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Leading Medical Experts Fault Arbitrary, Outdated Medical Criteria in Asbestos Bill

Flawed Standards Will Deny Compensation to Many Legitimate Victims of Asbestos Disease

Four of the country's leading experts in the diagnosis and treatment of asbestos diseases are opposing the medical standards that claimants must meet to qualify for coverage under the \$140 billion trust fund set up by the asbestos bill, S. 852, to compensate individuals injured by exposure to the toxic mineral. These clinicians and researchers are:

Michael Harbut, MD, MPH, FCCP, Chief of the Center for Occupational and Environmental Medicine, Co-Director of the National Center for Vermiculite and Asbestos-Related Cancers at the Karmanos Cancer Institute and past chair of the American College of Chest Physicians. According to Dr. Harbut, who currently treats over 2,000 individuals a year, most of whom suffer from asbestos-related diseases, the bill would exclude over 40 percent of his patients despite the fact that their illnesses are clearly attributable to asbestos exposure. Dr. Harbut contends that one former iron worker he has treated for about eight years, and who recently required a double lung transplant, would not have qualified for relief under the bill until perhaps two years ago, when his condition was already so advanced that there was little hope of saving his lungs.

Philip J. Landrigan, MD, MSc, DIH, Chair of the Department of Community and Preventive Medicine at Mount Sinai School of Medicine (the department founded by Dr. Irving J. Selikoff, renowned "Father of Asbestos Research in the United States"), which has been the major provider of diagnostic services to over 12,000 workers at the Ground Zero site of the World Trade Center destruction. According to Dr. Landrigan, a board-certified specialist in occupational medicine (among other specialties) and a member of the National Academy of Sciences' Institute of Medicine, tens of thousands of legitimate lung cancer victims would be shut out of the fund by the bill's medical criteria.

Alan C. Whitehouse, MD, FCCP, Senior consulting physician at the Center for Asbestos Related Disease in Libby, Montana, and the pulmonary specialist who first identified asbestos-induced disease among W.R. Grace miners and factory workers in Libby. According to Dr. Whitehouse, whose patients are largely community members with no direct occupational exposure but who nevertheless developed asbestos diseases because of the toxic dust deposited by the W.R. Grace mine and factory into the air and soil, the bill's medical criteria would exclude 90 percent of the individuals he treats, knocking them down to the lowest disease

category, “Level 1,” where they are only entitled to x-ray and lung function tests once every three years.

L. Christine Oliver, MD, MPH, MS, FACPM, Assistant Clinical Professor of Medicine at Harvard Medical School and Associate Physician of Pulmonary and Critical Medicine at Massachusetts General Hospital. According to Dr. Oliver, who has spent years treating asbestos victims, thousands of exposed individuals who have demonstrated abnormalities on chest x-rays and are therefore at significantly increased risk of developing cancer will be denied vital long-term follow up because of the limitations on medical monitoring in the Level 1 category. These individuals may be prevented from discovering they have cancer until it is too late to stall or reverse the progress of the disease.

And that’s not all. The *American Thoracic Society* has published criteria that disagree considerably with the medical criteria in the bill, although they do not take a position for or against the legislation. The *American Public Health Association*, a membership organization consisting of over 50,000 public health professionals, also disagrees with the medical criteria put forth in the bill.

What is at Stake

The staggering scale of the asbestos epidemic that has already sickened or killed hundreds of thousands of people in the U.S. is underscored by the number of potential victims: some 27.5 million workers exposed to asbestos on the job from 1940-1978, and who in turn contaminated their own families; thousands of residents of Libby, Montana, where asbestos-tainted vermiculite was mined and manufactured into Zonolite insulation for 70 years; hundreds of thousands of people living in the 28 sites nationwide that received 80 percent of the vermiculite mined in Libby from 1964-1980, and those living in the remaining 172 sites where vermiculite was used in factory processing; the residents of over 30 million houses in the U.S. that, according to the EPA, still have vermiculite insulation; the thousands of New Yorkers living and working in proximity to the site of the World Trade Center’s destruction.

