Testimony of

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Written Statement of Dr. James D. Crapo, Professor of Medicine, National Jewish Medical and Research Center and University of Colorado Health Sciences Center
Before the Senate Committee on the Judiciary
Concerning S.852, "FAIR Act of 2005"

Introduction

My name is James Crapo, M.D. I am certified in Internal Medicine and Pulmonary Diseases. I am currently Professor of Medicine at the National Jewish Medical and Research Center in Denver, Colorado. National Jewish is a specialty hospital that is the nation's top ranked hospital in pulmonary disease. I am also a Professor of Medicine at the University of Colorado Health Sciences Center. I am a Past President of the American Thoracic Society. I am the current President of the Fleischner Society, a leading international society of selected specialists in radiology and pulmonary medicine. A copy of my curriculum vitae is attached. I have more than 25 years of experience with asbestos-related issues, including medical research and clinical treatment of patients suffering from asbestos-related diseases. I have published in the field of environmental toxicology, including the basis of asbestos-induced lung injury. My research involving asbestos was funded by the National Institute of Environmental Health Sciences. My current research is funded by the National Heart Lung and Blood Institute, and I currently serve on the Board of External Advisors for this Institute. I have previously served as an expert witness on behalf of defendants involved in asbestos litigation.

This written statement is intended to supplement the statement I provided to the Senate Committee on the Judiciary on June 4, 2003, related to S.1125, The "FAIR Act of 2003." I have reviewed the Medical Criteria in S. 852 and will confine my comments to assessment of these Medical Criteria.

Medical Criteria for Identifying Asbestos-Related Diseases

Occupational exposure to significant levels of inhaled asbestos causes a number of diseases including:
? Mesothelioma
? Lung Cancer
? Nonmalignant Lung Conditions
- Asbestosis
- Pleural Reactions

The challenge in writing medical criteria for a national trust is that the above conditions are not always related to asbestos exposure and some do not involve functional impairment. Individuals may develop similar diseases but without contributory causation from asbestos exposure. Distinguishing non-asbestos-related cases from those caused by asbestos exposure, based on scientific and medical standards, is an important element in setting up a valid trust.

One of the Primary challenges for this trust is to ensure that those individuals with a significant injury and impairment from exposure receive an appropriate compensation while minimizing inappropriate compensation of individuals who have no impairment due to asbestos exposure including those whose disease or injury is similar to, but not caused by asbestos. If large amounts of trust funds are distributed to individuals who do not have an asbestos related injury it puts the entire trust at risk and could lead to those with asbestos related injury not being compensated.

I have review the medical criteria in the current version of S. 852. There are a number of changes from S. 1125 that lead to my comments below. To begin, two important changes that strengthen S. 852 are the addition of the concept of requiring a "substantial occupational exposure" to asbestos, and the deletion of compensation for Exposure-only lung cancers (old Level VII).

There remain two major areas in the proposed bill that in my opinion will lead to high level compensation for large numbers of individuals who do not have an asbestos related injury or impairment. These involve those with pleural reactions and those with "other cancers."

Pleural Reactions and Diseases

S. 852 should include medical criteria for payment of claims for pleural reactions only when there is evidence of significant impairment related to extensive pleural disease.

Pleural reactions in the lungs are different than asbestosis. Most pleural reactions are asymptomatic (i.e., do not have any discernible physical effect). For example, a pleural plaque can be characterized as a callus on the chest wall. It does not involve the lung. Pleural plaques are a marker of asbestos exposure but do not cause impairment. Pleural plaques or thickening, unless extensive, do not affect lung function. In medical textbooks these are most commonly referred to as "benign pleural plaques" and not "pleural disease."

In certain rare cases, very extensive pleural thickening can lead to entrapment of the lung and cause impairment. This is called diffuse pleural thickening and is properly termed a disease. Fortunately, new cases of asbestos-induced diffuse pleural thickening are extremely rare since high-level occupational exposures have been virtually eliminated for almost 20 years.

In addition, the presence of pleural plaques or pleural thickening due to asbestos exposure does not increase the risk of developing either asbestosis or lung cancer. When compared to other individuals with similar asbestos exposure but no pleural manifestations, patients with pleural plaques have not been shown to be at increased risk of more serious asbestos-related diseases.

