IN THE
COURT OF APPEALS OF MARYLAND

SEPTEMBER TERM 2012
NO. 82

BERNARD DIXON, ET AL.

Appellant,

V.

FORD MOTOR COMPANY

Appellee

BRIEF OF AMICI CURIAE INTERESTED PHYSICIANS AND SCIENTIFIC RESEARCHERS IN SUPPORT OF APPELLANT

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INTERESTS OF *AMICI CURIAE*

It has come to our attention that Appellee Ford Motor Company, a company that manufactured and sold asbestos-containing brakes for decades, has claimed that the testimony of Dr. Laura Welch that exposure to asbestos dust brought into the home as a result of working on asbestos brakes can cause mesothelioma in a household member is scientifically unreliable. It has also been further claimed that it is necessary to attempt to quantify the amount of asbestos exposure in an occupational or domestic setting in order to assess its role in mesothelioma causation. Both statements are incorrect and contravened by extensive published biomedical literature as we demonstrate below.

The scientists and medical professionals listed below are concerned by the resurrection of arguments that have been rejected for the past 30 years. Contrary to the suggestion of Ford and other asbestos brake manufacturers, the world scientific, regulatory and legal communities have consistently and repeatedly determined that these arguments proposed by Ford and other asbestos brake manufacturers are both scientifically and logically unsound.

We submit this brief to (a) review the evidence that is accepted by the mainstream scientific community regarding asbestos and disease, (b) discuss the scientific and analytical basis for concluding that demonstrated exposures to asbestos from asbestos-containing brake products can and do cause and contribute to asbestos-related diseases such as mesothelioma, and (c) reject the industry-sponsored attempts to fabricate uncertainty regarding topics about which the mainstream scientific community has long reached consensus.

The medical professionals, epidemiologists, toxicologists and other scientists that have signed this brief have dedicated a substantial portion of their careers to researching, diagnosing and/or treating asbestos-related diseases in workers and their family members. Collectively, we have published hundreds of peer-reviewed articles in this field including dozens of epidemiological studies. Some of us have testified in court at the request of individuals diagnosed with mesothelioma and other asbestos-related disease. Many of us have appeared before legislative and regulatory bodies and given testimony regarding exposure to asbestos and the risk of disease.

We offer no opinion as to whether Ms. Dixon's mesothelioma was caused, in whole or in part, by her domestic exposure to asbestos from her husband's work with asbestos-containing brakes. Instead, our concern is with the breadth of the challenge to Dr. Welch's testimony. In particular, we are concerned about the claim that an expert must quantify the amount of exposure to asbestos from working with brakes, or quantify the amount of asbestos brought into the home as a result, before expressing an opinion on whether such an exposure caused or contributed to the development of a mesothelioma. We further take issue with the assertion that Dr. Welch's opinion that all exposures to asbestos above background ambient air levels contribute to cause a malignant mesothelioma is unscientific or somehow constitutes "junk science."

Our review of the available medical and scientific literature below demonstrates Dr. Welch's opinions to be based upon sound and generally accepted scientific knowledge. While this is not to say that other scientists could not hold different opinions, there is no legitimate argument, in our opinion, that Dr. Welch's opinions or testimony

were not based upon sound scientific principles and generally accepted scientific knowledge about asbestos.

SIGNEES IN ALPHABETICAL ORDER

Henry A. Anderson, M.D. – Dr. Anderson is an Adjunct Professor of Population Health at the University of Wisconsin School of Medicine and Public Health located in Madison, Wisconsin.

John Balmes – Professor Balmes is a Professor of Medicine at the University of California, School of Medicine in the Division of Occupational and Environmental Medicine.

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Benedetto Terracini, M.D., Ph.D. – Dr. Terrancini is a retired Professor from the University of Torino, Department of Cancer Epidemiology.

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None of the *amici* have been paid for their involvement in the preparation or submission of this brief and the views expressed herein are those of the individuals

signing it. The affiliations listed with each *amici* are for identification purposes only, and the views expressed are not necessarily the views of those affiliate entities.

NATURE OF THE CASE AND MATERIAL PROCEEDINGS BELOW

Amici adopt the statements of the Nature of the Case and Material Proceedings set forth in the Brief of Appellant.

STATEMENT OF FACTS

Amici adopt the Statement of Facts set forth in the Brief of Appellant.

STANDARD OF REVIEW APPLICABLE TO ALL ASSIGNMENTS OF ERROR

Amici adopt the Standard of Review Applicable to All Assignments of Error set forth in the Brief of Appellant.

