UNITED STATES DEPARTMENT OF LABOR

+ + + + +

ADVISORY BOARD ON TOXIC SUBSTANCES AND WORKER HEALTH

+ + + + +

SUMMARY MINUTES

+ + + + +

JUNE 16, 2020

+ + + + +

The Advisory Board met via teleconference, Steven Markowitz, Chair, presiding.

MEMBERS

SCIENTIFIC COMMUNITY

JOHN DEMENT
GEORGE FRIEDMAN-JIMENEZ
MAREK MIKULSKI
KENNETH SILVER

MEDICAL COMMUNITY

MANIJEH BERENJI
ROSE GOLDMAN
STEVEN MARKOWITZ, Chair
CARRIE A. REDLICH

CLAIMANT COMMUNITY

KIRK DOMINA
RON MAHS
DURONDA POPE
CALIN TEBAY

DESIGNATED FEDERAL OFFICIAL

MICHAEL CHANCE

Welcome/Introductions:

Mr. Chance called the meeting to order at 12:12 p.m. and noted that the meeting was conducted via teleconference as a precaution against the COVID-19 pandemic. He reminded board members that the specific content of some materials provided to them in their capacity as special government employees could not be shared or discussed publicly during the meeting.

The above-listed board members were in attendance. After a round of introductions, Steven Markowitz, Board Chair, welcomed participants and outlined the day's agenda. He noted that the current board's term expires in July 2020 and that during this meeting they hoped to vote on certain recommendations and discuss remaining issues, then complete additional work over the remaining four weeks of their term so that they could hand off various items to the next board.

DEEOIC Updates

Rachel Pond, Director of the Division of Energy Employees Occupational Illness Compensation (DEEOIC), presented updates from the DEEOIC program. She summarized the program's new case assignment process, which assigns cases to district offices based on a round robin system rather than by jurisdiction. All district office staff members have transitioned to complete telework in response to COVID-19, and an interactive voice response system transfers incoming calls to claims examiners' phone lines. Quality and timeliness remain fairly constant, though some record centers and physicians are not able to provide materials as quickly as they could before the pandemic. The program has published bulletins to allow the temporary use of telemedicine, including telemedicine appointments for home health care, and under certain circumstances routine physician appointments. Resource center hours have changed, but staff members have been able to continue teleworking. Starting in June at least one staff member will be in the office each day to process claims and answer phones. All hearings are currently conducted via WebEx or telephone rather than in person.

Due to COVID-19, the program has not conducted their normal level of outreach, but they planned to hold a webinar on June 25 to provide updates to stakeholders. The program received the board's recommendations from its last meeting related to the occupational health questionnaire (OHQ). As of the current meeting, the recommendations were in clearance within the Department of Labor, but Ms. Pond said that the program was

making changes to the OHQ, and they hoped to start piloting those changes soon. They have also made some changes to the language in Exhibit 15-4 related to asthma, specifically removing the reference to mechanism of disease as the board suggested in its March 5 letter. In response to the board's data requests, the program provided IH reports on lung cancer and post-1995 claims. They have also provided the board with examples of physician development letters. Recently the program provided the contracts that the board requested, and they are working on gathering information related to the board's site exposure matrices (SEM) data request.

Chair Markowitz asked whether the new case assignment process could lead to a loss of site-specific expertise developed by district offices. Ms. Pond said that the program had considered this and they conducted extensive training prior to implementing the change. Specialists from each district office gave presentations to the other district offices to teach them what to look for at certain sites. Those points of contact have also been maintained so that claims examiners around the country can contact those individuals with questions. They have also shared books containing specific site information with each district office.

Parkinson's and Related Diseases – Report and Review of Proposed Recommendation

Member Mikulski led the discussion on proposed recommendations for Parkinson's and related diseases. The board developed these recommendations in response to several sets of questions from the Department. The first set of questions related to the diagnosis and terminology of Parkinsonian-type disorders and the differentiation between Parkinsonism versus Parkinson's disease. Member Mikulski summarized the board's recommendation for these questions: for purposes of claim adjudication, the clinical diagnosis of Parkinsonism should be treated the same as the diagnosis of Parkinson's disease. This recommendation was based on the lack of valid clinical diagnostic tests to allow differentiation between the disorders. The board also provided ICD-9 and ICD-10 codes to assist with the adjudication process.

