ORIGINAL RESEARCH

Association between Financial Conflicts of Interest and International Labor Office Classifications for Black Lung Disease

Lee S. Friedman, Sudeshna De, Kirsten S. Almberg, and Robert A. Cohen

Division of Environmental and Occupational Health Sciences, School of Public Health, University of Illinois Chicago, Chicago, Illinois

ORCID IDs: 0000-0001-9312-6099 (L.S.F.); 0000-0002-8405-6997 (K.S.A.); 0000-0001-7141-8795 (R.A.C.).

Abstract

Rationale: The U.S. Department of Labor administers the Federal Black Lung Program (FBLP), an administrative system charged with managing claims by coal miners for workers' compensation for totally disabling coal mine dust lung disease. Specific case reports have raised concern that financial conflicts of interest (COIs) may systematically bias physicians when they are classifying chest X-rays (CXRs) for the absence, presence, and severity of pneumoconiosis.

Objectives: To evaluate the direction and magnitude of association between financial COIs of physicians participating in the FBLP and international standards for the classification of radiographs of pneumoconiosis.

Methods: An epidemiologic assessment of black lung claims filed to the FBLP from 2000 to 2013 was conducted to determine physician classifications of radiographs. FBLP court decisions from 2002 to 2019 (n = 7,656) were used to evaluate financial COIs of each physician. The main outcome measures used were classifications of radiographs for the absence of pneumoconiosis (small opacity classifications of 0/0 or 0/1), simple pneumoconiosis (small opacity classifications of 1/0 through 3/+), and progressive massive fibrosis (PMF) (large opacities with classifications of A, B, or C).

Results: Of 63,780 radiograph classifications made by 264 physicians, 31.4% were read positive for simple pneumoconiosis and 3.6% were read as having PMF. There were 52 physicians who classified CXRs as having no evidence of pneumoconiosis in 99%+ of their readings and 18 physicians who classified CXRs as positive for simple pneumoconiosis in 99%+ of their readings. The adjusted odds of a negative classification of pneumoconiosis was 1.46 (95% confidence interval [CI], 1.44–1.47) per 10% increase in the proportion of court records demonstrating that a physician was hired by the employer. Per 10% increase in court records indicating a physician was hired by the miner/claimant, the adjusted odds ratio for classifying simple pneumoconiosis was 1.51 (95% CI, 1.49–1.52), and the adjusted odds ratio for finding PMF was 1.28 (95% CI, 1.26–1.30).

Conclusions: There was a strong association between source of payment and radiograph classification, suggesting the importance of eliminating financial COIs in what should be an objective determination of eligibility for Black Lung Workers' compensation benefits.

Keywords: pneumoconiosis; black lung; conflict of interest; workers' compensation; bioethics

(Received in original form October 30, 2020; accepted in final form March 29, 2021)

Author Contributions: All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. L.S.F. and K.S.A. had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. L.S.F was involved in the conception and design, acquisition of data, analysis and interpretation of the data, drafting of the article, and statistical expertise. S.D. was involved with the analysis of the data and drafting of the article. K.S.A. was involved in the acquisition of data, conception and design, analysis and interpretation of the data, drafting of the article, and statistical expertise. R.A.C. was involved in the conception and design, interpretation of the data, and drafting of the manuscript.

Correspondence and requests for reprints should be addressed to Lee S. Friedman, Ph.D., Environmental and Occupational Health Sciences, School of Public Health, University of Illinois Chicago, 1603 W. Taylor Street, Chicago, IL 60612. E-mail: lfried1@uic.edu.

This article has a related editorial.

This article has an online supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

Ann Am Thorac Soc Vol 18, No 10, pp 1634–1641, Oct 2021

DOI: 10.1513/AnnalsATS.202010-1350OC
Internet address: www.atsjournals.org

The U.S. Department of Labor (USDOL) administers the Federal Black Lung Program (FBLP) (also referred to as the Division of Coal Mine Workers' Compensation), an administrative system charged with managing claims for the compensation for disabling coal mine dust lung disease. A chest X-ray (CXR) is a key element in determining an individual's eligibility for benefits. To standardize the classifications of CXRs and improve interrater reliability between physicians (1, 2), the USDOL requires all physicians to use the International Labor Office (ILO) guidelines for assessing CXRs for pneumoconiosis (3). The ILO guidelines involve the recording of the location, opacity type, size, and profusion of parenchymal and pleural changes. The ILO classification guidelines are analogous to the American Medical Association guides or the Social Security Disability Insurance guides used to assess impairment in a uniform manner. Furthermore, the National Institute for Occupational Safety and Health (NIOSH) established a program to train, certify, and improve reliability across physicians who classify CXRs, who are called B-readers. The B-readers are licensed physicians certified in using the ILO system to classify radiographs for pneumoconiosis caused by mineral dust exposure. B-readers must successfully pass an examination offered by NIOSH and are required to be recertified every 5 years. Typically, there are approximately 200 B-readers in the United States.

Physicians play an integral role in the claim process and charge $60–$750 per classification. ILO classifications take approximately 5–10 minutes to complete, with some physicians reading hundreds of CXRs each year. Because of the lucrative and adversarial nature of the process, there is concern that financial conflicts of interest (COIs) may bias some B-readers' decision-making for classifications (4, 5). Although there is no broad consensus for any single definition of a financial COI, a practical approach is to define a financial COI as a condition, not a behavior, in which the circumstances and not the outcomes determine the presence of COI (6, 7). Under this definition, physicians who might benefit financially from their work have a COI regardless of whether this status actually impacts their decision-making. However, financial relationships in and of themselves are not detrimental. Without the professional expertise of physicians, it would be difficult to provide the evaluations required by the Black Lung Benefits Act.