I would recommend deleting bilateral pleural disease as a qualification for compensation in the following Levels:

? Level II: Pleural plaques do not cause the airway obstructive disease that would meet the PFT requirements in Level II. A smoker with mild airway obstruction and who has pleural plaques would qualify for Level II, but would not have an impairment due to asbestos exposure.
? Levels III, IV and V: These Levels describe increasing levels of restrictive impairment due to asbestosis. To qualify for these levels the claimants should have asbestosis as defined by radiographic and clinical data. Bilateral pleural disease does not cause this type of impairment and should not be used to meet the radiographic criteria for these levels.
? Level VII: Pleural plaques and pleural thickening are not independent risk factors for enhancing the risk of lung cancer. This level will primarily compensate smoking induced lung cancers.

Other Cancers

S. 852 should not include claims for cancer other than lung cancer and mesothelioma because current medical science does not establish a causal relationship between asbestos exposure and these other cancers.

At least 69 cohorts have been studied for the risk of lung cancer from occupational exposure to asbestos. Of those, nine cohorts were larger than 5,000 persons. The lung cancer risk of those nine cohorts is shown in the table below. Note that two of the cohorts showed no increase of lung cancer risk (Relative Risks (RR) of 0.84 and 1.03). Five of the cohorts showed modest increases in lung cancer risks (RR's ranging from 1.25 to 1.96), and two cohorts showed high lung cancer risk (RR's 2.64 and 3.7).

Table: Lung Cancer Risk in Asbestos Cohorts >5000
N Observed Expected RR
Rossiter and Coles, 1980 6,292 84 100.0 0.84
Newhouse and Sullivan, 1989 8,404 229 221.4 1.03
McDonald et al., 1980 11,379 230 184.0 1.25
Hughes et al., 1987 6,931 154 115.5 1.33
Clemmesen et al., 1981 5,686 47 27.3 1.72
Raffin et al., 1989 7,996 162 89.8 1.80
Acheson et al., 1984 5,969 57 29.1 1.96
Armstrong et al., 1988 6,916 91 34.5 2.64
Selikoff et al., 1991 17,800 1,008 269 3.7

Goodman et al. in 1999 did a meta-analysis on all 69 cohorts to determine the magnitude of association between asbestos exposure and lung cancer. He found that overall the increased risk of lung cancer associated with asbestos exposure was about 50%, as shown in the table below.
(A RR (Relative Risk) of 1.00 means no increased risk over that of a non-exposed population.)

Table: Lung Cancer Mortality - Asbestos Cohorts Meta-Analysis
Asbestos Exposure
69 Cohorts RR = 1.48 - 1.63
M. Goodman et al., Cancer Causes and Control 10:453, 1999
While it is well accepted that exposure to asbestos is associated with mesothelioma and lung cancer, no meaningful association with other cancers has been established. In the past, several epidemiological studies suggested a relationship between asbestos and malignancies at sites such as the gastrointestinal tract, larynx, kidney, liver, pancreas, ovary and hematopoietic systems. Many of those studies involved case-reports or case-control studies. The best assessment of risk association is done with cohort studies and not case-control studies since exposure assessment in case-control studies is usually derived from questionnaires and is frequently inaccurate. Since those early studies, a substantial number of additional studies of this issue were undertaken, and the weight of current medical and scientific information suggests no clear association between asbestos and cancers other than lung cancer and mesothelioma.

As of 1999, fourteen cohorts had been evaluated for various aspects of gastrointestinal cancer and its relationship to asbestos exposure. In addition, three cohorts evaluated kidney and/or bladder cancer. Two cohorts evaluated prostate cancer and one cohort has evaluated leukemia and other lymphatic or hematopoietic malignancies. A recent meta-analysis of these cohorts shows that for these cancers there is either no evidence of a significant association with asbestos exposure or no dose-response effect. The table below shows the results of that meta-analysis. Besides lung cancer and mesothelioma the only cancer for which a possible association with asbestos exists is laryngeal cancer where the meta-analysis showed an SMR of 1.57. However, variance in these studies was large and there was no evidence of a dose-response effect, raising serious question as to whether cancer of the larynx has a true correlation with asbestos exposure. (Note: A Standard Mortality Ratio (SMR) is similar to Relative Risk with the normal or control value being 1.00 and a 50% increase in death due to that disease being expressed as 1.50.)

