr. Howard, the Administrator of the World Trade Center (WTC) Health Program, reopen the June 30, 2026, determination denying Ischemic Cardiovascular Disease (Petition 024, 042, 046, 047, 051, 056, 058, 067) and instead immediately refer the petition to the Scientific/Technical Advisory Committee (STAC) for review.

An evaluation of the available evidence indicates numerous significant flaws in the federal government's determination that Ischemic Cardiovascular Disease should *not* be added to the WTC Health Program's list of covered conditions. Moreover, when the evidence for Ischemic Cardiovascular Disease is evaluated using the same standards and approach that were applied in prior decisions to add various cancers to the list of WTC covered conditions, the scientific support is at least as strong or stronger than the evidence that supported the inclusion of several cancers.

Therefore, this petition for reconsideration respectfully requests the WTC Administrator to reconsider this decision and, as per the WTC Programs protocol, refer the petition to the WTC Scientific/Technical Advisory Committee (STAC) for an independent review of the evidence for adding Ischemic Cardiovascular Disease to the list of WTC covered conditions.

We believe the Administrator's decision that Ischemic Cardiovascular Disease *NOT* be added to the WTC Health Program's list of covered conditions was based on numerous flaws including:

- Underweighting of dose-response evidence from FDNY and GRC cohorts.
- Omission of strong mechanistic evidence from particulate toxicology.
- Failure to account for under-ascertainment bias.
- Misuse of mortality data influenced by the healthy worker effect.
- Lack of transparent evidentiary threshold standard, inconsistent with 2012–2013 cancer decisions.

Given these issues, the "insufficient evidence" conclusion is scientifically flawed and inconsistent with prior decisions. Our petition demonstrates that epidemiologic findings, appropriately adjusted confounding, mechanistic plausibility, and procedural precedent support the inclusion of Ischemic Cardiovascular Disease to the WTC covered condition list – consistent and exceeding the evidentiary standards previously used when the Administrator added various cancers to the WTC covered condition list.

II. Procedural Context & Statutory Framework

Under the James Zadroga 9/11 Health and Compensation Act and implementing regulations pursuant to 42 C.F.R. § 88.15 and § 88.16, the Administrator has the authority at any time in the petition review process to refer the petition to the STAC for review. The Administrator's denial cited insufficient evidence. In contrast, the 2012 decision to add ~60 cancer types, and many more since then, used a hazard-based, multi-method evaluation that included cohort studies, mechanistic evidence, and exposure science—later supported / agreed upon by both the STAC and the General Accounting Office (GAO). But then ignored by the NIOSH WTC Health Program when making the decision to NOT add Ischemic Cardiovascular Disease to the list of WTC covered conditions.

III. Scientific Evidence—WTC Exposure & Ischemic Cardiovascular Disease

TABLE: Key Cardiovascular Disease Findings in WTC Cohorts

WTC Cohort	Publication	Study Population and type	Type of data	Exposure Measures	Main Statistical Findings
FDNY	Cohen et al 2019 (ref	FDNY firefighters (n=9,796), longitudinal 16 year follow up	Medical records	Arrival time (morning 9/11, afternoon 9/11, later); Duration ≥6 months vs <6 months	Morning 9/11 arrival vs later: HR 1.44 (1.09–1.90) Afternoon 9/11 arrival vs later: HR 1.24 (1.00–1.54) Worked ≥6 months vs fewer: HR 1.33 (1.05–1.60)
	Mueller et al 2023(ref	WTC and non-WTC firefighters, cross sectional	Self-reported diagnoses and for WTC, medical records	WTC exposed vs not; Arrival time (morning 9/11, afternoon 9/11, later vs not exposed)	Morning 9/11 arrival vs non: HR 1.45 (1.18–1.79) Afternoon 9/11 arrival vs non: HR 1.31 (1.11–1.54) Exposure gradient attenuated when using medical-record confirmed CVD cases
GRC	Sloan NL et al 2022 (ref	WTC General Responder Cohort n=37,725; 17-year follow-up	Self-reported diagnoses	Dust exposure on 9/11, no dust exposure on 9/11 vs arrived later, stratified by sex	Men: HR 1.40 (1.26–1.56) 9/11 with dust vs later; HR 1.43 (1.29–1.58) 9/11 without dust vs later Women: HR 2.16 (1.49–3.11) with dust vs later; HR 1.59 (1.11–2.27) 9/11 without dust vs later
WTCHR	Jordan et al 2011 (ref	All WTC enrollees; longitudinal 4 year follow up	Self-reported diagnoses	Dust exposure, time of arrival	RR men: 9/11 pile vs >9/18 HR 1.39 (1.04-1.86) Resident men: heavy dust vs non HR 2.05 (1.15-3.67) Area worker men: heavy dust vs non HR 1.55 (1.03-2.31) All women: intense 9/11 dust vs non HR 1.28 (1.02-1.61)

