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TESTIMONY OF JOHN E. PARKER, M.D.

Employment and Workplace Safety Subcommittee Hearing: "Coal Miners' Struggle for Justice: How Unethical Legal and Medical Practices Stack the Deck Against Black Lung Claimants."

"The first priority and concern of all in the coal or other mining industry must be the health and safety of its most precious resource – the miner."
(Federal Coal Mine Health and Safety Act of 1969, amended 1977.)

Thank you for the invitation to provide testimony at this Employment and Workplace Safety Subcommittee hearing "Coal Miners' Struggle for Justice: How Unethical Legal and Medical Practices Stack the Deck Against Black Lung Claimants."

I could not resist introducing the profound quote above as a preface to my remarks and comments. This meaningful quotation always reminds me of the noble mission and indeed the challenge that was issued over forty five years ago - to protect the miner from disease and injury.

The questions. It is my understanding that concerns have arisen about the backlog of unresolved claims at the Department of Labor's (DOL) Office of Administrative Law Judges (OALJ). I also understand concerns have been advanced about the veracity of medical work performed by physicians and ethical questions about the legal work provided by attorneys representing mining companies in these matters of compensation claims for coal miners.

I have been more specifically asked to provide testimony focused on the consensus medical standards for reading or classifying chest radiographs of miners and the diagnosis or recognition of the presence or absence of pneumoconiosis. I have also been asked to explain common fee structures for evaluating such radiographs and to describe a typical range of reimbursement or fees charged by physicians.

I am honored to be asked to render testimony on these questions and issues.

My background. Let me briefly introduce the experience and training that I believe qualifies me to provide such testimony. I am currently a Professor and Chief of Pulmonary and Critical Care Medicine at West Virginia University Health

Sciences Center. I am the Program Director of the Pulmonary and Critical Care Fellowship at West Virginia University. I am the Director of the Adult Cystic Fibrosis Center. I have maintained an active clinical practice at West Virginia University since 1985, participating in the care of patients with pulmonary diseases, sleep disorders, and other life threatening illnesses in the intensive care unit. I have evaluated over one hundred thousand patients, research subjects, and/or their imaging studies, both nationally and internationally, for occupational lung diseases, including asbestosis, silicosis, coal workers' pneumoconiosis, occupational asthma, hypersensitivity pneumonitis, or malignancies.

From 1985 through 1998, I worked in a number of capacities for the National Institute for Occupational Safety and Health ("NIOSH"). I was the Chief of the Examination Processing Branch at the Division of Respiratory Disease Studies for NIOSH from July 1991 through August 1998. In this position, I provided oversight for the NIOSH Coal Workers' Respiratory Health Program as well as the NIOSH B-reader program and served as teaching faculty for the American College of Radiology View-box Seminar on Pneumoconiosis. Additionally, I was the co-author of NIOSH Hazard Alerts regarding toxicity of silica in sand blasters, rock drillers, and construction workers.

I also developed a cooperative agreement with the Finnish Institute for Occupational Health for studying the health effects of asbestos on Russian asbestos miners and millers. Concurrently while serving as Chief of the Examination Processing Branch, I was also the Acting Chief of the Clinical Investigations Branch and the Acting Chief of the Epidemiological Investigations Branch at the Division of Respiratory Disease Studies for NIOSH. I also served as the Chief of the Protective Technology Branch of the Division of Safety Research for NIOSH. In this capacity, I supervised NIOSH research in workplace respiratory protection.

I offered extensive expert testimony in the *In re Silica MDL* about the proper methods for conducting an ILO classification (B-reading) of chest radiographs; generating a differential diagnosis of chest radiographic abnormalities, and the implausibility of thousands of claimants having both asbestosis and silicosis. I also testified in June of 2003 before the U.S. Senate Judiciary Committee while they were considering "Fair Act" legislation, which related to establishing uniform medical criteria for asbestos related disease compensation.

I have consulted for both the World Health Organization and the International Labor Office (ILO) on many issues related to respiratory diseases. I have assisted the ILO in the 2000 and 2011 revision of the ILO system and on issues of quality

assurance, training and the adoption of digital radiology, and the role of high resolution computed tomography.

