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Good morning, Mr. Chairman, Ranking Member Isakson, and distinguished members of the Subcommittee. My name is John Howard and I am the Director of the National Institute for Occupational Safety and Health, or NIOSH, which is part of the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS). I am here today to provide an update on NIOSH's efforts to provide high-quality health surveillance to coal miners to protect their respiratory health.

B Reader Certification Program

The need for the B Reader Certification Program was recognized soon after NIOSH was established in 1970. One of NIOSH's very first responsibilities was to provide ongoing, periodic health surveillance to underground coal miners, using chest radiographs to screen for a type of dust-induced lung disease (pneumoconiosis). The requirement to provide this surveillance was established in 1969 by section 203(a) of the Federal Coal Mine Health and Safety Act (Public Law 91-173), hereby referred to as the "Coal Act."

The Coal Act required that miners found to have evidence of pneumoconiosis be offered the opportunity for transfer to jobs with lower dust exposures to minimize progression of their disease. It was found at that time that there was substantial disagreement between physicians in determining whether chest radiographs showed evidence of pneumoconiosis. This was attributed in part to physicians' lack of experience with the classification systems employed to describe chest radiographic changes and their lack of familiarity with the radiographic manifestations of pneumoconiosis. In response, efforts were initiated to develop a pool of physicians with the skills needed to provide high quality, reproducible documentation of changes in miners' chest radiographs. These efforts led in 1978 to the regulations, codified at 42 CFR part 37, under which the B Reader Certification Program operates. It was also recognized that accurate, reproducible results depended as much on the system within which B Readers were used as upon their individual skills. Thus, Part 37 also included regulations describing how B Readers were to be employed in classifying chest radiographs for the presence and severity of changes associated with pneumoconiosis.

The B Reader Certification Program trains and tests physicians for their ability to use a standardized system for describing changes found on chest radiographic images that are associated with pneumoconiosis. This system is called the *International Labor Organization (ILO) International Classification of Radiographs of the Pneumoconioses*. The ILO Classification System is used in many

countries to provide a framework for reproducible "classification" or description of chest radiograph quality and the presence and severity of changes associated with pneumoconiosis on chest radiographs. The focus of the classification is to have standardized, reproducible reporting of what changes can be seen on the chest radiographs. Relatively few physicians are familiar with the system since it is not typically used to provide clinical care. Rather, a classification using the ILO system (sometimes referred to as a "B reading") is more often used in epidemiological research, health surveillance, legal and compensation systems where greater standardization is required. Making a clinical diagnosis about what medical condition or disease has caused visible radiographic changes that are classified in an individual is a separate process from image classification. Clinical diagnosis involves considering additional clinically relevant information, for example: work or exposure history, medical history and physical examination, and the results of other medical tests.

Physicians seeking to become B Readers can learn to perform ILO classification using a self-study syllabus available from NIOSH or can take a course periodically offered by the American College of Radiology. Physicians can become B Readers by taking a certification examination in which they are graded on their ability to classify a group of chest radiographs. They must take a re-certification examination every four years to maintain their certification. Over the years, the certification examination has had an approximately 50 percent pass rate and the recertification examination an approximately 85 percent pass rate. There are currently 221 B Readers in the United States—down from the high of 634 in 1997.

Part 37 specifies how B Readers are employed to classify chest radiographs for the NIOSH Coal Workers' Health Surveillance Program (CWHSP). At least two readers independently classify each chest radiograph. If the first two readers are in disagreement, a third reader classifies the film and, if there is sufficient agreement, a median classification is used. However, if there is still insufficient agreement, up to five readers may be used. This system inherently assures that classifications represent mainstream views and minimizes the impact of extreme individual classifications that differ from those of other B Readers.

The B Reader Certification Program was developed to improve the quality of NIOSH's CWHSP and the same regulations that established the B Reader Program also established an appropriate system of employing B Readers to optimize the accuracy and reproducibility of their classifications. Over time, successful completion of the B Reader Certification Examination has been recognized internationally as evidence of competence in using the ILO Classification System to classify changes on chest radiographs. Even though only physicians with U.S. licensure can become B Readers, NIOSH allows international physicians and scientists to take the B Reader certification and recertification examinations. If they pass, their names are listed on the NIOSH website. The website currently lists 63 of these successful international examinees.