A. Epidemiologic Cohort Studies: Recent peer-reviewed analyses, including those referenced in petition submissions, demonstrate consistent associations between WTC exposure and cardiovascular outcomes. FDNY responders with high-intensity exposure (e.g., arrival on morning of 9/11 or long-duration site work) exhibit elevated hazard ratios for ischemic cardiovascular diseases with dose dependency (ref 1, 2). The General Responder Cohort (ref 3, 4) and the WTC Health Registry (ref 5-8) found similar patterns, particularly among dust-cloud-exposed individuals. Adjusted models remain significant when properly accounting for confounders. Consistency across cohorts is a core Hill criterion for causation, yet the federal decision did not discuss or weigh this replication.

B. Mechanistic Bioplausibility & Environmental Toxicology: WTC dust contained high concentrations of alkaline particulates, heavy metals, combustion byproducts, and fine/ultrafine particles known to induce inflammation, endothelial dysfunction, and accelerated atherosclerosis—recognized pathways toward Ischemic Cardiovascular Disease. This supports a biological causal mechanism consistent with Ischemic Cardiovascular Disease outcomes. Mechanistic evidence supporting increased Ischemic Cardiovascular Disease risk was not adequately considered. WTC dust contained extreme concentrations of $PM_{2.5}$, a pollutant with well-documented causal links to myocardial infarction, stroke, and atherosclerosis (refs 9, 10). Animal and in-vitro studies confirm that WTC particulate matter produces cardiac injury and systemic inflammation, providing biological plausibility for the observed epidemiologic associations (refs 11-13).

In fact, WTC Exposure was *far more intense* than chronic $PM_{2.5}$ exposure. Ambient $PM_{2.5}$ studies typically examine exposures in the 5–35 $\mu g/m^3$ range (refs 9, 14). The WTC collapse produced $PM_{2.5}$ concentrations near 100,000 $\mu g/m^3$ for hours—an exposure level *orders of magnitude higher*, and of a type known to trigger acute cardiovascular instability (ref 10, 15-17). If chronic $PM_{2.5}$ at low levels raises CVD risk slightly, extreme $PM_{2.5}$ exposure at WTC levels would reasonably increase risk *far more*, not less. WTC Dust was compositionally more toxic than ambient $PM_{2.5}$ (ref 10, 15-17). Whereas typical $PM_{2.5}$ consists mostly of carbonaceous combustion particles (refs 9, 14), WTC dust contained highly alkaline pulverized concrete, gypsum and calcite, heavy metals (lead, iron), synthetic vitreous fibers, and coarse and super-coarse particulates (ref 10, 15-17).

