The Advisory Board met telephonically at 2:00 p.m. Eastern Time, Steven Markowitz, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY

JOHN DEMENT
GEORGE FRIEDMAN-JIMENEZ
MAREK MIKULSKI
KENNETH SILVER

MEDICAL COMMUNITY

MANIJEH BERENJI
STEVEN MARKOWITZ, Chair
CARRIE A. REDLICH

CLAIMANT COMMUNITY

KIRK DOMINA
RON MAHS
DURONDA POPE
CALIN TEBAY

DESIGNATED FEDERAL OFFICIAL

DOUGLAS FITZGERALD
Call to order

Mr. Fitzgerald called the meeting to order at 2:07 p.m. Eastern Time. All members of the Board were present with the exception of Member Cassano.

Chairperson Markowitz comments:

EEOICP Bulletin 19-03

The bulletin was updated to include the following:

• Reduced the days of aggregate exposure to asbestos from 250 days to 30 days and the latency period from 30 years to 15 years for mesothelioma.

• Reduced the latency period for exposure to asbestos from 20 years to 15 years for ovarian cancer.

• Reduced the latency period for exposure to asbestos from 20 years to 10 years for pleural plaques.

• Added benzidine as an agent related to bladder cancer.

• Added carbon disulfide and n-Hexane as agents related to hearing loss.

• Added a presumption about lung cancer related to asbestos exposure.

The bulletin also provides insight on how DOL goes back to look at prior claims when the criteria for compensation changes and evolves over time.

Chairperson Markowitz comments:

Proposed revised asbestos presumption recommendation

DOL has accepted much of the Board's advice on asbestos.

In the current asbestos presumption causation, the Procedure Manual only refers to the fact that a claimant needs to have a significant level of exposure. Whether that exposure is high, medium, or low doesn't enter into consideration in the causation presumption. Thus, there is no need for potentially confusing language about high, medium, and low levels of exposure as currently exists in the Procedure Manual.
For labor categories other than those on list 3a(1) of the Procedure Manual, it is reasonable to retain a presumption that they have some level of exposure to asbestos. Currently, the Procedure Manual has a negative presumption about asbestos exposure after 1995 for jobs other than those on the list. The Board's recommendation is that the Procedure Manual have more neutral language about exposure and, when there is uncertainty, leave the question of causation to an industrial hygienist to resolve.

The asbestos diseases causation presumption adds a requirement of “day by day” exposure for all but two asbestos disease categories. This measure of exposure frequency should be presumed for claimants who meet the asbestos exposure presumption of significant exposure noted in list 3a(1). The Board recommends that “day by day” be retained only for evaluating the claims that are undergoing review by an industrial hygienist.

The most important part of the Board's revised recommendations on asbestos is that the list of job titles that can be presumed to have asbestos exposure prior to 1997 is incomplete. The Board recommends that a Board committee work with the EEOICP and their industrial hygiene contractor to examine all SEM job titles and aliases and identify job titles that should be added to list 3a(1) for the purposes of a presumption of asbestos exposure.

**Board vote on the revised asbestos presumption recommendation (note: See final revised recommendation document for exact language)**

1) To recommend the deletion of the rubric for high, medium, and low significance.

2) To recommend for the current language on labor categories other than those on list 3a(1) that it is reasonable to retain the presumption that workers in those labor categories had “some level of exposure to asbestos” prior to 1987, and that the industrial hygienist should determine the significance of that exposure in decision-making on claims.

3) To recommend that the language regarding the presumption that the labor categories "do not have significant exposure prior to 1996" be deleted.

4) To recommend that the issue of day by day exposure not be
applied to any labor categories that are presumed to have significant asbestos exposures.

5) To recommend that the Board work with DOL to identify relevant job titles that should be added to list 3a(1) for the purpose of asbestos exposure.

The above recommendations were adopted unanimously by the Board members present.

Member Dement comments:

Proposed revised Occupational Health Questionnaire (OHQ) recommendation
(note: See final revised recommendation document for exact language)

DOL did not consider the Board's prior recommendations on the revised OHQ to be useful. The Board has made recommendations specific to DOL's new questionnaire. Member Dement described the history of the Board's recommendations regarding the OHQ. The Board recommended that an expedited review of the Board's revised recommendations occur so that timely progress can be made on the creation of a revised OHQ and its pilot testing and implementation. The Board voted unanimously to accept the recommendations.