The next set of questions from the Department was related to exposures associated with the diagnosis of Parkinsonism, with specific emphasis on causation and presumptions. For these questions, Member Mikulski summarized the board's recommendation that in addition to carbon monoxide and manganese products, exposure to carbon disulfide and trichloroethylene (TCE) should

be presumed to cause, contribute to, or aggravate Parkinsonism. This recommendation was based on ample evidence that these exposures were historically common throughout the DOE weapons complex and human studies that found an association with increased risk of Parkinson's disease. Epidemiological studies formed the basis for the board's recommendation to include the minimum exposure duration of eight years. They did not feel that there was strong enough evidence to issue a recommendation around solvents including methanol, n-hexane, toluene, polychlorinated biphenyls, and pesticides. Because this is an evolving field, DOL should perform a periodic review of human studies to update the list of toxicants associated with Parkinson's diagnoses. The recommendation also included a statement to help clarify the recommended use of causation presumptions throughout the claim adjudications process.

Member Goldman made a motion to accept the recommendation, and the motion was seconded by Member Dement. Chair Markowitz opened the floor for discussion. Member Redlich asked about methods to determine whether or not a claimant had sufficient exposure to the solvents in question. Member Mikulski said that there was no quantification of exposure in the studies, but most of them were low chronic exposures, which would have been typical for most DOE operations. Member Goldman added that the eight-year recommendation came from one study that looked at workers with long-term exposure. Member Redlich asked if skin exposure was another contributing factor, and Member Mikulski said that the two main routes of exposure would have been inhalational and dermal. Member Goldman noted that the recommendation did not specify that the exposure needed to be inhalational. After some discussion, board members decided to amend the recommendation to specifically include skin exposure as well as inhalation.

Board Recommendation

After some discussion, the board voted unanimously to submit the following formal recommendations to DOL:

1) "The board recommends that the clinical diagnosis of Parkinsonism, as established primarily but not exclusively by a neurologist, is treated the same as the diagnosis of Parkinson disease throughout the EEOICP claim adjudication process, with respective entries of both terms and aliases recommended in the DOL's Site Exposure Matrix (SEM). The board has identified the following aliases that are in use for both terms with corresponding ICD-9 and ICD-10 codes:

- ICD-9 332 – Parkinson’s disease
- ICD-9 332.0 – Paralysis agitans, Parkinsonism or Parkinson’s disease NOS - not otherwise specified, idiopathic, primary
- ICD-9 332.1 – Secondary Parkinsonism
- ICD-10 G20 – Parkinson’s disease, Hemiparkinsonism, Idiopathic Parkinsonism, Paralysis agitans, Primary Parkinsonism
- ICD-10 G21 – Secondary Parkinsonism.”

2) “The board recommends that in addition to carbon monoxide and steel/manganese products already included in the EEOICPA Procedure Manual and DOL Site Exposure Matrix, exposures to carbon disulfide (CS2) and trichloroethylene (TCE) be presumed to cause, contribute, or aggravate Parkinsonism. These exposures were present in the DOE weapons complex and have been shown to be associated with increased risk of Parkinsonism in human studies. The board also recommends, based on epidemiologic studies, a minimum exposure duration of eight (8) years, either through inhalation and/or skin absorption, for Part E causation in adjudicating Parkinsonism claims with exposures to carbon disulfide and trichloroethylene.”

“At present, the board issues no recommendations for methanol, toluene, n-hexane, and polychlorinated biphenyls (PCBs), or other work–related exposures common throughout the DOE weapons complex. The board also issues no recommendation for pesticides or specific pesticide products that may have been used on DOE installations. Current evidence is not sufficient to support a presumption of these additional agents with regard to Parkinsonism. As new research is emerging, the board recommends a periodic review of human studies literature on risk factors for Parkinsonism for DOL to provide updates in this field. Presumption of causation implies the judgment that the literature at the current time is sufficient to support the statement that the exposure can contribute to causation of the disease or aggravate the course of the disease in exposed populations, and the judgment that the degree of exposure in the individual is sufficient to have produced this contribution to causation in that individual.”

