EXECUTIVE SUMMARY

On October 15, 1990, Congress passed the Radiation Exposure Compensation Act of 1990 (RECA), which provided for compassionate payments to individuals who suffered from specified diseases presumably as a result of exposure to radiation in connection with the federal government's nuclear weapons testing program. Among those eligible for compensation under the Act are individuals who were employed in underground uranium mines in Arizona, Colorado, New Mexico, Utah or Wyoming during the 1947 to 1971 time period, who were exposed to specified minimum levels of radon, and who contracted specified lung disorders. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program (Program).

The provisions of the RECA defining compensation for uranium miners have been characterized by critics as unfair and inconsistent with current scientific information. The regulations of the Department of Justice implementing the statute have also been criticized as being unnecessarily stringent and unreasonably burdensome. These criticisms were noted, and in some cases affirmed, by the President's Advisory Committee on Human Radiation Experiments, charged by the President to investigate the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, issued on October 3, 1995, the Advisory Committee recommended, among other things, that the Administration review the provisions of RECA governing compensation for uranium miners and the implementing regulations to ensure that they are fair, consistent with current scientific evidence, and compatible with the objectives of the Act.

In response to this recommendation, the Human Radiation Interagency Working Group established a committee of government scientists and attorneys to study the RECA provisions relating to underground uranium miners and the Department's implementing regulations. The Interagency Working Group charged the committee to respond within six months with a list of recommended statutory amendments and modifications to the regulations. The accompanying Report is intended to fulfill this obligation.

Listed below is a summary of the Committee's recommended changes to the statute and implementing regulations.

I. Proposed Amendments to the Statute

RECOMMENDATION 1:	**Amend the Act to incorporate a new set of compensation criteria for lung cancer based on minimum levels of radon exposure**

The legislative history of the RECA convinces us that Congress set the exposure criteria at a level it thought would compensate those miners whose lung cancer more likely than not was caused by their exposure to radon progeny in the mines. The latest epidemiological data suggest that the current exposure criteria do not accurately distinguish among lung cancer cases on a "more likely than not" basis, and, therefore, do not effectively implement congressional intent. The present statutory criteria, we conclude, exclude some deserving miners and inappropriately compensate others.

In place of the present criteria, we recommend alternative exposure-based criteria that more accurately effect congressional intent. To generate these criteria we modified a relative risk model developed by the National Research Council's Committee on the Biological Effects of Ionizing Radiations (BEIR IV), and applied it to updated cohorts of Colorado Plateau and New Mexico underground uranium miners. The model conditions compensation on the variables that the latest data indicate most significantly affect the risk of lung cancer in underground uranium miners: cumulative exposure to radon progeny, attained age (the age at which the claimant developed cancer), and time since last exposure.

RECOMMENDATION 2:	**Amend the Act to incorporate an alternative set of criteria conditioning compensation on minimum duration of employment**

The present RECA criteria and the alternatives discussed in Recommendation 1, above, are based in part on a measure of the claimant's cumulative exposure to radon, which is calculated from historical measurements of radon levels in the mines. These historical measurements are widely believed to be inaccurate and imprecise measures of miners' true exposures; for many mines, measurements either do not exist at all or do not exist for all work areas. Using the modified BEIR-IV risk model, we generated compensation criteria for lung cancer based on duration of employment underground in uranium mines, instead of cumulative exposure.

The exposure-based criteria we propose better "fit" the observed

data, and will, therefore, result in a more valid characterization of a miner's risk than the proposed employment duration-based criteria. Nonetheless, we recommend a claimant should be allowed to qualify under either the exposure or duration standard.

RECOMMENDATION 3:	**Amend the Act to condition compensation for nonmalignant respiratory disease on different criteria**

The present statutory criteria require that a claimant prove exposure to minimum levels of radon as a condition for compensation for one of the specified nonmalignant respiratory diseases (NMRD) -- pulmonary fibrosis, corpulmonale related to fibrosis, silicosis and pneumoconiosis. Although it is physiologically plausible that radon causes pulmonary fibrosis, or contributes to the development of silicosis, the two principal compensable NMRDs, the prevailing hypothesis in the scientific community is that the more likely cause of these diseases is exposure to various agents in the mining environment, most notably silica and other dusts. The radon levels in a mine are not believed to be a good proxy for dust levels, so there is no scientifically justifiable reason to tie NMRDs to radon exposure levels.

Unlike the case with lung cancer, above, we do not recommend specific alternative criteria in this case. It is unclear whether and to what extent reliable data are available, and whether appropriate standards can be derived from available data. The Committee did not have the time to identify and analyze the extant data. We recommend that such a project be undertaken.

RECOMMENDATION 4:	**Amend the Act to extent compensation for silicosis or pneumoconiosis to all miners covered by the Act**

The RECA limits compensation for two NMRDs -- silicosis and pneumoconiosis -- to miners who were employed in mines on an Indian reservation. The principal risk factor for silicosis (or pneumoconiosis) is the amount of silica released in the mining environment. The mines both off and on the Navajo Reservation were in silica-bearing rock, and there is no reason to believe the risk of silicosis was any greater in mines on than off the Reservation. We recommend that this statutory limitation be eliminated.

II. Recommended Modifications to the Department of Justice Regulations

RECOMMENDATION 5: **Modify the regulations to presume all Native Americans are nonsmokers, absent evidence to the contrary**

The existing compensation criteria for both lung cancer and NMRDs set different minimum exposure levels depending on a claimant's smoking status; smokers must meet a higher exposure threshold, presumably to offset the risks from smoking. The regulations define a smoker as one who has smoked one pack-year of cigarettes or more. Smoking status is generally derived from references in historical health records. Most smoking information in the records is self-reported. The overwhelming number of Native American underground uranium miners were Navajo. Navajo generally smoked only for ceremonial purposes or not at all; those who smoked did so at substantially lower rates than their White counterparts. Nonetheless, many Navajo reported themselves as smokers, though their consumption was less than one pack-year. We recommend, therefore, that all Native American's be considered nonsmokers, absent evidence in any individual's record of a smoking rate greater than one pack-year.

RECOMMENDATION 6: **Modify the definition of nonsmoker in the regulations to include certain ex- smokers**

The regulations presume that once a smoker, always a smoker. The latest evidence suggests that the risk of lung cancer in an ex-smoker declines over time, approaching, though possibly never returning, to the background risk of a nonsmoker. The rate of decline of risk depends, among other factors, on the number of cigarettes smoked per day, the number of years the individual smoked, their age at time of cessation, and the years since cessation. We recommend that a claimant be classified as a nonsmoker if he can prove he stopped smoking at least 15 years before diagnosis of lung cancer.

RECOMMENDATION 7: **Modify the regulations to allow proof of NMRD by HRCT scans**

The regulations require that a claimant prove both physical changes indicating the presence of a compensable NMRD and functional pulmonary impairment. Proof of the presence of disease is made by submitting chest radiographs (x-rays) interpreted by two "B"-readers, physicians specially certified by National Institute for Occupational Safety and Health (NIOSH) as proficient in the classification of radiographic evidence of pneumoconioses

(occupational dust-induced lung diseases). It is well established that chest radiographs, even when interpreted by "B"-readers, have significant false negative and false positive rates. Thus, a claimant with evidence of functional impairment may be denied compensation because a chest radiograph does not show evidence of disease; conversely, a chest radiograph may falsely be read to show evidence of a compensable disease though that disease is not in fact present. Because of the false negative rate associated with the detection of pneumoconioses by chest radiograph, some critics argue that the Program should dispense with the requirement that the claimant submit radiographic evidence of disease process.

We recommend that the Program continue to require radiographic proof of disease. We further recommend that the Program accept high-resolution computed tomography (HRCT) scans as proof of change to lung structure where the claimant has proven physiological pulmonary impairment yet chest radiographs are negative. HRCT is a more sensitive and specific diagnostic technology: in an appreciable number of cases, it will pick up disease that does not appear on chest radiographs, and allows for more accurate diagnosis.

RECOMMENDATION 8:	**Modify the regulations to allow proof of disease process by biopsy from all miners**

The regulations allow surviving beneficiaries to prove a deceased miner had a compensable NMRD through biopsy results, but do not allow living miners to submit this form of proof. This was done to avoid creating an incentive among living miners for invasive and dangerous surgery. Biopsy results, however, are the "gold" standard for diagnosis. We recommend that where a biopsy is performed for a medically-justified reason independent of the desire for compensation, it be accepted as proof of lung abnormality. We also recommend the Program reserve the right to demand appropriate medical evidence demonstrating the justification for the procedure.

RECOMMENDATION 9:	**Modify the regulations to establish a random audit procedure for "B"-reader reports**

The diagnosis of fibrosis or pneumoconiosis by chest radiograph is an inexact science. It is well established that there is significant variability in radiographic interpretation among readers, including "B"-readers, particularly where the disease is in a mild state. The Program has the interpretive reports of some "B"-readers reviewed by experts selected by NIOSH where there may be a question about

the accuracy of the interpretation. Some in the affected community perceive the Program as selectively reviewing the reports of the most "liberal" "B"-readers, and thus evidencing a bias against compensation. Some critics also recommend dispensing with the "B"-reader requirement as unnecessary.

We recommend that the Program retain the requirement that chest radiographs be interpreted by certified "B"-readers. We further recommend that the Program adopt an audit procedure that will provide for the review of all "B"-readers, and thus protect against the possibility of improper application of the professional diagnostic standards, yet eliminate the possibility of selective enforcement.

RECOMMENDATION 10:	**Modify the pulmonary function standards in the regulations to define impairment consistent with the recommendations of the ATS**

As noted in Recommendation 10, above, the regulations define impairment as 25% or more reduction in lung function as measured by pulmonary function tests. The American Thoracic Society (ATS) and American Medical Association (AMA) recommend guidelines that define impairment as more than a 20% reduction, measured against standard reference values. We recommend that the regulations be modified to define impairment consistent with the guidelines recommended by the ATS and AMA.

I. INTRODUCTION

On October 15, 1990, Congress enacted and the President signed into law P.L. 101-426, the Radiation Exposure Compensation Act of 1990 ("RECA" or "Act"). The Act established a procedure to make partial restitution to three classes of individuals who were put at serious risk by the federal government's nuclear weapons testing program during the Cold War era, and who, presumably as a result of exposure to resulting radiation, developed certain diseases.[1] The three classes of eligible claimants recognized in the Act are: individuals who lived downwind of the Nevada Test Site during designated time periods when above-ground nuclear tests were conducted, and who suffer(ed) from any of thirteen radiogenic malignant diseases; Department of Defense and Department of Energy personnel and contractors physically present at one of the federal government's nuclear testing sites during an atmospheric detonation of a nuclear device, and who suffer(ed) from any of thirteen radiogenic malignant disease; and individuals employed in underground uranium mines in five states during a designated time period, and who suffer(ed) from either lung cancer or a specified

nonmalignant respiratory disease.[2] The Act provides a set level of compensation to an eligible claimant (defined to include the exposed individual or specified surviving beneficiaries) in each class: a "downwinder" receives $50,000; an "on-site participant" receives $75,000; and a uranium miner receives $100,000.[3]

With regard to the class of uranium miners, Congress specifically found in the Act that:

> [R]adiation released in underground uranium mines that provided uranium for the primary use and benefit of the nuclear weapons program of the United States Government exposed miners to large doses of radiation and other airborne hazards in the mine environment that are presumed to have produced an increased incidence of lung cancer and respiratory diseases among these miners; ....[4]

The Act provides compensation to miners who were employed in underground uranium mines in the states of Arizona, Colorado, New Mexico, Utah and Wyoming during the period January 1, 1947 through December 31, 1971, and who contracted either lung cancer or one of the following nonmalignant respiratory diseases: "fibrosis of the lung, pulmonary fibrosis, and corpulmonale related to fibrosis of the lung; and if the claimant, whether Indian or non-Indian, worked in an uranium mine located on or within an Indian Reservation, the term shall also include moderate or severe silicosis or pneumoconiosis; ...."[5] The Act further requires proof that the miner was exposed to specified minimum levels of radiation, the specific level depending on the miner's age when the disease develops and whether the miner was a smoker or nonsmoker.[6]

The Act delegated responsibility for establishing regulations for the submission and payment of claims to the Attorney General.[7] On April 10, 1992, the Department of Justice issued final regulations implementing the Act; the regulations became effective May 11, 1992.[8] The regulations define the proof claimants are required to submit to demonstrate entitlement to compensation. The Attorney General established the Radiation Exposure Compensation Unit ("the Program") in the Civil Division of the Department of Justice to administer the Act and regulations. The Program has been accepting and paying qualifying claims since May 1992.

