Testimony of

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WRITTEN STATEMENT OF DR. JAMES D. CRAPO, PROFESSOR OF MEDICINE, NATIONAL JEWISH CENTER AND UNIVERISTY OF COLORADO HEALTH SCIENCES CENTER,
BEFORE THE SENATE COMMITTEE ON THE JUDICIARY
CONCERNING S. 1125, THE FAIRNESS IN ASBESTOS INJURY RESOLUTION ACT OF 2003

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Mr. Chairman, my name is Dr. James Crapo. I am a pulmonary specialist in Denver, Colorado. I appreciate your inviting me here today to testify with respect to S. 1125, the "Fairness in Asbestos Injury Resolution Act of 2003." I shall discuss, in particular, the medical provisions of the bill.

My remarks fall into three parts. First, I will explain my background, and why I am here to testify. Second, I will briefly describe the health effects of asbestos exposure. Third, I will summarize the medical provisions of the proposed statute and explain my conclusion that those provisions are generally reasonable in the context of an overall compromise among conflicting viewpoints. I will also note, however, certain areas in which I believe the medical provisions of the bill may be unduly lax, resulting in the possible payment of awards to people who are not sick as a result of any asbestos-related illness.

I am being compensated for my time at my usual consulting rates by the Asbestos Alliance and the Asbestos Study Group, both of which support the bill before the committee.

My Background

I am currently Professor and Chairman of the Department of Medicine at the National Jewish Center and University of Colorado Health Sciences Center. I graduated from the University of Rochester School of Medicine in June of 1971 and subsequently trained at Harbor General Hospital in Torrance, California, the National Institute of Environmental Health Sciences, and Duke University. Before coming to the National Jewish Center I served for more than 20 years on the medical faculty of Duke University, and for 17 of those years I was the Chief of Duke's Division of Pulmonary and Critical Care Medicine. I am also the member of numerous professional societies. I served as the President of the American Thoracic Society in 1992 and I am currently President Elect of the Fleischner Society, a leading international society of selected specialists in radiology and pulmonary medicine. I am Board Certified in Internal Medicine and Pulmonary Diseases.

In my current position I care for patients. I teach medical students and direct the PhD Program for Graduate Health Care Professionals at the University of Colorado Health Sciences Center. I also conduct research and have published a multitude of peer-reviewed articles on the respiratory system. I am the co-author of several leading textbooks on pulmonary medicine. I have also served from time to time as an expert witness in asbestos litigation and have had the opportunity to observe that litigation first hand.

The Health Effects of Asbestos

All of us are exposed to asbestos from the environment and consequently have asbestos in our lungs. This "background" level of exposure does not cause any asbestos-related disease. Those diseases normally require substantial occupational exposures or the equivalent. Moreover, the amount of asbestos to which people have been exposed varies greatly by occupation and work setting. Due to federal regulation of asbestos that began in the early 1970s, current occupational exposure levels are a tiny fraction of those that existed in the 1940s and 1950s. All of the asbestos-related diseases are considered dose dependent, and the pre-1973 exposures to asbestos that resulted in severe asbestosis and lung cancer are not present today.

We know that substantial exposure is required to produce asbestos-related diseases for several reasons. First, a 1997 study of Canadian miners and millers who were exposed to substantial amounts of asbestosis - up to 300 particles/cu. ft.-year - showed minimal increases in asbestos-related diseases. Second, a 1998 study of women who lived near mining and milling operations showed no increased incidence of lung cancer, although there were several excess mesotheliomas. These women received primarily take-home and environmental exposures, averaging of 25 fibers/cc-years - a level normally seen only occupationally. Third, ambient levels of asbestos very greatly across the United States with urban environments such as New York City and San Francisco having levels from 0.003 to 0.03

fibers/cc. These ambient levels of asbestos can lead to lifetime exposure in the range of 2-3 fiber/cc years and yet have not been shown to be associated with an increased incidence of asbestos-related diseases. Finally, my laboratory has undertaken an extensive evaluation of lung injury responses in rats after an acute exposure to asbestos dust. Animals exposed acutely to 2.5 fibers/cc-year showed only small local areas of inflammation in the short term. After one year these animals were able to repair the initial inflammation and had normal lungs. There was no long term fibrosis and no progression. The important point here is that, while asbestos can be responsible for very serious and even fatal diseases, that is not true of low level or incidental, background exposures. The lungs are good at defending themselves, and it takes a significant exposure to produce most asbestos-related conditions.

