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How Litigation Shapes the Scientific Literature: Asbestos & Disease Among Automobile Mechanics

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HOW LITIGATION SHAPES THE SCIENTIFIC LITERATURE: ASBESTOS AND DISEASE AMONG AUTOMOBILE MECHANICS

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INTRODUCTION

In August 2003, the law firm of Morgan, Lewis & Bockius LLP filed a Data Quality Act (DQA) petition[1] with the U.S. Environmental Protection Agency (EPA) challenging the agency's 1986 publication, "Guidance for Preventing Asbestos

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[1] Letter from Privitera D (Morgan, Lewis, & Bockius, Counselors at Law) to Office of Information Quality Guidelines; U.S. Environmental Protection Agency, *re: Request for Correction of Information*, Aug. 19, 2003, *available at* http://www.epa.gov/quality/informationguidelines/documents/12467.pdf (last visited Mar. 2007) [hereinafter Privitera Aug. 2006 letter].

Disease Among Auto Mechanics."[2] The DQA[3] allows affected individuals to challenge and request corrections to reports, pamphlets, studies and other information disseminated by federal agencies. In this DQA challenge, the attorney from Morgan, Lewis & Bockius asked the EPA to either stop disseminating the asbestos disease prevention guide, and either alert the public that the booklet is scientifically outdated, or review the latest scientific literature and update the booklet.[4]

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[2] U.S. ENVIRONMENTAL PROTECTION AGENCY, GUIDANCE FOR PREVENTING ASBESTOS DISEASE AMONG AUTO MECHANICS, PUBLICATION NO. EPA-560-OPTS-86-002 (1986), *available at* http://www.defendingscience.org/public_health_regulations/upload/EPA-Gold-Book-1986.pdf.

[3] The law, which is also known as the "Information Quality Act," was enacted as part of the Treasury and General Government Appropriations Act for Fiscal Year 2001. It required the Office of Management and Budget (OMB) to issue data quality guidelines to federal agencies by September 30, 2001. Under the OMB's DQA guidelines, federal agencies were required to establish and follow data quality guidelines that: (1) Ensure and maximize the quality, objectivity, utility and integrity of information including statistical information prior to dissemination; (2) Allow affected individuals and or organizations to seek and obtain correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines; and (3) Report to OMB regarding the number and nature of complaints received by the agency regarding agency compliance with OMB guidelines. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 105-554, § 515 (2001).

[4] The petition from D. Privitera, Morgan, Lewis & Bockius stated:

> [W]e respectfully request that EPA discontinue disseminating the Gold Book and post a caveat on EPA's website to the effect that the 1986 Gold Book is no longer current from a scientific perspective. In the alternative, we request that EPA engage in an analysis of the scientific information contained in the Gold Book and update it so that it reflects a complete assessment of the extensive medical and scientific literature on the subject, particularly given the developments since 1986 of a significant body of scientific data showing no increased asbestos-related health risks associated with brake work.

Letter from Privitera D (Morgan, Lewis, & Bockius, Counselors at Law) to Office of Information Quality Guidelines; U.S. Environmental Protection Agency, re: Request for Correction of Information, Aug. 19, 2003, *available at* http://www.epa.gov/quality/informationguidelines/documents/12467.pdf (last visited Oct. 2006) [hereinafter Privitera Oct.

This challenged pamphlet, known as the Gold Book, is a manual written to inform auto mechanics about ways to work safely around asbestos, such as that found in vehicle brakes. The law firm claimed that the Gold Book failed to comply with the data quality standards of "objectivity" and "utility" because it relied on inadequate and inappropriate data; was outdated because contradictory studies have since been published; and verification of its origins, preparations, funding, review and approval were unknown. In addition, the petition stated that the more rigorous standard for "influential information" applies to the Gold Book, since its scope and intended effect is to change the work-behavior practices of an entire industry; it relied on information derived from scientific sources; and is routinely proffered during litigation as evidence of EPA's current thinking on whether asbestos-containing friction products are dangerous to users.[5]

Morgan, Lewis & Bockius did not reveal the identity of its client. To many observers, the contention that the Gold Book was used in civil litigation suggested that the law firm's petition to the EPA was a component of the defense strategy in asbestos litigation involving automobile mechanics. Evidently, plaintiffs' attorneys were using the Gold Book in court cases, and defendants wanted the government-issued pamphlet discredited. This suspicion was confirmed with the release of invoices sent by Exponent, Inc., a leading product defense firm[6] to the big three United States automakers for services in support of asbestos litigation. Scientists employed by Exponent, Inc. produced several of the papers paid for by the three auto manufacturers who were sharing the costs of the litigation

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2006 letter].

[5] *Id.*

[6] Consulting firms that assist manufacturers of hazardous products limit their regulatory burden or defend against law suits alleging harm as a result of exposure to the product often describe their work as "product defense" or litigation support. *See* David Michaels, *Doubt Is Their Product*, SCIENTIFIC AMERICAN 96 (June 2005); D. Michaels & C. Monforton, *Manufacturing Uncertainty: Contested Science and the Protection of the Public's Health and Environment*, 95 AM. J. PUB. HLTH. S39 (2005).

support activities.[7] Although there is no mention of Exponent, Inc., in the DQA challenge documents, the consulting firm's July 2, 2003, invoice to the automakers for services in support of asbestos litigation included the item "Prepare Materials to Challenge 1986 EPA."[8] Once the revised EPA booklet for brake mechanics[9] was released to receive public comment, two Exponent, Inc. scientists wrote to the EPA complaining that since their studies found asbestos in brake shoes to be innocuous, the brochure should be modified to "avoid introducing unnecessary concerns among current and former automotive mechanics."[10] It is not known whether the

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[7] *See generally* Dennis J. Paustenbach et al., *An Evaluation of the Historical Exposures of Mechanics to Asbestos in Brake Dust*, 18 APPLIED OCC. & ENV. HYGIENE 786 (2003). *See also* Dennis J. Paustenbach, Brett L. Finley et al., *Environmental and Occupational Health Hazards Associated with the Presence of Asbestos in Brake Linings and Pads (1900 to Present): A "State of the Art" Review*, 7(1) J. OF TOX. & ENV. HLTH. B CRITICAL REVS. 25 (2004); Michael Goodman et al., *Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: A Meta-Analysis*, 48(4) ANNALS OCC. HYGIENE 309 (2004); Patrick A. Hessel et al., E. Lau, *Mesothelioma Among Brake Mechanics: An Expanded Analysis of a Case-Control Study*, 24(3) RISK ANALYSIS 547 (2004); Dennis J. Paustenbach et al., *Re: Evaluation of the Size and Type of Free Particulates Collected from Unused Asbestos-Containing Brake Components as Related to Potential for Respirability*, 49 AM. J. INDUS. MED. 60 (2006).

[8] Letter from Castleman B to Docket EPA-HQ-OPPT-2006-0398: Release of Updated Guidance for Preventing Asbestos Exposure Among Brake and Clutch Repair Workers, re: EPA Revised Gold Book, Oct. 23, 2006, Document ID No. EPA-HQ-OPPT-2006-0398-0011, *available at* http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064801d9898&disposition=attachment&contentType=pdf (last visited Mar, 2007).

[9] The 15-page 1986 "Gold Book" pamphlet entitled "Guidance for Preventing Asbestos Disease Among Auto Mechanics," was being replaced with a two-page fact sheet called "Current Best Practices for Preventing Asbestos Exposure Among Brake and Clutch Repair Worker." *See* U.S. ENVIRONMENTAL PROTECTION AGENCY, *supra* note 2.

[10] Letter from M.A. Kelsh & V.A. Craven (principal scientist and managing scientist, respectively, Exponent Health Sciences) to Docket EPA-HQ-OPPT-2006-0398, Release of Updated Guidance for Preventing Asbestos Exposure Among Brake and Clutch Repair Workers, Oct. 20, 2006, Document ID no. EPA-HQ-OPPT-2006-0398-0007.1, *available at*

automakers also paid Exponent, Inc. to prepare and submit these comments to the EPA; the scientists' letter to the agency makes no mention of the financial relationship between Exponent, Inc. and the auto manufacturers.

The EPA responded to the Gold Book petition first by posting on its website a disclaimer about the Gold Book,[11] promising to prepare a revised brochure.[12] In August 2006, the agency released a draft version and asked for public comments on the draft, which had shrunk from 15 pages to two. It still contained information useful to mechanics, albeit with much less detail. By soliciting public comments on the two-page brochure, many more months passed before the EPA issued new guidance on the hazards to auto mechanics of asbestos-containing friction products. The sponsors of the DQA challenge achieved their desired outcome: the 15-page booklet is no more. A new two-page brochure "replaces" the Gold Book and is described by the EPA as "part of an effort to bring its asbestos guidance up to date."[13] The 1986 Gold Book is no longer posted on the

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http://www.regulations.gov/fdmspublic/ContentViewer?objectId=09000064801d801a&disposition=attachment&contentType=pdf (last visited Jan. 2007).