An analysis conducted in 1982 projected up to 9,700 cancer deaths each year of workers occupationally exposure to asbestos, and an estimated total 500,000 worker mortalities between 1967 and 2030. But this did not include sickness and death from non-malignant asbestos diseases, nor the full range of potential occupational victims (such as demolition and renovation workers), or those exposed to risks after 1979. And, it only covered workers. Some 10,000 people died of asbestos-related diseases in 2003 alone, and because of the 20-50 year latency period between toxic exposure and manifestation of symptoms—and the fact that asbestos was not strictly regulated until 1986—experts now predict that the peak for both malignant and non-malignant forms of asbestos-related diseases will not be reached until 2018.¹ Disease projections vary widely, ranging from 750,000 to 2.6 million future claims of sickness and death associated with asbestos.² A 2003 Congressional Budget Office estimated some 1.7 million claims over the next three decades.³

¹ Nicholson WJ, Perkel G, Selikoff IJ. 1982. *Occupational exposure to asbestos: population at risk and projected mortality -- 1980-2003*. Am J Ind Med 3:259-311.

² Testimony of Laura S. Welch, MD, Medical Director, Center to Protect Workers Rights, before the Senate Judiciary Committee, June 2003.

³ Congressional Budget Office *Cost Estimate: S. 1125 Fairness in Asbestos Injury Resolution Act*, October 2003.

What the Experts Say

Summary

The bill's medical standards are designed to exclude hundreds of thousands of otherwise legitimate asbestos-poisoned individuals from compensation. The aforementioned specialists in occupational medicine with particular expertise in the effects of asbestos contamination maintain that S. 852 uses arbitrary, outdated medical criteria to define asbestos-related disease that are not based on or are inconsistent with current medical and scientific knowledge. The legislation:

- Requires x-ray evidence of disease instead of more technologically accurate, sensitive and readily available methods such as CT scan, defines disease based on pre-1995 thinking that has since been conclusively disproved, sets fixed exposure thresholds contrary to epidemiological evidence, arbitrarily reduces benefits to smokers and fails to recognize injuries to consumers and residents living in proximity to asbestos processing plants.
- Rejects most of the criteria for determining the existence and extent of asbestos-related disease established by the American Medical Association *Guides to the Evaluation of Permanent Impairment*—standards widely accepted by the medical community and used by 42 states and some Canadian provinces as the basis for workers compensation claims.
- Ignores the recommendations of the American Thoracic Society (ATS), which were developed over the course of three years by the preeminent experts in the field of lung disease, as set forth in its *Guidelines for the Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos*.
- Relies on the term “substantial” as a determinant in a variety of contexts, a word that has no commonly understood meaning in the medical community, nor definition in medical literature or in the bill itself. This means that an administrator will be left to make a decision tantamount to medical diagnosis, which should be made by a physician.

Those excluded will lose their right to seek compensation in court for the harms inflicted by companies that knowingly exposed them to a powerful human carcinogen. As diagnosed sufferers of asbestos-related diseases (although not eligible for financial assistance under the bill) they will be unable to obtain health or life insurance. Some will be unable to continue in their current trade or to work at all. The cost of their continuing medical care—which for someone stricken with asbestosis could be several thousand dollars a month for oxygen alone—will ultimately be borne by taxpayers, if at all.

What follows is a detailed critique of the bill's medical criteria compiled from the testimony, statements and letters to Senate Judiciary Committee members by the aforementioned experts:

Diagnosis based on crude, outdated technology

1. X-rays are a poor substitute for CT scans

The bill almost completely relies on x-rays and a limited set of pulmonary function tests—a more than century-old, forced breathing test—as the basic diagnostic tools and, by extension, determinants of a claimant’s compensation level. Studies comparing x-ray with CT scan technology, have conclusively shown that the x-ray is a comparatively crude way of diagnosing asbestosis. CT scans are about 33 percent more sensitive in detecting interstitial disease, and over 50 percent more sensitive in detecting pleural disease.⁴

X-rays fail to diagnose many victims of lung disease caused by inhalation of asbestos fibers. One reason is that asbestosis—a progressive, sometimes fatal disease that leaves its victims dependent on external oxygen supplies for survival—can be present in the lung even though the x-ray is normal using the ILO classification system specified in the bill. The ATS guidelines affirm the use of high resolution CT scanning for diagnosis of asbestosis when the chest x-ray is normal. As described in numerous peer-reviewed publications and in the ATS report, high-resolution computer tomography (HRCT) is now widely accepted as a diagnostic tool for asbestosis and asbestos-related lung scarring. Recent studies show that readers using a scoring index for HRCT were more accurate and reliable in the diagnosis of asbestosis than when using plain chest x-rays. The most notable study concluded that “the examined HRCT scoring method proved to be a simple, reliable, and reproducible method for classifying lung fibrosis and diagnosing asbestosis also in large populations with occupational disease, and it would be possible to use it as a part of an international classification.”⁵ Expert consensus supports this conclusion.