On October 3, 1995, the President's Advisory Committee on Human Radiation Experiments (Advisory Committee) submitted its Final Report to the President and the Human Radiation Interagency Working Group (IAWG). In its Final Report, the Advisory Committee documented the results of its investigation into various

Cold War-era activities of the federal government, including the government's relationship to the uranium miners in the American West. The Advisory Committee concluded that the federal government wronged the uranium miners by allowing them unwittingly to be exposed to radiation hazards, and by studying the health effects of their exposures without adequate consent and disclosure.[9]

During the course of its investigation, the Advisory Committee received testimony asserting that the eligibility criteria in the RECA relating to uranium miners were not consistent with the latest scientific information.[10] Additionally, the Advisory Committee heard testimony critical of both the Department of Justice's implementing regulations and its administration of the Act. As summarized by the Advisory Committee, "since 1990, there has been considerable experience with the administration of the act, and apparently much of it has been negative."[11]

In the Final Report, the Advisory Committee included the following recommendation:

> The Advisory Committee recommends to the Human Radiation Interagency Working Group that it, together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to all miners who develop lung cancer after some minimal duration of employment underground (such as one year), without requiring a specific level of exposure. The act should also be reviewed to determine whether the documentation standards for compensation should be liberalized.[12]

In response to this recommendation the IAWG requested that the Department of Justice establish a committee of government scientists and attorneys to review the Act and the implementing regulations to ensure that they are fair, comparable to compensation standards for other radiation-exposed populations, and consistent with current scientific data. The IAWG requested that the designated committee recommend to the Administration within six months possible statutory changes to be proposed to Congress and appropriate amendments to the Department's existing regulations.

Acting upon this request, the Attorney General, through the offices of the Deputy Assistant Attorney General for the Civil Division, established the present Committee.[13]

The Committee, which first met in January 1996, has reviewed

much of the published criticism of RECA. We reviewed all the critical testimony submitted to the Advisory Committee; the 1993 RECA oversight hearings before the Senate Committee on Labor and Human Resources; and many of the comments on the Department's regulations submitted by interested parties prior to and since the promulgation of the regulations. We spoke with leading researchers following the Colorado Plateau and New Mexico mining populations, Indian Health Service and private physicians who regularly treat uranium miners, officials and representatives of the Navajo Nation, former miners, claimants' attorneys, and other claimants' consultants and advocates. Some of the individuals with whom we spoke had previously provided testimony to the Advisory Committee and the 1993 congressional oversight hearings.

We also interviewed members of the Program staff to learn their concerns regarding the existing statutory and regulatory scheme, and to obtain the Program's response to the criticisms we heard. We feel obliged to note our perception that the Program staff often go to impressive and commendable lengths to aid claimants. In the course of our admittedly limited investigation, we found little evidence to support the perception in some of the affected communities that the Program staff is biased against compensation or seeks to deny compensation where possible. While we identified a number of possible shortcomings in the administration of the Act (which we passed on to the Program separately),[14] we also heard from some attorneys and miners' advocates who regularly work with the Program that the staff are knowledgeable, helpful and professional.[15] We surmise that the perceptions among some that the Program is biased against the miners is more the unfortunate result of the existing statutory and regulatory restrictions than any systematic bias in the administration.

We set forth in this Report our understanding and analysis of the major criticisms of the Act and implementing regulations, and recommendations for changes to both. The Report is preceded by a summary that lists our recommended changes to the Act and regulations, and is followed by an appendix (Appendix A) that contains a detailed explanation of the relative risk models and statistical analyses upon which we base parts of the Report.

As a final introductory matter, we wish to make explicit three caveats that should be borne in mind when reading the Report. First, the Committee recognizes that the recommendations we put forward may be modified in whole or in part by the Administration because of extrinsic considerations we did not include in our calculus. The Committee has operated on the premise that we were tasked to make recommendations regarding the RECA and implementing regulations that, based on our technical expertise, are warranted. Our recommendations rest on analyses replete with discretionary

judgments, but the touchstone for these various judgments were scientific and technical criteria. We do not believe we were empowered to make policy-based judgments. As a consequence, we did not consider various potentially relevant policy-based factors in our analysis of the issues -- indeed, we made a conscious effort to avoid doing so.

Second, the recommendations we put forth represent only the opinions of the members of the Committee; nothing in the Report should be construed to represent the opinions of any of the federal agencies or departments which employ the members of the Committee.

And, third, in the time allotted we could not investigate every criticism of the Act or the regulations brought to our attention, although we believe we have addressed the major criticisms. In a few instances, discussed below, we were able to determine that a criticism had merit and warrants changes to the statute, but for lack of time and resources, were unable to generate substitute criteria. In other instances, we concluded that the criticism did not raise issues of the same systemic importance as those discussed below, and, consequently, we simply did not have sufficient opportunity in the time allotted to determine whether the criticism was sound. The fact that we did not address an issue, therefore, does not imply that we found it without merit.

II. ISSUES RELATING TO COMPENSATION FOR LUNG CANCER

A. Statutory and Regulatory Framework for Compensation

Congress explicitly recognized in the RECA a causal relationship between exposure to radiation in underground uranium mines and an increased risk of lung cancer.[16] The Act provides for compensation to uranium miners who develop(ed) lung cancer if they can establish they were exposed to specified minimum levels of radiation. The statute sets the minimum level of radiation depending on the miner's age at the time the lung cancer is diagnosed (referred to as the miner's "attained age"), and his smoking status: a nonsmoking miner must have been exposed to 200 Working Level Months (WLMs)[17] of radiation; a miner who smoked, and who developed lung cancer before age 45 must have been exposed to 300 WLMs of radiation; and a miner who smoked, and who developed lung cancer after the age of 45, must have been exposed to 500 WLMs.[18] The regulations define a smoker as "an individual who has smoked at least one (1) pack-year of cigarette products."[19] A nonsmoker is defined as an individual who has never smoked cigarette products or has smoked less than one pack- year.[20]

These exposure criteria, and to a slightly lesser extent the definition of smoking in the regulations, have been severely criticized. The principal criticisms have come from scientists who study the uranium mining population. They insist that the present exposure criteria are inconsistent with or unsupported by the latest scientific data. The present criteria, the scientists charge, have the unfortunate and unjust effect of denying compensation to many miners who were subject to a considerable risk of lung cancer from exposure to radon progeny, and who later developed lung cancer.

The critics charge that the present statutory criteria are defective in five fundamental ways. First, the latest data indicate that the numerical exposure minima misrepresent the risk of lung cancer for many miners. As a consequence, the Act effectively compensates only those miners who meet a threshold risk much greater than Congress intended. Second, the exposure minima vary depending on smoking status, though the latest data suggest that the risk of lung cancer due to exposure to radon may not be dependent on this variable. Third, the distinction in exposure minima for smokers based on whether lung cancer was diagnosed before or after age 45 is curious. Although the latest data do suggest attained age is an important variable, the critics note that there is little support in the data for the proposition that the risk of lung cancer varies dramatically only around age 45. Fourth, the Program uses actual and estimated historical radon level measurements in mines to compute miners' exposure. The existing measurement data, however, do not cover all mines or all work areas within mines. The resulting estimates of a miner's true exposure are imprecise and inaccurate, and, consequently, any calculated risk of lung cancer may be seriously in error. And, fifth, the existing exposure minima for uranium miners translate to a much higher risk than is imposed on either the downwinders or on-site participants for compensation.

These criticisms have been echoed most recently and forcefully by the President's Advisory Committee in their Final Report. They have also been voiced by almost every group with an interest in RECA, including the miners, their attorneys, advocacy groups, treating physicians, medical researchers and government officials.

In light of these criticisms, this Committee reviewed the latest epidemiologic data on lung cancer in underground uranium miners employed in Colorado and New Mexico. We have concluded that most of the concerns raised about the present statutory criteria have merit, and warrant amendment of the Act. Our analysis of the epidemiological data convinces us that the present exposure minima underestimate the risk of lung cancer to some miners, with the result that these miners may unfairly be denied compensation though it is likely their exposure in fact is the cause of their lung cancer.[21] Moreover, the criteria do not properly account for or incorporate

two factors that significantly affect the risk of lung cancer in uranium miners: attained age independent of smoking and time since last exposure.

However, we have also concluded, contrary to many critics, that the distinction between smokers and nonsmokers should be retained. Based on our analysis of the data, we suggest two possible substitute compensation models -- one, similar to RECA, that bases compensation on cumulative minimum radiation exposure; and a second, as suggested by the Advisory Committee, that conditions compensation on duration of employment. We are convinced that either alternative model more accurately identifies those miners Congress intended to compensate: individuals whose lung cancer "more likely than not" was caused by exposure to radon in the uranium mines. We recommend that the Act be amended to incorporate both compensation models, so that a miner qualifies for compensation if he satisfies the criteria of either model.

We also conclude that there is significant merit to the charge that the Act's compensation criteria for uranium miners are not comparable to the criteria for downwinders and on-site participants, to the gross disadvantage of the miners. We believe, however, that the respective compensation criteria and associated legislative history imply a desire by Congress to treat the covered classes differently. Because the issue is at heart a policy matter, we make no recommendation. We do put forth a number of options that would provide greater parity among the eligible groups, if so desired.

B. Fairness of the Present Statutory Compensation Criteria

Since the early 1970s, a substantial amount of research has been published, including numerous epidemiological studies of underground uranium miners, that convincingly demonstrates a causal link between exposure to radon and its decay products and the development of lung cancer.[22] The results of this research and a good deal of the literature were presented to Congress in the years preceding the passage of the RECA.[23]

Since 1990, however, some of the principal studies have been updated and reanalyzed, producing important new information regarding the relative risk of lung cancer posed by exposure to radon. Data on lung cancer mortality in both the Colorado Plateau and New Mexico cohorts have been updated.[24] Most importantly, in 1994, scientists from the National Cancer Institute, in collaboration with the principal investigators of the eleven cohort studies of radon-exposed underground miners, pooled and analyzed the original data from all eleven studies.[25] This 1994 NCI-led study refined an existing statistical model that describes the relationship between exposure to radon and the risk of lung cancer.[26]

The President's Advisory Committee relied heavily on the 1994 NCI-led analysis in criticizing the present RECA criteria and recommending reform of the Act. Citing the NCI-led analysis as its principal if not sole support, the Advisory Committee concluded:

> Since 1990, additional scientific information has become available to support the view that radon exposure is responsible for a much higher proportion of the lung cancer cases among the miners than had been previously thought. In particular, the [A]ct's current requirement of a minimum of 200 WLM ... exposure for nonsmokers or 300 to 500 WLM (depending on age) for smokers translates to quite large probabilities of causation, according to a recent report of the National Cancer Institute. That analysis finds little evidence to support a distinction between smokers and nonsmokers and suggests that a majority of lung cancer deaths among Colorado white miners and New Mexico Navajo miners are attributable to radon exposure. Furthermore, it finds that the lung cancer risk is strongly modified by a number of factors and uncertainties that are not accounted for in the total dose; thus, for many miners, the level of exposure that would merit compensation on the basis of the principle of "balance of probabilities" might be far lower than the present criteria.[27]

This Committee agrees with the President's Advisory Committee that the BEIR-IV/NCI model is the best available tool by which to judge whether the present RECA compensation criteria (for lung cancer) fairly compensate miners. The model was developed by leading experts in the field and has been accepted by the scientific community. As recently refined by NCI, it employs the latest data and statistical methods. It should represent, therefore, the best estimate of the true risks of exposure to radon sustained by the uranium miners covered by RECA. Moreover, we adapted the BEIR-IV/NCI analysis to pooled data from the Colorado Plateau and New Mexico cohorts to derive risk models, and from these models compensation criteria that we propose in place of the existing statutory criteria.

The crucial question, however, is how one defines the "fairness" of the compensation criteria. The Committee believes that the fairness of the present statutory criteria, or any proposed alternative criteria, should be judged by the extent to which they effect the intent of Congress. We conclude, as did the Advisory Committee, that the present standards are not very fair by this definition: that is, they do not accurately provide for the compensation of those miners Congress intended to compensate. We propose instead two

alternative sets of criteria that, either used alone or in combination, more accurately identify those miners whom Congress sought to compensate.

1. The Legislative History Reveals That Congress Sought to Compensate Uranium Miners On A Balance of Probabilities Standard

To determine the class of miners Congress intended to enfranchise through the statutory criteria in RECA, we examined both the text of the Act and its legislative history. Based upon this review, we have concluded that Congress intended in the RECA to compensate uranium miners whose lung cancer "more likely than not" was caused by exposure to radon and its decay products during employment in underground uranium mines.[28] In the statistical terms employed by the BEIR-IV and NCI analyses, this standard is equivalent to a probability of causation (PC) equal to or exceeding 0.5.[29]

The Act itself provides some guidance as to congressional intent, but ultimately is ambiguous as to the underlying standard of causation. Congress included as one of the legislative findings that "radiation released in underground uranium mines ... and other airborne hazards in the mine environment ... together are presumed to have produced an increased incidence of lung cancer and respiratory diseases among miners ...."[30] It also found that "the lives and health of uranium miners and of individuals who were exposed to radiation were subjected to increased risk of injury and disease to serve the national security interests of the United States."[31] While Congress acknowledged in these statements that miners were subject to an increased risk from exposure to radon, they leave unclear precisely how much risk, when followed by disease, warranted compensation. Yet, the fact that Congress explicitly conditioned compensation on specific minimum exposure criteria strongly implies that it intended to compensate only those miners in which the increased risk due to radon exposure -- the likelihood of causation -- exceeded some threshold level of confidence.