[11] EPA indicated "In the interim, both the hard copy and electronic version of the brochure will include a note that states that the Agency is in the process of updating the material in the document." Letter from Hazen SB (Principal Deputy Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency) to Privitera D (Morgan, Lewis & Bockius, LLP), re: Response to Request for Correction (FRC) regarding the United States (US) Environmental Protection Agency's (EPA's) Guidance for Preventing Asbestos Disease Among Auto Mechanics (the Gold Book) pursuant to the U.S. EPA's Information Quality Guidelines (RFC# 12467), Nov. 24, 2003, *available at* http://www.epa.gov/quality/informationguidelines/documents/12467response-morgan-lewis.pdf (last visited Jan. 2007) [hereinafter Privitera Jan. 2007 letter].

[12] *Id*.

[13] U.S. ENVIRONMENTAL PROTECTION AGENCY, CURRENT BEST PRACTICES FOR PREVENTING ASBESTOS EXPOSURE AMONG BRAKE AND CLUTCH REPAIR WORKERS PUB. NO. EPA-747-F-04-004 (2007). This brochure replaced the existing document entitled, GUIDANCE FOR PREVENTING ASBESTOS DISEASE AMONG AUTO MECHANICS, *see supra* note 2, commonly referred to as the "Gold Book." *Id*. EPA revised this brochure as part of an effort to bring its asbestos guidance up to date. This brochure replaced the

agency's website or even listed as an available additional resource. As the petition author argued, "jurors inevitably are swayed by the impression that EPA's 'official position' is that friction products are hazardous."[14] By using the DQA, defendants in litigation involving asbestos-containing friction products have successfully modified an official EPA document which they viewed as "alarmist and inflammatory."[15]

This Article attempts to examine the impact of litigation on the scientific literature. Using as an example the issues of asbestos disease among automobile mechanics, we examine how the contours and content of the scientific literature are directly and intentionally shaped by parties seeking to succeed in litigation. Part I of this paper defines litigation-generated science and describes two different types of research which falls into this category. We posit that if not for the litigation, or fear of

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original "Gold Book" which was issued in 1986 prior to official OSHA guidance to brake and clutch workers. *See id.*

[13] U.S. ENVIRONMENTAL PROTECTION AGENCY, CURRENT BEST PRACTICES FOR PREVENTING ASBESTOS EXPOSURE AMONG BRAKE AND CLUTCH REPAIR WORKERS, PUB. NO. EPA-747-F-04-004 (2007).

[14] *See* Privitera Aug. 2006 letter, *supra* note 1.

[15] *Id.* Additionally, Mr. Privitera wrote:

> In the highly-charged environment of such litigation, the Gold Book has been used to try to sway jurors, who are told that it represents EPA's current position and thinking on the question of whether asbestos-containing friction products are dangerous to users. In the courtroom, the Gold Book is routinely portrayed as a thoroughly researched, up-to-date, and definitive EPA statement that friction products are indeed hazardous and cause asbestos-related disease . . . . jurors inevitably are swayed by the impression that EPA's "official position" is that friction products are hazardous. The impact of such an argument is particularly powerful both because EPA's status as a respected agency charged with protecting safety and health and because whether auto mechanics face a risk from asbestos in friction products is precisely the question jurors are being asked to answer . . . . EPA's implicit endorsement of the statements in the Gold Book gives it undue (and unnecessary) weight in any discussion of the matter.

Id.

future litigation, the body of scientific literature about a particular topic would be quite different. Certain components of the literature would not have been created, others would have been modified or delayed. Part II provides a history of the use of asbestos in automobile brakes and other vehicle components, and the longstanding public health evidence on health hazards associated with exposure to asbestos, including the risk to vehicle mechanics. Part III outlines the major regulatory initiatives in the U.S. to protect asbestos-exposed workers, in particular individuals repairing automobiles, from adverse health effects related to asbestos exposure. Part IV explains the process used by scientists to assess disease risk and the practicalities considered by government agencies with respect to funding epidemiological studies on subgroups of exposed workers. We note that topics solely of importance in litigation may not be accorded priority in the system through which independent scientists (that is, scientists not involved in the litigation) select research topics, obtain funding support, undertake investigations and publish their findings. As a result, the impact of the litigation-generated additions and modifications to the scientific literature made by scientists associated with the litigation is magnified. Part V provides an assessment of the litigation-generated science on asbestos exposure and/or asbestos disease among vehicle mechanics, and published during the 10-year period 1997-2006. Lastly, Part VI describes the use of the Data Quality Act by interested parties to "subtract" from the body of evidence government documents that make assertions about disease causation and risk. We conclude that this process, in which litigation manipulates the production and suppression of content within the scientific literature, has an impact beyond the courtroom; it has the potential to have a deleterious effect on disease prevention and public health.

I. LITIGATION-GENERATED SCIENCE

In March 2007, a Delaware jury found General Motors (GM), Ford and several other companies liable for injuries suffered by an individual exposed to asbestos in brake and clutches components during his 35 year career as an auto mechanic.[16] The jury awarded $2 million to the plaintiff, who suffered from pleural mesothelioma, a rare and fatal cancer of the lining of the lungs. After expressing sympathy to the victim, a GM spokesperson said the company was "disappointed in the jury's verdict" and asserted that "expert studies have shown that automobile mechanics are not at an increased risk of developing asbestos-related disease as compared to the general population."[17] The spokesperson was likely referring to a series of studies paid for by GM and other automobile manufacturers for the purpose of aiding the litigation effort; the studies were conducted by scientists who specialize in "litigation support" or "product defense."[18]

The acceptability of litigation-generated scientific research in litigation has been the subject of some controversy over the past decade. Judge Alex Kozinski wrote in a Ninth Circuit decision on the remand of *Daubert v. Merrell Dow Pharmaceuticals* that science done for the purpose of litigation should be subject to more stringent standards of admissibility than other science. In

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[16] PR Newswire, *Baron & Budd, P.C., Announces $2 Million Asbestos Verdict Against General Motors Corp., Ford Motor Co. in Delaware*, CNNMONEY, Mar. 2, 2007, *available a* http://money.cnn.com/news/newsfeeds/articles/prnewswire/DAF02902032007-1.htm.

[17] Josh Beckerman, *Law Firm Says Jury Returns Verdict vs. GM, Ford in Asbestos Case*, DOW JONES MARKETWATCH, Mar. 3, 2007, *available at* http://www.marketwatch.com/news/story/law-firm-says-jury-returns/story.aspx?guid=%7b55ED6481-FADD-4593-AA79-1E191A293F7D%7d&print=true&dist=printTop.

[18] Susanna R Bohme et al., *Maximizing Profit and Endangering Health: Corporate Strategies To Avoid Litigation and Regulation*, 11(4) INT'L J. OF OCC. ENV. HLTH. 338 (2005). *See also* D.S. Egilman & M.A. Billings, *Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability,* 11(4) INT'L J. OF OCC. & ENV. HLTH. 360 (2005).

the decision, he wrote: "That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method."[19] Judge Kozinski's concerns in the *Daubert* case addressed studies funded by parties (or their attorneys) in the case expressly for use in the case.[20]

Studies commissioned and performed for a specific case, such as *Daubert*, are a subset of a larger group of studies what may be called "litigation-generated science" (LGS). Boden and Ozonoff identify two types of LGS, "Science done expressly for litigation and commencing after litigation has begun," which they label as LGS-1, and "science done in advance of litigation with the express purpose of providing information in support of marketing a substance, product, or procedure, of providing safety or toxicity information" or LGS-2.[21] The relationship between litigation and sponsored scientific research is often not transparent.[22] As a result, Boden and Ozonoff note that:

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[19] Daubert v. Merrell Dow Pharmaceuticals, 43 F.3d 1311 (9th Cir. 1995).

[20] Judge Kozinski's concern is shared by others in the legal system. *See* W.L. Anderson, B.M. Parsons & D. Rennie, *Daubert's Backwash: Litigation-Generated Science*, 34(4) U. MICH J. L. REFORM 619 (2001) (focusing primarily on the effects of litigation-generated scientific literature on the litigation itself).

[21] L.I. Boden & D. Ozonoff, *Litigation-Generated Science: Why Should We Care?*, ENV. HLTH. PERSPECTIVES (forthcoming 2007) (on file with authors).

[22] For example, the US oil industry sponsored a series of studies in China on the toxic effects of benzene. In presenting the rationale for the study, internal industry documents assert that "litigation alleging induction of various forms of leukemias and other hematopoietic disease from exposure to petroleum derived benzene result in millions of dollars in expenses to industry." American Petroleum Institute, Background and Overview of Proposed Investigation of the Risk of Benzene-induced Hematopoietic Disease (manuscript pages at MOC00044374 unpublished papers on file with authors). However, publications from the studies do not mention the authors' involvement in litigation in the conflict disclosure. The publications simply say "we are grateful to the Benzene Health Research Consortium." *See* O. Wong & H. Fu, *Exposure to Benzene and Non-Hodgkin Lymphoma, an*

> [O]ne can even make the argument that LGS-2 is even more likely to mislead than LGS-1.Well financed industries have the resources to seed the literature with strategic science . . . . There is a covert litigation driven relationship between LGS2 and the general literature that is currently less likely to be subjected to the same additional scrutiny routinely applied to science that is explicitly case-specific.[23]

Our analysis in Part 4 of this paper focuses on litigation-related research, of the LSG-2 type. Based on our assessment of the studies published between 1997 and 2006, we believe most, if not all, fall into the LSG-2 category

II. ASBESTOS DISEASE AMONG AUTOMOBILE MECHANICS: THE HISTORICAL SCIENTIFIC EVIDENCE

The marriage of automobile brakes and asbestos is more than 100 years old. Asbestos cloth was first used in vehicle brake

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Epidemiologic Overview and an Ongoing Case-Control Study in Shanghai, 153 CHEMICO-BIOLOGICAL INTERACTIONS 33 (2005); L. Wang et al., *Benzene Exposure in the Shoemaking Industry in China, a Literature Survey, 1978-2004*, 46 REG. TOX. & PHARM. 149 (2006).