I've published numerous peer-reviewed studies, a textbook and textbook chapters on occupational lung disease. I was an invited participant at three Helsinki criteria meetings, which addressed asbestos, asbestos-related diseases, and imaging methodology. I also served as a B-reader for ATSDR in multiple studies of health effects from potential exposure to tremolite in Libby, Montana and was a co-author of a peer-reviewed published HRCT study of this cohort. I have made over 100 international trips to nearly 60 nations for research, teaching, training, or patient care, primarily related to occupational and infectious lung diseases. I have a passionate commitment to the recognition, prevention, and treatment of occupational lung diseases. The important role for imaging in dust related diseases has been of particular interest. I have also a strong interest in the ethical conduct of physicians as they have a sacred social contract with the nation and its citizens to accurately present scientific truth in medical legal proceedings.

Lung diseases in miners. Let me provide the following short background discussion about dust related lung diseases, with an emphasis on coalmine related dust diseases.

The pneumoconiosis, silicosis, asbestosis, and coal workers' pneumoconiosis are diseases related to the cumulative respiratory exposures to the respective dusts, and the lung tissue reaction to the dust. The diagnosis is made during life, typically without a lung biopsy, based primarily upon a history of exposure and latency, a compatible chest radiographic abnormality, and no better medical explanation for the findings than the dust exposure. These concepts are well described in medical textbooks and other medical literature.

The major radiographic system to establish the presence or absence of abnormalities in dust exposed workers is the International Labour Office (ILO) classification system, and this is also used in the United States, and NIOSH devotes staff and resources to administering a B reader program, for education, training, and certification of qualified chest radiographic interpreters, or physicians.

Coal mine dust levels in coal mines have historically been regulated at about 2 to 3 milligrams of respirable dust per liter of ambient air. Respirable dust is dust that is five microns or less in aerodynamic diameter. The permissible respirable dust level has more recently been reduced to 1.5 mg/liter by the Mine Safety and Health

Administration. This is an effort to further protect miners from the adverse health effects of coalmine dust.

These regulatory levels are in general agreement with enforced levels of exposure throughout the world. The science supporting this recommendation is well documented in is available for review in the publication - Criteria for a recommended standard: Occupational exposure to respirable coal mine dust (DHHS (NIOSH) Publication No. 1995-106).

Coal miners are at risk to develop several lung diseases from their mining exposures to respirable dusts, such as bronchitis, expiratory airflow obstruction, and the radiographic abnormalities of coalworkers' pneumoconiosis. Recent advances in the understanding of respiratory health issues in coal miners have focused on the spectrum of disease caused by inhalation of coal mine dust, termed coal mine dust lung disease (CMDLD).

This disease, CMDLD includes the classic occupational interstitial lung diseases such as coal workers pneumoconiosis (CWP), silicosis, and mixed dust pneumoconiosis, but also include the more recently described entity labeled dust-related diffuse fibrosis (DDF). Again, CMDLD is a preventable occupational disease that results from inhalation of coal mine dust into the lungs leading to parenchymal and airway damage, not only from the foreign material itself but also the tissue's reaction to the dust.

As most readers of this testimony will know, Congress passed comprehensive legislation with the Federal Coal Mine Health and Safety Act of 1969. This Act went above and beyond previous legislation by providing for the first mandatory standards for working conditions in U.S. mines, a system for enforcement, and ongoing monitoring of miner health, as well as a mechanism for seeking financial compensation for coal miners who could demonstrate total disability arising from their dust exposure (aka "black lung").

Since the time of this landmark legislation further acts by Congress and enforcement agencies have improved miners' working conditions, which now fall under the purview of the Mine Safety and Health Administration (MSHA). Much of our improved understanding of the nature and extent of lung disease associated with mining coal in the United States over the past half century comes from the large number of studies performed by the National Institute for Occupational Safety and Health (NIOSH).

Despite increased understanding of CWP and previous reports of stable or improved dust levels in mines, dust-related respiratory disease remains a significant burden. Most worrisome are recent data suggesting that contemporary dust exposure is leading to rapidly progressive pneumoconiosis particularly in young miners, with a significant impact on pulmonary function and premature death.

Medical diagnosis of lung diseases in miners. Establishing a medical diagnosis of "black lung disease" requires several elements, including but not limited to, a careful medical history and examination, an occupational exposure history, the use of lung function testing, and chest radiographic imaging studies, along with considerations of alternative causes of any and all abnormalities identified.

For chest imaging, it is the ILO radiographic classification system that is the most widely accepted and standardized method to classify chest radiographs for the presence or absence of dust related radiographic lung injury. The system uses written guidelines, standard comparison films, and a recording or reading sheet.

