



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 11 2005

The Honorable Richard Cheney
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

Pursuant to the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) and 42 C.F.R. pt. 83, a petition was filed on behalf of a class of workers from the Mallinckrodt Destrehan Street facility in St. Louis, Missouri, to have Mallinckrodt added to the Special Exposure Cohort (SEC).

On July 21, 2004, the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) received a petition on behalf of a class of employees to have the following Mallinckrodt class added to the SEC:

All employees that worked in the uranium division at the Mallinckrodt Destrehan Street facility in St. Louis, Missouri, from 1942-1957.

On November 24, 2004, the Mallinckrodt petition qualified for evaluation under 42 C.F.R §§ 83.7-83.9. NIOSH evaluated the petition using the procedures in 42 C.F.R. § 83.13 and on February 2, 2005, submitted its findings to the petitioners and the Advisory Board on Radiation and Worker Health (ABRWH). On February 8, 2005, the ABRWH heard presentations by NIOSH summarizing its evaluation of the petition and heard comments from the petitioners and the public. On March 14, 2005, the ABRWH provided me with recommendations concerning this petition that were limited to employees at this facility during the period 1942 through 1948, followed on March 14, 2005, by a proposed decision from the Director, NIOSH.

Based upon consideration of the recommendations, findings, and deliberations of the ABRWH and concurrence by the Director, NIOSH, and also by the Director, Centers for Disease Control, I have designated the following class for addition to the SEC:

Employees of the Department of Energy (DOE) or DOE contractors or subcontractors employed by the Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility, during the period from 1942 through 1948 and who were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days within the parameters (excluding


aggregate work day requirements) established for other classes of employees included in the SEC.

The criteria and findings upon which this designation is based are provided in the enclosed report.

Please note that ABRWH and NIOSH have not completed consideration of the petition submitted for the Mallinckrodt Destrehan Street Facility. The class of employees at the Destrehan facility from 1949 through 1957 will receive further consideration at a meeting of the Board on April 25-27, 2005. Furthermore, the current designation in the enclosed report may be subject to administrative review should the petitioner seek further consideration of the health endangerment finding included therein.

Please call me if you have any further questions regarding this matter.

Sincerely,


Michael O. Leavitt

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 11 2005

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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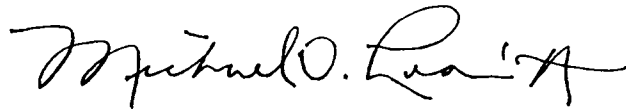
aggregate work day requirements) established for other classes of employees included in the SEC.

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Please call me if you have any further questions regarding this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael O. Leavitt". The signature is fluid and cursive, with a large initial "M" and a stylized "L".

Michael O. Leavitt

Enclosure

HHS Designation of Additional Members of the
Special Exposure Cohort
under the
Energy Employees Occupational Illness Compensation Program Act

Designating a Class of Employees from
Uranium Division of Mallinckrodt Chemical Works,
Destrehan Street Facility,
St. Louis, Missouri



HHS Special Exposure Cohort Designation:
Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility

I. Designation

I, Michael O. Leavitt, Secretary of Health and Human Services (“the Secretary”), designate the class of employees defined in Section II of this report for addition to the Special Exposure Cohort (“the SEC”), as authorized under the Energy Employees Occupational Illness Compensation Program Act of 2000 (“EEOICPA”), 42 U.S.C. § 7384q.

Date:

APR 11 2005



Michael O. Leavitt

II. Employee Class Definition

Employees of the Department of Energy (DOE) or DOE contractors or subcontractors employed by the Uranium Division of Mallinckrodt Chemical Works, Destrehan Street Facility, during the period from 1942 through 1948 and who were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

III. Designation Criteria and Recommendations

Pursuant to 42 U.S.C. § 7384q, the Secretary has determined for the class defined in Section II of this report, upon recommendation of the Advisory Board on Radiation and Worker Health (“the Board”), that –

- (1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and
- (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.

The SEC Final Rule, 42 C.F.R. § 83.13(c)(1), states that it is feasible to estimate the radiation dose that the class received with sufficient accuracy under two situations. The Rule states first, that radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of the class. Alternatively, radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than a maximum dose estimate. 42 C.F.R. § 83.13(c)(1)(i).

The Advisory Board on Radiation and Worker Health (“the Board”), pursuant to 42 U.S.C. § 7384q, and as governed by 42 C.F.R. § 83.13(c), advised the Secretary to designate the class as an addition to the SEC in a letter dated March 11, 2005, and received on March 14, 2005.