[23] Boden & Ozonoff, *supra* note 21. Boden and Ozonoff conclude that "there may be reasons to treat science involving conflict of interest differently" but question "whether litigation-generated science should be singled out." *Id*. *They* "discuss the similar problems raised by strategically-motivated science done in anticipation of possible future litigation or otherwise designed to benefit the sponsor and ask what special treatment, if any, should be given to science undertaken to support existing or potential future litigation." *Id*. Concluding that "the problems with litigation-generated science are not special. *Id*. On the contrary, they are very general and apply to much or most science that is relevant and reliable in the courtroom setting." *Id.*

See also Sheila Jasanoff, *Law's Knowledge: Science for Justice in Legal Settings*, 95 AM J. PUB. HLTH., S49 (2005); Sheila Jasanoff, *Representation and Re-Presentation in Litigation Science*, ENV. HLTH. PERSPECTIVES (forthcoming 2007) (on file with authors).

linings in 1906[24] and by the 1930's rigid molded asbestos linings were in use.[25] In the boom years of U.S. car production in the 1960's, five to six million cars were manufactured annually[26] and asbestos-containing brake linings and clutches were standard issue. In the period 1965 through 2003, 12 percent of the asbestos consumed in the United States was used in friction products,[27] including vehicle brake linings, disc brake pads, brake block, clutch components and gaskets.[28] In their popular show "Car Talk," National Public Radio's automotive experts Tom and Ray Magliozzi extol its virtues and its deadly shortcoming: "Asbestos was a perfect material for brake pads. It

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[24] United States Geological Survey, *Worldwide Asbestos Supply and Consumption Trends from 1900 through 2003,* at 27 (Table 1: Early developments of the asbestos industry), *available at* http://pubs.usgs.gov/circ/2006/1298/c1298.pdf. *See also* D. Ozonoff, *Failed Warnings: Asbestos-Related Disease and Industrial Medicine*, *in* THE HLTH. & SAFETY OF WORKERS: CASE STUDIES IN THE POLITICS OF PROFESSIONAL RESPONSIBILITY 139, 152-53 (R. Bayer ed., Oxford Univ. Press, 1988).

[25] *See e.g.,* B.I. Castleman, ASBESTOS: MEDICAL AND LEGAL ASPECTS 451 (5th ed., Aspen Publishers 2005).

[26] *See* S. Cooney & B.D. Yacobucci, *U.S. Automotive Industry: Policy Overview and Recent History, Congressional Research Service Report to Congress*, Appendix 4, U.S. Motor Vehicle Sales, at CRS-101 (2005), *available at* http://www.ncseonline.org/NLE/CRSreports/05apr/RL32883.pdf. *See also* U.S. Census 2000, Table 1030, Motor Vehicle Production and Trade, *available at* http://www.allcountries.org/uscensus/transportation_land.html.

[27] United States Geological Survey, *Worldwide Asbestos Supply and Consumption Trends from 1900 through 2003*, at 3-6, *available at* http://pubs.usgs.gov/circ/2006/1298/c1298.pdf.

[28] National Industrial Chemicals Notification and Assessment Scheme, Chrysotile Asbestos: Priority Existing Chemical No. 9, Commonwealth of Australia, Feb. 1999, *avalable at* http://www.nicnas.gov.au/publications/car/pec/pec9/pec_9_full_report_pdf.pdf. In 1973, U.S. manufacturers' consumption of asbestos had reached its peak of 795,000 metric tons (Mt), with 198,000 Mt used in flooring materials and 72 Mt used in friction products. By 1994, total consumption of asbestos in the U.S. had fallen to 27,000 Mt, but one-third (9 Mt) of it was still used in friction materials. United States Geological Survey, *Worldwide Asbestos Supply and Consumption Trends from 1900 through 2003*, Table 3: U.S. End Uses for Asbestos, 1965 through 2003, at 31, *available at* http://pubs.usgs.gov/circ/2006/1298/c1298.pdf.

was durable, it performed well at high temperatures and it was relatively soft, so it didn't squeal when it made contact with the hard steel rotors"[29] and left "the rotors relatively unscathed."[30] "It was perfect! Just perfect! The only problem was that it was killing people."[31]

Although the use of asbestos in brakes has been dramatically curtailed, automobile mechanics may still be exposed while replacing old brakes. Mechanics would be ill advised to assume that newer cars do not have asbestos brakes, since new asbestos brakes are still marketed. At a March 1, 2007, hearing before the U.S. Senate Committee on Health, Education, Labor and Pensions, subcommittee chairwoman Patty Murray (D-WA) held aloft a box with a new automotive brake part. She turned it to the cameras and read the label "Warning: Contains Asbestos." The Senator reported that her staff purchased the product a few days earlier at an automobile supply shop. It was her attempt to dispel the myth that in the United States asbestos-containing products are banned. Moreover, there is no authoritative source of data on imports into the United States of asbestos-containing products.[32] Unlike other countries, like Australia which conduct

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[29] *See* Car Talk, Dec. 1996, *available at* http://www.cartalk.com/content/columns/Archive/1996/December/16.html.

[30] *See* Car Talk, Aug. 2003, *available at* http://www.cartalk.com/content/ columns/Archive/2003/August/01.html.

[31] *See* Car Talk, Dec. 1996, *available at* http://www.cartalk.com/content/ columns/Archive/1996/December/16.html.

[32] Those attempting to discern whether new vehicles are equipped with asbestos-containing brake shoes or clutches receive contradictory information. When the U.S. Environmental Protection Agency surveyed the nine major automobile manufacturers in 2004 about asbestos-containing brake components, they all indicated that they no longer sold asbestos brakes in new vehicles or as replacement parts in the U.S. This survey is available at http://www.epa.gov/fedrgstr/EPA-TOX/2006/August/Day-24/t14057.htm.

When a similar inquiry was made by an OSHA official, representatives of the General Motors Corporation and the Ford Motor Company said that some of their vehicles were still equipped with asbestos-containing friction products. *Asbestos and Brakes: Hearing Before the Senate Health, Education, Labor and Pensions Comm., Sub. on Employment and Workplace Safety*, 110th Cong. (2007) (statement of Barry Castleman, Environmental Consultant), *available at* http://help.senate.gov/Hearings/2007_03_01/

detailed surveys of imports containing asbestos,[33] public health scientists are starved for data about imports of asbestos-containing products into the U.S. and the prevalence of existing goods and materials.

The history of the development of knowledge of asbestos-related disease, and the failure of the asbestos industry to disseminate this information, is well known.[34] Case reports of disease among asbestos-exposed workers first appeared in 1898.[35] In the early decades of the 20th century, medical journals contained numerous descriptive reports on patterns of asbestos-related respiratory disease. By the 1930s, researchers began conducting organized surveys of the workers in factories where asbestos was used and by the 1950s, cohort mortality studies were underway.[36] By the 1960's and 1970's, hundreds of articles had been published in the scientific literature linking exposure to asbestos fibers to respiratory disease and cancer.

Since at least the 1930s, automobile mechanics have been one of the many occupational groups regularly identified as having asbestos exposure and as a result having an increased risk of asbestos-related disease.[37] Starting in the 1970s, there

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Castleman.pdf [hereinafter Castleman Testimony].

[33] National Industrial Chemicals Notification and Assessment Scheme, *Chrysotile Asbestos: Priority Existing Chemical No. 9* (Commonwealth of Australia, Feb. 1999), *available at* http://www.nicnas.gov.au/publications/car/pec/pec9/pec_9_full_report_pdf.pdf.

[34] Among the excellent sources recounting this history are: P. BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL (Pantheon Books 1985); B. CASTLEMAN, ASBESTOS: MEDICAL AND LEGAL ASPECTS (5th ed., Aspen Publishers 2005); D. Ozonoff, *Failed Warnings: Asbestos-Related Disease and Industrial Medicine in* CASE STUDIES IN THE POLITICS OF PROFESSIONAL RESPONSIBILITY (Bayer R, ed., Oxford Univ. Press 1988); G. TWEEDALE, MAGIC MINERAL TO KILLER DUST (Oxford Univ. Press 2000).

[35] Annual Report of Her Majesty's Lady Inspectors, London, England (1898) *in* ANNUAL REPORT OF THE CHIEF INSPECTOR OF FACTORIES AND WORKSHOPS FOR THE YEAR 1898, PART II: REPORTS.