Burden of Pneumoconiosis Documented by the Coal Workers' Health Surveillance Program

The ability of the CWHSP to obtain accurate classifications of underground coal miners' chest radiographs has allowed it to longitudinally monitor the burden of pneumoconiosis in U.S. underground coal miners since the 1970s. Because it takes five years to complete a full national surveillance cycle, NIOSH typically shows pneumoconiosis rates over five-year intervals.

Pneumoconiosis most often takes several decades to become apparent, so only trends for those engaged in underground coal mining for 20 years or more are discussed.

In this tenure group, prevalence of pneumoconiosis in CWHSP participants was at its highest, 29.3 percent, in the five-year period of 1970-74. Rates fell continuously after that until 1995-1999, reaching a low of 3.2 percent. Rates subsequently increased to 6.1 percent and 6.4 percent in 2000-2004 and 2005-2009, respectively. NIOSH will soon complete another five-year period and it appears that rates will be similar. Prevalence rates have been higher among underground coal miners working in the Central Appalachian region and in smaller mines, although pneumoconiosis continues to be a problem nationwide.

NIOSH does not have similar longitudinal data for surface coal miners, who have not previously been required to be offered health surveillance. This situation will change as of August 1, 2014, when the Mine Safety and Health Administration's new respirable coal mine dust regulations go into effect. At that time, NIOSH's CWHSP will be expanded to include surface coal miners. Required health surveillance will also add a lung function test called spirometry to the screening that is offered to coal miners.

Updating the B Reader Certification Program to Digital Format

In recent years, most clinical facilities have moved from film-based chest radiography to digital chest imaging. In response, NIOSH assisted the ILO to enable digital chest images to be classified using the ILO system. This involved doing research to document technical approaches that would yield the same classification regardless of whether an individual was evaluated using a film-based chest radiograph or a digital chest image. NIOSH is now updating the B Reader Certification Program to digital format. NIOSH has entered into a contract with the American College of Radiology to accomplish this work, which will include updating the B Reader Certification Program's educational syllabus, certification examination, and recertification examination into modern digital format. This modernization of the program is critically important for us to maintain an adequate pool of physicians able to classify chest radiographs using the ILO Classification System.

B Reader Classifications in Non-NIOSH Settings

The B Reader Certification Program is the only formal national program that provides training and evidence of competency in classifying chest radiographs according to the ILO Classification System. Because there is also a need for classification of chest radiographs using the ILO Classification System in a range of non-NIOSH settings, B Readers have been sought after to provide classification in those settings. Examples include research, industry health surveillance programs, legal proceedings, and various governmental eligibility programs, including the Department of Labor's Black Lung Compensation Program. Examples of non-NIOSH employers in these settings include academia, medical practices, industry, legal firms, and other governmental agencies.

Because NIOSH's authority for operating the B Reader Certification Program is tied to operation of the Coal Workers Surveillance Program, we do not have any formal role or authority in

many of these settings. For example, we do not have the authority to obtain information about what non-NIOSH classifications are performed, the results of the classifications, or to obtain the images that were classified. Also, many of these settings—chiefly adversarial proceedings—do not employ B Readers in a way that optimizes accuracy and mainstream classifications, as I have described for the Coal Workers Surveillance Program.

Thus, over the decades that the B Reader Certification Program has been in existence, NIOSH has not monitored or guaranteed the accuracy of classifications performed by B Readers in non-NIOSH settings. For those seeking to assess the quality of classifications performed in non-NIOSH settings, NIOSH has developed a set of recommended practices for obtaining accurate classifications of chest radiographs, which are posted on the NIOSH website. Classifications resulting from practices such as using a summary classification of multiple independent readers, blinding the readers to the source of the radiograph, picking readers randomly (or taking other steps to assure they are in the mainstream), and conducting quality assurance can in general be viewed as more credible than classifications that do not employ these measures to optimize accuracy.