To date, the relationship between financial COIs and the diagnosis of pneumoconiosis has been limited to news reports, anecdotal evidence, and case reports (4, 5, 8, 9). Furthermore, there are no analytic studies evaluating financial COI as it relates to the workers' compensation system in general. Although sporadic anecdotal evidence is informative, it does not provide empirical evidence on whether these relationships are pervasive or associated with a specific classification of black lung disease. The specific aims of this study are to *1*) describe the physicians' characteristics in relation to the parties hiring them (miner, employer, and USDOL), *2*) characterize ILO CXR classifications of individual cases, and *3*) evaluate the direction and magnitude of association between financial COIs and ILO CXR classifications of pneumoconiosis.

Methods

USDOL Coal Mine Workers' Compensation Dataset

Any physician who desires to perform examinations for the FBLP applies to become an authorized provider. The USDOL reviews the physician's credentials and, if the physician is appropriately qualified, they are added to the list of approved examining providers. To initiate an FBLP benefits claim, the miner submits a request to the USDOL and then selects an approved provider within their residential geographic region for a complete pulmonary examination. The clinic that conducts the USDOL pulmonary examination then selects a NIOSH approved B-reader to conduct the initial radiograph classification. The miner and employer can request a reclassification of the initial CXR by alternative B-readers. Consequently, a single claim may contain multiple ILO classifications for the same CXR. We obtained all 110,304 ILO classifications of CXRs submitted to the FBLP between January 1, 2000, and December 31, 2013 (10), which included the initial and subsequent classifications. Records that only assessed image quality rather than the presence of pneumoconiosis were excluded (N = 30,065). An additional 7,958 records were excluded because the ILO classification of opacities was incomplete or missing. We manually cleaned the physicians' names for the remaining 72,281 records. We deleted 6,312 more records because the physician's name was missing entirely, the first name was abbreviated and there were two or more physicians with the same last name and first initial, the family name was misspelled, or the name did not match any recognized physician in the National Provider Identifier (NPI) database or NIOSH list of B-readers.

Identifying Information for B-Readers Involved in the Black Lung Program

For all the physicians in the final dataset, we gathered information on their degree (M.D., D.O., or a United States equivalent degree if the physician trained internationally), licensing states, whether the license was still active, NPI and state license numbers, medical school, residency program, specialization, years in practice, and history of medical malpractice suits and other legal settlements. Physicians' information was verified using the NIOSH B-reader lists (11), the NPI database (12), and state licensing board websites.

Method for Identifying Financial Relationships with USDOL, Miner, and Employer

We downloaded all 7,656 published and unpublished court decisions from 2002 to 2019 that were publicly available on the USDOL website (13). Two raters (L.F. and S.D.) searched the court records to evaluate whether a physician was hired by USDOL, the claimant (miner), or the respondent (employer) or whether it was unclear. We searched a maximum of 20 records per physician. If the search produced $\geqslant$20 records, we divided the total number of records by 20 and searched in a regular skip pattern so that we searched a total of 20 records. For every court record in which the affiliation was determined to be unclear, we reviewed a new record that referred to the physician. The κ for the interrater agreement between the two raters was 0.78 (95% confidence interval [CI], 0.70–0.87).

In addition, we requested five experts involved in the FBLP process (one physician, three lawyers hired by miners, and one lawyer hired by employers) to identify affiliations of the B-readers in the USDOL dataset. Each external expert was asked to identify whether the physician was hired by USDOL, the claimant (miner), or the respondent (employer) or whether it was unclear. The raters could select more than one category. The external raters provided information on 83 physicians who completed 57,205 ILO classifications (89.7% of final records used). The κ for the interrater agreement between the principal author (L.F.) and the combined expert evaluations was 0.86 (95% CI, 0.74–0.97). Of the 65,969 remaining

classifications, we removed another 1,874 classifications because financial COI information was unavailable for these physicians in the court records, and the external raters were unfamiliar with them.

Statistical Analysis

For the descriptive analysis, we described ILO classifications, physician characteristics, and financial affiliations on the basis of the primary rater's (L.F.) abstraction of court records. The following categories for financial affiliations based on court records were used for the tables: *1*) hired by the employer in the majority of cases (if 50.1% or more of court records indicated that the physician was hired by the employer), *2*) hired by the employer in the plurality of cases (if the largest proportion of court records indicated that the physician was hired by the employer), *3*) hired by the USDOL in the majority of cases (≥50.1% hired by USDOL), *4*) hired by the miner in the plurality of cases (the largest proportion of court records hired by the claimant's legal team), *5*) hired by the miner in the majority of cases (≥50.1% hired by the claimant's legal team), and *6*) unclear affiliation (<5% difference in proportions between the separate parties). If the party hiring a physician could not be ascertained through the court records, we used the affiliations reported by the external experts if two or more of the experts provided feedback on a specific physician (n = 16 B-readers, involving 319 classifications).

The dataset also had a unique identification code for each claim associated with a miner that was used to assess disagreement between physicians on ILO classifications for pneumoconiosis. In addition, because nearly all of the B-readers were hired by the USDOL and the first classification in a series for a claimant using the case identification number represents the classification contracted by the USDOL, we compared the differences in classification patterns between physicians hired by USDOL and physicians hired by one of the other parties.