[36] R. Doll, *Mortality from Lung Cancer in Asbestos Workers*, 12(2) BRITISH J. INDUS. MED. 81 (1955).

[37] The potential of exposure to asbestos associated with friction products was noted in E.R.A. Merewether, C.W. Price, REPORT ON EFFECTS OF ASBESTOS DUST ON THE LUNGS AND DUST SUPPRESSION IN THE ASBESTOS

have been a series of studies that examined asbestos exposure among workers doing brake maintenance activities.[38] For example, a 1970 study conducted by the Medical Services Division of Ford of Britain,[39] determined that mechanics repairing brakes were exposed to chrysotile asbestos fibers. The authors called for "strict precautions to prevent the inhalation of fibres," especially when filing or grinding brake linings.[40] Similarly, a study funded by the National Institute for Environmental Health Sciences (NIEHS), scientists at the Mt. Sinai School of Medicine collected and examined automobile brake drum dust and air samples from repair shops servicing automobiles, taxis and municipal trucks.[41] The researchers

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INDUSTRY (1930), submitted by the H.M. Chief Inspector of Factories to H.M. Secretary of State for the Home Department, described the risk of asbestos exposure among workers manufacturing and repairing "(d) Brake and Clutch Linings." In addition, the Memorandum on the Industrial Diseases of Silicosis and Asbestosis, published by His Majesty's Stationery Office (July 1932), describes the range of industries in which asbestos exposure occurs, including "the sawing, grinding, and turning in the dry state of articles composed wholly or partly of asbestos such as motor car brake and clutch linings. . ." *The Memorandum on the Industrial Diseases of Silicosis and Asbestosis*, published by His Majesty's Stationery Office (July 1932) (on file with authors).

[38] *See generally* D. Hatch, *Possible Alternatives to Asbestos as a Friction Material*, 13(1) ANNALS OCC. HYGIENE 25 (1970). *See also* D.E. Hickish & K.L. Knight, *Exposure to Asbestos During Brake Maintenance*, 13(1) ANNALS OCC. HYGIENE 17 (Jan. 1970); D.M. Rowson, *The Chrysotile Content of the Wear Debris of Brake Linings*, 47 WEAR 315 (1978); K.L Knight & D.E. Hickish, *Investigations Into Alternative Forms of Control for Dust Generated During the Cleaning of Brake Assemblies and Drums,* 13(1) ANNALS OCC. HYGIENE 37 (1970); A.N. Rohl et al., *Asbestos Content of Dust Encountered in Brake Maintenance and Repair*, 70(1) PROCEEDINGS ROYAL SOCIETY MED. 32 (1977); A.N. Rohl et al., *Asbestos Exposure During Brake Lining Maintenance and Repair*, 12 ENV. RES. 110 (1976); K. Rodelsperger, H. Jahn, B. Bruckel, J. Manke, R. Paur, & H.J. Woitowitz HJ, *Asbestos Dust Exposure During Brake Repair*, 10(1) AM. J. INDUS. MED. 63 (1986).

[39] Later called Ford of Europe.

[40] D.E. Hickish & K.L. Knight, *Exposure to Asbestos During Brake Maintenance*, 13(1) ANNALS OCC. HYGIENE 17 (1970).

[41] A.N. Rohl, A.M. Langer, M.S. Wolf, & I. Weisman, *Asbestos*

identified chrysotile asbestos in both the bulk-dust samples and the air samples which provided concrete evidence that workers in repair shops were potentially exposed to asbestos. In addition, most of the air samples, especially those taken on workers performing the dustiest jobs (e.g., blowing dust from brake drums, beveling new linings) exceeded OSHA's current 30 minute excursion limit of 1 f/cc (fiber per cubic centimeter of air).[42]

According to one review, there have been at least 165 cases of mesothelioma presented in the peer-reviewed literature among end-product users of asbestos-containing friction products.[43] In 1982, for example, a case report published in *The Lancet* described a 55-year-old individual with mesothelioma who had worked since age 19 as an automobile mechanic.[44] His job duties included replacing asbestos-containing brake parts; he had no other known history of asbestos exposure. Through autopsy and electron microscopy, the researchers confirmed the presence of chrysotile asbestos in the deceased mechanic's lung tissue, the type of asbestos used exclusively in automobile friction products.

In the 1970s and 1980s, researchers conducted medical screening programs that identified and attempted to quantify the presence of asbestos-related diseases in specific occupations and workplaces. Many of these screening programs were undertaken by researchers at the Mt. Sinai School of Medicine, working under the direction of Dr. Irving Selikoff,[45] the pre-eminent

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Exposure During Brake Lining Maintenance and Repair, 12 ENV. RES. 110 (1976); A.N. Rohl, A.M. Langer, R. Klimentidis, M.S. Wolff, & I.J. Seilikoff, *Asbestos Content of Dust Encountered in Brake Maintenance and Repair*, 70(1) PROC. R. SOC. MED. 32 (1977).

[42] 29 CFR 1910.1001(c)(2), Asbestos.

[43] R.A. Lemen, *Asbestos in Brakes: Exposure and Risk of Disease*, 45 AM. J. INDUS. MED. 229 (2004).

[44] A.M. Langer & W.T.E. McCaughey, *Mesothelioma in a Brake Repair Worker* 2(8307) THE LANCET 1101 (Nov. 13, 1982).

[45] *See* I.J. Selikoffet et. al., *Asbestos Exposure and Neoplasia*, 188 JAMA 22 (1964). *See also* I.J. Selikoff et al. *Relation Between Exposure to Asbestos and Mesothelioma*, 18 NEW ENG. J. MED. 560 (1965); I.J. Selikoff, J. Churg, & E.C. Hammond, *The Occurrence of Asbestosis Among Insulation*

asbestos disease expert in the United States until his death in 1992. In 1976, the Mt. Sinai group published the results of asbestos exposure and disease among 104 brake maintenance workers, along with clinical findings of respiratory impairment.[46] The scientists reported significant asbestos exposures in the repair garages, and abnormal chest x-rays and/or pulmonary function in more than 25 percent of the study subjects. They wrote: "While this preliminary study was limited in scope . . . the findings suggest that asbestos disease will be present among such workers and that appropriate control measures should be urgently instituted."[47]

III. U.S. REGULATORY POLICIES TO PROTECT ASBESTOS-EXPOSED AUTO MECHANICS

Until very recently, there was little if any controversy among public health scientists regarding the ability of asbestos in automobile brake shoes to cause asbestos disease in exposed workers. As described above, airborne concentrations of asbestos fibers were measured in workplaces where the source of the asbestos was automobile parts, such as brake shoes and clutches. Numerous scientific papers reported on asbestos disease in automobile mechanics. As a result, public health regulatory agencies have long considered exposure to asbestos coming from brake shoes as a risk factor for asbestos-related cancer and lung disease, and issued regulations for protecting these workers from that very exposure.

When the newly formed Occupational Safety and Health Administration (OSHA) issued its first standard mandating protection from asbestos exposure in 1971, the new regulation covered all workers, including auto mechanics who worked with asbestos-containing brakes, clutches and other automobile

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Workers in the United States, 132(1) ANNALS N.Y. ACADEMY SCI. 139 (1965); I.J. Selikoff, E.C. Hammond, & J. Churg, A*sbestos Exposure, Smoking, and Neoplasia,* 204(2) JAMA 106 (1968).

[46] W.V. Lorimer et al., *Asbestos Exposure of Brake Repair Workers in the United States*, 43(3) MT. SINAI J. MED. 207 (1976).

[47] *See id.*

parts.[48]

In September 1984, the Natural Resources Defense Council (NRDC) petitioned the EPA to prohibit the use of asbestos in brakes for new cars and trucks, and in replacement brake components for existing vehicles. Before that year ended, EPA Administrator William D. Ruckelshaus granted the NRDC's petition saying, "the Agency believes that the use of asbestos in brakes does present risks to human health."[49] The EPA agreed to move forward with rulemaking to implement the ban, including a determination that the products present an "unreasonable risk of injury to human health or the environment."[50] In December 1986, EPA published a proposal under section 6 of the Toxic Substances Control Act (TSCA) "to prohibit the manufacture, importation, and processing of asbestos in certain products and to phase out the use of asbestos in all other products."[51] The proposed ban included a variety of

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[48] Occupational Safety and Health Administration, *Emergency Temporary Standard, Asbestos*, 36 FED. REG. 23207 (1971). The only exception to the rule were employees working in the construction industry who would be covered by a different OSHA regulation. *Id.*

[49] U.S. Environmental Protection Agency, *Response to Citizens' Petition*, 49 FED. REG. 49311 (Dec. 19, 1984). In the response, EPA stated:

> Asbestos is a demonstrated human carcinogen that causes lung cancer and mesothelioma (a cancer of the chest and abdominal linings), as well as other lung disorders. People are exposed to asbestos throughout the life cycle of the substance—when asbestos is mined, milled, processed, fabricated into industrial and consumer products, and when those products are used, repaired, and disposed of. With regard to the use of asbestos in brakes, it has been estimated that about 2,750 people are potentially exposed during primary manufacturing of brake friction materials, and that about 550,000 people are potentially exposed to asbestos during servicing and repair of vehicle brakes. For example, persons in brake service and repair shops typically are exposed to asbestos when dust is blown out of brake drums being replaced, when brake linings are roughened to increase friction properties, and when brake shoes are relined.

