THE 9/11 CANCER CONUNDRUM: THE LAW, POLICY, & POLITICS OF THE ZADROGA ACT

Kimberly Gordy†

I. INTRODUCTION 34
II. DUST & DISCLOSURE: THE AFTERMATH OF THE COLLAPSE 38
A. WTC Exposure: Pollutants versus the People 38
1. The Exposed Populations 38
2. Assessment of the Toxins 43
a) Asbestos 45
b) Polycyclic Aromatic Hydrocarbons 47
c) Lead, Mercury & Cadmium 48
d) Polychlorinated Biphenyls 48
e) Benzene 48
B. WTC Health Conditions: Ten Years Later 50
1. Latent-Illness Development 52
2. The Financial Burden of Managing WTC-Illnesses 53
III. INCONSISTENT HEALTHCARE FUNDING AND THE TROUBLED PATH TO THE ZADROGA ACT 55
A. The Zadroga Act's Namesake 56
B. H.R. 847 57
C. Jon Stewart and Shepard Smith Step In 59
IV. AN OVERVIEW OF THE WORLD TRADE CENTER HEALTH PROGRAM 61
A. World Trade Center Health Program Objectives and Operations 62
B. Eligibility 63
C. Treatment under the World Trade Center Health Program 64

† Law Clerk to the Honorable George C. Hanks, Jr., United States District Court, Southern District of Texas; J.D. University of Houston Law Center, 2010; M.A. University of Texas Medical Branch, 2012, B.S. Texas A&M University, 2007. This Article is dedicated to the Fire Department of New York City, and in particular, the firefighters of Ladder 113, Engine 249. I wish 9/11 firefighter Daniel McKay strength in his battle against cancer. Additionally, many thanks to Laura Hermer, Associate Professor, Hamline University School of Law, for her invaluable feedback on this Article.

V. THE STANDARD OF REVIEW SET FORTH IN THE ACT IS INFEASIBLE 65
A. The Zadroga Act Should Incorporate Presumptions 65
B. The Admissibility Standard for the Periodic Reviews is Unreasonable 69
1. The Purpose and Weight of the February 2012 STAC Recommendation 72
2. The Zadroga Act Does Not Provide Guidance to the Administrator on Weighing Evidence 75
VI. APPLYING TOXIC TORT JURISPRUDENCE TO ENSURE THE PERIODIC REVIEW PROCESS IS FAIR AND EQUITABLE 76
A. The Position of the Restatement Third Promotes A Flexible, But Not Relaxed, Causation Inquiry 78
1. Recent Case Law Supports a Flexible Causation Inquiry When Epidemiologic Evidence is Limited 79
2. A Flexible Standard Should be Adopted by the WTCHP Administrator 80
B. All Reliable Evidence Should be Admissible for Consideration by the Administrator 81
VII. CONCLUSION 84
AUTHOR'S NOTE 85

I. INTRODUCTION

The tenth anniversary of the September 11th terrorist attack has come and gone. For most Americans, the memories of the day remain etched in our minds, yet most have moved forward in the post-9/11 world. However, for the first responders who spent weeks laboring in the wreckage of the collapsed towers, or "the Pile," the ten-year anniversary marks more than the passage of time.[1] It serves as another reminder that many 9/11 first responders are now suffering from illnesses associated with their service at Ground Zero. As we move further away from 9/11, the health consequences of Ground Zero exposure will manifest with increasing ferocity.[2]

Enacted in 2011, the James Zadroga 9/11 Health and Compensation Act is a federal effort to alleviate the burden of 9/11

[1] *9/11: Ten Years Later* †CBS television broadcast Sept. 11, 2011) (featuring an update of the multiple award-winning documentary film, 9/11).

[2] *Id.* (interviewing Dr. David Prezant about the toxicity of the dust at Ground Zero). The film features the cancer battles of several New York City firefighters.

related-illness.[3] The Zadroga Act established the landmark World Trade Center Health Program ("WTC Health Program"); this program provides first responders and survivors with medical care and health monitoring for a pre-determined list of diseases associated with Ground Zero exposure (hereinafter "the List") and sets aside $4.3 billion to provide eligible individuals with medical monitoring and treatment for those health conditions specified on the List.[4] The List primarily covers aerodigestive diseases, including "Chronic cough syndrome" and "Gastroesophageal reflux disorder," better known as heartburn.[5] But the List expressly precludes the one condition first responders are developing at an alarmingly high rate: cancer.[6]

In April of 2011, the president of the New York City Firefighters Union commented:

> It's a fact that New York City firefighters are dying of cancer in record numbers. We have buried 10 firefighters in just the last 15 weeks, seven with cancer. On September 10 2001 they were young, healthy firefighters.[7]

The number of Ground Zero responders lost to cancer has now surpassed the number of firefighters killed in the collapse of the Twin Towers.[8] Every day, 9/11 responders are diagnosed with illnesses,

---

[3] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011) [hereinafter "Zadroga Act"].

[4] Zadroga Act § 101 (amending Public Health Service Act, 42 U.S.C. ch. 6A (2001) by adding §§ 3301-51 in order to establish the World Trade Center Health Program (current version at 42 U.S.C. §§ 300mm-300mm61 (2012)). Title II, which re-opens the Victim Compensation Fund to provide economic and non-economic compensation to eligible responders and survivors, is beyond the scope of this Article. Zadroga Act §§ 201-05 (amending the Air Transportation Safety and System Stabilization Act, 107 Pub. L. No. 42, 115 Stat. 230 (2001) in order to re-open the Victim Compensation Fund (VCF)); Anemona Hartocollis, *10 Years and a Diagnosis Later, 9/11 Demons Haunt Thousands*, N.Y. TIMES, A20 (Aug. 10, 2011), *available at* http://www.nytimes.com/2011/08/10/nyregion/post-traumatic-stress-disorder-from-911still-haunts.html?pagewanted=all&_moc.semityn.www.

[5] Zadroga Act § 101.

[6] Neil Tweedie, *9/11: The Toxic Legacy of the World Trade Center Attacks*, THE TELEGRAPH (Sept. 3, 2011), *available at* http://www.telegraph.co.uk/news/worldnews/september-11-attacks/8737674/911-the-toxic-legacy-of-the-World-Trade-Center-attacks.html.

[7] *See, e.g.*, *id.*

[8] *See* Sally Goldenberg & Susan Edelman, *FDNY Cancer Up Post 9/11: Bravest's Doc Bares Hero Risk*, N.Y. POST (Apr. 3, 2011), http://www.nypost.com/p/news/local/fdny_cancer_up_post_n4vfuHFoUROuJYtmyt4Y2K (citing a report from the NY State Health Department stating that 345 9/11 responders had died of cancer as of June 2010); *see also* NATIONAL COMMISSION ON TERRORIST ATTACKS

including cancers, typically found in persons decades older.[9]

Unfortunately, it remains unclear if the Act will provide adequate medical coverage for cancer. Under the Act, the WTC Health Program Administrator is only required to conduct a "Periodic Review" of the scientific literature to determine whether cancers should be added to the List—and cancer was again excluded during the first Periodic Review.[10]

After the first Periodic Review, many felt that the data considered presented an incomplete picture of the health crises. As a result of a bipartisan congressional petition to add cancer to the List, the Administrator is now conducting the second Periodic Review. In February of 2012, the WTC Health Program Scientific and Technical Advisory Committee ("STAC"), a panel created under the Act to assess emerging health issues found that it is "reasonable to expand" the WTC Health Program to cover cancer while research continues.[11]

This recommendation does not guarantee that the WTC Health Program will be amended to include cancer treatment; it is purely advisory.[12] The current Administrator, John Howard, M.D., M.P.H., J.D., L.L.M., will decide in the upcoming months if the WTC Health Program will (1) provide coverage for some cancers; (2) grant eligible individuals full cancer coverage; or (3) confirm its current exclusion, reserving the decision for a future Periodic Review.[13]

Although the Act's enactment was in and of itself a success, many first responders and advocates fear that truly adequate coverage will once again be denied. The Daily Show's host, Jon Stewart, credited by many for securing the Bill's passage, captured these sentiments in his

---

UPON THE UNITED States, *Heroism and Horror* 9.1 (2004) *available at* http://govinfo.library.unt.edu/911/report/911Report_Ch9.htm [hereinafter COMMISSION REPORT] (stating the number of firefighters killed on September 11th was 343).

[9] Goldenberg & Edelman, *supra* note 8.

[10] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, § 3312(a)(3), 124 Stat. 3623 (2011).

[11] David B. Caruso, *Feds Consider Expanding Cancer Coverage for WTC Workers: Advisory Committee Believes it Reasonable that Cancer Link Would Eventually be Found*, ASSOCIATED PRESS (Feb. 17, 2012), *available at* http://www.jems.com/article/news/feds-consider-expanding-cancer-coverage.

[12] *Id.*

[13] Press Release, N.Y. Representatives Carolyn Maloney, Jerrold Nadler, & Peter King, & Senators Charles Schumer & Kristin Gillibrand, NY Lawmakers Applaud Progress Toward Adding Cancer Coverage to WTC Health Program (Feb. 16, 2012), *available at* http://maloney.house.gov/press-release/ny-lawmakers-applaud-progress-toward-adding-cancer-coverage-wtc-health-program.

episode, *I Thought We Already Took Care of This S@#t*:

> It took 9 years of committed legislators working tirelessly with first responder advocates, some of them sadly passing away before the Bill's signing, to bring much needed relief to those who gave so much down at Ground Zero. . . . As it turns out, as part of a political compromise to get the [Zadroga] bill passed, the bill does not cover cancer treatments. . . *how did we not include cancer?*[14]

This Article tackles this question through an in-depth analysis of the toxic exposure at Ground Zero, the political turmoil associated with the Zadroga Act, and the mechanics of the WTC Health Program. Part II outlines the toxic exposure at Ground Zero and explains the latent-disease development in 9/11 responders and survivors. Part III details the political process leading to the Zadroga Act's passage, offering insight into the contentious battles over cancer coverage.

Part IV then provides an overview of the WTC Health Program and its various statutory requirements, including the required Periodic Reviews. Part V examines the current Periodic Review process, incorporating the most recent recommendations of the STAC and the WTC Health Program Administrator. This Article endorses the recommendation that, at a minimum, some form of cancer coverage must be included under the WTC Health Program's umbrella of conditions.

Part VI outlines a series of recommendations tailored to ensure a fair and equitable review process for the inclusion of cancer coverage. First, this Article argues that an official disease presumption may be warranted in the case of 9/11 toxic exposures. Second, in lieu of the current statutory standard, this Article also recommends that the WTC Health Program Administrator adopt evidentiary criteria equivalent to the admissibility standard endorsed by the Restatement Third of Torts § 28, Comment c. Comment c directs courts to admit non-peer reviewed evidence when litigation must occur before epidemiologic evidence of causation exists.[15] The adoption of these recommendations will ensure an equitable review process for those first responders dependent on the Act for their medical care.

---

[14] *The Daily Show with Jon Stewart: I Thought We Already Took Care of This S@#t*, (Comedy Central television broadcast July 28, 2011) *available at* http://www.thedailyshow.com/watch/thu-july-28-2011/i-thought-we-already-took-care-of-this-s—t [hereinafter Daily Show 2].

[15] *See generally* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 cmt. c (2010).

II. DUST & DISCLOSURE: THE AFTERMATH OF THE COLLAPSE

The debris pile at what was once the WTC burned for three months, and during that time, first responders, recovery workers, and residents of local residential and commercial building communities were continually exposed to the fallout of the Twin Towers' collapse.[16] Both buildings collapsed from the combined effects of the combustion of 90,000 liters of jet fuel, structural impact damage, reduced elevated temperature strength, and the bowing and buckling of the exterior walls under the redistributed gravity load.[17] In a matter of seconds, the towers were transformed into 1,000,000 tons of rubble and a cloud of dust, debris, and smoke that blanketed lower Manhattan and western Brooklyn.[18] Whether in the immediate aftermath or over the course of the clean-up process, any degree of exposure to the Pile was toxic exposure. The following sections examine the nature of this exposure and the resultant disease development.

A. WTC Exposure: Pollutants versus the People

1. The Exposed Populations

The STAC identified three categories of exposed populations: (1) persons exposed during the initial collapse of the Twin Towers; (2) persons exposed to the re-suspension of dust and smoke during the first week; and (3) persons exposed to the re-suspension of dust and smoke during the subsequent weeks and months.[19]

---

[16] Philip Landrigan et al., *Health and Environmental Consequences of the World Trade Center Disaster*, 112 ENVTL. HEALTH PERSPECTIVE 731, 731, 733 (2004). The Pile burned from September 11, 2001 until December 20, 2001.

[17] S.W. Banovic, *The Role of Metallurgy in the NIST Investigation of the World Trade Center Towers Collapse*, 59 JOM 22, 28 (2007), *available at* http://www.tms.org/pubs/journals/jom/0711/banovic-0711.html. JOM was known as the Journal of Metals from 1949 to 1988, at which point it changed its name to JOM. It is a technical journal published by The Minerals, Metals & Materials Society. John Howard, *The World Trade Center Disaster: Health Effects and Compensation Mechanisms*, 16 J.L. & POL'Y 69, 71 (2007).

[18] Howard, *supra* note 17, at 71. John Howard, M.D., MPH, J.D., LLM is the current director of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. He has held this position since 2002. Thomas W. Eagar & Christopher Musso, *Why Did the World Trade Center Collapse? Science, Engineering, and Speculation*, 53 JOM 8, 8-11 (2001).

[19] Elizabeth Ward, Ph.D., Petition on Cancer (Feb. 15, 2012), *available at*

Everyone present in the World Trade Center area during the attack falls into Category One.[20] This includes an estimated 50,000 office workers and anyone simply passing through the WTC complex – up to 40,000 people on any given day.[21] In addition to those inside the complex, this category represents area businesses and their customers, commuters, and local and downwind residents.[22]

Category One also includes the first responders who arrived on scene immediately following the attack.[23] The New York City Police Department ("NYPD") mobilized at an amazing rate, dispatching over 800 police officers within the first twelve minutes.[24] The Fire Department of New York ("FDNY") was equally impressive, mobilizing its response within *five seconds* of the first plane hitting the North Tower.[25] Division Chief for Lower Manhattan, Peter Hayden, explains, "[w]e had a very strong sense that we would lose firefighters and that we were in deep trouble, but we had estimates of 25,000 to 50,000 civilians, and we had to try to rescue them."[26] Within fifteen minutes, approximately 235 firefighters were on scene from twenty-one engine companies, nine ladder companies, four of the FDNY elite rescue teams, the Hazmat team, and two elite squad companies.[27]

When the second plane struck the South Tower seventeen minutes later, thousands of first responders were already on site working to evacuate the WTC.[28] The South Tower collapsed approximately one hour later—it took only ten seconds for the tower to become a pile of rubble and dust.[29] The North Tower fell thirty minutes after the South

---

http://ia600805.us.archive.org/29/items/WorldTradeCenterStacMeetingPresentation-Cancer/WardWTCSTAC_JDedit.pdf [hereinafter Petition on Cancer]. The categories were based in part on the work of Lioy et al. *See* Paul J. Lioy et al., *The World Trade Center Aftermath and Its Effects on Health: Understanding and Learning through Human-Exposure Science*, 40 ENVTL. SCI. & TECH. 6876, 6878-85 (2006).

[20] Petition on Cancer, *supra* note 19.

[21] COMMISSION REPORT, *supra* note 8.

[22] Petition on Cancer, *supra* note 19.

[23] *Id.*

[24] COMMISSION REPORT, *supra* note 8 at 9.2. The attack on the North Tower was at 8:46 a.m

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] COMMISSION REPORT, *supra* note 8 at 9.2. It collapsed at 9:58 a.m.