The system provides a method to record findings, after classifying chest radiographs for film quality, parenchymal abnormalities, pleural abnormalities, and additional observations to allow systematic categorizations and/or comparisons between readers, using a common measure or standard. The lung parenchyma is assigned profusion abnormalities in one of four major categories. Category 0 designates normal films, and categories 1, 2, and 3 record progressive degrees of profusion abnormality. Profusion is further expanded into a 12 point scale. Major category 0 includes designations 0/-, 0/0, and 0/1, while major category 1 includes 1/0, 1/1, and 1/2; and so forth for major categories 2 (2/1, 2/2, 2/3) and major category 3 (2/3, 3/3, 3/+).

It is noteworthy that the ILO system, including refinements over time has been used for over five decades, and is a critical tool that has provided the scientific data for exposure-response relationships in occupational dust diseases. This data has allowed the United States and nations throughout the world to establish protective workplace standards.

The ILO system has been consistently validated by workplace dust exposure histories, cumulative dust measurements, pathology, tissue mineral measurements, and additional radiological techniques such as high resolution computed tomography. **When correctly applied without bias**, the ILO system is a reliable tool to assess both groups and individuals for radiologic abnormalities from workplace exposures.

With this background, allow me to address the specific concern about application of consensus medical standards for reading or classifying chest radiographs of miners and the diagnosis of the presence or absence of pneumoconiosis, and the common fee structures for evaluating such radiographs, and to describe a typical range of fees charged by physicians.

The ILO system for classifying radiographs is the consensus standard medical method. Ideally, more than one reader should be used to reach consensus normal or abnormal. Science and experience has shown, multiple readers are more reliable than one reader alone with veto power. Typically, two readers with a third tie-breaker reader, or three readers by consensus have been the most widely used methods. NIOSH and other authorities have traditionally reached profusion consensus among three readers of the same PA radiograph based upon the median profusion classification.

Profusion is a concept embracing severity of disease of the lung parenchyma by comparison to standard example images. Again, the numerical designations 0/0 and 0/1 are normal or nearly normal, while designations with a number higher than 1 as the first numeral are abnormal. Most research, surveillance and compensation systems use 1/0 or greater as abnormal (the scale progresses to include twelve values 0/-, 0/0, 0/1, 1/0, 1/1, 1/2, 2/1, 2/2, 2/3, 3/2, 3/3, 3/+) A median profusion consensus reading is the middle reading of the three classifications for profusion abnormality. For example, if the three reader classifications are 1/0, 1/1, 1/2, the consensus reading is 1/1; if classifications are 1/0, 1/1, 1/1, the consensus reading is 1/1; and so on.

As previously stated, the ILO system is highly validated with research comparing radiographic findings to pathology, exposure assessment, lung tissue mineral analysis, and other techniques.

Physician fees for radiographic readings. Information regarding fee structures. In my four decade career, I have seen the professional or physician reimbursement for the ILO classification of images, ranging from two dollars per radiograph to one hundred dollars per radiograph. Two dollars per radiograph was what NIOSH paid readers in the 1980's and early 1990's, in their research and surveillance programs. The US Navy often reimbursed at about six to eight dollars per image for their asbestos related screening programs, during that time period. The current

NIOSH payment for images in their coal miner surveillance program is twelve dollars per radiograph. A chest radiograph professional interpretation in the hospital or clinic setting for clinical purposes is reimbursed at a lower rate than ILO classifications, and this is currently by most insurance companies about nine dollars per image. Chest computed tomography is reimbursed at a higher rate, about sixty dollars per study. There is also technical component charge for radiographic imaging by hospitals or clinics, as they often own, operate, and maintain the radiographic equipment and supplies. For a single view chest that technical component reimbursement is about twelve dollars, and for Chest computed tomography it is about one hundred and fifty dollars.

Integrity in science and medical testimony. Now a short discussion about profession integrity of physicians, in compensation and litigation of occupational lung disorders.

In my career, I have been aware examples of apparent systematic over-reading of radiographic abnormalities, as well as, systematic under-reading of radiographic abnormalities in dust exposed workers. Some of the apparent mis-application of the ILO system has led to concern about large scale fraud as outlined in the written decision from Judge Jack in the *In re Silica MDL* in 2005; and another federal court decision, a Racketeer Influenced and Corrupt Organizations Act (RICO) claim in *CSX Transp. Inc. v. Peirce, et al. in* 2012. Other examples of potential mis-application of the ILO system have been outlined in the Center for Public Integrity reporting by Mr. Chris Hamby.

