PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

1. The authority citation for part 300 continues to read as follows:


2. Table 1 of appendix B to part 300 is amended by revising the entry for “FL”, “Escambia Wood—Pensacola”, “Pensacola” to read as follows:

Appendix B to Part 300—National Priorities List

<table>
<thead>
<tr>
<th>State</th>
<th>Site name</th>
<th>City/county</th>
<th>Notes a</th>
</tr>
</thead>
<tbody>
<tr>
<td>FL</td>
<td>Escambia Wood—Pensacola</td>
<td>Pensacola</td>
<td>P.</td>
</tr>
</tbody>
</table>

= Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

P = Sites with partial deletion(s).

[FR Doc. 2019–20347 Filed 9–23–19; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 023—Uterine Cancer, Including Endometrial Cancer; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

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

SUMMARY: On April 23, 2019, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 023) to add “endometrial cancer” to the List.

Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add the major site uterine cancer, including its subtype, endometrial cancer, to the List. The Administrator also finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of September 24, 2019.

ADDRESSES: Visit the WTC Health Program website at https://www.cdc.gov/wtc/received.html to review Petition 023.

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

SUPPLEMENTARY INFORMATION:

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service (PHS) Act, establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits for health conditions on the List to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

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

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

B. Procedures for Evaluating a Petition for Cancer

In addition to the regulatory provisions, the WTC Health Program has developed policies to guide the
deciding whether to propose adding the type of cancer to the List. If the Program determines that the relevant studies have the potential to provide a basis for deciding whether to propose adding the type of cancer to the List, the cancer type may be added to the List if one of the following methods is met:

**Method 1. Epidemiologic Studies of September 11, 2001-Exposed Populations.** The peer-reviewed, published, epidemiologic studies of 9/11-exposed populations are assessed by applying the following criteria extrapolated from the Bradford Hill criteria, as appropriate:

a. Strength of the association between a 9/11 exposure and a type of cancer (including the precision of the risk estimate). A precise risk estimate is expected to have a low uncertainty interval containing the true risk estimate for the association and the precision of the risk estimate.

b. Consistency of the findings across multiple studies. If only a single published epidemiologic study is available for assessment, the consistency of findings cannot be evaluated and more emphasis will be placed on evaluating the strength of the association and the precision of the risk estimate.

c. Biological gradient, or dose-response relationships between 9/11 exposures and the type of cancer, and

d. Plausibility and coherence with known facts about the biology of the type of cancer.

**Method 2. Established Causal Associations.** A type of cancer may be added to the List if there is well-established scientific support published in multiple epidemiologic studies for a causal association between that cancer and a condition already on the List of WTC-Related Health Conditions.

**Method 3. Review of Evaluations of Carcinogenicity in Humans.** A type of cancer may be added to the List under Method 3 if both of the following criteria are satisfied:

3A. Published Exposure Assessment Information. A 9/11 agent included in the Inventory of 9/11 Agents is identified, and

3B. Evaluation of Carcinogenicity in Humans from Scientific Studies. NTP has determined that the [identified] 9/11 agent is known to be a human carcinogen or is reasonably anticipated to be a human carcinogen, and IARC has determined there is sufficient or limited evidence that the 9/11 agent causes [the requested] type of cancer.

**Method 4. Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee.**

A type of cancer may be added to the List if the STAC has provided a reasonable basis for adding a type of cancer. If the evaluation of evidence required for any of the four methods demonstrates that the criteria in that method are satisfied, the Administrator will propose the addition of the type of cancer to the List.

C. Petition 023

On April 23, 2019, the Administrator received a petition (Petition 023) requesting the addition of “endometrial cancer” to the List. The petition included a 2002 study by Lioy et al. and a 2017 study by McElroy et al., which together provided sufficient medical basis for the petition to be considered valid because they demonstrate the presence of 9/11 agents, including cadmium, at the WTC site and that cadmium exposure is associated with a statistically significant increase in endometrial cancer risk. However, because neither Lioy et al. (2002) nor McElroy et al. (2017) is a peer-reviewed, published, epidemiologic study of endometrial cancer (or the major site, uterine cancer) in a 9/11-exposed population, neither study is considered relevant nor are they further reviewed in this action.