The primary asbestos-related conditions found in humans include 1) pleural changes or reactions, 2) pulmonary fibrosis (which, when caused by asbestos, is called asbestosis), 3) lung cancer, and 4) mesothelioma. It is sometimes asserted, based on early work done by Selikoff, that several other kinds of cancer - including gastro-intestinal cancers - are associated with asbestos exposure. However, the early results have not been confirmed in subsequent studies, and most medical experts at present believe that there is no persuasive evidence of a linkage between asbestos and any cancers other than lung cancer and mesothelioma.

None of these asbestos-related conditions is due exclusively to asbestos, and if asbestos could somehow be eliminated from the planet, all of those conditions would continue to exist. This is true even of mesothelioma. While asbestos is today the only clearly identified cause of mesothelioma, it is generally accepted that a substantial proportion of all mesothelioma cases are "idiopathic" - i.e., they have some as-yet unidentified cause other than asbestos exposure. A major task of the medical eligibility requirements in the bill is to determine when a given medical condition is due to asbestos exposure and when it is due to an alternative cause.

Pleural Changes. The pleura is a membrane that surrounds the lungs. It is not itself a part of the lung tissue. Asbestos can cause changes in pleura, such as pleural plaques or pleural thickening. These pleural changes are not the same as asbestosis and do not increase the risk of developing asbestosis. Unless they are very extensive, pleural changes do not affect lung function, and there is no evidence that they increase the risk of an asbestos-related cancer. Pleural plaques may be a marker of asbestos exposure, but they can also result from other causes such as trauma or inflammation. Similarly, pleural thickening has a number of causes other than asbestos.

Asbestosis. Clinical asbestosis is a kind of pulmonary fibrosis -- a diffuse, bilateral scarring of lung tissue which in the case of asbestosis is due to asbestos fibers in the lungs. This type of lung fibrosis can also occur as a result of a large number of other lung diseases, and a chest x-ray determination of lung fibrosis is not specific for asbestosis. The scarring or fibrosis of the lung can lead to a reduction in total lung capacity, which ultimately can produce severe breathing impairment and even death. In many cases, however, asbestosis has few or no symptoms. Moreover, while asbestosis is often considered a "progressive" disease - that is, it can get worse even after exposure to asbestos stops - with the relative small exposures that are typical of people who have asbestosis today, the disease progresses very slowly, if at all. Most people who have asymptomatic asbestosis today never will develop any breathing impairment as a result of their disease.

There is an exposure threshold below which clinical asbestosis will not occur. Individual susceptibility is also an important factor. Even among individuals who are exposed to levels above the threshold necessary to develop disease, some may develop asbestosis and others may not.

The threshold for the development of clinically detectable asbestosis is a cumulative dose of approximately 25 fibers/cc-years. Reaching this threshold of exposure does not necessarily indicate that clinical asbestosis will occur. At a cumulative dose of approximately 75 to 100 fibers/cc-years, the risk of contracting clinical asbestos is on the order of 1 percent.

Lung Cancer. The development of lung cancer can be associated with asbestos. It is, however, impossible to distinguish clinically between a lung cancer caused by asbestos and one caused by something else. Physicians must therefore rely on statistical evidence. There is a debate in the medical community as to whether lung cancer can be attributed to exposure to asbestos in the absence of clinically significant asbestosis. I personally believe that the answer to that question is no. Most of my colleagues agree with that view or believe that lung cancer cannot be attributed to asbestos unless there is at least enough exposure to have caused asbestosis. Thus the exposure threshold for causation of asbestosis would also apply to the causation of lung cancer. There is a small minority viewpoint, however, in favor of the "single-fiber" theory, which holds that any exposure to asbestos is sufficient to cause a lung cancer.