These larger and chemically caustic particles caused immediate airway injury and heightened systemic inflammation—known triggers for Ischemic Cardiovascular Disease(18-20). Numerous studies demonstrating chronic inflammation after WTC Dust exposure, are consistent with autonomic imbalance, oxidative stress, and high cortisol and sympathetic activation – known physiologic precipitants of Ischemic Cardiovascular Disease (18-20). These findings are supported by a study in WTC-exposed children demonstrating metabolic and increased risk factors for Ischemic Cardiovascular Diseases (ref 21)

Further support is found in rodent studies demonstrating myocardial dysfunction, systemic inflammation, and vascular injury after acute, actual WTC dust exposure at levels *stronger* than those found after exposure to conventional $PM_{2.5}$. (refs 11-13, 22)

C. **Analytical Rigor:** The Administrator's decision likely stemmed from interpretation of adjusted models, many of which did not adjust for baseline healthy worker effect and occupational health differences, thereby suppressing true exposure effects. Alternatively, the analyses might have been over-adjusted by including variables influenced by WTC exposure (e.g., PTSD, inflammation, hypertension) that are potential mediators or colliders, leading to nullified associations. The decision to deny Ischemic Cardiovascular Disease as a covered condition misapplied the "healthy worker effect"—a known artifact in occupational epidemiology—by relying on mortality studies showing fewer Ischemic Cardiovascular Disease deaths compared with the general population. Such mortality patterns reflect the high baseline fitness of firefighters and other responders, not the absence of exposure effects. State-of-the-art causal principles indicate that such analytic strategies can attenuate or mask real effects, hindering accurate exposure assessment. Reanalysis using causal diagrams, adjusting only for confounders (e.g., age, sex, smoking, baseline fitness) while excluding mediators/colliders, yields stronger Ischemic Cardiovascular Disease risk signals—comparable to those observed for cancers already added to this program as covered conditions.

   The decision underestimates strong and replicated epidemiological findings showing increased Ischemic Cardiovascular Disease risk among WTC-exposed responders. FDNY's long-term cohort study demonstrated an increased hazard of major cardiovascular events for the most heavily exposed firefighters, with a clear dose–response gradient based on arrival time and duration of exposure. Specifically, early arrival (morning of 9/11) resulted in a 44% increased hazard of major Ischemic Cardiovascular Disease events, and working ≥6 months on the pile resulted in a 33% increased hazard of major Ischemic Cardiovascular Disease events. Similar exposure-related increases were confirmed in the WTC General Responder Cohort (GRC) and the WTC Health Registry. These associations are epidemiologically robust, meet multiple causal criteria, and are consistent across independent cohorts. These are confirmatory *dose–response findings*—the strongest standard of epidemiologic evidence—yet federal reviewers did not acknowledge them as meeting the regulatory threshold.

   Moreover, these positive associations occurred despite under-ascertainment likely biasing risk estimates; as Ischemic Cardiovascular Disease is not a WTC covered condition, WTC-exposed members have little incentive to report these diagnoses to the Program. This ascertainment bias was not addressed in the federal analysis.

IV. Inconsistency With Prior Cancer Additions to the Covered List of Conditions:

The 2012 cancer inclusion process leveraged a hazard-based framework requiring epidemiologic hazard demonstration, mechanistic plausibility, toxicologic exposure assessment, and peer-reviewed evidence. These criteria / analytic approaches were supported by the STAC and the GAO and remain unmodified in the revised policy exclusive to non-cancer conditions. Current Ischemic Cardiovascular Disease evidence exceeds these thresholds—but was deemed insufficient—revealing inconsistent application of policy. This undermines the WTC Health Program's credibility, equity, and scientific reliability.

Specifically, in 2013, the Administrator authored a white paper summarizing the basis for his decision to add cancers to the list of WTC-covered conditions. He did not solely rely on statistical association measures such as odds ratios, relative risks, or hazard ratios to justify adding cancer. Instead, the document emphasized that while epidemiologic effect size estimates were less than sufficient for WTC-related exposures, they were in the correct trend and therefore allowed his decision to be augmented by additional latency evidence, toxicologic plausibility, and the presence of numerous known carcinogens at Ground Zero. These factors led to a hazard-based, multiple-method scientific approach rather than sole reliance on quantitative statistical risk estimates. Thus, the Administrator's determination rested on the best available latency and mechanistic evidence, not just on statistical associations typical of epidemiologic risk studies. Furthermore, the STAC's supporting rationale likewise emphasized a hazard-based rather than a risk-based approach.

Using this approach, Ischemic Cardiovascular Disease exceeds the scientific evidence used to add cancers to the covered condition list as shown in the following table.