“This use of presumptions is intended to identify the subset of people with the straightforward presentations to streamline the compensation process by eliminating the need for detailed causal evaluation by the physician and industrial hygienist. It must be emphasized that if an individual does not meet the criteria for the presumption of causation, this does not imply that there is not sufficient evidence of causation. It simply means that individuals who do not meet these presumptive criteria and would

need to be evaluated through a fact-based process entailing industrial hygiene and medical review to make the judgment whether the exposure contributed to causation of the disease."

Asbestos Job Titles – Report and Review of Proposed Recommendation

Chair Markowitz summarized the proposed recommendation that the Department evaluate the SEM job categories and revise its list of occupations with presumed pre-1995 asbestos exposure. He presented a list of the current job titles in the Procedure Manual (PM) that are presumed to have had significant asbestos exposure and summarized the board's engagement with this issue. One publication that the board looked at examined death certificate data compiled by NIOSH and provided proportionate mortality ratios (PMRs) for different job categories. While in 2000 very few occupations were identified as having excess risk of malignant mesothelioma (a cancer almost always associated with asbestos exposure), a 2016 study conducted with more extensive data identified more job titles as having excess risk.

After reviewing this literature, the working group used a larger data set from the National Occupational Mortality System (NOMS) to look at malignant mesothelioma risk. Compared to the 17 job titles that were found to have higher risk in the 2016 study, the NOMS identified 64 individual job titles with increased malignant mesothelioma risk, based on deaths from 1999-2014. The PMR rates were also far higher than those from the previous studies. Chair Markowitz said that based on these data, it was reasonable to interpret that there was sufficient exposure to asbestos in each occupation such that a broad look at malignant mesothelioma rates in those occupations showed significant elevation.

Member Silver made a motion to accept the proposed recommendation. Member Mahs seconded the motion, and Chair Markowitz opened the floor for discussion. Member Dement noted that the current list of jobs with asbestos exposure came from an older set of the same data that the board was currently looking at. The current data set provides more focused attention to specific jobs and more data on which to base determinations. Chair Markowitz added that even though some occupations did not appear to have excess risk based on thesee data, individual workers who did those jobs could still have elevated risk.

Member Goldman asked if custodians, whose low level chronic asbestos exposure was often overlooked, would fall under the

category of maintenance. Chair Markowitz said that they would be included in a group called janitors and building cleaners, but that group did not appear to be listed as having an increased risk of mesothelioma. He and Member Goldman agreed to add language to the recommendation clarifying that even if a claimant does not meet the presumptive criteria, a close look at the claimant's prior exposures should be undertaken in order to ascertain whether causation exists. Member Silver suggested that they add a sentence advising DOL to continue monitoring the occupational epidemiological literature for occupations that meet the same criteria. Member Dement suggested that they add that point to the rationale, and Member Silver agreed.

Board Recommendation

After some discussion, the board voted unanimously to submit the following formal recommendation to DOL:

"We recommend that the Department of Labor evaluate the job categories and associated aliases for all DOE sites in the Site Exposure Matrices and revise its list of occupations with presumed pre-1995 asbestos exposure (Exhibit 15-4) to reflect current knowledge as summarized in the rationale provided below and associated data and references. Supervisors of the listed job categories should also be considered for inclusion. For people who have other job titles with claims in relation to asbestos exposure, a careful investigation of possible occupational sources of asbestos exposure should be undertaken. In the case of mesothelioma, with greater than 90 percent linkage to asbestos exposure, all cases should have additional inquiry into potential asbestos exposure, even if not among job titles for presumed asbestos exposure. A committee of the board should work with the Department to conduct this exercise and achieve a consensus on a revised list of occupations with presumed pre-1995 asbestos exposure."

SEM – IARC Group 2A Carcinogen – Report

Member Berenji led the discussion on IARC Group 2A carcinogens. She summarized the working group's previous discussions and their review of Group 2A carcinogens, which specifically focused on 22 of the most recent agents reviewed by IARC. Member Friedman-Jimenez gave his feedback on the quality of IARC's analyses. He suggested that they include a statement, similar to those in the previous two recommendations, clarifying what the board means by presumption of causation. This statement should emphasize the fact that presumption of causation is a tool to

streamline the process for evaluating cases. He also noted that the EPA's process for establishing causation for chemicals did not seem to be as detailed, well-documented or transparent as those of IARC or the National Toxicology Program (NTP).

