



# **Comments on Lowering Miners' Exposure to Respirable Coal Mine Dust: Health Effects**

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## **Health Research Experience: Dr. Kelsh**

- Epidemiologist—over 25 years experience in occupational and environmental health research
- Principal Scientist at Exponent, a scientific and engineering consulting company
- Former Adjunct Professor at UCLA School of Public Health (1999–2008)
  - Taught courses in occupational and environmental health
- Participated in a number of epidemiologic studies that encompass a wide range of occupational groups (including miners) and environmental exposures

## Disclosure

- Dr. Kelsh and Dr. Doemland were asked to independently review available health studies and NIOSH publications related to coal-miner health studies
- Exponent received funding from Murray Energy Corporation to conduct an independent review of the health, exposure, and economic data, and methods used for risk assessment in the proposed MSHA Coal Dust Standard
- The opinions and comments presented herein reflect the independent scientific assessment of Drs. Kelsh and Doemland, not necessarily that of Murray Energy

## Epidemiology and Policy

- Numerous epidemiologic studies have examined respiratory diseases [CWP, PMF, COPD (bronchitis and emphysema)] and coal-mine dust exposures
- Understanding what epidemiologic data tell us for workers exposed to the current 2-mg/m<sup>3</sup> standard is critical to develop effective health and safety programs
- Assumptions regarding CWP and PMF prevalence, study limitations, and generalizability of surveillance data require further evaluation and careful consideration

## Discussion Points

- Discuss the design and limitations of the U.S. Coal Workers Health Surveillance Programs
- Highlight recent findings from surveillance programs
- Review the cross-sectional study design
- Provide questions on:
  - Design and analysis of surveillance programs
  - The reported increase in CWP and PMF in U.S.
- Highlight the need for:
  - More transparency in presentation of coal miner health data
  - More complete analyses (e.g., sensitivity analyses)
  - Acknowledgement of study limitations
  - More research to design a better standard

## **NIOSH Research and Monitoring Programs**

- Programs established to study and monitor coal-miner health as part of regulatory mandate and Congressional directives:
  - The National Study of Coal Workers Pneumoconiosis (1969–1988)
  - The Coal Workers X-Ray Surveillance Program (1970–present)
  - The Miners' Choice Program (1999–2002)
  - The Enhanced Coal Workers Health Surveillance Program (2006–present)
- Despite the extensive body of data, many questions not addressed

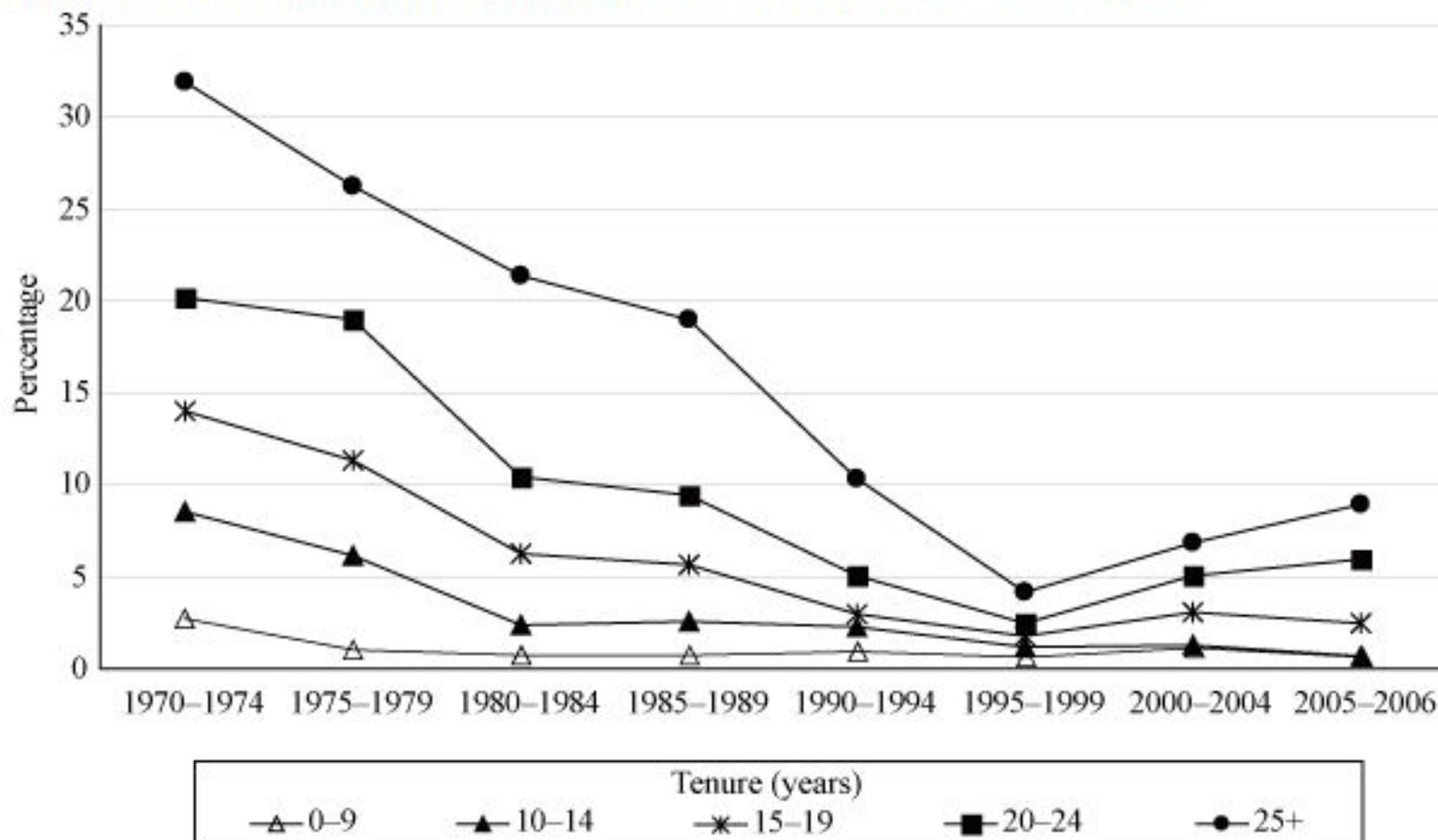
# Trends Reported from Surveillance Program Data