Tower collapsed.[30] From that point forward, thousands of firefighters, police officers, and Port Authority of New York and New Jersey personnel began working twenty-four hour shifts at Ground Zero.[31]

The dust cloud began settling approximately twenty-four hours after the collapse.[32] As rescue efforts intensified, people were exposed to this re-suspension of dust, smoke, and debris—these individuals are members of Category Two.[33] Members include professional and volunteer rescuers, members of the outdoor and indoor cleanup crews, and the residents and workers located downwind of Ground Zero and in the Financial District.[34] Category Two also covers the healthcare workers, members of the press, and city officials who continuously accessed the Pile in the first two weeks.[35] Many of these individuals were present at Ground Zero within twenty-four hours of the attack, and therefore also qualify as members of Category One.[36]

During the crucial Category One and Category Two exposure periods, the Environmental Protection Agency (EPA) did not collect dust and debris samples, nor did they compile data on the air-quality.[37] With the exception of asbestos testing, pollutant and toxin sampling did not begin until September 16, 2001.[38] Even after the EPA began measuring for pollutants, the benchmarks applied to determine any potential health risks were inappropriate because they could not provide an accurate assessment.[39] At the time, health-based benchmarks for an intense, short-term but highly toxic exposure did not exist; without established predictive factors, the EPA estimated the potentiality of

---

[30] *Id*.

[31] *See id.*; *see also 9/11: Ten Years Later*, *supra* note 1.

[32] Petition on Cancer, *supra* note 19.

[33] *Id*.

[34] *Id*.

[35] *See* Jean Macchiaroli Eggen, *Toxic Torts at Ground Zero*, 39 ARIZ. ST. L.J. 384, 392-93 (2007) [hereinafter Eggen Ground Zero]; *see also* Steven Levin et al., *Health Effects of World Trade Center Site Workers*, 42 J. INDUS. MED. 545, 545 (2002).

[36] *Id.;* Petition on Cancer, *supra* note 19.

[37] Petition on Cancer, *supra* note 19.

[38] OFFICE OF INSPECTOR GENERAL, REPORT NO. 2003-P-00012, EPA'S RESPONSE TO THE WORLD TRADE CENTER COLLAPSE: CHALLENGES, SUCCESSES, AND AREAS FOR IMPROVEMENTS, 11 (2003), *available at* http://www.epa.gov/oig/reports/2003/WTC_report_20030821.pdf [hereinafter EPA 2003 Response].

[39] *Id*.

harm using the benchmarks created for lifetime exposure.[40] Equally problematic was the fact that more than one toxin was released at Ground Zero—the EPA's benchmarks applied only to single-toxin exposure and could not accurately predict risk of harm associated with the combined effect of the various pollutants.[41] Instead of releasing estimated risks, the EPA made no statements regarding the potential health harm of spending longer than one week on the Pile; this decision deprived members of Category One and Category Two of important health information.[42]

The final category, Category Three, is comprised of persons exposed to the re-suspension of dust and smoke in the weeks and months following the attack.[43] This population includes first responders who had been working at Ground Zero since 9/11, as well as the clean-up and recovery workers who arrived in the subsequent weeks.[44] Category Three members were heavily involved in all aspects of debris removal, some reported spending as many as 900 hours on-site.[45] Recovery workers also handled the material at marine transport points and at the Fresh Kills Landfill in Staten Island, the final deposit point of all WTC wreckage and debris.[46] Whether hauling material from the Pile to the deposit points or demolishing the damaged buildings in the WTC complex, Category Three workers were continuously on-site through December of 2001.[47]

---

[40] *Id*.

[41] *Id*. at 10-12.

[42] *Id*.

[43] Petition on Cancer, *supra* note 19, at 12.

[44] *Id*. *See also* Eggen Ground Zero, *supra* note 35, at 387-89.

[45] *Q&A: Anthony DePalma, Environment and Conservation Reporter*, N.Y. TIMES, *available at* http://www.nytimes.com/ref/nyregion/depalma_qa.html (citing the statement of Reggie H, a first responder who reported spending over 900 hours at the Fresh Kills Landfill and also reported a diagnosis of thyroid cancer and multiple myeloma)[hereinafter *DePalma Q&A*]. *See* Eggen Ground Zero, *supra* note 35, at 387-89.

[46] *See* Eggen Ground Zero, *supra* note 35, at 388.

[47] *See id*.; *see also* EPA 2003 Response, *supra* note 38, at 35-36.

During the clean-up and recovery process, OSHA officials coordinated the dust suppression efforts.[48] However, the STAC declared their efforts insufficient—recovery and cleanup workers did not even have respiratory protection during the process.[49] Debris was transported in open-top trucks and barges, only occasionally using tarps to cover the debris.[50] While New York City officials and the National Guard set up wash stations to wet-down the debris before leaving Ground Zero, reports differ regarding whether or not these procedures were consistently followed.[51]

Category Three also encompasses the individuals living and working in the area surrounding Ground Zero.[52] This includes an estimated 19,000 students, who were more likely susceptible to inhaling the dust because "[c]hildren inhale more air as compared to their body size than adults do' and 'they are close to the ground, which brings them in closer contact with higher concentrations of dust.'"[53] Acknowledgment of exposure and the risk of potential harm to Category Three populations has been the source of considerable controversy.[54] Often frustrated by a lack of information, many residents

---

[48] *See* EPA 2003 Response, *supra* note 38, at 35-36. The majority of asbestos-containing materials were found during the removal of the basement remnants of WTC Building 6. Nine of the 12 samples contained asbestos levels greater than 1%. A spot sample of pipe wrap from WTC 6 contained sixty-six percent amosite asbestos (often considered more harmful than chrysotile asbestos). *Id.* at 36.

[49] Petition on Cancer, *supra* note 19.

[50] *See* EPA 2003 Response, *supra* note 38, at 37-38.

[51] *Id.* at 37-38 & 37 n.12.

[52] *See* Eggen Ground Zero, *supra* note 35, at 388-89.

[53] *Id.* at 388-89 n.24.

[54] Ronald Spadafora, *Firefighter Safety and Health Issues at the World Trade Center Site*, 42 AM. J. INDUST. MED. 532, 533 (quoting John Henshaw, Assistant Secretary of Labor, OSHA). Congressman Jerrold Nadler has publicly fought against the exclusion of residents living north of Canal Street and in Brooklyn from the WTC Health Registry:

> I don't care who decided, what was that based on other than arbitrary ruling? Was there a Star Trek type force field or a 3,000 foot high wall at Canal Street that prevented the toxins from going north of Canal Street or for that matter across the East River into Brooklyn? Do we have any scientific basis for believing that a registry with that geographic boundary has any validity at all?

See Assessing September 11th Health Effects: Hearing Before the Subcomm. On National Security, Emerging Threats and International Relations of the H. Comm. on Government Reform, 108th Cong. 24-25 (2004) [hereinafter *Assessing September 11th Health Effects*], *available at* http://www.gpo.gov/fdsys/pkg/CHRG-108hhrg98999/pdf/CHRG-108hhrg98999.pdf (statement of Rep. Jerrold Nadler, Congressional Representative for the 8th District of New York during the Testimony of John Howard, Director, National Institute for Occupational Safety and Health). The boundary was set by the CDC, ATSDR, and New

questioned the area's safety:

> I, too, wonder about possible health consequences for people who were in the area on 9/11 and returned to work the following week. I was on park row when the first building fell, and returned to work each day for months to a desk covered in grey dust. The ruins of the WTC were trucked to and loaded onto barges across the street from my office for months. My apartment, just above 14th street, was coated for weeks with a green, slimy dust. Why has no one even spoken about the possible effect on those who work downtown?[55]

As evidenced above, returning to normal life after 9/11 was hampered by the lack of professional assistance in cleaning private homes and businesses. Unlike the professional recovery process at Ground Zero, described by OSHA's Assistant Secretary of Labor as "potentially the most dangerous workplace in the United States," area residents were personally responsible for cleaning their indoor spaces.[56] The EPA delegated responsibility for indoor air safety to the City of New York and did not assume responsibility for the cleanup of private residences until May of 2002.[57] The EPA and the City of New York were heavily criticized for their inaction and inattention to the homes and businesses in Lower Manhattan, and the full extent of the harm to area residents and workers will likely be unknown for many years come.[58]

2. Assessment of the Toxins

The first responders serving at Ground Zero unknowingly placed their short-term and their long-term health in jeopardy.[59] On September 18, 2001, EPA administrator Christine Todd Whitman falsely stated that the New York City and Washington D.C. air was safe to breathe.[60]

York City based on information provided by the EPA, NASA, and ATSDR. *Id.*

[55] *DePalma Q&A*, supra note 45(citing a comment from "Cynthia").

[56] Spadafora, *supra* note 54, at 533.

[57] Eggen Ground Zero, *supra* note 35, at 400-02.

[58] *Id. See* Petition on Cancer, *supra* note 19.

[59] *See* Sharon E. Perlman et al., *Short-term and Medium-term Health Effects of 9/11*, 378 THE LANCET 925, 925, 927-31 (noting the strong evidence for associations between exposure and respiratory illness, sarcoidosis, and gastrointestinal disease).

[60] EPA 2003 RESPONSE, *supra* note 38. A portion of the press release is as follows:

We are very encouraged that the results for our monitoring air quality and drinking water conditions in both New York and near the Pentagon show that the public in these areas is not being exposed to excessive levels of asbestos or other harmful substances. Given the scope of the tragedy from last week, I am glad to reassure the people of New York and

Statements of this nature continued in the weeks following 9/11—yet these statements were made prior to testing for chemicals (other than asbestos), before any indoor air-quality data existed, and without policies and procedures for evaluating the results of such tests.[61]

Once testing began, experts surmised that the Pile released toxins for at least six weeks.[62] Speaking of the various types of pollutants, chemical engineering professor Thomas Cahill of the University of California at Davis noted, "[f]or each of these classes of pollutant, we recorded the highest levels we have ever seen in over 7,000 measurements we have made of very fine air pollution throughout the world, including Kuwait [during the 1991 Gulf War oil fires] and China."[63]

The sudden collapse of the Twin Towers resulted in the simultaneous release of several classes of toxins into the atmosphere, including seventy known and potential carcinogens; fifteen of these toxins definitively cause cancer in humans, and the remaining toxins are listed as either "reasonably anticipated" to cause cancer or "probable and possible carcinogens."[64] The most common classes are discussed in the following Sections, each independently, as every toxin maintains its own risk of harm.

Washington, DC, that their air is safe to breathe and their water is safe to drink.

Press Release, EPA, Whitman Details Ongoing Agency Efforts to Monitor Disaster Sites, Contribute to Cleanup Efforts (Sept. 18, 2001), *available at* http://yosemite.epa.gov/opa/admpress.nsf/d2a3eb622562e96b85257359003d4809/ed368f43303656488525744c00039488!OpenDocument.

[61] *See* Susan Ferraro, *EPA Chief Says Water, Air are Safe*, NYDAILYNEWS.COM, Sept. 14, 2001, *available at* http://articles.nydailynews.com/2001-09-14/news/18361409_1_ground-zero-christie-whitman-safe; *see also* EPA STATEMENT, EPA REGION II Press Release 3, January 17, 2002. *See generally* EPA 2003 Response, *supra* note 38.

[62] John Herzfeld, *Study Finds World Trade Center Debris Pile Emitted Dangerous Fine Particles for Weeks*, 18 TOXICS L. REP. 938, 939 (2003) (referencing Prof. Thomas Cahill of Univ. of Cal. at Davis).

[63] *Id*. (quoting Thomas Cahill).

[64] WORLD TRADE CENTER SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) RECOMMENDATION ON PETITION 001, April 2, 2012, *available at* http://www.cdc.gov/niosh/topics/wtc/pdfs/WTC_STAC_Petition_001.pdf [hereinafter 2012 Recommendation].

a) Asbestos

Like many carcinogens, cancer caused by asbestos exposure can take years to manifest—hence, it is often used as the classic example of a latent toxic illness.[65] Given its commonality in building materials, asbestos was the first toxin tested for by the EPA in the days following 9/11, and the asbestos levels were found to be higher than those deemed safe by the EPA. In a draft of a press release prepared for distribution on September 16, 2001, the EPA stated:

> Seven debris and dust samples taken Thursday, showed levels of asbestos ranging from 2.1 percent to 3.3 percent. EPA views a 1 percent level of asbestos as the definition for asbestos-containing material.[66]

The issued press release was euphemistically modified to state:

> Debris samples collected outside buildings on cars and other surfaces contained small percentages of asbestos, [sic] ranging from 2.1 to 3.3 – slightly above the 1 percent trigger for defining asbestos material.[67]

Asbestos is most commonly associated with lung disease.[68] However, asbestos is a known carcinogen and numerous clinical and epidemiological studies have established causation between exposure and the development of cancers, most notably mesothelioma.[69] Jean Macchiaroli Eggen, a leading toxic tort expert, has conducted extensive research on the WTC asbestos exposure and aptly summarizes the issue as follows:

> With regard to the asbestos content of WTC dust, several debates have ensued over its hazardous qualities. First, questions have arisen about the accuracy of the exposure estimates for the various populations. Because the amounts have varied depending upon location and time of sampling, data regarding exact exposures is nonexistent, and no clear parameters are available for generalizing to larger populations or different locations. Second, although longer asbestos fibers have been deemed to be more carcinogenic than

---

[65] Jean Macchiaroli Eggen, *Clinical Medical Evidence of Causation in Toxic Tort Cases: Into the Crucible of Daubert*, 38 HOUS. L. REV. 369, 424 (citing Borel v. Fibreboard Paper Prods. Corp. 493 F.2d 1076, 1083 (5th Cir. 1973)).

[66] *See* EPA 2003 Response *supra* note 38, at 16-17.

[67] *Id.*

[68] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR ASBESTOS § 1.5, 5-6 (2001), *available at* www.atsdr.cdc.gov/toxprofiles/tp.asp?id=30&tid=4.

[69] *Id.*

> shorter fibers, a risk of serious illness exists for exposure to all types of asbestos.[70]

Sprayed as a fireproof coating during construction, the asbestos detected in and around Ground Zero came directly from the steel skeleton of the Twin Towers.[71] Experts conclude that recovery workers had unpredictable, intermittent exposure to asbestos, mostly the result of moving steel beams.[72]

Since 9/11, there has been some debate as to whether or not the exposure was prolonged enough to cause harm.[73] EPA representatives and several scientists have asserted that there are no health benchmarks for high-level asbestos exposure, and that exposure is not harmful if only for a limited duration.[74] However, many other scientists and physicians disagree with this supposition; instead, they argue that the asbestos at Ground Zero was unique because it was pulverized into ultra-fine particles.[75] Because a person's lungs cannot eliminate particles of this size, the variable of temporal exposure is negated and even short-term exposure may be harmful.[76] Other scientists suggest that a risk remains despite the fact that the WTC asbestos, chrysotile asbestos, has smaller fibers; while larger fibers may cause more cellular damage than their smaller counterparts, small fibers penetrate the lung at a deeper level and with greater ease.[77] As such, WTC toxic exposure experts

---

[70] Eggen Ground Zero, *supra* note 35, at 392-93 (cautioning that "no generalization can be made that the presence of smaller fibers means no threat to the health of those exposed.").

[71] Philip J. Landrigan, *The WTC Disaster: Landrigan's Response* 112 ENVTL. HEALTH PERSPECTIVE A607 (2004).

[72] *Id.*

[73] *Compare, e.g.*, *id.*, *with* R.P. Nolan et al., *Risk Assessment for Asbestos-related Cancer from the 9/11 Attack on the World Trade Center*, 47 J. OCCUPATIONAL ENVTL. MED. 817, 817-25 (concluding that the cancer risk associated with asbestos exposure for residents of Lower Manhattan is less than one case over the lifetime of the population).

[74] Memorandum from Cate Jenkins, Ph.D., Envtl. Scientist, Envtl. Prot. Agency, on World Trade Center Asbestos to Lillian Bagus, Chief, Waste Identification Branch, Office of Solid Waste, Envtl. Prot. Agency & Robert Dellinger, Director, Hazardous Waste Identification Division, Office of Solid Waste, Envtl. Prot. Agency, 1, 9 (Dec. 3, 2001), *available at* http://old.911digitalarchive.org/objects/106.pdf. *See also* EPA 2003 Response, *supra* note 38, at 11. The EPA reported that "[h]ealth-based benchmarks for short-term and acute exposures did not exist for pollutants of concern resulting from the collapse of the WTC." *Id.*

[75] Memo from Jenkins, *supra* note 74, at 9.