ARGUMENT

I. THE APPELLATE COURT'S REQUIREMENT THAT A MEDICAL EXPERT MUST BASE A CAUSATION OPINION UPON QUANTITATIVE "PROBABALISTIC" ESTIMATES OF ASBESTOS EXPOSURE LEVELS IN A MESOTHELIOMA CASE WHERE THERE IS A PATIENT HISTORY OF PARA-OCCUPATIONAL OR DOMESTIC ASBESTOS EXPOSURE IS CONTRARY TO GENERALLY ACCEPTED SCIENTIFIC PRACTICE

Amici have no opinion about what "substantial contributing factor" or "significant contributing factor" means or should mean in the context of courtroom expert testimony. "Substantial contributing factor" is in part a legal term and is not a term that is normally used in the published medical literature. To the extent that "substantial contributing factor" means "was this exposure something that made a real and non-imaginary contribution to the mesothelioma that killed Ms. Dixon?", we respectfully suggest that the Court of Special Appeals erred in holding that Dr. Welch's opinions on this question

were not sufficiently reliable or scientific to be considered by the jury. Even if one were to define "substantial contributing factor" to require the exposure at issue to be independently capable of causing harm in a human being, there is ample scientific evidence to support the conclusion that had Ms. Dixon's only asbestos exposure been from take home exposure to asbestos from a family member's occupational work on asbestos containing brakes, and she developed mesothelioma, that exposure would have been sufficient to attribute the disease to asbestos exposure.

More importantly however, in evaluating Ford's challenge to the admissibility of Dr. Welch's testimony, and the Court of Special Appeal's decision, we respectfully submit that this Court should bear in mind the following considerations:

1. The attribution of a disease to a given cause (Medical causation), particularly in dealing with a signature disease of asbestos exposure like mesothelioma, is based on a weight of the evidence approach and not on the ability to quantify a given exposure or set of exposures. Both generally accepted medical and scientific principles followed by scientists knowledgeable about the characteristics of asbestos, and the Helsinki Criteria for the Diagnosis and Attribution of Mesothelioma to Asbestos Exposure[1] (which was written in 1997 by a group of 19 scientists from differing disciplines who collectively had published over 1,000 articles about asbestos and disease) recognize this approach. Specifically, we submit that it is generally accepted in the medical and scientific community that once you have a mesothelioma patient with a

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[1] *Asbestos, Asbestosis, and Cancer: the Helsinki Criteria for Diagnosis and Attribution*, 23 Scand. J. Work Environ. Health 311, 311-16 (1997) (the "Helsinki Criteria").

patient history of occupational, domestic or para occupational exposure, the mesothelioma is attributed to asbestos exposure. Under the Helsinki Criteria and the generally accepted science on which it is based, there is no need to quantify any particular occupational, para-occupational or domestic asbestos exposure to assess disease causation because a) any "occupational level" exposure results in fiber levels thousands of times higher than ambient air b) no safe or threshold level of exposure to asbestos has ever been identified and c) asbestos exposures as short in duration as a few days have been shown to cause mesothelioma.[2]

2. Occupational asbestos exposures from brakes, and Domestic Exposures which result from occupational exposures (including Brake Work activities), are the kind of "occupational, para-occupational or domestic" asbestos exposures that can and do cause mesotheliomas. There is an extensive body of published literature that documents a) that working with asbestos containing brakes results in high levels of occupational asbestos exposure b) that asbestos exposures from brakes results in asbestosis, pleural disease, lung cancer and mesotheliomas and c) it is well documented that wives or children of persons who are occupationally exposed to asbestos are at an increased risk of developing mesothelioma themselves.

3. The absence of evidence of a risk of mesothelioma based on a group of epidemiology studies is not the same thing as evidence of the absence of risk. This is

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[2] Morris Greenberg & T.A. Lloyd Davies, *Mesothelioma Register 1967-68*, 31 Brit. J. Ind. Med. 91, 91-104 (1974); E. Skammeritz et al., *Asbestos Exposure and Survival in Malignant Mesothelioma: A Description of 122 Consecutive Cases at an Occupational Clinic*, 2(4) J. Occupational & Envtl. Med. 228, 228-29 (Oct. 2011).

particularly true when the studies under consideration lack sufficient latency or statistical power to detect small increased risks of a rare disease like mesothelioma.

For all of these reasons, we respectfully submit that the Court of Special Appeals erred in holding that Dr. Welch should not have been permitted to offer her specific causation opinions to the jury. A more comprehensive explanation of the points discussed above follows.

II. GENERALLY ACCEPTED PRINCIPLES OF ASSESSING THE ROLE OF ASBESTOS IN CAUSING MESOTHELIOMA

A. Mesothelioma is a Signature Malignancy for Asbestos Exposure

There is no dispute that asbestos causes mesothelioma, and that the great majority of mesotheliomas are demonstrably caused by asbestos. The link between asbestos exposure and mesothelioma is so strong that mesothelioma is called a "signature disease" of asbestos exposure. As noted epidemiologist Dr. Harvey Checkoway explained:

> Certain conditions, known as "sentinel" health events, are so closely associated with occupational exposures that the occurrence of any cases serves as an indication of an occupational hazard Malignant mesothelioma (which is nearly always attributable to asbestos exposure), silicosis, and adult lead poisoning, fit this description.[3]

Although some mesotheliomas are never able to be linked to asbestos exposure in the individual because many individuals do not know that they have been exposed to asbestos this does not mean that asbestos exposure was not the cause of a mesothelioma even when no identifiable source of asbestos can be located.

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[3] Harvey Checkoway, Neil Pearce & Douglas J. Crawford-Brown, *Research Methods in Occupational Epidemiology* 248 (London: Oxford Univ. Press 2d ed. 2004).

