

Chronic Lymphocytic Leukemia: Reconsideration of Exclusion from Eligibility for Compensation under EEOICPA

EEOICPA

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) provides a lump sum payment of \$150,000 plus medical benefits to any covered former U.S. nuclear weapons worker diagnosed with cancer, if that cancer was judged to be “as least as likely as not” (a 50% or greater probability) caused by occupational exposure to ionizing radiation. The Department of Health and Human Services (HHS) is charged with developing and updating, as needed, the scientific guidelines for assessing eligibility for compensation. The Office of Compensation Analysis and Support (OCAS) of the National Institute for Occupational Safety and Health (NIOSH) performs this function for HHS.

Each cancer claim filed under EEOICPA is individually evaluated according to the claimant’s radiation dose, type of cancer, and other relevant factors via a computerized set of quantitative risk assessment models. Most of the computerized models are derived from a set of radio-epidemiological tables that were created to provide “probability of causation” estimates for individuals with cancer who were exposed to ionizing radiation. Under EEOICPA, “probability of causation” is the likelihood, expressed as a percentage, that a worker’s cancer was caused by occupational exposure to ionizing radiation.

The amount and type of radiation exposure incurred by a claimant is established by a process called “dose reconstruction.” Dose reconstruction consists of systematic research and analysis leading to a quantitative estimate of dose. This reconstructed radiation dose, along with the type of cancer and related factors, are the key determinants of probability of causation and the success or failure of a claim. A probability of causation of 50% or greater means that the cancer was at least as likely as not induced by radiation and, thus, that it merits compensation.

The primary source of data for the Radio-Epidemiological Tables is the excess cancer incidence among Japanese A-bomb survivors from World War II. The Tables were originally created by the National Institutes of Health (NIH) in 1985 and have since been updated by the National Cancer Institute (NCI.) They have been modified further by NIOSH to fit the Cold War radiation exposures of U.S. nuclear weapons workers.

Treatment of Chronic Lymphocytic Leukemia (CLL) under EEOICPA

Chronic lymphocytic leukemia (CLL), the most prevalent form of leukemia in the United States, is a slowly progressing cancer that is strongly associated with older ages. CLL is currently regarded as non-radiogenic under HHS regulations (42 CFR Part 81, published in May 2002) that established the guidelines for determining probability of causation under EEOICPA. CLL is the only type of cancer that is assigned, a priori, a probability of causation of zero (42 CFR 81.21 & 81.30.)

Why CLL was Excluded from Coverage

NIOSH excluded CLL from coverage under EEOICPA because:

(1) No elevation of CLL incidence had been observed among the Japanese A-bomb survivors; nor, in NIOSH's judgment at the time 42 CFR 81 was published, did other epidemiological evidence convincingly support a positive association between ionizing radiation and an increased risk of CLL.

(2) CLL has traditionally been regarded as non-radiogenic and, as such, had been omitted from the 1985 NIH Radio-epidemiological Tables and from subsequent NCI updates to those tables, and is not covered by other radiation compensation programs.

Reconsideration of CLL

Although NIOSH initially designated CLL as non-radiogenic, as discussed above, other types of cancer lacking compelling evidence of radiogenicity (prostate cancer, non-Hodgkin's lymphoma, hairy cell leukemia, etc.) were not excluded from eligibility for compensation. For those cancers, NIOSH judged that the weight of the evidence, though in some instances marginal, was nonetheless sufficient to err on the side of eligibility.

This perceived inconsistency in the treatment of cancers with questionable evidence of radiogenicity has generated concern among EEOICPA claimants and other stakeholders. To address this concern, NIOSH is reconsidering its exclusion of CLL from eligibility for compensation.

Arguments for Including CLL

EEOICPA stakeholders have advanced the following arguments for including CLL:

(1) Of the hundreds of different types and sub-types of cancer, including many with sparse evidence of radiogenicity, only CLL is specifically excluded from compensation under EEOICPA. It is simply not plausible that CLL could be the only type of cancer that can not possibly be induced by some level of radiation. Moreover, there is no scientific evidence that convincingly demonstrates it is non-radiogenic.

NIOSH comment: NIOSH does not assert that evidence proves CLL is non-radiogenic, only that the weight of the evidence has not supported the case for radiogenicity.