[76] *Id.* at 3, 9.

[77] Luz Claudio, *Environmental Aftermath*, 109 ENVTL. HEALTH PERSPECTIVE. A529, A531, A533 (November 2001) (citing Dr. Philip Landrigan, Chair of the Dep't of

concur that harm from smaller fibers cannot be discounted.[78]

b) Polycyclic Aromatic Hydrocarbons

Although asbestos is the most openly debated toxin, it was not the only dangerous toxin released from the Pile in the weeks and months following 9/11. Polycyclic Aromatic Hydrocarbons (PAHs) were released into the air when building materials and office contents, including tens of thousands of computers, were incinerated during the explosion.[79]

According to the Agency for Toxic Substances & Disease Registry (hereinafter ATSDR), PAHs are recognized as human carcinogens and are known to compromise the dermal, hepatic, and neurologic organ systems.[80] PAHs are also associated with fetal harm.[81] When inhaled during pregnancy, PAHs can cross the placental barrier and bind to the DNA of the fetus. [82] The Columbia Center for Children's Environmental Health conducted a study to measure the PAH fetal exposure and found that newborns of mothers who were both pregnant on 9/11 and lived within two miles of Ground Zero had higher levels of PAH in their cord blood than would normally be expected.[83] In a separate analysis of this same group of mothers, findings "suggest[] that the fetus may be 10-fold more susceptible to DNA damage than the mother, and that in-utero exposure to polycyclic aromatic hydrocarbons may disproportionately increase carcinogenic risk."[84]

Community and Preventive Medicine at the Mount Sinai School of Medicine).

[78] *Id.*

[79] Eggen Ground Zero, *supra* note 35, at 390.

[80] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR POLYCYCLIC AROMATIC HYDROCARBONS, § 1.5 at 16 (1995), *available at* www.atsdr.cdc.gov/toxprofiles/tp69.pdf. Furthermore, in animal studies, inhaling, ingesting, or topically applying PAHs caused lung cancer, stomach cancer, or skin cancer, respectively. AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXFAQS FOR PAHS (1996), *available at* www.atsdr.cdc.gov/toxfaqs/TF.asp?id=121&tid=25.

[81] *See generally* Frederica P. Perera et al., *Relationships Among Polycyclic Aromatic Hydrocarbon-DNA Adducts, Proximity to the World Trade Center, and Effects on Fetal Growth*, 113 ENVTL. HEALTH PERSPECTIVE 1062 (2005). An "adduct" is formed in the cord blood and provides a biologic measure of toxin exposure. *Id.*

[82] *Id.*

[83] *Id.*

[84] *See generally* Frederica P. Perera et al., *DNA Damage From Polycyclic Aromatic Hydrocarbons Measured by Benzo[a]pyrene-DNA Adducts in Mothers and Newborns From Northern Manhattan, the World Trade Center Area, Poland, and China*, 14 CANCER

c) Lead, Mercury & Cadmium

Lead, mercury, and cadmium were also detected in the pulverized computers.[85] Lead, found in the solder on the computers' circuit boards, is well established as a toxic substance, having been designated as a harmful substance by the EPA in 2000.[86] Lead exposure is associated with nervous system disorders and poor blood levels in children, and it causes latent health effects because it remains in a person's bones long after exposure.[87] It is also a possible human carcinogen.[88]

d) Polychlorinated Biphenyls

Like PAHs and lead, the office content also produced polychlorinated biphenyls (PCBs) and chlorodifluoromethane, which were present in much of the electrical equipment.[89] PCBs are known to affect the liver, endocrine system, immune system, reproductive system, and neurological system.[90] The EPA, the International Agency for Research on Cancer, and the ATSDR have stated that PCBs are "probably carcinogenic to humans." The limited studies available have associated PCBs with cancer of the liver and biliary tract.[91]

e) Benzene

Benzene, a toxin associated with combustion events, was released following the ignition of the towers' plastics and polyvinyl chloride.[92] A highly dangerous toxin, even brief exposure to benzene will cause

---

EPIDEMIOLOGY BIOMARKERS & PREVENTION 709, 709 (2005).

[85] Eggen Ground Zero, *supra* note 35, at 390 (citing Phil Mulkins, *WTC Mercury Came from Computers, Lights*, TULSA WORLD (Jan. 12, 2002), at 2).

[86] Eggen Ground Zero, *supra* note 35, at 395 (citing 42 U.S.C. § 48529d (2000) (authorizing the EPA to set regulations on lead-based paint).

[87] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR LEAD § 2.2 (2007), *available at* www.atsdr.cdc.gov/toxprofiles/tp13.pdf.

[88] Eggen Ground Zero *supra* note 35, at 395.

[89] *Id.* at 391.

[90] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR POLYCHLORINATED BIPHENYLS § 2.2 (2000), *available at* http://www.atsdr.cdc.gov/toxprofiles/tp17.pdf.

[91] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXFAQS FOR POLYCHLORINATED BIPHENYLS (2001), *available at* www.atsdr.cdc.gov/toxfaqs/tf.asp?id=140&tid=26.

[92] Petition on Cancer, *supra* note 19.

serious health effects and possibly death; the acute health effects include dizziness, stomach irritation, rapid heart rate, and other neurological and cognitive symptoms, with the possibility of convulsions and coma.[93]

Benzene has also been designated a known human carcinogen by the U.S. Department of Health and Human Services, the EPA, and the International Agency for Cancer Research.[94] Long-term exposure disrupts blood cell production, and is associated with the development of leukemia.[95] Epidemiological studies have also established a causal relationship between a person's occupational exposure to benzene (and benzene-containing solvents) and the development of acute myelogenous leukemia.[96]

According to the National Institute of Occupational Safety and Health ("NIOSH"), unsafe levels of benzene were detected in and around the Pile following 9/11.[97] The Minimal Risk Level for acute inhaled exposure to benzene is 0.009 ppm, 0.004 ppm for intermediate inhalation, and 0.003 ppm for chronic inhalation.[98] Researchers estimate that the benzene concentrations released during the combustion at Ground Zero were in excess of 100 ppb.[99] When spot measurements were taken from the Pile following 9/11, benzene levels were recorded in excess of 1ppm.[100] Measurable benzene spikes continued to occur well into 2002.[101]

---

[93] Eggen Ground Zero, *supra* note 35, at 396.

[94] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR BENZENE § 1.5 (2007), *available at* www.atsdr.cdc.gov/toxprofiles/tp3.pdf.

[95] *Id*.

[96] *Id*. at § 2.2. "These studies are 'generally limited by confounding chemical exposures and methodological problems, including inadequate or lack of exposure monitoring and low statistical power (due to small number of cases), but a consistent excess risk of leukemia across studies indicates that benzene is the causal factor.'" *Id*. at § 3.2.1.7.

[97] Paul J. Lioy & Panos Georgopoulos, *The Anatomy of the Exposures that Occurred Around the World Trade Center Site: 9/11 and Beyond*, 1076 ANNALS OF THE N.Y. ACAD. OF SCIENCES 54, 69 (2006). *See* Claudio, *supra* note 78, at A530.

[98] BENZENE TEACH CHEMICAL SUMMARY, U.S. ENVTL. PROT. AGENCY § VI (2009), *available at* http://www.epa.gov/teach/chem_summ/BENZ_summary.pdf.

[99] Lioy & Georgopoulos, *supra* note 97, at 69 (2006). *See* Claudio, *supra* note 77, at A530.

[100] *Id.*

[101] Robin Herbert et al., *The World Trade Center Disaster and the Health of Workers: Five-Year Assessment of a Unique Medical Screening Program*, 114 ENVTL. HEALTH PERSPECTIVES 1853, 1853 (2006).

B. WTC Health Conditions: Ten Years Later

> Even with the most advanced science, we do not yet know what the wicked concoction of dust, ash, and toxic materials did when it landed deep inside the heaving lungs of responders. We don't know how it short-circuited their immune systems or toyed with their genes. And we won't know for years if it combined with other poisons to speed up or exacerbate carcinogenic attacks on the bodies of people who were coated with it.[102]

Although insufficient time has passed for some diseases to manifest, uncontroverted evidence proves that WTC exposure is associated with chronic physical illnesses, including cardiovascular disease, hematological malignancies with short latency periods, and respiratory disease.[103] Within forty-eight hours of the attack, 90 percent of firefighters and EMS workers reported respiratory symptoms—symptoms which later became labeled the "World Trade Center Cough."[104] In an effort to document the health consequences associated with Pile exposure, the Fire Department of New York (FDNY) created the WTC Medical Screening and Treatment Program in October of 2001 and evaluated over 10,000 first responders during the program's first four months.[105] This program provided excellent comparative data because the FDNY had access to the records of their firefighters' pre-9/11 health examinations.[106] Federally funded by the Center for Disease Control and Prevention ("CDC") and NIOSH, this program screened well over 14,000 FDNY employees by 2007.[107]

---

[102] ANTHONY DEPALMA, CITY OF DUST: ILLNESS, ARROGANCE, AND 9/11, 5 (1st ed. 2010).

[103] *See* Hannah T. Jordan et al., *Mortality Among Survivors of the Sept 11, 2001, World Trade Center Disaster: Results from the World Trade Center Health Registry Cohort*, 328 THE LANCET 879, 879 (2011).

[104] David J. Prezant et al., *Cough and Bronchial Responsiveness in Firefighters at the World Trade Center Site*, 347 NEW ENGLAND J.MED. 806, 806-15 (2002). Lisa Zamosky, *A Legacy of Illnesses from 9/11*, LATIMES.COM (Sept. 5, 2011), *available at* http://articles.latimes.com/2011/sep/05/health/la-he-911-wtc-cough-20110905.

[105] *Long Term Health Impacts from September 11: A Review of Treatment, Diagnosis and Monitoring Efforts, Hearing Before the Senate Comm. On Health, Education, Labor, and Pensions* 110th Cong. 110-197 (Mar. 21, 2007) (statement of Kerry Kelly, Chief Medical Officer, New York City Fire Department).

[106] *Id.*

[107] *Id.*

In 2002, the CDC helped fund Mount Sinai School of Medicine's Center for Occupational Environmental Medicine.[108] The Federal Occupational Health Service followed suit in 2003 in order to screen the health of federal responders.[109] In 2003, The World Trade Center Health Registry was created in order to centralize the health information collected by these various agencies.[110] By 2004, the Registry obtained baseline data on 14,665 residents, 2,646 students and school workers, 30,665 responders, and 43,487 others.[111]

The health information collected demonstrated the seriousness of WTC exposure, especially regarding respiratory function.[112] For example, within one year of 9/11, dramatic declines in lung function were detected among firefighters, including nonsmokers.[113] In testimony before Congress, FDNY Chief Medical Officer, Kerry J. Kelly, testified:

> When we compared our first responders' pulmonary functions during the first year after 9/11 to the annual change in pulmonary functions in the five years prior to 9/11, we observed a significant decline in those functions, with the *magnitude of the decline correlating to the member's initial time of arrival at Ground Zero*.[114]

Seven years after 9/11, quadruple the number of firefighters had below-normal lung function for their respective age groups.[115] The rate of decline in lung capacity is eleven times greater than the average rate of decline associated with the normal process of aging.[116]

---

[108] *Assessing September 11th Health Effects*, *supra* note 54, at Prepared Statement of John Howard, 20-21. This program screened over 15,000 individuals by 2006. Eggen Ground Zero, *supra* note 35, at 401.

[109] Eggen Ground Zero, *supra* note 35, at 401.

[110] *Id.* at 402.

[111] *Progress Since 9/11: Protecting Public Health and Safety Against Terrorist Attacks: Hearings Before the Subcomm. on National Security, Emerging Threats and International Relations of the H. Comm. on Government Reform*, 109th Cong. 883-84 (2006) [hereinafter *Progress Since 9/11*](testimony of Kerry J. Kelly, FDNY Chief Medical Office).

[112] *See id.*

[113] WORLD TRADE CENTER MEDICAL WORKING GROUP OF NEW YORK CITY, 2010 ANNUAL REPORT ON 9/11 HEALTH 3 (2010) [hereinafter WTC ANNUAL REPORT].

[114] *Progress Since 9/11*, *supra* note 111, at 80-81 (emphasis added).

[115] T.K. Aldrich, et. al., *Lung Function in Rescue Workers at the World Trade Center After Seven Years*, 362 NEW ENGLAND J. MED 1263, 1263 (2010).

[116] *Progress Since 9/11*, *supra* note 111, at 81.

As of 2010, approximately 50,000 rescue and recovery workers, New York City residents, and office workers in the New York area have enrolled in 9/11 health programs, most often exhibiting asthma, sinus problems, and loss of lung function.[117] Additionally, multiple studies have confirmed a causal link between WTC exposure and the development of sarcoidosis and gastroesophageal reflux symptoms.[118]

1. Latent-Illness Development

Illnesses with short latency periods have already been positively linked to WTC exposure.[119] However, cancer from toxic exposure takes years to manifest because it has a long latency period—only with the ten-year anniversary behind us are we beginning to see this type of disease development.[120]

Published almost exactly ten years after 9/11, the 2011 Zeig-Owens study is the first study causally linking exposure to WTC toxic dust with the development of cancer.[121] In this study, researchers evaluated the association between 9/11 exposure and the development of cancer within seven years of 9/11.[122] According to the study's lead author, firefighters with Ground Zero exposure have a 19 percent higher risk of developing cancer than their colleagues who were not exposed to the toxic fallout.[123]

---

[117] WTC ANNUAL REPORT, *supra* note 113, at 3.

[118] *Id.* at 4. *See, e.g.*, Lorna E. Thorpe, *Health Consequences of the World Trade Center Disaster: A 10 Anniversary Perspective* 306 JAMA 1133, 1133-34 (2011).

[119] *See* Hannah T. Jordan et al., *Mortality Among Survivors of the Sept 11, 2001, World Trade Center Disaster: Results from the World Trade Center Health Registry Cohort*, 328 THE LANCET 879, 879-81 (2011).

[120] *See id.* at 879.

[121] *See, e.g.*, Rachel Zeig-Owens et al., *Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks; An Observational Cohort Study*, 378 THE LANCET 898, 903-04 (2011).

[122] *Id.*

[123] *Id.* at 904 ("This excess of cancer cases remained after correction for possible surveillance bias and after classification of cancers occurring only in 2005 or later as potentially related to WTC-exposure"). In an interview with CNN, Dr. David Prezant, the study's lead author, further explained, "'We excluded cancers that might have been diagnosed early (that may have existed before the attack) . . . and we still see a 19% increase . . . When we put those cancers back in, we see a 32% increase.'" Stephanie Smith, *Firefighters Responding to 9/11 at Increased Cancer Risk*, CNN (Sept. 2, 2011), *available at* http://www.cnn.com/2011/HEALTH/09/01/911.firefighters.cancer/index.html.

Although this is a critical first study, the research team acknowledges that there is more work ahead:

> We remain cautious in our interpretation of these findings because the time interval since 9/11 is short for cancer outcomes, the recorded excess of cancers is not limited to specific sites, and the biological plausibility of chronic inflammation as a possible mediator between WTC-exposure and cancer outcomes remains speculative.[124]

Dr. Philip Landrigan, director of the September 11 Treatment, Monitoring, and Research Program at Mount Sinai Medical Center summarized the need for continued research: "[w]e know full well that the responders were exposed to a whole soup of carcinogens . . . We're all looking for a signal today, but we're anticipating that the signal will get stronger in the years ahead."[125]

Despite the need for a cautious outlook, many families of fallen firefighters see this study as much needed validation.[126] The wife of deceased New York City firefighter and multiple myeloma victim, Roy Chelsen, commented: "[i]n time, research will prove that [his death was caused by chemicals at Ground Zero], but in medicine, everything is evidence-based. He wouldn't have died at 51, that's for sure."[127]

2. The Financial Burden of Managing WTC-Illnesses

Prior to the enactment of the Zadroga Act, the availability of funding for World Trade Center Health Programs was both intermittent and unpredictable.[128] For example, some grants would cover funding for physical conditions, but not mental health conditions, while others would cover monitoring, but not treatment. Notably, several NIOSH grants awarded to the FDNY and Mt. Sinai Programs covered health

---

[124] Zeig-Owens et al., *supra* note 121, at 904.