NIOSH Actions in Response to Center for Public Integrity/ABC News Reports

Even though NIOSH has a limited role and a limited ability to address chest radiograph classifications performed in non-NIOSH settings, we still want to do what we can to promote high quality, accurate classifications of chest radiographs. We also believe that B Readers should demonstrate high levels of ethics and integrity, which is why we developed a B Reader Code of Ethics. Devotion to accurate classification of chest images is an important feature of the Code. In view of this, NIOSH was disturbed by evidence presented in the Center for Public Integrity and ABC News reports suggesting that a B Reader involved in Black Lung compensation cases systematically misclassified chest radiographs. NIOSH has taken several actions in response to these reports.

First, when the particular B Reader's employer, Johns Hopkins University, announced that they were suspending their program of providing expert medical testimony for legal firms, NIOSH offered Johns Hopkins help with their internal investigation. NIOSH subsequently answered questions and provided information to help them with their investigation.

Second, in reading the Center for Public Integrity report and viewing the companion report on ABC News, NIOSH noted that the particular B Reader reportedly argued he should not classify clearly visible chest radiographic changes because he thought they had a cause other than pneumoconiosis. As I have previously described, this is not consistent with the purpose of the ILO Classification System, which provides a standardized way to record the changes that can be plainly seen on a radiograph. In response, NIOSH obtained approval from the Office of Management and Budget (OMB) to revise the NIOSH form which many B Readers use in non-NIOSH settings to report the results of chest radiograph classifications. The new form clearly requires that all findings described by the ILO Classification System that are seen on the chest radiograph must be classified regardless of opinions about underlying cause, which are entered elsewhere on the form.

Third, NIOSH has been in discussions with the Department of Labor (DOL), Office of Workers' Compensation Programs (OWCP), which operates the Black Lung Compensation Program

about the feasibility of implementing a quality assurance program to determine whether B Readers are providing accurate classifications of chest radiographs for consideration in compensation proceedings. NIOSH and OWCP have agreed in principle to establish the program and are currently evaluating technical issues such as the availability of chest radiographic images for re-classification, appropriate methods for using re-classifications to assess B Reader performance, and how this information will be used for quality improvement. It should be noted that the quality assurance program will operate separately from the process of adjudicating individual compensation claims. We hope to implement the quality assurance program during fiscal year 2015.

Fourth, for many years, NIOSH has had a policy that if provided with a written complaint about the ethics or competence of an individual B Reader that performed services in non-NIOSH settings, NIOSH would refer the complaint to the appropriate State Medical Licensing Board. The reasoning for this policy was that the practice of medicine in the United States is regulated at the State level and thus State Medical Licensing Boards have investigative authorities in non-NIOSH settings that are not available to NIOSH. State Boards also have the ability to restrict or suspend a physician's privilege to practice medicine based on the outcome of an investigation. It should be noted that since the B Reader Certification Program was established in 1978, we are aware of only two B Readers who have lost their licenses to practice medicine because of the way they classified chest radiographs. In response to the current situation, NIOSH is taking the additional action of formally offering our technical assistance to any State Medical Licensing Board that makes the decision to investigate chest radiograph classifications performed by a B Reader. NIOSH will also consider requests for technical assistance from other government agencies that wish to develop quality assurance programs or to investigate the performance of individual B Readers in chest image classification.

Conclusion

Since the current NIOSH B Reader Certification Program was established in 1978, it has played a critical role in ensuring the availability of a pool of physicians able to classify chest radiographs for the NIOSH Coal Workers' Health Surveillance Program using the ILO system. Part 37 also specifies that readers be employed in a way that favors mainstream classifications and minimizes the impact of outliers, thus optimizing the accuracy of chest radiograph classifications used by the surveillance program. Because the B Reader Certification Program is unique in providing formal documentation of the competency of physicians to classify chest radiographs using the ILO system, B Readers are often sought after to perform classifications in non-NIOSH settings. These settings do not always follow NIOSH recommendations to ensure high quality classifications.

NIOSH has taken action to help DOL in its efforts to improve the quality of classifications submitted for consideration by the Black Lung Compensation Program, and, within our ability to do so, NIOSH stands ready to assist others undertaking similar efforts in other non-NIOSH settings.

Thank you for the opportunity to provide this testimony. I am pleased to answer any questions you may have.