Many individuals do not know that they have been exposed to asbestos,[4] others die before being interviewed regarding potential exposures, and still others are classified as "unexposed" because of their job title even though they may well have suffered large asbestos exposure. The fact that a percentage of mesotheliomas are labeled "idiopathic" does not, however, support the conclusion that there are large numbers of spontaneous (i.e., non-asbestos related) mesotheliomas. To the contrary, a large study of numerous sources of information failed to demonstrate evidence for "spontaneous" mesotheliomas,[5] and a detailed review of mesotheliomas in Australia found that over 90% had a history of exposure and in 80% of those with no asbestos history upon interview, asbestos was found in their lungs thus indicating such exposure.[6]

B. All Asbestos Fiber Types and Sources of Asbestos Exposure Contribute to Cause Mesothelioma

The general causation question of whether chrysotile asbestos causes mesothelioma in humans has been examined in the scientific literature from the perspective of many different disciplines including epidemiology, toxicology, animal experiments, medical research, industrial hygiene, and fiber analysis. The general consensus in the scientific community is that all commercially available fiber types of

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[4] J. Leigh, P. Davidson, L. Hendrie & D. Berry, *Malignant Mesothelioma in Australia 1945-2000*, 46 Annals Occupational Hygiene 160, 160-65 (2002).

[5] E.J. Mark & T. Yokoi, *Absence of evidence for a significant background incidence of diffuse malignant mesothelioma apart from asbestos exposure*, 643 Ann. N.Y. Acad. Scis. 196, 196-204 (Dec. 31, 1991).

[6] J. Leigh & T. Driscoll, *Malignant mesothelioma in Australia, 1945-2002*, 9(3) Int'l J. Occupational & Envtl. Health 206, 206-17 (July-Sept. 2003).

asbestos, including the serpentine form chrysotile, cause mesothelioma.[7] Several recent epidemiology studies have further strengthened the link between chrysotile asbestos and mesothelioma.[8]

The connection between asbestos exposure and mesothelioma is so strong that medical science has been unable to determine a threshold or minimum level of exposure

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[7] *See, e.g.*, *Monographs on the Evaluation of Carcinogenic Risks to Humans, A Review of Human Carcinogens, Part C: Arsenic, Metals, Fibres, and Dusts* (International Agency for Research on Cancer ("IARC"), May 2009) ("Epidemiological evidence has increasingly shown an association of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) with an increased risk of lung cancer and mesothelioma."); *Asbestos*, 238 (IARC, 2012) (Chrysotile, Amosite, Crocidolite, Tremolite, Actinolite and Anthophyllite) (Although all forms of asbestos can cause mesothelioma, there is considerable evidence that the potency for the induction of mesothelioma varies by fibre type, and in particular that chrysotile asbestos is less potent then amphibole forms of asbestos."); *Toxicological Profile for Asbestos* (U.S. Dep't of Health & Human Servs. 2001); *Occupational Exposure to Asbestos*, 29 C.F.R. 1910, Vol. 59, No. 153 at 40979 (OSHA Aug. 10, 1994) ("There are at least three reasons for OSHA's decision not to separate fiber types. First, OSHA believes that the evidence in the record supports similar potency for chrysotile and amphiboles with regard to lung cancer and asbestosis. The evidence submitted in support of the claim that chrysotile asbestos is less toxic than other asbestos fiber types is related primarily to mesothelioma. This evidence is unpersuasive, and it provides an insufficient basis upon which to regulate that fiber type less stringently."); *Elimination of Asbestos-Related Diseases*, 2 (World Health Org'n 2006) ("Mesotheliomas have been observed after occupational exposure to crocidolite, amosite, tremolite and chrysotile, as well as among the general population living in the neighbourhood of asbestos factories and mines and in people living with asbestos workers. . . . No threshold has been identified for the carcinogenic risk of chrysotile.").

[8] *See* Enrico Pira, C. Pelucchi, P.G. Piolatto, E. Negri, T. Bilei & C. LaVecchia, *Mortality from Cancer and other Causes in the Balangero Cohort of Chrysotile Asbestos Miners*, 66 Occupational & Envtl. Med. 805, 805-09 (2009); D. Loomis, J.M. Dement, S.H. Wolf, S.H. & D.B. Richardson, *Lung Cancer Mortality and Fibre Exposures Among North Carolina Textile Workers*, 66 Occupational & Envtl. Med. 535, 535-42 (2009); Xiaorong Wang et al., *Cause-Specific Mortality in a Chinese Chrysotile Textile Worker Cohort*, J. Japanese Cancer Ass'n (2012).

to asbestos that has not been shown to cause the disease.[9] Multiple epidemiological studies designed to determine the lowest quantum of exposure to asbestos capable of causing mesothelioma have established that miniscule *cumulative* lifetime exposure levels can greatly increase an individual's risk of contracting mesothelioma.[10] The medical literature also contains numerous case reports and case series of mesothelioma caused by as little as a few months, weeks, or even days of asbestos exposure.[11]

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[9] *See, e.g.*, J. Wiggins, *Statement on malignant mesothelioma in the United Kingdom*, 56 Thorax 250, 252 (2001) ("[t]here is no evidence for a threshold dose of asbestos below which there is no risk" of mesothelioma); World Health Org'n, *Environmental Health Criteria 203: Chrysotile Asbestos*, 144 (1998) ("No threshold has been identified for carcinogenic risks."). In fact, attempts to deduce such a threshold for mesothelioma have been dismissed as "logical nonsense." *See* John T. Hodgson & Andrew Darnton, *The Qualitative Risks of Mesothelioma and Lung Cancer in Relation to Asbestos Exposure*, 44 Annals Occupational Hygiene 565, 583 (2000).