[125] Sydney Ember, *Study Suggest Higher Cancer Risk for 9/11 Firefighters*, N.Y. TIMES, A17 (Sept. 1, 2011), *available at* http://www.nytimes.com/2011/09/02/health/research/02cancer.html?_r=0.

[126] *Id.*

[127] *Id.* Trish Chelsen described her firefighter husband as a "typical Viking" prior to chemotherapy and two stem-cell transplants.

[128] *See id. See generally* LLOYD DIXON & RACHEL KAGANOFF STERN, RAND INSTITUTE FOR CIVIL JUSTICE, COMPENSATION FOR LOSSES FROM THE 9/11 ATTACKS (2004) (outlining the policies, programs, and sources of funding).

monitoring, yet excluded all treatment costs.[129]

Yet, the demand for medical care continued to rise—in 2006, the City of New York estimated the cost to evaluate and treat all those affected by the WTC attacks to be in excess of $392 million, per year, for the foreseeable future.[130] This estimate did not account for the additional cost to treat any late-emerging, chronic conditions, such as cancer, nor did the estimate include increased pension and disability costs associated with the 9/11 attacks.[131] As such, the financial burden of medical treatment weighs not only on families, but on the city and state governments as well.

The Zadroga Bill is desperately needed to assuage the increased burden on the FDNY and NYPD pension systems. The post-9/11 demand for accidental disability pensions is causing a "dramatic financial impact on the FDNY pension system"—conservative estimates report that the increased financial impact of 9/11-related illnesses is over $826 million.[132] This figure is based on those respiratory, musculoskeletal, and psychological-related accidental disability retirement claims made after 9/11 and before 2008.[133] Given the temporal limitations, experts estimate that the cost of WTC-associated

---

[129] WORLD TRADE CENTER HEALTH PANEL, ADDRESSING THE HEALTH IMPACTS OF 9/11: REPORT AND RECOMMENDATIONS TO MAYOR MICHAEL R. BLOOMBERG 17 n.39 (2006).

[130] *Id.* at 5.

[131] *Id.*

[132] J.K. Niles et al., *Impact of the World Trade Center Attack on Firefighter Retirement, Disabilities, and Pension Benefits*, 54 AM. J. INDUSTRIAL MEDICINE 672, 678-80 (2011). Had the WTC attack not occurred, the estimated funds necessary to cover disability retirement benefits was $926. *Id.* "Estimates based on *actual* numbers and types of retirement and *actual* over-time for these members after the WTC amounted to $1,752.8." *Id.* at 677-78.

[133] *Id.* at 679. A limited number of cancer pension claims are included in the financial analysis for the following reasons:

> Before 2006, cancer-related accidental disability retirements were awarded to active firefighters who developed a disabling cancer under the ''Cancer Bills.'' There has been no significant increase in the number of ''Cancer Bills'' awarded post-9/11, and, as a result, we excluded ''Cancer Bills'' from the financial impact analysis. However, in 2006, the ''WTC Bills'' broadened eligibility to include members developing cancer after retirement. ''WTC Bills'' granted for cancer-related illnesses have been deemed WTC-related by the FDNY Pension Board, and are, therefore, included in all analyses.

Id. Given the latent nature of cancer, an increase in WTC –related cancer would not be expected prior to 2006. John Howard, *First Period Review of Scientific and Medical Evidence Related to Career for the World Trade Center Health Program*, 2010 NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH 40 [hereinafter *First Periodic Review*].

illnesses will continue to disproportionately burden the pension system as latent illnesses manifest over time.[134]

Many non-city employees and first responders now living out-of-state receive little to no health coverage for their 9/11-related conditions.[135] For example, in the wake of 9/11, many retired FDNY firefighters returned to volunteer at Ground Zero.[136] If a retiree now lives outside of New York, treatment for a 9/11-related illness is not covered by insurance because out-of-state doctors are "out of network" for 9/11-related conditions."[137] Additionally, if a city worker is not eligible for a disability pension (e.g., he or she was part-time or temporary), his or her private insurance will not cover 9/11-associated illness because it is considered a work-related claim; therefore, any coverage linked to a health condition attributed to time spent working at Ground Zero will be denied.[138] Under the Zadroga Act, however, individuals in the above-described circumstances will be eligible for coverage through the WTC Health Program.[139]

III. INCONSISTENT HEALTHCARE FUNDING AND THE TROUBLED PATH TO THE ZADROGA ACT

In 2004, recognizing the need for continued funding, U.S. Representative Carolyn Maloney of New York introduced legislation to reopen the Victim's Compensation Fund ("VCF").[140] After this effort failed, a second attempt came in the form of the James Zadroga Act of 2006, jointly introduced by Representative Maloney and Senator Robert Menendez of New Jersey.[141] This legislation, which again failed to pass, would have reopened the VCF for those who became ill after the deadline and extended eligibility to those who were exposed later than the first ninety-six hours.[142] The bill was poignantly named for James

---

[134] *Id.* at 678.

[135] *See e.g.*, Parija Kavilanz, *Some 9/11 First Responders Get Help – and Some Don't*, CNNMONEY (Sept. 6, 2011), *available at* http://money.cnn.com/2011/09/02/news/economy/911_health_insurance/index.htm.

[136] *Id.*

[137] *Id.*

[138] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011).

[139] *Id*

[140] H.R. 5076, 108th Cong. (2004).

[141] H.R. 6045, 109th Cong. (2006); S. 3891, 109th Cong. (2006).

[142] A third failed attempt to secure funding occurred in 2006 when Representative

Zadroga, the first New York City Police officer whose death was directly attributed to the toxic chemicals at Ground Zero.[143]

A. The Zadroga Act's Namesake

Although off-duty on 9/11, Detective Zadroga returned to the city after the first plane struck the Twin Towers.[144] According to his own testimony, he arrived just after the towers collapsed, was caught in the dust cloud resulting from the collapse of Building 7, and worked securing buildings, serving in the bucket brigade, and recovering human remains.[145]

Zadroga testified:

> The dust so thick you couldn't read your partner's shield standing next to you, your eyes burning, itching, and the smell, oh, the smell. We started looking for survivors or even bodies, but the soot was so thick you couldn't tell if you were standing on a piece of steel or a human arm. The dead silence was eerie, and the dust looked as if it was snowing. . . . After being down at Ground Zero for some 20 hours over 40 hours without sleep, I headed back to the base covered from head to toe in dust and gray mud, my feet soaking wet and my eyes and skin itching and burning.[146]

Detective Zadroga was exposed to what experts have deemed the "heaviest and most dangerous dust" for over three weeks.[147] In October of 2002, his lung capacity was half of what it had been prior to 9/11; he was seriously ill by 2003 and therefore qualified under the VCF.[148] He passed away in 2004 at the age of thirty-four. After his death in 2004, the medical examiner concluded "with a reasonable degree of medical certainty that the cause of death in this case was directly related to the

---

Jerrold Nadler introduced the 9/11 Comprehensive Health Benefits Act of 2006. The bill would have amended title XVIII of the Social Security Act to provide Medicare benefits to individuals with physical and mental conditions associated with WTC exposure. However, this bill was also voted down. H.R. 6046, 109th Cong. (2006).

[143] DEPALMA, *supra* note 102, at 185.

[144] *Id.* at 181.

[145] James Zadroga, *The Pain of 9/11 & the Days After: Detective James Zadroga's Statement to the 9/11 Commission*, NEW YORK DAILY NEWS (Oct. 22, 2009) http://www.nydailynews.com/opinion/pain-9-11-days-det-james-zadroga-statement-9-11-commission-article-1.386753.

[146] *Id.*

[147] DEPALMA, *supra* note 102, at 181.

[148] *Id.* at 181-82.

9/11 incident."[149]

In 2007, Dr. Charles Hirsch, a veteran of the New York City Medical Examiner's Office, re-reviewed the autopsy report and concluded that the death was caused by the presence of cellulose and talc granulomas in his lungs, the result of self-injection of prescription drugs.[150] According to Detective Zadroga's family, he did use prescription drugs for pain relief purposes during the end of his life.

A third forensic pathologist, Dr. Michael Baden, one of the nation's leading forensic pathologists, disagreed with Hirsch's conclusion. He determined that the areas in question on the autopsy slides were packed so closely together that it was equally possible that the dust was in the alveoli and blood vessels—meaning the dust had been inhaled, not injected.[151] However, the ruling by Hirsch remained and therefore prevented Zadroga's name from being inscribed on the 9/11 memorial.[152] In October of 2008, the Commissioner of the New York City Police Department presented Distinguished Service Medals to James Zadroga's family and the families of seven other officers who had died of illness after serving at Ground Zero—the decision to do so clearly demonstrated the Police Department's position regarding the root cause of Detective Zadroga's death.[153]

The considerable disagreement associated with Zadroga's case infuriated many people, ranging from WTC first responders to members of Congress, all wondering "*what difference it made*—after all, Zadroga unquestionably had been exposed to the dust."[154] Whatever else it may have been, this conflict served as a bell-weather of what was to come the next time the issues of causation and compensation were broached.

B. H.R. 847

In 2009, Representative Maloney introduced H.R. 847, a bill to provide funding for the monitoring and treatment of Ground Zero workers; the bill once again honored Zadroga as its namesake.[155] Before its enactment in December of 2010, H.R. 847 went through seven

---

[149] *Id.* at 183.
[150] *Id.* at 230-31.
[151] *Id.* at 232-33.
[152] DEPALMA, *supra* note 102, at 237.
[153] *Id.*
[154] *Id.* at 233 (emphasis added).
[155] *Id.* at 236-38.

revisions. In its original form, the James Zadroga 9/11 Health and Compensation Act appropriated $3.2 billion dollars over the next eight years to monitor and treat WTC-exposure related illness, with New York City paying 10 percent of the costs and the federal government covering the remainder.[156] The WTC Program Administrator had authority to promulgate regulations to add an illness or health condition.[157]

> In promulgating such regulations, the WTC Program Administrator shall take into account the findings and recommendations of Clinical Centers of Excellence published in peer reviewed journals in the determination of whether an additional illness or health condition, *such as cancer*, should be added to the list of identified WTC-related health conditions for eligible WTC responders.[158]

It also set aside $4.2 billion to reopen the September 11th VCF.[159] Considerable debate ensued, with Republicans describing the bill as an "irresponsible overreach," and Democrats calling a rejection "heartless and unpatriotic." The bill fell short of the two-thirds margin required for passage on July 29, 2010.[160]

On September 29, 2010, the House passed a revised H.R. 847 by a vote of 268 to 160.[161] Two critical changes were made in order to make this possible. First, as a political compromise to ensure the Bill's passage, cancer was specifically excluded from the List, and the procedure for the addition of cancer was changed to the following:

> The WTC Program Administrator shall periodically conduct a review of all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such

---

[156] H.R. 847, 111th Cong. (2009) (as introduced by House, Feb. 4, 2009); *see also* Raymond Hernandez, *Plan to Aid 9/11 Victims is Rejected in the House*, N.Y. TIMES, July 29, 2010, at A20, *available at* http://www.nytimes.com/2010/07/30/nyregion/30zadroga.html.

[157] H.R. 847, 111th Cong. § 3012(a)(4)(A) (2009).

[158] *Id.* (emphasis added).

[159] *Id.*. *See also* Hernandez, *Plan to Aid 9/11 Victims is Rejected in the House*, *supra* note 156, at A20.

[160] Hernandez, *Plan to Aid 9/11 Victims is Rejected in the House*, *supra* note 156, at A20.

[161] Raymond Hernandez, *House Passes Measure to Help With 9/11 Health Care*, N.Y. TIMES, Sept. 30, 2010, at A32, *available at* http://cityroom.blogs.nytimes.com/2010/09/29/911-health-care-bill-passes/. Seventeen Republicans voted in favor of the bill and three Democrats were opposed. *Id.*

> evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related health conditions. The WTC Program Administrator shall conduct the first review under this subparagraph not later than 180 days after the date of the enactment of this title.[162]

Second, Title III was added as a means to fund the program, imposing a limitation on treaty benefits for certain deductible payments under Section 894 of the Internal Revenue Code.[163] The bill was received in the Senate on September 29, 2010. Threatening a filibuster, Senate Republicans rejected a procedural move, which would have brought the bill to a vote in early December 2010.[164] In response, Senate Democrats reduced the cost and proposed Amendment 4923, which would fund the project with two foreign tax increases: (1) increased visa fees[165] and (2) a two percent tax on foreign contractors.[166]

C. Jon Stewart and Shepard Smith Step In

Seven significant revisions, including the political compromise to exclude cancer, were not enough to overcome the filibuster.[167] Political analysts agree that Jon Stewart and Shepard Smith were largely responsible for the passage of the Act.[168] When it looked as though the

---

[162] H.R. 847, 111th Cong. § 3312(a)(5)(A) (as passed by House, Sept. 29, 2009). *See* Anemona Hartocollis, *Not Enough Evidence to Link 9/11 & Cancer, a Federal Report Says*, N.Y. TIMES (July 27, 2011), at A20.

[163] H.R. 847, 111th Cong. § 301(d)(1):

> In the case of any deductible related-party payment, any withholding tax imposed under chapter 3 (and any tax imposed under subpart A or B of this part) with respect to such payment may not be reduced under any treaty of the United States unless any such withholding tax would be reduced under a treaty of the United States if such payment were made directly to the foreign parent corporation.

[164] Raymond Hernandez, *Republicans Block U.S. Health Aid for 9/11 Workers*, N.Y. TIMES Dec. 9, 2010, at A28, *available at* http://www.nytimes.com/2010/12/10/nyregion/10health.html (quoting Mayor Bloomburg criticizing Republicans for their "wrongheaded political strategy").

[165] H.R. 847, 111th Cong. § 302 (2009).

[166] *Id.* at § 301.

[167] *Id.;* Hartocollis, *10 Years and a Diagnosis Later, 9/11 Demons Haunt Thousands*, *supra* note 4.

[168] *See* Onika K. Williams, *How Jon Stewart and Lady Gaga Made Congress Less Lame: The Impact of Social Media on the Passage of Bills Through the "Lame Duck" Session of the 111th Congress and Beyond*, 87 IND. L.J. SUPP. 17, 17-19 (2012); *see also* Ari Shapiro, *Jon Stewart's Latest Act: Sept. 11 Responders Bill*, NPR (Dec. 26, 2010), *available at* http://www.npr.org/2010/12/26/132310870/jon-stewarts-latest-act-sept-11-responders-bill.

bill would not be passed, an unexpected champion emerged: the host of The Daily Show, Jon Stewart. The evening after Senate Republicans blocked the Bill, Stewart devoted his entire show to the Zadroga Bill.[169] Foregoing his usual satire, Stewart blasted Senate Republicans for blocking the bill, calling it "an outrageous abdication of our responsibility to those who were most heroic on 9/11."[170] He criticized CBS, NBC, ABC, and Fox News for failing to even mention the Zadroga Bill and interviewed a panel of New York City First Responders, all of whom have cancer, about their reactions to the filibuster.[171]

The next day, Fox News anchor Shepard Smith agreed with Stewart:

> Who's going to hold these people's feet to the fire? . . . Do people know what this city was like that day? People were . . . covered in ash, they were running for their lives, they were crying, their family members were dead. And these people ran to Ground Zero to save people's lives. And we're not going to even give them medicine for the illnesses they got down there? It's disgusting, it's a national disgrace, it's a shame and everybody who voted against should have to stand up and account for himself or herself.[172]

When many Senate Republicans promised to block legislation until the stalemate over tax cuts resolved, Smith proceeded to name, on air, those lawmakers who refused to explain on air why they were blocking the Bill.[173] He then questioned Senator Tom Coburn's motive for

---

[169] *Senate Republicans Block 9/11 Health Bill*, REUTERS (Dec. 9, 2010, 8:33 PM), *available at* http://www.reuters.com/article/2010/12/10/us-usa-congress-firefighters-idUSTRE6B903120101210. *The Daily Show with Jon Stewart: 9/11 First Responders React to Senate Filibuster* (Comedy Central television broadcast Dec. 16, 2010), *available at* http://www.thedailyshow.com/watch/thu-december-16-2010/9-11-firstresponders-react-tothe-senate-filibuster [hereinafter Daily Show 1].