The history of the Act is extensive; legislative efforts to compensate uranium miners date back to the late 1970s. Specific minimum exposure standards first appeared in H.R. 5022, an earlier version of a compensation scheme introduced into the House of Representatives in July, 1988. The bill would have created a cause of action in the (then) United States Claims Court for uranium miners employed in mines in certain designated states within a specific time period, who contracted lung cancer or "other serious respiratory disease," and who were exposed to at least 100 WLMs if a nonsmoker or 250 WLMs if a smoker.[32] The source of these specific exposure levels is not apparent, but subsequent testimony

before two congressional committees suggests that the levels may have been approximations of exposures at which it was more likely than not that the subsequent development of lung cancer or a nonmalignant disease was due principally to the exposure. In February, 1988, in testimony before the Senate Committee on Labor and Human Resources, Dr. Victor Archer, a physician who has spent his career studying the incidence of disease among uranium miners, and who was formerly the principal investigator for the Public Health Service's prospective epidemiological study of uranium miners of the Colorado Plateau area, stated:

> I have been involved in a number of workers' compensation cases in about five States in the West with uranium miners, and I have been frequently asked to determine whether the particular lung cancer was more likely or not caused by the radiation in the mines. For nonsmokers, this is quite easy if their radiation exposure has been above 100 Work Level Months, and among the nonmining population, the rate of lung cancer among nonsmokers is so extremely low. For heavy cigarette smokers, however, this is a little more difficult. Usually above 800 [*sic*] Work Level Months, it is more likely than not that the lung cancer is due to radiation. At Work Level Months below 300, then it is more often than not that cigarette smoking turns out to be the more important cause. This is not to say that lung cancer does not occur among miners who have had less than 300 Work Level Months, that it does not occur as a result of radiation, but in groups of heavy smokers with less than 300 Work Level Months, we have found that smoking does cause a higher fraction of the cases than the radiation does.[33]

Less than one month later, before a different Senate committee, Dr. Richard Hornung, of the National Institute of Occupational Safety and Health, another leading researcher of the effects of radon, testified that a cumulative exposure to 120 WLMs would result in a doubling of the risk of lung cancer.[34] The exposure that causes an individual's risk to double, also called the "doubling dose," is the point at which it is more likely than not that the individual's exposure to radon was the cause of any resulting lung cancer.

Thus, the exposure criteria suggested to Congress by the leading experts explicitly sought to distinguish for compensation those miners whose disease more probably was caused by their exposure. Significantly, the various legislative schemes proposed after 1988, including H.R. 2372, which became the RECA, all contained threshold exposure criteria equal to or greater than these suggested levels.

The legislative history of H.R. 2372 suggests strongly that the existing exposure minima were intended to define the class of miners who developed diseases probably caused by radiation. To begin with, the bill, as originally introduced in the House, established a single exposure criteria of 250 WLM, more than twice the level recommended by Drs. Archer and Hornung.[35]

Additionally, during House consideration of the bill, one Representative expressed his concern that the bill did not require claimants to prove causation, and included diseases that the medical community did not yet agree were caused by radiation.[36] These concerns were immediately addressed by one of the bill's sponsors:

> "Considering all those people who have suffered, I do not think that I would agree with the gentleman from Florida [Mr. James] as to whether there would be a preponderance of evidence, and the proximate cause would be difficult. We can all see that. But the case that was tried in Salt Lake City ... turned out the type of evidence that we feel is necessary.[37]

While not without ambiguity, this response appears to assume that claimants would in effect be required to prove causation (in legal parlance, "proximate cause") by a "preponderance of the evidence," a standard legal description of a burden of proof equivalent to the "more likely than not" standard.

Senate consideration of H.R. 2372 more clearly reflects congressional understanding that the exposure criteria were intended to identify cases where exposure to radon was the cause of lung cancer or a nonmalignant disease. Senator Hatch, one of the sponsors of the bill, made it clear that the legislation demanded a high standard of association between exposure and disease:

> In recognition of the fact that legal avenues are closed because of the Tort Claims Act and the fact that the Government's failure to monitor the downwind areas has made a case by case determination on the issue extremely difficult, the legislation now before us has been designed to provide compensation for those victims whose cancers were most likely to have been caused by their prolonged exposure to radiation. ... Uranium miners must have worked in mines during those times when there were minimum efforts to reduce the level of radium in the air and they must have been exposed to levels of radiation of at least 200 working level months, ...[38]

The Senate amended the bill to add, inter alia, the present three-

tiered exposure minima, dependent on age and smoking status, for uranium miners.[39] Explaining these amendments, Senator Hatch reiterated the requirement that the claimants' radiation exposures be the most likely cause of their compensable diseases:

> In addition, as a request of the Senator from Wyoming, we have incorporated additional changes in the uranium miners section of the bill to ensure that the lung cancer and respiratory diseases for which compensation is provided are those which are most likely to have been caused by the radiation in the mines. Distinctions have been made with respect to exposure levels and whether or not the miners were smokers.[40]

The purpose and effect of the Senate amendments were understood by the House as well when it reconsidered and passed H.R. 2372, as amended. Representative Owens, one of the bill's original sponsors, stated that "[o]ther changes were made in the House version to ensure that the lung cancers and respiratory diseases for which compensation is provided are those which are most likely to have been caused by the radiation in the mines."[41]

The purpose of the amendments was made even more explicit by Representative Kyle, who stated:

> The one flaw I did find in the House version of the measure has now been corrected by the Senate. That flaw related to diseases that may have [been] brought on by an individual's own conduct -- conduct such as tobacco or alcohol abuse. ... We have to be sure that the Government's misconduct, not the individual's is the cause.[42]

Additional evidence of congressional intent is apparent from a pair of bills introduced by Senator Hatch in 1989 and 1990, respectively, relatively contemporaneous with the introduction of H.R. 2372. S. 1994, introduced in November, 1989, would have authorized miners to file petitions with Special Masters of the then United States Claims Court, who were authorized in the legislation to award money damages to miners employed in uranium mines located in designated states during the period January 1, 1947, and December 31, 1971, who contracted lung cancer "or other serious respiratory diseases," and who were exposed to at least 100 WLMs.[43] S. 2466, introduced shortly thereafter in April 1990 contained the same compensation criteria for miners with the exception that the minimum exposure level for compensation was set at 200 WLM.[44] The Senate Report recommending passage of S. 2466 makes absolutely clear the standard of proof underlying the compensation

criteria for miners:

The law also requires a demonstration through a preponderance of the evidence that the nuclear fallout was the proximate cause of the cancers in question. ... In recognition of the fact that ... causation is such a difficult matter to prove on a case by case basis, especially in light of the Government's failure to monitor the downwind population, the Committee has designed this bill to provide compensation to those victims whose cancers were most likely to have been caused by their prolonged exposure to radiation. ....[45]

Moreover, S. 2466 would have directed the Secretary of Health and Human Services to prepare a report on "the existence of evidence or data supporting the conclusion that exposure of uranium miners to less than 200 working level months of radiation is associated with lung cancers or other serious respiratory disorders."[46] This requirement would seem to confirm that the bill's sponsors believed 200 WLM represented the point at which the causal association between exposure to radiation in the mines and the development of the designated diseases had been proven.

Finally, our conclusion that RECA is intended to compensate only those miners whose disease "more likely than not" was caused by their exposure to radon progeny is supported by the Senate's rejection of a compensation plan introduced by Senator Hatch in 1985 that would have allowed for payments to miners on a less rigorous standard. This legislative scheme would have created a commission empowered to pay damages to miners with lung cancer if there was a "sizeable possibility" that the disease was the result of exposure to radiation in uranium mines in designated states during a specified time period; the commission was empowered to pay prorated damages to miners where the "sizeable possibility" of causation was less than fifty percent.(47)

Numerous Senators spoke against the proposal for, among other reasons, providing compensation where the probability of causation was less than fifty percent. For example, Senator Simpson argued that

> [T]his amendment allows awards even where the claimant is absolutely unable to show that his or her cancer was caused by the fallout under our traditional tort principles. In fact ... the amendment allows prorated awards where the probability of causation ... is less than 50 percent. There is a fundamental change in traditional court rules under this approach, where you would make awards based upon a probability of less than 50 percent.
>
> ...

> This amendment would, if adopted, provide for compensation of individual claimants, even though those claimants could not establish that it was `more likely than not' that their cancer was caused by exposure to fallout -- the standard traditionally imposed under our tort system as a condition of recovery. Under Section 209(c) of this amendment, the Commission would be authorized to provide prorated compensation for persons with probabilities of causation less than 50 percent. This provision represents a fundamental and grievous departure from the principles of fault and compensation that have served as the foundation of our tort system, and in my judgment, the Congress should reject what has been proposed.[48]

In sum, the available legislative history of proposals to compensate uranium miners strongly suggests that Congress intended the existing exposure criteria to compensate only miners whose disease "more probably than not" was caused by exposure to radiation in the mines.[49]

2. The Present RECA Criteria for Lung Cancer Are Not Consistent With A Compensation Standard of PC Greater Than Or Equal To 0.5

The present RECA criteria reflect Congress' assumption that the relative risk of lung cancer among uranium miners is principally related to three factors: (1) a miner's cumulative exposure to radiation (measured in WLMs); (2) the miner's smoking status; and, (3), if the miner is a smoker, attained age, i.e., age at the date of diagnosis. More recent studies and data, particularly the 1994 NCI-led analysis, have convinced the Committee that we can now offer Congress a more accurate assessment of the radon exposure-lung cancer relationship. While the NCI pooled analysis indicates that the first and third factors, and possibly the second, do significantly affect the relative risk of lung cancer, the present RECA criteria (1) do not properly reflect the effect of increasing age; and (2) do not account at all for an additional significant variable -- time since last exposure.

First, RECA does not properly account for the effect on the risk of lung cancer of attained age. The present criteria set one exposure standard for smokers under age 45, and a second, higher standard for smokers over age 45. Analysis of the miner studies indicates that the relative risk of lung cancer due to radon progeny exposure decreases with attained age in both smokers and non-smokers. The data do not indicate any dramatic changes in relative risk at age 45. Indeed, the decline in the relative risk continues throughout the middle and older ages. This is principally due to the fact that the

background rate of lung cancer increases with age in smokers and non-smokers; the proportional increase in risk of lung cancer due to radon progeny does not keep pace with the increasing background risk.

Moreover, the present criteria necessarily imply that all smoking miners 45 years of age and older face the same or nearly the same risk of lung cancer: all such miners must meet the 500 WLM minimum exposure level standard, regardless of any other factors. Yet, the BEIR-IV analysis conclusively demonstrated that a risk model that depends only on cumulative exposure will generate results that do not reasonably "fit" the observed data - - i.e., the model does not adequately describe the association between exposure and the development of lung cancer.(50)

Second, the present criteria do not include an additional variable that has been demonstrated to have a significant effect on risk: the time since the miner's last exposure to radon in the mines. The BEIR-IV and NCI-led analyses indicate that the relative risk of lung cancer decreases as the time since exposure to radon increases. Thus, the relative risk of lung cancer due to radon exposure for a miner who has been out of the mines only 5 years is substantially greater than the relative risk for a miner with the same cumulative exposure whose last exposure was 30 years ago. To put it slightly differently, for two miners with lung cancer who had the same total exposure, there is a greater chance that radon exposure is the cause of the lung cancer in the miner who developed the disease within a few years of his last mining employment than in the case of the miner who developed lung cancer 20 or 30 years after last exposure.

To assess how well the present statutory criteria reasonably advance Congress' objective -- compensating miners with lung cancer where the probability of causation due to radon exposure is greater than 0.5 -- we created the relative risk model described by the criteria (or a good first-order approximation). We applied this model to the known lung cancer cases in the pooled Colorado Plateau and New Mexico cohorts to determine which would qualify for compensation under the present statutory scheme. We did the same analysis with a risk model derived directly from the pooled cohorts, and based on the BEIR-IV and NCI-led models. The results of both models are compared in Figure 3 in Appendix A. The comparison shows that a large number of miners who met the requisite level of risk according to the model based on the BEIR-IV/NCI analyses are not eligible for compensation under the present statutory criteria (Quadrant A of Figure 3). On the other hand, a smaller number of miners are eligible for compensation under the RECA criteria though, according to the latest data, they do not have the requisite level of risk (Quadrant D of Figure 3). This indicates that the risk model based on the present statutory compensation criteria is not a good description of the relationship between exposure to radon and the

development of lung cancer. The obvious implication is that the statute at present does not accurately identify (and compensate) those miners whom Congress sought to compensate.