Member Goldman commented on her review of malathion and diazinon, both of which were categorized as 2A probable carcinogens by IARC in 2014 despite the fact that EPA and ATSDR do not list them as carcinogenic. Member Goldman said that based on these varying analyses, it was difficult to develop a clear cut presumption, though it might be beneficial to suggest added history-taking for claimants who used these pesticides in order to establish causal connections. Member Friedman-Jimenez said that making a presumption of causation involved a presumption of general causation in populations as well as a presumption of exposure in the individual. He said that he was concerned about including 2A carcinogens under presumption because by definition, it was uncertain whether Group 2A agents caused cancer in humans and which organs they affected.

Member Dement said that DOL was asking the board whether there was sufficient evidence to link exposures to 2A carcinogens to cancers in the SEM, not to establish a presumption. Member Friedman-Jimenez agreed that there was a difference between having a substance listed in the SEM and having a presumption spelled out in the PM. Ms. Pond agreed with Member Dement's summary of the program's request from the board. Chair Markowitz said that if IARC rated Group 2A agents as probable human carcinogens, the board should take that at face value. He said that the only piece of the working group's review that needed to be developed further was to determine which cancer sites could be reasonably related to the 2A carcinogens. Member Berenji agreed that that would be relatively easy to do before the board's term ends in July.

Board Resources Request – Report

Chair Markowitz began a discussion on the board's request for additional resources from the Department. The board needs assistance in two areas, the first of which is organizing, reviewing, and abstracting data from claims and analyzing those data. This would involve tasks such as organizing and developing a database for abstracted claims data; organizing and indexing claims for review; reviewing and abstracting selected data from claims; entering and organizing data; and analyzing and describing data. These tasks would require certain skills and expertise, including administrative assistance, occupational

medical and epidemiological expertise, IH expertise, and limited data analysis and description.

The board also requires assistance to conduct and describe scientific and technical reviews on selected topics. For this the required tasks would be searching and identifying relevant scientific and technical literature in response to board requests, and reading and objectively summarizing relevant literature with provisional conclusions to board queries. The expertise needed would be research assistance, occupational medicine, epidemiology, and IH expertise. Member Dement commented that these categories captured the board's most time-consuming tasks and suggested adding data management as another area of expertise.

Member Friedman-Jimenez said that the people with occupational medicine and epidemiology expertise should be able to critically evaluate the literature in addition to reading and summarizing. Member Dement added that the IH experts should be industrial hygienists who are familiar with epidemiology and causation. Chair Markowitz suggested adding exposure assessment to the skills required, and Member Dement agreed. Member Silver suggested adding familiarity with the DOE complex as another item under the skills and expertise category. Chair Markowitz said that at some point a future board would need to make an official request for resources, and at that time the write-up that this board compiled would help to identify core functions.

CMC and IH Assessment – Report

Chair Markowitz summarized the working group's discussions about CMC and IH assessments. During their deliberations the working group realized that the board needed to understand the specifics of the program's current evaluations of CMCs and IHs. This led them to request that the Department provide the specific language of IH and CMC contracts with Banda Group International (BGI) and QTC respectively. Chair Markowitz presented the preliminary recommendation: "The board recommends that the Department develop an ongoing independent third party-based system of periodic evaluation of the objectivity, quality and consistency of individual claims assessments provided by program industrial hygienists and physicians."

In the rationale, the working group noted that the program currently assessed aspects of the quality of CMC reports through a quarterly review of approximately 50 claims by the EEOICP medical director. They included a table summarizing the total

number of each type of review as well as the number of reviews that were found to need improvement. As the board had discussed previously, while causation reviews did not detect any problems, a high percentage of other reports needed improvement. The board was still seeking clarification from the Department about the extent to which generic problems identified through the CMC review were addressed more broadly. The IH assessments do not go through a periodic analysis to evaluate patterns of errors; instead they are reviewed one by one by federal industrial hygienists as they are submitted during the claims evaluation process. The board awaits additional information on quality assessments of IH reports by BGI.

Member Dement agreed that there should be an independent assessment of CMCs and IHs to eliminate systematic errors. Member Silver agreed and asked if, after a DOE denial was reversed, the CMC or IH received feedback on what new evidence or interpretation was presented to overturn their work. Ms. Pond said that the program did not usually send treating physicians' rebuttals back to CMCs, though they did conduct follow-up calls with CMCs on a regular basis. Chair Markowitz said that the working group will look at the provisions of the contracts and incorporate that into the rationale of a draft recommendation, which will go to the next board.

