

assumptions that have led to incorrect estimates of the percent of miners who would be at reduced risk on the new plan, and have misrepresented the degree of risk reduction among the miners who would have reduced risk." In support of this position, Nicolich and Gamble argued that (a) the sample data on which the QRA was based were not independent and (b) that the distribution of values by which concentrations exceeded the applicable dust standard was likely to be skewed and would, therefore, be better represented by its median than by its mean. They argued, further, that as a consequence of (a), the estimated "number of workers that will have reduced risk will likely be too high and the degree of risk among these fewer workers will be under-estimated * * *" and that, as a consequence of (b), "the degree of risk reduction among the miners experiencing over-exposure will likely be too large (because of an overestimate of the intensity of the exposure of the over-exposed miners)."

Both parts of this argument are flawed. The discussion that Nicolich and Gamble offer in support of (a) has nothing to do with independence of sample data and provides no basis for concluding that MSHA has overestimated the percentage of miners expected to experience reduced risk if overexposures on individual shift are eliminated. It should also be noted that this part of their argument involves an apparent misunderstanding of how MSHA estimated the number of miners that would be affected by this rule. Contrary to Nicolich and Gamble's line of reasoning, the estimated percentage of shifts exceeding the applicable dust standard at MMUs exhibiting a pattern of recurrent overexposures was not used to estimate the size of the mining population at risk. It is true that the number of affected miners used in calculating benefits was estimated from the proportion of MMUs exhibiting a pattern of recurrent overexposures (see section IX.A.2. Benefits). However, this estimate would remain the same, regardless of the overexposure rate observed for MMUs defined as exhibiting a pattern. It is also true that if a more stringent criterion were used to define MMUs exhibiting a pattern, then fewer MMUs (and, therefore, fewer miners) would be included in the benefit estimates. The rule, however, applies to all MMUs, not just those defined as exhibiting a pattern of recurrent overexposures for purposes of the QRA. Therefore, adopting a more stringent criterion for recurrence would simply mean that additional miners

benefitting from the rule would be left out of the benefit estimates.

Furthermore, the second part of their argument (b) is not relevant to the calculation of the accumulated effect of individual shift exposures, as modeled by the Attfield/Seixas model being employed. In support of their position, Nicolich and Gamble present the example of nine laborers who earn \$10,000 per year and a boss who earns \$100,000 per year and point out that the mean income "is not a good measure of the 'typical value.'" They then propose (based on no supporting data other than that of this example) that the median would be a better measure of the "typical" degree by which individual shift overexposures exceed the applicable dust standard.

Nicolich and Gamble fail to consider that the objective is not to estimate a "typical" degree of excess but, rather, to estimate the total degree of excess, accumulated over an occupational lifetime. The variable used in the Attfield/Seixas model is cumulative exposure, defined by the product of exposure duration and mean "intensity" (i.e., dust concentration), not median intensity. In the example of nine laborers and a boss, the total annual payout is ten times *mean* salary, not median salary. Similarly, cumulative exposure is given by the product of exposure duration and *mean* intensity regardless of the shape of the statistical distribution of excess dust concentrations. Since MSHA's use of the mean value fully accords with the Attfield/Seixas model employed, the commenters have provided no basis for concluding that MSHA has overestimated the degree of risk reduction to be expected among miners experiencing individual shift overexposures.

(2) According to Nicolich and Gamble, "[t]he Attfield and Seixas model does not take into account the over-exposures identified by MSHA." Based on this premise, they argue that "the estimates of exposure in the model are less than actual exposure and the E-R [i.e., exposure-response] slope is steeper than the actual slope." More specifically, they attempt to show that Attfield and Seixas should have estimated the mean concentration for face occupations to be 1.57 mg/m³ rather than 1.46 mg/m³. From this, they conclude that "[t]he toxicity of coal mine dust is therefore over-estimated."

This argument is based on the false premise that individual shift overexposures were not included in the data from which the Attfield/Seixas model was generated. Contrary to Nicolich and Gamble, however, neither

MMUs with a pattern of recurrent overexposures nor individual shift overexposures *per se* were excluded from the data used by Attfield and Seixas. Therefore, contrary to their argument, the existence of such overexposures does not create a "bias in exposure estimates" that "produces an overestimate in the toxicity of coal mine dust." Specifically, the value of 1.46 mg/m³ used by Attfield and Seixas to represent the mean concentration for faceworkers already includes those measurements exceeding the applicable dust standard. Therefore, the corresponding value (1.57 mg/m³) proposed by Nicolich and Gamble essentially double-counts those measurements.

(3) According to Nicolich and Gamble, "[t]here is a background prevalence of CWP that is not related to coal mine dust exposure" and "prevalences that occur at zero exposure should be subtracted from the observed prevalence." Nicolich and Gamble failed to note that background prevalences have no bearing on the expected reductions in risk as calculated and presented in this risk assessment. All estimates of expected risk reduction in this QRA are based on calculating a difference between two estimated risks: with and without the elimination of individual shift overexposures accumulated over an occupational lifetime. Both of these estimated risks include the same background effect that is not attributable to coal mine dust exposure. Therefore, any background effect is canceled out when the difference is calculated. The estimated reduction in risk is, according to the Attfield/Seixas model, free of any background effect.²⁷

(4) Nicolich and Gamble criticized the use of irregular opacities as indicating coal workers' pneumoconiosis. However, studies have shown that the prevalences of both small rounded and small irregular opacities increase with increasing years worked underground (Amandus *et al.*, 1976; Cockcroft *et al.*, 1983) and with increasing coal mine dust exposure (Collins *et al.*, 1988). The relationship between irregular opacities and coal mine dust exposure has been observed among both smokers and nonsmokers (Cockcroft *et al.*, 1983). Amandus *et al.* (1976) found that smoking, age, and years underground

²⁷ Although it is canceled by subtraction when estimating the effect of reducing cumulative exposure, the Attfield/Seixas model does, in fact, incorporate an age-dependent background effect. Therefore, since the model allows for a positive response at zero exposure, the slope of the exposure-response relationship is not artificially inflated.