In the Program’s List of WTC-Related Health Conditions, types of cancer are identified by the major cancer site/histology groups that are commonly used in the reporting of cancer incidence data, using the groupings standardized by the National Cancer Institute’s Surveillance, Epidemiology and End Results Program (SEER) for national cancer surveillance. Cancer subtypes are not included in the List. Because endometrial cancer is a subtype of uterine cancer, the Program has

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4 See supra note 2.

5 9/11 agents are chemical, physical, biological, or other hazards reported in a published, peer-reviewed exposure assessment study of responders, recovery workers, or survivors who were present in the New York City disaster area, or at the Pentagon site, or the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1, as well as those hazards not identified in a published, peer-reviewed exposure assessment study, but which are reasonably assumed to have been present at any of the three sites. See WTC Health Program [2018], Development of the Inventory of 9/11 Agents, July 17, 2018, https://www.cdc.gov/ResearchGateway/Content/pdfs/Development_of_the_Inventory_of_9-11_Agents_20180717.pdf.

6 A precision of the risk estimate describes the uncertainty inherent in estimating the strength of association (the effect size) between exposure and health effect from observational data. It is expressed as a confidence interval illustrating a range of values that contains the true effect size. A narrow confidence interval indicates a more precise measure of the effect size and a wider interval indicates greater uncertainty.

7 The Inventory of 9/11 Agents is composed of those agents identified in Tables 1–4 of the document, Development of the Inventory of 9/11 Agents. See supra note 5.

8 The WTC Health Program Scientific/Technical Advisory Committee may be convened by the Administrator if he determines that its advice would be helpful. See supra note 3 at Sec. V.

9 See Petition 023, WTC Health Program: Petitions Received, http://www.cdc.gov/wtc/received.html.


13 Endometrial cancer develops in the lining of the uterus, called the endometrium. Although endometrial uterine cancer is the most common type of uterine cancer, accounting for more than 90 percent of cases, there are other types of uterine...
determined that the scope of this petition and subsequent Program review should include both endometrial cancer and the major site, uterine cancer.

D. Assessment of Scientific and Medical Information

In response to Petition 023, the Program conducted both a systematic literature search to identify peer-reviewed, published studies of uterine cancer, including endometrial cancer, in 9/11-exposed women, as well as a review of NTP and IARC classifications of 9/11 agents, including those 9/11 agents identified by IARC as carcinogenic agents with sufficient or limited evidence that the agent causes uterine cancer, including endometrial cancer, in humans.14 The National Cancer Institute has not identified any known risk factors for uterine cancer, including endometrial cancer; therefore, a systematic literature search for studies regarding a causal association between uterine or endometrial cancer and a health condition on the List was not conducted.15

Literature Search Results

Two publications were identified in the search for studies specifically regarding uterine cancer, including endometrial cancer, among 9/11-exposed populations, thus meeting the Program’s criteria for further evaluation: Li et al. [2012]16 and its update Li et al. [2016].17 In addition to the two Li et al. publications found in the literature search, the Program was aware of additional studies examining all types of cancer. See https://www.cancer.gov/types/uterine/patient/endometrial-treatment-pdq.

14 Databases searched include: CINAHL, Embase, NIOSHTIC-2, ProQuest Health & Safety, PsycINFO, Ovid MEDLINE, Scopus, Toxicology Abstracts/TOXLINE, and WTC Health Program Bibliographic Database. Keywords used to conduct the search include: Endometrial neoplasm, endometrial cancer, endometrial carcinoma, malignant neoplasm of endometrium, adenocarcinoma of endometrium, cancer of the endometrium, Uterine Neoplasm, malignant neoplasm of corpus uteri, uterine carcinoma. The literature search was conducted in English-language journals on May 23, 2019.


The studies identified as relevant during the literature review process were further assessed to determine whether they have sufficient quality and quantity to demonstrate a potential to support the addition of uterine cancer, including endometrial cancer. The relevant studies introduced above are described below, including a description of their respective strengths and limitations.