Member Redlich comments:

Proposed revised occupational asthma recommendation
(note: See final revised recommendation document for exact language)

A considerable part of the recommendation has been accepted by DOL and they have revised the language of the Procedure Manual with regard to the criteria for medical diagnosis of asthma. The issue of exposure is still outstanding, as well as the issue of what type of exposure can be presumed to be related to work-related asthma. The Board noted that most cases of work-related asthma are not preceded by a specific exposure incident or by identification of one specific inciting toxic substance. Rather, most cases of work-related asthma work in environments with multiple toxic substances, often precluding the ability to narrow the cause to a single toxic substance.

The Board recommended the following revised wording for the Procedure Manual:
"ii. After a period of covered employment, a qualified physician conducts an examination of either the patient or available medical records and he or she concludes that the evidence supports that the employee had asthma and that an occupational exposure to a toxic substance was at least as likely as not a significant factor in causing, contributing to, or aggravating the condition. The qualified physician must provide a well-rationalized explanation with specific supporting information, including the basis for diagnosing asthma or worsening asthma at the time of covered employment and the basis for the relationship between asthma and the covered workplace (examples of supporting information could be provided here or in training materials). If the CE is unable to obtain the necessary medical evidence from the treating physician to substantiate the claim for work-related asthma, the CE will need to seek an opinion from a CMC. If a CMC referral is required, the CE will need to provide the CMC with the relevant medical evidence from the claim file and provide a detailed description of the employee’s covered employment which should include each covered worksite, dates of covered employment, labor categories, and details about the jobs performed."

The Board voted unanimously to accept the revised recommendations on asthma, including the revised language for the Procedure Manual.

Chairperson Markowitz notes that the Board requested 20 asthma cases from DOL to review on December 10, 2018.

**Parkinson-related diseases (report from working group and review of data)**

Member Mikulski summarized the work group's efforts at looking into the relationship between Parkinson-related diseases and occupational exposures. Parkinson-related diseases affect the dopamine system. There has been epidemiological research on the possible causes of Parkinson's disease and occupational factors. The work group looked at the correlation between work processes and Parkinson's disease using the SEM. The two biggest work processes/job categories related to Parkinson's were machinists and welding/welders.

An action item for DOL is to provide the Board with a list of all of the toxic substances in the SEM that relate to the Parkinson's codes that DOL uses with regard to health effects. The work group should have more information for the full Board
meeting in Augusta, Georgia.

Chairperson Markowitz notes that the Board requested 10 denied and 10 accepted Parkinson's claims from DOL for review on December 10, 2018.

**Public comment tracking**

Chair Markowitz presented the extensive public comment Excel spreadsheet to the Board. The intent of the comment spreadsheet is to keep some of the concerns that the public has in mind on the Board's agenda.

**Review of final DOL EEOICP rule regarding Board recommendations**

Chair Markowitz noted that most of the Board's comments/recommendations on the proposed regulations were not accepted in the final regulation. The details are in the extensive rule that was published in the Federal Register. The rule cites the Board's comments and responds to them.

**Board Action list, November 2018 Board meeting**

Chair Markowitz summarized the progress of the Board's action list:

*How many cases have been reopened as a result of Board recommendations?*

DEEOIC has published Bulletin 19-03, which provides guidance to staff for the implementation of a review of 2,010 potentially affected cases due to the changes to causation standards updated as part of Version 2.3 of the Federal (EEOICPA) Procedure Manual. The Board would like information on the reasons why the cases were reopened.

*The Board requests to meet the DEEOIC Medical Director and Toxicologist in person*

DEEOIC does not consider it appropriate to permit staff employees, including the Medical Director or Toxicologist, to interact with the Board in a public forum. DEEOIC requests that the Board submit any questions relating to medical health science topics to the program in writing. DOL did provide CVs for Dr. Armstrong (Medical Director) and Dr. Stokes (Toxicologist). The Board notes that the CVs should be posted to the website for the public to access.
The Board would like to see annual statistics on cases and claims (Annual Report numbers for Part B versus Part E), especially by year for the most recent four years.

DOL sent the Board web statistics for 2015 to 2018. The statistics provided by DOL represented cumulative numbers. The Board wanted a more detailed breakdown of the data so they could get a better sense of the volume of claims flowing through the program by year and rates of approval/denial for both Parts B and E.

What percentage of cases now go to an IH? Are there categories of reasons for why cases are sent to an IH?

DOL response:

Generally, an IH referral will occur when certain criteria are satisfied, as described in the Federal (EEOICPA) Procedure Manual (PM) Chapter 15 (Version 2.3):

1. Given the claim filed, DEEOIC obtains evidence to establish that an employee has a diagnosed medical illness and that the employee has verified covered Part E employment.