[10] *See, e.g.*, Klaus Rödelsperger et al., *Asbestos and Man-made Vitreous Fibers as Risk Factors for Diffuse Malignant Mesothelioma: Results from a German Hospital-Based Case-Control Study*, 39 Am. J. Indus. Med. 262, 269 (2001) (noting [0.15 asbestos fibers per cubic centimeter ("f/cc/yr" or "f/yr")] creates an almost eight fold increased risk of mesothelioma); Y. Iwatsubo et al., *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-based Case-Control Study*, 148(2) Am. J Epidemiology 133, 141, 139 tbl.5 (1998) ("A significant excess of mesothelioma was observed for levels of cumulative exposure that were probably far below the limits adopted in most industrial countries during the 1980s.").

[11] *See, e.g.*, Skammeritz et al, *supra* note 2 (noting that for some patients the total asbestos exposure was "a few days"); Muriel L. Newhouse & Hilda Thompson, *Mesothelioma of Pleura and Peritoneum Following Exposure to Asbestos in the London Area*, 22(4) Brit. J. Indus. Med. 261, 261-66 (1965) (two cases with 2 months or less exposure to asbestos); Maxwell Borow et al., *Critical Review, Mesothelioma following Exposure to Asbestos: A review of 72 Cases*, 64(5) Chest J. 641 (1973); Greenberg & Davies, *supra* note 2; K. Browne & W.J. Smither, *Asbestos-Related Mesothelioma: Factors Discriminating Between Pleural and Peritoneal Sites*, 40 Brit. J. Indus. Med. 145, 145-52 (1983); *Workplace Exposure to Asbestos: Review and Recommendations* (DHHS (NIOSH) pub. no. 81-103, Apr. 1980) ("Studies of duration of exposure suggest that even at very short exposure periods (1 day to 3 months) significant disease can occur.").

Epidemiology has also shown that a person's risk of contracting mesothelioma becomes greater as exposure to asbestos increases and that the more exposure a person has the shorter the latency period between first exposure to asbestos and manifestation of mesothelioma.[12] Accordingly, cumulative dose best explains the increased risk of mesothelioma in the population.[13]

Asbestos is also a complete carcinogen, which is generally recognized by the scientific community as a substance that can both initiate and promote cancer.[14] The cumulative dose of asbestos causes mesothelioma through a variety of both direct and indirect mechanisms over the evolution of the cancer.[15] In-vitro studies support the relevance of continuous inhalation of fibers in the etiology of mesothelioma.[16]

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[12] Claudio Bianchi et al., *Asbestos Exposure in Malignant Mesothelioma of the Pleura: A Survey of 557 Cases*, 39 Indus. Health 161, 166 (2001) ("In general, there was an inverse relationship between intensity of exposure and duration of the latency period."); V. Neumann et al., *Malignant mesothelioma – German mesothelioma register 1987-1999*, 74(6) Int'l Archives Occupational & Envtl. Health 383, 388 (2001) ("There was a trend towards shorter latency periods in the presence of higher asbestos burdens.")

[13] 2 Dail & Hammar's Pulmonary Pathology 587 (Joseph F. Tomashefski, Jr. et al. eds., 3d ed. 2008) ("[W]hen there are multiple asbestos exposures, each contributes to cumulative exposure and, hence, to the risk and causation of MM [malignant mesothelioma]."); Jean Bignon, Y. Iwatsubo, F. Galateau-Salle & A. Valleron, *History and Experience of Mesothelioma in Europe*, Mesothelioma 36 (Bruce W. Robinson & Phillippe Chahinian eds., 2002).

[14] L. Tomatis, S. Cantoni, F. Carnevale, E. Merler, F. Mollo, P. Ricci, S. Silvestri, P. Vineis & B. Terracini, *The role of asbestos fiber dimensions in the prevention of mesothelioma*, 13(1) Int'l J. Occupational & Envtl. Health 64, 64-69 (2007).

[15] IARC (2009), *supra* note 7; Dail & Hammar's, *supra* note 13 at 587-99.

[16] M. Governa, M. Amati, S. Fontana, I. Visona, G.C. Botta, F. Mollo, D. Bellis, P. Bo, *Role of Iron in Asbestos-Body-Induced Oxidant Radical Generation*, 58(5) J. Toxicology & Envtl. Health 279, 279-87 (Nov. 12, 1999).

While epidemiology can tell us what happens in a population of people with similar characteristics, it cannot tell us what happens within each individual within that population. Many environmental carcinogens only produce about 10% cancer in exposed individuals, which is similar for asbestos induced mesothelioma in heavier exposed populations.[17] Various factors may affect this; one of the more important factors includes genetic or individual susceptibility.[18] Because of the nature of asbestos, the fact that epidemiology has detected an excess risk of mesothelioma at levels of exposure that can be reached in a few days of exposure, and that any occupational, para-occupational or domestic exposure to asbestos is by definition an exposure that is thousands of times greater than the minute levels of asbestos seen in the background ambient air, it is not necessary to quantify an occupational or para occupational exposure to asbestos before concluding that it caused or contributed to cause a mesothelioma. The "Helsinki Attribution Criteria"[19] for mesothelioma state that the following points need to be considered in the assessment of occupational etiology:

- The great majority of mesotheliomas are due to asbestos exposure.