Jordan et al. [2011] conducted a mortality study among the cohort of WTC Health Registry enrollees that included 13,337 rescue/recovery workers (3,188 women) and 28,593 survivors (16,733 women) living in New York City at the time of their enrollment. The authors identified deaths occurring in 2003–2009 through linkage to New York City vital records and the National Death Index (NDI). Standardized mortality ratios (SMRs) were calculated with New York City rates from 2000 to 2009 as the reference. Within the cohort, proportional hazards were used to examine the relation between WTC-related exposure levels (high, intermediate, or low for each group, based on exposure to the dust cloud, and time and duration working on the pile) and all-cause mortality, but not mortality for specific cancers. All-
cause SMRs were significantly lower than that expected for rescue/recovery workers (SMR = 0.45, 95% CI [0.38–0.53]) and survivors (SMR = 0.61, 95% CI 0.56–0.66). There were no significantly elevated SMRs for any category of cancer examined, including cancer of female genital organs, among all studied Registry enrollees (SMR = 0.82, 95% CI 0.49–1.28), rescue/recovery workers (SMR = 0.67, 95% CI 0.08–2.43), or survivors (SMR = 0.84, 95% CI 0.49–1.35). Separate SMRs for cancer of specific types of female genital organs, including uterine cancer, were not provided. SMRs were adjusted for age, sex, race, and calendar year. Adjusted hazard ratios (AHRs) were adjusted for age, sex, and ethnic origin, income, smoking, and, for survivors, Registry recruitment source. This study’s limitations include possible selection bias, since enrollment in the Registry is voluntary. Exposure reporting may also be subject to recall error because 9/11 exposures were self-reported 2 to 3 years after the September 11, 2001 terrorist attacks and subsequent cleanup of the sites. The healthy worker effect puts the population of rescue/recovery workers at a lower risk of cancer compared to the general population, which includes persons who are chronically ill, hospitalized, or otherwise unemployable. In addition, other potential confounders, such as family cancer history and occupational exposures prior to September 11, 2001, were not measured.

Jordan et al. [2018] updated their 2011 study, discussed above, by including the full cohort of WTC Health Registry enrollees, not only those living in New York City at time of enrollment, and adding 5 years of follow-up. The 2018 update included 29,280 rescue/recovery workers (6,422 women) and 39,643 survivors (21,126 women). The authors used New York City population mortality rates from 2003 to 2012 as the primary reference, and also conducted a secondary analysis using U.S. population comparison rates from 2003 to 2011. Proportional hazards were used to examine the relation between WTC-related exposure levels (high, intermediate, or low for each group, based on time and duration in lower Manhattan) and total mortality, as well as overall cancer mortality, but not mortality for specific cancer types. Overall cancer SMRs were not elevated for rescue/recovery workers (SMR = 0.94, 95% CI 0.84–1.05), but were significantly elevated among survivors (SMR = 1.14, 95% CI 1.06–1.24) when compared to the New York City population; no elevated SMRs were reported for all cancers using the general U.S. population as reference. Cancers of the female genital organs were not significantly elevated among rescue/recovery workers or survivors (observed deaths = 7, SMR = 0.67, 95% CI 0.27–1.39 and observed deaths = 43, SMR = 1.17, 95% CI 0.85–1.58, respectively). The authors also examined 119 sub-categories of the major causes of death, but only reported statistically significant results: uterine cancers were not among the not reported causes of death, suggesting that the risk of uterine cancer was not significantly elevated. No statistically significant elevations and no significant trends were observed in the analyses of the association between WTC-related exposures and overall cancer mortality. Like the previously reviewed study, Jordan et al. [2018] is prone to selection bias, because enrollment in the Registry was voluntary. Further, 9/11 exposures were self-reported 2 to 3 years after the September 11, 2001 terrorist attacks, and thus are subject to recall error. The healthy worker effect may put the population of rescue/recovery workers at a lower risk of cancer compared with the general population. An analogous effect has been seen in people who volunteer for health studies and might have contributed to the low relative mortality in both the rescue/recovery and survivor participants. As in the previously described study, other potential confounders, such as family cancer history and occupational exposure prior to September 11, 2001, were not measured.