- Although there are limitations with data—several trends have been reported
- Exposures to respirable coal-mine dust (RCMD) have decreased following the Federal Coal Mine Health and Safety Act of 1969
- Reported CWP prevalence rates appear to have decreased after the RCMD standard of  $2 \text{ mg/m}^3$
- Reported CWP prevalence varies with coal rank and geographic region

# Trends Reported from Surveillance Program Data

- Higher prevalence of CWP and PMF reported among participants who:
  - Worked longer
  - Worked in smaller mines
  - Worked in the southern Appalachian region
- Low participation rates could produce misleading results
- Prevalence of CWP and PMF reported to increase following the 6th round of the CWXSP (which ended in 1999)

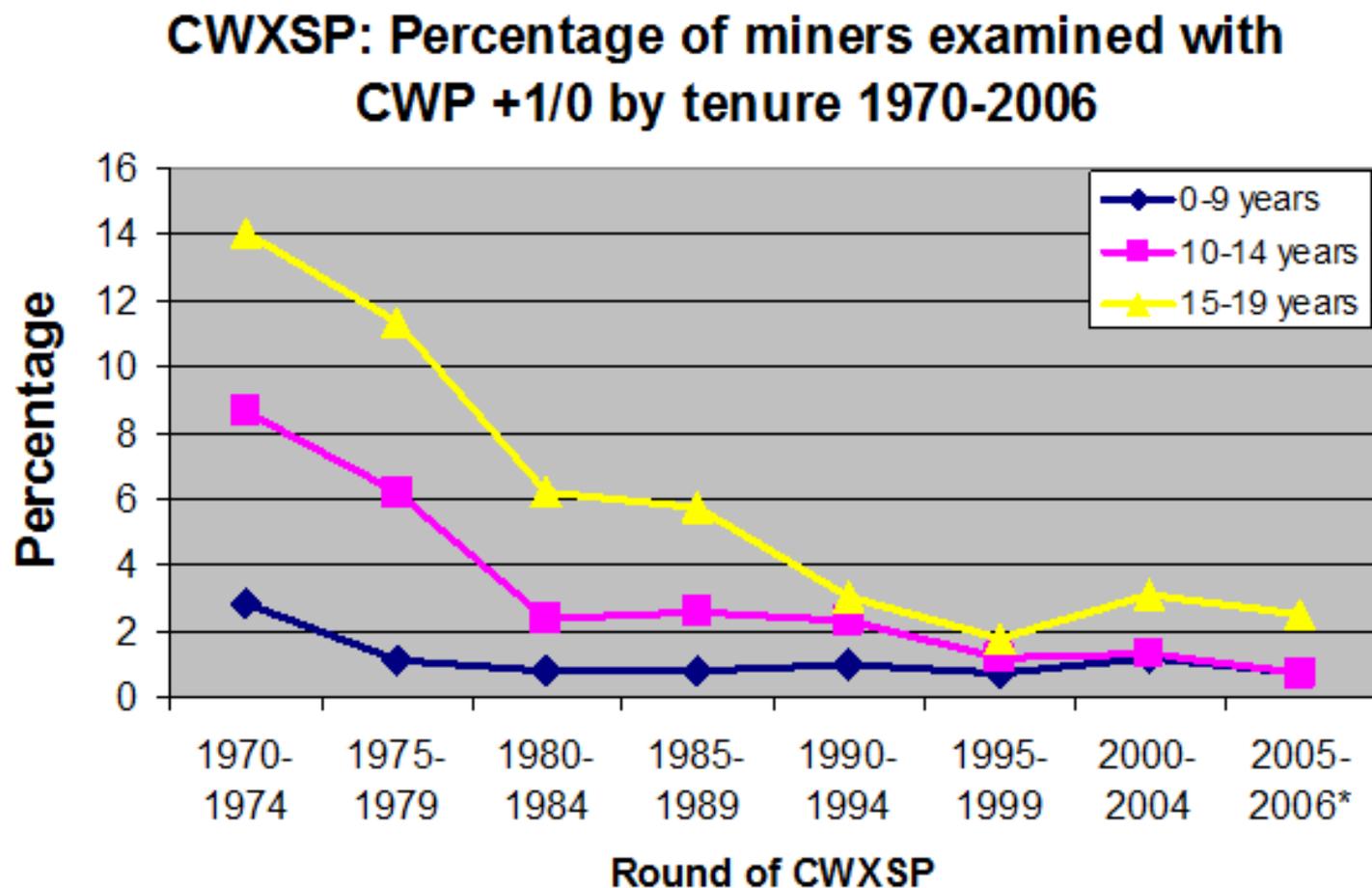
**Figure 2-4. CWXSP: Percentage of examined miners with coal workers' pneumoconiosis (category 1/0+) by tenure in mining, 1970–2006**



Note: See appendices for source description and methods.

Source: NIOSH Coal Workers' X-ray Surveillance Program (CWXSP).

# CWP Prevalence Rates Among Miners with only Post-1969 MSHA Rule Exposures



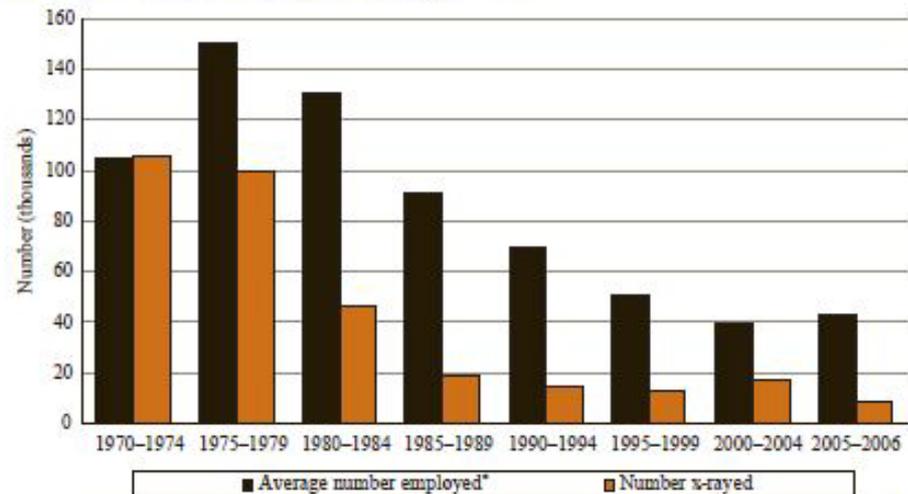
# Participation in CWXSP

Number and proportion of miners participating in the CWXSP dropped dramatically starting in the 3<sup>rd</sup> round in 1980, and continued declining until the 7<sup>th</sup> round in 2000. Overall miner participation was low.