C. Alternative Compensation Criteria

Because the present statutory criteria do not condition compensation on all the factors known to affect significantly the risk of lung cancer, and, as a consequence, do not effectively ensure that the appropriate group of miners is compensated, the Committee suggests modifications to the present statutory criteria that will yield results more faithful to Congress' intentions. We propose in this section two sets of criteria, either of which should produce a "fairer" distribution of compensation: one set is based in part on a miner's cumulative exposure to radon; the second set substitutes a duration of employment factor for cumulative exposure, due to the perceived shortcomings of the former. We recommend, however, that both sets be incorporated into any new statutory scheme, and that claimants who qualify under either set of criteria be eligible for compensation.

1. Description Of The Relative Risk Model Used To Derive Proposed Alternative Criteria, And Model Parameters

To derive more accurate compensation criteria, we employed a risk model based on the analytical approach developed in the BEIR-IV and NCI models. We applied this model to the pooled data from the Colorado Plateau and New Mexico cohorts. The patterns of risks identified by our model were consistent with those found by the BEIR-IV and NCI analyses. The analyses conclusively demonstrate that the relative risk of lung cancer increases with increasing exposure to radon progeny. The analyses also demonstrate that the radon exposure-lung cancer relationship (exposure-response effect) is significantly affected by at least two factors: the miner's attained age, and the time since the miner's last exposure to radon in the mines. Although the risk of lung cancer due to radon exposure increases with cumulative exposure, the strength of that relationship decreases with attained age, and decreases with increasing time since last exposure.

The data, however, are ambiguous on the effect of smoking. Analyses of the various mining cohorts have demonstrated rather conclusively that there is a synergistic relationship between exposure to radon and smoking -- that is, the lung cancer risk to a uranium miner who smokes is greater than the sum of the risk for exposure to radon and the risk for smoking. The data do not conclusively indicate, however, the exact nature of the relationship.

An analysis of the data from the Colorado and New Mexico cohorts, which cover many of the miners eligible under the RECA, indicates

that the relative risk of exposure jointly to radon progeny and smoking is consistent with a multiplicative association -- the combined risk is a product of the two risks. A multiplicative association implies that the proportional increase in risk of lung cancer due to radon progeny exposure is the same in nonsmokers and smokers.[51] However, the data are "consistent with" a multiplicative relationship; one cannot conclude with statistical confidence that a multiplicative relationship is the true characterization of the association -- that is, the result could be due to chance alone.

Although the data are consistent with a multiplicative relationship, the best estimate of the association between the joint exposure to radon progeny and smoking and the risk of lung cancer is sub-multiplicative -- the combined risk is greater than the addition of the two risks, but less than the product of the risks. A sub-multiplicative relationship implies that the effect of radon exposure is greater in nonsmokers than in smokers; that an equivalent dose of exposure increases the relative risk of lung cancer in a nonsmoker more than in a smoker.

Although a sub-multiplicative association best describes the data, again, one cannot be sure, statistically speaking, that this describes the actual relationship. The data are only consistent with a sub-multiplicative relationship; the possibility such an association is due to chance cannot be statistically eliminated. More problematical, there is a limited amount of data on the incidence of lung cancer among nonsmokers, and the resulting lack of adequate statistical power makes it difficult to estimate precisely the strength of the association - - the "degree of submultiplicativeness." Because of the difficulty in estimating with precision the strength of the association, most researchers and committees examining mining populations have opted to apply a multiplicative model, and, therefore, do not differentiate between smokers and nonsmokers in determining the excess relative risk posed by exposure to radon progeny.[52]

The conclusion in the BEIR-IV and NCI analyses that the data are consistent with a multiplicative relationship has led some scientists (and miners' advocates) to criticize the present statutory criteria as unfairly discriminating against miners who smoke. The critics charge that if the proportional effect of radon exposure is equivalent in both nonsmokers and smokers, the latter should not be required, as they are in RECA, to prove a greater amount of exposure. This position is well summarized by Dr. Jonathan Samet, one of the leading researchers on the incidence of disease in uranium mining populations, and one of the authors of the 1994 NCI pooled analysis:

> I think another problem in the Act is the handling of smokers who, in essence, are penalized by their unfortunate addiction and are required to have higher levels of exposure and, in essence, a higher level of risk before they are compensated.
>
> ...
>
> For radon progeny and cigarette smoking, the available evidence suggests synergism between the two agents. In the presence in such synergism, the higher exposure requirements for smokers implies that for compensation they must accept a higher relative risk than never smokers, ...[53]

The Advisory Committee echoed this same concern.[54] If these criticisms are correct, smoking should no longer be a factor in the compensation analysis.

Nonetheless, the Committee believes that the eligibility criteria should continue to include a miner's smoking status. We have concluded, for the reasons stated below, that the most appropriate risk model for the purposes of RECA should presume a sub-multiplicative effect between exposure to radon progeny and smoking.

First, as emphasized above, an analysis of the latest data from the Colorado Plateau and New Mexico cohorts suggests that a sub-multiplicative model is the best estimate of the association. Moreover, the 1994 NCI-led analysis confirmed that a sub-multiplicative association is consistent with the data from the six (of eleven) cohorts with smoking information. A pooled analysis of these six cohorts indicated that the exposure- response effect (the increase in the risk of lung cancer due to exposure to radon progeny) in nonsmokers is approximately 3 times the effect in smokers, implying a sub-multiplicative association.

Second, the present statutory criteria would seem to reflect Congress' desire that miners not be compensated for lung cancers most likely caused by smoking. It is well established, of course, that smoking causes lung cancer. The greater exposure standards in the Act for smokers strongly suggest that Congress wanted at least some measure of assurance that miners would be compensated for the effects of exposure to radon, not smoking. Thus, where the data are uncertain it seems appropriate to resolve the question in favor of the policy expressed by Congress.

Third, if one derives a separate set of criteria for nonsmokers, the resulting exposure levels are substantially lower than those derived

from the set of all miners without regard to smoking status. This necessarily implies that selection of a multiplicative association will work to the disadvantage of nonsmokers.[55] We believe that in resolving this uncertainty, we should favor nonsmokers, a population in which an alternative major risk factor for lung cancer is absent.[56]

2. Proposed Alternative Compensation Criteria

Using the relative risk model described above, and explained in detail in Appendix A, we generated two sets of compensation criteria -- one based on a miner's cumulative radon exposure, the other on the miner's duration of employment underground -- that will more accurately reflect the intent of Congress than the present statutory criteria. Each set of criteria is captured in a matrix that identifies the relevant variables which must be known. (See Tables in Appendix A). Table 3(a) sets forth the criteria generated by the risk model based on a miner's cumulative radon exposure; Table 4 (a) sets forth the criteria generated by the risk model based on a miner's duration of employment.

At the risk of complicating matters, however, we put forth two additional, alternative matrices for each set of criteria (Tables 3b-c; 4b-c); the selection of the appropriate matrix rests on a policy choice we leave to the Administration. These two additional matrices in each set contain the criterion representing the best estimate derived from the risk model but modified to take into account statistical uncertainty. The process of statistical risk estimation gives rise to multiple sources of uncertainty. Thus, the miner's true relative risk lies somewhere within an interval defined by the computed criterion multiplied or divided by an amount that represents the uncertainty, or potential error. The size of the interval will depend on the level of assurance desired that the true relative risk lies somewhere within the interval -- i.e., the extent to which the uncertainty is accounted for. The greater the desired assurance, the larger the interval.

One known source of uncertainty that we can reasonably approximate is the statistical sampling variability.[57] We recommend that the criteria generated by the risk model be modified to account for this uncertainty. The alternative matrices, therefore, contain criteria modified to account for this uncertainty to two separate levels of assurance: they represent the upper bound of the interval that captures the miner's true relative risk with either 80% assurance (Tables 3b and 4b), or 90% assurance (Tables 3c and 4c).[58] There is no overwhelming scientific justification for selecting one of these matrices over the other: the choice depends on the level of assurance desired, which we believe is ultimately a policy decision, and beyond our warrant.

Tables 3a-c set out exposure criteria that condition compensation for miners, distinguished by smoking status, on two variables: attained age and time since last exposure. We did not use individual values for the latter two variables; for simplicity, both attained age and time since last exposure were categorized into four and three levels, respectively. Thus, a miner's attained age is either less than 50, 50-59, 60-69, or over 70. Similarly, time since last exposure is measured as less than 10 years, 10-19 years, or 20 or more years. Tables containing individual exposure criterion for every possible combination of attained age and time since last exposure would be too cumbersome to use.

Numerous critics, including most recently the President's Advisory Committee, have expressed concern with compensation criteria based on cumulative exposures because of limitations associated with the existing historical exposure data.[59] There is particular concern that historical measurements of radon levels do not exist for many mines or for many work areas within mines. These historical radon measurements are used by the Program to calculate a claimant's cumulative WLM exposure.[60] There is a distinct possibility, therefore, that the calculated estimates of claimants' exposures are inaccurate and imprecise. Thus, it is argued, some miners likely are being denied compensation unfairly because their calculated exposure -- which fails to meet the relevant statutory minimum -- is not accurate.

In response to this criticism, we created an alternative set of criteria, set out in Tables 4a-c, that relate the risk of lung cancer to a miner's duration of employment in underground uranium mines. These criteria are dependent on attained age, time since last exposure and the calendar year of first employment.[61] This last factor is significant because the mean level of radon in the mines declined appreciably over the years.[62] See Figure 1 in Appendix A. Again, for simplicity, we have grouped calendar years into categories that roughly reflect appreciable differences in the average radon level in mines.

Either set of criteria, we believe, represents a significant improvement over the present statutory scheme.[63] We recommend that both sets of criteria be used, so that a claimant who qualifies under either criteria is compensated.

On the one hand, the employment duration model has distinct advantages. As the Advisory Committee and others have noted, the use of the historical mine data is perceived as unfair by many. An approach based on employment duration is more transparent and intuitive, and may be more readily accepted. Moreover, the criteria generated by this model can be understood and used by miners and their survivors much more easily than exposure-based criteria to

determine if they are eligible for compensation.

On the other hand, the exposure-based model has the advantage of being more accurate: it better "fits" the observed data, indicating that it more accurately describes the relationship between exposure to radon progeny and risk of lung cancer. This implies necessarily that use of this model will result in a fairer distribution of compensation.

We believe that if the employment duration-based criteria are used, the alternative exposure-based criteria must also be used. It is possible for a claimant to be denied compensation under the employment-based criteria we recommend (Tables 4a-c), yet qualify for compensation under the exposure-based criteria (Tables 3a-c). We believe it would be unjust to deny compensation to any claimant who can demonstrate eligibility under the exposure-based criteria. This model is the more accurate, so a claimant who can meet its criteria has demonstrated the most legitimate claim to compensation.

3. Proposed Modifications to the Definition of Smoking in the Regulations

Our recommendation that smoking continue to be a factor in the compensation calculus requires us to face two additional questions that relate to the definition of smoking in the regulations. As noted above, the regulations define a smoker as an individual who has smoked at least one (1) pack-year of cigarette products[64], and, correspondingly, a nonsmoker is defined as an individual who has never smoked cigarette products or has smoked less than one pack-year.[65] To determine if a claimant was/is a smoker, the regulations require him (or his surviving beneficiaries) to submit all medical records of specified types created within the six month period before and after the date of diagnosis of lung cancer.[66] If any of these records, or any of the historical health and mining survey records held by the Program, contain information indicating that the miner was a smoker, even if no smoking quantity is noted, he is presumed to be a smoker.[67]

We have learned that in practice, however, the Program does not require the so-called "six months documents" from a miner if he is designated a nonsmoker in certain historical health survey databases held by the Program. Where these historical records code the miner as a smoker, he is presumed to be a smoker. Where the miner is not listed in any of these databases, or is listed but smoking information is either not provided or is unclear, the miner is required to submit the so-called "six months documents" to overcome a presumption of smoking.[68]

This regulatory scheme has been heavily criticized in at least two respects: it discriminates against Navajo, who were generally nonsmokers or only occasional smokers; and it does not allow former smokers who stopped smoking for many years to be treated as nonsmokers. We believe both of these concerns are justified, and can be accounted for by modifications in the regulations.