Li et al. [2012] conducted a cancer incidence study among enrollees in the WTC Health Registry who were residents of New York State on September 11, 2001, and had no history of cancer at the time of enrollment. A total of 55,778 individuals were eligible for the study, including 21,850 involved in rescue/recovery (4,185 women and 33,928 survivors not involved in rescue/recovery (18,922 women). The authors identified cancers by linkage to 11 state cancer registries based on the state of residence of the cohort member, and based expected numbers of cancers on New York State cancer rates. They used qualitative descriptions of 9/11 exposures to classify Registry enrollee exposure as high, intermediate, or low based on time and duration in lower Manhattan. The authors conducted separate analyses for rescue/recovery workers and for survivors, and presented separate results for the period of enrollment through 2006 (early period) and 2007 through 2008 (later period). Among rescue/recovery workers, the standardized incidence ratio (SIR) for all cancer sites combined was not statistically significantly elevated in either period (early period, SIR = 0.94; 95% CI, 0.82–1.08; late period SIR = 1.14; 95% CI, 0.99–1.30). Uterine cancer incidence was not elevated for rescue/recovery workers during the early period (five cases or less [the precise number of cases was not reported, likely because of restrictions on reporting small numbers], SIR = 0.97, 95% CI 0.2–2.83), and no cases were reported during the later period. Among survivors, no significantly increased incidence for all cancer sites combined was observed in either period. Uterine cancer incidence was not elevated for survivors during the early or late periods (early: observed uterine cancers = 16, SIR = 1.01, 95% CI 0.58–1.65 and late: observed uterine cancers = 14, SIR = 1.01, 95% CI 0.53–1.69, respectively). Results of analyses to assess the risk of uterine cancer as a function of 9/11 exposure levels were not reported. SIRs were stratified by age (5-year age groups), race/ethnicity, sex, and calendar period (2003–2006 and 2007–2008). Exposure covariates included age at enrollment, sex, race/ethnicity, 2002 household income level, education level, smoking status, enrollment source (identified by employers, government agencies, and other entities or by an outreach campaign), and history of asthma, cardiovascular disease, stroke, emphysema, or diabetes reported at enrollment. But other potential confounders, such as family cancer history and occupational exposures prior to September 11, 2001, were not measured. The study by Li et al. [2012] is prone to selection bias because enrollment in the Registry was voluntary. The authors attempted to mitigate this bias by restricting the analyses to individuals without prior invasive cancer history documented in any of the 11 state cancer registries and focusing on cancer incidence from 2007 to 2008. Self-reported 9/11 exposures may be subject to recall error. Cancer cases identified through linkages with

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29 SIR is a mathematical expression that compares the incidence experience between the population under study and the experience of that population had they had the same incidence experience of a comparison population.
state cancer registries might be underestimated, especially among those
without a known Social Security number because a percentage of Registry
enrollees did not provide one. The findings on rescue/recovery workers
may also be prone to the healthy worker effect.

Li et al. [2016] updated their 2012 study, discussed above, which
evaluated excess cancer among WTC Health Registry enrollees. In the 2016
update, the authors added 3 years of follow-up to allow for 10 years of cancer
latency since the WTC-related exposures. The 2016 study recalibrated
the definition of “WTC disaster physical exposures” to emphasize potential
contaminants containing carcinogens. The analysis focused on cancers
occurring from 2007 through 2011. In
this study included a total of 60,339 eligible
individuals, including 24,863 rescue/
recovery workers (5,015 women) and
35,476 survivors not involved in rescue/
recovery (18,845 women). The authors
identified cancers by linkage to 11 state
cancer registries based on the state of
residence of the cohort member, and based
expected numbers of cancers on overall New York State rates and
person-years of follow-up during 2007–2011, adjusted for age (5-year groups),
race/ethnicity, sex, and calendar period
(2007–2011). The study found that
overall cancer incidence was significantly greater than the reference
(non-9/11-exposed) population among both rescue/recovery workers (SIR =
1.11, 95% CI 1.03–1.20) and survivors (SIR = 1.08, 95% CI 1.02–1.15). Uterine
cancer incidence was not significantly
higher among rescue/recovery workers
nor among survivors (observed uterine
cancers = 8, SIR = 0.82, 95% CI 0.35–
1.62 and observed uterine cancers = 37,
SIR = 1.03, 95% CI 0.72–1.41,
respectively). Comparisons among
exposure groups were not reported for
uterine cancer. In internal analyses,
hazard ratios and 95% CI were adjusted
for age at enrollment, sex, race/ethnicity,
smoking, education, income, and history of a serious non-malignant
medical condition; however, findings
for uterine cancer were not reported.
Other potential confounders were not measured. This study was prone
to selection bias, because enrollment in the Registry was voluntary; the authors
attempted to mitigate this bias by
restricting the analyses to individuals
without prior invasive cancer history
documented in any of the 11 state
cancer registries and focusing on cancer incidence from 2007 through 2011. In
addition, findings on rescue/recovery
workers may also be subject to the healthy worker effect.

