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

June 27, 2012

Dear Ms.

Thank you for your letter requesting an administrative review of my determination not to add a class of employees from the Bliss & Laughlin Steel Company in Buffalo, New York to the Special Exposure Cohort (SEC).

Pursuant to 42 CFR § 83.18(b), and because you filed a challenge of this determination, I appointed a panel of three U.S. Department of Health and Human Services (HHS) personnel, independent of the National Institute for Occupational Safety and Health (NIOSH), to conduct an administrative review. The panel completed its review of the challenge.

After reviewing the administrative record in this case, the panel concluded that: (1) HHS complied with the regulatory procedures set out in 42 CFR part 83; (2) my decision contained no evidence of factual error and was supported by factually accurate information; and (3) there were no errors of fact or omission in the principal findings and recommendations of NIOSH and the Advisory Board on Radiation and Worker Health. In summary, the panel concluded that the challenge to my decision is without merit, and they have not recommended any change to my decision to deny adding a class of Bliss & Laughlin employees to the SEC.

After review of the administrative review panel's thorough report, I have decided not to revise my June 3, 2011, final decision. I am enclosing a copy of the administrative review panel's final report to me. I will also provide this response to Ms. and Ms. who cosigned your letter.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

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Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

May 23, 2012

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

RE: Bliss & Laughlin Special Exposure Cohort Administrative Review Panel

Dear Madam Secretary:

On June 3, 2011, as authorized under the Energy Employees Occupational Illness Compensation Act of 2000 (EEOICPA), 42 U.S.C. § 7384*q*(b), you determined that the following class of employees does not meet the statutory criteria for addition to the Special Exposure Cohort (SEC):

> All Atomic Weapons Employees who worked at the Bliss & Laughlin Steel Company located at 110 Hopkins Street, Buffalo, New York, for the period from January 1, 1951 through December 31, 1952 and/or during the residual period from January 1, 1953 through December 31, 1998.

Pursuant to 42 U.S.C. § 7384q, a class may be designated for addition to the SEC if the Secretary determines, 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 reasonable likelihood that such radiation dose may have endangered the health of members of the class. The basis for your decision in this case was the determination that it is feasible to reconstruct the radiation dose estimates encountered by Bliss & Laughlin employees with sufficient accuracy; accordingly, a determination of health endangerment was not required.

In a letter dated July 13, 2011, petitioners
surviving daughters of a former employee at the Bliss & Laughlin Steel Company, filed a challenge to your June 3, 2011, determination. A copy of petitioners' appeal letter is attached. EEOICPA implementing regulations at 42 CFR § 83.18(a) provide that, in order to contest a final decision by the Secretary to deny adding a class to the Cohort, a challenge "must include evidence that the final decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures" set out in 42 CFR part 83. The petitioners' appeal letter states "We feel that there are factual errors and substantial errors implementing your decision that there are no records available with sufficient information. We feel that we were denied information crucial to making our plea. These errors must be addressed."

Because of the challenge and pursuant to 42 CFR § 83.18(b), you appointed a panel of three Department of Health and Human Services (HHS) personnel, independent of the National Institute for Occupational Safety and Health (NIOSH), to conduct an administrative review and provide recommendations concerning the merits of the challenge and the resolution of the issues contested by the challenge. The undersigned, Steven L. Simon, PhD, C. Norman Coleman, MD, and Orhan Suleiman, PhD, comprise that panel. Our collective expertise includes radiation medicine, health physics, radiation exposure, dose assessment and dose reconstruction, and radiation risk analysis. We were charged with conducting an administrative review of your determination not to add a class of Bliss & Laughlin employees to the SEC, which included reviewing the data and information that formed the basis of your decision. Pursuant to 42 CFR § 83.18(b), we considered whether HHS substantially complied with the regulatory procedures set out in 42 CFR part 83 and whether the Secretary's final decision was supported by accurate factual information, and we also reviewed the principal findings and recommendations of NIOSH and the Board. As explained below, we concluded that petitioners' challenge to your decision is without merit, and we do not recommend any change to your decision to deny adding a class of Bliss & Laughlin employees to the SEC.