[170] Daily Show 1, *supra* note 169.

[171] *Id*. Only Al Jazeera covered the Bill.

[172] *Shepard Smith Unloads on Blockers of 9/11 Responders Bill: 'How Do They Sleep At Night?'* HUFFINGTON POST (Dec. 18, 2010), *available at* http://www.huffingtonpost.com/2010/12/18/shepard-smith-911-first-responders-bill_n_798625.html.

[173] *See, e.g.*, Colby Hall, *Shep Smith Calls Out Sen. Coburn Over His Threat to Block 9/11 First-Responders Bill*, MEDIATE.COM (Dec. 21, 2010), *available at* http://www.mediaite.com/tv/shep-smith-calls-out-sen-coburn-over-911-first-responders-bill/.

vowing to block the bill until the Congressional session ended.[174] The advocacy of Stewart and Shepard accomplished what nine years of legislative skirmishing could not; within one week, the Zadroga Bill was passed.[175]

IV. AN OVERVIEW OF THE WORLD TRADE CENTER HEALTH PROGRAM

The passage of the Zadroga Act ensures a steady flow of funding for the medical monitoring and treatment of WTC-related health conditions through 2016, if funding remains available.[176] As enacted, the Zadroga Act sets aside $4.3 billion to compensate, monitor, and treat both responders and survivors of the 9/11 attacks through the establishment of the WTC Health Program.[177] Title II re-opens the VCF to provide economic and non-economic compensation to eligible responders and survivors; the Act allots $2.775 billion for new VCF claims, of which $875 million may be spent in the first five years.[178]

---

[174] *Id. See also* Phil Milazo, *How Jon Stewart & Shep Smith Got the 9-11 First Responders Bill Passed*, MILAZZ ON POLITICS (Jan. 24, 2011), http://milazzonpolitics.com/2011/01/24/how-jon-stewart-shep-smith-got-the-9-11-first-responders-bill-passed/ (including links to the video of Shepard Smith calling out Tom Coburn). Shepard Smith stated on air:

> This is the picture of Senator Tom Coburn, Republican from Oklahoma . . . he is the man who is trying to slow this down or block it, so that the necessary funding for the illnesses of the first responders who made it to Ground Zero to try to save lives on the day that America changed, remember? This is the senator who is vowing to block it, so that it doesn't make it through: Senator Tom Coburn, Republican of Oklahoma.

Id.

[175] The Bill passed on December 22, 2011. Jonathan Karl & Matthew Jaffe, *EXCLUSIVE: Senate Strikes Deal on 9/11 First Responders Bill*, ABC NEWS (Dec. 22, 2010), *available at* http://abcnews.go.com/Politics/exclusive-senate-strikes-deal-911-responders-bill/story?id=12459170.

[176] *See generally* James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011).

[177] *Id.* at § 205*;* Hartocollis, *10 Years and a Diagnosis Later, 9/11 Demons Haunt Thousands*, *supra* note 4, at A20.

[178] Zadroga Act § 205. A more comprehensive analysis of Title II is beyond the scope of this Article.

A. World Trade Center Health Program Objectives and Operations

Title I of the Zadroga Act expands the Public Health Service Act, adding "Title XXXIII – WORLD TRADE CENTER HEALTH PROGRAM" to the end of the Act.[179] Section 3301 sets forth two program objectives: (1) to provide medical monitoring and treatment benefits to eligible emergency responders and recovery and cleanup workers (including federal employees) who responded to the terrorist attacks on the World Trade Center, and (2) to provide initial health evaluation, monitoring, and treatment benefits to eligible residents and other building occupants and area workers who were directly impacted and adversely affected by such attacks.[180] Additionally, the WTC Health Program Administrator, in consultation with the WTC Scientific/Technical Advisory Committee, or STAC, must conduct or support research on conditions, diagnoses, and the treatment of WTC-related health conditions.[181] The research must include epidemiologic studies on WTC-related health conditions or emerging conditions among enrolled WTC responders and eligible survivors.[182]

The WTC Health Program is not an insurance program nor does it require any cost sharing on the part of the participants.[183] It is considered a *federal health program*, established within the Department of Health and Human Services, satisfying the requirements of a federal health program as defined by Section 1128B(f) of the Social Security Act.[184] It is also considered a *federal health plan* for the purposes of applying Sections 1128 through 1128E, also of the Social Security Act.[185] As such, the Health and Human Services Inspector General is required to develop and implement both a fraud prevention program and an oversight program to guard against unreasonable administrative costs.[186]

---

[179] *Id.* at sec. 101, § 3301 (amending Public Health Service Act, 42 U.S.C. ch. 6A (2001) by adding §§ 3301-51 (current version at 42 U.S.C. §§ 300mm-300mm61 (2012))).

[180] *Id.*

[181] *Id.*

[182] *Id.* (Research must extend as far north as 14th Street in Manhattan and in Brooklyn and must include control groups.).

[183] *Id.* at sec. 101, § 3301(c).

[184] *Id.* at sec. 101, § 3301(d).

[185] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, sec. 101, § 3301(d), 124 Stat. 3623 (2011).

[186] *Id.* at sec. 101, § 3301(d)(1), (2).

B. *Eligibility*

The WTC Health Program provides eligibility requirements, which are considerably more liberal than those in the original VCF, which limited eligibility to those who worked at the site within a set number of hours after the attack.[187] It has set a limit of 25,000 enrollees, not to include those already considered an *identified responder*, or an individual who has previously been identified as eligible for care coordinated by Mt. Sinai, NIOSH, and the FDNY.[188]

The Zadroga Act distinguishes between *responders* and *survivors.* Section 3311 defines *responders* as members of the FDNY; law enforcement, rescue, recovery, and cleanup workers; and those first responders to the Pentagon and Shanksville, PA sites.[189] To qualify for care as a firefighter, the individual must have been a member, active or retired, of the FDNY at the time of the attack.[190] He or she must have participated for at least one day in the rescue or recovery effort at Ground Zero, at Fresh Kill—the Staten Island landfill, or the NYC Medical Examiner's Office during the period between September 11, 2001 and July 31, 2002.[191] The Zadroga Act also includes surviving immediate family members of an FDNY firefighter who was killed at the WTC on September 11, so long as they received any treatment for a WTC-related mental health condition on or before September 1, 2008.[192]

The requirements are slightly more stringent for law enforcement (NYPD, Port Authority of NY, or New Jersey Police), rescue, recovery, and cleanup workers.[193] To be eligible, an individual must have worked or volunteered in rescue, recovery, or debris cleanup in lower Manhattan below Canal Street, the Staten Island Landfill, or the barge loading piers for one of the following: (1) for at least 4 hours between September 11 and September 14, (2) for at least 24 hours between September 11 and September 30, or (3) for at least 80 hours between

---

[187] LLOYD DIXON & RACHEL KAGANOFF STERN, COMPENSATION FOR LOSSES FROM THE 9/11 ATTACKS 21 (2004).

[188] Zadroga Act sec. 101, § 3311(a)(4)(A).

[189] *Id.* at sec. 101, § 3311(a)(2)(A)-(C).

[190] *Id.* at sec. 101, § 3311(a)(2)(A).

[191] *Id.*

[192] *Id.*

[193] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, sec. 101, § 3311(a)(2)(B), 124 Stat. 3623 (2011).

September 11, 2001 and July 31, 2002.[194] The Act also includes provisions for *survivors*, defined as persons who were living or working near the sites, based on the individual's temporal and geographic relationship to Ground Zero.[195]

In order for an eligible responder to receive treatment through the WTC Health Program, he or she need only demonstrate physician documentation that he or she is suffering from a health condition included on the List of identified WTC-related conditions. The List divides conditions into two groups: aerodigestive disorders[196] and mental health conditions.[197] Musculoskeletal disorders, including lower back pain or repetitive stress injuries, are included for those responders who worked at Ground Zero on or before September 11, 2003.[198]

C. Treatment under the World Trade Center Health Program

The scope of treatment covered by the WTC Health Program includes physician services, diagnostic and laboratory tests, inpatient and outpatient prescription drugs, and inpatient and outpatient hospitals services.[199] Section 331 provides that all costs of the initial health evaluation, monitoring, and medical treatment for eligible individuals is paid for by the WTC Health Program from the WTC Health Program Fund, except for any costs paid by a (1) health insurance program or (2) workers' compensation program. For eligible beneficiaries with private health insurance, the WTC Health Program acts as a secondary payer of all uninsured costs, including co-pays and deductibles, for covered

---

[194] *Id.* at sec. 101, § 3311(a)(2)(B)(i).

[195] *Id.* at sec. 101, § 3321(a)(1)(B).

[196] *Id.* at sec. 101, § 3312(a)(3)(A) (covering (1) Interstitial lung diseases; (2) Chronic Respiratory Disorder –Fumes/Vapors; (3) Asthma; (4) Reactive Airways Dysfunction Syndrome (RADS); (5) WTC-exacerbated chronic obstructive pulmonary disease (COPD); (6) Chronic Cough Syndrome; (7) Upper airway hyperreactivity; (8) Chronic rhinosinusitis; (9) Chronic nasopharyngitis; (10) Chronic laryngitis; (11) Gastroesophageal Reflux Disorder (GERD); and (12) Sleep apnea exacerbated by or related to the above conditions).

[197] *Id.* at sec. 101, §3312(a)(3)(B) (covering (1) Post Traumatic Stress Disorder (PTSD); (2) Major Depressive Disorder; (3) Panic Disorder; (4) Generalized Anxiety Disorder; (5) Anxiety Disorder (not otherwise specified); (6) Depression (not otherwise specified); (7) Acute Stress Disorder; (8) Dysthymic Disorder; (9) Adjustment Disorder; and (10) Substance Abuse).

[198] *Id.* at sec. 101, § 3312(a)(4).

[199] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, sec. 101, § 3312(b)(4)(A), 124 Stat. 3623 (2011).

services.[200] Payment for work-related conditions is reduced or recouped by any amounts paid under a workers' compensation law or plan.[201] However, a health care entity is not required to seek reimbursement from a health plan with which it does not have a contract for reimbursement.[202]

V. THE STANDARD OF REVIEW SET FORTH IN THE ACT IS INFEASIBLE

A. The Zadroga Act Should Incorporate Presumptions

In order to receive treatment, the burden of proof is on the eligible responder to provide documentation from a medical professional with "experience in treating or diagnosing the medical conditions" on the List, and also to provide documentation that the World Trade Center attack is "substantially likely to be a significant factor in aggravating, contributing to, or causing an individual's illness or health condition."[203]

Because the party seeking compensation must meet the above-specified burden of proof, the conditions on the List are not "presumptive diseases."[204] The Zadroga Act's requirement is an unusual

---

[200] *Id.* at sec. 101, § 3331(c)(1).

[201] *Id.* at sec. 101, § 3331(b)(1).

[202] *Id.* at sec. 101, § 3331(c)(2).

[203] *Id.* at sec. 101, § 3312(a)(2). "[S]ubstantially likely to be a significant factor in aggravating, contributing to, or causing an individual's illness or health condition" is determined by an assessment of:

> (A) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the attacks. . .(i) [as] evaluated and characterized through the use of a standardized, population-appropriate questionnaire approved by the Director of National Institute for Occupational Safety and Health; and (ii) assessed and documented by a medical professional with experience treating or diagnosing health conditions included on the list of WTC-related health conditions. . .[and] (B) The type and temporal sequence of symptoms . . .(i) assessed through the use of a standardized, population-appropriate medical questionnaire approved by the director of National Institute for Occupational Safety Health and a medical examination; and (ii) diagnosed and documented by a medical professional with experience in treating or diagnosing health conditions on the list of WTC-related health conditions.

[204] The United States Department of Veterans Affairs recognizes presumptive diseases, in which certain health conditions are assumed to be related to Agent Orange exposure during qualifying military service. *See* COMM. ON EVALUATION OF THE PRESUMPTIVE DISABILITY DECISION-REVIEW MAKING PROCESS, INST. OF MED., IMPROVING THE PRESUMPTIVE DECISION-MAKING PROCESS FOR VETERANS G1-G2 (Jonathan M. Samet & Catherine C. Bodurow eds., 2008).

stipulation in this type of compensation program. The Department of Veterans Affairs (VA) compensation program, which operates similarly, has used presumptions in its legislation since 1921.[205] Legally, a presumption is a procedural device dictating that "once basic fact A is established, the existence of fact B must be assumed unless the presumed fact is rebutted."[206] A disease presumption operates to bridge the gap between available scientific data and medical knowledge. The VA provides disability compensation for certain medical conditions appearing after a veteran's military service because the condition is presumed to be caused by or "aggravated by an exposure or an event that occurred during military service."[207] This alleviates the burden on the veteran to prove that his or her medical condition, often cancer, was causally connected to the exposure and that the exposure occurred during the veteran's military service.[208]

Presumptions are established by Congress and the VA because they promote fairness and equitable outcomes.[209] By streamlining and simplifying the adjudication process, presumptions ensure that similarly situated claimants receive comparable relief.[210] It is also less burdensome on both the claimant and the VA because causation does not require adjudication, as the probability of the presumed fact is already high.

Presumptions are often the product of public policy decisions.[211] "Medical health outcome presumptions have generally been adopted after periods of war and have been driven by the concerns of and for returning Service members."[212] The reasoning is in part the result of the unpredictability of military service; service members often do not know to which toxins they will be exposed.[213] "Presumptions may [also] implement policy judgments that the burdens arising in certain cases be borne by the government rather than the veteran claimants."[214] This

[205] *Id.* at 27.
[206] *Id.* at 36-37.
[207] *Id.* at 39.
[208] *Id.* at 37.
[209] *See* INST. OF MED., *supra* note 204, at 37-39.
[210] *Id.*
[211] *Id.*
[212] *Id.* at 40.
[213] *Id.* at 39.
[214] *Id.* (quoting D. E. Zeglin, Presumptions of Serv. Connection (2006) (prepared for the Veterans' Disability Benefits Commission)).

occurs in spite of the "uncertainty surrounding the issue of whether the claimants' disabilities were, in fact, incurred or aggravated by service."[215] For instance, when epidemiologic information, such as exposure data, "is unavailable because it was not collected at the relevant time," a presumption can be created to relieve the claimant's burden of proof.[216] The circumstances justifying VA presumptions are analogous to those following the 9/11 attack—exposure to a conflagration of so many different toxins had never been anticipated or studied, no exposure data was collected in that critical first week, and the data that was obtained after is of questionable accuracy.[217]

Finally, presumptions are created because they provide an ethical way to demonstrate "gratitude and sympathy for those who served their country."[218] These principles are also shared by state legislatures, as thirty-four states, including New York and New Jersey, have some type of presumption in place for the coverage of respiratory illness in firefighters.[219] Under New Jersey Law, the *Lindquist* court held that the legislative intent of the firefighter pension program is social good and is, therefore, to be interpreted as expanding, rather than limiting coverage.[220] Thus, a petitioner's burden of proof is less than in a common-law tort action.[221] In New York City, the Firefighters Cancer Bill includes a presumption that any cancer is presumed to be the result of occupational exposure.[222] In 2005, The New York State Retirement and Social Security Law began providing those who worked during the WTC rescue, recovery, or clean up with a disability pension per the World Trade Center Accidental Disability Presumption Law.[223] Under the Cancer Bill, the city now presumes any cancer is related to 9/11 exposures if a patient meets the set criteria for 9/11-related service.[224]

---

[215] INST. OF MED., *supra* note 204, at 40.

[216] *Id.* at 37.

[217] Petition on Cancer, *supra* note 19.

[218] INST. OF MED., *supra* note 204, at 37-40.

[219] *See* Lindquist v. City of Jersey City Fire Dep't, 814 A.2d 1069, 1092 (N.J. 2003).

[220] *Id.* at 1092.

[221] *Id.* ("The absence of peer-reviewed epidemiological studies does not, as defendants contend, make it 'almost impossible' for Dr. Smith's opinion to be admissible.").

[222] N.Y. GEN. MUN. LAW § 207-kk, (McKinney 1999).