Claims Review (lung cancer, post-1995 claims)

In response to a request from the board, the Department provided several lung cancer claims and post-1995 claims. Member Dement shared one of the lung cancer claims that he reviewed with the last four digits 0541. The claimant worked at the Idaho National Lab for 11 years between 1980 and 2012 as a heavy equipment operator, operating engineer, and working operator foreman. The SEM identified asbestos as an exposure, as well as silica, diesel, cadmium, nickel, and beryllium. The IH found that exposures after 1995 would not be in excess of applicable standards under the regulations. The CMC report confused diesel fuel with diesel exhaust exposure and misstated the IARC categorization of multiple agents. Member Dement said that the CMC seemed to cut and paste materials from the Internet, and the report should be looked at in detail.

Chair Markowitz discussed a claim with the last four digits 1985, where the claimant was a cafeteria worker who was misreported as a laborer. He also reviewed a claim ending in 0932 involving a roofer and janitor who worked at DOE from 2003 to 2014 and did not meet the criteria for latency. The statement

of accepted facts (SOAF) stated that the exposures were within regulatory limits, and that fact was accepted by the CMC and stated as the reason that there would be no occupational contribution. The claimant's personal physician wrote a report in opposition to the CMC's conclusion, and the district office director overrode the denial. Chair Markowitz shared another claim ending in 5648, which was denied due to the short period of time that the claimant worked at DOE. He said that he could not find a link in the SEM between the glazier job title and lung cancer, but Exhibit 15-4 recognized that job title as having significant exposure to asbestos prior to 1995.

Member Silver said that he reviewed two lung cancer claims where the CMCs asserted that because there was no radiographic evidence of asbestosis or pleural plaques, the lung cancer could not have arisen from asbestos exposure. Chair Markowitz said that it was widely accepted that scarring was not necessary to confirm asbestos exposure and therefore a causal association between lung cancer and asbestos did not require the presence of asbestosis or pleural plaques. He presented a claim ending in 7497 where the claimant spent nine months as a carpenter and did not meet the presumption of 250 days of exposure to asbestos. The CMC cited a lack of air monitoring results as the reason that causality could not be determined, which was an unreasonable criterion on which to base the decision. The CMC also cited cigarette smoking as critical to the development of lung cancer, even though the program has stated that consideration of the claims should not include cigarette smoking.

Chair Markowitz presented another lung cancer claim ending in 6018. The claimant was an iron worker who met the 250-day presumption criterion for asbestos but did not meet the 15-year latency requirement. Chair Markowitz commented that if they gave that case to several different CMCs, they would probably see half deciding one way and half deciding the other way, which is problematic for consistency. He said that his take-away from these reviews was that there is considerable variation in the quality of the CMCs, some of which is due to the inadequacy of some CMCs.

Member Dement presented several post-1995 claims that he reviewed. In a COPD claim ending in 5756, the claimant was a non-smoker who worked as a pipefitter at Portsmouth. Most of his work took place after 1995, and in the OHQ he mentioned exposures to welding fumes while welding in an unventilated shop and other confined spaces. The IH assessment relied on the SEM,

and the CMC used the IH report to find lack of causation. Member Dement said that he found the assessment to be flawed due to the CMC's assumptions about occupational health and safety standards, and the failure of the IH to consider specific exposure circumstances. In a case ending in 4550, the claimant worked in data quality control near Yucca Mountain and was required to come on to the site several times each month and enter the exploratory studies facility. The claimant, who was diagnosed with silicosis based on a chest x ray and a B read, described dusty conditions while driving to the facility and inside the facility itself. A supporting physician's report ruled out other causes and identified exposure to silica at Yucca Mountain as at least contributory to the claimant's silicosis. Member Dement commented that IHs need to look closely at more than just the SEM and the claimant's job description when making claim determinations.