To evaluate the directionality of the association, we used logistic regression models to evaluate the following three different binary outcome variables: negative for pneumoconiosis (small opacities with an ILO classification of 0/0 or 0/1), simple pneumoconiosis (small opacities with ILO classifications of 1/0 through 3/+ and no large opacities), and progressive massive fibrosis (PMF) (also referred to as complicated pneumoconiosis; large opacities with ILO classifications of A, B, or C). For the first model, we evaluated the hypothesis that the odds of classifying a radiograph as negative for opacities increases with the percentage of court cases for which a physician was hired by the employer and/or mine operator, which ranged from 0 to 100 (continuous). For the next two models, we evaluated the hypothesis that the odds of classifying a radiograph with simple pneumoconiosis or PMF increases with the percentage of court cases a physician was hired for by the miner and/or claimant, which ranged from 0 to 100 (continuous). The odds ratios reflect the change in odds per 10% increase in the proportion of court records and/or expert ratings for which a physician was affiliated with a specific party (claimant or respondent).

The statistical evaluation of covariates, as well as *a priori* knowledge, was used to determine the inclusion of covariates in the final models. We evaluated the inclusion of the state of primary practice, medical specialty, years in practice at the time of classification, U.S. medical school training, and reported medical malpractice claims or other suits. We also included the year of classification to control for overall trend and account for changes in physician training, mining methods, and workplace exposures. A two-sided P value of less than 0.05 was considered

Table 1. Characteristics of the physicians who participate in the U.S. Federal Black Lung Program by their financial affiliations from 2000 to 2013

	All Physicians Combined	Hired by Employer/ Respondent in Majority of Cases	Hired by Employer/ Respondent in Plurality of Cases	Hired by USDOL/ Director in Majority of Cases	Hired by Miner/ Claimant in Plurality of Cases	Hired by Miner/ Claimant in Majority of Cases	Unclear Affiliation
Number of physicians	264	56	13	106	32	47	10
Determination of financial affiliation, %	100	21.2	4.9	40.2	12.1	17.8	3.8
Both court and external rater, *n* (%)	71 (26.9)	32 (57.1)	2 (15.4)	16 (15.1)	8 (25.0)	11 (23.4)	2 (20.0)
Court records only	184 (69.7)	22 (39.3)	9 (69.2)	89 (84.0)	23 (71.9)	35 (74.5)	6 (60.0)
External rater only	9 (3.4)	2 (3.6)	2 (15.4)	1 (0.9)	1 (3.1)	1 (2.1)	2 (20.0)
Years in practice at time of medical determination, mean (SD)	31.3 (11.8)	34.6 (11.9)	25.3 (10.3)	32.1 (12.0)	26.7 (9.2)	26.5 (9.2)	25.8 (14.3)
Completed medical school in the United States, *n* (%)	184 (69.7)	49 (87.5)	12 (92.3)	67 (63.2)	23 (71.9)	26 (55.3)	7 (70.0)
Specialization,* *n* (%)							
Radiology	131 (49.6)	27 (48.2)	8 (61.5)	47 (44.3)	21 (65.6)	22 (46.8)	6 (60.0)
Internal medicine	83 (31.4)	23 (41.1)	3 (23.1)	31 (29.2)	9 (28.1)	16 (34.0)	1 (10.0)
Pulmonary medicine	82 (31.1)	21 (37.5)	3 (23.1)	35 (33.0)	9 (28.1)	14 (29.8)	0 (0.0)
Occupational medicine	8 (3.0)	4 (7.1)	1 (7.7)	1 (0.9)	1 (3.1)	1 (2.1)	0 (0.0)
Other	17 (6.4)	1 (1.8)	1 (7.7)	13 (12.3)	1 (3.1)	1 (2.1)	0 (0.0)
Medical malpractice suits and other legal settlements, *n* (%)	27 (10.2)	6 (10.7)	2 (15.4)	10 (9.4)	1 (3.1)	6 (12.8)	2 (20.0)

Definition of abbreviations: SD = standard deviation; USDOL = U.S. Department of Labor.
*Many physicians had multiple specializations. Numbers exceed column totals.

Table 2. Profusion of opacities by financial affiliations of physicians performing International Labor Office classifications of chest radiographs in the U.S. Federal Black Lung Program from 2000 to 2013

	Total Classifications (*N* = 63,780)	Hired by Employer/ Respondent in Majority of Cases (*n* = 18,403)	Hired by Employer/ Respondent in Plurality of Cases (*n* = 3,393)	Hired by USDOL/ Director in Majority of Cases (*n* = 28,753)	Hired by Miner/ Claimant in Plurality of Cases (*n* = 5,973)	Hired by Miner/ Claimant in Majority of Cases (*n* = 6,284)	Unclear Affiliation (*n* = 974)
Negative for pneumoconiosis, *n* (%)	41,453 (65.0)	17,048 (92.6)	2,659 (78.4)	16,822 (58.5)	2,682 (44.9)	1,558 (24.8)	684 (70.2)
Simple pneumoconiosis,* *n* (%)	20,051 (31.4)	1,156 (6.3)	661 (19.5)	10,757 (37.4)	3,008 (50.4)	4,223 (67.2)	246 (25.3)
1/0 to 1/2	17,196 (27.0)	798 (4.3)	577 (17.0)	9,402 (32.7)	2,708 (45.3)	3,506 (55.8)	205 (21.0)
2/1 to 2/3	2,560 (4.0)	308 (1.7)	78 (2.3)	1,202 (4.2)	267 (4.5)	667 (10.6)	38 (3.9)
3/2 to 3/+	295 (0.5)	50 (0.3)	6 (0.2)	153 (0.5)	33 (0.6)	50 (0.8)	3 (0.3)
Progressive massive fibrosis,† *n* (%)	2,276 (3.6)	199 (1.1)	73 (2.2)	1,174 (4.1)	283 (4.7)	503 (8.0)	44 (4.5)

