# IN THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BLUE MOUNTAIN ENERGY

and

OLD REPUBLIC INSURANCE COMPANY,

Petitioners

v.

TERRY GUNDERSON

and

DIRECTOR, OFFICE OF WORKERS' COMPENSATION PROGRAMS, UNITED STATES DEPARTMENT OF LABOR,

Respondents

On Petition for Review of an Order of the Benefits Review Board, United States Department of Labor

#### BRIEF FOR THE FEDERAL RESPONDENT

(Oral Argument Not Requested)

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### STATEMENT OF RELATED CASES

This case has been before the Court once before. The Court's prior decision is reported as *Gunderson v. U.S. Dep't of Labor*, 601 F.3d 1013 (10th Cir. 2010). To the Director's knowledge, there are no related appeals pending.

# IN THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

	No. 14-9561
BLUE	MOUNTAIN ENERGY

and

OLD REPUBLIC INSURANCE COMPANY,

Petitioners

v.

#### TERRY GUNDERSON

and

DIRECTOR, OFFICE OF WORKERS' COMPENSATION PROGRAMS, UNITED STATES DEPARTMENT OF LABOR,

Responde	ents
On Petition for Review of a Final Order Review Board, United States Departm	
BRIEF FOR THE FEDERAL RESP	ONDENT

Terry Gunderson worked as an underground coal miner for more than thirty years. This appeal involves his June 2001 claim for benefits under the Black Lung Benefits Act (BLBA), 30 U.S.C. §§

901-44.<sup>1</sup> A Department of Labor (DOL) administrative law judge (ALJ) awarded his claim, and the Benefits Review Board affirmed. Blue Mountain Energy, Mr. Gunderson's former employer, has petitioned the Court to review the Board's decision. The Director, Office of Workers' Compensation Programs, responds in support of the Board's decision.<sup>2</sup>

Harcum held that in cases arising under the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. §§901-50, the Director does not have standing to petition the courts of appeals for review of Board decisions in which the Longshore Special Fund (33 U.S.C. § 944) does not have a financial interest. 514 U.S. at 130-136. It has no relevance to the Director's standing to otherwise participate in Longshore Act litigation. See, e.g., Renfroe v. Ingalls Shipbuilding, Inc., 30 Ben. Rev. Bd. Serv. (MB) 101, 104 (BRB 1996). More importantly, Harcum's holding is expressly limited to cases under the Longshore Act (which does not grant the Director party status), (cont'd . . .)

<sup>&</sup>lt;sup>1</sup> Because Mr. Gunderson filed his claim before 2005, the amendments to the BLBA contained in Section 1556 of the Affordable Care Act do not apply. *See* Pub. L. No. 111-148, § 1556(c) (2010); *Antelope Coal Co./Rio Tinto Energy Am. v. Goodin*, 743 F.3d 1331, 1336 (10th Cir. 2014) (discussing changes to BLBA made by Section 1556).

<sup>&</sup>lt;sup>2</sup> Blue Mountain, citing *Director, OWCP v. Newport News Shipbuilding & Dry Dock Co.* (*Harcum*), 514 U.S. 122, 134 (1995), asserts that "[t]here is some question whether the Department of Labor has standing . . . to take sides on the merits of a [BLBA] claim [absent a financial interest in the outcome]." Pet. Br. at 8, n.3. This contention is without merit.

#### STATEMENT OF JURISDICTION

This Court has both appellate and subject matter jurisdiction over Blue Mountain's petition for review under Section 21(c) of the Longshore Act, 33 U.S.C. § 921(c), as incorporated into the BLBA by 30 U.S.C. § 932(a). Blue Mountain petitioned for review of the Board's May 11, 2014, decision on July 3, 2014, within the sixty-day limit prescribed by Section 21(c). Moreover, the "injury" as contemplated by Section 21(c)—Mr. Gunderson's exposure to coalmine dust—occurred in Colorado, within this Court's territorial jurisdiction.

<sup>(. . .</sup> cont'd)

and does not apply to the BLBA, which makes the Director (as designee of the Secretary of Labor) "a party in any proceeding relative to a claim for benefits." 30 U.S.C. § 932(k). *Accord Harcum*, 514 U.S. at 135; *see also id.* at 139-42 (Ginsburg, J., dissenting).

In any event, the Director has a financial interest in Mr. Gunderson's claim, assuming that is needed to justify his participation. As of December 15, 2014, the Black Lung Disability Trust Fund has paid Mr. Gunderson a total of \$118,208.70 in interim benefits, none of which has been reimbursed by Blue Mountain. See 20 C.F.R. § 725.522(a). If the Court affirms Mr. Gunderson's award, Blue Mountain (or Old Republic) will have to reimburse the Trust Fund for all payments made, see 20 C.F.R. § 725.602; by contrast, a reversal would require the Director to seek repayment from Mr. Gunderson.

This Court previously remanded the case for further consideration by the ALJ. Gunderson v. U.S. Dep't of Labor, 601 F.3d 1013 (10th Cir. 2010) (Gunderson I). The Board had jurisdiction to review both of the ALJ's decisions on remand under Section 21(b)(3) of the Longshore Act, 33 U.S.C. § 921(b)(3), as incorporated. The ALJ issued his first remand decision on June 15, 2011. Mr. Gunderson filed a notice of appeal with the Board on June 28, 2011, within the thirty-day period prescribed by Section 21(a) of the Longshore Act, 33 U.S.C. § 921(a), as incorporated. After the Board remanded the case, the ALJ issued his second remand decision on March 18, 2013. Blue Mountain filed a timely motion for reconsideration with the ALJ on April 16, 2013. See 20 C.F.R. § 725.479(b) (providing a thirty-day period to seek reconsideration of ALJ decision). The ALJ issued his decision on the motion (granting it in part and denying in part) on May 20, 2013. Blue Mountain then timely appealed to the Board on June 12, 2013. See 33 U.S.C. § 921(a); 20 C.F.R. § 725.479(c) (period for appeal to Board suspended and reset by timely motion for reconsideration).

#### STATEMENT OF THE ISSUES

It is uncontested that Mr. Gunderson suffers from chronic obstructive pulmonary disease (COPD).<sup>3</sup> Moreover, Blue Mountain no longer contests that Mr. Gunderson has a totally disabling pulmonary impairment, or that COPD (the only pulmonary disease identified in the record) is a substantially contributing cause of his disability. The only remaining issue is whether his COPD is legal pneumoconiosis, *i.e.*, whether his COPD is "significantly related to, or substantially aggravated by, dust exposure" during his thirty

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COPD encompasses chronic bronchitis, emphysema and certain forms of asthma. 65 Fed. Reg. 79939 (Dec. 20, 2000). Both cigarette smoking and dust exposure during coal-mine employment can cause COPD. See 65 Fed. Reg. 79939-43 (summarizing medical and scientific evidence linking COPD and coal-mine work); The Merck Manual 1889 (discussing smoking as cause of COPD).

<sup>&</sup>lt;sup>3</sup> COPD is a lung disease characterized by airflow obstruction. *The Merck Manual* 1889 (19th ed. 2011); *see Andersen v. Director*, *OWCP*, 455 F.3d 1102, 1104 n.3 (10th Cir. 2006). "Obstructive disorders are characterized by a reduction in airflow." *The Merck Manual* 1853. In contrast, "[r]estrictive disorders are characterized by a reduction in lung volume." *Id.* at 1855. In lay terms, restrictive disease makes it more difficult to inhale, while obstructive disease makes it more difficult to exhale. *See Gulf & Western Indus. v. Ling*, 176 F.3d 226, 229 n.6 (4th Cir. 1999).

years of underground coal-mine employment. 20 C.F.R. § 718.201(b). The particular questions at issue in this appeal are:

- 1. Was the ALJ permitted to consult the preamble to DOL's 2001 regulations (65. Fed. Reg. 79920-80107 (Dec. 20, 2000)) as part of his evaluation of the conflicting medical-opinion evidence regarding the existence of legal pneumoconiosis?
- 2. Relatedly, did the ALJ abuse his discretion in refusing to reopen the record seven years after it had closed in order for Blue Mountain to submit evidence allegedly challenging the preamble's evaluation of the scientific literature on the effects of coal-mine dust and smoking on COPD?
- 3. Apart from the preamble, the ALJ provided several additional reasons for crediting the medical opinions diagnosing legal pneumoconiosis over those diagnosing smoking-related COPD. Does Blue Mountain's failure to challenge the validity of these additional reasons mandate affirmance of the finding of legal pneumoconiosis and the award below?