Id.

[50] Toxic Substances Control Act § 6(c)(1), 15 U.S.C. § 2601 (1976).

[51] US Environmental Protection Agency, *Proposed Mining and Import*

asbestos-containing automobile parts (e.g., drum brake linings, brake blocks, disc pads, and clutch facings).[52] (The ban was finalized in July 1989, but was struck down in federal court and never took effect.)[53]

A few months before the NRDC petitioned EPA to ban asbestos in automobile parts, the Occupational Safety and Health Administration (OSHA) had published an emergency temporary standard to reduce workers' exposure to asbestos. The November 1983 rule specifically discussed exposures in the "automotive aftermarket industry"[54] which the agency described as businesses involved in: "(1) refacing or rebuilding of friction materials, (2) repackaging of friction materials, and (3) general brake repair and maintenance" and noted, ". . . the major source of exposure to asbestos in this industry occurs during brake repair and maintenance."[55] OSHA estimated that 370 excess cancer deaths could be avoided in the automotive aftermarket sector if the workplace permissible exposure limit for asbestos was reduced from 2.0 fibers/cc to 0.1 fibers/cc.

When OSHA published a revised final rule in June 1986, the agency included a special appendix for automotive brake repair

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Restrictions and Proposed Manufacturing, Importation, and Processing Prohibitions, 51 FED. REG. 3738 (Jan. 29, 1986).

[52] The proposed ban also include other asbestos containing products like roofing felt, floor tiles, pipes and millboard. *Id*.

[53] When the final ban was issued in July 1989, it prescribed a phased-in prohibition of asbestos-containing automotive component so that by August 1996 these products would no longer be manufactured or imported. The July 1989 EPA rule was challenged in federal court, however, and the ban on asbestos-containing brake components never took effect. Corrosion Proof Fittings, et al v. EPA, 947 F.2d 1201 (5th Cir. 1991) (ruling, among other things, that EPA did not consider the least burdensome regulatory alternative).

[54] Occupational Safety and Health Administration, *Emergency Temporary Standard: Occupational Exposure to Asbestos*, 48 FED. REG. 51086 (Nov. 4, 1983). The proposal for the permanent health standard was published on April 10, 1984. Occupational Safety and Health Administration, *Proposed Rule and Notice of Hearing: Occupational Exposure to Asbestos*, 49 FED. REG. 14116 (Apr. 10, 1984).

[55] *See* Occupational Safety and Health Administration, 49 FED. REG. 14116.

operations with model "best practice" methods for reducing mechanics' asbestos exposure to concentrations below the 0.1 fiber/cc full-shift limit.[56] That same month, the EPA published a gold-covered booklet entitled "Guidance for Preventing Asbestos Disease Among Mechanics,"[57] and shortly thereafter, a fact sheet called "Controlling Brake Dust to Protect Your Health: What Every Auto Mechanic Should Know."[58]

In 1989, the National Institute for Occupational Safety and Health (NIOSH), the federal agency responsible for research on workplace safety, issued a lengthy report on the industrial hygiene practices used to control workers' exposure to asbestos during vehicle brake drum service.[59] The report was prepared in collaboration with the U.S. Environmental Protection Agency,[60] (whose Administrator noted at the time of the EPA's proposed asbestos ban: "I believe there can be no debate about the health risks of asbestos.").[61] The tone and content of the report were clear: as far as these federal public health agencies were concerned there was no dispute that asbestos-exposed auto mechanics were at increased risk of asbestos-related disease. Brake and other components contain asbestos, asbestos is a known human carcinogen, and workers are potentially exposed to asbestos when performing brake repair and maintenance. It is therefore perhaps not surprising that asbestos disease among

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[56] Occupational Safety and Health Administration, *Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite*, Appendix F: Work Practices and Engineering Controls for Automotive Brake Repair Operations, 51 FED. REG. 22612 (June 20, 1986).

[57] US Environmental Protection Agency, *Guidance for Preventing Asbestos Disease Among Auto Mechanics* (1986).

[58] US Environmental Protection Agency, *Controlling Brake Dust to Protect Your Health: What Every Auto Mechanic Should Know* (1986).

[59] J.W. SHEEHY ET AL., CONTROL OF ASBESTOS EXPOSURE DURING BRAKE DRUM SERVICE, PUBLICATION NO. 89-121 (DHHS (NIOSH) 1989).

[60] The report notes, "This study was supported under Interagency Agreement No. DW75931956-01 with the Chemical Engineering Branch, Office of Toxic Substances, U.S. Environmental Protection Agency." *Id*. at viii.

[61] C. Peterson, *EPA Seeks Total Ban of Asbestos*, WASHINGTON POST, Jan. 24, 1986, at A1.

auto mechanics was not a topic that attracted research; in the 10 years following OSHA's 1986 final asbestos standard, we could only identify one new epidemiological study on disease risk for car mechanics,[62] including those exposed to asbestos.

IV. ASBESTOS DISEASE AMONG AUTOMOBILE MECHANICS: THE MAKING OF A CONSENSUS

The national and international agencies that categorize and classify carcinogens have concluded that all types of asbestos (both serpentine and amphibole) are capable of causing lung cancer and mesothelioma,[63] although not with the same potency.[64] The government agencies that fund scientific research

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[62] E. Hansen, *Mortality of Auto Mechanics*, 15 SCAND. J. WORK ENV. HLTH. 43 (1989). This study, funded by the Danish National Anti-Cancer League, examined a host of workplace exposures (e.g., solvents, paints, gasoline exhaust) among a population of 21,800 car mechanics. The investigators reported one pleural mesothelioma case in study population. Other contributions to the literature during this time were case reports of mechanics with mesothelioma. *See, e.g.,* M. Huncharek, J. Muscat & J.V. Capotorto, *Pleural Mesothelioma in a Brake Mechanic*, 46 BRITISH J. INDUST. MED. 69 (1989) (describing a 47-year old lifetime non-smoker with no known exposure to asbestos except for his 11 years working as an automobile mechanic). *See also* H.J. Woitowitz & K. Rodelsperger, *Chrysotile Asbestos and Mesothelioma*, 19 AM. J. INDUST. MED. 551 (1991) (describing 10 former garage mechanics who died with mesothelioma in 1980-1985); H.J. Woitowitz & K. Rodelsperger, *Mesothelioma Among Car Mechanics*, 38(4) ANNALS OCC. HYGIENE 635 (1994); N. Plato, G. Tornling, C. Hogstedt, & S. Krantz S., *An Index of Past Asbestos Exposure as Applied to Car and Bus Mechanics*, 39(4) ANNALS OCC. HYGIENE 441 (1995) (funding provided by the Swedish Work Environment Fund on a proposed model for estimating bus and car mechanics cumulative exposure to asbestos).

[63] International Agency for Research on Cancer, *Monograph on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs, Volumes 1 to 42*, Supplement 7, 1987, *available at* http://monographs.iarc.fr/ENG/Monographs/suppl7/suppl7.pdf. *See also* National Toxicology Program, *Eleventh Report on Carcinogens* (2005), *available at* http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s016asbe.pdf.

[64] Members of the Institute of Medicine's 2006 panel examining the scientific evidence on asbestos and disease noted that chrysotile fibers may be

have spent many millions of dollars in support of the studies on which these conclusions are based. Studies of miners, textile workers, insulators, construction workers, and other asbestos-exposed workers have documented the relationship between exposure to asbestos fibers and increased risk of asbestos, mesothelioma, lung cancer, and some other cancers.[65] Further, since extremely low levels of asbestos exposure have been associated with increased risk of disease,[66] the default assumption is that there is no safe level of asbestos exposure.[67] These studies have served as the basis for public health

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generally less potent than amphibole fibers. The panel was careful, however, to distinguished their statement from any suggestion that chrysotile fibers are not capable of causing cancer. National Academy of Sciences, *Asbestos: Selected Cancers*, (National Academy Press 2006) at 4, *available at* http://books.nap.edu/openbook.php?record_id=11665&page=R1. The World Health Organization's International Agency for Research on Cancer (IARC) and the National Institutes of Health's NTP both conclude that amphibole and serpentine asbestos fibers are carcinogenic. International Agency for Research on Cancer, *Monograph on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs, Volumes 1 to 42*, Supplement 7, 1987, *available at* http://monographs.iarc.fr/ENG/Monographs/suppl7/suppl7.pdf.

[65] *See* National Academy of Sciences, *Asbestos: Selected Cancers*, (National Academy Press 2006), *available at* http://books.nap.edu/openbook.php?record_id=11665&page=R1. *See also* International Agency for Research on Cancer, *Monograph on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs*, Volumes 1 to 42, Supplement 7, 1987, *available at* http://monographs.iarc.fr/ENG/Monographs/suppl7/suppl7.pdf. National Toxicology Program, Eleventh Report on Carcinogens (2005), *available at* http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s016asbe.pdf.