In conducting our review, pursuant to 42 CFR § 83.18(b), we examined the views and information submitted by the petitioners in the challenge, the NIOSH evaluation report, the report containing the recommendations of the Board, the recommendations of the Director of NIOSH to the Secretary, information presented or submitted to the Board, and the deliberations of the Board prior to the issuance of its recommendations. Since 42 CFR § 83.18(a) prohibits petitioners from introducing any new information or documentation, our review was based entirely on the administrative record in this case, as described above.

A memorandum to you, dated May 4, 2011, from the Director of NIOSH, which was initialed by the Director of the CDC and which you approved and signed, states that NIOSH concluded that there were sufficient data to perform individual dose reconstructions for the Bliss & Laughlin class of employees. This conclusion was based on the NIOSH Evaluation Report, which evaluated the feasibility for completing dose reconstructions for all Atomic Weapons Employees who worked at the Bliss & Laughlin Steel Company in Buffalo, New York, for the operational period from January 1, 1951, through December 31, 1952, and for the residual contamination period from January 1, 1953, through December 31, 1998. Specifically, this memorandum states as follows:

1. NIOSH determined that the principal source of internal radiation doses for the class evaluated was from the inhalation and ingestion of uranium particles in the dust generated by the machining and handling of uranium metal, and the principal source of external radiation doses were from deposition of uranium particles in the dust from the machining of uranium rods and the direct handling of uranium.
2. NIOSH found that the available monitoring records, process descriptions, and source-term data and alternative data sources are adequate to complete internal and external dose reconstruction with sufficient accuracy for the evaluated class of employees.

3. NIOSH obtained process information and air monitoring data collected during the rod-turning operations, and has assessed Battelle-TBD-6000 and monitoring data bounding similar operations at other sites sufficient to bound internal and external dose.
4. NIOSH determined that it has access to sufficient information to bound internal and external dose for all members of the evaluated class.
5. Although no records have been identified that indicate that occupational medical X-rays were required during the operational period, the dose associated with X-ray exams can be assessed using the methodology defined in ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures.*

In that memorandum, NIOSH concluded that it has access to sufficient Bliss & Laughlin information to either (1) estimate the maximum external and internal radiation dose for every type of cancer that could have been incurred under plausible circumstances by any member of the evaluated class; or (2) estimate the external and internal radiation doses to members of the evaluated class more precisely than a maximum dose estimate.

With respect to the five points above as enumerated by NIOSH and the conclusions which they supported, we provide the following comments as part of our administrative review:

1. With regard to the first point, this panel strongly agrees that the principal source of internal radiation doses was from the inhalation and ingestion of uranium particles and that the principal sources of external radiation doses would have been from the deposition of uranium particles in the dust from the machining of uranium rods and the direct handling of uranium.
2. With regard to the second point that the available records and alternative sources are adequate to reconstruct doses with sufficient accuracy, this panel agrees that the available records and alternative sources selected were adequate. Regulations implementing EEOICPA specifically allow for various types of data to be used in reconstructing dose.

   Here it is useful to note that for the purposes of inhalation dose calculations, NIOSH used the largest reported average value from air sampling at facilities that machined uranium (*see* Battelle-TBD-6000, rev0, Table 7.5, p.46). The value of 5480 dpm/m^3 for the job category of "Centerless Grinder" was the highest value in the table and would give the highest inhalation dose. This is clearly an estimate representing a "worst case condition" and would result in the highest credible dose estimate.

3. With respect to the third point above, this panel agrees that air monitoring data collected during the rod-turning operations, assessed in Battelle-TBD-6000, and monitoring data bounding similar operations at other sites were all sufficient to bound internal and external dose. It is our understanding that NIOSH relied on data from the Battelle-TBD-6000 report which was a comprehensive report on "Site Profiles for Atomic Weapons Employers that Worked Uranium and Thorium Metals." We note that EEOICPA regulations allow for the use of workplace monitoring data. Specifically, 42 CFR § 82.2(b) states that: "If individual monitoring data are not available or adequate, dose

reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose." The data from the report BattelleTBD-6000, are relevant and, thus, are allowed by law as a substitute for individual monitoring data. Moreover, as explained in the second point above, the highest values were chosen so as to give the largest estimate of radiation dose to the claimant.