(a) Navajo and Smoking[69]

Critics have charged that the definition of smoking, in combination with the presumption a miner is a smoker, unjustly results in the misclassification of many Navajo as smokers, which obviously increases the burden of proving eligibility. We heard from numerous credible sources (including Navajo Nation officials, present and former Indian Health Service physicians, and scientists who study the Navajo mining population), that the incidence of smoking among Navajo was very low, particularly among the generation that mined during the years specified in the statute. According to these sources, there is a cultural bias against smoking, so the majority of Navajo smoked only for ceremonial purposes if at all, and those who did smoke did so only occasionally and significantly fewer cigarettes than their non-Navajo counterparts.

However, many Navajo apparently classified themselves as smokers when asked about smoking status during a health study or in response to questioning by a physician. Thus, for many Navajo there is a reference to smoking in the historical records that they cannot overcome.

The contention that Navajo were never-smokers or only light smokers is confirmed in the research literature published before the RECA was enacted.[70] The first reported study of the Colorado Plateau miners, published in 1971, found that 62% of the Native American miners in the cohort were never smokers, and the median consumption of cigarettes by Native American smokers was only 4 cigarettes per day. A later report summarized the limited additional data:

> Of a sample of adult Navajos admitted to the Phoenix Public Health Service Indian Hospital from 1961 through 1965, only 4.3 per cent smoked more than one pack of cigarettes daily. In a 1977 survey of Navajos, only 13 per cent smoked and only 6 per cent of the smokers [.78% of the sample] consumed at least one pack daily.[71]

The cohort data we use to generate our alternative compensation criteria strongly bears out the concern that Navajo are being misclassified. In the Colorado Plateau and New Mexico cohorts

combined, 47% of Native Americans classified themselves as smokers; yet among this group of self-reported smokers, the average consumption of cigarettes was .3 packs per day, or 6 cigarettes. In contrast, 81% of non-Native Americans in the combined cohorts were ever smokers, and of this group the average consumption was 1.2 packs/day.

This suggests that many Navajo may be held to the present 300 WLM or 500 WLM standard though their smoking history suggests that they probably do not meet the definition of smoker in the regulations. Although it is generally believed that any smoking increases an individuals risk of lung cancer, the smoking rate among Navajo as borne out by the literature is so minor, and so much less than the average among White miners, that their increased risk due to smoking is relatively insignificant, as a group. We believe, consequently, it is inappropriate to presume on the basis of a bare self-reported reference in the historical records, that a Navajo meets the definition of smoking in the regulations. We believe it is more appropriate to presume the opposite: a Navajo miner should be presumed to be a nonsmoker absent evidence in the historical records specifically documenting cigarette consumption in excess of (or at a rate likely to lead to an excess of) one pack-year. We recommend, therefore, that the regulations be modified accordingly to presume all Navajo are nonsmokers.[72]

(b) Cessation of Smoking

The regulations irrevocably presume that a claimant who once was a smoker is always a smoker. No provisions are made for smokers who have stopped for such an extended period of time that the added risk of lung cancer due to their smoking is no longer significant. The absence of such a provision has been criticized, particularly in light of the minimal smoking history required to meet the definition of smoking in the regulations.

It is now accepted that the risk of lung cancer in ever smokers drops after the cessation of smoking.[73] The reduction in the risk of lung cancer can be quite appreciable over time, though the risk is not generally believed ever to drop to the background risk of a never-smoker.[74]

The extent of the reduction in risk and the rate of decline are believed to depend not only on the time since cessation of smoking, but also on a number of other factors, including the age at cessation, and the intensity and duration of cigarette use.[75] According to the data, for smokers who smoked 20 or more cigarettes per day, the relative risk of lung cancer decreases to less than two times the background rate of never-smokers after approximately twenty years.[76] At this point, where the relative risk in an ex-smoker is less

than twice that of a never-smoker, one cannot say that if the ex-smoker develops lung cancer, it is more likely than not due to the smoking; in the statistical terms we have used above, below this point the probability of causation from smoking is less than 0.5. For smokers who smoked less than 20 cigarettes per day, the relevant point is less certain; based on the lower confidence limits of the available data, we estimate that the relative risk of lung cancer decreases to less than two after 15 years.[77]

We recommend that the definition of smoking be modified to classify as anonsmoker any ex-smoker who can prove through contemporaneous medical records that he stopped smoking at least 15 years prior to the diagnosis of lung cancer. We favor the 15 year threshold for two reasons. First, the data on smoking are uncertain. Second, the definition of smoking in the regulations covers a considerable range of smoking rates; similarly, the age distribution of ex-smoking miners at the time of cessation of smoking, given that the Act covers the period 1947 to the present, is likely quite broad. Both factors are known to affect the rate of decline in lung cancer risk. Their potential variability among the population at issue suggests to us erring on the side of liberality.

D. Comparison of the Compensable Risk Thresholds Required of Uranium Miners and Downwinders

A troubling criticism of the RECA is the charge that there is an unjustified disparity in the level of risk that the miners, on the one hand, and the downwinders, on the other hand, must establish to be eligible for compensation. The Act, critics maintain, imposes more stringent criteria on miners, effectively forcing them to demonstrate that they were subjected to a much higher risk of disease as a result of their exposure than is required of downwinders.[78]

The Committee believes that the criticism has merit. While we are sympathetic to the concern, for the reasons discussed below, we do not recommend any particular solution.

The Act does not impose any specific minimum exposure criteria for downwinders. To be eligible for compensation as a downwinder, an individual must demonstrate that he/she resided for a specified period of time within a defined geographic area during a designated period.[79]

The legislative history suggests Congress did not require a specific dose threshold of downwinders because no reliable dose data reportedly were available from which to estimate their exposures and deduce the appropriate causal relationships.[80] The residency and proximity requirements are intended to serve as a proxy for exposure. As stated by Senator Hatch during the debate preceding

the passage of the RECA, "[i]n order to qualify for compensation under this Bill, the fallout victims must have lived in the designated area long enough to have been exposed to repeated doses of fallout."[81]

The scientific literature, however, does not at present support an association between exposure to fallout and development of malignancies.[82] Based on the latest data, the risk of developing any of the malignancies for which downwinders are eligible under RECA, as a result of estimated exposures typical of the downwind population, simply is not of the same magnitude as the proven risk of lung cancer associated with the doses of radon typical of the uranium mining population between the period 1947 and 1971.[83] As a consequence, downwinders are compensated though the risk resulting from the effective dose they received is many times lower than the risk to uranium miners at the exposure levels required for compensation.[84] Put another way, a miner has to prove a probability of causation between his exposure and resulting disease that is substantially greater than the probability of causation demanded of most downwinders between their likely exposure and any compensable radiogenic cancer.

It can be argued that the disparity in threshold risks for compensation between miners and downwinders may be justified in part by the fact that the former were exposed occupationally, while the latter were exposed environmentally and thus did not voluntarily assume any risk or receive any compensation for risks, known or unknown. Additionally, the disparity in risk is reflected in the different levels of compensation to the two groups -- downwinders receive $50,000 in compensation, one-half the amount paid to eligible miners.

Notwithstanding these differences, the lack of comparable treatment for miners seems unfair in light of the well-accepted association between exposure and lung cancer, and the documented history of the federal government's failure to protect the uranium mining population.[85] The Act curiously requires the one group that can conclusively establish that the government's misconduct proximately caused them substantial harm to meet the highest threshold for compensation.

Nonetheless, we have concluded that we can do no more than report the validity and potency of this criticism. We can conceive of only a limited number of ways to begin to address this problem within the existing statutory framework: all require the exercise of policy judgment.[86] The merits of various alternative approaches cannot be judged principally by reference to technical or scientific standards, as we believe is true in each case where we have advanced a

recommendation. To determine which solution among the alternatives is "best" or most appropriate ultimately requires reference to political and social concerns. We do not believe we were empaneled to make such judgments, and respectfully defer to those with the appropriate expertise and responsibility.

III. ISSUES RELATING TO COMPENSATION FOR NONMALIGNANT RESPIRATORY DISEASES

A. Statutory and Regulatory Background

In addition to compensating cases of lung cancer, the Act compensates miners (or surviving family members) who suffer (or suffered) from specified nonmalignant respiratory diseases. The Act limits the compensable nonmalignant diseases to:

> [F]ibrosis of the lung, pulmonary fibrosis, and corpulmonale related to fibrosis of the lung; and if the claimant, whether Indian or nonIndian, worked in an uranium mine located on or within an Indian Reservation, the term shall also include moderate or severe silicosis or pneumoconiosis; ....[87]

The Act explicitly conditions compensation for these nonmalignant disorders on proof the claimant was exposed to minimum levels of radiation; the required exposure levels are the same as those specified for compensation for lung cancer. Thus, to qualify for compensation for a nonmalignant disorder, a nonsmoking claimant must have been exposed to 200 WLMs of radiation in the mines; a smoking claimant who developed the nonmalignant disorder before age 45 must have been exposed to 300 WLMs of radiation; and a smoking claimant who developed the nonmalignant disorder after age 45 must have been exposed to 500 WLMs of radiation.[(88)]

The regulations require that a claimant with a compensable nonmalignant disease prove exposure in the same manner as a claimant seeking compensation for lung cancer.[(89)] That is, a claimant must first document underground uranium mining employment during the time period and within the states specified in the Act, either through information held by the Program or by submitting trustworthy historical records verifying employment.[90] The Program then calculates the claimant's cumulative exposure according to the algorithm described in the regulations.[91] The regulations also require written medical documentation proving that the claimant suffers (or suffered) from one of the compensable nonmalignant diseases.[92] To establish this criterion, the regulations presently require most claimants to submit appropriate medical documentation demonstrating both the presence of the nonmalignant

disease and physiological (functional) impairment.[93] The claimant is required to prove the presence of the disease through chest radiographs (x-rays) interpreted by two certified "B"-readers -- physicians specially certified by National Institute for Occupational Safety and Health (NIOSH) as proficient in the classification of radiographic evidence of pneumoconioses -- and to prove impairment through pulmonary function tests or arterial blood gas studies documenting reduced pulmonary function.[94]

A number of the statutory criteria for the nonmalignant disorders have been criticized as being scientifically unjustified or redundant. Additionally, the regulations defining proof of medical condition have been criticized. Advocates complain principally that the regulations should not require proof of disease process; that the proof of disease required is highly subjective; that the regulations do not allow claimants to submit accurate and trustworthy proof of disease process; and, that they establish standards for functional impairment that are ethnically-biased.

B. Recommendations Regarding Statutory Compensation Criteria

1. Proof of Radon Progeny Exposure As A Condition For Compensation For Pulmonary Fibrosis

The Act, as explained above, explicitly ties compensation for pulmonary fibrosis[95] to proof the claimant was exposed to minimum levels of radon progeny.[96] Thus, the Act necessarily presumes that exposure to radon progeny causes or significantly contributes to the development of the specified nonmalignant diseases.

Critics have argued that the association between exposure to radon and pulmonary fibrosis is not justified by the available scientific evidence; that, instead, the risk of fibrosis is likely related to a combination of agents in the mining environment, (including, possibly, radon), some or all of which are not accounted for in the statutory criteria. This criticism was expressed most succinctly by Dr. Samet, in testimony before the Senate Committee on Labor and Human Resources:

> The linking of compensation for non-malignant respiratory diseases and achieving exposure threshold for radium progeny is not biologically appropriate. Whether an entity of radon-related pulmonary fibrosis has clearly occurred in former underground uranium miners remains uncertain, and, in any case, radon progeny are only some of the pollutants in uranium mines that can cause lung damage. ... Criteria for

> compensating non-malignant respiratory disease in underground miners which are not based on exposure to radon progeny are needed. [The] linkage is really inappropriate on a medical basis.[97]

The Committee believes that this criticism is justified, and recommends that the Act be modified to condition compensation for pulmonary fibrosis on some alternative compensation criteria. Based on our review of the published data, we believe that the alternative criteria should be based at least on a claimant's duration of employment. We have not had either the time or resources to locate and analyze sufficient reliable data, assuming it exists, to recommend alternative criteria.[98]

The Committee recognizes that the legislatively-presumed statutory connection between exposure to radon and the development of fibrosis is not without support. By the time Congress enacted the RECA, it had before it considerable testimony and documentation supporting an association between exposure to radon progeny and fibrosis. In hearings before the Senate Committee on Labor and Human Resources in February, 1990, Dr. Victor Archer, a physician who has spent his career studying the incidence of disease among uranium miners, and who was formerly the principal investigator for the Public Health Service's prospective epidemiological study of uranium miners of the Colorado Plateau area, testified:

> There have also been a large excess of deaths among uranium miners from other lung diseases, which we group together as non- malignant respiratory diseases, NMRD. This includes pulmonary fibrosis, radiation pneumonitis, emphysema, silicosis, chronic bronchitis, chronic obstructive lung disease, and corpulmonale. We have shown that the radiation in the mines does contribute to this group of deaths. We cannot assign radiation to any particular one of these diseases, but it does seem to contribute somewhat to all of them. We also know that there are other contributors to these diseases, such as silicate dust, cigarette smoking, chronic infections, and we are unable to really separate them out as to causation.[99]

Dr. Archer's testimony was based on the results of pioneering studies he and others published in the 1960s and 1970s.[100] These studies and others were summarized, cited and/or submitted to Congress in later hearings.[101]

Dr. Archer explicitly affirmed the association in the following colloquy with Senator Hatch:

Sen. Hatch: In your opinion, what nonmalignant respiratory diseases did the uranium miners develop as a result of exposure to radiation?