#### STATEMENT OF THE CASE

### A. Statutory and Regulatory Background

The BLBA provides benefits to coal miners who are totally disabled due to pneumoconiosis. 30 U.S.C. § 901(a). To obtain benefits, a miner must prove 1) that he has pneumoconiosis; 2) that the disease arose out of his coal-mine employment; 3) that he has a totally disabling pulmonary impairment; and 4) that his disability is due to pneumoconiosis. 20 C.F.R. §§ 718.202-.204, 725.202(d)(2); see Antelope Coal, 743 F.3d at 1335 (citations omitted).

"Pneumoconiosis" includes both "clinical pneumoconiosis" (diseases commonly recognized as pneumoconiosis by the medical community) and the broader category of "legal pneumoconiosis" (any chronic lung disease caused by coal-mine-dust inhalation, including "any chronic restrictive or obstructive pulmonary disease arising out of coal mine employment"). 20 C.F.R. § 718.201(a)(1), (2); Antelope Coal, 743 F.3d at 1335 (citation omitted). Proof that a miner has legal pneumoconiosis (a disease that, by definition, arises out of coal-mine employment) satisfies both the first and second elements of a miner's claim. See Andersen, 455 F.3d at 1105.

Moreover, the definition of legal pneumoconiosis encompasses both obstructive and restrictive lung diseases caused by exposure to coal-mine dust. 20 C.F.R. § 718.201(a)(2). The central issue in this case is whether Mr. Gunderson's COPD is "significantly related to, or substantially aggravated by, dust exposure in [his] coal mine employment." 20 C.F.R. § 718.201(b).

The current regulation defining legal pneumoconiosis, 20 C.F.R. § 718.201(a)(2), was promulgated on December 20, 2000. 65 Fed. Reg. 79920. When the regulation was promulgated, DOL published a regulatory preamble, which describes the development of, and bases for, the rule. 65 Fed. Reg. 79937-45. This portion of the preamble relies heavily on the *Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust* § 4.2.2. et seq. (1995) (available on the Internet at http://www.cdc.gov/niosh/docs/95-106/) published by the National Institute of Occupational Safety and Health (NIOSH) (hereafter referred to as

"the *Criteria*" or "the NIOSH *Criteria*"). See 65 Fed. Reg. 79937-38. The preamble states that coal-mine dust inhalation may cause COPD and that the effects and contributions of cigarette smoking and coal-mine dust exposure to COPD are similar and "additive." 65 Fed. Reg. 79939-41.

#### B. Statement of the Facts

There are two significant exposures that could have contributed to Mr. Gunderson's totally disabling COPD. First, he worked as an underground miner for more than thirty years, ending in 2004. *Gunderson I*, 601 F.3d at 1016. Second, he had an extensive cigarette-smoking history, extending from 1962 to 1996. *Id.* There are four relevant medical opinions addressing the etiology of Mr. Gunderson's COPD from Drs. Parker, Cohen, Repsher and Renn.<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> Congress designated NIOSH as DOL's scientific consultant regarding the development of medical criteria for claims under the BLBA. 30 U.S.C. § 902(f)(1)(D).

<sup>&</sup>lt;sup>5</sup> The record contains a fifth medical opinion, Dr. Shockey's. Director's Exhibit (DX) 11 (exhibit numbers refer to the record created before the ALJ). Dr. Shockey found that Mr. Gunderson's COPD was caused by a combination of coal-mine-dust exposure (cont'd . . .)

Drs. Parker and Cohen opined that Mr. Gunderson's COPD resulted from both dust exposure and smoking. Claimant's Exhibits (CX) 5, 6. Parker reviewed Gunderson's treatment records, medical reports, and his social, work and other medical records. He explained that both coal-mine dust and smoking can cause COPD, citing numerous medical journal articles as well as NIOSH's Criteria, and stated that there was no basis for ruling out dust exposure as a cause of Mr. Gunderson's disease. CX 6 at 5-7. Observing that the lung damage usually plateaus after the cessation of smoking, Parker found it especially significant that Mr. Gunderson's COPD continued to worsen during the four years he worked as a miner after quitting smoking. *Id.* at 6-7. Dr. Parker concluded that "[i]n view of the scientific evidence regarding the etiology of COPD, and in view of Mr. Gunderson's particular history, physical findings, symptoms, and pattern of lung function testing, arterial blood gases, exercise testing, and radiographic findings, the

<sup>(. . .</sup> cont'd)

and smoking. While the ALJ found Dr. Shockey's opinion well-reasoned, he ultimately found it less probative than the other opinions because of its brevity. Petitioner's Appendix (PA) at 112-13.

only rational conclusion is that both assaults to his lungs [coaldust exposure and smoking] contributed to his COPD." *Id.* at 6.

Dr. Cohen reached the same conclusion following his examination of Mr. Gunderson, in which he reported Mr. Gunderson's work and medical histories and performed a battery of pulmonary tests. In finding legal pneumoconiosis, Dr. Cohen relied on many findings particular to Mr. Gunderson, including thirty years of underground and dusty coal mine employment, his symptomology, his severe diffusion impairment, and a significant gas exchange abnormality with exercise on cardiopulmonary exercise testing. CX 5 at 11. As further support, Dr. Cohen thoroughly discussed numerous medical journal articles demonstrating that coal-mine dust can cause significant COPD, that the incidence of dust-related COPD is not far less common

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<sup>&</sup>lt;sup>6</sup> Diffusing capacity for carbon monoxide (often referred to by the acronym DLco) "is a measure of the ability of gas to transfer from the [lungs to red blood cells]." *The Merck Manual* 1856. "Gas exchange" refers to the transfer of oxygen to the blood. *See id.* 1855-59. An impairment or abnormality in these exchanges generally leads to hypoxemia (inadequate oxygenation of the blood). *See id.*; *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) 908.

than that of smoking-related COPD, and that dust-related COPD cannot be distinguished from smoking-related COPD. *Id.* at 12-17. Considering that Mr. Gunderson had extensive histories of exposure to both dust and smoking, and his clinical findings, Cohen attributed his COPD to both conditions. *Id.* at 17.

On the other side, Drs. Repsher and Renn found that Mr. Gunderson's COPD is due to smoking alone. DX 23; Employer's Exhibit (EX 4). Repsher based his conclusion on the fact that Mr. Gunderson's chest x-ray was negative for clinical pneumoconiosis, and because he has a purely obstructive impairment (with no restriction), which he claimed is characteristic of smoking-induced COPD. DX 23. Renn initially did not give much explanation for his conclusion.

Repsher further explained his smoking-alone conclusion while testifying at the ALJ hearing: Mr. Gunderson's COPD was due to smoking because "if you compare the effect of cigarette smoke on the lungs with the effect of coal mine dust . . ., on the average the effect of the coal mine dust to an overwhelming probability is not detectable in an individual." Hearing Transcript at 99; see also id. at 111-16. He further stated "the overwhelming statistical

probability or medical probability is that he is not one of those [with COPD caused by dust], that in him, the overwhelming probability is the cigarette smoke and not the coal mine dust." *Id*.

On deposition, Dr. Renn gave two reasons for attributing Mr. Gunderson's COPD solely to smoking. First, smoking-related COPD exhibits a disproportionate reduction in the FEF 25-75 value on a pulmonary-function study (while there is a proportionate FEF 25-75 reduction in dust-related COPD). EX 10 at 6-7, 52. Mr. Gunderson's FEF 25-75 values were disproportionately reduced, therefore smoking was the cause. *Id.* Second, dust-related COPD results in a reduced diffusing capacity, whereas diffusing capacity remains normal in smoking-related COPD. *Id.* at 6-7, 30-32. Since

<sup>&</sup>lt;sup>7</sup> A pulmonary-function test measures pulmonary capacity, and is used in determining pulmonary disability in BLBA claims. *See* 20 C.F.R. § 718.204(b)(2)(i). The BLBA regulations require that the test measure three values: the FEV<sub>1</sub> (forced expiratory volume in one second), the FVC (forced vital capacity), and the MVV (maximum voluntary ventilation). *See Dotson v. Peabody Coal Co.*, 846 F.2d 1134, 1138 nn.6, 7 (7th Cir. 1988); 20 C.F.R. § 718.103; Part 718, App. B. The FEF 25-75 (a value not required by the regulations) represents the average airflow during the middle portion of the FVC maneuver. *See NIOSH Spirometry Training Guide* (2003) 5-35 (available on the internet at http://www.cdc.gov/niosh/docs/2004-154c/pdfs/2004-154c.pdf).