Definition of abbreviation: USDOL = U.S. Department of Labor.
*Simple pneumoconiosis cases with small opacity profusion categories 1/0 to 3/+. This does not include those with classification for large opacities (progressive massive fibrosis).
†Progressive massive fibrosis includes the classification of large opacities (A, B, and C).

statistically significant. The c-statistic was used as a diagnostic measure to assess the predictive model fit. On the basis of the unadjusted models, we presented the predicted probability of an ILO classification for the absence of pneumoconiosis per percentage change in the proportion of court cases for which the physician was hired by either the employer, miner, or USDOL. SAS 9.4 (SAS Institute) was used for all statistical analyses.

Results

A total of 63,780 ILO classifications made by 264 physicians were included in the final dataset. All of the physicians in the final dataset were B-readers. The B-readers provided an average of 241.6 ILO classifications of pneumoconiosis each, with 20% of the B-readers (*n* = 53) reading 87.7% of the CXRs in the USDOL dataset (*n* = 55,960). Almost half of all the CXRs were read by 10 B-readers (*n* = 29,531; 46.3%); 6 of the 10 B-readers were predominately hired by the USDOL.

Physician Affiliations with the USDOL, Employers, and Miners

Table 1 presents the characteristics of the B-readers included in the analysis. The physicians were predominately identified as having M.D.s (96.2%) as opposed to D.O.s, were licensed in states near the Appalachian and Illinois coal basins (*n* = 173; 65.5%), and specialized in radiology and pulmonology.

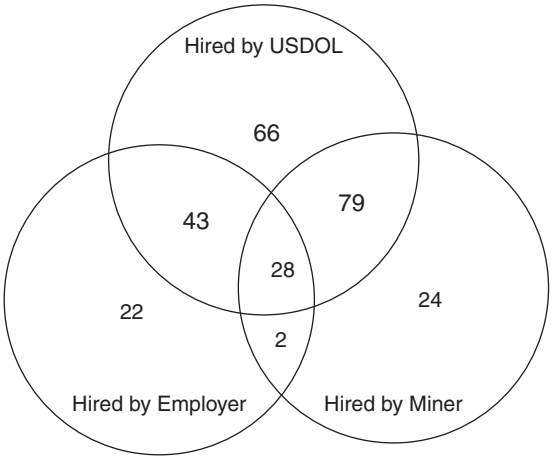

Figure 1. Distribution of physicians by the party hiring them for International Labor Office classifications of chest radiographs in the U.S. Federal Black Lung Program from 2000 to 2013. USDOL = U.S. Department of Labor.

Figure 1 shows the affiliations of the physicians included in the final dataset. Based on the court records, nearly all B-readers at some time were hired to provide medical assessments by the USDOL (*n* = 216 B-readers; 81.8%).

Financial Affiliations and ILO Classifications

Table 2 presents the distribution of ILO classifications made by B-readers based on their financial affiliations. Overall, 31.4% of records were read as positive for simple pneumoconiosis, and 3.6% were read as positive for PMF. There is a clear association between affiliation with a specific party and the proportion of classifications for an absence of opacities, simple pneumoconiosis, and PMF (Table 2). B-readers who were identified as having ever been hired by an employer read the CXRs as negative for pneumoconiosis in 84.8% of the records (*n* = 27,780/32,744) compared with 51.3% (*n* = 18,941/36,898) among B-readers who were identified as having ever been hired by a miner. B-readers who were exclusively hired by the USDOL read the radiographs as negative for pneumoconiosis in 63.2% of the records (*n* = 4,125/6,532).

Sixty-four B-readers classified an absence of pneumoconiosis in 95% of their classifications (*n* = 10,505 classifications), with 9,805 (93.3%) of these classifications made by B-readers who were hired by the employer a majority of the time. The majority of these B-readers (*n* = 51) classified CXRs as negative for pneumoconiosis in 99%+ of their classifications (3,424 classifications). In

Table 3. Association between the percentage of records hired by employer/respondent and miner/claimant with the final International Labor Office classifications of chest radiographs for pneumoconiosis in U.S. Federal Black Lung Program from 2000 to 2013

Outcome variable	Independent Variable	Unadjusted Odds Ratio*	Adjusted Odds Ratio*	c-Statistic Adjusted Model
Primary rater†				
No opacities	Per 10% increase in records indicating physician hired by employer/respondent‡	1.48 (1.46–1.49)	1.46 (1.44–1.47)	0.771
Simple pneumoconiosis	Per 10% increase in records indicating physician hired by miner/claimant§	1.46 (1.45–1.47)	1.51 (1.49–1.52)	0.759
Progressive massive fibrosis	Per 10% increase in records indicating physician hired by miner/claimant‖	1.26 (1.24–1.28)	1.28 (1.26–1.30)	0.701
Second rater†				
No opacities	Per 10% increase in records indicating physician hired by employer/respondent‡	1.46 (1.45–1.47)	1.46 (1.44–1.47)	0.772
Simple pneumoconiosis	Per 10% increase in records indicating physician hired by miner/claimant§	1.54 (1.53–1.56)	1.53 (1.52–1.55)	0.784
Progressive massive fibrosis	Per 10% increase in records indicating physician hired by miner/claimant‖	1.26 (1.24–1.28)	1.29 (1.26–1.31)	0.696
External experts†				
No opacities	Per 10% increase in records indicating physician hired by employer/respondent‡	1.31 (1.30–1.32)	1.33 (1.33–1.34)	0.817
Simple pneumoconiosis	Per 10% increase in records indicating physician hired by miner/claimant§	1.41 (1.40–1.42)	1.40 (1.39–1.41)	0.807
Progressive massive fibrosis	Per 10% increase in records indicating physician hired by miner/claimant‖	1.20 (1.18–1.22)	1.19 (1.18–1.21)	0.698