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[17] Tomatis et. al, *supra* note 14.

[18] *See id.*

[19] *See* Helsinki Criteria, *supra* note 1, at 311-16. The Helsinki Criteria was published as a result of the International Expert Meeting on Asbestos, Asbestosis and Cancer, which took place in Helsinki, Finland in January 1997. The meeting was held to discuss and agree on state-of-the-art criteria for the diagnosis and attribution of asbestos-related diseases. It was attended by 19 participants from around the world, and the group was comprised of pathologists, radiologists, occupational and pulmonary physicians, epidemiologists, toxicologists, industrial hygienists and clinical and laboratory scientists specializing in tissue fiber analysis. Collectively, the group had published over 1000 papers on asbestos and asbestos-related diseases. The participants decided to name the published report *The Helsinki Criteria.*

- Mesothelioma can occur in cases with low asbestos exposure. However, very low background environmental exposures carry only an extremely low risk.

- About 80% of mesothelioma patients have had some occupational exposure to asbestos, and therefore a careful occupational and environmental history should be taken.

- An occupational history of brief or low-level exposure should be considered sufficient for mesothelioma to be designated as occupationally related.

- A minimum of 10 years from the first exposure is required to attribute the mesothelioma to asbestos exposure, though in most cases the latency interval is longer (e.g., on the order of 30 to 40 years).

- Smoking has no influence on the risk of mesothelioma.

III. ASBESTOS EXPOSURE FROM BRAKES CAN AND DOES CAUSE MESOTHELIOMA[20]

A. Mechanics Who Worked With Asbestos Brakes Without Dust Control Measures Were Exposed to Substantial Amounts of Asbestos

Contrary to the assertions made that dust in the brake drums from the wearing of old brakes does not contain asbestos, industry studies have shown that literally billions and trillions of asbestos fibers survive the braking process and are contained within that dust.[21] Numerous studies have demonstrated that mechanics that worked with asbestos-containing brakes without dust control measures were exposed to

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[20] Most of the information in this section of the brief can be found in L.S. Welch, *Asbestos Exposure Causes Mesothelioma, But Not This Asbestos Exposure: An Amicus Brief to the Michigan Supreme Court*, 13(3) Int'l J. Occupational & Envtl. Health 318, 318-27 (2007). The fact that 51 respected researchers on asbestos disease from all over the world signed off on this document is a testament to the fact that Dr. Welch's opinions are in the mainstream of the scientific community.

[21] R.A. Lemen, *Asbestos in brakes: exposure and risk of disease*, 45 Am. J. Indus. Med. 229, 229-37 (2004) (citing to R.L. Williams & J.L. Muhlbaier, *Characterization of asbestos emission from brakes* (Gen. Motors Research Labs. 1980)).

asbestos dust at levels thousands of times higher than what is seen in the ambient air -- particularly when compressed air or dry brushing is used to clean out the wear dust from old asbestos brakes.[22] In addition, the EPA and OSHA and other regulatory agencies throughout the country have issued guidance documents to reduce the risk of disease from asbestos exposure during brake work.[23]

B. Increased Incidence Of Non-Malignant Asbestos-Related Diseases Among Mechanics is Further Proof of Sufficient Exposure to Cause Mesothelioma

It is universally accepted that asbestosis is caused only by asbestos exposure, and that the amount of asbestos exposure needed to cause asbestosis is greater than the amount needed to cause mesothelioma.[24] Studies have shown non-malignant

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[22] K. Sakai, N. Hisanaga, E. Shibata, Y. Ono, Y. Takeuchi, *Asbestos Exposures During Reprocessing of Automobile Brakes and Clutches*, 12(2) Int'l J. Occupational & Envtl. Health 95, 95-105 (2006); W.V. Lorimer, A.N. Rohl, A. Miller A, W.J. Nicholson & I.J. Selikoff, *Asbestos exposure of brake repair workers in the United States*, 43(3) Mt. Sinai J. Med. 207, 207-18 (1976); Arthur N. Rohl, Arthur M. Langer, Mary S. Wolff & Irving Weisman, *Asbestos Exposure During Brake Lining Maintenance and Repair*, 12 Envtl. Res. 110, 110-28 (Aug. 1976); D.E. Hickish & K.L. Knight, *Exposure to Asbestos During Brake Maintenance*, 13(1) Annals of Occupational Hygiene 17, 17-21(1970).