[66] *See, e.g.*, X.L. Pan et al., *Residential Proximity to Naturally Occurring Asbestos and Mesothelioma Risk in California*, 172(8) AM. J. RESPIRATORY & CRITICAL CARE MED. 1019 (2005).

[67] As noted by the 2006 document released by the World Health Organization, "bearing in mind that there is no evidence for a threshold for the carcinogenic effects of asbestos and that increased cancer risks have been observed in populations exposed to very low levels . . ." World Health Organization, Elimination of Asbestos-Related Disease, Policy Paper (2006), *available at* http://www.who.int/occupational_health/publications/asbestos-relateddiseases.pdf.

protections imposed by OSHA, EPA and other regulatory agencies. As a result, while asbestos exposure in the United States is not yet a thing of the past, it is substantially controlled.[68] From a regulatory perspective, there is little clamor for studies of additional worker cohorts; it is assumed that, no matter what the occupation or setting, asbestos exposure results in increased risk of disease. Lower exposure levels are associated with lower risk, but as long as there is exposure, there is risk.

There is a wealth of epidemiological evidence about the risk of asbestos-related disease among asbestos exposed factory or construction workers, but much less information of this type on asbestos disease in automobile mechanics.[69] Given the high visibility of litigation involving asbestos disease among brake workers, it is reasonable for legal practitioners to wonder why there aren't more studies on mechanics and asbestos-related disease. The answer requires a little understanding of epidemiology and the challenges of designing a study that is capable of providing useful information.

The primary reason, in our view, is that brake mechanics as an occupational group did not lend itself to study in the same way that asbestos-textile workers, shipbuilders or construction workers did. The large asbestos disease studies of the 1960s through 1980s examined disease or mortality risk among groups of workers who were either employed in the same workplace over a number of years, or who belonged to the same union and performed similar jobs, but possibly at different workplaces. In contrast, auto mechanics who perform brake repair, are often employed in small, non-union shops. As their occupational name implies, they do many tasks, not just brake repair, and the

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[68] Significant exposures are occasionally reported in building renovation or demolition work, when works are hired to rip out or remove asbestos insulation. These cases generally involve unscrupulous contractors who are breaking the law. Michelle York, *Dather and Son Faked Removal of Asbestos*, N.Y. TIMES, Feb. 3, 2004, at B1.

[69] E. Hansen, *Mortality of Auto Mechanics*. 15 SCAND J. WORK ENV. HLTH. 43, (1989); H.J. Woitowitz & K. Rodelsperger, *Mesothelioma Among Car Mechanics*, 38(4) ANNALS OCC. HYGIENE 635 (1994).

distribution of their work (along with their asbestos exposure) may vary from shop to shop. The resulting variation of exposure between individuals, combined with the difficulty in even identifying these workers and organizing them for the purpose of conducting a long-term study, makes undertaking a cohort study of brake workers a formidable task, even for the most skilled research team. Additional challenges involve the assessment of airborne asbestos levels experienced by auto mechanics, since current exposures are far lower than historic ones, and the long latency period between exposure and disease, which in the case of asbestos is generally a minimum of 20 years, but can be far longer.

Case control studies investigating risk factors for mesothelioma have elicited information about exposure to asbestos while working as an automobile mechanic. These studies have not demonstrated an increase in mesothelioma risk among auto mechanics.[70] Some observers, especially those associated with defendants, interpret the absence of increased mesothelioma risk in the case control studies as proof that a case of mesothelioma in an auto mechanic cannot be caused by asbestos liberated from brake shoes. Other observers, especially those associated with plaintiffs, point out the methodological limitations in the case control studies, asserting that results from this one set of studies cannot trump the extensive scientific literature of the carcinogenic mechanisms of asbestos.[71]

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[70] *See* A.D. McDonald & J.C. McDonald, *Malignant Mesothelioma in North America*, 46 CANCER 1650 (1980). *See also* R. Spirtas, E.F. Heineman, L. Bernstein, G.W. Beebe, R.J. Keehn, A. Stark, B.L. Harlow, & J. Benichou, *Malignant Mesothelioma: Attributable Risk of Asbestos Exposure*, 51 OCC. & ENV. MED. 804 (1994); H.J. Woitowitz & K. Rodelsperger, *Mesothelioma Among Car Mechanics*, 38(4) ANNALS OCC. HYGIENE 635 (1994). On the other hand, analysis of data from the Australian Mesothelioma Register found risk of mesothelioma was increased among persons whose only exposure to asbestos came through work as an auto mechanic. J. Leigh, P. Davidson, L. Hendrie, & D. Berry, Letter to U.S. Environmental Protection Agency, Information Quality Guidelines Staff, Oct. 1, 2003 (on file with authors).

[71] This is the position of the authors of this study; however, in writing this paper, we have made every effort to step away from this position to

Beyond the methodological impediments to mounting a study on asbestos-related disease among auto mechanics, there is an additional reason they are unlikely to be undertaken. The answer to the question now frequently raised in litigation: "How much does asbestos exposure from brakes increase the risk of asbestos disease in an auto mechanic?" is of little or no interest outside the courtroom. New studies that quantify asbestos disease risk in yet another industry or occupation are unlikely to have much impact on disease prevention requirements promulgated by regulatory agencies like OSHA and the EPA. The risk of disease in humans associated with asbestos exposure has already been demonstrated, confirmed and reconfirmed in many and varied occupations and industries.

The topic isn't sexy in the academic sense; reports quantifying risk of asbestos disease in yet another asbestos exposed cohort are unlikely to be accepted in the more prestigious medical journals. As a result, this research direction is unlikely to have great appeal to science research funding agencies or university-based public health researchers. With many environmental hazards unstudied, and shrinking research budgets, it is difficult to justify spending public research dollars quantifying the risk of asbestos disease in one more asbestos-exposed population.

V. LITIGATION-GENERATED SCIENCE ON ASBESTOS EXPOSURE AND DISEASE AMONG AUTOMOBILE MECHANICS

Although there may be little interest in researching asbestos disease among automobile mechanics on the part of university scientists and funding agencies, over the past few years, we have observed that there appears to be an increase in the rate of publication of papers on this topic. Many of the authors and sponsors of the papers disclose or are known to be involved in asbestos litigation. Furthermore, many of the papers seem to be written for use in litigation, in that they did not include new

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focus not on what the studies say but on how the literature is shaped by those involved in the litigation. For the purpose of this paper, we are suspending judgment on the validity or reliability of any of the papers discussed.

scientific data, but instead offered conclusions, based on review of previously collected data, on issues likely to arise in litigation like causation or historical exposure levels. Their conclusions often seem presented in a way that would be particularly useful in litigation.

In order to begin to examine the effect of litigation on the scientific literature, we conducted a search of PubMed and Google Scholar looking for papers whose primary focus is asbestos exposure or asbestos disease in automobile mechanics published during the 10-year period 1997-2006. We limited the review to papers whose titles, keywords or abstracts included the word "asbestos" along with either automobile, mechanic, brake or clutch. We did not include editorials or letters to the editor. We reviewed these papers to identify those that focused on asbestos exposure or asbestos-related disease among auto mechanics. This resulted in a collection of 39 papers. For these papers, we attempted to determine if the study appeared to be associated with litigation.[72] To do this, we examined the authors' conflict of interest disclosures (if printed with the article), the sponsor of the study (if it were a party to litigation and the study's findings were about an issue that arises in that litigation), or if any of the authors were easily identified in electronic searches as an expert witness in an asbestos brake, clutch or gasket case. Of these 39 papers, we identified 26 papers[73] in the scientific literature that met our criteria for

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[72] Based on research, it may not always be possible to establish definitively that a study was done for litigation purposes. In some cases, however, invoices and other documents obtained through the discovery process provide evidence that the studies were done to support litigation.

[73] No papers meeting these criteria were published in 1997 or 1998. *See, e.g.,* J.W. Spencer, M.J. Plisko & J.L. Balzer, *Asbestos Fiber Release from the Brake Pads of Overhead Industrial Cranes*, 14(6) APPLIED OCC. ENV. HYGIENE 397 (1999). *See also* J.L. Levin, M.F. O'Sullivan, C.J. Corn, M.G. Williams & R.F. Dodson, *Asbestosis and Small Cell Lung Cancer in a Clutch Refabricator*, 56(9) OCC. & ENV. MED. 602 (1999); D.P. Fowler, *Exposure to Asbestos Arising from Bandsawing Gasket Material*, 15(5) APPLIED OCC. & ENV. HYGIENE 404 (2000); F.W. Weir & L.B. Meraz, *Morphological Characteristics of Asbestos Fibers Released During Grinding and Drilling of Friction Products*, 16(12) APPLIED OCC. & ENV. HYGIENE

