



ADVISORY BOARD ON RADIATION AND WORKER HEALTH

4676 Columbia Parkway, MS: C-46
Cincinnati, Ohio 45226
(513) 533-6825

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The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

The Advisory Board on Radiation and Worker Health (ABRWH) is submitting comments to you pertaining to Department of Health and Human Services Regulation proposed changes to 42 CFR Part 81, Guidelines for Determining Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Revision of Guidelines on Non-Radiogenic Cancers. [Docket Number NIOSH-209 (RIN 0920-AA39)] These comments were approved by the Board at its recent meeting on July 11, 2011.

1. The ABRWH offers the following comments on the question "Does epidemiological and other scientific research support finding that Chronic Lymphocytic Leukemia (CLL) is caused by radiation?"
 - Although most members of this Board do not have expertise in epidemiological research, several do and with their expertise we were able, as a Board, to assess the approach used by NIOSH to answer this specific question. That approach has been detailed in Docket Number NIOSH-209. Through the use of recognized experts, NIOSH has been able to demonstrate that the available limited epidemiological evidence is supportive of a possible association between ionizing radiation and CLL.
 - Including CLL as radiogenic is appropriate in that it follows NIOSH's approach of erring on the side of the claimant when scientific knowledge is lacking.
2. The ABRWH agrees with the NIOSH position set forth in the docket as follows:
 - "Given that the law requires the use of the upper 99 percent credibility level in making compensation decisions, the inclusion of CLL despite the limited evidence of radiogenicity, is considered appropriate by NIOSH."
3. The ABRWH offers the following comments on the question "If CLL were to be covered under EEOICPA, does the risk model proposed by the

National Institute for Occupational Safety and Health use the best available science and methodological approaches to express the dose-response relationship between radiation exposure and CLL?”

- We agree that the use of the lymphoma and multiple myeloma risk models as a starting point is appropriate, given the fact that CLL is now classified by the National Cancer Institute and by the World Health Organization as a form of non-Hodgkin's lymphoma.
- The proposed risk model makes use of the available scientific literature concerning the latency period for CLL and selects a conservative (claimant favorable) value for the midpoint of the latency period and is therefore appropriate.
- The proposed uncertainty band for the midpoint of the latency period is sufficiently large so as to fairly reflect the spread seen in the available studies.
- We concur with the approach of using the weighted radiation dose to the B lymphocytes, based on the dose to a given site and the probability that a B cell precursor for CLL will occupy that site.

The ABRWH appreciates the opportunity to comment on the proposed revision of the Guidelines for Determining Probability of Causation under the Energy Employees Occupational Illness Compensation Program Act of 2000.

Sincerely,

[Signature on file]

James M. Melius, M.D., Dr. PH
Chairman, ABRWH