Solan et al. [2013] conducted a cancer
incidence study among 20,984 non-
FDNY WTC Health Program members
(3,203 women) involved in rescue,
recovery, and cleanup efforts at Ground
Zero after 9/11. The authors identified
cancer cases through linkage with the
tumor registries in the four states in
which 98 percent of WTC responders resided at time of enrollment in the
Program. Self-reported exposures were
analyzed using four variables: Pre-
September 11, 2001 occupation, extent
of exposure to the dust cloud on
September 11, 2001, duration of time
spent working at the site, and work on
the debris pile during four periods
(September 2001, October 2001,
November–December 2001, and
January–June 2002). An integrated
exposure variable was created using a 4-
point scale (very high, high,
intermediate, and low) based on total
time spent working at Ground Zero,
exposure to the dust cloud, and work on
the debris pile. The authors obtained
data on vital status through linkage with the
NDI and next-of-kin reports. Expected
numbers of cancer cases were calculated
based on state rates (for New York, New
Jersey, and Connecticut residents) and
national rates (for Pennsylvania
residents) according to age (in 5-year groups), sex, and race/ethnicity for each
year at risk. The observed and expected
numbers of cancers were used to
calculate SIRs. The SIR among study
participants was elevated and
statistically significant for all cancer
sites combined (SIR = 1.15; 95%
confidence interval (CI), 1.06–1.25).
Fewer than six cases of uterine cancer
were observed, and no additional
information was reported for this type of
cancer. Furthermore, no SIRs were
reported for uterine cancer nor were risk
eras reported for the association
between 9/11 exposure variables and
uterine cancer. Certain potential
confounders, such as family cancer
history, were not measured. The study
is also prone to selection bias, because
enrollment in the WTC Health Program
is voluntary. Although the authors used
all available exposure metrics, relative
risk was not reported for the association
between 9/11 exposure variables and
uterine cancer. This study may also be
subject to the healthy worker effect,
which puts this population at a lower
risk of cancer compared to the general
population.

Kleinman et al. [2015] investigated
cancer incidence in 29,946 police
officers employed by the New York City
Police Department (NYPD) on
September 11, 2001 (6,366 women),
followed during the time periods 1995
to 2000 and 2002 to 2014. The authors
reported a 44 percent increase in the
overall median age-adjusted incidence
rate for all cancers, but no increase in
the overall median age-adjusted incidence
rates for either malignant
neoplasms of the uterus, unspecified
part (based on two cases diagnosed pre-
9/11 and zero cases diagnosed post-9/11)
or uterine adenosarcomas (based on
zero cases diagnosed pre-9/11 and three
cases post-9/11). This study is limited
by the inherent problems with its design
(i.e., the effects of age, time period, and
cohort parameters are intertwined in a
manner which complicates study
interpretation); the study is further
limited by the small number of cancer
cases observed as well as the absence of
information regarding participants’
presence in the dust cloud and the dates
and duration of their 9/11 exposures.

Stein et al. [2016] conducted a
mortality study of 28,918 rescue/
recovery workers (4,286 women)
enrolled in the WTC Health Program
between July 16, 2002, and December
31, 2011. The authors were aware that
16,177 WTC responders were alive due
to follow-up visits after the end of 2011,
and therefore linked the remainder (n =
12,741) to the National Death Index
(NDI). Mortality information from the
NDI was supplemented by next-of-kin
report. Similar to the study by Solan et al. [2013], discussed above, the authors
of this study created an integrated
exposure variable using a 4-point scale
(very high, high, intermediate, and low)
based on total time spent working at
Ground Zero, exposure to the dust
cloud, and work on the debris pile.
SMRs were standardized for age (5-year groups), sex, race, and calendar year to
compare all-cause and cause-specific
mortality among responders with
mortality in the U.S. general population.
Hazard ratios were adjusted for age on
September 11, 2001, pre-September 11,
2001 occupation, race/ethnicity, year of WTC Health Program
enrollment, smoking, and measured
body mass index. Overall mortality in
this cohort was statistically significantly
declined (SMR = 0.43; 95% CI, 0.39–
0.48), although an overall cancer SMR
was not reported. Most cancer site-
specific SMRs were significantly
declined; however, the SMR for cancer of
the female genital organs was
decreased but was not statistically
significant (SMR = 0.65, 95% CI 0.88–
2.37) and was based on only two deaths.
An SMR for uterine cancer was not
provided, neither were hazard ratios for
the association between WTC-related
exposure variables and mortality from
uterine cancer. Some potential confounders, such as family cancer history, were not measured. The study is prone to selection bias because enrollment in the WTC Health Program was voluntary. Social Security numbers were available for only 37 percent of the records sent to NDI for linkage, limiting the quality of the matches. The healthy worker effect may put this population at a lower risk of cancer compared to the general population.