4. The fourth point above indicates that NIOSH believed it has access to sufficient information to bound internal and external dose for all members of the evaluated class. This panel agrees with this conclusion. In addition, as noted above, NIOSH has used data that has maximized the estimation of dose to and all other members of the evaluated class (thus resulting in the largest credible value of the Probability of Causation, a situation in favor of the claimant).

5. The fifth point above describes the use of ORAUT-OTIB-0006, *Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures*. Based on our accumulated experience, we know that dose records from diagnostic x-ray procedures during this period of time were rarely calculated, if at all. Moreover, such diagnostic x-ray doses would have been small, were necessary for health maintenance, and in our opinion, not materially significant to the health risk of the worker. In any case, ORAUT-OTIB-0006 cited above would be adequate for dose reconstruction, particularly since the methods described in this document, as in other NIOSH dose reconstruction strategies for compensation purposes, made conservative assumptions that maximized the possible dose received.

In our review of this case, we have concluded:

1. HHS complied with the regulatory procedures set out in 42 CFR part 83.
2. Your decision contained no evidence of factual error and was supported by factually accurate information.
3. There were no errors of fact or omission in the principal findings and recommendations of NIOSH and the Advisory Board.

In summary: Based upon our review of the administrative record in this case, this panel believes that the regulatory procedures have been complied with in making your decision, that credible sources of information have been used as allowed for under EEOICPA implementing regulations 42 CFR parts 82 and 83, and that you, NIOSH, and the Advisory Board came to reasonable and appropriate conclusions. In short, we have concluded that petitioners' challenge to your decision is without merit, and we see no reason to recommend any change to your decision to deny adding a class of Bliss & Laughlin employees to the SEC.

As an administrative review panel, we are also concerned about providing a full and satisfactory response to the petitioners. We believe their concerns are legitimate and serious and deserve full attention. Although we cannot answer the questions raised in the petitioners' appeal letter that

are outside the scope of our review, we have attempted to respond to those questions that are within our purview.

The petitioners' letter set out three general categories of questions, as follows: (1) why some Bliss & Laughlin employees were compensated and others were not; (2) how a determination was made not to add Bliss & Laughlin employees to the SEC with limited or no monitoring records ; and (3) whether petitioners could be provided with the records relied on in making the determination.

In response to category (1) questions: This panel does not have access to information about the compensation of individual workers, and determinations regarding individual compensation are not within the scope of our charge to review your determination not to add a class of employees to the SEC. Nonetheless, the very short time in which the Bliss & Laughlin workers milled uranium rods was simply not long enough to impart enough radiation exposure to qualify for compensation.

In response to category (2) questions: Although monitoring records may have been incomplete or unavailable, the principles of dose reconstruction allow NIOSH to use other data to determine doses received by Bliss & Laughlin employees. In cases where records were not maintained, incomplete, or unavailable for this specific group of workers, the documents that we reviewed make clear that NIOSH used measurement data from other sites that performed the same type of work. These sites often had much greater workloads and, therefore the estimates were higher, which resulted in a higher estimate of dose. Even with these higher estimates, the class of Bliss & Laughlin workers still did not receive enough radiation to warrant compensation.

In response to category (3) questions: The documents relied upon in making your determination were either transmitted to petitioners pursuant to the regulations (e.g., the NIOSH Evaluation report), presented at meetings which petitioners attended, posted on the NIOSH website, or have been or will be provided to petitioners pursuant to a request under the Freedom of Information Act. Thus, petitioners have received or have access to all of these records..

Finally, we note the petitioners' overall concern: "All Bliss & Laughlin employees contributed to this project, some with their very lives by your own admission. How can you deny the remaining claimants access to the materials and information essential to their compensation claims?" Here, we acknowledge the sacrifice that many such employees made during that period of time and we express our sympathy to the claimants. However, we have articulated above that the data have been made available to the claimants and, moreover, we have found the petitioners' overall claim to not be supported.