Mr. Gunderson's diffusing capacity was normal (when adjusted for alveolar volume, or total lung capacity), his COPD was due to smoking.<sup>8</sup> *Id.* Dr. Renn cited various articles in support of his diffusion-capacity theory (which Blue Mountain submitted with his deposition; *see* Exhibits 2-5 to EX 10), but none in support of his FEF 25-75 theory.

Dr. Cohen disputed Renn's conclusions. CX 13. He stated that Renn had identified no scientific basis for his FEF 25-75 theory, and that FEF 25-75 values are of little value due to their high variability. *Id.* at 1-2. As to diffusion capacity, Cohen observed that Mr. Gunderson's capacity *was in fact reduced* (even when corrected for alveolar volume) on tests performed in 2002 and 2005. *Id.* at 2. Moreover, Cohen stated that, in any event, the corrected-diffusing-capacity value is not recognized as a valid tool. *Id.* at 2-3. Finally, Cohen noted that the articles cited by Renn in support of his diffusion-capacity theory were based on studies of working miners (who are generally healthier than retired miners,

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<sup>&</sup>lt;sup>8</sup> Later, when confronted with the reduced diffusing-capacity values obtained by Dr. Cohen, Dr. Renn offered that those values were *too low* to have been caused by dust exposure. EX 10 at 31-32.

such as Mr. Gunderson). *Id.* at 3. In addition, the articles reported only average diffusion-capacity values across a population, which were not useful with respect to any particular individual. *Id.* 

Dr. Renn replied to these criticisms. EX 14. This time, he cited four articles in support of FEF 25-75 theory—two from 1964 and 1967 addressing pulmonary disease in miners, and two from 1971 addressing the effect of smoking on teenagers and college-age adults. *Id.* at 1-2. He reiterated his view that adjusting diffusion-capacity values for alveolar volume was appropriate, and that a normal adjusted diffusion capacity was indicative of smoking-related COPD. *Id.* at 2-3.

Dr. Cohen fired the last volley in this exchange. CX 14. He stated that the "ancient articles" Renn relied on were not "born[e] out by the huge body of literature on coal mine dust and [COPD] which has been published in the last 3 decades . . . ." *Id.* at 1. In particular, he explained that American and European pulmonary medical societies do not recommend using the FEF 25-75 measurement at all, and the author of a noted textbook had omitted it because it did not provide significant information. *Id.* at 2. Cohen also reiterated his criticism of Renn's adjusted-diffusing-

capacity theory, noting that neither American nor European medical societies recommend giving any significance to the adjusted value. *Id.* at 2. Cohen again challenged Renn's reliance on values averaged over a population in addressing the etiology of a particular individual's condition. *Id.* at 3.

### C. Procedural History

Mr. Gunderson filed his claim in 2001. DX 2. A DOL district director awarded his claim, and Blue Mountain requested an ALJ hearing, which was held in 2006. DX 29, 30; see PA at 5.

#### 1. First ALJ Decision and First Board Decision.

The ALJ denied Mr. Gunderson's claim in 2007. PA at 9. He found that Mr. Gunderson does not have either clinical or legal pneumoconiosis. PA at 13-17, 29-30; see 20 C.F.R. § 718.202. Regarding legal pneumoconiosis, the ALJ found that all of the medical opinions on the etiology of Mr. Gunderson's COPD were well-reasoned (although, other than summarizing their conclusions, he did not examine their reasoning) and concluded that the opinions were "evenly balanced and should receive equal weight."

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<sup>&</sup>lt;sup>9</sup> The ALJ did not address the other elements of entitlement.

PA at 27, 29-30. Because Mr. Gunderson bore the burden of proof, the ALJ concluded that that he failed to prove the existence of legal pneumoconiosis. PA at 30 Mr. Gunderson appealed to the Board, which affirmed the ALJ's decision. PA at 31. Mr. Gunderson then petitioned the Court for review.

2. Gunderson I. The Court vacated the denial of benefits, and remanded the case for further consideration. Gunderson I, 601 F.3d 1013. The Court affirmed the ALJ's finding of no clinical pneumoconiosis, 601 F.3d at 1027-28, but vacated his finding of no legal pneumoconiosis. 601 F.3d at 1021-27. The majority held that the ALJ failed to adequately explain his legal-pneumoconiosis determination, as he failed to assess the reasoning of the medical opinions at issue, as required by the Administrative Procedure Act (APA), 5 U.S.C. § 557(c)(3)(A). 10 601 F.3d at 1021-25. The Court explained that

<sup>&</sup>lt;sup>10</sup> The APA provides that all ALJ decisions "shall include . . . findings and conclusions, *and the reasons or basis therefor*, on all material issues of fact, law, or discretion . . . ." 5 U.S.C. § 557(c)(3)(A), as incorporated by 33 U.S.C. § 919(d), 30 U.S.C. § 932(a), and 5 U.S.C. § 554(c)(2) (emphasis added).

from the ALJ's statement that the conflicting opinions [on the cause of Mr. Gunderson's COPD] "are evenly balanced, and should receive equal weight," . . . we cannot tell how he evaluated [the] opinions [and]. [t]he mere fact that equally qualified experts gave conflicting testimony does not authorize the ALJ to avoid the scientific controversy by declaring a tie.[11]

601 F.3d at 1024 (citations omitted). The Court therefore vacated the finding of no legal pneumoconiosis, and remanded the case. 12 601 F.3d at 1026. By way of assistance to the ALJ, the majority noted that in weighing the medical opinions on remand, he "has the benefit of a substantial inquiry by [DOL]" in the form of the blacklung program regulations, particularly 20 C.F.R. § 718.201, on which he "may properly rely . . . when assessing scientific

[o]f course, there may be issues as to which scientific knowledge does not permit an ALJ to identify the more probable of the disputed expert opinions. However, if that is the case, then [the] ALJ had a duty to explain, on scientific grounds, why a conclusion cannot be reached.

601 F.3d at 1024 (citation omitted).

<sup>&</sup>lt;sup>11</sup> The majority noted that

<sup>&</sup>lt;sup>12</sup> Judge O'Brien dissented on this issue, and would have affirmed the ALJ's finding of no legal pneumoconiosis and his resulting denial of benefits. 601 F.3d at 1027-31.

testimony." 601 F.3d at 1024-25. The Court, however, did not mention (or require the ALJ to rely on) DOL's regulatory preamble. The Court subsequently denied Blue Mountain's petition for rehearing en banc. PA at 73a.

#### 3. Second ALJ Decision.

On remand, the ALJ again denied benefits. PA at 74. After summarizing the conflicting opinions, the ALJ again conducted a cursory and superficial evaluation of them, as follows:

[T]he Circuit Court has required that the undersigned choose one party's argument over the other.

Drs. Repsher, Renn, and Cohen have given extensive explanations as to their reasoning in this case.

Spirometry in this case is not remarkable, but the miner has significant blood gas abnormality. Dr. Cohen states that this is due in part to coal dust exposure, and Dr. Renn indicates that this could be due to [non-dust-related] factors.

I find Dr. Renn's opinion to be persuasive as Dr. Cohen has not adequately explained why these other factors are not responsible for the blood gas abnormality.

PA at 79-80. Mr. Gunderson then appealed to the Board.

#### 4. Second Board Decision.

The Board vacated the ALJ's decision and remanded the case for further consideration. PA at 82. The Board specifically rejected

Mr. Gunderson's argument that the ALJ was *required* to assess the medical opinions in light of DOL's regulatory preamble, but noted that he *could* consider the preamble, along with the regulations. PA at 87 n.5. It remanded the case because the ALJ had conflated the issues of legal pneumoconiosis, total disability and disability causation; incorrectly found that the Court had required him to choose one side's evidence over another's; mischaracterized Dr. Renn's opinion; and failed to consider Dr. Parker's opinion. PA at 85-86 & n.4.

#### 5. Third ALJ Decision and Order on Reconsideration.

On remand, Blue Mountain requested that the ALJ reopen the record "so that new medical evidence may be brought to bare [sic] on the case." PA at 89-90. But it did not identify the evidence it wanted to submit or the issues to which the evidence might pertain. Likewise, in its remand brief to the ALJ, Blue Mountain "request[ed] notice and an opportunity to respond [to the preamble]," but again gave no hint as to what its response would be. Blue Mountain Remand Brief at 17, n.4.