Comparison Table: Evidence for Adding Ischemic Cardiovascular Disease vs. Adding Cancers

Criterion	Evidence for Adding Cancers (based on 2012–2013 NIOSH decision)	Evidence for Ischemic Cardiovascular Disease (current literature)
Exposure-response gradient	Often absent or indirect	Strong and replicated: arrival time and duration produced hazard increases. (ref 1,2)
Physician-verified outcomes	Mixed across cancers	Robust in FDNY & WTC health Registry cohorts with direct medical verification. (ref 1,6,8)
Mechanistic plausibility	Based on known carcinogens; sometimes limited	Very strong: $PM_{2.5}$, inflammation, systemic vascular injury; validated in animal & in-vitro models. (ref 11-13, 22)
Consistency across cohorts	Variable; not all cancers replicated	High: FDNY + GRC + WTC Health Registry cardiovascular findings align directionally (refs 1-8)
Under-ascertainment considerations	Less prominent	Significant: non-covered status leads to underreporting and bias toward the null.
Healthy worker effect distortion	Not major	Major issue that confounds mortality comparisons and was misinterpreted in federal decision.
Regulatory outcome	Cancers added with sometimes limited evidence	CVD denied due to "insufficient evidence" despite stronger epidemiologic signals.

V. WTC Program Policy Lacks a Defined Evidentiary Threshold for Determining "Sufficient Evidence."

The decision NOT to add Ischemic Cardiovascular Disease to the covered conditions list is in notable contrast to the Program's earlier decisions to add numerous cancers. This apparent inconsistency raises an important question: is a clear and transparent evidentiary threshold being applied when determining whether the available scientific evidence is sufficient to support the addition of a condition?

Based on this current decision, there appears NOT to be one. Such thresholds are glaringly missing from the official policy, a policy so detailed in every other aspect of the process. For example, the response to the petition uses language from the Bradford Hill criteria, which have not been described as NIOSH

policy in these matters. These criteria were generated to develop a sense of causality from the preponderance of research but are susceptible to several failings. For example, conservative effect estimates from issues surrounding ascertainment bias, as described in studies of Ischemic Cardiovascular Diseases, can cause policymakers to reject causality despite a preponderance of evidence. Importantly, these well-established limitations (noted in relation to Cancer above) should be recognized and considered carefully. Without clearly defined evidentiary standards, stakeholders are left uncertain as to why one condition is added while another is not. Despite comparable or stronger scientific support; members and their clinicians are unaware of the required evidentiary thresholds needed to support their petitions. Establishing transparent criteria would strengthen the integrity, consistency, and credibility of the Program's decision-making process and better serve affected members and patients.

VI. The WTC Clinical Centers and Data Centers, Our Members, and Our Patients Unanimously Request the STAC be Allowed to Consider Our Petition

Based on these numerous significant flaws in the review process, we implore Dr. Howard, the WTC Health Program Administrator, to reopen our petition and immediately refer it to the WTC STAC for their review. This review should use a transparent, hazard-based approach consistent with the methodology used to add cancers to the WTC covered condition list. Such an approach would fully incorporate exposure-response evidence, mechanistic bio-plausibility, and the realities of structural under-diagnosis in healthy worker cohorts.

When rigorously analyzed—respecting causal inference principles and building on recognized hazard-based frameworks—the body of epidemiologic and mechanistic evidence supports a significant and scientifically credible association between WTC exposure and Ischemic Cardiovascular Disease. The current denial, based on improperly adjusted analyses and uneven policy standards, does not withstand scrutiny. A reasonable scientific conclusion is that Ischemic Cardiovascular Disease is plausibly associated with WTC exposure. We therefore request that the decision denying our petition be reversed so the STAC can have time to provide a full and independent review. In light of the stakes for our member's health and this Program's integrity and credibility, this petitioner (the WTC Clinical Centers of Excellence) unanimously requests formal reconsideration and procedural redress so that the decision to add Ischemic Cardiovascular Disease to the WTC covered condition be aligned with that already used to add cancers to the covered condition list.

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