As I have explained before, these reports of systematic un-reliable diagnosis, give credence to justified and serious concern about bias and the lack of scientific independence or credibility of some physicians in compensation and medical legal matters. Are some medical experts not being "scientifically credible"; being "disingenuous and scientifically dishonest"; presenting testimony that is "invalid and scientifically wrong"; reporting incorrect medical decisions "not explainable as an 'honest mistake' or through lack of competence and skill"; but rather reporting medical findings that are the product of a purposeful and systematic pattern of incorrect reading that does not match the scientific literature?"

And again, rather than rely exclusively on my thoughts on this matter, I would refer readers to the NIOSH web site that provides guidance to B readers about the proper methodology for reviewing and classifying chest images, including ethics for contested readings.

The website contains some of the following succinct and forceful language, and I primarily quote NIOSH in the following:

"NIOSH has prepared **ethical guidelines** that should be considered when readers classify radiographs in contested settings."

"Also, the American Medical Association (AMA) and the American College of Radiology (ACR) have published guidelines for physicians serving as expert witnesses (ACR 2007, AMA H-265.994, AMA E-9.07)"

"All of these professional bodies and these guidelines discuss the need to be impartial, objective, and unbiased. Testimony must be scientifically valid and be able to withstand peer review."

"The NIOSH B Reader Code of Ethics is intended to assist B Readers in recognizing and maintaining a high level of ethical conduct. **The outcome of chest radiograph classification can have important medical, legal, and social implications.** It is critical that B Readers perform chest radiograph classifications properly and with integrity. This code, modeled after those of the American Medical Association (AMA) and the American College of Radiology (ACR), is a framework to help B Readers achieve this goal."

B Reader Code of Ethics is as follows:

"The B Reader's primary commitment is to serve the welfare and best interests of patients, workers, and society by striving to classify chest radiographs as accurately as possible.

B Readers shall uphold the standards of professionalism, be honest and objective in all professional interactions, and strive to report individuals or enterprises that they know to be deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

B Readers shall recognize the limitations of chest radiograph classifications, and shall not make clinical diagnoses about pneumoconioses based on chest radiograph classification alone.

When a contemporary chest radiograph is classified, the B Reader shall either take responsibility for assuring to the extent feasible that the examined individual is promptly notified of all clinically important findings or must be assured that another appropriate party is taking that responsibility.

B Readers shall respect the law; the rights of patients, other health professionals, and clients; and shall safeguard medical information and other confidences within the constraints of the law.

B Readers shall continue to study and apply advances or changes to the International Labour Office International Classification of Radiographs of Pneumoconioses as specified by the NIOSH B Reader Program.

In providing expert medical testimony, B Readers shall ensure that the testimony provided is unbiased, medically and scientifically correct, and clinically accurate.

B Readers shall recognize and disclose any conflicts of interest in the outcome of a chest radiograph classification. B Readers shall not accept compensation that is contingent upon the findings of their chest radiograph classifications or the outcome of compensation proceedings or litigation for which they undertake readings.

B Readers shall not advertise or publicize themselves through any medium or forum of public communication in an untruthful, misleading, or deceptive manner.

B Readers shall promptly report to the NIOSH B Reader Program any revocation or suspension of a medical license, voluntary relinquishment of a medical license or conversion to inactive status, or the voluntary surrender of a medical license while under investigation."

I have no doubt that if all involved in the evaluation of miners for potential adverse respiratory health consequences of mining utilized the principles embodied it these guidelines outlined by NIOSH and other professional organizations, the nation and its miners, and its system of justice, would be better served.

John E. Parker

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(Federal Coal Mine Health and Safety Act of 1969, amended 1977.)

Pertinent References

<u>Criteria for a recommended standard: Occupational exposure to respirable coal mine dust</u> (DHHS (NIOSH) Publication No. 1995-106)

Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses.

NIOSH. Chest radiography, NIOSH B reader program, ILO Classification System, Issues in classification of chest radiographs, recommended practices: worker monitoring and surveillance, epidemiologic research, medical diagnosis, government programs, best technical practices.
http://www.cdc.gov/niosh/topics/chestradiography/interpretation.html

Petsonk EL, Rose C, Cohen R: Coal mine dust lung disease: New lessons from an old exposure. *Am J Respir Crit Care Med* 187(11):1178-85, 2013.

Wagner GR, Attfield MD, Parker JE. Chest Radiography in Dust-Exposed Miners: Promise and Problems, Potential and Imperfections. *Occupational Medicine: State of the Art Reviews* 8(1); 127-141, 1993.