2. DEEOIC then seeks to establish that the diagnosed illness has a medical health science link (health effect) to a particular toxic substance. To do this, DEEOIC applies health effect data maintained in SEM or the opinion of a claimant’s physician to determine such linkages. See PM 15.3 for more information.

3. Employment evidence from different sources can establish a potential exposure by the employee to one (or more) toxic substances that have a health effect link to the diagnosed condition. See PM 15.9 for more information.

Once these conditions are satisfied, DEEOIC will usually submit the claim, including relevant exposure data from the claim or developed by a CE, to the IH for a more detailed characterization of the employee’s likely exposure (See PM 15.11). Depending on the unique features of a claim, validation of potential exposure by SEM or other records sources may not require an IH referral.
DEEOIC is developing a report that will identify the total number of Part E claims filed with a final decision to accept or deny that also have an IH referral. DEEOIC will share the report with the Board once it becomes available.

DOL sent the Board a table of claims that had been reviewed by an IH.

Accountability review findings – see link below

https://www.dol.gov/owcp/energy/regs/compliance/accountability_reviews.htm

DOL conducts accountability reviews of the district offices. The Board wants clarification on what metrics DOL uses in its accountability reviews.

The Board requests to see the drafts of documents that will address auditing of industrial hygiene work and reports.

DOL response:

All IH referral reports undergo individual screening and/or certification by the Lead Industrial Hygienist for consistency and quality. Moreover, DEEOIC also evaluates the quality of IH development during the annual Accountability Review conducted for each district office. There are no further audits outside of these processes.

The Board will be requesting additional details beyond DOL's response.

When will the medical audits conducted after the 4th quarter of 2017 and for 2018 be posted online?

DEEOIC has posted the quarterly audits through the 1st quarter of 2018. DEEOIC uploads all audit reports as they become available at the following online link:

https://www.dol.gov/owcp/energy/regs/compliance/cmc_audits.htm

Most of the weaknesses of the contract medical physician reports centered on impairment analysis; almost nothing in the audits addresses causation.

The Board requests, if they exist, the listing(s) of scientific
articles or sources in support of Exhibits 15-4 and 18-1.

DOL response:
The causation and exposure standards listed in Exhibit 15-4 have developed over time, with some having been influenced by input from the Board. It would be helpful if the Board could identify particular standards that are the focus of interest so DEEOIC can provide background information.

DOL provided a contractor analysis by Econometrica, Inc., conducted in 2005, which is the source for Exhibit 18-1.

The Board thought that the "Matrix for confirming sufficient evidence for non-cancerous covered illness" needs to be reexamined because much of it is in conflict with what the Procedure Manual now says for asbestos, COPD, etc.

How many claims are there for Parkinson’s/Parkinsonism/related conditions?

DOL reported that there were 1,154 claims for Parkinson's related conditions since 2006. DOL also provided ICD codes for Parkinson's-related diseases.

Is it possible to see recent data on claim filings from different specific DOE sites? Number of claims filed and accepted or denied by DOE site for recent 3 years (by year and by B versus E) would be a useful starting point.

DOL response:

DEEOIC does not keep data on the number of claims by DOE site. A given claim can include employment from multiple sites. DEEOIC does not understand the nature of this request and it asks the Board to provide clarification and specifically link the request to one of its assigned responsibilities.

Claims paid by DOE site can be viewed on the DOL website.

Information/data on the volume of public submissions to SEM, and the turnaround time; that is, are they verified or not and how long does it take to make a decision on them?

DOL response:

For CY2016, CY2017, and CY2018 there were 62, 62, and 57
submissions to the SEM website, respectively, and the average response time was 6.0 days, 6.6 days, and 4.5 days, respectively. The actual response time is extended when DOE verification of submitted information is necessary.

The average response time to the submitter includes: receipt, verification, research, and submittal of a draft reply to DOL; editing (if needed) and approval of the draft reply by DOL; and transmission of the approved reply to the submitter by the SEM Site Administrator.

Public submittals to the SEM website or by mail can be generally classified as seeking information, suggesting changes in SEM, or being inappropriate for further evaluation.

Submissions are considered valid except in those rare cases when they are obviously submitted in error; e.g., inputs for work in non-DOE facilities.