Dr. Archer: Well, it is the group of nonmalignant respiratory diseases which I mentioned earlier, primarily pulmonary fibrosis, emphysema, chronic bronchitis, chronic obstructive lung disease, and corpulmonale.

> Sen. Hatch: And these are the types of radiation diseases that the uranium miners developed as a result of exposure to radiation?
>
> Dr. Archer: Well, I can't say that directly because of the contribution of other items to those diseases, but we did show epidemiologically that the exposure to radiation almost certainly contributed to the development of these diseases, and they are much higher among the uranium miners than among nonmining groups.
>
> Sen. Hatch: So you were saying there is a high probability that the exposure to radiation contributed to these diseases, these nonmalignant diseases?
>
> Dr. Archer: Yes, yes, that's correct.[102]

Explicit support for this position came from a physician who treated Navajo miners during his tenure at the Indian Health Service facility at Shiprock, New Mexico in the late 1970s.[103] In written testimony submitted at the same hearing at which Dr. Archer testified, Dr. Leon Gottlieb stated:

> In our Shiprock Navajo Clinic for uranium miners, we observed also, in addition to lung cancer, other lung diseases associated with uranium mining and milling. These pulmonary disorders consisted of silicosis and pulmonary fibrosis (scarring of the lung tissue). These conditions were the sequelae of inhaling rock dust and radioactive particles (radon daughters). Hazardous exposure in uranium mines may lead to malignant or non-malignant lung disease. The malignant type obviously is cancer of the lung; the non-malignant type comprises silicosis of the lung (fibrosis), and radiation pneumonitis (fibrosis).[104]

Much of the testimony submitted to Congress in support of an association, including the testimony cited above, can be interpreted as suggesting only that the development of various nonmalignant diseases appears to be related to some agents in the mining environment, including radiation, acting alone or in combination.

There is only one reference in the legislative history of which the Committee is aware advocating that compensation for the nonmalignant disorders explicitly be tied to the same exposure standards set for lung cancer compensation. That reference, interestingly, is from Dr. Archer: in testimony advocating separate exposure standards for lung cancer based on a claimant'ssmoking status, Dr. Archer stated:

> I have been involved in a number of workers' compensation cases in about five States in the West with uranium miners, and I have been frequently asked to determine whether the particular lung cancer was more likely or not caused by the radiation in the mines. For nonsmokers, this is quite easy if their radiation exposure has been above 100 Work Level Months, ... For heavy cigarette smokers, however, this is a little more difficult. Usually above 800 [*sic*] Work Level Months, it is more likely than not that the lung cancer is due to radiation. .... But we cannot make that sort of division for the NMRD cases, so that I would recommend that if any thresholds for exposure are used, that they be set the same as for the lung cancers.[105]

However, the most recent and analytically rigorous review of the pertinent scientific information on this issue is found in a 1992 report prepared by Dr. Samet and colleagues at the University of New Mexico School of Medicine for the Department of Health and Human Services in response to a congressional mandate in the RECA.[106] This report concludes that the presumed association between exposure to radon and the development of pulmonary fibrosis has not been conclusively established.[107] The report further concludes, consistent with the earlier hypothesis of Dr. Archer, that the disease process in miners is possibly related to exposure to other agents in the mining environment. The authors of the report noted that the existence of a distinct disease of radiation-induced pulmonary fibrosis is plausible, given our present understanding of pathogenetic mechanisms of lung injury, and the results of animal studies that report radiation-induced changes to lung structure that could be precursors of interstitial fibrosis.[108] Nonetheless, they concluded, the latest and most scientifically sound epidemiological studies of uranium miners cannot establish the existence of the disease because one cannot separate out the effects of radon exposure from the effects of other known or potentially toxic agents in the mining environment, such as silica, diesel exhaust, dust and other particles and gases.[109] The prior studies originally relied on by Dr. Archer and others, the report maintains, suffer from sufficient methodological shortcomings to render their results ambiguous.[110]

No data or analyses contradicting the conclusions of the 1992 HHS Report have been brought to the Committee's attention. Because the Act presently conditions compensation for nonmalignant disorders on criteria possibly unrelated to the development of fibrosis, it may unjustly deny compensation to miners whose nonmalignant disorders were likely caused by their mining experience. We have concluded, therefore, that the Act would more accurately compensate claimants who developed fibrosis as a result of their mining employment if the present exposure- based criteria were replaced with alternative criteria, such as duration of employment, that better represent the relevant risks posed by the mining environment.

2. Proof of Radon Exposure As A Condition For Compensation For Silicosis or Pneumoconiosis

As explained above, the Act explicitly ties compensation for all the nonmalignant respiratory diseases, including silicosis and pneumoconiosis, to proof that the claimant was exposed to minimum levels of radon progeny during employment in the mines.[111] The Act limits compensation for these two diseases, moreover, to miners who were employed in mines on Indian Reservations.[112]

As was the case with fibrosis, above, the Committee heard from numerous critics that the Act inappropriately presumes an association between exposure to radon and silicosis that is not medically justified. Indeed, the criticisms suggest that the case for reform of the Act is even more compelling for these two nonmalignant diseases. Again, these criticisms were brought out by Dr. Samet during his testimony at the Senate hearings on oversight of RECA in 1993:

> Silicosis is caused by inhalation of crystalline silicon dioxide and levels of exposures to radon progeny are not known to be strongly associated with those of silicosis exposure. ... Silica causes silicosis; radon exposure does not cause silicosis. So the requirement that, there, in fact, be a threshold value or any particular value of radiation exposure before a miner receive compensation for silicosis is not correct.[113]

The Committee also heard or reviewed comments from most every interested group critical of the limitation on compensation for silicosis and pneumoconiosis to mines located on an Indian Reservation.[114]

The Committee believes that these criticisms are justified. We recommend, first, that the Act be modified to incorporate alternative

compensation criteria for silicosis;[115] and second, that compensation for silicosis or pneumoconiosis be extended to all claimants who were employed in underground uranium mines in any of the five states specified in the Act.

Although the Act explicitly provides compensation for silicosis and pneumoconiosis to any miner, whether Native American or not, who was employed in mines on an Indian Reservation, there is no explicit indication in the legislative history that Congress intended to link compensation for silicosis and pneumoconiosis to radiation exposure. The legislative history suggests that these two nonmalignant diseases were added to the Act at the last moment principally because of reports that Native American miners suffered an increased incidence of these diseases. As Senator Hatch explained just prior to the Senate's passage of the RECA:

> Finally, at the request of several of the co- sponsors to this measure, I have included two additional uranium mining related diseases for which compensation will be available, if the miners worked in uranium mines that were located on or within an Indian Reservation. As I have noted several times before, many of the uranium miners involved in the production of uranium were Native Americans from some of the Southwestern Indian Tribes. Furthermore, many of the mines were located within their reservations. Given the special trust relationship of the United States Government over the activity of these tribal members, it is only fair that we also include compensation for these diseases. These mines were some of the earliest and consequently most contaminated mines. In addition, they were not subject to any form of state regulation.[116]

There is little if any evidence in the legislative history supporting a direct association between radiation exposure and silicosis. Most of the testimony on nonmalignant diseases, including the testimony of Dr. Archer cited above, suggests that radiation at best contributed to the development of silicosis.[117] For example, Leonard Haskie, Interim Chairman of the Navajo Tribal Council testified before the Senate Committee on Energy and Natural Resources in March, 1990, that

> "[s]erious respiratory diseases such as ... silicosis, fibrosis, and others became prevalent [among Navajo miners]. Studies show these diseases are caused by exposure to radiation and radioactive dust particles present in the mines. ... Unfortunately, many Navajo uranium miners are suffering from serious respiratory diseases to which radiation is only a contributing

> factor."[118]

Similarly, another witness at the same hearing, testified:

> Although the Act clearly calls for compensating former uranium miners with some non-malignant respiratory diseases, the Act appears to include only those non-malignant diseases which have been linked to radiation exposure, such as fibrosis. Other diseases found in excess among this population such as silicosis may be left out because a clear relationship between radiation cause and effect has not been established. The point here is that silicosis as well as other non- malignant respiratory diseases, have been clearly linked to working in these early uranium mines, most probably associated with dust from blasting.[119]

Most of the uranium mines in the designated states were located in mineral belts comprised of ore-bearing sandstone, which contains silica dust.[120] The silica-containing mineral belts were mined throughout portions of the West; they were not restricted to areas within Indian Reservations.[121] As a result, individuals who were employed in underground uranium mines in the states covered by the Act are at risk of developing silicosis.[122] The incidence of silicosis among uranium miners has been documented in epidemiological studies and by clinicians in mining areas.[123] While it has long been known that silicosis is caused by exposure to dust containing silica, according to the 1992 HHS report to Congress it is still uncertain if or how exposure to radon progeny affects a miner's risk of developing silicosis.[124]

The Committee believes that the demonstrated incidence of silicosis among uranium miners, and the almost complete absence of data indicating if and how radon exposure affects the risk of silicosis, counsel strongly against the present statutory scheme that compensates silicosis purely as a function of exposure to radon. We recommend, again, that compensation for silicosis (or pneumoconiosis), as with the other nonmalignant respiratory diseases, be conditioned on alternative criteria, such as duration of employment for designated period(s) of time. Moreover, because the geological information indicates that uranium mines both on and off Indian reservations were in sandstone-bearing ore, posing a risk of silicosis to the miners, the Committee recommends that the Act be amended to eliminate the geographic limitation on compensation for silicosis and pneumoconiosis.

Again, as was the case with fibrosis above, we cannot recommend specific alternative compensation criteria for these two diseases.

Although some historical dust data does exist, we do not know if there is a sufficient amount, or if it is sufficiently accurate, to serve as a basis for quantitative analysis.[125]

C. Recommendations for Modification of the Existing Regulations Governing Proof of A Nonmalignant Respiratory Disease

The bulk of the Committee's recommendations relating to nonmalignant respiratory disorders propose changes to the existing regulations that govern the proof required of a claimant to establish the compensable medical condition. During the course of our review, the Committee heard numerous criticisms of these regulations and the manner in which they were being administrated by the Program. The Committee has concluded that some, though not all, of the criticisms are well founded and warrant changes. We also concluded, however, that some of the criticized regulations effect a reasonable balance between the statutory mandate to compensate deserving miners and legitimate policies of the Program, given the medical evidence that can reasonably be demanded of claimants.

1. Requirement That Claimant Prove Functional Impairment in Addition to the Presence of Disease

The regulations require living miners seeking compensation for a nonmalignant disorder to submit reliable written medical records documenting both the presence of a compensable disease process and reduction in pulmonary function.[126] Proof of disease is made by submitting chest radiographs evidencing the disease; proof of functional impairment is made by submitting the results of one of two clinical tests showing a reduction in pulmonary function.[127] Thus, an individual with a mild case of a nonmalignant disorder detectable by chest radiograph but with no appreciable reduction in lung function would not qualify under the regulations.

The requirement that a claimant prove both structural abnormality and functional impairment has been criticized, chiefly by claimants' attorneys, as going beyond the text of the statute. The critics point to the explicit language of the statute, which requires only "written medical documentation that [the miner], ... developed a nonmalignant respiratory disease ...."[128] This language does not impose any impairment requirement, the critics maintain; claimants should be entitled to compensation if they can produce either radiographic evidence of the disease process or the appropriate clinical evidence of reduced pulmonary function.

The Committee finds this criticism without merit: we believe that the regulations accurately and appropriately express the intent of

Congress. Although the Act does not explicitly include a requirement that a claimant with a nonmalignant disease prove impairment, the Committee believes such a requirement is clearly implied in the statutory scheme.

To begin with, the Act all but demands a functional impairment requirement in the case of silicosis and pneumoconiosis: the Act specifically defines the term nonmalignant respiratory disorder to include only "moderate or severe silicosis or pneumoconiosis."[129] A uniform system for classifying the extent of a pneumoconiotic disease process as evidenced on chest radiographs does exist; in fact, this system is used by the Program for the interpretation of chest radiographs for proof of disease.[130] This classification scheme, however, does not purport to grade the severity of the disease process, or distinguish radiographic evidence of disease as mild, moderate or severe.[131] On the other hand, these distinctions are terms employed by physicians to differentiate the degree of functional impairment resulting from respiratory disease.[132] This suggests to us that Congress intended proof of at least silicosis and pneumoconiosis to be made by reference to impairment.