Quantity and Quality Review of Relevant Studies

The quantity and quality of these seven studies were reviewed together to examine whether the available evidence has the potential to provide a basis for a decision on whether to add uterine cancer, including endometrial cancer, to the List. Prospective cohort studies, like those described above, have the advantage that study participants are considered to be disease-free at the beginning of the observation period when their exposure occurred; therefore, in such studies it is often possible to establish the temporal sequence between exposure and outcome. Cancer studies, however, present unique concerns since some cancers become apparent only after long periods of time following exposure.31 This latency effect means it is possible that a cancer may have been present but undetected prior to September 11, 2001. In addition, all of the studies described above have had a relatively short period of follow-up since September 11, 2001. The size and makeup of the cohorts studied may also limit the usefulness of the studies. The studies discussed above may not have the necessary statistical power to detect excesses in uterine cancer, due to the small number of females in the cohort. This is especially a concern with studies of 9/11-exposed rescue/recovery workers since those cohorts are not sizeable and only approximately 15 percent female. Moreover, the overlap in participation among the studies. Approximately 20 percent of 9/11-exposed rescue/recovery workers enrolled in the WTC Health Program are also enrolled in the WTC Health Registry. These two cohorts also may be prone to selection bias, because enrollment in the respective programs was voluntary. For the WTC Health Registry cohort, it is possible that differential participation due to race/ethnicity, socioeconomic status, age, or their perception of being affected by the 9/11 attacks, may have occurred. For the rescue/recovery worker cohort enrolled in the WTC Health Program, their health status, including their cancer diagnosis, may have prompted them to enroll. A strength of these studies is that findings are available for both 9/11-exposed rescue/recovery workers as well as survivors.

The relevant studies published to date, and reviewed above, do not provide consistent evidence that uterine cancer, including endometrial cancer, incidence or mortality is elevated among WTC responders and/or survivors. In addition, the studies did not report a dose-response relationship between WTC-related exposures and uterine cancer, including endometrial cancer. Taken together, these studies do not have sufficient quality and quantity to demonstrate a potential to provide a basis for a decision on whether to add uterine cancer, including endometrial cancer, to the List. Accordingly, these studies are not further reviewed.

Administrator Determination

Upon review of the evidence available in peer-reviewed, published, epidemiological studies and updates regarding uterine cancer, including endometrial cancer, among 9/11-exposed populations, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to propose adding uterine cancer, including endometrial cancer, to the List. Accordingly, the Administrator has not directed the Program to assess the available evidence using Methods 1, 2, or 3, nor has he directed the Program to request advice from the STAC pursuant to Method 4, discussed above.

The WTC Health Program may consider uterine cancer, including endometrial cancer, to be a condition medically associated with a certified WTC-related health condition in individual cases. Program members who think their uterine or endometrial cancer is a side effect of treatment of a certified WTC-related health condition should ask their WTC Health Program medical provider whether their endometrial cancer might be considered a medically associated health condition.

E. Administrator’s Final Decision on Whether To Propose the Addition of Uterine Cancer, Including Endometrial Cancer, to the List

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

For the reasons discussed above, the Petition 023 request to add endometrial cancer to the List of WTC-Related Health Conditions is denied.

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

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit this document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Robert Redfield M.D., Director, CDC, and Administrator, ATSDR, approved this document for publication on September 12, 2019.

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

[FR Doc. 2019–20364 Filed 9–23–19; 8:45 am]

BILLING CODE 4163–18–P