There is a separate debate about the interaction between asbestos exposure and smoking and whether the scientific evidence supports an association between asbestos and lung cancer in the absence of smoking. I believe that the synergistic relationship with smoking described in the literature is most appropriately a relationship of clinically significant asbestosis and cigarette smoking. The risk of lung cancer among smokers is influenced by several factors such as, for example, the age at which a person starts to smoke, the number of cigarettes smoked per day, the number of years smoked, and the depth of inhalation of the smoke. Exposure to side stream smoke or second hand

has also been shown to increase the risk of lung cancer. There is no debate that the increased smoking cessation will reduce the risk of lung cancer, however. This benefit from smoking cessation is markedly reduced in those who have smoked heavily. Smoking 40-50 pack years is associated with an elevated risk of lung cancer that persists for decades after smoking cessation. Lung-cancer risk of non-smokers exposed to asbestos, if any, is far less than the risk of smokers.

Mesothelioma. Mesothelioma is a relatively rare tumor of the pleura or peritoneum. Although asbestos exposure has been associated with mesothelioma, there are a substantial number of cases a year of mesothelioma where these is no indication that the individual was ever exposed to elevated levels of asbestos. However, more than half the cases of mesothelioma in the United States can be shown to be caused by exposure to amphibole types of asbestos. The most commonly used type of asbestos in the United States, chrysotile, has a much lower propensity to cause mesothelioma in comparison to the amphibole forms of asbestos. Although most mesotheliomas are caused by exposures to high cumulative doses of amphiboles, these tumors can occur after relatively low exposures. There is a threshold for exposure to asbestos below which there is no risk for development of mesothelioma. For chrysotile, exposure levels at least equivalent to that required to cause asbestosis are required to contribute to the causation of mesothelioma.

The Medical Criteria of S. 1125

Having discussed the major health effects of asbestos, I turn now to the medical eligibility requirements of S. 1125. At the outset, it is important to note two general requirements. First, every claim upon the Fund created by the bill must be supported by a medical diagnosis that meets the requirements of Section 122. The provisions of Section 122 are comprehensive. They speak to the qualifications of the physician, the requirement of an in-person exam by a treating physician who has done a review of the patient's medical, smoking, work and exposure history, the technical sufficiency of x-rays, pulmonary function tests, and other laboratory results, and the usual medical requirement that the physician exclude other more likely causes of the claimant's condition in determining whether that condition is due to asbestos exposure. As a practicing physician, I think those diagnostic requirements are completely appropriate. In particular, the requirement that the physician exclude more likely causes of the claimant's condition is extremely important. As I indicated above, all of the health effects of asbestos are caused by other things as well, and a diagnosis cannot be well founded if it does not exclude these other alternative causes.

The second general requirement is latency - i.e., the time that has elapsed from first exposure to the date of diagnosis. While Section 123 of the bill would give the asbestos court flexibility in setting different latency periods for different diseases, at the outset the bill establishes a 10-year latency requirement across the board. This period of time is much lower than the average latency of many asbestos-related conditions, particularly under conditions of low asbestos exposures. The latency period for mesothelioma, for example, can be 40 years. While a 10-year latency requirement may be somewhat permissive, it is not inappropriate in the context of a compromise for settling all asbestos cases outside the court system.

The bill's medical criteria are divided into eight levels. With one trivial exception, Levels I through IV address non-cancerous conditions, while Levels V through VIII deal with cancers.

Non-Malignant Conditions. Levels I and II define asymptomatic, non-cancerous conditions. Level I requires (a) a diagnosis of an "asbestos-related non-malignant disease," which must be based on x-ray evidence of asbestosis (i.e., an ILO reading of 1/0) or pleural changes, and (b) a brief (6-month period) of occupational exposure to asbestos prior to December 31, 1982. Level II requires a similar diagnosis but has a more stringent exposure requirement. A claimant can qualify for either of these levels without showing any breathing impairment.

The bill provides medical monitoring for people who fall within these two levels. I believe that that is appropriate. Medical monitoring may provide some reassurance, and it will allow people with potentially abnormal x-rays to discover promptly when they may qualify for an award. Because of the large number of people who could qualify for Levels I and II, an award of compensation to people in these categories could result in a diversion of funds away from people who are genuinely sick to people who have basically asymptomatic conditions. Moreover, the definition of bilateral asbestos-related nonmalignant disease is general and could apply to a large number of diseases with causes unrelated to asbestos.