[223] WORLD TRADE CENTER ACCIDENTAL DISABILITY PRESUMPTION, A LAW AFFECTING PUBLIC EMPLOYEES WHO PARTICIPATED IN THE WORLD TRADE CENTER SITE RESCUE OR CLEAN UP OPERATIONS, *available at* http://www.osc.state.ny.us/retire/publications/vo1834.htm.

[224] *Id.*

The moral economy associated with the debt felt toward 9/11 first responders has been a consistent argument for the inclusion of cancer treatment under the umbrella of covered conditions. When the Zadroga Act went into effect on July 1, 2010, Representative Maloney voiced her relief that gratitude and recompense were finally being given to 9/11 first responders:

> To the living victims of 9/11, we have great news: today, the Zadroga Act is taking effect and 9/11 health clinics are officially open for business under the new law. This is an historic milestone for the more than 36,000 people who have become ill because of the terrible events of 9/11, and the fulfillment of our moral obligation to care for those who rise to the defense of our nation in a time of war.[225]

Although gratitude and recompense are cornerstones of the Zadroga Act, experts agree that proving causation is always "a contentious process, both scientifically and politically."[226] Both the Gulf War health debate and the effort required to institute the Agent Orange presumption are evidence of the challenges associated with achieving a scientific and political compromise.[227] Unfortunately, the nine-year struggle to pass the Zadroga Act demonstrates that neither a plea to conscience nor an appeal to patriotism will be sufficiently persuasive to force the creation of a disease presumption or the inclusion of cancer coverage. Advocates must instead rely on the available scientific data to prove a presumption is warranted. Yet, unlike other federal compensation programs, the language of the Zadroga Act establishes an unreasonable admissibility standard for scientific evidence. As enacted, any decision regarding the inclusion of cancer is contingent on whether or not the Administrator finds the available peer-reviewed data sufficient to establish a causal link between WTC exposure and cancer.[228] The following Section explains why this limitation is

---

[225] Press Release, Congresswoman Carolyn B. Maloney, Reps. Maloney, Nadler & King Celebrate As Zadroga 9/11 Health Law Goes Into Effect Today (July 1, 2011), *available at* http://maloney.house.gov/press-release/reps-maloney-nadler-king-celebrate-zadroga-911-health-law-goes-effect-today.

[226] Mark Brown, *Toxicological Assessments of Gulf War Veterans*, 361 PHIL. TRANSACTIONS OF ROYAL SOC'Y OF LONDON BIOLOGICAL SCI. 649, 649-79 (2006). Brown is with the US Department of Veterans Affairs, Office of Public Health and Environmental Hazards.

[227] *Id.*

[228] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, sec. 101, § 3312(a)(5)(A), 124 Stat. 3623 (2011). This Section requires the Administrator of

inequitable.

B. The Admissibility Standard for the Periodic Reviews is Unreasonable

> *Sir, clearly you have cancer, and clearly you spent a heroic amount of time sifting through a smoldering smorgasbord of carcinogens in search of your own loved ones and colleagues, and the loved ones and colleagues of others. But how do I know your cancer isn't from dental x-rays and red M&Ms? So if you just give me 20 years, I think we'll be able to have some statistics and then that's that.*[229]
>
> - Jon Stewart

When making a determination to add a health condition to the List, admissible evidence is limited to that which has been published in a peer-reviewed scientific or medical journal.[230] At the time WTC Health Program Administrator John Howard conducted the first Periodic Review in July of 2010, the only published, peer-reviewed, epidemiological study on cancer was the Zeig-Owens study.[231] He therefore was forced to conclude that "insufficient evidence exist[ed] to propose a rule to add cancer" to the List.[232]

The Act permits the Administrator to collect evidence from the following three information sources:

- A systematic search was conducted for peer-reviewed findings on exposure and cancer resulting from the September 11, 2001, terrorist attacks that have been published in the scientific and medical literature between September 11, 2001 and July 1, 2011.
- Findings and recommendations related to cancer were

---

the WTCHP to:

> [P]eriodically conduct a review of all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related Health conditions.

[229] Daily Show 2, *supra* note 14.

[230] Zadroga Act sec. 101, § 3322(a).

[231] *Id. See also First Periodic Review*, *supra* note 133 (stating that the only peer-reviewed study was the Zeig-Owens study).

[232] *First Periodic Review*, *supra* note 133.

> solicited from the WTC Clinical Centers of Excellence and Data Centers, the WTC Health Registry at the New York City Department of Health and Mental Hygiene, and the New York State Department of Health.
>
> - Information from the public about cancer was solicited through a *Request for Information* published in the Federal Register on March 8, 2011 and March 29, 2011.[233]

However, as the Act expressly limits evidence to "*only* the scientific and medical evidence that is published in peer-reviewed journals," the Administrator could not consider the non-peer-reviewed data received as a result of solicitation in the Federal Register.[234] For example, the following evidence, submitted by Bill Romaka, Uniformed Firefighters Association Sergeant-at-Arms/Health and Safety Officer, was not eligible for official consideration even though it was submitted in response to the NIOSH Docket #227 request for information on conditions relating to cancer:

> [L]et's recap our most recent past. 4 firefighters/fire officers diagnosed with Non-Hodgkin's Lymphoma and 1 with Leukemia in the LAST THREE WEEKS!!! 8 of the last 10 FDYNY WTC-Related Line of Duty Deaths in the last few months (as determined by independent doctors and the Pension Board made up of government and union representatives) were all assigned to Manhattan fire companies and worked on 9/11.[235]

Similarly, the World Trade Center Health Registry program is expected to release its third health survey of approximately 68,000 people, including many rescue and recovery workers however, this study may not be available for inclusion in the review because it will be published at approximately the same time as the periodic review deadline.[236]

The requirement that the Administrator's review be confined to published peer-reviewed studies is unreasonable because it is too soon to have an established body of scientific literature on the latent effects

---

[233] *Id.* at iii.

[234] *Id.* at 29 (emphasis in original).

[235] E-mail from Bill Romaka, Uniformed Firefighters Association Sergeant-at-Arms/Health and Safety Officer, to Karen E. Dragon, NIOSH Docket Office (CDC), (Mar. 28, 2011, 03:06 PM EST) (on file with author) (Romaka is a member of the WTC Medical Monitoring and Treatment Steering Committee).

[236] *See* Sarah Dorsey, *For Post-9/11 Responders, Illness, Frustration Lingers*, CHIEF LEADER: UNIFORMED FIREFIGHTERS ASSOCIATION (Nov. 15, 2011), *available at* http://www.ufanyc.org/cms/contents/view/11962.

of Ground Zero exposure.[237] When establishing scientific causation, researchers must compare the cancer rate in the affected population against the rate in the general population, a process taking at least two to three years.[238] When insufficient time has passed for an adequate number of studies, any data will present an incomplete picture; when the "observation period is shorter than the average time that it takes for cancer to develop biologically following exposure (i.e., latent period), an excess of cancer cases would not be expected to be seen."[239]

At the time of the first Periodic Review, an insufficient amount of time had passed to produce a significant body of research.[240] Of all of the studies conducted, only one peer-reviewed epidemiological study had been published within the past five years.[241] In other words, only one peer-reviewed study had been published within the appropriate time frame to evaluate latent-illness. Ignoring the temporal impossibilities, NIOSH, which administers the WTC Health Program, determined that too few studies had been published to prove that WTC exposure causes cancer.[242] Therefore, the Administrator was forced to conclude that the first Periodic Review showed insufficient peer-reviewed evidence to support a causal connection between exposure at Ground Zero and the latent development of cancer.[243]

---

[237] *First Periodic Review*, *supra* note 133, at 29.

[238] Dorsey, *supra* note 236.

[239] *First Periodic Review*, *supra* note 133, at 27.

[240] Jacqueline Moline et al., *Health Consequences of the September 11 World Trade Center Attacks: A Review*, 24 CANCER INVESTIGATION 294 (2006); Jacqueline Moline et al., *Multiple Myeloma in World Trade Center Responders: A Case Series*, 51 J. OCCUPATIONAL ENVTL. MED. 896, 897 (2009); Robert P. Nolan, *Risk Assessment for Asbestos-Related Cancer From the 9/11 Attack on the World Trade Center*, 47 J. OCCUPATIONAL ENVTL. MED. 817 (2005); Sierra Rayne, *Using Exterior Building Surface Films to Assess Human Exposure and Health Risks From PCDD/Fs in New York City, USA, After the World Trade Center Attacks*, 127 J. HAZARDOUS MATERIALS 33 (2005); Jonathon M. Samet et al., *The Legacy of World Trade Center Dust*, 356 NEW ENG. J. MED. 2233 (2007).

[241] *See generally id.*

[242] Dorsey, *supra* note 236.

[243] *First Periodic Review*, *supra* note 133, at 40.

1. The Purpose and Weight of the February 2012 STAC Recommendation

In September of 2012, a bipartisan group of nine Congressmen and Congresswomen formally petitioned for cancer's addition to the List.[244] In accordance with the Act, the Administrator requested that the WTC Health Program STAC review the available information and "provide advice on whether to add cancer, or a certain type of cancer, to the List."[245] Howard asked the committee to consider the report from the first Periodic Review and the study by Zeig-Owens.[246]

When the STAC met on February 15th & 16th, 2012, members evaluated all available epidemiologic data and found the Zeig-Owens study particularly important because this work represents the *only* assessment of latent health conditions in a specific study population.[247] Previous studies relied on qualitative or semi-quantitative data obtained from exposure questionnaires, often completed by the study participants themselves.[248] Zeig-Owens and colleagues assessed 9,853 men who were employed as firefighters on January 1, 1996, 8,927 of whom were WTC-exposed.[249] Every firefighter in the study had health information

---

[244] Letter from John Howard, WTCHP Administrator, to Elizabeth Ward, Chair WTCHP-STAC (Oct. 5, 2012) , *available at* http://www.cdc.gov/NIOSH/topics/wtc/stac/pdfs/LTRWard.pdf [hereinafter Letter from Howard]. Jonathan Lemire, *Zadroga Act Should Cover Cancer Care for Bravest who Worked Ground Zero: Lawmakers*, N.Y. DAILY NEWS Sept. 7, 2011, *available at* http://articles.nydailynews.com/2011-09-07/news/30147050_1_zadroga-act-cancer-care-lung-cancer.

[245] Letter from Howard, *supra* note 244.

[246] STAC Email Traffic During Preparatory Work on Report for Petition 001-Cancer-03/22/12 (Mar. 22, 2012), *available at* http://www.cdc.gov/niosh/topics/wtc/stac/; 2012 Recommendation, *supra* note 64. *See* Petition on Cancer, *supra* note 19.

[247] Petition on Cancer, *supra* note 19; Zeig-Owens et al., *supra* note 121, at 898-99.

[248] James M. Melius, *Medical Care for Workers Exposed to the WTC Disaster*, 378 THE LANCET 854, 854-55 (2011).

[249] Zeig-Owens et al., *supra* note 121, at 898-99. The researcher's methodology is summarized as follows:

> We assessed 9853 men who were employed as firefighters on Jan. 1, 1996. On and after 9/11, person-time for 8927 firefighters was classified as WTC-exposed; all person-time before 9/11, and person-time after 9/11 for 926 non-WTC-exposed firefighters, was classified as non-WTC exposed. Cancer cases were confirmed by matches with state tumour [*sic*] registries or through appropriate documentation. We estimated the ratio of incidence rates in WTC-exposed firefighters to non-exposed firefighters, adjusted for age, race and ethnic origin, and secular trends, with the US National Cancer Institute Surveillance Epidemiology and End Results (SEER) reference population.

available prior to 9/11, and each received careful follow-up in the post-9/11 years.[250]

Also relevant is a forthcoming study by the Mount Sinai School of Medicine, as it reports a 14 percent increase in cancer rates among rescue workers, including prostate, thyroid, and blood cancers.[251] Unfortunately, as this study is in the process of being published, it is not yet eligible for official consideration. In addition to epidemiologic data, the STAC members reviewed the carcinogens present at the WTC site.[252] Similar to the process used by the VA, the STAC also used exposure data to evaluate potential cancer risk; it also examined the composition of the dust and smoke at Ground Zero.[253] This information, combined with epidemiologic studies and the known mechanisms of carcinogenesis, led to the unanimous conclusion that the addition of cancer is not unreasonable.[254]

The STAC released the final version of their recommendation to the Administrator on March 31, 2012.[255] Several options were proposed for determining which cancers to add, the most limited being a case-by-case review of every eligible cancer victim.[256] Other members proposed creating a tailored list of cancers commonly associated with toxic exposure or even including all cancers because of the "limited epidemiological data available to identify specific cancers."[257] While presumably less costly and time consuming, a narrowly-tailored List risks excluding some of those who are entitled to care.[258]

> [Cancer incidences] were estimated with overdispersed Poisson models. Additionally analyses included corrections for potential surveillance bias and modified cohort inclusion criteria.

[250] *Id.*

[251] *See, e.g.*, Sally Goldenberg, *40 K Came to Help at WTC Site*, N.Y. POST (Feb. 28, 2012), http://www.nypost.com/p/news/local/came_to_help_at_wtc_site_t4RlyYSaQU79z84OANUeEP.

[252] Petition on Cancer, *supra* note 19.

[253] *Id.*

[254] Caruso, *supra* note 11.

[255] 2012 Recommendation, *supra* note 64.

[256] Caruso, *supra* note 11.

[257] 2012 Recommendation, *supra* note 64, at 2.

[258] *Id.*

After much discussion, "the committee agreed to proceed by generating a list of cancers potentially related to WTC exposures" based on three sources of evidence:

1. Cancers with *limited* or *sufficient* evidence in humans based on the International Agency for Research (IARC) Monographs reviews for carcinogens present at the WTC site;
2. Cancers arising in regions of the respiratory and digestive tracts where WTC-related inflammatory conditions have been documented; and
3. Cancers for which epidemiologic studies have found some evidence of increased risk in WTC responder and survivor populations[259]

The STAC committee recommended coverage for malignant neoplasms of the respiratory system, skin cancers, mesothelioma, ovarian, urinary tract, eye and orbit, thyroid cancer, lymphatic, and hematopoietic cancers.[260] They also recommended the coverage of all childhood cancers; in other words, all cancers diagnosed before age twenty-one should be covered if a health care provider confirms a "substantial likelihood of association with World Trade Center exposures."[261]

However, it is critical to note that any opinion is just that, an opinion; under the Act, the Administrator is not obligated to even include the recommendation in his decision-making process.[262] When the final decision is made by the Administrator, it is not unreasonable to anticipate opposition to finding causation on limited epidemiologic evidence—cancer coverage will ultimately add a financial burden to the federal budget. After STAC's vote to include cancer, VCF Special Master Sheila Birnbaum cautioned that if cancer victims are included, "everyone would still get paid, but they would get paid less than they were awarded, and we all may run out of money."[263] The VCF is

[259] *Id.*

[260] *Id.* at 2-3.

[261] *Id.* at 26.

[262] *First Periodic Review*, *supra* note 133, at 28-29.

[263] Sarah Frier, *Victim Funds for Sept. 11 Should Cover Cancer, Panel Chief Says*, BUSINESSWEEK.COM (Feb. 16, 2012), *available at* http://www.businessweek.com/news/2012-02-16/victim-funds-for-sept-11-should-cover-cancer-panel-chief-says.html#p1. Sheila Birnbaum is an attorney at Skadden, Arps, Slate, Meagher & Flom LLP in New York.

allocated $2.8 billion for the reimbursement of non-medical losses.[264] Birnbaum also commented that she would be willing to cover cancer patients if a second treatment fund covered the cost of their medical expenses.[265] A final recommendation from Administrator Howard was due midsummer of 2012.[266]

2. The Zadroga Act Does Not Provide Guidance to the Administrator on Weighing Evidence

The Zadroga Act does not include issues such as public policy, the cost of cancer treatment, or resource allocation as factors for the Administrator to consider when making his final determination.[267] Rather, the Administrator's decision is supposed to reflect the scientific evidence published in peer-reviewed literature.[268] The statutory language, however, is too vague; it does not provide the Administrator any guidelines for weighing evidence other than the prohibition against non-peer-reviewed evidence. It gives no indication on how the Administrator should evaluate the evidence to determine which, if any, cancer will be added to the List.[269]

---

[264] Bloomberg News, *Cancer Coverage Would Decrease 9/11 Victim Payouts*, CRAINSNEWYORK.COM, (Feb. 15, 2012), *available at* http://www.crainsnewyork.com/article/20120215/HEALTH_CARE/120219938&utm_source=Daily%2BAlert&utm_medium=email&utm_campaign=Newsletters.

