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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

World Trade Center Health Program; Certification of Breast Cancer in WTC Responders and Survivors Exposed to PCBs

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Change in certification requirements.

SUMMARY: On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of World Trade Center (WTC)-Related Health Conditions (List) established in the WTC Health Program regulation. Breast cancer was included on the List, although only individuals experiencing nighttime sleep disruption as a result of response and cleanup activities involving shiftwork are currently considered to have experienced exposure relevant for certification. A recent publication in The Lancet Oncology by the International Agency for Research on Cancer (IARC) concludes that there is limited evidence that polychlorinated biphenyls (PCBs) cause breast

cancer in humans. As described below, the WTC Program Administrator (Administrator) has found that PCBs were present in WTC dust in the New York City disaster area and, accordingly, the Program will now certify breast cancer in eligible WTC responders and survivors who were exposed to either shiftwork/nighttime sleep disruption or PCBs as a result of the 9/11 attacks.

DATES: This change in certification requirements is effective [Insert date of publication in the Federal Register].

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SUPPLEMENTARY INFORMATION:

A. Background

On September 7, 2011, the Administrator received a written petition to add cancers to the List of WTC-Related Health Conditions in 42 CFR 88.1 (Petition 001). On October 5, 2011, the Administrator formally exercised his option to request a

recommendation from the WTC Health Program Scientific/Technical Advisory Committee (STAC) regarding the petition.¹ The Administrator requested that the STAC “review the available information on cancer outcomes associated with the exposures resulting from the September 11, 2001, terrorist attacks, and provide advice on whether to add cancer, or a certain type of cancer, to the List specified in the Zadroga Act.” Following three public meetings where the Committee deliberated on the issues, the STAC submitted its recommendation on Petition 001 to the Administrator on April 2, 2012. After considering the STAC’s recommendation, the Administrator issued a notice of proposed rulemaking on June 13, 2012 [77 FR 35574]. On September 12, 2012, HHS published a final rule in the **Federal Register** adding certain types of cancer to the List of WTC-Related Health Conditions in 42 CFR 88.1 [77 FR 56138]. On October 12, 2012, HHS published a Federal Register notice to correct errors in Table 1 of the final rule (the list of cancers covered by the Program) [77 FR 62167].

B. Administrator’s Determination on the Inclusion of Female Breast Cancer

¹ See 42 CFR 88.17(a)(2)(i).

In the final rule, the Administrator established a four-pronged Methodology for evaluating whether to add certain types of cancer to the List: Epidemiologic Studies of September 11, 2001 Exposed Populations (Method 1); Established Causal Associations (Method 2); Review of Evaluations of Carcinogenicity in Humans, requiring **both** Published Exposure Assessment Information, and Evaluation of Carcinogenicity in Humans from Scientific Studies (Method 3, including criteria 3A and 3B); and Review of Information Provided by the WTC Health Program Scientific/Technical Advisory Committee (Method 4). A full narrative description and graphic of the Methodology were published in the final rule [77 FR 56138, 56142-56143 (September 12, 2012)].

At the time of the Administrator's deliberation, breast cancer was determined to meet Method 4 (the STAC had provided a reasonable basis for its inclusion on the List). In its April 2, 2012 recommendation, the STAC had reported that:

There is evidence of PCB [polychlorinated biphenyl] exposures to WTC responders and survivors based on air samples, window film samples and one biomonitoring study. Studies have linked total and congener-specific PCB levels in serum and adipose tissue with breast cancer, although evidence has been conflicting. PCBs and some other substances at the WTC site are endocrine disruptors. Breast cancer risks are highly related to hormonal factors, including endogenous and exogenous estrogens, and could plausibly be affected by endocrine disruptors. A recent study found that PCBs enhanced the metastatic properties of breast cancer cells by activating rho-associated kinase. Shiftwork involving circadian rhythm disruption has been

classified by IARC as probably carcinogenic to humans, based in part on epidemiologic studies associating shiftwork with increased risks of breast cancer. Both shiftwork and long shifts were common for workers involved in rescue, recovery, clean up, restoration and other activities at the WTC site.² [references omitted]

Although the STAC specified that PCBs might be causally associated with breast cancer, the Committee provided stronger evidence (IARC classification as a carcinogen) that shiftwork involving circadian rhythm disruption, as a 9/11 exposure, could be associated with breast cancer.³ For that reason, the Administrator determined that breast cancer would be included on the List, but that the relevant exposures would be limited to nighttime sleep disruption related to response and cleanup activities (including shiftwork). Accordingly, the WTC Health Program has only considered exposure to nighttime sleep disruption related to response and cleanup activities when certifying breast cancers for treatment in WTC responders and survivors.