After Mr. Gunderson objected to this request, Blue Mountain argued that the preamble should not be used to evaluate particular

medical opinions. PA at 93-98. The company cited various articles addressing the effects of smoking (none of which addressed the effects of dust exposure and only one of which post-dated the preamble), but did not assert that these studies invalidated the preamble. PA at 95-97. Nor did it ask the ALJ to reject the preamble based upon them. Neither Dr. Repsher nor Dr. Renn cited or relied upon these articles, and Blue Mountain did not submit the actual articles for the ALJ to consider.

The ALJ did not specifically rule on Blue Mountain's request to reopen the record, but instead issued a decision and order awarding benefits. PA at 99. With respect to legal pneumoconiosis, he again summarized the conflicting medical opinions at great length, and found that all were "well documented" reports. PA at 100-13. This time, however, the ALJ closely examined the doctors' underlying reasoning and their cross-criticisms and reached a conclusion that satisfied the APA requirement for reasoned decision making.

The ALJ discounted the opinions of Drs. Repsher and Renn largely without reference to the preamble. PA at 113. He gave diminished weight to Dr. Repsher—who had admitted that his

diagnosis of smoking-induced COPD was based entirely on statistical probability—because "it does not focus on Claimant's specific symptoms and conditions, but on statistics." *Id.* The ALJ likewise gave little weight to Renn's identical diagnosis, relying on "Dr. Cohen's explanation that the FEF 25-75 value . . . has been found to have no useful interpretation and . . . that [diffusing capacity] should not be adjusted for alveolar volume." *Id.* 

On the other hand, the ALJ found persuasive the opinions of Drs. Parker and Cohen. Id. Parker "specifically linked Claimant's symptoms to the documented effects of coal mine dust and cited to literature that had been approved by [DOL's preamble]," and his explanation that Mr. Gunderson's condition continued to deteriorate after the cessation of both coal-mine employment and smoking was consistent with "the acknowledged view that pneumoconiosis is a latent and progressive condition." Id. Similarly, the ALJ was impressed by Cohen's credible explanation disputing the value and reliability of the FEF 25-75 and adjusteddiffusion capacity measures relied on by Renn, leaving both dust and smoking as factors in Mr. Gunderson's COPD. See id. In the end, the ALJ gave more weight to Parker's and Cohen's opinions

because they "more thoroughly evaluated [Mr. Gunderson's] specific condition." *Id.* Accordingly, he found that Mr. Gunderson's COPD falls within the definition of legal pneumoconiosis based on their opinions.<sup>13</sup> *Id.* 

The ALJ only sparingly mentioned the preamble, citing it as a second (or third) reason for giving less weight to Dr. Repsher's opinion. Specifically, the ALJ faulted the doctor for "fail[ing] to address whether coal dust exposure and smoking could have been additive causes of [Mr. Gunderson's COPD]", noting that DOL's regulatory preamble had "adopted" the view that coal-mine dust and smoking could combine to cause COPD. *Id*.

Despite the preamble's limited impact, Blue Mountain again asked on reconsideration for permission to submit additional evidence in response to it (again not identifying the evidence or the particular issues the evidence might address), as well as contesting the ALJ's finding as to the date on which Mr. Gunderson's entitlement commenced. PA at 117. The ALJ modified Mr.

<sup>&</sup>lt;sup>13</sup> The ALJ also found that Mr. Gunderson established all other elements of his claim, and awarded benefits. PA at 113-16.

Gunderson's entitlement date, but denied the request to reopen the record. PA at 130-32. Blue Mountain then appealed to the Board.

6. Third Board Decision.

The Board affirmed the ALJ's award of benefits in 2014. PA at 139. Relying on numerous appellate court decisions, the Board rejected Blue Mountain's contention that the ALJ was forbidden to consult DOL's regulatory preamble in evaluating the medical-opinion evidence. PA at 144. It further held that the ALJ did not have to give notice and an opportunity to respond before consulting the preamble. *Id.* The Board then affirmed the ALJ crediting of the Parker and Cohen opinions over those of Repsher and Renn. <sup>14</sup> PA at 144-46. Blue Mountain petitioned this Court for review.

#### SUMMARY OF THE ARGUMENT

The Court should affirm the award of Mr. Gunderson's claim. At issue is whether Mr. Gunderson's totally disabling COPD is due to smoking *and* thirty years of coal-dust exposure, or to smoking alone. Mr. Gunderson's medical experts believed both assaults

<sup>&</sup>lt;sup>14</sup> The Board also affirmed the ALJ's findings on the other elements of entitlement. PA at 146-47.

contributed to his COPD and therefore he has legal pneumoconiosis; Blue Mountain's experts attributed his COPD solely to smoking, making his condition non-compensable.

Among other reasons, the ALJ found Mr. Gunderson's medical experts more persuasive because they more thoroughly evaluated Mr. Gunderson's "specific condition." This basis, which is entirely independent of any consultation of, or reference to, the regulatory preamble, has not been challenged by Blue Mountain on appeal, and it is supported by substantial evidence. The Court should therefore affirm the award of benefits irrespective of Blue Mountain's arguments regarding the preamble.

In any event, Blue Mountain's argument that the ALJ was precluded from consulting the preamble to assist him in understanding the scientific dispute is plainly wrong. This remarkable contention has already been unanimously rejected by the five courts of appeals to have considered it. The preamble is not a legislative rule, as Blue Mountain claims, but a summary of the medical and scientific evidence supporting the promulgated regulation that coal-mine dust may cause obstructive lung disease, such as COPD. 20 C.F.R. § 718.201(a)(2). An ALJ may (but is not

required to) consult the preamble to aid his understanding in evaluating conflicting physicians' opinions on disputed scientific matters. To the extent he relied on the preamble at all, the ALJ did no more than that.

Lastly, Blue Mountain has failed to prove that the ALJ abused his discretion in refusing to reopen the record—seven years after it closed—for the submission of additional medical evidence related to the preamble. While the record was open, the company had the opportunity to (and did) submit evidence purportedly supporting its physicians' views that dust-related COPD can be distinguished from smoking-related COPD, but it failed to show good cause for submitting additional evidence seven years later following *Gunderson I's* remand. Notably, Blue Mountain failed to proffer any evidence that would invalidate the preamble and, thus, cannot now complain that the ALJ did not allow it to submit such evidence.

#### **ARGUMENT**

### A. Standard of Review

Blue Mountain's primary issue on appeal—whether the ALJ permissibly consulted the regulatory preamble—is a question of law, which the Court reviews de novo. *Antelope Coal Co.*, 743 F.3d

at 1331 (citation omitted). The company also contends that the ALJ erred in failing to reopen the record and permitting it to submit additional evidence. The Court reviews the ALJ's evidentiary and procedural rulings under an abuse-of-discretion standard.

Gunderson I, 601 F.3d at 1021.

Finally, to the extent that Blue Mountain's appeal implicates the ALJ's factual findings, the Court determines "whether the . . . Board properly concluded that the ALJ's decision was supported by substantial evidence," but the Court does not reweigh the evidence, as "the task of weighing conflicting medical evidence is within the sole province of the ALJ." *Antelope Coal Co.*, 743 F.3d at 1331 (citations and internal quotations omitted).

B. The ALJ determined that Mr. Gunderson's COPD is legal pneumoconiosis for reasons unrelated to the preamble. Because Blue Mountain has not challenged these independent bases, the finding of legal pneumoconiosis and resulting award of benefits should be affirmed.

Blue Mountain repeatedly asserts that the Board (and to a lesser extent this Court) compelled the ALJ to rely on DOL's regulatory preamble in weighing the evidence of legal pneumoconiosis, and that his reliance on the preamble was the only basis for his legal pneumoconiosis finding. The ALJ, however,

was not forced to consider the preamble and, more importantly, the ALJ provided several reasons entirely unrelated to the preamble for according more weight to Mr. Gunderson's experts and their diagnosis of legal pneumoconiosis. The Court should therefore affirm the ALJ's factual finding on this point (and the resulting award of benefits) because Blue Mountain has not challenged these independent bases, which are supported by substantial evidence in any event. Accordingly, the Court need not reach Blue Mountain's meritless legal arguments regarding the preamble.