1147, (2001); O. Wong, *Malignant Mesothelioma and Asbestos Exposure Among Auto Mechanics: Appraisal of Scientific Evidence*, 34(2) REG. TOX. & PHARM., 170 (2001); F.W. Weir et al., *Characterization of Vehicular Brake Service Personnel Exposure to Airborne Asbestos and Particulate*, 16(12) APPLIED OCC. & ENV. HYGIENE 1139 (2001); W.E. Longo, W.B. Egeland, R.L. Hatfield & L.R. Newton, *Fiber Release During the Removal of Asbestos-Containing Gaskets: A Work Practice Simulation*, 17(1) APPLIED OCC. & ENV. HYGIENE 55 (2002); K.J. Butnor, T.A. Sporn & V.L. Roggli, *Exposure to Brake Dust and Malignant Mesothelioma: A Study of 10 Cases with Mineral Fiber Analysis*, 47(4) ANNALS OCC. HYGIENE 325 (2003); Dennis J. Paustenbach et al., *An Evaluation of Historical Exposures of Mechanics to Asbestos in Brake Dust*, 18(10) APPLIED OCC. & ENV. HYGIENE 786 (2003); A.M. Langer, *Reduction of the Biological Potential of Chrysotile Asbestos Arising from Conditions of Service on Brake Pads*, 38(1) REG. TOX. & PHARM. 71 (2003); C.L. Blake, D.R. Van Orden, M. Banasik & R.D. Harbison, *Airborne Asbestos Concentration from Brake Changing Does Not Exceed Permissible Exposure Limit*, 38(1) REG. TOX. & PHARM. 58 (2003); P.G. Sanders, N. Xu, T.M. Dalka & M.M. Maricq, *Airborne Brake Wear Debris: Size Distributions, Composition, and a Comparison of Dynamometer and Vehicle Tests*, 37(18) ENV. SCI. & TECH. 4060 (2003); J.L. Levin, M. O'Sullivan & R.F. Dodson, *Environmental Sample Correlation with Clinical and Historical Data in a Friction Product Exposure*, 15(7) INHALATION TOX. 639 (2003); M.A. Atkinson, M. O'Sullivan, S. Zuber & R.F. Dodson, *Evaluation of the Size and Type of Free Particulates Collected from Unused Asbestos-Containing Brake Components as Related to Potential for Respirability*, 46(6) AM. J. INDUST. MED. 545 (2004); F. Laden, M.J. Stampfer & A.M. Walker, *Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review*, 19(1) REV. ON ENV. HLTH. 39 (2004); M. Goodman et al., *Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: A Meta-Analysis*, 48(4) ANNALS OCC. HYGIENE 309 (2004); Dennis J. Paustenbach, B.L. Finley, E.T. Lu, G.P. Brorby & P.J. Sheehan, *Environmental and Occupational Health Hazards Associated With the Presence of Asbestos in Brake Linings and Pads (1900 to present): A "State of the Art" Review*, 7(1) J. TOX. & ENV. HLTH. B. CRITICAL REV. 25 (2004); P.A. Hessel, M.J. Teta, M. Goodman & E. Lau, *Mesothelioma Among Brake Mechanics: An Expanded Analysis of a Case-Control Study*, 24(3) RISK ANALYSIS 547 (2004); R.A. Lemen, *Asbestos in Brakes: Exposure and Risk of Disease*, 45(3) AM. J. INDUST. MED. 229 (2004); D.S. Egilman & M.A. Billings, *Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability*, 11(4) INT'L J. OF OCC. & ENV. HLTH. 360 (2004); L.R. Luikonen & F.W. Weir, *Asbestos Exposure from Gaskets During Disassembly of a Medium Duty Diesel Engine*, 41(2) REG. TOX. & PHARM. 113 (2005); C.L. Blake, G.S. Doton & R.D. Harbison, *Assessment*

litigation-generated research. All 26 of these were conducted by U.S. researchers. The remaining 13 papers[74] did not appear to

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of Airborne Asbestos Exposure During the Servicing and Handling of Automobile Asbestos-Containing Gaskets, 45(2) REG. TOX. & PHARM. 214 (2006); B. Castleman, *Asbestos Products, Hazards, and Regulation*, 36(2) INT'L. J. HLTH. SERVICES 295 (2006); C. Mangold et al., *An Exposure Study of Bystanders and Workers During the Installation and Removal of Asbestos Gaskets and Packing*, 3(2) J. OCC. & ENV. HYGIENE 87 (2006); Dennis J. Paustenbach et al., *Chrysotile Asbestos Exposure Associated with Removal of Automobile Exhaust Systems (ca. 1945-1975) By Mechanics: Results of a Simulation Study*, 16(2) J. EXP. SCI. & ENV. EPIDEMIOL. 156 (2006); O. Wong, *The Interpretation of Occupational Epidemiologic Data in Regulation and Litigation: Studies of Auto Mechanics and Petroleum Workers*, 44(3) REG. TOX. & PHARM. 191 (2006).

[74] P. Yeung et al., *Distribution of Mesothelioma Cases in Different Occupational Groups and Industries in Australia, 1979-1995*, 14(11) APPLIED OCC. & ENV. HYGIENE 759 (1999); P. Yeung, K. Patience, L. Apthorpe & D. Willcocks, *An Australian Study to Evaluate Worker Exposure to Chrysotile in the Automotive Service Industry*, 14(7), APPLIED OCC. & ENV. HYGIENE 448 (1999); A. Mandi et al., *Role of Occupational Asbestos Exposure in Hungarian Lung Cancer Patients*, 73(8) INT'L ARCHIVES OCC. & ENV. HLTH. 555 (2000); M. Erdinc et al., *Respiratory Impairment Due to Asbestos Exposure in Brake-lining Workers*, 91(3) ENVIRON. RES. 151 (2003); G. Chiappino, C. Mensi, L. Riboldi & G. Rivolta, *Asbestos Risk in the Textile Industry; Final Confirmation of Data from the Lombardy Mesothelioma Registry*, 94(6), MED. LAV. 521 (2003); V. Subramanian & N. Madhavan, *Asbestos Problem in India*, 49(1) LUNG CANCER S9 (2005); E. Imbernon et al., *Quantitative Assessment of the Risk of Lung Cancer and Pleural Mesothelioma Among Automobile Mechanics*, 53(5) REV. EPIDEMIOL. SANTE. PUBLIQUE. 491 (2005); G. Chiappino et al., *Asbestos Risk in the Textile Industry: Braking Systems on Machinery Used Until the 1990's*, 96(3) MED. LAV. 250 (2005); G. Chiappino. *Mesothelioma: the Aetiological Role of Ultrathin Fibres and Repercussions on Prevention and Medical Legal Evaluation*, 96(1) MED. LAV. 3 (2005); K. Steinsvag et al., *Exposure to Carcinogens for Defined Job Categories in Norway's Offshore Petroleum Industry, 1970-2005*, 64(4) OCC. ENV. MED. 250 (2006); K. Sakai et al., *Asbestos Exposure During Reprocessing of Automobile Brakes and Clutches* 12(2) INT'L. J. OCC. & ENV. HLTH. 95 (2006); S. Poti, R.K. Bellomo, C. DiPierri, N. L'Abbate, *Poliomyelitis Vaccine Contaminated Wwith SV40 and Prior Exposure to Asbestos: Cognitive Study in a Group of Car Repair Workers*, 28(2) G. ITAL. MED. LAV. ERGON. 168 (2006); B. M'Barek, L. Kochbati, H.BenMansour, M. BenLaiba & M. Maalej, *Occupational Cancer in Tunisia*, 84(1) TUNIS. MED. 30 (2006).

us to be LGS, in that they were prepared by researchers working for institutions outside the U.S., and several were published in non-English language scientific journals.

Of the 26 papers we surmised to be litigation-generated, 20 (77 percent) were published in 2002 through 2006, the last four years of the period under study. Only two in the set presented any new health effects data;[75] the remainder include eight literature reviews or re-analyses,[76] as well as 14 analyses which attempted to estimate the amount of exposure a worker might have received while repairing asbestos-containing friction products. Of the 26, we observed that 18 of the papers were

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[75] J.L. Levin et al., *Asbestosis and Small Cell Cancer in a Clutch Refabricator*, 56(9) OCC. & ENV. MED. 602 (1999) (reporting a case of small cell lung cancer in a clutch refabricator and describe the pathological evidence which revealed chrysotile fibers consistent with those found in the individual's workplace). *See also* K.J. Butnor, T.A. Sporn & V.L. Roggli, *Exposure to Brake Dust and Malignant Mesothelioma: A Study of 10 Cases with Mineral Fiber Analyses*, 47(4) ANNALS OCC. HYGIENE 325 (2003) (attributing the disease to the workers' unknown exposure to amphibole asbestos rather than chrysotile fibers).