[265] *Id.*

[266] David B. Caruso, *Feds Consider Expanding Cancer Coverage for WTC Workers: Advisory Committee Believes it Reasonable that Cancer Link Would Eventually be Found*, ASSOCIATED PRESS (Feb. 17, 2012), *available at* http://www.jems.com/article/news/feds-consider-expanding-cancer-coverage;

> Once the Administrator receives the Advisory Committee's recommendation he has 60 days to publish in the Federal Register either a notice of proposed rulemaking regarding the recommendation or a determination not to propose a rule and the basis for that determination. If the Administrator publishes a notice of proposed rulemaking to add cancer, or certain types of cancer, to the List of WTC-Related Health Conditions, the WTC Health Program must follow the normal regulatory process, including a minimum 30 day public comment period and review of those comments, before issuing a final rule.

Next Steps: WTC Health Program - Statement from WTC Program Administrator John Howard, M.D., CENTERS FOR DISEASE CONTROL AND PREVENTION (Apr. 2, 2012), http://www.cdc.gov/niosh/topics/wtc/stacpetition001.html.

[267] *See generally* James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011).

[268] *Id.*

[269] *Id.*

In the first Periodic Review, Howard noted that the lack of guidance was challenging, stating that although "'weight of the evidence' is a common term in the risk assessment literature, . . . it can have different meanings and applications."[270] Howard's report provided a cursory reference to the Persian Gulf War Veterans Act, which defines a positive association between exposure and illness as one in which "the association is equal to or outweighs the credible evidence against the association."[271] However, this language reflects general scientific principles and does not apply when insufficient time prevents the completion of multiple epidemiological studies.[272]

Given the lack of guidance and the Act's limitation on admissible evidence, there is a clear need for an improved decision-making framework. The following section explains the evidentiary guidelines set forth in the Restatement Third's discussion of toxic tort law and recommends that the Administrator be permitted to adopt a comparable decision-making framework.

VI. APPLYING TOXIC TORT JURISPRUDENCE TO ENSURE THE PERIODIC REVIEW PROCESS IS FAIR AND EQUITABLE

Given the contentious history of the Zadroga Act, any decision by the Administrator to cover cancer must be supported by sufficient evidence.[273] At the same time, the Periodic Review process must also guarantee a fair and equitable consideration of all reliable scientific and medical evidence.

This Article proposes the review process be modeled after toxic tort jurisprudence. Reflecting current standards of evidentiary admissibility, both the Restatement Third of Torts Section 28, Comment c and recent case precedent outline a comprehensive review process designed to evaluate all reliable evidence, including, but not limited to,

---

[270] *Id.*

[271] *First Periodic Review*, *supra* note 133, at n.7.

[272] *See* INST. OF MED., *supra* note 204, at G1, G2.

[273] Although colorful, it is unlikely that Jon Stewart's suggestion on this issue will pass muster:

> So if you're someone who spent time on the Pile, I don't care if you ate 200 sweet n low packets a day sprinkled on your favorite cereal, Tumor O's, while wearing a cell phone suit, and smoking Chernobyl Lites unfiltered, while making regular stops to your favorite snack joint, Agent Orange Julius, you get cancer, we cover it!

Daily Show 2, *supra* note 14.

epidemiology.

Toxic tort jurisprudence applies a framework tailor-made to accommodate the "dynamic process" of toxic exposure and the development of latent illness.[274] It differs from traditional tort law, in which causation is inferred from the temporal sequence of events (i.e. the plaintiff was unharmed prior to the incident but was injured as a result of some action taken against him).[275] In a toxic exposure case, the toxins often cause latent illness, which may take years to manifest, and likely involve intricate temporal and medical issues.[276] Further complicating the analysis is the fact that the "background rate" of an illness must be weighed against the rate of illness in the population at large.[277] A toxic exposure claimant must establish an association between the toxic exposure (i.e. WTC dust) and the development of the disease (cancer) and then determine whether the exposure is a contributing factor to "an additional burden of cancer" in this population.[278] If the answer is "yes," there is an "association."[279] Causation can then be inferred from the "association." The following section explains this process in more detail.[280]

---

[274] Eggen Ground Zero, *supra* note 35, at 385.

[275] *See* Steve C. Gold, *The "Restatement" of the False Negative Asymmetry in Toxic Tort Causation* 37 WILLIAM MITCHEL L. REV. 1507, 1511 (2011) (quoting Hyman & Armstrong, P.S.C. v. Gunderson, 279 S.W.3d 93, 104 (Ky. 2008)).

[276] *See, e.g.*, Eggen Ground Zero, *supra* note 35, at 385.

[277] *Id.* at 446 (explaining that generic illnesses may be caused by a variety of exposures or appear idiopathically). The "latency periods open up the possibility that intervening causes may be responsible for an illness that develops years after the exposure." *Id.* at 446-47.

[278] Michael D. Green et al., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 83, 335-36 (Fed. Judicial Ctr. ed., 2d ed. 2000). *See, e.g.*, Henricksen v. ConocoPhillips Co., 605 F. Supp. 2d 1142, 1176 (E.D. Wash. 2009) This does not address specific causation. Specific causation, or that particular plaintiff's illness was caused by a substance, is not applicable in the context of the Zadroga Act because the WTCHP Administrator does not consider individual claims for cancer coverage. Therefore, the Administrator must examine the available peer-reviewed evidence in light of the eligible population, and not on an individual basis. *See also* In re World Trade Center Disaster Site Litig. 456 F. Supp. 2d 520, 575 (S.D.N.Y. Oct. 17, 2007). During the WTC settlement litigation, over 10,000 WTC cases were consolidated under Federal Rule 42 as a non-class mass action. The decision by Judge Hellerstein to certify the cases as a mass action, and not as a class action, eliminated the requirement that each individual plaintiff prove causation. *See generally* Alexandra N. Rothman, *Bringing an End to the Trend: Cutting Judicial "Approval" and "Rejection" Out of Non-Class Mass Settlement*, 80 FORDHAM L. REV. 319 (2011) for an excellent overview of mass action settlements and the WTC litigation.

[279] *First Periodic Review*, *supra* note 133, at 25-26.

[280] *Id.*

A. The Position of the Restatement Third Promotes A Flexible, But Not Relaxed, Causation Inquiry

Epidemiologic evidence is one methodology used to establish an association between an exposure and a disease. In a toxic exposure case, such as the WTC exposure, "evidence consists of studies comparing the disease rate in groups of individuals. . . with varying levels of exposure. When a study finds a difference in the incidence of disease in the exposed and unexposed groups, an 'association' exists between exposure and disease."[281] A second type of study "identif[ies] toxic substances at the aggregate population level."[282] An "association" is found when there is "a higher incidence of disease in the group exposed to the substance."[283]

Once an association is found, the Bradford Hill criteria are used to determine whether or not a causal relationship can be inferred.[284] The Hill Guidelines are frequently applied in cancer epidemiology when the number of studies is limited.[285] The criteria evaluate (1) the consistency of the association, (2) the temporal relationship between the disease, (3) the posited cause, and (4) the coherence of the inference given existing scientific knowledge.[286] Discussing the evaluation of studies, Comment c cautions that an algorithm does not exist for applying the Hill guidelines because concluding that an inference of causation is appropriate is a matter of informed judgment, not scientific methodology.[287]

---

[281] RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 cmt. c(3) (2010).

[282] *Id.*

[283] *Id.*

[284] *First Periodic Review*, *supra* note 133, at 25-26.

[285] RESTATEMENT THIRD, § 28 cmt. c. *See* Milward v. Acuity Specialty Prods. Grp., 639 F.3d 11, 13-17 (1st Cir. 2011) (citing Michele Carbon et al., *Modern Criteria to Establish Human Cancer Etiology*, 64 CANCER RES. 5518, 5522 (2004)).

[286] *See, e.g.*, *Milward*, 639 F.3d at 17. The Hill criteria include: the strength or frequency of the association; the consistency of the association in varied circumstances; the specificity of the association; the temporal relationship between the disease and the posited cause; the dose response curve between them; the biological plausibility of the causal explanation given existing scientific knowledge; the coherence of the explanation with generally known facts about the disease; the experimental data that relates to it; and the existence of analogous causal relationships.

[287] RESTATEMENT THIRD, § 28 cmt. c(3).

1. Recent Case Law Supports a Flexible Causation Inquiry When Epidemiologic Evidence is Limited

Unless there is a substantial body of exonerative epidemiologic evidence, Comment c states that the causation analysis cannot alone rely on the quantity of epidemiological studies. Significantly, when the disease process has a long latency period:

> [S]tudies *cannot* be performed until the disease has manifested itself. As a consequence, some plaintiffs may be forced to litigate long before epidemiologic research is available. . . . Thus, most courts have *appropriately declined to impose a threshold requirement that a plaintiff always must prove causation with epidemiologic evidence.*[288]

In these cases, a flexible approach is appropriate, as epidemiologic evidence is admissible, but not necessary to prove causation.[289]

In line with the Restatement Third, a significant body of case law rejects the use of an epidemiological threshold for proving causation.[290] For example, in 2010, the Ninth Circuit Court of Appeals reversed a ruling for summary judgment on the basis that the district court incorrectly demanded epidemiological studies when no studies were possible at the time of review.[291] The court held that "peer reviewed scientific literature may be unavailable because the issue may be too particular, new, or of insufficiently broad interest, to be in the literature."[292] In these circumstances, the "inquiry must be flexible."[293]

In *Lindquist*, an agent-disease-causation fireman workers' compensation case, the court held that "causation should [be] determined based upon the scientific evidence that is currently available" at the time of review.[294] The *Lindquist* court reinstated a

---

[288] *Id.* (emphasis added).

[289] *Id.* These studies are also "expensive and can take considerable time to design, conduct, and publish." *Id.*

[290] *Id. See, e.g.*, Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882-83 (10th Cir. 2005) (specifying that epidemiology is not required to prove causation); Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1198 (11th Cir. 2002); In re Berg Litig., 293 F.3d 1127, 1130 (9th Cir. 2002); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1211-12 (10th Cir. 2002); Bonner v. ISP Tech., Inc., 259 F.3d 924, 929 (8th Cir. 2001); Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998); Zuchowicz v. United States, 140 F.3d 381, 389-90 (2d Cir. 1998); Ambrosini v. Labarraque, 101 F.3d 129, 138-39 (D.C. Cir. 1996).

[291] Primiano v. Cook, 598 F.3d 558 (9th Cir. 2010).

[292] *Id.* at 565.

[293] *Id.*

[294] RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 cmt.

firefighter's award of disability, holding that when scientific evidence is unavailable, "the judicial system does not have the leisure to defer decision until proper and definitive scientific or medical studies are available."[295] Further, "courts must not penalize workers suffering from diseases for which science has not yet clearly established causation."[296]

In 2011, *Geraghty* furthered *Lindquist*'s treatment of limited evidence.[297] The court affirmed the decision to deny worker's compensation, holding that "unlike the petitioner in *Lindquist*, Geraghty was not advancing a scientific theory of causation that has not yet reached general acceptance as neither expert suggested a lack of scientific basis for the impact of lung disease."[298] This case illustrates that the flexible approach praised by the Restatement Third is not synonymous with the relaxation of the court's role as evidentiary gatekeeper.[299]

2. A Flexible Standard Should be Adopted by the WTCHP Administrator

The above jurisprudence indicates that if the issue of Ground Zero exposure and latent cancer were to be decided in a court of law, the lack of available epidemiologic evidence would not be outcome-determinative. Following the precedent set by the *Primiano* and *Lindquist* courts, it is likely that the STAC recommendation and the Zeig-Owens study would be sufficiently persuasive to warrant providing some degree of cancer coverage. From a policy perspective, the language of Comment c specifies that an eligible individual should not be penalized for the lack of available research.

> When the possibility of causal connection is accepted, we cannot deny relief in all cases simply because science is unable decisively to dissipate the blur between possibility and probability. In such

c(3) (2010) (citing *Lindquist*, 814 A.2d at 1069).

[295] *Lindquist*, 814 A.2d at 1090 (citing Magaw v. Middletown Bd. of Educ., 731 A.2d 1196, 1203 (N.J. Super. Ct. App. Div. 1999)).

[296] *Id.*

[297] Geraghty v. Jersey City Mun. Utils. Auth , No. A-5467-09T2, 2011 N.J. Super. Unpub LEXIS 1337 (N.J. Super Ct. App. Div. 2011).

[298] *Id.* at *16-17.

[299] *Compare id. with* Hildy Bowbeer, *Flying Trampolines and Falling Bookcases: Understanding the Third Restatement of Torts (Spring 2010)*, 37 WM. MITCHELL L. REV. 1034 (2011) (expressing concern that Comment c may direct a court to "relax its vigilance" as gatekeeper).

> circumstances judges must do the best they can, with the hope that their decisions square with the truth, and with a willingness to consider in succeeding cases whatever contribution scientific advances may offer.[300]

STAC member Dr. William Rom expressed a similar sentiment shortly after the STAC announcement: "[w]aiting for harder evidence that could still be years or decades away could mean that deserving people are denied care when they need it most. I just don't think [first responders] can wait that long."[301]

B. All Reliable Evidence Should be Admissible for Consideration by the Administrator

In toxic tort cases, *reliable* scientific, technical, or other specialized evidence is admissible to assist the trier of fact, typically a jury, in determining causation.[302] Under Rule 702 of the Federal Rules of Evidence, any testimony considered by the trier of fact must be "(1) based on sufficient facts or data, (2) the testimony [must be] the product of reliable principles and methods, and (3) the witness [must apply] the principles and methods reliably to the facts of the case."[303] The *Daubert* Court identified factors to aid judges in the determination of whether or not an expert's testimony meets the element of reliability. The factors are: "(1) whether the theory of technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline."[304]

However, courts are frequently criticized for applying the *Daubert* factors too broadly.[305] The *Daubert* line of cases does not demand scientific certainty—the evidence of toxic causation must only be trustworthy in order for it to be admissible.[306] Because of the many

---

[300] *Lindquist*, 814 A.2d at 1090. (citing Dwyer v. Ford Motor Co., 178 A.2d 161, 164-65 (N.J. 1962)).

[301] *Government panel favors some WTC cancer claims*, Wall St. J. (Feb. 16, 2012), *available at* online.wsj.com/article/APc6e30a2ffd044fba8cc58b026669aa05.html.

[302] *See* Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579, 593-94 (1993).

[303] FED. R. EVID. 702.

[304] United States v. Mooney, 315 F.3d 54, 62 (1st Cir. 2002) (citing *Daubert*, 509 U.S. 579).

[305] *See, e.g.*, *Milward*, 639 F.3d at 22 (holding that the district court took the demands of Daubert "too far").

[306] *See* Gold, *supra* note 275, at 1537 n.147 (quoting Hyman & Armstrong, P.S.C. v.

different kinds of expertise and medical testimony, these factors should not be construed as "a definitive checklist or test."[307] For example, the Seventh Circuit Court of Appeals reversed a district court ruling excluding expert testimony on the basis of the expert's failure to refer to peer-reviewed literature.[308] While peer-reviewed literature is a factor for consideration under *Daubert*, the question of admissibility "must be tied to the facts of a particular case."[309]

Given the comparable case precedent, this Article recommends that the WTC Health Program Administrator be permitted to conduct a comprehensive analysis in which *all reliable evidence* is admissible, not just that found in peer-reviewed epidemiologic studies. A paradigm for this type of analysis is set forth in the 2011 case *Milward v. Acuity Specialty Products Group, Inc.* The plaintiff, suffering from acute promyelocytic leukemia (APL), claimed his disease was caused by workplace exposure to benzene—one of the same toxins present at the WTC.[310] The lower court excluded the expert's testimony and explained that it was unreliable because only five peer-reviewed studies had been published on this type of cancer.[311] Citing Comment c, the First Circuit Court of Appeals reversed the lower court's judgment excluding the expert testimony for lack of peer-reviewed literature; it held that the testimony was reliable despite the lack of epidemiology.[312]

The *Milward* case is analogous to the situation confronting Administrator Howard and the STAC; both situations involve latent illness and both have a limited body of available peer-reviewed

Gunderson, 279 S.W.3d 93, 104 (Ky. 2008)).