Steven L. Simon, PhD
Dosimetry Unit Head
Radiation Epidemiology Branch
Division of Cancer Epidemiology and Genetics
National Cancer Institute
National Institutes of Health

C. Norman Coleman, MD
Associate Director
Radiation Research Program
National Cancer Institute
National Institutes of Health

Orhan Suleiman, MS, PhD, FAAPM
Senior Science Policy Advisor
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Attachments:

Petitioners' Appeal Letter dated July 13, 2011

SEC Tracking Number: SEC00131

July 13, 2011

Dawn L. Smalls
Executive Secretary to the
Department of Health and Human Services
200 Independence Ave. SW #603H
Washington, DC 20201

Dear Ms. Smalls:

As per your letter, we are requesting an Administrative Review of this Secretary's final determination eliminating the Bliss and Laughlin Employees to the SEC.

We understand that some employees from Bliss and Laughlin have been compensated but others have not. How was this determined? Why were the specifics of other approvals withheld from us? All employees assigned, worked in the same area at the same time. Please note that our father, was the authorative figure who activated the Bliss and Laughlin Security System, permitting employees to enter the Mill on days of the uranium runs. He was responsible for all these employees scheduled to work on the rods. He remained among these employees for their entire work shifts, and then activated the Security System at the Bliss and Laughlin Plant at closings. Also, he was responsible for supervising the runs on the floor with all Mill employees. He arrived before them, remained throughout their entire shifts and left after them.

In your Determination Findings it states that NIOSH found the monitoring records. Previous correspondence has repeatedly stated that no records were available. Now you state that monitoring records exist and are instrumental in making your decision. How did these records suddenly appear? How were they obtained? How were they used by you? What technology, possibly outdated, did they employ in the monitoring process? How was it determined that these records are accurate? Who

completed and kept the records? What were the qualifications of the record keepers? Why has this information been kept from claimants?

At a time in Buffalo NY when job competition was keen, unemployment was high, and "good" jobs were protected and coveted, wouldn't it have been advantageous to make sure the records did not negatively impact a laborer's chance to earn a paycheck? It is only common sense that the integrity of the monitoring data be severely scrutinized and brought into question. May we please have a copy of the records, as they apparently are so essential to your determination of your denial for Special Exposure Cohort?

What other sites has NIOSH obtained their information from on the air monitoring data that was used to determine their decision regarding the Bliss & Laughlin Plant?

NIOSH has also stated that there is sufficient Bliss and Laughlin information to determine external and internal radiation doses. What and where is this information? We need to know this for all the same reasons stated earlier in this letter.

At the closing of the TBD-6000 Advisory Meeting of February 24, 2011, a statement from one of the board members was made stating that Bliss & Laughlin "ran the rods for only three days". All along this process we have been advised that there were no records available on the duration of this activity. We claimants need this information. Specifically, where did this information come from? Why were claimants denied access to it? Doesn't it conflict with other data on the scope of the work performed at Bliss & Laughlin? Does the "three day run" time frame cover all aspects of handling and work from the time of the rods arrival to their departure from Bliss & Laughlin? The information from NIOSH and HHS appear to be vastly different, if not contradictory, in many categories. We believe this is an error that needs to be addressed.

On March 30, 2011, we researched our Buffalo & Erie County Main Library for more concrete information. No information was available we were told. It was suggested that we contact The Army Corp of Engineers. On May 4, 2011 The Army Corp of engineers told us that 2 years after clean up of the Bliss and Laughlin Plant, that all site records are sent to the Department of Energy. Did you access these records? We need access to these records. If these records were not utilized, this is an error that must be addressed.

We feel that there are factual errors and substantial errors implementing your decision that there are no records available with sufficient information. We feel that we were denied information crucial to making our plea. These errors must be addressed.

How was it determined to be appropriate to compensate only 13 employees when all of the employees reported to the Bliss and Laughlin Plant specifically to work on the machining of these rods?

All Bliss & Laughlin employees contributed to this project, some with their very lives by your own admission. How can you deny the remaining claimants access to the materials and information essential to their compensation claims?

Sincerely