Ref. No. 2007F02-06

*Coal Workers' Pneumoconiosis: Morbidity*

**CWXSP: Estimated number of actively employed workers at underground mines and number of miners examined, 1970–2006**

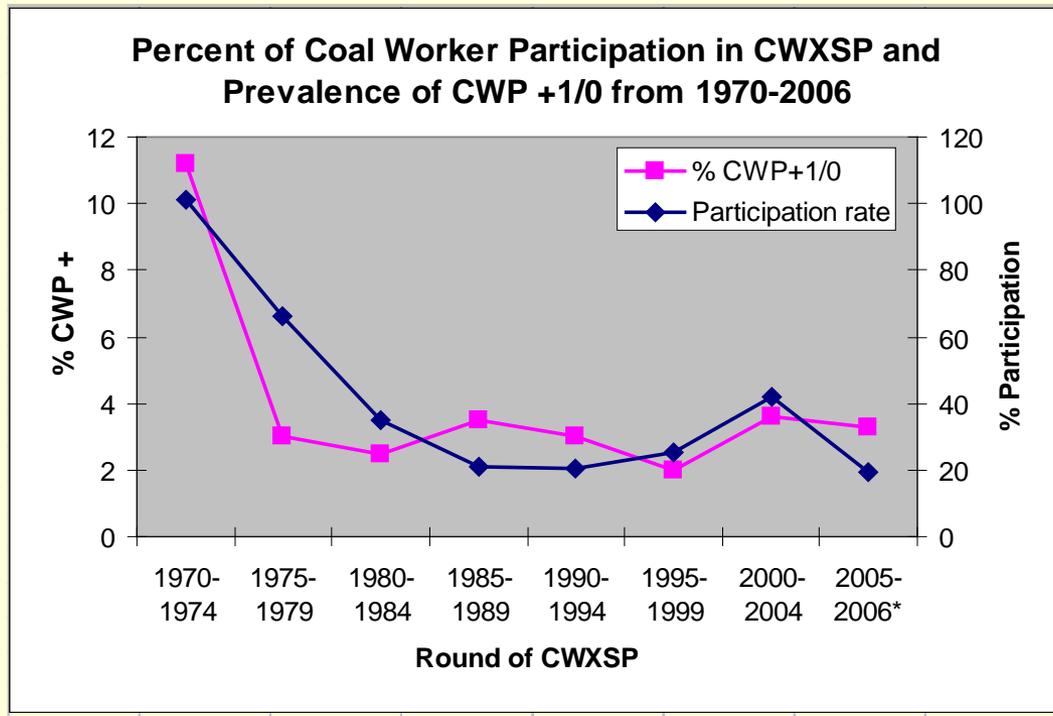


\* Average number employed during the period, based upon quarterly reports by coal mine operators to the Mine Safety and Health Administration (MSHA). Because of hiring and layoffs, the total number of individuals who worked at underground mines in any period exceeds the average employment.  
NOTE: See appendices for source description and methods.

SOURCE: NIOSH Coal Workers' X-ray Surveillance Program (CWXSP). MSHA coal mine employment data.

# Participation Rates and CWP Prevalence

Decrease in participation rates starting in 1970 parallels the decrease in the reported prevalence of CWP, as well as the reported increase in CWP noted from the 1995–1999 round to the 2000–2004 round



- Incomplete round data.  
Raw data downloaded from NIOSH Ref. No. 2007F02-05 and Ref .No. 2007T02-12.

## Cross-Sectional Studies: Limitations

- Medical monitoring and surveillance of U.S. coal miners are conducted using cross-sectional surveys
  - Limited to measuring the prevalence of disease (number of cases of CWP and PMF in the population at a point in time)
- The diminishing number of miners examined and low participation rates limit the interpretation of the prevalence data
- Cross-sectional studies have limited ability to estimate risk for specific coal-dust exposure levels
- In coal-miner studies, it has not been feasible to examine everyone in the coal-miner population
  - Thus, this requires appropriate sampling methods to generalize results from a sample of coal miners to all coal miners
  - To date, only volunteer samples have been studied

# Sources of Potential Bias in Cross-sectional Studies

- Use of prevalence rather than incidence data
- Limiting study to active workers or other selected groups
- When there are differences between participants and non-participants (e.g., participants older or sicker than nonparticipants)
- Relying on self-reported data such as work history data (rather than occupational records) or disease symptoms (rather than clinical diagnoses)

# Observations Regarding the Coal-Miner Cross-Sectional Respiratory Health Studies

- NIOSH surveillance programs provide valuable medical information primarily for actual participants
- Design limitations and issues with implementation of the CWXSP, MCP, and ECWHSP limit the generalizability of the findings
- The assertion that “In recent years, the prevalence of CWP has increased among experienced miners, and in some cases, CWP has progressed rapidly to PMF” needs to be re-evaluated in the context of these design limitations and implementation issues