[23] *See e.g*, *Occupational Exposure to Asbestos*, *supra* note 7; Envtl. Protection Agency ("EPA"), *Current Best Practices for Preventing Asbestos Exposure Among Brake and Clutch Repair Workers*, EPA 747-F-04-004 (Mar. 2007); OSHA, *Asbestos-Automotive Brake and Clutch Repair Work. 2006*; SHIB 07-26-2006; Wash. St. Dep't of Labor & Indus., *Working Safely with Asbestos in Clutch and Brake Linings*. F41 3-049-000, Olympia WA, Wash. State Dep't of Labor & Indus. (2001); N.H. Pollution Prevention Program, *Pitstops Manual: Best Management Practices for Automobile Service Facilities* (2001); Worksafe Alberta, *Control of asbestos during brake maintenance and repair*, Dep't of Human Res. & Emp't, Gov't of Alberta (2004); Minn. Pollution Control Agency, *Facts About Controlling Brake Dust to Protect Your Health, What Every Mechanic Should Know* (1998).

[24] Andrew Churg & Francis H.Y. Green, Pathology of Occupational Lung Disease (1998).

asbestos disease (both asbestosis and pleural disease) in individuals known to have worked with asbestos-containing brakes.[25] Accordingly, these workers were historically exposed to quantities of asbestos far in excess of that needed to cause mesothelioma.

C. The Multiple Occurrence of Reported Cases Of Mesothelioma In Mechanics Support a Causal Link

As discussed above, given the rarity of mesothelioma, it is difficult to gather enough subjects to conduct an epidemiological study with sufficient power to reliably detect an increased risk of contracting the disease.[26] When examining a signature disease like mesothelioma, however, the scientific community has recognized that published case reports and case series are useful in determining causation:

> Case series are particularly informative in situations where there are identified occurrences of very rare conditions for which there are few, if any, established causal factors . . . In fact, recognition of even a small number of cases of the "sentinel" disease – such as liver angiosarcoma and malignant mesothelioma, which is strongly related to asbestos exposure (Russi and Cone, 1994) – can sometimes be invoked as prima facie evidence of exposure to the putative causal agent.[27]

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[25] *See e.g.*, Lorimer et al., *supra* note 22; William J. Nicholson, Investigation of Health Hazards in Brake Lining Repair and Maintenance Workers Occupationally Exposed to Asbestos (NIOSH 1984); Jacques Ameille et al., *Asbestos Related Diseases in Automobile Mechanics*, Annals Occupational Hygiene (2011).

[26] J.C. Bailar, *How to Distort the Scientific Record Without Actually Lying: Truth, and the Arts of Science*, 11(4) Eur. J. Oncology 217, 217-224 (2006); S. Hernberg, *"Negative" results in cohort studies-how to recognize fallacies*, 4 Scandinavian J. Work & Envtl. Health 121, 121-26 (Suppl. 1981).

[27] Checkoway, Pearce & Crawford-Brown, *supra* note 3, at 60.

In fact, noted epidemiologist Dr. Harvey Checkoway has stated that:

> Case series reports can be virtually conclusive in their own right when the health outcome is a very rare disease or an uncommon manifestation of a relatively common condition.[28]

In reviewing the medical and scientific literature, multiple cases of mesothelioma in mechanics have been reported.[29] The precise number of cases is not important as they represent only the tip of the iceberg as most cases of mesothelioma diagnosed in mechanics are not the subject of peer-reviewed publications. What is that proper scientific inquiry not only can consider these reports, but also, in fact, must consider them. Contrary to the suggestion of the asbestos brake manufacturers, these cases cannot be cavalierly dismissed as "unscientific" or "insufficient to support conclusions regarding causation." When considering the important question of whether working with asbestos-containing brakes can cause incurable, inevitably terminal diseases, like mesothelioma, case series must be considered and evaluated, along with all other available evidence.

D. Take Home Asbestos Exposures Cause Mesothelioma

It is well established that take-home asbestos on workers' clothes, shoes, or hair can cause mesothelioma in household members living with the asbestos exposed worker. These types of exposures and their resultant disease manifestations are outlined very effectively in the National Institute for Occupational Safety and Health Report to Congress on Workers' Home Contamination Study, which was conducted under The

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[28] *Id.*

[29] Lemen, *supra* note 21.

Workers' Family Protection Act (29 U.S.C. § 671a).[30] In this report NIOSH concludes that:

> families of asbestos-exposed workers have been at increased risk of pleural, pericardial, or peritoneal mesothelioma, lung cancer, cancer of the gastrointestinal tract, and non-malignant pleural and parenchymal abnormalities as well as asbestosis.

In 1965, two events documented asbestos take-home exposure as a cause of mesothelioma in the wives or family members of persons with occupational asbestos exposure. The first was the publication of Newhouse & Thompson reporting mesothelioma among persons with a history of living with asbestos workers and of cases in persons living in the neighborhood of asbestos factories.[31] Also, at a meeting of the New York Academy of Sciences, published in December 1965, discussion of the Newhouse & Thompson findings, the Wagner findings of community disease in South Africa, first published in 1960 and re-reported at the NYAS meeting, and the Kiviluoto finding of bilateral pleural calcification in a 50 year old woman whose only known exposure to asbestos was living in the immediate vicinity of an asbestos mill and playing with asbestos, as a child.[32]

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[30] National Institute of Occupation Safety & Health ("NIOSH"), *Report to Congress on Workers' Home Contamination Study Conducted Under The Workers' Family Protection Act* (29 U.S.C. 671a) (Sept. 1995) at 6-11, 45-46, 55, 62-63, 86-87, 145-59 tbls.2-6.

[31] Newhouse & Thompson, *supra* note 11 at 261-69.