Nevertheless, there is only limited call in the bill for use of HRCT technology. The cost for HRCT diagnosis compared to x-rays may be a concern, but there is every reason to believe affordable prices for HRCT scans can be achieved, especially as the volume of such scans would grow if the technology were permitted beyond the narrow fashion now contemplated by the bill. Some treating centers have already managed to get the cost down to just a few hundred dollars per CT scan.

2. Mesothelioma diagnosis remains elusive

The bill fails to require the use of sufficiently sophisticated technology to diagnose mesothelioma, cancer of the lining of the abdominal or chest cavity, which is so difficult to detect accurately that a large number of cases go undiagnosed until after death. Mesothelioma cases are the most expensive for industry to compensate. The only documented cause of mesothelioma is asbestos exposure; although it is often referred to as a rare disease, the 2,500-4000 cases of mesothelioma diagnosed annually kill more people in the U.S. than ovarian cancer. PET scans, which can be more sensitive than CT scans, should be incorporated into the diagnostic criteria of the bill. Flexibility to allow for serological diagnosis should also be included in the bill. A blood test field tested in the U.S. and already in use in Australia has

⁴ *Fraser and Paré’s diagnosis of Diseases of the Chest, 4th Ed.*, pp. 2431, 2440.

⁵ O. Huuskonen, et al., *High-resolution computed tomography classification of lung fibrosis for patients with asbestos-related disease*, *Scandinavian Journal of Work, Environment and Health* 27(2):106-12, April 2001.

proven very sensitive in diagnosing the disease. U.S. clinical trials for blood tests for mesothelioma are occurring right now at the Karmanos Cancer Institute in Michigan. Individuals at risk of mesothelioma would be barred from offering the results provided by such emerging technology under the bill.

Diagnosis based on arbitrary criteria inconsistent with the current state of medical knowledge

1. Barriers to proving asbestos-related lung disease

The bill requires *bilateral* pleural disease—thick scarring on the lining of both lungs—in order to establish that asbestos exposure is the cause of illness. Moreover, the scarring, which resembles an orange rind, must be of a certain width and be associated with specific breathing impairment. The dimension and impairment requirements have no basis in medical literature. And as acknowledged by the ATS in its guidelines, pleural scarring associated with asbestos *almost always* begins unilaterally—in just one lung—and often progresses unevenly. Thus, the bill would exclude from compensation, at the very least, individuals in the early stages of asbestosis.

2. Flawed lung function testing

The bill requires abnormal spirometry—a test of the ability to blow air in and out—for a diagnosis of asbestosis, despite the fact that individuals with asbestos-related disease do not necessarily evidence spirometric abnormalities. For example, a construction worker who suffers from obstructive lung disease caused by dust and welding fumes may also suffer from restrictive lung disease due to asbestos exposure on the construction site. The worker may not exhibit abnormal spirometry, however, because the obstructive-restrictive combination can produce an overall normal spirometric test result.

Exposure criteria are unreasonably rigid

1. Minimum exposures exclude valid cases

The bill sets minimum durations of exposure to asbestos in order to establish valid claims of asbestos-related disease. For example, there is a minimum 5-weighted-year duration of asbestos exposure to support a diagnosis of asbestosis. There is an 8-12 year requirement of exposure to establish asbestos causation in the case of lung cancer. There is no support for strict exposure thresholds in medical or scientific literature. On the contrary, evidence points to situations where, under some exposure conditions, a one-month occupational exposure to asbestos can markedly heighten the risk of lung cancer and increase the risk of asbestosis-related death.

2. Unreasonable discounting of exposure after 1976 and 1986

The bill discounts exposure based on the years during which it occurred, counting each year of exposure after 1976 as only half a year, and after 1986 as one-tenth of a year. The rationale for this is presumably the reduced opportunities for toxic exposure after these dates due to the implementation of OSHA and EPA regulations. There is, however, no medical or scientific basis for the discount formula used in the bill, nor any other discount formula. Furthermore, the

formula is ludicrous on its face: an individual with colorectal, laryngeal, esophageal, pharyngeal or stomach cancer whose exposure occurred after 1976 would need 105 years to meet the criteria for a valid claim, according to Dr. Philip Landrigan.