² STAC [World Trade Center Health Program Scientific/Technical Advisory Committee] [2012]. Letter from Elizabeth Ward, Chair to John Howard, MD, Administrator. This letter is included in NIOSH Docket 257, <http://www.cdc.gov/niosh/docket/archive/docket257.html>.

³ Shiftwork involving circadian rhythm disruption has been classified by IARC as probably carcinogenic based in part on limited evidence in humans demonstrating an increased risk of breast cancer among shiftworkers who work at night. IARC notes that mechanistic studies suggest that exposure to light at night may increase the risk of breast cancer by suppressing the normal nocturnal production of melatonin, which in turn, may alter gene expression in cancer-related pathways [Straif, et al. 2007]. NTP has not yet examined the evidence for an association of shiftwork and breast cancer, however, NTP recently requested comment from the public on whether shiftwork involving light at night should be nominated for possible review for future editions of the RoC. [NTP 2012] The Administrator was not aware of any published exposure assessment study of shiftwork and 9/11, although the Administrator was aware that extended work hours for many responders occurred at all three 9/11 sites over several months. Thus the evidence supporting an association between shiftwork and breast cancer did not meet all of the requirements of Method 3; however, the Administrator felt the STAC's recommendation and support for an association between shiftwork and female breast cancer was sufficient to add breast cancer to the List of WTC-Related Health Conditions based on Method 4.

C. New Information on Breast Cancer and PCBs

On March 15, 2013, the IARC Monograph Working Group announced a change in its classification of polychlorinated biphenyls (PCBs). According to the Working Group's article, published in The Lancet Oncology,⁴ a review of more than 70 epidemiological studies led IARC to determine that the studies provided limited evidence of increased risks for breast cancer for individuals with exposures to PCBs.⁵

In reviewing this new information, the Administrator finds that all of the criteria in Method 3 supporting the addition of breast cancer to the List based on PCB exposures are now satisfied: PCBs have been reported in several exposure assessment studies of responders or survivors of the September 11, 2001, terrorist attacks in New York City (Method 3A);⁶ NTP identified PCBs as reasonably anticipated to be a human

⁴ Lauby-Secretan B, Loomis D, Grosse Y, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Baan R, Mattock H, Straif K (on behalf of IARC Monograph Working Group) [2013]. Carcinogenicity of Polychlorinated Biphenyls and Polybrominated Biphenyls. *The Lancet Oncology* 14(4):287-288.

⁵ According to the Lancet article, the Working Group's assessments will be published as volume 107 of the IARC Monographs.

⁶ Butt CM, Diamond ML, Truong J, Ikonomou MG, Helm PA, Stern GA [2004]. Semivolatile organic compounds in window films from lower Manhattan after the September 11th World Trade Center attacks. *Environmental Science & Technology*. 38(13):3514-3524.

Lorber M, Gibb H, Grant L, Pinto J, Pleil J, Cleverly D [2007] Assessment of inhalation exposures and potential health risks to the general population that resulted from the collapse of the World Trade Center towers. *Risk Anal* 27(5):1203-21.

Lioy PJ, Gochfeld M [2002]. Lessons learned on environmental, occupational, and residential exposures from the attack on the World Trade Center. *Am J Ind Med* 42(6):560-565.

carcinogen⁷ **and** IARC has recently found limited evidence that PCBs cause breast cancer (Method 3B).

Consequently, the Administrator finds that PCB exposures associated with the 9/11 attacks (including response and remediation activities) qualify as another exposure basis -- in addition to nighttime sleep disruption related to response and cleanup activities (including shiftwork) -- for certifying a member's breast cancer for treatment.

D. Effect on Breast Cancer Coverage

As a result of this finding by the Administrator, eligible responders and survivors who experienced the requisite exposure to either nighttime sleep disruption related to response and cleanup activities (including shiftwork) or PCBs (in dust and smoke) resulting from the 9/11 attacks may be certified for treatment of breast cancer.

April 11, 2013

John Howard, M.D.

Dated

Director, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

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⁷ NTP (National Toxicology Program) [2011]. 12th Report on Carcinogens. National Toxicology Program, Public Health Service, U.S. Department of Health and Human Services, Research Triangle Park, NC. <http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/PolychlorinatedBiphenyls.pdf>. Accessed March 28, 2013.