Contrary to Blue Mountain's assertions, the ALJ was not compelled to rely on the preamble in resolving the scientific dispute on the cause of Mr. Gunderson's COPD. When this Court remanded the case to the ALJ, it did not command him to rely on the preamble. In fact, the majority opinion does not mention the preamble at all. Rather, it simply noted that "an ALJ has the benefit of a substantial inquiry by [DOL]," and then referenced DOL's black lung regulations, not the preamble. *Gunderson I*, 601 F.3d at 1024-25. Even with respect to the regulations, the Court emphasized the ALJ's discretion by noting that "[a]n ALJ may properly rely on those regulations when assessing scientific

testimony." *Id.* at 1025 (emphasis added). Clearly, *Gunderson I* did not command the ALJ here to consider the preamble.

The Board (in remanding the case following *Gunderson I*) went even further, specifically rejecting Mr. Gunderson's "assertion that an [ALJ] is required to determine the credibility of an expert's opinion in light of the preamble . . . . " PA at 87, n.5 (emphasis added). Finally, Blue Mountain points to nothing in the ALJ's decision awarding benefits indicating that he had been forced to consider the preamble. In fact, the decision contains only a few passing references to the preamble. In short, Blue Mountain's contention that the ALJ was compelled to rely on the preamble is belied by the facts.

Moreover, Blue Mountain is wrong that the ALJ based his legal pneumoconiosis finding solely on the preamble. He credited the opinions of Drs. Parker and Cohen over those of Drs. Renn and Repsher because the former were better reasoned, and "more thoroughly evaluated [Mr. Gunderson's] specific condition," whereas the latter relied on general statistics and unreliable test data (the outdated the FEF 25-75 measurement and the non-informative adjusted-diffusing-capacity value). PA at 113. These reasons are

entirely independent of any ALJ reference to or reliance on the preamble, a fact that Blue Mountain apparently concedes. *See* Pet. Br. at 20 (conceding that the ALJ had "a few other bases" besides the preamble for his determination that Mr. Gunderson's COPD is legal pneumoconiosis); *see also* Gunderson Resp. Br. at 23-32 (detailing ALJ's non-preamble bases for finding Drs. Parker and Cohen's opinions more persuasive).

Further, the ALJ's rationales—the thoroughness and specificity of a medical report, and the reliability of underlying data—are well-established bases for evaluating and weighing conflicting medical opinions. See Gunderson I, 601 F.3d at 1024 (in evaluating medical opinions, ALJ may look to "many factors, including . . . the explanation of their medical opinions, the documentation underlying their medical judgments, [and] the sophistication and bases of their diagnoses") (internal quotations and citations omitted); see also Antelope Coal Co. 743 F.3d at 1331

<sup>&</sup>lt;sup>15</sup> We took the same position before the Board. Because Mr. Gunderson has effectively made these points, we will not belabor this case by fully restating our views. Instead, we adopt Mr. Gunderson's arguments.

("the task of weighing conflicting medical evidence is within the sole province of the ALJ") (citations and internal quotations omitted).

Critically, Blue Mountain's brief before this Court contains no challenge to the ALJ's findings beyond its preamble arguments. The company has thus waived any such contentions. See Headrick v. Rockwell Int'l Corp., 24 F.3d 1272, 1277-78 (10th Cir. 1994) (issues not raised in opening brief waived) (citations omitted); see generally Fed. R. App. P. 28(a)(8)(A) (petitioner's opening brief must contain "[petitioner's] contentions and the reasons for them, with citations to the authorities and parts of the record on which the [petitioner] relies"). The Court should therefore affirm the ALJ's award of benefits on that basis, and need not reach Blue Mountain's preamble arguments. See Westmoreland Coal Co. v. Cochran, 718 F.3d 319, 324 (4th Cir. 2014) (ALJ's factual findings affirmable on alternative bases "even if his use of the Preamble were error—although we conclude that it was not") (citation omitted); Harman Min. Co. v. Director, OWCP, 678 F.3d 305, 313 (4th Cir. 2012) (same); see generally, e.g., U.S. v. Benard, 680 F.3d 1206, 1210 (10th Cir. 2012) (where decision below affirmed on one ground, need not consider alternative grounds for same result).

C. The ALJ permissibly consulted the preamble in evaluating the conflicting medical opinions on whether Mr. Gunderson's COPD was significantly related to or substantially aggravated by thirty years of underground coal-mine employment.

In any event, Blue Mountain's misguided preamble argument is without merit. <sup>16</sup> While an ALJ is not required to consult the preamble in resolving a scientific dispute (such as the dispute here on the etiology of Mr. Gunderson's COPD), he is plainly permitted to do so.

As the Court explained in *Gunderson I*, an ALJ must resolve "scientific dispute[s] . . . on scientific grounds," and he must "articulate a reason and provide support for favoring one opinion over another." 601 F.3d at 1022 (internal quotation and citation

<sup>&</sup>quot;scientific document" and that NIOSH, DOL's statutory medical consultant, had "no involvement" in it. Pet. Br. at 11, 16-17. These representations are incorrect. As the preamble itself demonstrates, DOL relied on NIOSH's *Criteria* in concluding that dust exposure can cause COPD and that the effects of smoking and coal dust are additive; NIOSH reviewed DOL's original regulatory proposal and approved it, concluding that "[our] scientific analysis supports the proposed definitional changes;" DOL engaged in additional consultation with NIOSH before promulgating the final rule, including having NIOSH review comments and testimony received by DOL; and NIOSH reaffirmed its support for the regulations after reviewing those materials. 65 Fed. Reg. 79937-38.

omitted). In resolving such disputes, an agency must use its skill and expertise in "evaluating technical evidence," and once utilized, will thereby receive "the deference courts generally afford to agency action that implicates scientific and technical judgments within the scope of agency expertise." 601 F.3d at 1022-23 (internal quotation and citation omitted) (emphasis in quoted material).

The DOL preamble and an ALJ's permissible consideration of it both represent the agency's utilization of its expertise. There can be no dispute that DOL's preamble presents and assesses a substantial amount of medical and scientific literature related to the impact of smoking and coal-mine-dust exposure on obstructive lung disease. 65 Fed. Reg. at 79937-45. It is further indisputable that the preamble supports DOL's conclusions that coal-mine dust can cause COPD, and that the effects of dust and smoking on COPD are similar and additive. Id.; see Harman Min., 678 F.3d at 314 ("The preamble . . . simply sets forth the medical and scientific premises relied on by [DOL]."). The preamble, like the regulation, 20 C.F.R. § 718.201, however, makes no global pronouncement regarding the cause of COPD in all cases. It neither requires nor forbids a physician to attribute COPD to a particular cause in any

individual case. 65 Fed. Reg. 79938, 79941 (miner has the right, but bears the burden, to prove his obstructive lung disease arose out of coal mine employment); *Nat'l Min. Assoc. v. Dep't of Labor* (*NMA*), 292 F.3d 849, 863 (D.C. Cir. 2002) (rejecting industry argument that new rule and preamble "create a presumption that all or most obstructive diseases are caused by exposure to coal dust"). Nor do DOL's regulations, or the preamble itself, mandate consultation with the preamble. Instead, the preamble is available simply as a resource "to give an ALJ understanding of a scientific or medical issue." *Peabody Coal v. Director, OWCP*, 746 F.3d 1119, 1125 (9th Cir. 2014); *see NMA* at 863 (describing as "entirely

<sup>&</sup>lt;sup>17</sup> Blue Mountain contends that an ALJ's consultation of the preamble creates an improper "consistency with the preamble" rule to diminish the credibility of physicians, thus violating both due process and the Administrative Procedure Act. Pet. Br. at 11, 21 (citing 5 U.S.C. § 553, as incorporated by 30 U.S.C. § 936(a)). This is simply wrong. "[N]othing in the preamble . . . suggest[s] that it is binding." *A & E Coal Co. v. Adams*, 694 F.3d 798, 801 (6th Cir. 2012); *accord Harman Min.*, 678 F.3d at 315 (ALJ's citation to the preamble did not "imbue it with the force of law or to transform it into a legislative rule"). And Blue Mountain cites no case where an ALJ or the Board determined that reliance on the preamble is mandatory. Here, for instance, the Board specifically rejected Mr. Gunderson's argument that the ALJ *is required to* consult the preamble. PA at 87 n.6.

meritless" industry's contention that the preamble permits an adjudicator to ignore medical reports ascribing obstructive lung disease to smoking).