[307] Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) (noting that there are "many different kinds of experts, and many different kinds of expertise," and that as such these factors "may or may not be pertinent in assessing reliability").

[308] Smith v. Ford Motor Co., 215 F.3d 713, 721 (7th Cir. 2000). Furthermore, courts have incorrectly extended *Daubert* to demand scientific certainty when the evidence of toxic causation must only be trustworthy in order for it to be admissible. The judge's role as gatekeeper does not extend to his or her being required to find the proffered opinion scientifically correct. *See also Hyman*, 278 S.W.3d at 105; King v. Burlington N. Santa Fe Ry. Co., 762 N.W.2d 24, 42-43 (Neb. 2009).

[309] Beaudette v. Louisville Ladder, Inc., 462 F.3d 22, 25-26 (1st. Cir. 2006) (quoting *Kumho Tire*, 526 U.S. at 150).

[310] *Milward*, 639 F.3d at 22.

[311] *Id.*

[312] *See generally Milward*, 639 F.3d 11. *See* Gold, *supra* note 275, at 1577 (noting that "Comment c offers courts the teaching of experts one step further removed, as they considered the issues in general, with no specific party's legal rights riding on the outcome.").

literature. However, unlike Howard, the *Milward* court was not constrained by statutory language. As such, *Milward* held that limited epidemiologic studies do not automatically render expert testimony inadmissible when the expert offers other reliable evidence supporting an inference of causal association.[313]

In the *Milward* opinion, the First Circuit Court of Appeals remanded the case for a jury trial and chastised the lower court for "read[ing] too much into the paucity of epidemiological studies" when the issue is "currently the focus of extensive scientific research and debate."[314] Embracing Comment c, the court reiterated that epidemiological studies are not per se required as a condition of admissibility.[315] When peer-reviewed evidence "does not exist and is not reasonably available" other "probative evidence" should be given full consideration.[316]

If the WTC Health Program cancer issue was evaluated using the standard in *Milward*, the Administrator would be permitted to consider all reliable evidence, including physician testimony, case studies, and the environmental findings, with the Administrator adopting the role of juror.

The *Milward* court also provides useful guidance for weighing evidence, an element that is lacking in the Zadroga Act. It endorsed the "weight of the evidence" approach, which encompasses the Bradford Hill methodology.[317] The weight of the evidence methodology requires the scientist to:

> (1) identify an association between an exposure and a disease;
> (2) consider a range of plausible explanations for the association;
> (3) rank the rival explanations according to their plausibility;
> (4) seek additional evidence to separate the more plausible from the less plausible explanations;
> (5) consider all of the relevant plausible explanations; and
> (6) integrate the evidence using professional judgment to come to a conclusion about the best explanation.[318]

According to toxic tort experts, "the court of appeals issued the

---

[313] *Milward*, 639 F.3d at 13-17.

[314] *Id.* at 23-24.

[315] *Id.* at 23.

[316] *See id.* at 23; *see* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 cmt. c(3) (2010).

[317] *See Milward*, 639 F.3d at 17.

[318] *Id.* at 18.

strongest and most explicit judicial endorsement to date of the weight of the evidence methodology for proof of causation in a toxic tort case."[319] Unlike courts that have equated the absence of quantitative analysis with the absence of scientific rigor, the First Circuit embraced Comment c's position that the "saliency of other evidence of causation often entails considerable [scientific] judgment."[320] The Zadroga Act should, as a matter of equity, be amended to include a formal procedure for weighing evidence like that accepted in *Milward*.

VII. CONCLUSION

The tenth anniversary of the terrorist attack serves as a stark reminder that first responders are still feeling the reverberations as though it were yesterday. The methodology presented in this Article will better ensure a fair determination of whether cancer warrants inclusion in the WTC Health Program. If WTC Health Program Administrator Howard adheres to the statutory guidelines, the Zeig-Owens study is the only work meeting both the peer-reviewed stipulation and the temporal proximity needed to adequately assess latent cancer. Therefore, Administrator Howard should consider the forward-thinking approach exemplified in Comment c's analysis of causation in cases of limited epidemiology. As expressed in *Milward*, peer-review should not per se be required as a condition of admissibility.[321]

In his 2011 book, *City of Dust*, Anthony DePalma wrote:

> We do know that the doubts sown in the very earliest days have been long lasting. What might have been a sentinel case of emergency response that raised an entire nation from its knees instead became an endless cycle of bickering, mistrust, sickness, and uncertainty as officials tried to deflect blame, responders became crusaders for themselves, lawyers sought to make courtroom history, and emotions that had never before been felt rose to the surface.[322]

It is the hope of this Author that 2012 marks the end of the destructive behavior so eloquently captured in the words above and echoed in the debate surrounding the Zadroga Act. Expressing the sentiment of so many World Trade Center survivors, Stanley Mieses

---

[319] Gold, *supra* note 275, at 1577.
[320] RESTATEMENT THIRD, § 28 cmt. c(3).
[321] *See Milward*, 639 F.3d at 23.
[322] DEPALMA, *supra* note 102, at 116.

said, "I tend to think of 9/11 as the trapdoor that opened up. Whatever else I'm doing past that, is climbing back up."[323] Let's hope the Zadroga Bill eases this climb.

AUTHOR'S NOTE

After this Article went to press, the Administrator exercised his option to add fourteen categories of cancer to the Zadroga Act's List of Covered Conditions.[324] The final rule included fifty-eight cancers and went into effect on October 12, 2012.[325]

The Administrator's arguments for including cancer mirror many of the recommendations in this Article. In an about-face from the first Periodic Review, the Administrator identified the need for a broader decision-making process and agreed that limited peer-reviewed evidence should not be an absolute barrier to cancer's inclusion on the List.[326] The methodology suggested by the Administrator utilizes the practical approach taken in Comment C and will better ensure an equitable review of 9/11-related health conditions.

The Administrator began the process of adding the cancers three months after the STAC released their formal recommendation.[327] Section 3312(a)(6) of the Public Health Service Act required that the Administrator conduct rulemaking to formally add a condition to the List.[328] The notice of proposed rulemaking, published by Health and Human Services ("HHS") on June 13, 2012, sought comments and feedback on the methodology used to evaluate evidence of cancer and on the proposed cost estimates associated with adding cancer coverage.[329] In response, HHS received twenty-seven substantive

---

[323] Hartocollis, *10 Years and a Diagnosis Later, 9/11 Demons Haunt Thousands*, *supra* note 4, at A20.

[324] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88).

[325] *See id.* for a complete listing of the types of cancers now included on the List. *See also* 42 C.F.R. 88.1 (2011).

[326] *See generally* World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88).

[327] *Id.* at 56140.

[328] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011) (amending Public Health Service Act, 42 U.S.C. ch. 6A (2001) by adding § 3312).

[329] World Trade Center Health Program; Addition of Certain Types of Cancer to the

submissions from a variety of stakeholders, including labors unions representing WTC responders, physicians specializing in 9/11 health care, and the WTC Health Program Survivors Steering Committee.[330] Individual first responders, survivors, and the families of those who have already died from 9/11-related cancer also submitted a number of comments.[331] The majority of comments were centered on preserving an equitable review process, ensuring that the WTC Health Program is not abused, and creating a methodology that is scientifically prudent.[332]

The final rulemaking adopts a methodology that uses a hierarchy of four methods to determine whether or not to add cancers or types of cancer.[333] In making this determination, the evidentiary review must demonstrate fulfillment of at least one of the four methods, listed below in order of preference:

- Method 1: Epidemiological Studies of September 11, 2001 Exposed Populations
- Method 2: Established Causal Associations
- Method 3: Review of Evaluations of Carcinogenicity in Humans
- Method 4: Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee.[334]

Method 1, the most traditional method, is the criteria initially outlined in the language of the Zadroga Act.[335] Under Method 1, a type of cancer can "be added to the List if published, peer-reviewed epidemiologic evidence supports a causal association between 9/11 exposures and the cancer type."[336] As recommended in this Article, the Administrator will use the Bradford Hill criteria to evaluate the

List of WTC-Related Health Conditions; Proposed Rule, 77 Fed. Reg. 35574 (June 13, 2012).

[330] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. at 56140.

[331] *Id.*

[332] *Id.* at 56144-47.

[333] *Id* at 56142.

[334] *Id.*

[335] James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. No. 111-347, 124 Stat. 3623 (2011) (amending Public Health Service Act, 42 U.S.C. ch. 6A (2001) by adding § 3312). *See also* World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138, 56142 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88).

[336] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. at 56142.

exposure-cancer relationship.[337] The strength of the association, the consistency of findings over multiple studies, the biological gradient (dose-response relationship) between the exposure and the type of cancer, and the biological plausibility will be considered.[338] When only one peer-reviewed study is available, the strength association must "place greater emphasis on statistical significance than on the magnitude of the effect."[339] As such, Method 1 is most useful when there is a large body of research available.[340]

If Method 1 cannot determine a causal relationship, the Administrator will consider the condition under Method 2.[341] Under Method 2, a type of cancer may be added to the List if there is "well-established scientific support published in multiple epidemiologic studies" showing a causal relationship between a health condition already covered by the List and the development of cancer.[342] In other words, it relies on the medical relationship between a WTC-health condition (i.e. inflammation) and the development of a certain type of cancer.[343]

Method 1 and Method 2 provide the most scientific certainty and are recognized as traditional methodologies for determining causation.[344] However, as this Article indicates, these Methods are "substantially limited in their ability to provide timely guidance" on whether or not an association exists.[345] Relying only on epidemiological evidence is not an equitable method for apportioning care. In the final rule-making, the Administrator likewise argues that "[w]aiting for definitive scientifically-unassailable epidemiological results before adding types of cancer to the List would prevent treatment of currently-enrolled WTC responders and survivors."[346] In addition to the temporal impossibilities, the Administrator also cites difficulties with such small

---

[337] *Id.*
[338] *Id.*
[339] *Id.*
[340] *Id.* at 56143-45.
[341] *Id.*
[342] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138, 56142 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88).
[343] *Id.*
[344] *Id.* at 56145-47.
[345] *Id.* at 56145.
[346] *Id.*

sample sizes and the rarity of many cancers as reasons to explore other methodologies, albeit with less scientific certainty.[347] As such, Methods 3 and 4 are available when epidemiologic evidence is not.

Method 3 determines causation by evaluating the risk of carcinogenicity from a certain compound or toxin.[348] In order to add a cancer under this Method, the agent (i.e. pollutant or toxin) must be documented as part of 9/11 exposures *and* must also be categorized as a human carcinogen.[349] The Method further specifies that the National Toxicology Program must determine that the 9/11 agent is known or reasonably anticipated to be a carcinogen and the International Agency for Research on Cancer must determine that "there is *sufficient or limited* evidence that the 9/11 agent causes a type of cancer."[350] The reliability of Method 3 stems from previous scientific scrutiny—toxic agents have long been the subject of numerous studies regarding their carcinogenic properties and are known to cause specific cancers in humans.

Method 4 is the final opportunity to establish causation between 9/11 exposure and cancer. Unlike the previous Methods, which rely on scientific data, Method 4 relies on other relevant evidentiary sources. When determining whether the occurrence of cancer is related to 9/11 exposure, this Method evaluates whether or not the STAC has a reasonable basis for its recommendation.[351] Because the STAC evaluates all types of evidence, including non-peer reviewed data (i.e. case studies and pubic commentary), this Method is not limited to statistical significance. For example, the STAC recommended that childhood cancers be covered because children are especially vulnerable to cancer, drink more water, breathe more air, and have overall higher environmental exposure than adults.[352] As further evidence supporting coverage, the STAC noted that the excess risks will likely go unnoticed in epidemiologic studies.[353] Given these arguments, childhood cancers (cancers diagnosed in persons under twenty years of age) are being

[347] *Id.*

[348] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138, 56145 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88).

[349] *Id.* at 56142.

[350] *Id.* at 56142-45.

[351] *Id.* at 56142.

[352] 2012 Recommendation, *supra* note 64 at 25-26.

[353] *Id.*

added to the List using Method 4.[354]

As with so many 9/11-related matters, the cancer conundrum is much more complicated than it appears—simply amending the List will not guarantee coverage. The next hurdle is cost. To date, the WTC Health Program has 55,000 participating first responders and anticipates enrolling an additional 25,000 first responders through 2016—for those needing cancer treatments under the Zadroga Act, the budget for providing this coverage is a serious concern.[355] The cost analysis in the Final Rule report estimates that WTC Health Program cancer coverage will cost $147,496,066 by 2016.[356] This estimate included four years of cancer treatment and assumed an incidence of cancer 21 percent higher than the average U.S. population cancer rate.[357] The 21 percent increase in cancer development for those with 9/11 exposure was derived from the data in the Zeig-Owens study and is considered a possible outcome.[358]

An immediate financial concern is the significant loss of funding from the possible automatic sequestration of federal funds in 2013.[359] Should Congress fail to enact deficit-cutting measures by January 2, 2013, approximately $118 million will be cut from the WTC Health Program—every dollar of which is needed to cover the cost of cancer treatment.[360] An estimated $38 million will be cut in 2013 alone.[361]

---

[354] *Id. See also* World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. 56138, 56142 (Sept. 12, 2012) (to be codified at 42 C.F.R. pt. 88) (stating that certain cancer types "may be added to the List if the STAC has provided a reasonable basis for adding a type of cancer and the basis for inclusion does not meet the criteria for Method 1, Method 2, or Method 3.").

[355] World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions, 77 Fed. Reg. at 56147-48.

[356] *Id.* at 56154, Table H.

[357] *Id.* at 56151.

[358] *Id.* at 56148 (as opposed to characterizing it as a "likely" outcome). The cost to cover cancer under the Zadroga Act will alter the amount distributed under the re-opened Victim's Compensation Fund. The Special Master is currently considering how to best prorate the share of claims for those now eligible for compensation as a result of cancer coverage. This may result in a smaller claim for claimants with non-cancer conditions.

[359] *9/11 Responders May Face Deep Cuts in Zadroga Funds*, WNYC.ORG, (Oct. 15, 2012), *available at* http://www.wnyc.org/articles/wnyc-news/2012/oct/15/911-responders-face-deep-cuts-if-zadroga-act-isnt-exempt/. *See also* Joseph Orovic, *Crowley: Reverser Zadroga Act Cuts*, QUEENS CHRONICLE, Nov. 8, 2012.

[360] Press Release, N.Y. State Representative Carolyn B. Maloney, *Representatives Maloney, Nadler, and King Pledge Bipartisan Effort Against Sequestration of 9/11 Health & Victim Compensation Funds*, (Sept. 20, 2012), *available at* http://maloney.house.gov/press-release/representatives-maloney-nadler-king-pledge-

Overall, the total cuts to the Zadroga Act will reach $329 million by 2016, which would be devastating to the WTC Health Program's ability to provide care.[362]

The following is a bipartisan plea by the three U.S. Representatives who fought for the Zadroga Act for nearly a decade:

> Considering how long it took Congress to act, we cannot allow those receiving the care they need and deserve from the Zadroga Act to be stranded by a sequester. This is one of the many compelling and urgent reasons why we pledge to work together in a bipartisan manner to prevent deficit cuts from jeopardizing these vital programs.[363]

On behalf of those first responders dependent on the WTC Health Program for cancer treatment, this Author could not agree more.

bipartisan-effort-against-sequestration-911.

[361] *9/11 Responders May Face Deep Cuts in Zadroga Funds*, *supra* note 359.

[362] *Representatives Maloney, Nadler, and King Pledge Bipartisan Effort Against Sequestration of 9/11 Health & Victim Compensation Funds*, *supra* note 360.

[363] *Id.*