(2) A major reason for excluding CLL was the apparent absence of excess risk among the Japanese A-bomb survivor cohort. However, the reported incidence of CLL varies widely among populations throughout the world. In fact, CLL is rare among the Japanese population and extremely rare among Japanese females (the majority of the A-bomb cohort) prior to age 70. Thus, the ability to detect excess CLL risk due to radiation exposure from atomic bombs is poor.

NIOSH comment: NIOSH agrees that the statistical power to detect excess CLL risk among the Japanese survivor cohort is limited.

(3) Hairy cell leukemia (HCL) is a slowly progressing lymphocytic leukemia. Because its symptoms are similar to CLL, it has sometimes been misdiagnosed as CLL. In fact, the Hairy Cell Leukemia Research Foundation refers to it on their Web site as a type of CLL. Misdiagnoses of cancers of the blood and bone marrow were much more common in the time period during which many EEOICPA claimants were diagnosed with cancer, i.e., before improvements in diagnostic techniques had been achieved. For that reason, it's very likely that medical records for some claimants may contain inaccurate diagnoses. Despite the similarities between HCL and CLL and the diagnostic problems associated with those similarities, HCL is eligible for compensation under EEOICPA, but CLL is not. The disparity in treatment of these diseases is neither fair nor justified.

NIOSH comment: NIOSH defers to NCI for expertise on the classification of cancers, and NCI regards HCL and CLL as separate diseases. Moreover, HCL was covered under the original NIH Radio-Epidemiological Tables, whereas CLL was excluded. Diagnostic issues notwithstanding, NCI has consistently maintained the distinction between CLL and HCL in its updates to those tables. On the other hand, it should also be noted that this distinction is not universal; for example, the United Kingdom's radiation compensation program excludes CLL and HCL from compensation eligibility.

(4) NIOSH convened a public meeting in Washington, DC on July 21, 2004 to seek input on gaps in CLL research. This meeting featured a panel discussion of experts from the fields of epidemiology, medicine, radiobiology, and related health sciences. There was a clear consensus among this NIOSH-convened panel that scientific evidence is inconclusive with respect to CLL's association with ionizing radiation. The intent of EEOICPA, and the often stated intention of NIOSH in carrying out its mandate under EEOICPA, is to err on the side of the claimant whenever scientific evidence is lacking. The arbitrary exclusion of CLL, without regard to an individual's degree of radiation exposure or to the stochastic nature of cancer risk, is clearly contrary to that intent.

NIOSH comment: The public meeting referred to above was convened by NIOSH's Health-Related Energy Research Branch (HERB) as part of an ongoing effort to investigate the possible relationship between ionizing radiation and CLL. HERB has not yet released a written summary report of that meeting. However, OCAS staff who attended had the impression that, although expert opinion was rather wide-ranging, at least some panel members seemed to agree that scientific evidence is inconclusive with respect to CLL's etiology and to its association with radiation. Pending release of the HERB report, NIOSH reaffirms its commitment to err on the side of the claimant when the state of scientific knowledge is lacking.

Question

Please review the above issues raised by EEOICPA stakeholders. In your expert judgment, is the evidence of an association, or lack thereof, between radiation exposure

and the risk of developing CLL sufficient to continue to regard CLL as a non-radiogenic cancer and to continue to exclude it, a priori, from eligibility for compensation under EEOICPA? Your professional conclusion may be based on any combination of personal expertise, reference materials of your own choosing, the documents attached, or the arguments summarized above. Please provide the rationale for your conclusion.

As noted in the cover letter, E-mail is an acceptable mode of transmission for your response and for your invoice for payment. These, as well as questions or requests for additional reference materials, should be directed to:

NIOSH

Acronyms

CLL: chronic lymphocytic leukemia

EEOICPA: Energy Employees Occupational Illness Compensation Program Act of 2000, as amended

HCL: hairy cell leukemia

HERB: Health-Related Energy Research Branch (a branch of NIOSH)

HHS: Department of Health and Human Services

NCI: National Cancer Institute

NIH: National Institutes of Health

NIOSH: National Institute for Occupational Safety and Health

OCAS: Office of Compensation Analysis and Support (an office of NIOSH created to carry out HHS' responsibilities under EEOICPA)

Attachments

42 CFR Parts 81 and 82: Guidelines for Determining the Probability of Causation and Methods for Radiation Dose Reconstruction under the Employees Occupational Illness Compensation Program Act of 2000; Final Rules. HHS: May 2002

Chronic Lymphocytic Leukemia: Annotated Bibliography. Health-Related Energy Research Branch, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH: 2004.