*Odds ratios reflect a change in odds per 10% change in the proportion of court records/expert ratings that physician was affiliated with a specific party (claimant or respondent); all *P* values were <0.01 for the adjusted odds ratios for the independent variables presented in the table.
†Primary rater's (L.S.F.) evaluation of court records was used for the primary set of models. Evaluations from the secondary rater (S.D.) and the group of five external experts were used to confirm the reliability of the initial set of model estimates.
‡Covariates in the full adjusted model included year of chest X-ray classification; years in practice at the time of classification; training in a U.S. medical school; medical specialty of diagnostic radiology, occupational medicine, or other specialties (pulmonology as the reference group); having an M.D. (vs. D.O.) degree; and primary licensing state of Ohio.
§Covariates in the full adjusted model included the year of chest X-ray classification; years in practice at the time of classification; training in a U.S. medical school; medical specialty of pulmonology; and primary licensing state of Kentucky and Pennsylvania.
‖Covariates in the full adjusted model included the year of chest X-ray classification; training in a U.S. medical school; medical specialty of pulmonology; and primary licensing state of Kentucky.

contrast, 23 B-readers diagnosed simple pneumoconiosis in 95% of their classifications (n = 2,414 classifications), with 530 (22.0%) of these classifications made by B-readers who were hired by the claimant miner the majority of the time; 18 of these B-readers diagnosed simple pneumoconiosis in 99%+ of their classifications (410 classifications). Court records identified 30 B-readers as having been hired by both the employer and miner (n = 12,690 classifications; n = 9,532 negative for pneumoconiosis).

We observed that, among the B-readers ever hired by the employer, when their classification was the first one in the series for a claimant (the classification contracted by the USDOL), the B-reader classified an absence of pneumoconiosis in 77.2% of cases compared with 90.2% of subsequent classifications (i.e., classification not contracted by the USDOL). In contrast, among the B-readers ever hired by the miner, when the classification was the first one in the series for a claimant, they classified an absence of pneumoconiosis in 52.3% of cases compared with 48.4% of subsequent classifications.

Description of Filings Seeking ILO Classification of Black Lung Compensation

The 63,780 classifications included in the analysis involved 37,530 miners. Among the cases that had two or more classifications, there was an average of 2.9 classifications per miner. There was disagreement across 25,315 classifications involving 7,784 miners (Table E1 in the online supplement). In 1,713 classifications, B-readers disagreed on whether the classification was negative for pneumoconiosis versus high-profusion simple pneumoconiosis (2/1 to 3/+); there were an additional 2,210 classifications in which the B-readers disagreed on whether the CXR was negative for pneumoconiosis or demonstrated PMF. In cases in which there was disagreement between the absence or presence of pneumoconiosis, classifications submitted by B-readers primarily hired by employers outnumbered those submitted by B-readers primarily hired by miners by twofold to fourfold.

Multivariable Models

Table 3 shows that the odds of a classification finding no pneumoconiosis increases substantially per 10% change in the proportion of court records and expert ratings indicating that a B-reader was hired by the employer (Figure 2). In addition, the odds of a classification finding the presence of simple