Notwithstanding the case-by-case discretion afforded doctors and ALJs, Blue Mountain argues that any consideration of the preamble is prohibited in BLBA cases. This Court has not addressed the issue of whether an ALJ may consult DOL's preamble in resolving scientific disputes. Five other courts of appeals—the Third, Fourth, Sixth, Seventh and Ninth Circuits—have already confronted the issue, however, and have unanimously held that an ALJ may consult the preamble when evaluating whether a miner's lung disease constitutes legal pneumoconiosis. Not only are these

<sup>18</sup> Blue Mountain attempts to distinguish these cases based on how the issues were presented or simply on the company's disagreement with the results. Pet. Br. at 25-28. Counsel for Blue Mountain, however, was also counsel for the coal company in three of these cases and raised the same arguments made here. Blue Mountain's attempt to distinguish the Fourth Circuit's *Harman Mining* decision on the ground that the coal company exaggerated in that case the ALJ's reliance on the preamble, Pet. Br. at 26, is especially noteworthy since counsel here also represented the coal company in that case. In *Harman Mining*, the coal company "vehemently object[ed] to the ALJ's brief invocation of the preamble to the regulations" and "exaggerate[d] [his] reliance on [it]." 678 F.3d at (cont'd . . .)

decisions undoubtedly correct, but it was altogether fitting for the ALJ to consult this scientific resource in answering *Gunderson I's* call "to resolve [this] scientific dispute[] on scientific grounds."

In *Harman Mining*, the Fourth Circuit rejected the coal company's APA contention that the ALJ's citation to the preamble "imbued it with the force of law or transformed it into a legislative rule." 678 F.3d at 315. Instead, the court found that the preamble was simply "a source of explanation as to the Department's rationale in amending the regulations." *Id.* Thus, "]b]ecause the ALJ found Dr. Fino's views conflicted with [the preamble on whether dust exposure can cause disabling COPD], it was well within her

In any event, in each of the cases cited in the ensuing paragraphs, the ALJ looked to the preamble for guidance in evaluating conflicting medical opinions on the cause of a miner's lung disease, and in each case the court of appeals held that he was entitled to do so. These cases, therefore, are powerful persuasive authority (although not controlling, as they are out-of-circuit) in support of our view that an ALJ may consult the preamble.

<sup>(. . .</sup> cont'd)

<sup>313, 314.</sup> The Fourth Circuit's observation holds true here: "although a casual reader of [the coal company's] briefs might assume that the ALJ rested her entire rationale on the preamble, this is simply not the case." 678 F.3d at 314; see supra at 27-31; Gunderson Resp. Br. at 24-32.

discretion to find his opinion less persuasive." *Id.* at 316. It emphasized, however, that "[a]lthough the ALJ did not need to look to the preamble in assessing the credibility of Dr. Fino's views, we conclude that the ALJ was entitled to do so." *Harman Min. Co.*, 678 F.3d at 314-15 (footnote omitted). That court reaffirmed this principle in a later case dealing with the same scientific dispute as the instant case—whether smoking-related COPD can be distinguished from dust-related COPD. *Westmoreland Coal*, 718 F.3d at 323 ("an ALJ may consider the . . . Preamble in assessing medical expert opinions") (citation omitted).

Similarly, the Sixth Circuit held that an ALJ properly consulted preamble in evaluating medical opinions on the causation of COPD, as "the preamble merely explains why the regulations were amended[, but] does not expand their reach." *A & E Coal*, 694 F.3d at 801. That court has twice reaffirmed the holding of *A & E Coal*: Central Ohio Coal Co. v. Director, OWCP, 762 F.3d 483, 491-92 (6th Cir. 2012) ("The sole issue presented here is whether the ALJ was entitled to discredit Dr. Rosenberg's medical opinion because it was inconsistent with the DOL position set forth in the preamble, and the answer to that question is unequivocally yes.")

(citations omitted); *Arch on the Green, Inc., v. Groves*, 761 F.3d 594, 601 (6th Cir. 2014) ("The ALJ did not err when he referred to the preamble to the regulations [in evaluating a physician's opinion].").

The Seventh and Third Circuits have also said that an ALJ can look to the preamble in evaluating medical opinions addressing the cause of a miner's COPD. *Consolidation Coal Co. v. Director, OWCP*, 521 F.3d 723, 726 (7th Cir. 2008) (ALJ according less weight to medical opinion on cause of COPD that was in conflict with preamble was "sensible"); *Helen Min. Co. v. Director, OWCP*, 650 F.3d 248, 257 (3d Cir. 2011) ("[t]he ALJ's reference to the preamble . . . unquestionably supports the reasonableness of his decision to assign less weight to Dr. Renn's opinion.").

Finally, the Ninth Circuit became the most recent court of appeals to address this issue and, unsurprisingly, reached the same conclusion as its sister circuits. After extensively discussing exactly what the preamble says, the court held that "the ALJ simply—and not improperly—considered the regulatory preamble to evaluate conflicting expert medical opinions [on the etiology of a

miner's COPD]"). 19 Peabody Coal Co., 746 F.3d at 1125.

These decisions are plainly right, as consulting the preamble is fully consistent with the long-established principle that reviewing courts should generally give great deference to an administrative agency's determination of scientific or technical matters within its area of expertise. See Marsh v. Oregon Natural Res. Council, 490 U.S. 360, 377 (1989); Baltimore Gas & Elec. Co. v. Natural Res. Defense Council, 462 U.S. 87, 103 (1983). And this principle particularly applies to the federal black lung program, "a complex and highly technical regulatory program," in which the identification and classification of relevant "criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." Pauley v. BethEnergy Mines, Inc.,

<sup>&</sup>lt;sup>19</sup> Contrary to Blue Mountain's contention, Pet. Br. at 28, this is not a principle that first sprang into being after *Gunderson I*. For example, as long ago as 2001, the Seventh Circuit cited the preamble in affirming an ALJ's rejection of a medical opinion asserting that coal-dust inhalation causes no significant obstructive lung disease. It observed that the doctor's opinion is "not in accord with the prevailing view of the medical community or the substantial weight of the medical and scientific literature." *Freeman United Coal Min. Co. v. Summers*, 272 F.3d 473, 483 & n.7 (7th Cir. 2001) (quoting 65 Fed. Reg. 79939).

501 U.S. 680, 697 (1991); accord Midland Coal Co. v. Director, OWCP, 358 F.3d 486, 490 (7th Cir. 2004) ("we see no reason to substitute our scientific judgment, such as it is, for that of the responsible agency," and holding that coal company failed to make required showing that DOL's scientific conclusion that pneumoconiosis can be progressive and latent was not supported by substantial evidence). Blue Mountain's position—which would positively forbid an ALJ from considering DOL's evaluation of the scientific literature on the origins of black lung disease—turns this principle on its head. Thus, this Court should join its sister circuits and reject Blue Mountain's arguments.

Blue Mountain's reliance on far afield cases to support its position is entirely misplaced. Its primary support for the view that the preamble is off limits, *Home Concrete & Supply, LLC v. U.S.*, 634 F.3d 249 (4th Cir. 2011), stands for nothing of the sort.<sup>20</sup> In *Harman Mining*, the Fourth Circuit addressed this precise point and

<sup>&</sup>lt;sup>20</sup> *Home Concrete* involved the Internal Revenue Service's (IRS) attempt to rely on a policy position set forth in a regulatory preamble to extend a limitations period set by statute. 634 F.3d at 257-58.

wasted no words in finding it too dull to hit home:

[Home Concrete] provides a clear example of a regulatory preamble on which any reliance would be problematic. For there we concluded that the preamble contradicted the plain statutory language. 634 F.3d at 256-57. For this reason, we properly refused to defer to the IRS's interpretation of the statute contained in the preamble. By contrast, here, the preamble is entirely consistent with the [BLBA] and its regulations and simply explains the scientific and medical basis for the regulations.

678 F.3d at 315 n.4 (emphasis in original); accord Peabody Coal, 746 F.3d at 1126 (petitioner's reliance on Home Concrete inapposite); A & E Coal, 694 F.3d at 802 (same).

Blue Mountain's reliance on *Wyeth v. Levine*, 555 U.S. 555 (2009), is similarly unavailing. The preamble in question in *Wyeth* addressed a legal issue—the preemptive effect of Food and Drug Administration (FDA) regulations on state law remedies—rather than a scientific or technical one. *Id.* at 577 ("agencies have no special authority to pronounce on pre-emption absent delegation by Congress"). It was also "at odds with what evidence we have of Congress' purposes" and, to top it off, "revers[ed] the FDA's own longstanding position without providing a reasoned explanation[.]" *Id.* None of these facts are true of the regulatory preamble at issue in this case. *See Peabody Coal*, 746 F.3d at 1126 (distinguishing

Wyeth preamble from DOL's regulatory preamble).