The legislative history supports this interpretation. During the Senate's debate leading to the passage of the Act, Senator DeConcini stated: "As I understand it, the respiratory diseases that are most prevalent among these Native Americans miners are silicosis or pneumoconiosis. There is a requirement in the Act that those eligible for compensation have a moderate or severe case because the intent of this legislation is to compensate those individuals with both serious respiratory diseases."[133]

Moreover, in 1992, during the Senate's consideration of amendments to the RECA, Senator McCain stated:

> [W]hen the Congress enacted the Radiation Exposure Compensation Act, that Act included a Native American provision which extended compensation to any former uranium miner who is a member of an Indian tribe and has contracted moderate or severe silicosis or pneumoconiosis, in addition to lung cancer and other serious respiratory diseases. ... In keeping with the intent of the Act, compensation is limited to those individuals that are severely disabled.[134]

This intent seems evident to us not only because of the express limitations on recovery for silicosis and pneumoconiosis, but in light of the severity of the other compensable medical conditions in the Act. In addition to the nonmalignant respiratory disorders, uranium miners are compensated for lung cancer, a malignancy that is often

fatal or at least life threatening, and which in most cases seriously and irrevocably disrupts and impairs the quality of life of the individual afflicted.[135] Moreover, the diseases for which the other two classes of claimants covered by the Act are compensated are, like lung cancer, malignant, life-threatening conditions which are either accompanied by, or the treatment of which causes, significant and often debilitating side effects.[136] It does not seem reasonable to us that Congress intended to compensate miners who develop a mild case of a nonmalignant disease that imposes little or no disability the same or a greater amount than other miners or eligible claimants who developed fatal or life-threatening diseases.

Two final considerations help convince us that the present regulation should not be changed. First, fibrosis and silicosis are generally progressive disorders; if and when they progress to a moderate or severe state, a claimant can demonstrate the necessary impairment and receive compensation. Although the claimant with mild disease would surely like the money sooner rather than later, he is not irrevocably denied compensation. Second, we recommend below that the regulations be modified so that claimants, in some circumstances, can submit high- resolution computed tomograph (HRCT) scans as evidence of the disease process. The medical literature indicates that HRCTs may be significantly more sensitive than chest radiographs, and, consequently, will pick up evidence of fibrosis and silicosis more often, and in more mild states, than the chest radiographs.[137] Accepting these sensitive scans as evidence of disease without requiring commensurate proof of functional impairment would make it likely that individuals will be compensated whose quality of life is not appreciably altered or disturbed by the disease.[138]

2. Regulations Governing Proof of Disease Process

The regulations require proof that a miner suffers or suffered from one of the compensable nonmalignant diseases. For living miners, this is done by submitting a chest radiograph evidencing changes to the lung structure consistent with the specified diseases.[139] Beneficiaries of deceased miners need only submit one of a series of specified medical records containing a diagnosis of a compensable disease, including, if they exist and are of appropriate quality, chest radiographs.[140]

The regulations specifically set out the technical standards that constitute radiographic proof of disease, and the necessary documentation. A claimant must submit a radiograph and interpretative reports of at least 2 certified "B"-readers concluding that the radiograph demonstrates the existence of fibrosis of at least category 1/0 according to a widely-accepted classification scheme

for assessing the existence and extent of pneumoconioses.[141] Under this classification scheme, a radiograph is given one of 12 grades according to the degree of "profusion," which is an assessment of the concentration of small opacities that mark scarring of the lungs, as compared with standard radiographs.[142] A radiograph graded as category 0 (profusion scores of 0/-, 0/0, 0/1) is considered to be consistent with normal lung structure. A classification of 1/0 means that the radiograph reveals abnormalities in the lung structure consistent with fibrosis or pneumoconiosis.[143] The regulations thus require the lowest score that is consistent with the existence of a compensable disease.

The regulations require that the radiograph be classified by a certified "B"-reader.[144] A "B"-reader is a physician who has been certified by NIOSH as having demonstrated proficiency in the application of the ILO classification system of radiographs for pneumoconioses.[145]

Critics have raised four major objections to this regulatory scheme governing proof of disease. First, it is inappropriate, burdensome and unwarranted to require claimants who can prove pulmonary impairment as required in the regulations to also submit proof of disease process. Second, the regulations should allow claimants to prove disease by means of high-resolution computed tomography (HRCT) scans in addition to chest radiographs. Third, the regulations should allow claimants to prove disease by means of biopsy. And, fourth, the requirement that chest radiographs be interpreted only by "B"-readers is unnecessary and oppressive to claimants, and is being administered arbitrarily by the Program. We will take each in turn.

(a) Regulation Requiring Proof of Disease Process Where A Claimant Can Prove Impairment

The Committee heard from some critics who found fault with the regulations in the converse situation to that addressed immediately above: that where claimants can prove functional impairment through the required clinical tests, they should not also be required to prove the presence of the nonmalignant disease. The concern in these circumstances arises from limitations of chest radiographs in detecting interstitial lung diseases such as fibrosis and silicosis, coupled with the belief that proof of disease is unnecessary where functional impairment has been verified. Critics contend that requiring all claimants to prove disease has the effect of denying timely compensation to those claimants who suffer from a compensable disease and are impaired, but may not develop radiographic evidence for some time -- possibly after the claimant is too disabled to benefit from the compensation.

It is well established that chest radiographs have a high rate of "false negatives" -- that is, they falsely report the absence of disease that in fact exists. The medical literature reports that chest radiographs will appear normal in as much as 10-18% of patients with interstitial lung diseases proven by biopsy results.[146] Moreover, studies have demonstrated that persons exposed to dusts occupationally may suffer from significantly reduced pulmonary function years before the disease becomes evident on a chest radiograph.[147] The Committee believes it is quite likely, therefore, as critics charge, that some claimants with a compensable nonmalignant disease are not being timely compensated despite clinically-evident impairment.

Nonetheless, the Committee recommends that claimants continue to be required to submit radiographic evidence of disease. We believe it would be inappropriate to rely solely on proof of physiologic impairment for at least two reasons. First, the tests accepted by the Program for proof of impairment -- pulmonary function tests and arterial blood gas studies -- are not specific for the statutorily-specified nonmalignant diseases. These tests reveal a reduction in the patient's pulmonary function, but do not identify the specific etiology or disease process that caused the reduction. These tests will detect reduced pulmonary function due to both restrictive lung diseases -- a class that includes, but is not limited to, interstitial fibrotic disorders -- and obstructive lung diseases -- a class that includes chronic obstructive pulmonary disease.[148] It is well documented that the majority of miners were smokers, putting many at an increased risk of obstructive disease.[149] Consequently, if the Program were to rely solely on proof of functional impairment, there is a serious risk that an appreciable number of miners would be compensated improperly.[150]

Second, although the problem of false negative chest radiographs is compelling, the Committee does not believe the appropriate answer is to eliminate the requirement that the claimant prove disease. Instead, as discussed below, we recommend that claimants be allowed in some circumstances to demonstrate the presence of disease by HRCT. This imaging technique is often more sensitive and specific than a chest radiograph; most claimants with even low levels of fibrosis, silicosis or pneumoconiosis will be able to demonstrate sufficient abnormalities to justify compensation.

(b) Lack of Authority in the Regulations for Proof of Disease By HRCT Scans

The regulations require claimants to prove disease process by chest radiographs.[151] No provisions exist for the submission of other evidence of lung abnormality. There is relative unanimity among all interested groups, including physicians who treat miners and

medical researchers who study the mining population, that a complete ban on proof by modalities other than chest radiograph is unwarranted. The objection rests on the accepted proposition, noted above, that chest radiographs have a significant false negative rate for detection of interstitial lung diseases such as fibrosis and silicosis. Critics advocate that the Program modify the regulations to accept HRCT, which they maintain is an accepted and available diagnostic technology of greater sensitivity and specificity than chest radiography. While HRCT is not itself without limitations, it is argued, miners should not be denied the ability to prove eligibility by means of available and reliable medical tests. The Committee agrees.

The Program's reliance on chest radiographs is not unreasonable. Chest radiographs are the modality used most often in the assessment of interstitial lung disease[152], and, when coded by the ILO classification, are generally accepted as the basis for a diagnosis of pneumoconiosis without additional histologic proof.[153]

Nonetheless, it is well recognized that chest radiographs and the interpretative process suffer from significant limitations. Radiographs have only limited resolving power; the two dimensional nature of the medium results in the superimposition of structures, obscuring significant portions of the lung; and the radiographic image is affected by the background density of the lung, and the shape and composition of lesions. The ILO classification scheme, created for descriptive and semiquantitative analysis, not diagnostic purposes, permits substantial reader error and interreader variability, particularly at low profusion scores.

Because of these limitations on the sensitivity (the ability to detect disease) and selectivity (the ability to differentiate among diseases) of chest radiographs, it is often difficult to make a confident and accurate diagnosis of pneumoconiosis on the basis of a radiograph alone.[154] Indeed, the medical literature documents that chest radiographs have an appreciable false negative rate, and underestimate the incidence of diseases such as fibrosis and silicosis.[155]

High-resolution computed tomography is now widely accepted as a reliable diagnostic modality. Because of its significantly greater resolving power, HRCT is more selective and more sensitive than chest radiographs, and allows for a better assessment of the type and severity of lung abnormalities. Consequently, HRCT allows for a more confident and specific diagnosis than a chest radiograph, and one that is more accurate.[156] Of particular significance, recent studies demonstrate that HRCT is more sensitive than chest radiographs in detecting interstitial lung diseases. Studies indicate that HRCT detects significantly more evidence of pneumoconiosis

(such as silicosis) than a radiograph, resulting in earlier detection and detection of disease in a more mild state.[157] HRCT also significantly reduces the variability of diagnosis among readers.[158]

There are, however, problems associated with the use of HRCT evidence, as even those advocating their use concede. HRCT scans are costly(159) and entail yet an additional dose of radiation to the claimant.[160] Equally problematic, there apparently are no official, uniform, accepted standards for the diagnosis of interstitial lung diseases by HRCT.[161]

In light of the many advantages of HRCT over chest radiographs, and the strong advocacy of treating physicians and researchers in the affected areas, the Committee recommends that the regulations be modified to allow claimants to submit HRCT evidence as proof of disease. The increased sensitivity and selectivity of HRCT should reduce significantly the number of claimants who are unjustly denied compensation because of the absence of evidence or misdiagnosis of radiographs.[162]

We do not recommend that claimants be required to submit HRCT evidence in every case: we recommend that it be accepted only in those circumstances where a claimant has demonstrated sufficient impairment to qualify, but has a chest radiograph that does not indicate fibrosis, silicosis or pneumoconiosis. The Program should continue to use the chest radiograph in the first instance to identify fibrosis or silicosis; radiographs are widely available and inexpensive. We also believe the Program should continue to accept as proof of disease a radiograph interpreted as showing profusion of 1/0 or more, as the regulations presently provide, though there is an acknowledged risk of a false positive interpretation. In our opinion, it is only where a claimant is impaired because of a proven lung disease, and the radiograph does not show a compensable abnormality, that the cost of the HRCT and additional radiation dose is justified.

We believe that the disadvantages of HRCT evidence noted above are not insuperable obstacles. First, the lack of official standards for the diagnosis of pneumoconiosis by HRCT, such as an ILO-type classification scheme, should not be a major problem. The increased sensitivity of HRCT reveals significant morphologic detail of the lung, and accepted descriptions of the appearance of normal and abnormal lung anatomy on HRCT have been published.[163]

To minimize, if not avoid the problem entirely, we recommend that the Program establish a panel of appropriately-credentialed radiologists to interpret the HRCT evidence. We recognize that this is at odds with the philosophy governing the submission of

radiographic evidence: the regulations allow claimants to identify and obtain reports from B- readers of their choosing. In the case of HRCTs, however, we believe centralizing the task of interpretation is warranted. The use of HRCT to diagnose pneumoconiosis is a relatively recent phenomenon; while its effectiveness and reliability for this purpose has been established and accepted by the specialist medical community, there is some concern that it is not so common nor widespread that sufficient expertise has developed in all communities. A single panel of authorities will allow for consistent application of diagnostic and interpretative standards.[164] It will also lessen the cost to claimants.

Second, while the cost of an HRCT scan is significant, we do not believe it is excessive given the potential compensation at stake. Indeed, we have been informed by a number of attorneys representing claimants that miners presently are obtaining HRCT scans. Moreover, it is not a large class of claimants who will be forced to bear the cost if our recommendation is accepted.