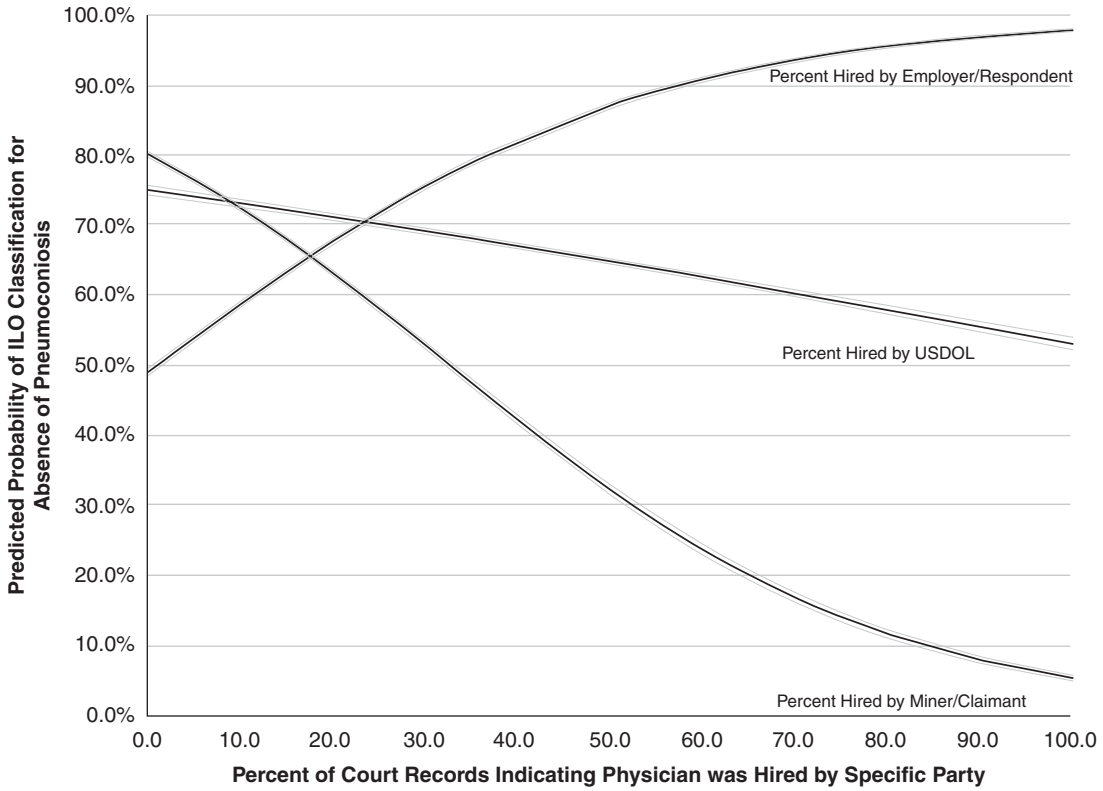

Figure 2. Relationship between the classification for the absence of pneumoconiosis and the percentage of court records indicating a physician was hired by a specific party—employer/respondent, miner/claimant, or USDOL. Bounds around predicted probability regression lines represent 95% confidence intervals. ILO = International Labor Office; USDOL = U.S. Department of Labor.

pneumoconiosis and PMF increased per 10% change in the proportion of court records and expert ratings indicating that a B-reader was hired by the claimant (Table 3). Separate odds ratios are presented for the primary rater (L.F.), the secondary rater (S.D.), and the combined five external experts. Consistent with the high interrater reliability (*see* METHODS), all three sets of models present similar odds ratios.

Discussion

The extent to which a physician works for a specific party in the FBLP legal process can readily predict the direction of their ILO classification for the absence, presence, and severity of pneumoconiosis. Although the radiograph data ended in 2013, nearly all the physicians are still classifying radiographs today, and many of these cases are still pending. Although there was a strong association between the direction of ILO classifications and the financial affiliation of B-readers with both parties, when looking only at B-readers who read almost exclusively in one direction (99% of cases), there were three times more B-readers providing eight times more classifications among those affiliated with employers compared with those affiliated with miners. Furthermore, nearly 20% of all the classifications in the dataset were submitted by physicians who classified 95% of their cases in a specific direction ($n = 12{,}919$, of which 10,505 were classified as negative). In contrast, B-readers hired the majority of the time or exclusively by the USDOL submitted classifications that were equivalent to the overall average observed across all the B-readers.

An investigative report in 2013 (4) identified several hundred cases of disagreement between B-readers, which led to rule changes affecting the FBLP. Our study provides the first systematic description of disagreement between B-readers, and we identified thousands of cases, not hundreds, in which a B-reader reported an absence of pneumoconiosis in contrast with another B-reader who indicated high-profusion simple pneumoconiosis (2/1 to 3/+) or PMF. We also found that the number of classifications submitted by B-readers primarily hired by employers outnumbered classifications submitted by those primarily hired by miners by twofold to fourfold, which could impact the weight of evidence during the court proceedings.

Given the clear association between classifications and financial COIs, a lack of consistency in classifications within and between B-readers (1, 2, 14–20), and an absence of an objective gold standard for CXR classifications of pneumoconiosis, substantial improvements in transparency, oversight, and objectivity in the classifications of CXRs for black lung claims are clearly needed. To improve objectivity in classifications, each party should be required to submit requests for reclassification of radiographs by the physicians of their choice to the USDOL. All initial contact and payments should be made by the USDOL, and the other parties should be prohibited from communicating on a claim until the initial classifications are submitted, limiting coordination between the reader and requester (21). The USDOL would then have the capability of adding quality control images to assess accuracy and bias in classifications annually.

Another reform to improve oversight would be to build on NIOSH's proposed rule change to decertify B-readers who demonstrate "unreasonably inaccurate classifications" (22). NIOSH's rule change seeks to set up an investigative system to respond to complaints filed by any party. One simple addition would be to regularly analyze the dataset of classifications used for this analysis and make it publicly available because they are part of the court record, which would provide timely, proactive, and comprehensive information on historical classification patterns.

To improve transparency, COI practices implemented over the last two decades by the U.S. federal government for healthcare providers involved with medical manufacturers, distributors, and wholesalers can serve as a good model (23–25). B-readers should be required to report their total annual revenue from CXR classifications and expert testimonies or any other income generated from parties involved in the legal proceedings. These data should be made publicly available, similar to other reporting systems (23). In addition, to end the disparity in payments to B-readers who are hired by employers, B-readers should be paid a flat fee for CXR classifications, similar to fee schedules used in state workers' compensation systems.

Finally, as used in the Coal Workers Health Surveillance Program, instituting an independent expert panel of B-readers may resolve disagreement between physicians. However, panels typically comprise appointees representing different constituencies. Panels frequently experience enormous political pressures, gridlock caused by split decisions, recurring vacancies that impact the minimum quorum needed, and can be intentionally understaffed to produce the desired outcome of the administration in power (26–29). In addition, investment in new imaging technology combined with artificial intelligence algorithms to classify images may help in developing an objective standard for classifications, but it may not address disagreements regarding the cause of radiographic findings.