Table: Pooled Analysis of Studies of The Risk of Cancer
in Asbestos Exposed Cohorts
Cancer Sites by
Systems and Organs With Latency of at Least 10 Years
No. of Cohorts Meta-SMR 95% CI
Respiratory
Lung 37 1.63 1.58-1.69
Larynx 4 1.57 0.95-2.45
Gastrointestinal
Esophagus 2 - -
Stomach 9 0.92 0.77-1.10
Colorectal 9 0.89 0.72-1.08
All gastrointestinal 14 1.03 0.95-1.11
Urinary/Reproductive

Kidney 3 1.20 0.88-1.60
Bladder 3 0.98 0.73-1.78
Kidney and Bladder 3 1.07 0.87-1.30
Prostate 2 - -

Goodman et al., Cancer in asbestos-exposed occupational cohorts: a meta-analysis. Cancer Causes and Control 10:453-464, 1999.

With regard to "Other Cancers" I would recommend the following:

? Delete Level VI since this level would result in large compensations to large numbers of individuals who develop a cancer for which there is no established causal relationship to asbestos exposure.

Other Recommendations on Changes to the Medical Criteria to Improve the Function of the Trust to be Established under S. 852

? Make the requirements for Quality Assurance more rigorous. Reliable data is the cornerstone to ensuring that claims under S. 852 correctly meet the medical criteria. Currently S. 852 provides only for random audits. A comprehensive audit procedure to review all claims, including an independent B read of chest films would significantly strengthen the function of this proposed trust. No Quality Assurance is specified for Pulmonary Function testing. The medical criteria state that PFTs should substantially conform to the ATS criteria. These criteria are quite rigorous and many screening PFTs fail to meet these standards. The PFTs to be used by the proposed trust need a standardized audit procedure to ensure quality.

? Expand the definition and requirement to demonstrate "Substantial Occupational exposure." The definition of this term needs to include a requirement that the regular exposure to asbestos fibers must also be to a substantial concentration of airborne fibers. As written a claimant could qualify by doing repair or other work using a product with encapsulated asbestos fibers and which has fiber release under work conditions that are equivalent to or even an order of magnitude less than the current OSHA PEL. I would recommend that a minimum exposure fiber concentration be specified using a time weighted average. This exposure level should be on the order of 2-5 fibers per cc if it is to apply to work durations as short as 5 weighted years. This concept should also be included in the definitions of Moderate and Heavy exposure.

? Delete the use of DLCO in Level V - The gold standards for demonstrating functional disability in severe asbestosis (Level V) are decreases in TLC and in FVC. DLCO is more highly variable, non-specific and is not closely correlated with functional disability. It should not be used as a substitute for decreases in TLC and FVC to qualify for Level V. Keeping DLCO as an alternated criteria for PFT changes in Level V will result inappropriately qualifying individuals for Level V that should be Level IV.

? Delete the use of Chest CT scans - Level VIII appropriately recognizes the enhanced risk for lung cancer in individuals with asbestosis. The use of Chest CT as a diagnostic criteria is problematic because it is highly sensitive and there are no scientific standards or criteria for reliably using subtle CT findings to define individuals with enhanced risk for lung cancer. The chest radiograph should remain the standard for defining this relationship.

Conclusions

S. 852 is an appropriate approach to address the arbitrary and wasteful manner in which our current court system operates to compensate asbestos victims. The medical criteria in the current form of the bill will offer compensation to all individuals have an asbestos related disease or impairment, but unfortunately will also expend a large portion of the proposed trust's assets compensating individuals with pleural plaques and no impairment or with cancers that are not caused by asbestos exposure. These issues should be addressed to preserve the assets of the trust to compensate those who are truly impaired by a occupational exposure to asbestos.

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