Impairment criteria run counter to AMA guidelines

1. Important medically-accepted tests are left out

How well an individual's lungs are working can be measured accurately and reliably with pulmonary function testing. The diagnosis of asbestosis depends in part on characteristic findings of physical exam, pathology, chest x-ray or CT scan, but impairment must be measured with appropriate pulmonary function testing. The *AMA Guides* states that each worker should undergo spirometry *and* DLCO—a measure of the lungs' efficiency in transferring oxygen into the blood stream—as part of the evaluation of lung impairment, and exercise testing can add additional information if needed. Using a combination of forced vital capacity (FVC), forced expiratory volume in one second (FEV1), DLCO, and oxygen consumption on exercise testing (VO₂max) when needed, the patient is placed into one of four levels.

The asbestos bill refers to the *AMA Guides* and includes spirometry, but omits DLCO and oxygen consumption on exercise testing—both of which are important and readily available tests that the AMA has determined are reliable and essential to determine how badly a person's lungs are impaired. As a result, individuals with asbestosis may have to wait until their disease is advanced before they can qualify for treatment.

Causative criteria unreasonable and unscientific

1. Outdated reliance on “markers” excludes legitimate cancer victims

Versions of the bill in 2003 and 2004 provided three levels of compensation for victims of asbestos-related lung cancer: Level VII, for lung cancer victims with 15 years of substantial occupational exposure, but whose x-rays showed no “markers” of non-malignant asbestos-related disease; Level VIII, for victims with lung cancer whose x-rays showed pleural disease; and Level IX for lung cancer victims with x-rays showing asbestosis. S. 852 has eliminated compensation under the old Level VII criteria for exposure in the absence of radiographic “markers,” a determination that, based on Congressional Budget Office projections will potentially remove more than 40,000 asbestos-related lung cancer victims from coverage.⁶ Provisions recently added to the 2005 bill would allow some of the lung cancer victims without radiographic “markers” to use CT scans to show that they have asbestosis, but the bill does not specify that victims with pleural disease can also use this more sensitive and specific diagnostic test to show their disease and exposure. CT scans have been proven in scientific studies to identify pleural disease or asbestosis in approximately half of individuals without such findings on x-rays, and that about half of these identified by CT scans will have asbestosis and half will

⁶ Testimony of Peg Seminario, Director, AFL-CIO, before the Senate Judiciary Committee, April 2005.

have pleural disease. Thus, the net result of the bill as introduced is that 25,000 – 30,000 asbestos lung cancer victims previously covered may not be eligible for compensation.⁷

Numerous studies show that there is a dose-response relationship between exposure to asbestos and the risk of lung cancer, with increasing exposure leading to increasing risk of disease. There is no known safe level of exposure to asbestos. Workers at U.S. government facilities get an environmental pay differential if their job exposes them to airborne asbestos, regardless of the concentrations or length of time of exposure, so long as protective measures have not been implemented to eliminate the potential for injury.⁸ With 15 years of substantial occupational exposure to asbestos, lung cancer can be attributed to that exposure—it should not be necessary to document underlying non-malignant asbestos disease as well. More importantly, while workers with asbestosis have a two-to-four-fold higher risk of lung cancer than asbestos-exposed workers without asbestosis, asbestosis is merely a surrogate measure of exposure: significant asbestos exposure is required to cause asbestosis. Since 1995, scientific studies have clearly demonstrated that asbestosis itself is not a necessary intermediary for development of asbestos-related lung cancer. Thus, current medical thinking rejects the threshold requirement of a radiographic “marker” to prove that lung cancer has been caused by asbestos. As a secondary matter, even where there is asbestosis, lung disease may not meet the still further hurdle of being bilateral, as already discussed.