Limitations

There are several limitations to this analysis. First, some classifications may not have been submitted by one of the parties and therefore would not appear in the dataset. The USDOL noted that legal teams, in particular those hired by employers, may withhold classifications deemed unfavorable to their legal case (21). Although the total of unreported classifications is unknown, the USDOL was sufficiently concerned that they passed a rule in 2017 requiring disclosure of all solicited medical evidence (21). Second, misclassification of B-readers may have occurred because the evaluation of financial affiliations based on court records alone may not capture all financial relationships. Remuneration for consulting, employment, stock ownership, honoraria, grants, and other types is not considered in this analysis. Third, rather than financial COIs impacting physicians' medical opinions, the observed association may correspond with lawyers hiring physicians who they believe will provide preferable classifications or miners seeking clinics for the initial examination that are suspected of providing favorable classifications. However, our findings demonstrate that B-readers who have ever been hired by employers were substantially more likely to classify an absence of pneumoconiosis on classifications not part of the initial examination compared with initial classifications paid for by the USDOL (90.2% vs. 77.2%). In contrast, we did not observe substantial differences in classifications among those B-readers who had ever been hired by the miner (subsequent vs. initial USDOL classifications; 48.4% vs. 52.3%).

Conclusions

Though financial COI does not necessarily result in biased behavior, it can be a strong catalyst for it (30, 31). This analysis demonstrates the need to reduce subjectivity in the classification of CXRs for black lung disease. Today's system of oversite is ineffective at monitoring and regulating the role of physicians in this important compensation program that affects thousands of former and current miners. However, the FBLP program is just a microcosm of the larger workers' compensation system, and preliminary evidence indicates that the association noted in our study likely pervades this larger system. Research has demonstrated an association between financial relationships and adverse clinical decision-making (31–33), quality of care (32–34), and clinical outcomes, including return to work (35), as have studies demonstrated racial disparities in diagnoses, referrals, and disability ratings for work-related conditions (36, 37). However, there remains a need for empirical analyses specific to the workers' compensation system, which is wholly lacking. All parties involved deserve a compensation system that is objective and expeditious. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

References

1 Felson B, Morgan WK, Bristol LJ, Pendergrass EP, Dessen EL, Linton OW, *et al.* Observations on the results of multiple readings of chest films in coal miners' pneumoconiosis. *Radiology* 1973;109:19–23.
2 Halldin CN, Blackley DJ, Petsonk EL, Laney AS. Pneumoconioses radiographs in a large population of U.S. coal workers: variability in A reader and B reader classifications by using the International Labour Office classification. *Radiology* 2017;284:870–876.
3 International Labor Office. Guidelines for the use of the ILO international classification of radiographs of pneumoconioses. Geneva, Switzerland: International Labor Office; 2011.
4 Hamby C; The Center for Public Integrity. Breathless and burdened (3-part series). Washington, DC: The Center for Public Integrity; 2013 [accessed 2020 May 29]. Available from: https://publicintegrity.org/topics/environment/breathless-and-burdened/.
5 Fisher D. Embattled gasket maker sues asbestos lawyers for fraud. New York, NY: Forbes; 2014 [accessed 2020 May 29]. Available from: https://www.forbes.com/sites/danielfisher/2014/01/10/embattled-gasket-maker-sues-asbestos-lawyers-for-fraud/#4cb252231cad.
6 Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993;329:573–576.
7 Friedman L, Friedman M. Financial conflicts of interest and study results in environmental and occupational health research. *J Occup Environ Med* 2016;58:238–247.
8 Hardell L, Walker MJ, Walhjalt B, Friedman LS, Richter ED. Secret ties to industry and conflicting interests in cancer research. *Am J Ind Med* 2007; 50:227–233.
9 Baur X, Budnik LT, Ruff K, Egilman DS, Lemen RA, Soskolne CL. Ethics, morality, and conflicting interests: how questionable professional integrity in some scientists supports global corporate influence in public health. *Int J Occup Environ Health* 2015;21:172–175.
10 Graber JM, Harris G, Almberg KS, Rose CS, Petsonk EL, Cohen RA. Increasing severity of pneumoconiosis among younger former US coal miners working exclusively under modern dust-control regulations. *J Occup Environ Med* 2017;59:e105–e111.

11 National Institute for Occupational Safety and Health. Chest radiography: the NIOSH B Reader Program. Atlanta, GA: Centers for Disease Control and Prevention; 2020 [accessed 2020 May 30]. Available from: https://www.cdc.gov/niosh/topics/chestradiography/breader.html.

12 Centers for Medicare and Medicaid Services. National Plan and Provider Enumeration System, National Provider Identifier Registry. Baltimore, MD: Centers for Medicare and Medicaid Services [accessed 2020 May 30]. Available from: https://npiregistry.cms.hhs.gov/registry/.

13 U.S. Department of Labor. Benefits Review Board, Board Decisions: published and unpublished black lung cases. Washington, DC; U.S. Department of Labor [accessed 2020 May 30]. Available from: https://www.dol.gov/agencies/brb/decisions.

14 Lawson CC, LeMasters MK, Kawas Lemasters G, Simpson Reutman S, Rice CH, Lockey JE. Reliability and validity of chest radiograph surveillance programs. *Chest* 2001;120:64–68.

15 Gitlin JN, Cook LL, Linton OW, Garrett-Mayer E. Comparison of "B" readers' interpretations of chest radiographs for asbestos related changes. *Acad Radiol* 2004;11:843–856.