Level III is the first category that provides for a compensatory award. This level has four basic requirements. The first is a diagnosis of asbestosis or pleural changes. The asbestosis diagnosis must be based on either an ILO reading of 1/0 or pathology, while the diagnosis of pleural changes must be based x-ray evidence of pleural thickening or pleural plaques of a substantial size - i.e, those that are at least a B2 on the ILO scale. Second, the claimant must show breathing impairment of a kind that is consistent with asbestos-related disease. Third, the claimant must show 6 months exposure to asbestos in 1982 or earlier and "significant occupational exposure to asbestos." Fourth, the claimant must present medical documentation that asbestos-exposure is a contributory cause of his condition.

The medical criteria for Level III seem appropriate in the context of an overall compromise. I do, however, have two reservations. The first has to do with the measure of impairment. It is generally accepted that the cut-off between

normal and abnormal on such pulmonary function tests as "total lung capacity" ("TLC") or "forced vital capacity" ("FVC") should be set at the statistical 5th percentile rather than a rule-of-thumb number such as 80%, which does not take into consideration such factors as height or age. More importantly, one of the prescribed tests for impairment, FVC, will allow many people to qualify for an award even though their breathing impairment is due to emphysema or other obstructive diseases caused primarily by smoking. The reason for this is that the claimant can still qualify for an award with an FEV1/FVC ratio of as low as 65%, even though a ratio under 70% or 75% is indicative of obstructive (non-asbestos) lung disease.

My second reservation has to do with the definition of "significant occupational exposure" in Section 124(a)(8) of the bill. Generally, that definition requires employment for 5 years in an industry or occupation in which the claimant (a) handled raw asbestos fibers on a regular basis, (b) fabricated asbestos products in such a way that the claimant was regularly exposed to raw asbestos fibers, (c) altered, repaired, or worked with asbestos products in a way that the claimant was regularly exposed to asbestos fibers, or (d) worked in close proximity to workers covered by the above provisions. If applied strictly, this definition would be a reasonable proxy for the minimum levels of exposure that are necessary to cause asbestosis and lung cancers. It is conceivable, however, that clause (c) would be read broadly to include people who work with encapsulated asbestos-containing products under circumstances in which very few asbestos fibers escape into the air. To treat exposures of this kind as equivalent to exposures received working with raw asbestos fibers would not make any sense. This is important because, with the passage of time, fewer and fewer claimants will qualify on the basis of their work with raw fibers (because regulations will have limited such exposures) and more will seek to qualify on the basis of work with and around finished products, in low-dose environments. Such a shift would make significant occupational exposure mean less and less as time goes by. This problem is exacerbated by the language in clause (d), which would allow those who worked in proximity to workers satisfying the requirements of clause (c) also to qualify, even though their exposure is even more attenuated.

The final non-malignant category, Level IV, provides for cases of severe asbestosis. To qualify for this level, a claimant must demonstrate asbestosis (and not mere pleural changes) through either a definitive x-ray of 2/1 or pathology and must present pulmonary function tests showing severe impairment. The claimant must also meet the same exposure and medical documentation requirements as claimants for Level III.

My reservations about Level III - the danger that many people with obstructive pulmonary diseases rather than asbestos-related disease will obtain awards and concern about the interpretation of significant occupational exposure - apply in principle to Level IV. However, the requirement of a 2/1 chest x-ray, which may be strongly indicative of asbestosis, significantly limits the extent of the problem as a practical matter. Generally, therefore, I believe Level IV is an appropriate category.

Cancers. Cancer claims are divided into four levels. Level V consists of "other cancer" - i.e., primary cancers of the larynx, the esophagus, the pharynx, or the stomach. Level V does not include colo-rectal cancer, which is one of the most widespread cancers in the United States. Claimants may qualify for an award under Level V by showing (in addition to the requisite cancer) evidence of an underlying bilateral asbestos-related disease (generally, a 1/0 chest x-ray or x-ray evidence of pleural plaques), exposure (6 months exposure in 1982 or earlier and significant occupational exposure), and medical documentation of a causal relationship.