2. Smokers are unfairly punished

The bill reduces the ability of lung cancer patients with a history of asbestos exposure and who smoked to receive the same level of compensation as those who did not smoke, despite the well-documented synergistic effect of these two carcinogens. People exposed to asbestos are five times more likely to develop lung cancer than those not exposed. Smokers run a 10-fold risk of developing lung cancer compared to non-smokers. But a smoker who is also exposed to asbestos has 55 times the risk of developing lung cancer. To exclude a lung cancer sufferer with a history of occupational exposure to asbestos solely because the victim smoked is unreasonable because it implies assumption of a significantly heightened risk that, in fact, could not have been known by the victim: even those who would have been aware that smoking posed a danger would not have had knowledge of the synergistic combination, a fact that remains in the province of medical professionals and is not commonly advertised. It is prejudicial because it singles out smokers but ignores the synergistic interaction of other environmental carcinogens, such as drinking arsenic-contaminated well water, with asbestos exposure. It is unfair because it allows a corporation that concealed the dangers of smoking from consumers to blame a given individual’s lung cancer on occupational contact with asbestos, and a corporation that concealed the dangers of asbestos from workers to claim that the same individual, who was an employee, got lung cancer from smoking—thus exempting bad actors from legal liability. Finally, to arbitrarily attribute a smoker’s lung cancer to smoking rather than asbestos because there is no radiographic “marker” of exposure, i.e., pleural disease, flies in the face of epidemiological evidence as described above.

⁷ Ibid.

⁸ *U.S. Dep’t. of Veterans Affairs Medical Center v. American Federation of Government Employees*, 46 FLRA No. 107, January 1993.

3. Consumers and bystanders are left out

The bill only compensates those who were occupationally exposed to asbestos—and then, only if in contact with asbestos for more than 5 years—and the family members of exposed workers. It does not, for example, compensate the high school kids in factory towns across the country who unloaded boxcars filled with vermiculite ore to earn money over their summer vacations and now, maybe 20 years or more later, have developed lung disease. It makes no provision for individuals harmed by non-occupational exposure, other than the residents of Libby, Montana. The EPA currently has 28 nationwide factory site “hot spots” under priority surveillance to determine the health effects of asbestos exposure. These sites received 80% of the Libby, Montana vermiculite ore sent to a total 200 factories in the U.S. where the toxic material was processed for use in consumer goods. The remaining 172 sites are of secondary interest to the EPA, but are also included in its surveillance plan. None of the community members exposed to asbestos dust from factory exhaust and particles transmitted widely by workers on their clothing and skin in any of these 200 towns will be covered under the trust fund.

Also excluded from qualifying for benefits are consumers who purchased and indifferently used and disposed of some 3,000 commercial products containing asbestos, including people who did their own automotive repairs such as replacing brake linings. Nor does the bill include occupants of 30 million houses nationwide containing asbestos-laden insulation in their attics, the health consequences of which have as yet been unexplored—although it has been established that there is no safe level of exposure to asbestos. It leaves out the hundreds of thousands of New Yorkers who have lived and worked in the vicinity of Ground Zero from the World Trade Center’s destruction forward. The bottom line is that because the medical criteria rely on occupational exposure thresholds, they exclude millions of individuals who unwittingly incurred the risk of disabling and potentially fatal disease by purchasing products or living in communities with asbestos-related industries.

Contacts

Michael Harbut, MD, MPH, FCCP, Chief, Center for Occupational and Environmental Medicine; Co-Director, National Center for Vermiculite and Asbestos-Related Cancers, Karmanos Cancer Institute; Clinical Assistant Professor, Internal Medicine, Wayne State University. (248) 547-9100 (w), (248) 506-8871 (c), (248) 367-8265 (beeper), M1har@aol.com.

Philip J. Landrigan, MD, MSc, DIH, Chair, Dept. of Community and Preventive Medicine, Mount Sinai School of Medicine. (This is New York’s largest clinical facility in occupational medicine and one of the nation’s largest research and training programs in occupational health, established by Dr. Irving J. Selikoff, known as the “Father of Asbestos Research in the United States.” This department was the major provider of diagnostic services to Ground Zero workers in the aftermath of the World Trade Center destruction, examining over 12,000 workers, many of whom were exposed to asbestos.) (212) 241-4804 (w), phil.landrigan@mssm.edu.

L. Christine Oliver, MD, MPH, MS, FACPM, Assistant Clinical Professor of Medicine, Harvard Medical School; Associate Physician, Pulmonary and Critical Medicine, Massachusetts General Hospital. (617) 232-1704 (w), (617) 312-7219 (c), coliver@ohiinc.com.

Alan C. Whitehouse, MD, FCCP, Senior consulting physician at the Center for Asbestos Related Disease, Libby, Montana and the pulmonary specialist who first identified asbestos-induced disease among workers in the W.R. Grace mine and manufacturing plant at Libby. (509) 999-5500 (c), (509) 276-1342 (h), (406) 293-9274 (Libby CARD clinic), acw1@sisna.com

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