Finally, Blue Mountain's reliance on *Natural Res. Defense*Council v. South Coast Air Quality Mgmt. Dist., 651 F.3d 1066 (9th Cir. 2011); El Comite Para Bienestar de Earlimart v. Warmerdam,
539 F.3d 1062 (9th Cir. 2008); and Wyoming Outdoor Council v. U.S.

Forest Service, 165 F.3d 43 (D.C. Cir. 1999), is also misplaced.<sup>21</sup> All of these cases dealt with the question of whether a preamble may be used to interpret a regulation, not whether the preamble may be

<sup>&</sup>lt;sup>21</sup> Blue Mountain also cites *Christensen v. Harris County*, 529 U.S. 576 (2001), arguing that the Supreme Court there "criticized [DOL] for seeking deference for its views expressed in a preamble . . . . " Pet. Br. at 24. *Christensen*, however, did not involve a regulatory preamble. Rather, it involved an opinion letter which contained an interpretation of a regulation. 529 U.S. at 581. Moreover, the opinion letter interpreted the regulation (which addressed the use of compensatory time under the Fair Labor Standards Act) in a manner that the Court found directly contrary to the plain language of the regulation. See 529 U.S. at 586-88. Here, by contrast, the preamble (in relevant part) discusses how DOL evaluated scientific evidence on the relationship of coal-mine dust to COPD, and is fully consistent with the regulation at issue, 20 C.F.R. § 718.201. See Harman Min., 678 F.3d at 315, n.4 ("the preamble is entirely consistent with the . . . regulations"). Thus, Christensen has no relevance here.

consulted in evaluation of scientific evidence.<sup>22</sup> Here, by contrast, Section 718.201 unambiguously defines both clinical and legal pneumoconiosis and plainly requires that for a pulmonary disease such as COPD to be compensable it must be "significantly related to, or substantially aggravated by, dust exposure in coal mine employment." 20 C.F.R. § 718.201(a), (b). The preamble is not needed to interpret these clear provisions. Rather, it "simply sets forth the medical and scientific premises relied on by [DOL] in coming to these conclusions in its regulations," *Harman Min.*, 678 F.3d at 314, and an ALJ may consult it to aid in him in "understanding [] a scientific or medical issue." *Peabody Coal*, 746 F.3d at 1125.

<sup>&</sup>lt;sup>22</sup> Natural Resources Defense Council and El Comite held that the regulations at issue in those cases were unambiguous and, therefore, the court would not look to the preambles in interpreting them. 651 F.3d at 1073; 539 F.3d at 1070. In Wyoming Outdoor Council, by contrast, the court noted that '[a]lthough the preamble does not 'control' the meaning of the regulation, it may serve as a source of evidence concerning contemporaneous agency intent." 165 F.3d at 53. Although the regulation at issue there was ambiguous (permitting resort to the preamble to aid in its interpretation), the court found it of no assistance, as the preamble also was ambiguous. Id.

In sum, Blue Mountain is wrong that the preamble represents a legislative rule. Instead, it simply summarizes the medical authorities that DOL relied upon in revising the regulations. An ALJ is not required to consult the preamble when he evaluates medical opinions on a disputed scientific or medical issue, but he is entitled to consult it (if he so chooses) to aid in his resolution of such issues.

# D. The ALJ did not abuse his discretion in refusing to reopen the record for the submission of additional evidence challenging the preamble.

Finally, Blue Mountain contends that the ALJ erred in not reopening the record (at the time of his third decision and seven years after the record had closed) despite its failure to identify evidence challenging the preamble's evaluation of the scientific literature regarding the impact of coal-dust exposure and smoking on obstructive lung disease. Blue Mountain, however, fails to show that the ALJ abused his discretion in refusing to reopen the record. See Gunderson I, 601 F.3d at 1021 (ALJ's evidentiary rulings reviewed under abuse-of-discretion standard). Thus, the Court should reject the company's argument.

As an initial matter, Blue Mountain's assertion that the ALJ

could not consider the preamble unless the document itself was made part of the evidentiary record (with notice and opportunity to respond) is wrong. *See* 5 U.S.C. § 556(e) (requiring that the factual basis for an ALJ decision must be "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding"). As the Fourth Circuit explained, however,

the APA does not provide that public law documents, like the [BLBA], the regulations, and the preamble, need be made part of the administrative record. [The operator] cites no authority supporting its contrary view and we have found none.

Harman Min., 678 F.3d at 316. The Sixth Circuit subsequently adopted the Fourth Circuit's holding on this point. A & E Coal, 694 F.3d at 802 (adopting holding of Harman Min.). Blue Mountain adduces no contrary authority.<sup>23</sup> Thus, this Court should join the Fourth and Sixth Circuits in holding that the preamble, as a public law document, does not have to be made part of the administrative

<sup>&</sup>lt;sup>23</sup> Blue Mountain cites *Camp v. Pitts*, 411 U.S. 138, 143 (1973), and *S.E.C. v. Chenery Corp.*, 318 U.S. 80 (1943), but neither case says anything about whether public law documents must be made part of the administrative record before an adjudicator can consider them. Thus, they are not germane to Blue Mountain's argument.

record before an adjudicator can consider it.

Blue Mountain's contention that the ALJ erred in not reopening the record for it to submit additional evidence challenging the preamble's evaluation of the scientific literature on the etiology of COPD fares no better. The company knew of the preamble and the dispute regarding the cause(s) of Mr. Gunderson's COPD well before the hearing in this case. In fact, its experts identified authorities purporting to support their view that smoking-related COPD could be distinguished from dust-related COPD, which Blue Mountain timely submitted into the record. Nonetheless, Blue Mountain's waited seven years after the hearing to attempt to submit additional evidence on this point. For this exceedingly untimely request, Blue Mountain has failed to establish good cause, and the Court should hold that the ALJ did not abuse his discretion in rejecting it.

Blue Mountain's claim that it did not know the preamble might be considered or how it would be relevant, or that it did not have the opportunity to submit evidence on the key point of scientific dispute, rings hollow. The key dispute here—whether Mr. Gunderson's COPD is due (in part) to coal-mine-dust exposure or

due entirely to smoking—was apparent early on.<sup>24</sup> Blue Mountain's experts believed that they could distinguish between smoking-related COPD and dust-related COPD and cited medical literature purporting to support their view. Mr. Gunderson's experts disagreed, relying in part on the preamble's discussion of scientific evidence showing that the contributions of dust and smoking to COPD are similar and additive. 65 Fed. Reg. 79943; see Westmoreland Coal, 718 F.3d at 323. The ALJ ultimately did not believe Drs. Repsher and Renn (properly so, see supra at 26-29), but Blue Mountain cannot legitimately claim that it lacked the opportunity to validate views that disagreed with Mr. Gunderson's experts and the preamble.

The real gravamen of Blue Mountain's argument is that the ALJ should have given it another bite at the apple before he rendered his third decision in this case, seven years after the record

<sup>&</sup>lt;sup>24</sup> The preamble was published in the Federal Register on December 20, 2000 (65 Fed. Reg. 79920), six months *before* Mr. Gunderson filed his claim and over five years before the ALJ hearing. Blue Mountain thus had notice of its contents well before the record closed. *See* 44 U.S.C. 1507; *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384-85 (1947); *George v. U.S.*, 672 F.3d 942, 944-45 (10th Cir. 2012).

closed.<sup>25</sup> The regulations, however, expressly provide that medical evidence must be exchanged with other parties at least twenty days before a hearing (which occurred on May 18, 2006 in this case). 20 C.F.R. § 725.456(b)(2). After that point, medical evidence can only be admitted upon a showing of good cause. 20 C.F.R. § 725.456(b)(3). As with other matters related to the admission or exclusion of evidence, it is within the ALJ's discretion to determine whether good cause exists for the admission of late evidence. See Gunderson I, 601 F.3d at 1021. Other than repeated conclusory assertions that it is entitled to submit additional evidence, however, Blue Mountain failed to provide any reason why it should be able to submit additional evidence so long after the period for doing so had expired. Thus, it cannot now show that the ALJ abused his discretion in refusing to reopen the record.