Member Redlich noted that several of the post-1995 claims contained themes that the board has seen before. In a COPD claim ending in 2876, the SEM acknowledged exposure to asbestos dust, cement, diesel exhaust, crystal silica, and welding fumes, but the IH opined that exposures past March 11, 1996 would not have exceeded regulatory standards, and the CMC agreed that the exposures were not a significant factor in causing or contributing to COPD. The claimant appealed and gave a description of the work that they performed, and Member Redlich said that what they described seemed like sufficient exposure to establish causation. Member Silver agreed that the board has raised many of these issues in the past. Member Dement noted that there were a number of claims with four or five different exposures identified in the SEM as related to the relevant job category and linked to COPD, and the totality of those exposures was not taken into account. Chair Markowitz said that the default for the CMCs is to look at the IH report or the SOAF, which makes their decision much easier.

Member Silver suggested that while the Department was not open to including vapors, gases, dust and fumes in the PM, a middle ground approach could be guidance to the IH and CMC in cases of COPD to consider as many credibly-documented exposures as possible. He cited a claim ending in 4457, where a lab technician at Portsmouth was only allowed ammonia, asbestos and chlorine exposures in the SEM, even though his case file contained evidence that he was exposed to hydrogen fluoride and other substances. Chair Markowitz said that the board members' comments on these lung cancer and post-1995 cases could be incorporated into the board's report on the consistency, quality

and objectivity of IH and CMC reports. He suggested that board members follow up on the suggested COPD exposure guidance to IHs and CMCs offline and include it in the exit report for the next board.

DOL Request for Assistance – Provider Outreach

Chair Markowitz reminded the board that DOL requested their guidance on how to elicit responses from providers. The board members looked at examples of development letters provided by the Department, including a one-page letter on Parkinson's disease which Chair Markowitz presented as a positive example because it was concise and provided the necessary information. In contrast, he presented a letter about neuropathy, which was lengthy and full of bureaucratic language. Member Goldman commented that sometimes it might be helpful to include more details so that physicians know what the Department is asking them to do, and Chair Markowitz agreed that that could be helpful either in the body of the letter or as an attachment. He commented that these development letters are labor-intensive and should be constructed in such a way that the provider can extract the relevant details and insert them into their response letters.

Member Dement commented that many of the letters limited the assessments of exposures of interest to those that were identified by the IH or the SEM. He suggested that the development letters should be left more open-ended in case the physician had experience with other exposures. Member Redlich agreed that the board has raised this issue before, and the physician should be asked whether the claimant's DOE-covered work contributed to or caused the disease, rather than pre-supposing specific exposures. Chair Markowitz pointed out that that the language does not include the words "caused, aggravated or contributed to by toxic substances," which the law requires. Member Redlich said that the question could still be more open-ended to account for the information that the Department has provided as well as the physician's own interview of the patient.

Additional Issues

Chair Markowitz noted that the current board did not address the issue of pre-publication policy revisions. The next board should develop a mechanism to make sure that the policy revisions are discussed by the board.

Work Plan

Chair Markowitz summarized the remaining work for the current board to complete by the end of its term:

- The board completed its recommendations for Parkinson's disease and asbestos job titles, and Chair Markowitz will submit them to the Department.
- The IARC 2A working group will pinpoint which cancer sites are affected by 2A chemicals and attach an abridged table to their report.
- The board resource request and CMC/IH assessment working groups will continue their respective work based on this meeting's discussions, then pass along their draft recommendations or observations to the new board.
- The claims review observations from this meeting will feed back into the issue of CMC/IH assessment.
- Chair Markowitz will summarize the board's observations on provider outreach and send them to the Department.

Chair Markowitz asked the Department for an estimate as to how soon the new board might be identified. Ms. Rhoads said that they hoped to avoid gaps between the current board's term and the next board's term, but that will depend on how fast the process goes. Ms. Pond thanked the board members for all of their work. Chair Markowitz noted that the next board needed to follow up on the current board's request for documentation in the SEM on health physicists and security guards from gaseous diffusion plants. He thanked the board members for their work and reflected on their unique opportunity to provide concrete advice to the program, which is very meaningful to many people across the country. He thanked the Department for their interaction and cooperation throughout the board's term.

Close of Meeting

Mr. Chance adjourned the meeting at 4:31 p.m. EDT.

I hereby certify that, to the best of my knowledge, the foregoing minutes are on accurate summary of the meeting.
Submitted by:

Steven Markowitz, MD, DrPH.
Chair, Advisory Board on Toxic Substances and Worker Health
Date: 9/21/2020