# Potential Explanations for Reported Increase in CWP and PMF

- Increase is not real—or is not related to current standard
- If true—potential exposure considerations:
  - Increase in cumulative dust exposure—not likely
  - Increase in exposure to silica dust from mining silica-rich rock during mining of thinner coal seams; evidence not consistent (e.g., see McCunney et al. 2009)
  - Inadequate or inconsistent compliance with RCMD standard
  - Change in biological potency of coal

# Potential Explanation for Reported Increase in CWP and PMF—Artifact of Study Design?

- Disease detection:
  - Screening artifact
  - Participation bias
  - Misdiagnosis?
- Only occurring among more experienced miners—thus a reflection of earlier historical exposures
- Limitations of cross-sectional survey design

## Questions Regarding Migration Patterns in Miners

- How is miner migration accounted for in the CWXSP and ECWHSP and analyses of these data?
- Does MSHA or NIOSH track miners as they move from mine to mine to ensure monitoring every 5 years?
- How many eligible coal miners (employed  $\geq 3$  years) have never participated in surveillance programs?
- Is the current mine-based model, which assumes a stable long-term workforce, appropriate for the modern-day coal industry?

## Further Questions on Methodological Issues

- Was cumulative (or lifetime) dust exposure assumed to average  $2 \text{ mg/m}^3$  for all miners?
- How did the following factors of a miner's employment history affect differences in reported prevalence of CWP?
  - Specific job in mine, job changes during employment
  - Time in specific jobs
  - Number and size of mines worked in
  - Time employed in different mines, of different sizes, in different geographic areas
- What methods were used to address participation bias?

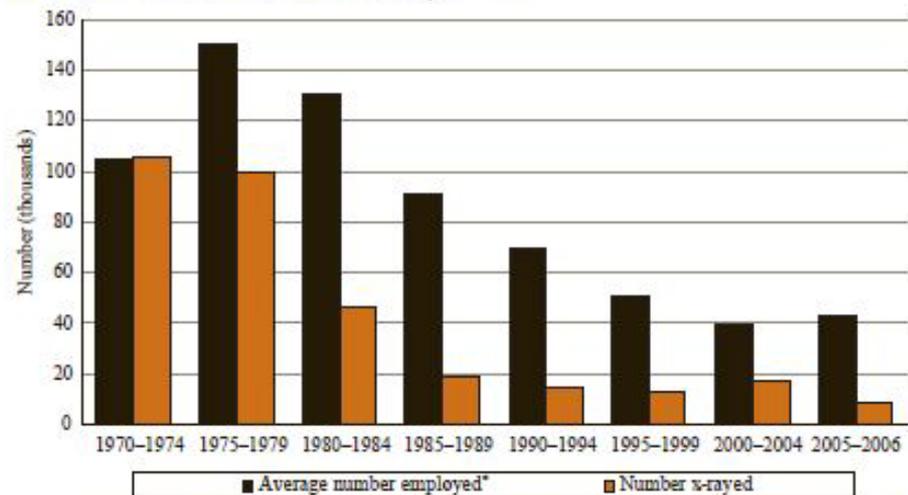
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## Questions Regarding Participation Rates

- Results may be strongly influenced by differential miner participation
- How do participants in the CWXSP and in the ECWHSP differ from miners who did not participate with respect to:
  - Age
  - Race
  - Tenure
  - Hours per week in the mine
  - Mine size
  - Time mine has been in operation
  - Number of mines worked in lifetime
  - Family history of mining
  - Non-coal-mine employment history
  - Time away from coal mining
  - Education level
  - History of smoking
  - History of other tobacco use

## Questions Regarding Assessment of Participation

- What accounts for the sizable increase in participation in 2000–2004 (in addition to underground miners who participated in the MCP)?
- Were the methods employed to increase underground miner participation applied systematically across all mines?
- How is the increase in participation rates distributed over mine size, geography, tenure (i.e., is the increase in the 2000–2004 participation limited to miners in one state, or in one tenure group?)
- What is the relationship between miner participation rate and prevalence of CWP and PMF over time among key subgroups?