[32] *See* J.G. Thomson, *Asbestos and the Urban Dweller*, 132 Annals N.Y. Acad. Scis. 196, 196-214 (Dec. 1965); Raimo Kiviluoto, *Pleural Plaques and Asbestos: Further Observations on Endemic and other Nonoccupational Asbestosis*, 132 Annals N.Y. Acad. Scis. 235, 235-45 (Dec. 1965); T. Mancuso, *Discussion*, 132 Annals N.Y. Acad. Scis. 589 (Dec. 1965); J.C. Wagner, C.A. Sleggs & Paul Marchand, *Diffuse pleural mesothelioma and asbestos exposure in the North Western Cape Province*, 17(4) Br. J. Ind'l Med. 260, 260-71 (1960).

Subsequent to the events of 1965 many studies have shown the effects of take-home asbestos exposure.[33] Lieben & Pistawka (1967) of the Pennsylvania Department of Health reported several cases from both neighborhood and household asbestos exposures that resulted in mesothelioma.[34] Anderson et al., 1976, 1979a &1979b and Anderson 1983 reported on familial exposure to asbestos and disease showing both non-malignant and malignant disease occurring in family members not otherwise exposed to asbestos.[35] Magnani et al. (1993) reported that among family members of Italian cement workers that 4 pleural tumors (1 mesothelioma) were observed when only 0.5 were expected and that 6 lung cancers were observed when only 4 were expected. This represented a significantly elevated SMR of 792.3 for cancer of the pleura among domestically exposed women. The authors reported that the plant had no laundering facilities and therefore the work clothes were laundered at home.[36]

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[33] M. Navrátil & F. Trippé, *Prevalence of Pleural Calcification in Persons Exposed to Asbestos Dust, and in the General Population in the Same District*, 5 Envtl. Res. 210, 210-16 (1972) (Prevalence of pleural calcification in persons exposed to asbestos dust, and in the general population in the same district.).

[34] J. Lieben & H. Pistawka, *Mesothelioma and Asbestos Exposure*, 14 Archives Envtl. Health 559, 559-68 (Apr. 1967).

[35] Henry A. Anderson et al., *Household Exposure to Asbestos and Risk of Subsequent Disease*, Dusts & Disease 145-46 (R.A. Lemon & J.M. Dement eds., 1979); Henry A. Anderson, Ruth Lilis, Susan M. Daum & Irving J. Selikoff, *Asbestosis Among Household Contacts of Asbestos Factory Workers*, 330 Annals N.Y. Acad. Scis. 387, 387-99 (1979); Henry A. Anderson, *Family contact exposure*, Proceedings of the World Symposium on Asbestos 349-362 (Canadian Asbestos Info. Ctr., 1983).

[36] C. Magnani et al., *A cohort study on mortality among wives of workers in the asbestos cement industry in Casale Monferrato, Italy*, 50 Br. J. Ind'l Med. 779, 779-84 (1993).

Many other community studies,[37] case-control studies,[38] and according to NIOSH some 17 case reports[39] and 22 case series reports[40] have also discussed both take-home asbestos exposure and subsequent disease development as well as neighborhood exposure to asbestos and disease.

The Vianna and Pollan study, discussed at length by Dr. Welch in her testimony, is particularly relevant, because it was a case control study documenting a substantially (10 times) elevated risk of mesothelioma in the wives or daughters of asbestos workers, one of whom had a husband who was a brake lining worker.[41]

IV. THE EPIDEMIOLOGICAL STUDIES SPECIFIC TO MECHANICS ARE NOT CONCLUSIVE

In attacking the opinions of Dr. Welch, Ford cites to a number of epidemiological studies claiming that the fact that these studies did not detect a statistically significant

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[37] K.H. Kilburn et al., *Asbestos Disease in Family Contacts of Shipyard Workers*, 75 Am. J. Pub. Health 615, 615-17 (1985).

[38] T. Ashcroft & A..G. Heppleston, *Mesothelioma and asbestos on Tyneside – a pathological and social study*, 177-79 (1970); A.D. McDonald & J.C. McDonald, *Malignant mesothelioma in North America*, 46 Cancer 1650, 1650-56 (1980); J. McEwen, A. Finlayson, A. Mair & A.A.M. Gibson, *Asbestos and Mesothelioma in Scotland. An Epidemiological Study*, 28 Int'l Archives Arbeitsmed 301, 301-11 (1971); G.F. Rubino, G. Scansetti, A. Donna & G. Palestro, *Epidemiology of pleural mesothelioma in north-Western Italy (Piedmont)*, 29 Brit. J. Ind'l Med. 436, 436-42 (1972); N.J. Vianna & A.K. Polan, *Non-occupational exposure to asbestos and malignant mesothelioma in women*, 1 Lancet 1061, 1061-63 (1978); F. Whitwell, J. Scott & M. Grinshaw, *Relationship between occupations and asbestos fibre content of the lungs in patients with pleural mesothelioma, lung cancer and other diseases*, 32 Thoraz 377, 377-86 (1977).

[39] NIOSH (1995), *supra* note 30, at 151-53 tbl.5.

[40] *See id.* at 154-59 tbl.6.