16 Muller JG, Lieske JM, Hernandez JE, Kubiak G, Rudolph WG, Jan MH. Variability in interpretation among B-readers in the U.S. Navy asbestos medical surveillance program. *Mil Med* 2008;173:375–380.

17 Sen A, Lee SY, Gillespie BW, Kazerooni EA, Goodsitt MM, Rosenman KD, *et al.* Comparing film and digital radiographs for reliability of pneumoconiosis classifications: a modeling approach. *Acad Radiol* 2010;17:511–519.

18 Laney AS, Petsonk EL, Attfield MD. Intramodality and intermodality comparisons of storage phosphor computed radiography and conventional film-screen radiography in the recognition of small pneumoconiotic opacities. *Chest* 2011;140:1574–1580.

19 Larson TC, Holiday DB, Antao VC, Thomas J, Pinheiro G, Kapil V, *et al.* Comparison of digital with film radiographs for the classification of pneumoconiotic pleural abnormalities. *Acad Radiol* 2012;19:131–140.

20 Halldin CN, Petsonk EL, Laney AS. Validation of the international labour office digitized standard images for recognition and classification of radiographs of pneumoconiosis. *Acad Radiol* 2014;21:305–311.

21 U.S. Federal Register; Office of Workers' Compensation Programs, Labor. Black Lung Benefits Act: disclosure of medical evidence and payment of benefits; technical amendment. Washington, DC: U.S. Federal Register; 2016 [accessed 2020 Jul 20]. Available from: https://www.federalregister.gov/documents/2016/05/20/2016–11840/black-lung-benefits-act-disclosure-of-medical-evidence-and-payment-of-benefits-technical-amendment.

22 Department of Health and Human Services; Centers for Disease Control and Prevention. National Institute of Occupational Safety and Health: notice of proposed rulemaking. Washington, DC: U.S. Federal Register; 2020 [accessed 2020 Jun 3]. Available from: https://www.federalregister.gov/documents/2020/02/14/2020–02705/coal-workers-health-surveillance-program-b-reader-decertification-and-autopsy-payment.

23 Centers for Medicare and Medicaid Services. Open payments. Baltimore, MD: Centers for Medicare and Medicaid Services [updated 2021 Mar 4; accessed 2020 Jun 3]. Available from: https://www.cms.gov/OpenPayments.

24 U.S. Congress. Patient Protection and Affordable Care Act; Public Law No. 111–148. Washington, DC: U.S. Government Publishing Office; 2010 [accessed 2020 Jun 3]. Available from: https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

25 U.S. Congress. Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the "SUPPORT for Patients and Communities Act" (Public Law No. 115–271). Washington, DC: U.S. Government Publishing Office; 2018 [accessed 2020 Jun 3]. Available from: https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf.

26 U.S. House of Representatives. Committee on education and the workforce report: Occupational Safety and Health Review Commission Efficiency Act of 2004. Washington, DC: U.S. Government Publishing Office; 2004 [accessed 2021 Feb 23]. Available from: https://www.govinfo.gov/content/pkg/CRPT-108hrpt486/html/CRPT-108hrpt486.htm.

27 U.S. General Accounting Office. Federal advisory committees: additional guidance could help agencies better ensure independence and balance. Washington, DC: US General Accounting Office; 2004 [accessed 2021 Feb 23]. Available from: https://www.gao.gov/products/gao-04-328.

28 Hill C, Painter R. Compromised fiduciaries: conflicts of interest in government and business. *Minn Law Rev* 2011;95:1637–1691.

29 Morera AF, Morris J; The Center for Public Integrity. Network of 900 advisory panels wields unseen power. Washington, DC: Center for Public Integrity; 2007 [accessed 2021 Feb 23]. Available from: https://publicintegrity.org/politics/white-house/shadow-government/network-of-900-advisory-panels-wields-unseen-power/.

30 Friedman LS, Richter ED. Relationship between conflicts of interest and research results. *J Gen Intern Med* 2004;19:51–56.

31 Association of American Medical Colleges, Task Force on Financial Conflicts of Interest in Clinical Care. In the interest of patients: recommendations for physician financial relationships and clinical decision making. Washington, DC: Association of American Medical Colleges; 2010 [accessed 2020 Jun 3]. Available from: https://www.aamc.org/data-reports/faculty-institutions/report/interest-patients-recommendations-physician-financial-relationships-and-clinical-decision-making.

32 Pourat N, Kominski G, Roby D, Cameron M. Physician perceptions of access to quality care in California's workers' compensation system. *J Occup Environ Med* 2007;49:618–625.

33 Lo B, Field MJ. Conflict of interest in medical research, education, and practice. Washington, DC: National Academies Press; 2009.

34 Kilgour E, Kosny A, McKenzie D, Collie A. Healing or harming? Healthcare provider interactions with injured workers and insurers in workers' compensation systems. *J Occup Rehabil* 2015;25:220–239.

35 Franklin GM, Wickizer TM, Coe NB, Fulton-Kehoe D. Workers' compensation: poor quality health care and the growing disability problem in the United States. *Am J Ind Med* 2015;58:245–251.

36 Chibnall JT, Tait RC. Disparities in occupational low back injuries: predicting pain-related disability from satisfaction with case management in African Americans and Caucasians. *Pain Med* 2005;6:39–48.

37 Tait RC, Chibnall JT, Andresen EM, Hadler NM. Disability determination: validity with occupational low back pain. *J Pain* 2006;7:951–957.