## Interpretation and Limitations of NIOSH Data

- The majority of data on the prevalence of CWP and PMF in U.S. coal miners is generated from the surveillance programs, not from more optimally designed epidemiologic studies
- The 1995 NIOSH Criteria Document, the 2010 MSHA Proposed Rule, and the Quantitative Risk Assessment based their conclusions and recommendations primarily on data generated through these programs
- The next set of slides examine the most recently published CWP and PMF prevalence data (Laney et al. 2010) to describe and highlight concerns with the interpretation of surveillance data

## **Latest NIOSH Analysis: Laney et al. (2010)**

- Laney et al. (Occup Environ Med 2010;67:428-431) published the most recent report on CWP and PMF prevalence that covers the period 1970-2009:
  - 145,512 miners contributed 240,067 x-rays for analysis
  - Participants from both the CWXSP and ECWHSP (limited to underground miners) were included
- The objective was to determine the extent to which mine size was associated with CWP or PMF prevalence
- The authors reported that miners from smaller mines (<50 miners) experienced significantly more CWP and PMF in the 1990s and 2000s than mines with >50 employees

## Questions Regarding this Recent NIOSH Study

- Why was the unit of analysis “miner from small mine,” rather than miner-specific employment time in small mine?
- Was the individual miner’s lifetime employment history used to define “miners from small mines”?
- How many days did a miner have to work in a “small mine” to be considered a “miner from a small mine”?
- Was time worked in a “small mine” considered in any of the analyses?
- What methods were employed to prevent misclassification of miners (i.e., were miners with limited time in a small mine classified as “miner from small mine”?)

## Further Questions on Laney et al. (2010)

- Approximately 1/3 of participants contributed more than one x-ray over the 39 years of monitoring. What is the tenure distribution of the remaining 2/3 of participants who contributed only one x-ray?
- How many small mines were in operation in the U.S. during each round of the CWXSP and in each year of the ECWHSP?
- What is the ratio of small participating mines to large participating mines, by state, for each round of the CWXSP and year of ECWHSP?
- What was the miner participation rate in the “small mines” compared to non-small mines for each round of the CWXSP and for each year of the ECWHSP?

## Laney Publication on Silica

- In a second publication, Laney et al. (Occup Environ Med 2010;67:652-656) examined the possible role of silica exposure on the increased prevalence of CWP and PMF in 90,973 participants of the CWXSP
- The authors reported that 50.7% of the 90,973 participants of the CWXSP from 1980 to 2008, of any tenure, were mining in Virginia, West Virginia, and Kentucky at the time of exam
- Historical data indicated that Virginia, West Virginia, and Kentucky were among the five states with the largest number of mines with <20 employees (Special Publication 18-94, United States Department of the Interior, Bureau of Mines 1994)

## **Regional Findings Require Further Evaluation**

- Results show that only miners in Virginia, West Virginia, and Kentucky experienced an increase in the proportion of CWP category 2 and 3 opacities, and only miners in those states experienced an increase in the prevalence of PMF
- Based on Laney et al., Virginia, West Virginia, and Kentucky:
  - Accounted for half of miners who participated in the CWXSP
  - Had the highest reported prevalence of CWP and PMF
- Has the interaction between number of mine employees (mine size), miner participation rates, and location of mine been examined?

## Discussion Points

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## Concluding Comments

- **Medical monitoring and surveillance are important tools for early detection of disease**
  - This information is essential for developing effective health and safety programs, and directing prevention efforts for both the individual and the entire workforce
- **Monitoring and surveillance programs need to be revised and updated**
  - Studies need to be miner (not mine) based
  - Use scientific sampling methods that allow for better external validity
- **Improved epidemiologic study designs are needed to better characterize the key risk factors of CWP and PWF and reduce uncertainties about the importance of these factors**

## **Concluding Comments: Additional Analyses are Needed to Design More Effective Regulations**

- Need to better understand the validity and reliability of the CWP and PMF prevalence rates. Low participation rates limit interpretation of the prevalence data.
- Better transparency and documentation of study protocols, more complete analyses, and recognition of data limitations will improve evaluation of studies
- Results from the CWXSP and CWHSP need to be interpreted properly within the limitations of cross-sectional surveys

# Concluding Comments: High-Quality Epidemiologic Data Needed for Developing Safety Policy

- Heterogeneity of CWP prevalence suggests that a “one-size-fits-all” standard for RCMD may not be most effective or practical approach
- The RCMD proposed rule involves complex and burdensome exposure monitoring
  - Costly and difficult to implement and analyze
  - May do little to realize disease reduction and prevention
- The World Health Organization has adopted a more regional approach that considers CWP risk by regions, type of coal, and other factors
  - Did MSHA consider such an approach?
  - Should such an approach be adopted in the U.S.?