[41] Vianna & Polan, *supra* note 38.

increased risk of mesothelioma is conclusive proof that no person can ever contract disease from working with asbestos brakes (or from asbestos brought home on the clothes of brake workers). That claim, while facially attractive because of its simplicity, is dubious upon examination of the studies cited.

Each of the cited studies has individual shortcomings that undermine the significance of their findings.[42] Perhaps the biggest problem is the lack of an adequate latency period in virtually all of the studies. Mesothelioma does not arise immediately after asbestos exposure; it typically occurs after an average latency period of thirty to forty years or more. None of the studies relied on by Ford follows an asbestos exposed population of vehicle mechanics for a period of thirty years or more after the first exposure for each member of the cohort. IARC has stated that in order to draw any conclusions about lack of carcinogenicity from a "negative" epidemiological study, there must be an adequate latency period, and that "latent periods substantially shorter than 30 years cannot provide evidence for lack of carcinogenicity."[43]

In addition, the studies cited by Ford define the occupational group that may have used asbestos brakes in different terms, "garage worker," "automobile repair," "motor vehicle mechanics," "vehicle mechanics," and "brake lining workers," some of which are not necessarily specific for only those workers exposed to asbestos. In addition, many of the studies did not have sufficient power to detect an increased risk even if it was present.

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[42] *See* Lemen, *supra* note 21; D.S. Egilman & M.A. Billings, *Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability*, 11(4) Int'l J. Occupational & Envtl. Health 360, 360-71 (2005).

[43] *See* IARC (2012), *supra* note 7; *see also id.* at Preamble at 22.

Scientifically, however, the fundamental flaw of their claim is their misinterpretation of a non-positive study, one that does not reveal a statistically significant increased risk. The brake manufacturers claim that the failure to detect a risk in a particular study is proof that there is no association between the cause and the effect.[44] There is, however, a significant difference between a truly negative result and a non-positive result.

A true negative study must be large, sensitive and contain accurate exposure data. Even then, the negative results only apply to the specific exposure level studied.[45] As explained in the scientific literature on significance testing, an absence of statistical significance in an epidemiology study does not correspond to an absence of evidence of causation.[46]

This does not mean, however, that causation cannot be proven. The examination of the question of whether a substance is capable of causing disease requires consideration of all scientific disciplines and all available evidence.[47] Epidemiologic

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[44] The brake manufacturers buttress this interpretation by citing to the peer-reviewed literature that they funded at an expense of $20 million or more. *See* David Michaels & Celeste Monforton, *How Litigation Shapes the Scientific Literature: Asbestos and Disease Among Automobile Mechanics*, 15 J. Law & Policy 1137, 1164-65 (2007) (18 of 26 papers on the topic of brakes and disease written by experts primarily associated with defendants).

[45] A. Ahlbom et al., *Interpretation of "Negative" Studies in Occupational Epidemiology*, 16(3) Scandinavian J. Work & Envtl. Health 153, 153-57 (1990); D.G. Altman & J.M. Bland, JM., *Absence of Evidence is Not Evidence of Absence*, 311 Brit. Med J. 485 (1995); Bailar, *supra* note 26, at 217-24; Hernberg, *supra* note 26, at 121-26.

[46] K.J. Rothman & S. Greenland, *Modern Epidemiology* 183-89 (2d ed. 1998).

[47] Reference Manual on Scientific Evidence 564 n.4 (Fed. Judicial Ctr., 3rd ed. 2011) (In determining when a substance is carcinogenic, the International Agency Research

evidence may, in some cases, be sufficient to make reasoned and well-founded judgments regarding causation. In the absence of unequivocal epidemiological data, consideration of other scientific evidence may allow reasoned conclusions regarding causation. This is particularly true when asserting that exposure cannot cause an effect:

> The conclusion that some exposure is devoid of harmful effect (e.g. a certain chemical is not carcinogenic) must be based on a synthesis of the whole available literature: it can never rely on one single study. Hence, all the scientific evidence (i.e. theoretical, experimental, and epidemiologic) that exists must be combined.[48]

There is no scientific basis for the brake manufacturers to assert that their cited epidemiological studies are conclusive on the issue of causation to the exclusion of all the other evidence. Proper application of the scientific method requires that all available evidence be considered when examining issues of causation.

CONCLUSION

There is ample scientific evidence to support the opinion that take home exposures to asbestos from a family member's work with asbestos containing brakes can cause or contribute to causing mesothelioma. It is neither generally accepted nor required in the medical or scientific community that a doctor must have a quantitative estimate of

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on Cancer, generally recognized as authoritative, evaluates and synthesizes all of the available human and evidence.).

[48] S. Hernberg, *Some guidelines for interpreting epidemiologic studies- Introduction to Occupational Epidemiology* 201-23 (Lewis Publ'g 1992).

asbestos exposure to attribute mesothelioma to asbestos in a patient who has a history of occupational, para occupational or take home asbestos exposure. We respectfully suggest that the Maryland Court of Special Appeals was incorrect to the extent it held otherwise.

Respectfully submitted,

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By counsel,

Dated: January 23, 2013

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 25th day of January, 2013, I caused to be hand-delivered two copies of *Amici Curiae* Brief of Interested Physicians and Scientific Researchers in Support of Appellant via first class Mail on each of the parties (four copies total):

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