As I explained above, the decided weight of the evidence is that these cancers are not caused by asbestos at all. However, since there is a minority viewpoint in the medical community on this point, including these cancers in a compensable category may make sense in the context of an overall compromise. As part of that compromise, however, it also makes sense to exclude colo-rectal cancers. According to the National Cancer Institute, there are 147,500 colo-rectal cancers each year. To allow recovery based on nothing more than plaques and the requisite exposure could expose the Trust to considerable, unpredictable liabilities in future years. This would be ironic, since asbestos litigation as it is today involves few "other cancer" cases, presumably because of the difficulties of proof. There is a danger that the medical criteria in the bill would open the door to many more claims of this kind than are currently seen.

Levels VI and VII both deal with Lung Cancer. The relationship between the two is somewhat complex. At the outset, only non-smokers - defined either as people who have never smoked or as people who have not smoked within the 12 years immediately prior to the diagnosis - can use Level VI, `because the scheduled value for smokers under Level VI is $0. This means that, as a practical matter, smokers must apply under Level VII.

In effect, Level VI allows non-smokers to obtain a limited award ($50,000) on a showing that they have a primary lung cancer, six months exposure to asbestos in 1982 or earlier, and documentation of causation. In my view, there is no adequate justification for Level VI. As noted above, I doubt that asbestos is associated with an increased risk of lung cancer in non-smokers, but in any event there is no basis whatever for attributing a lung cancer to asbestos on the basis of 6 months exposure unless that exposure was truly massive. Most, if not all, of the people who qualify for an award under Level VI will not in fact have an asbestos-related lung cancer.

To be sure, this problem is limited, because most asbestos workers smoked. Many, however, also quit smoking in

recent years, and thus may meet the bill's definition of a non-smoker - someone who hasn't smoked in the 12 years before the diagnosis. Moreover, it is difficult to establish in a non-adversarial administrative proceeding whether a person quit smoking at the requisite time or not. Consequently, I believe that Level VI as written poses an unjustified threat to the financial integrity of the Fund.

Level VII is, and should be, the principal Lung Cancer category. It requires a claimant to demonstrate (a) a primary lung cancer, (b) evidence of an asbestos-related non-malignant disease (asbestosis as shown by a 1/0 ILO reading or pleural plaques), (c) 6-months occupational exposure prior to December 31, 1982 and significant occupational exposure, and (d) supporting documentation of causation. I believe that these criteria are generally appropriate as part of an overall compromise. I do have two reservations, however. One is my concern that "significant occupational exposure" will be interpreted too loosely, leading to a large number of unjustified claims in future years. The second is that the provision requiring an underlying asbestos-related non-malignant disease is too permissive in that it allows a claimant to satisfy this requirement with pleural plaques alone. While asbestosis is a risk-factor for lung cancer, pleural plaques are not. Moreover, while pleural plaques confirm that the claimant was exposed to asbestos, such confirmation adds nothing important to the exposure requirements. In my opinion, it would make more sense to require, as a condition for a lung-cancer award, clinically significant asbestosis.

Finally, Level VIII addresses mesothelioma claims. It requires only a mesothelioma diagnosis plus evidence of some exposure to asbestos prior to December 31, 1982. Although the language is not clear, I assume that this provision does not permit an award based solely on the background exposure that everyone has to asbestos fibers in the environment. The bill should be interpreted as requiring a discrete and identifiable exposure that goes significantly beyond background.

Conclusion

My conclusion is that S. 1125 is a sensible compromise designed to provide a reasonable alternative to asbestos litigation in the courts. It is unlikely that any substantial number of people genuinely sick as a result of exposure to asbestos will be unable to recover from the Fund. Moreover, the Fund will direct most of its resources to the appropriate categories: severe asbestosis (Level IV), lung cancer (Level VII), and mesothelioma (Level VIII). As one would expect of a compromise, however, there are provisions in the bill that appear to me to be unduly permissive and that might be tightened in order to protect the financial integrity of the fund - and thus the ability of deserving asbestos victims to obtain awards in years to come. Level VI is a good example of an unwarrantedly liberal eligibility requirement.

In closing, I would like to commend you, Mr. Chairman, Senator Leahy, and this committee for the work you are is doing to find a better way to compensate asbestos victims. I have witnessed the operation of the court system for many years. It would be difficult to imagine a more arbitrary and wasteful way to compensate people with asbestos-related diseases. Substituting a sensibly designed, streamlined, inexpensive, no-fault system would benefit everyone. In my view, S. 1125 is an excellent first step.