The Director of the National Institute for Occupational Safety and Health (“NIOSH”), pursuant to 42 C.F.R. § 83.16(a), proposed designating the class as an addition to the SEC in a Memorandum to the Secretary dated March 14, 2005.

IV. Designation Findings

Feasibility of Estimating Radiation Doses with Sufficient Accuracy

The Secretary established the feasibility determination for the class of employees covered by this report upon the findings summarized below.

(1) NIOSH established in its reports SEC 00012-1 and SEC 00012-2, as governed by 42 C.F.R. § 83.13(c)(1), that it lacks access to sufficient information to either estimate the maximum radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of the class, or to estimate the radiation doses of members of the class more precisely than a maximum dose estimate.

(2) For the period from 1942 through 1945, NIOSH found the sum of information available is insufficient to document or estimate the maximum air concentrations of radionuclide dusts and radon gas that were generated and hence could have been inhaled and/or ingested by members of the class employed during this time period, resulting in internal radiation doses. On this basis, NIOSH cannot either estimate the maximum internal radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of this class, or estimate the internal radiation doses of members of this class more precisely than a maximum dose estimate received by any member of the class employed during this time period, and hence cannot conduct complete dose reconstructions for these individuals.

(3) For the period from 1946 through 1948, NIOSH found the limited workplace and worker monitoring data and the information on radiological sources and processes to be insufficient to estimate the maximum internal radiation dose for every type of cancer for which radiation doses are reconstructed that could have been incurred under plausible circumstances by any member of this class, or to estimate the internal radiation doses of members of this class more precisely than a maximum dose estimate received by any member of the class employed during this time period. This insufficiency of the monitoring data was based on a combination of three factors: (a) documentation showing that some of the data are technically unreliable; (b) documents that raise serious questions concerning the integrity of the recording,

management, and reporting of monitoring data at Mallinckrodt; and, (c) the lack of sufficient information or data to reasonably validate dose estimates in light of the established concerns regarding monitoring data integrity.

(4) For the period from 1942 through 1948, the Board found limited but inadequate radiation monitoring and monitoring records.

Health Endangerment

The Secretary established the health endangerment determination for the class of employees covered by this report upon the findings summarized below.

(1) NIOSH established in its reports SEC 00012-1 and SEC 00012-2, as governed by 42 C.F.R. § 83.13(c)(3), that there is a reasonable likelihood that such radiation doses may have endangered the health of members of the class. Pursuant to 42 C.F.R. § 83.13(c)(3)(ii), NIOSH specified a minimum duration of employment to satisfy this health endangerment criterion as “having been employed for a number of work days aggregating at least 250 work days within the parameters established for this class or in combination with work days within the parameters (excluding aggregate work day requirements) established for one or more other classes of employees in the Cohort.”

(2) NIOSH found members of the class received episodic exposures to radionuclide dusts and radon gas that could have cumulatively resulted in chronic, potentially substantial exposures to radiation.

(3) NIOSH did not identify any evidence from the petitioners or from other resources that would establish that the class was exposed to radiation during a discrete incident, such as a nuclear criticality incident, as defined under 42 C.F.R. § 83.13(c)(3)(i).

(4) The Board concurred with the finding of NIOSH that the health of the class may have been endangered and further concurred with NIOSH in this respect by defining the class according to the 250 work day employment requirement specified under 42 C.F.R. § 83.13(c)(3)(ii).

V. Effect and Effective Date of Designation

The Secretary submits this report on a designation of an additional class to the SEC for review by Congress, pursuant to 42 U.S.C. §§ 7384l(14)(C)(ii) and 7384q(c)(2)(A), as amended by the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375 (codified as amended in scattered sections of 42 U.S.C.). Pursuant to 42 U.S.C. § 7384l(14)(C)(ii), as amended by the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375 (codified as amended in scattered sections of 42 U.S.C.), the designation in this report will become effective 30 days after the date of this report’s submission to Congress, “unless Congress otherwise provides.”

VI. Administrative Review of Designation

The health endangerment determination of the designation provided in this report may be subject to an administrative review within HHS, pursuant to 42 C.F.R. § 83.16(b). If, on the basis of such a review, the Secretary were to decide to expand the class of employees covered by this designation, the Secretary would transmit a supplementary report to Congress providing the expanded employee class definition and the criterion and findings on which the decision was based.