There is another related reason to reject Blue Mountain's argument—it did not (contrary to its assertion) actually proffer the

<sup>&</sup>lt;sup>25</sup> Notably, despite its assertion that "the preamble has stalked this case" since the Court's prior decision, Pet. Br. at 17, Blue Mountain did not request an opportunity to submit additional evidence when the case was first returned to the ALJ following *Gunderson I*.

preamble-invalidating evidence it intended to submit.<sup>26</sup> After the Board remanded the case to the ALJ in 2012, Blue Mountain requested that the ALJ reopen the record "so that new medical evidence may be brought to bare [sic]," PA at 92, but did not identify the evidence it wanted to submit or the issue to which such evidence might relate. After Mr. Gunderson responded in opposition to this request, Blue Mountain filed a reply, in which it cited various medical literature (including NIOSH's *Criteria* and other studies cited in the preamble), but did not actually submit these articles to the ALJ or suggest that they invalidated the

<sup>&</sup>lt;sup>26</sup> In this context, it is notable that in 2011, sixteen years after the publication of the *Criteria*, NIOSH re-examined the interplay of dust and smoking in relation to COPD in coal miners, and surveyed the scientific literature published since the *Criteria*. Current Intelligence Bulletin 64, *Coal Mine Dust Exposure and Associated Health Outcomes*, *A Review of Information Published Since 1995* (2011) (available on the Internet at http://www.cdc.gov/niosh/docs/2011-72/) (hereafter "Current Intelligence Bulletin 64"). NIOSH concluded from the review of new information that the "new findings strengthen [the] conclusions and recommendations [reached in the original *Criteria*]." *Id.* at 5. Among other findings, the Bulletin confirms that coal-mine dust can cause or aggravate COPD, and that dust and smoking have similar effects. *Id.* at 23-24.

preamble's conclusions.<sup>27</sup> PA at 93-98. Instead, Blue Mountain merely argued that the preamble was not applicable to an individual claim and implied that the literature the company cited (but which its physicians had not relied upon) was not inconsistent with the preamble.<sup>28</sup> PA at 93-97.

This failure to timely proffer evidence that supposedly

<sup>&</sup>lt;sup>27</sup> In fact the only post-preamble study cited by Blue Mountain (Kohansal et al., The Natural History of Chronic Airflow Obstruction Revisited, An Analysis of the Framingham Offspring Cohort, 180 Am. J. Resp. Crit. Care Med. 3 (2009)) was a longitudinal study of smokers in one Massachusetts city, and did not address the effects of coal-mine-dust exposure. This is plainly not "the type and quality of medical evidence that would invalidate the DOL's position in th[e] scientific dispute [on the etiology of COPD in coal miners]." Central Ohio Coal, 762 F.3d at 492 (internal quotation and citation omitted). Simply relying on articles purporting to reach a different conclusion than the preamble—particularly an article that does not even address the effects of coal-mine-dust exposure—is plainly insufficient. See id. at 491; Westmoreland Coal, 718 F.3d at 324 (disapproving of physician's reliance on literature, "none of which appears to even discuss the effects of coal mine dust exposure on the lungs"); cf. Current Intelligence Bulletin 64 at 23-24 (NIOSH's affirmation, based on survey of literature published between 1995 and 2011, of earlier conclusion that effects of coal-mine dust and smoking on COPD are similar).

<sup>&</sup>lt;sup>28</sup> Likewise, when Blue Mountain sought reconsideration of the ALJ's third decision, it failed to identify or submit any additional evidence "challenging statements in the preamble." *See* PA at 117-18.

invalidated the preamble's conclusions is another reason for rejecting Blue Mountain's argument. As this Court held in an appeal of a district court decision, the failure of a party to proffer evidence forecloses a later challenge to the exclusion of that evidence. *Ploys v. Trans-Colorado Airlines, Inc.*, 941 F.2d 1404, 1406-07 (10th Cir. 1991). Moreover,

merely telling the court the content of . . . proposed testimony is not an offer of proof. . . . Rather, . . . the proponent must explain what it expects to show and the grounds for which the party believes the evidence to be admissible.

941 F.2d at 1407 (internal quotations and citations omitted).<sup>29</sup> Blue Mountain made no such proffer here. Thus, it cannot now complain about the ALJ's refusal to reopen the record.

Perhaps sensing the fatal defects in its position, Blue

Mountain now conjures two alleged "changes" since the submission

<sup>&</sup>lt;sup>29</sup> *Polys* involved Federal Rule of Evidence 103. The federal rules, of course, are not directly applicable to the adjudication of BLBA claims. *See* 33 U.S.C. 923(a), as incorporated 30 U.S.C. § 932(a) (BLBA factfinders not "bound by common law or statutory rules of evidence"). That said, the underlying purposes of Rule 103—that the fact-finder have an opportunity to "to make an informed evidentiary ruling," and the creation of "a clear record" for appellate review, *Polys*, 841 F.2d at 1406-1407—support the ALJ's refusal to reopen the record here.

of its original evidence—either a change in the law, or a change in DOL's view of the law—justifying its request to submit additional evidence. This argument collapses under its own weight.

Blue Mountain's legal-change argument relies on three Sixth Circuit cases which held that a coal-mine operator was entitled to submit new evidence after that court imposed a new legal standard making the operator's defense of BLBA claims more difficult: Cal-Glo Coal Co. v. Yeager, 104 F.3d 827, 831-32 (6th Cir. 1997); Peabody Coal Co. v. Greer, 62 F.3d 801, 804 (6th Cir. 1995); Harlan Bell Coal Co. v. Lemar, 941 F.2d 1042, 1045 (6th Cir. 1990); see 20 C.F.R. § 727.203 (2000). Blue Mountain, however, does not identify what change in the law has occurred here. And that is because there has been no change. The regulations governing Mr. Gunderson's claim, 20 C.F.R. § 718.201 in particular, took effect on January 19, 2001 (see 20 C.F.R. § 718.2). Under those provisions, Mr. Gunderson can recover based on his COPD if the medicalopinion evidence establishes that it is legal pneumoconiosis, 20 C.F.R. § 718.201(a)(2), but he must prove that his COPD was "significantly related to, or substantially aggravated by, dust exposure in coal mine employment. 20 C.F.R. § 718.201(b); see

Andersen, 455 F.3d at 1105. That is the rule and standard applied by the ALJ here. No change has occurred

There is another legal requirement which has not changed during the course of this litigation: ALJs are required to resolve scientific disputes in black lung cases on scientific grounds—that is, they must carefully analyze the rationales provided by physicians and determine whether the doctors' conclusions are well-supported and make sense. *Gunderson I*, 601 F.3d at 1022-23 (citations omitted). What changed here is that the ALJ failed to meet this requirement in his first two decisions, but finally did so in his third. Arriving at a reasoned decision is not a "legal change," and does not open the door to new evidence.

Similarly, Blue Mountain's contention that the Director has changed his position on what a miner must prove to recover when he has COPD is also groundless. When the current regulations were promulgated, DOL took pains in the preamble to emphasize that the burden is on a miner to show that his lung disease arose out of coal-mine employment in order to establish that he has legal pneumoconiosis. 65 Fed. Reg. 79937; *see NMA*, 292 F.3d at 862-63. According to Blue Mountain, DOL "changed its mind [after the

regulations were promulgated] and now believes that a claimant with COPD does not need to prove causation anymore." Pet. Br. at 31.

But the Court's own case law refutes this contention. In *Andersen*, the Court held that a miner with COPD could not take advantage of a causation presumption related to *clinical* pneumoconiosis, but must affirmatively prove that his disease arose out of coal-mine-dust exposure in order to recover. 455 F.3d at 1105. In so doing, the Court agreed with DOL, which *supported the denial* of Andersen's claim precisely because he lacked the requisite proof. *See* 2005 WL 3657915, \*\*8-21 (Brief of the Federal Respondent). Thus, DOL's position on this point has not changed.

In short, Blue Mountain's request to reopen the record came with far too little and came far too late. The Court should hold that the ALJ did not abuse his discretion in refusing to reopen the record.

### CONCLUSION

The Director requests that the Court affirm the decisions of the ALJ and Board awarding Mr. Gunderson's claim.

Respectfully submitted,

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# STATEMENT REGARDING ORAL ARGUMENT

The Director believes that this case, at base, is the ALJ's unchallenged factual findings, and does not actually present the legal issues raised by Petitioner. Thus, we do not believe that oral argument is necessary. We will, however, be happy to participate if the Court deems oral argument beneficial.

# CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with 1) the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 11,103 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and 2) the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Word 2010 in fourteen-point Bookman Old Style font.

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I hereby certify that on January 21, 2015, an electronic copy of the foregoing pleading was served via the CM/ECF system, and paper copies were served via first-class mail, on the following:

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