[76] O. Wong, *Malignant Mesothelioma and Asbestos Exposure Among Auto Mechanics: Appraisal of Scientific Evidence*, 34(2) REG. TOX. & PHARM. 170 (2001). *See also* Dennis J. Paustenbach, R.O. Richter, B.L. Finley & P.J. Sheehan, *An Evaluation of Historical Exposures of Mechanics to Asbestos in Brake Dust*, 18(10) APPLIED OCC. & ENV. HYGIENE 786 (2003); F. Laden, M.J. Stampfer & A.M. Walker, *Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review*, 19(1) REV. ENV. HLTH. 39 (2004); M. Goodman, M.J. Teta, P.A. Hessel, D.H. Garabrant, V.A. Craven, C.G. Scrafford & M.A. Kelsh, *Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: A Meta-Analysis*, 48(4) ANNALS OCC. HYGIENE 309 (2004); Dennis J. Paustenbach, B.L. Finley, E.T. Lu, G.P. Brorby & P.J. Sheehan, *Environmental and Occupational Health Hazards Associated with the Presence of Asbestos in Brake Linings and Pads (1900 to present): A "State of the Art" Review*, 7(1) J. TOX. & ENV. HLTH. B. CRITICAL REV. 25 (2004); P.A. Hessel, M.J. Teta, M. Goodman & E. Lau, *Mesothelioma Among Brake Mechanics: An Expanded Analysis of a Case-Control Study*, 24(3) RISK ANALYSIS 547 (2004); R.A. Lemen, *Asbestos in Brakes: Exposure and Risk of Disease*, 45(3) AM. J. INDUS. MED. 229 (2004); O. Wong, *The Interpretation of Occupational Epidemiologic Data in Regulation and Litigation: Studies of Auto Mechanics and Petroleum Workers*, 44(3) REG. TOX. & PHARM. 191 (2006).

written by experts primarily associated with defendants, while eight were written by experts who work primarily for plaintiffs.

Sponsorship by parties involved in litigation leads to an imbalance in the literature—data synthesis exercises, data re-analyses, and exposure estimations predominate. It appears these studies are being produced for use in litigation; whoever is willing to fund more studies will have more studies published. In this case, ChemRisk and Exponent, Inc., the two closely connected product defense firms that produced a number of these studies received more than $20 million for their litigation support work.[77] As a result, subsequent literature reviews that report a predominance of articles reaching a certain conclusion may then mistakenly report there is a new consensus in the literature; when that "consensus" is an artifact of sponsorship: wealthy sponsors have simply paid to have more papers published.

VI. SUBTRACTING FROM THE LITERATURE: CONSEQUENCES FOR PUBLIC HEALTH

The material in the previous section of this paper describes how, in attempting to prevail in asbestos litigation, parties involved in the litigation seed the scientific literature with papers written to be used as supporting evidence in court. The second component of the strategy appears to be to influence the statements made in government documents about the risk of disease associated with brake-related asbestos exposures. It is not surprising that as part of a litigation strategy, parties to suits have attempted to shape the content of government documents that make statements about disease causation and risk. Because they are seen as official formal pronouncements of a government agency, government-issued scientific documents may be accorded an elevated stature in litigation.

As part of their public health responsibilities, federal and state agencies often issue documents that contain literature reviews and make statements about exposure and causation.

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[77] *See* Castleman Testimony, *supra* note 32.

Government agencies issue formal regulations, which must include literature reviews that serve to justify why the agency has chosen to control exposure to a given substance or exposure. Agencies also produce other materials, such as toxicology profiles, information bulletins and advisories that provide information whose aim it is to assist individuals to protect themselves from toxic hazards. Although not published in academic journals, many of these documents contain data synthesis exercises that could easily be published in the scientific literature.

We described in Part I the successful use of the Data Quality Act to remove EPA's Gold Book from circulation. There is also evidence that a product defense consultant intervened with OSHA as well to influence the content of one of that agency's publications. In 2006, three weeks after OSHA posted a Safety and Health Information Bulletin (SHIB) entitled "Asbestos-Automotive Brake and Clutch Repair Work"[78] on its website, a

[78] Occupational Safety and Health Administration, Asbestos-Automotive Brake and Clutch Repair Work, July 26, 2006, *available at* http://www.osha.gov/dts/shib/shib072606.html (last visited March 26, 2007). The SHIB was designed to complement information contained in Mandatory Appendix F: Work Practices and Engineering Controls for Automotive Brake and Clutch Inspection, Disassembly, Repair and Assembly, 29 CFR 1910.1001; 51 *Federal Register* 22612-2270 (June 20, 1986) and raise workers' awareness of asbestos hazards associated with brake and clutch repair. Mr. Ira Wainless, a long-term OSHA employee, who is a chemical engineer and a certified industrial hygienist began working on the SHIB in 2004, but it was not approved by senior OSHA officials until July 2006, and only after consultation with the White House's Office of Management and Budget. After former Assistant Secretary Henshaw raised concerns about the "quality" and completeness of the document, Mr. Wainless' supervisor proposed suspending the OSHA employee for "issues related to the accuracy of the SHIB," including his failure to include "current" literature. The supervisor specifically mentioned the employee's exclusion of Paustenbach's work, but Mr. Wainless contends that decisions to exclude this article and other data were made by senior OSHA management. Stern E. Memorandum for David Ippolito, Director of Science, Technology, and Medicine, Nov, 15, 2006 (on file with authors). *See also* Dennis J. Paustenbach et al., *An Evaluation of the Historical Exposures of Mechanics to Asbestos in Brake Dust*. 18 APPLIED OCC. & ENV. HYGIENE 786 (2003),

senior OSHA official was contacted by John Henshaw, who from 2001 through December 2004 had been Assistant Secretary of Labor for OSHA.[79] Mr. Henshaw, who now runs a safety and health consulting firm,[80] sent an email to the head of OSHA's Directorate of Science, Technology and Medicine, asking the agency to retract the SHIB[81] because it failed to reference some of the papers sponsored by automobile manufacturers,[82] and therefore could be subject to a Data Quality Act challenge.[83] Mr. Henshaw claimed that he intervened in this matter of his own accord and his contact with OSHA "was not undertaken on behalf of anyone but myself."[84] However, after resigning his post at OSHA, the former Assistant Secretary's firm, Henshaw and Associates, Inc., was listed as one of the "Teaming Partners" of the product defense firm ChemRisk that had been assisting the auto makers in asbestos litigation.[85] In addition, Mr. Henshaw himself served as an expert witness for brake manufacturers in asbestos-related litigation.[86] As of May 2007, the OSHA SHIB is posted on the agency's website, with a prominent disclaimer that it "is not a

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[79] John L. Henshaw. Resume available at: http://www.chemrisk.com/pdf/JohnLHenshawCV_May2005.pdf (last visited Mar. 26, 2007).

[80] *See id.*

[81] A. Schneider, *Brake Warnings Remain*, BALTIMORE SUN, Dec. 17, 2006, at 1A.

[82] *Id.*; Memorandum from David Ippolito to Ira Wainless, Re: Proposed Suspension, Nov. 6, 2006 (Available from authors).

[83] Stern E. Memorandum for David Ippolito, Director of Science, Technology, and Medicine, Nov. 15, 2006 (Available from authors).

[84] A. Schneider, *Pressure at OSHA to Alter Warning Author of Advisory On Asbestos In Brakes Faces Suspension For Refusing to Revise It* BALTIMORE SUN, Nov. 20 2006, at 1A.

[85] The authors saw the firm Henshaw and Associates, Inc., listed in 2006 on the "Teaming Partners" section of ChemRisk's website at http://www.chemrisk.com/partners.htm, but it is no longer listed. *See also* Castleman Testimony, *supra* note 32; Schneider, *supra* note 84. (quoting Memorandum from Edward Stern, Steward AFGE Local 12 to David Ippolito, OSHA Directorate of Science, Technology and Medicine, Nov. 15, 2006 (on file with authors)).

[86] *See* Castleman Testimony, *supra* note 32.

standard or regulation, and it creates no new legal obligations."[87]

CONCLUSION

Since Judge Kozinski wrote in the remand of *Daubert v. Merrell Dow Pharmaceuticals* that science done for the purpose of litigation should be subject to more stringent standards of admissibility than other science, the acceptability of litigation-generated scientific research in litigation has been the subject of some controversy. Judge Kozinski was concerned about the impact of litigation-generated science on litigation; in this paper we examine the impact of litigation-generated science on science.

For more than 100 years, physicians and scientists have recognized the link between asbestos exposure and disease. By the mid-1970's regulations were in place to protect U.S. workers and the public from exposure to asbestos because of its disease-causing potential. From the public health science perspective, the fundamental question of a cause and effect relationship between asbestos and respiratory disease and cancer was answered decades ago. As a result, some of the questions that arise in current asbestos litigation are of little interest to the public health scientific community, and are therefore not likely to be the subject of government funded research.

An examination of the papers recently published on asbestos exposure and disease among vehicle mechanics, and now part of the body of scientific literature, demonstrates that parties involved in civil litigation have dramatically shaped the content and quality of the available scientific evidence. Much of the new literature is not focused on issues of particular scientific interest, but specifically address questions that arise in litigation. The conclusions expressed in the papers are ones that will be of use in the courtroom. The papers add little to our understanding of

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[87] Occupational Safety and Health Administration, Asbestos-Automotive Brake and Clutch Repair Work, July 26, 2006, *available at* http://www.osha.gov/dts/shib/shib072606.html (last visited May 7, 2007).

the workings of asbestos; publication in a scientific journal of litigation-generated literature reviews or data synthesis exercises appears to serve primarily as a mechanism to add credibility to an expert's opinion.

Litigants have not only added to the literature papers supportive of their position in court, they have attempted to subtract from the literature, pressuring government agencies to withdraw or modify documents they prefer not to have available to their opponents. As a result, litigation may have a direct and undesirable effect on the injury and disease prevention activities of government agencies.