(c) Lack of Authority in the Regulations for Proof of Disease By Biopsy in Living Miners

The regulations allow the surviving beneficiaries of a deceased miner to prove disease by means of a pathology report of tissue biopsy.[165] The regulations do not allow a living miner to submit the same evidence.[166] Presumably, this restriction was designed to discourage claimants from undergoing dangerous and invasive surgery solely to establish their right to compensation. A number of interested parties have criticized this restriction, pointing out that where a biopsy result exists, there is no good reason why the Program should not accept it as proof of disease. We agree.

The most accurate basis for diagnosis of disease is by a tissue biopsy; it is the medical equivalent of the "gold standard." The sensitivity of other diagnostic modalities, such as chest radiographs or HRCT scans, is often measured against findings on biopsy.[167]

We believe the Program's concern that it not create an incentive for unnecessary and dangerous surgery through the regulations is fully justified. However, where a tissue biopsy is performed for a medically- justified reason and not principally out of a desire to establish eligibility for compensation, we see little reason to ignore definitive evidence and allow a deserving claimant to be denied compensation.[168]

We recommend, therefore, that the regulations be modified to allow for living miners to submit tissue biopsy results as proof they have developed a compensable nonmalignant disease. We also believe it

is not unreasonable to rely on the ethics and sound judgment of physicians not to perform biopsies where medically unwarranted. The potential consequences of performing unnecessary surgery should prove a sufficient check. Nonetheless, the Program should be able to guard against the problem in a relatively simple fashion. The regulations should specify, first, that biopsies can be submitted only if performed for independent, medically-justified reasons; and second, the Program can, either routinely or where appropriate, require the claimant to submit medical documentation from the treating physician explaining and justifying the reason for the biopsy. The documentation can be audited by experts at NCI, NIOSH, or other appropriate federal agency.

(d) Requirement That Chest Radiographs Be Interpreted Only By "B"-Readers

As explained above, the regulations require that the claimant's chest radiograph be interpreted by "B"-readers.[169] A report finding fibrosis or silicosis by a treating physician or radiologist is not sufficient.[170]

This requirement is the object of considerable criticism. The criticism seems directed to two distinct though related issues: first, critics argued that the "B"-reader requirement is an unnecessary imposition on claimants, and is of correspondingly little benefit to the Program; and second, they accuse the Program of abusing its discretion by selectively having reports of some "B"-readers reinterpreted by its own in-house experts, almost always resulting in the denial of the claim. The Committee concludes that the "B"-reader requirement is worthwhile and should be retained, but recommends that the Program establish a fair and random audit procedure to ensure that "B"-readers are properly interpreting radiographs.

As discussed above, the diagnosis of pneumoconiosis by chest radiography is an inexact science. It is well established that there is significant variability in radiographic interpretation among readers, including "B"-readers. This variability contributes to the documented observation that the diagnosis of pneumoconiosis by chest radiograph has appreciable associated false negative and false positive rates.[171] As a rule, however, trained and certified "B" readers demonstrate less inter- and intra-reader variability in their readings than untrained and uncertified readers. The Program presumably requires reports of B- readers as a means of minimizing the risk of an erroneous diagnosis, with obvious benefits to both claimants and the Program.

The controversy over the use of "B"-readers arises, of course, because the Program relies on chest radiographs as proof of disease

in the majority of cases. The controversy could be practically eliminated by demanding HRCT evidence or other more powerful radiographic evidence of disease in every case. The Committee believes this would be inappropriate: we recommend that the Program retain the present regulation requiring chest radiographs of claimants with nonmalignant disorders. The risk of misdiagnosis notwithstanding, the chest radiograph is an accepted and valid technique for the diagnosis of pneumoconiosis.[172] If HRCT scans are accepted from claimants with proven impairment and negative chest radiographs, the risk of misdiagnosis is almost entirely on the Program: a claimant with a negative chest radiograph can submit HRCT evidence to prove that the earlier result is a false negative; but claimants with positive radiographs (graded as profusion of 1/0 or greater) are not required to submit HRCT evidence, and are compensated despite the risk of a false positive diagnosis. Such a system does not strike us as unfair.

Moreover, HRCT scans are much more expensive than chest radiographs, and subject the claimant to an additional dose of radiation.[173] The Committee believes that it is neither reasonable nor necessary to impose these burdens on all claimants.

The Committee also believes that the Program is justified in continuing to require the chest radiograph to be interpreted by "B"-readers. By definition, "B"-readers have been certified by the government as having special proficiency in the classification of radiographs for the presence of pneumoconiosis not generally shared by all physicians and radiologists. "B"-readers have demonstrated knowledge of the appropriate standards for the radiographic classification of pneumoconiosis, and, more importantly, an ability to apply those standards within an acceptable degree of variation. Relying on "B"-readers may not eliminate inter-reader variability,[174] but it does seem a reasonable way of limiting these risks. While the risk of misdiagnosis is present even if the Program relies on "B"-readers' expertise, there is plainly a much greater risk if one accepts the interpretations of physicians who do not have that expertise, or at least have not allowed their expertise to be verified.

On the other hand, the Committee expresses its concern with the Program's apparent practice of selectively re-reading the reports of B- readers. We heard from a number of critics who charge the Program with re-reading reports of "B"-readers that tend to be more "liberal" in their interpretation. The Program admits that they believe a small number of B-readers are not consistent and forthright in applying the appropriate interpretative standards. The Program admits that in many cases where they receive positive reports from these readers, they have the underlying chest radiographs reinterpreted by "B"-readers who serve as consultants to

NIOSH.

The Committee has no doubt that the Program is motivated by a sincere, good-faith desire to ensure that the appropriate diagnostic standards are being accurately and consistently applied. This is surely a legitimate and important programmatic end, particularly given the substantial sums involved, and the relatively claimant-friendly standard for proof of disease (1/0 profusion or greater). Yet, the practice of selectively auditing only some "B"-readers, and only those "biased" in favor of claimants, may be contrary to the spirit of the regulations, and has apparently led many in the affected communities to conclude that the Program is biased against compensation.(175)

The regulations were obviously designed to allow claimants to submit interpretative reports from "B"-readers of their own choosing.[176] Claimants should not be penalized for seeking out the most "liberal" certified readers, thus maximizing the possibility of compensation. They have done nothing more than the regulations provide.

We believe that the Program can and should audit "B"-readers, but should do so by means of a system that eliminates the potential for selective enforcement of the diagnostic standards. This should, in turn, eliminate the appearance that the Program is abusing its discretion. We offer two such systems as suggestions:

First, the Program can establish a procedure in which the interpretative reports are randomly audited. That is, every *xth* case will be sent to an independent panel of "B"-readers to be reinterpreted, regardless of who the "B"-reader is. The claimants' positive readings would be disregarded only if some percentage of the panel (majority, two-thirds, etc) conclude that the radiograph evidences profusion less than 1/0. Over time, one would expect all readers who regularly provide reports for claimants will be audited. Those who provide the most readings, and thus pose the greatest risk to the Program of misdiagnosis, will (over time) be audited most often.

There are obvious limitations to this system, however: it may be a considerable period of time before a problematic reader is audited; more importantly, the focus is on the reading and not the "B"-reader, who is free to misdiagnose additional radiographs until audited again.

Second, the Program can audit (and reaudit) every "B"-reader after he/she submits *x* reports. Each time a "B"-reader submits a predetermined number of reports,[177] the underlying radiographs would be sent to an independent panel of "B"-readers. The panel

would review the films to determine whether the audited reader's interpretations, as a whole, were reasonable: that is, were they within the range of scores one would expect from a reader conscientiously and forthrightly applying the accepted classification standards.[178] If the panel concludes they were not, the Program would then refuse to accept readings from that "B"-reader for a specific period of time.

This second procedure likely offers a better check than the first proposed audit process. It allows the Program to "decertify" readers who systematically misclassify the compensable diseases, (either by overestimating or underestimating their incidence), and thus represent a real, long-term threat to the integrity of the Program. Because the panel would review all of the audited readers' interpretations since the last audit, the reader cannot interpret radiographs likely to be audited conscientiously, and others more liberally or conservatively. Additionally, all B-readers would be audited, eliminating the appearance of bias. And, finally, because the audit would only "decertify" readers who have demonstrated repeated unacceptable professional judgment, claimants would still be allowed to take advantage of "B"-readers who tend to interpret more liberally, but within accepted professional bounds.[179]

D. Regulations Regarding Proof of Impairment

The regulations require all living miners to submit the results of physiologic testing evidencing significantly reduced lung function.[180] This is done by producing the results of either pulmonary function tests or arterial blood gas studies.[181] During our investigation, medical researchers at the University of New Mexico School of Medicine brought to our attention two problems in this area. Both have to do with the definition of "normal" lung function employed by the Program.

1. Pulmonary Function Test Standards

Claimants can prove impairment by undergoing tests of pulmonary function.[182] A claimant's lung function as measured by these tests is compared with predicted values based on sex, age and height. These predicted values are derived from external populations without evidence of pulmonary disease that are considered to be "normal."[183] The regulations consider a claimant to be impaired for purposes of compensation if his lung function is equal to or less than 75% of the predicted value (normed for age, sex and height).[184]

The predicted values adopted in the regulations were derived in a widely used study of non-Hispanic Whites in the Tucson, Arizona area.[185] However, it is now acknowledged that the "normal" values

for pulmonary function tests can vary by racial and ethnic differences.[186]

Predicted values for healthy Native Americans of the Southwest have been generated in at least one study.[187] This study concludes that the predicted values for the two pulmonary function measures employed in the regulations, FEV1 (forced expiratory volume in 1 second) and FVC (forced vital capacity), may be sufficiently different between male Native Americans and Non-Hispanic Whites to warrant separate ethnic-specific standards.[188] This study suggests that the predicted values for these two measures in Native Americans are sometimes greater than the predicted values for non-Hispanic Whites.[189] Consequently, it is possible that a Native American miner with greater than 25% reduction in spirometric values will fall above the minimum value in the regulations, and erroneously be judged to have "normal" pulmonary function.

The Committee is not convinced, however, that the one existing study of Native Americans is sufficiently compelling to justify at this time modifying the regulations to incorporate separate predicted values for Native Americans. For one thing, the extent to which the predicted values generated by the Crapo study are accurate for an older population, such as the miner-claimants, is not clear. The median age of the participants in the Crapo study is significantly lower than the age of most claimants seeking compensation for pulmonary function disorders.[190] Additionally, it is unclear whether the predicted values for the FVC and FEV1 measures used by the Program differ significantly from those derived by the Crapo study,[191] which suggests that ethnic- specific equations will in practice help few if any miners.

Additional studies that use a more representative, older population sample may conclusively demonstrate that there are significant differences in pulmonary function between Native American and White miners, thereby warranting separate standards. We recognize that some may argue for adopting separate ethnic-specific standards now even though a difference in "normal" pulmonary function has not been conclusively established, and any such difference appears small. Such an approach would err on the side of benefiting Native Americans, which would be consistent with the expressed intent of Congress to view evidence in a light most favorable to this class because of the federal government's breach of its special trust relationship.[192] Nonetheless, we believe that a stronger, more compelling scientific basis than presently exists in the literature is both a necessary and appropriate prerequisite for the adoption of this ethnic-based classification. We recommend, therefore, that the Program reconsider this question when additional data becomes available.

2. Required Reduction in Lung Function to Qualify As Impaired

As set out above, the regulations define pulmonary impairment for purposes of compensation as either an FEV1 or FVC result equal to or less than 75% of the predicted value. It was pointed out to the Committee that this standard is not quite consistent with the definition of impairment adopted by the American Thoracic Society (ATS). The ATS, in a 1986 official statement, defined "normal" pulmonary impairment as FVC and FEV1 greater than or equal to 80% of predicted value.[193] A claimant is classified as impaired if either measure is below 80%; the degree of impairment -- mild, moderate or severe -- is proportional to the percentage loss of pulmonary function.[194]

We recommend that the regulations be modified to comport with the definition of impairment adopted by the ATS. Indeed, the regulations expressly require that the pulmonary function tests be performed in accordance with the technical standards published by the ATS.[195] It seems reasonable to hold the Program to the definition of impairment employed by clinical physicians treating patients such as miners.

We recognize that Congress required claimants to demonstrate "moderate or severe" silicosis or pneumoconiosis, and that the ATS standard we advocate is "mild" impairment. These are not inconsistent, however. We believe that Congress, by requiring "moderate or severe" silicosis or pneumoconiosis, was attempting to exclude miners who might be diagnosed on a radiograph with a "mild" case of silicosis. As we have discussed at length, above, there is poor correlation between radiographic evidence of pneumoconiosis and functional impairment.[196] Thus, a claimant can be diagnosed with "mild" silicosis by radiograph without concomitantly suffering any significant disability. On the other hand, a patient with "mild" impairment as measured by the ATS definition -- having lost 20% or more pulmonary function -- is likely to be disabled from performing some tasks and to suffer some appreciable decline in quality of life.[197] We believe it is Congress' intent that these claimants be compensated.