If a document authored by DOE is submitted, it is used without further verification unless there is a reason to question its authenticity. In such cases, the SEM contractor contacts DOE for verification. Sometimes documents are submitted that the submitter says were authored by DOE but have no identifying markings. In these situations, the SEM contractor contacts DOE to verify the document prior to use in SEM. The public often submits suggestions with no or inadequate supporting documentation. In such cases, the submitter is requested to provide documentation that supports their submittal. Any documentation submitted with requests to make changes in health effects are provided to Dr. Jay Brown (Haz-Map) for evaluation.

The Board wants to find out whether DOL keeps track of all of the changes made to the SEM and whether the Board can see all of the revisions to the SEM.

Once aware of a new record/record source for the SEM, how does DOL (or the contractor) analyze the information for particular locations to make decisions about whether or how to add the new record(s) to the SEM? How and which Paragon staff evaluate the information?

DOL response:
A record used to make changes in SEM is one that provides valid information (1) specific to a DOE or RECA site, (2) applicable to many/all DOE or RECA sites, or (3) not applicable to a DOE site but applicable to SEM health effects and chemicals. Information specific to a DOE or RECA site is applied only to the SEM profile for that site. Information applicable to multiple sites is applied to the SEM profiles of all those sites. General information is applied to the SEM profile of the involved chemical or health effects.

How to add information to SEM is defined in SEM procedures. SEM team members involved with the review of source documents are engineers, chemists, technical managers, or similar with education and experience in the review of technical information. All have work experience in nuclear facilities and most have experience in DOE facilities where they authored and/or used such documents in the past.

SEM team members and Dr. Jay Brown review and evaluate the usefulness of resource materials. Chemical information is reviewed almost exclusively by the project chemist. Disease information is reviewed by Dr. Jay Brown. Site-specific information about labor categories, work processes, incidents and toxic material usage is evaluated by SEM researchers and the project manager. In all cases, staff with the National Office reviews and approves new information included in SEM.

Could the Solicitor’s Office and the EEOICP explain how they interpret the statute regarding the definition of “toxic substance”?

DOL response:

The regulatory definition of “toxic substance” used by the Department of Labor originates from the definition of that term that the Department of Energy (DOE) used to administer former Part D of the Act. With the repeal of Part D in 2004, and the transference of all of the requests for assistance that had been filed with DOE to DOL for processing as claims under the newly enacted Part E, DOL adopted DOE’s definition of “toxic substance” when it promulgated its regulations for administering those claims, since it would have been unfair to change the meaning of the term from what had been used by DOE.
Is there a process for the IH to ask questions or ask for additional information without interviewing the claimant?

DOL response:

Yes, the IH can contact a CE directly (or vice versa) to ask questions or seek clarification on any referral.

Is there information in SEM or otherwise on bystander exposures across the sites?

No.

How many conditions are in SEM? How many aliases are there in the SEM? Are aliases used elsewhere besides the SEM?

DOL response:

There are 124 active occupational diseases currently in SEM. There are 237 occupational disease aliases currently in SEM. The aliases in SEM come primarily from Haz-Map. There are a few based on DOL-National Office policy decisions.

**Board Data and Claims request, December 2018**

The request for data was submitted in December and the Board has yet to receive any information. Mr. Fitzgerald has made inquiries into when the information would be available and also suggested that the Board narrow the scope of the request given the resources involved in gathering the data. The Board suggested that DOL begin fulfilling the data request by providing the Board with data on lung diseases and 20 claims for occupational asthma and 20 claims for Parkinson’s-related conditions, as previously requested on December 10, 2018.

The Board previously asked (December 10, 2018) to review 20 claims for each of five pulmonary conditions and 20 additional claims for Parkinson's disease. As part of the closing out of the previous Board, all of the claims previously reviewed by the Board needed to be returned to the DOL. The Board asked for DOL to produce a timetable for getting the requested information.

**Non-cancerous Outcomes of radiogenic substances**

Member Silver provided a roadmap for a potential working group to follow in examining the topic of non-cancerous outcomes.
There are UNSCR reports, studies of atomic bomb survivors, and a study by Lee Newman that can form a starting point for the working group to begin its work. The literature contains a fair degree of health physics.

Member Silver, along with other members of the Board, rewrote the DOL's request to the Board regarding non-cancerous effects of radiogenic substances. That rewritten request will be presented to DOL for feedback.

Adjournment

The next Board meeting will be in Augusta, Georgia at the end of April. The Board will probably revisit two lingering recommendations on COPD and hearing loss at the next meeting.

The meeting was adjourned at 4:56 p.m. Eastern Time.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate summary of the meeting.

Submitted by:

Steven Markowitz, MD, Dr.Ph.
Chair, Advisory Board on Toxic Substances and Worker Health
Date: 3/28/2019