No. 10-36142 (consolidated with No. 11-35020)

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

HENRY BARABIN and GERALDINE BARABIN,

Plaintiffs-Appellees,

v.

ASTENJOHNSON, INC., and SCAPA DRYER FABRICS, INC.

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
No. C07-1454 RSL
(Hon. Robert S. Lasnik)

AMICI CURIAE BRIEF OF COALITION FOR LITIGATION JUSTICE, INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NFIB SMALL BUSINESS LEGAL CENTER, AMERICAN INSURANCE ASSOCIATION, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, AMERICAN CHEMISTRY COUNCIL, AND NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF DEFENDANTS-APPELLANTS

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IDENTITY AND INTEREST OF *AMICI CURIAE* AND SOURCE OF AUTHORITY TO FILE

Amici are organizations that represent companies involved in asbestos and other toxic tort litigation and their insurers. Consequently, *amici* have a substantial interest in addressing attempts by plaintiffs to advance the unscientific theory that every occupational exposure to a toxic substance, no matter how small, is a "substantial factor" in causing disease. The plaintiffs' "*any exposure*" theory has been rejected by multiple courts and should not be embraced here. The trial judge did not adequately examine the foundations of the hypothesis or the proffered methodology behind it, and as a result admitted testimony that cannot survive a true *Daubert*[1] inquiry. This Court is only the second federal court of appeals to address the *any exposure* theory in the context of an asbestos action. The Court's ruling will be important in helping to determine whether asbestos plaintiffs no longer need to prove causation, but only exposure – a novel and unwarranted principle that would usher in an unprecedented expansion of tort liability.

A Motion for Leave to File accompanies the brief.

STATEMENT OF THE CASE

Amici adopt Defendants-Appellants' Statement of the Case.

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[1] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

INTRODUCTION

This case involves a worker who contracted mesothelioma from asbestos exposures during his employment in a refinery and paper mill. The critical science and causation question at issue is *which* asbestos exposures in that environment should be deemed sufficient to be a contributory cause of his disease.

According to the experts who testified, Mr. Barabin apparently had sufficient exposure to amphibole[2] insulation products to cause his mesothelioma. Most former manufacturers of asbestos-containing insulation, however, have filed bankruptcy. Thus, instead of focusing on Mr. Barabin's insulation exposures, Plaintiff tried the case against manufacturers of a paper mill product – dryer felts. Unlike insulation consisting of loose asbestos fibers, the chrysotile asbestos fibers in dryer felt are bound in resins and woven into the fabric, producing only minimal (if any) exposure in the paper mill environment. Chrysotile asbestos is also considerably less toxic than amphibole asbestos. No published epidemiology study has shown an increased incidence of mesothelioma associated with work around dryer felts or work involving low doses of chrysotile fibers.

The critical toxicology question in this case should be framed as follows: *Given Mr. Barabin's apparently extensive amphibole insulation exposures, did he*

[2] "Amphibole" is the term for a group of mineral fibers that are typically long and rigid and can be difficult for the body to eliminate. "Amosite" and "crocidolite" are forms of amphibole asbestos. "Chrysotile" is a different fibrous mineral that is part of the "serpentine" family; chrysotile is flexible and breaks down easily in the body.

also receive enough of a dose of chrysotile fibers from his dryer felt work to meaningfully contribute to his disease? The issue thus framed illustrates a major battleground in today's asbestos litigation. Plaintiffs have reached out to capture increasingly trivial exposures to try to take those defendants to trial. An "increasing number of plaintiffs are bringing claims for *de minimis* or remote exposures, such as 'shade tree' brake work on the family car or one remodeling job using asbestos-containing joint compound." Mark A. Behrens, *What's New in Asbestos Litigation?*, 28 Rev. Litig. 501, 528 (2009).

These cases push the notion of causation well beyond the breaking point. In any ordinary tort context, the judge would require the plaintiff's expert to demonstrate, through a scientifically reliable methodology, that dryer felt work produces enough of a *dose* from the less toxic fiber involved to cause disease. Plaintiffs' medical causation experts like Dr. Carl Brodkin, however, testify that *all* occupational exposures, regardless of fiber type or dose, are causative:

> Q Is there any way for you to exclude any exposures from causation of Mr. Barabin's mesothelioma?
>
> A In terms of the direct and bystander exposures I have talked about, and the materials that I have talked about, no. Those were historically asbestos-containing materials that would add to his cumulative exposure, and as such would be substantial contributing factors in his development of mesothelioma.[3]

[3] Brodkin Trial Tr. 711-12, Nov. 3, 2009 (Appx. #41).

The question *how much dose did Mr. Barabin receive from his dryer felt work* never entered into Dr. Brodkin's causation equation, because he assumes that all exposures are contributory. His testimony would be the same if Mr. Barabin worked around one dryer felt or 1,000 felts, and the extent of plaintiff's actual exposures were thus largely irrelevant to his opinion.

This extremist view is known as the *any exposure* theory. It is usually stated as "each and every exposure to occupational (or hobby-related) asbestos is a substantial factor in causing asbestos disease." Dr. Brodkin's twist is that "all workplace exposures cumulate to cause disease so all must be causative." The *any exposure* theory – or, as Dr. Brodkin phrases it, the *all exposures are cumulative* theory – is the brainchild of a small cadre of testifying plaintiff experts in asbestos litigation. It is the engine driving the current attempt to bring increasingly trivial exposures into asbestos litigation. If the theory survives a *Daubert* inquiry, the case will likely go to the jury, regardless of the limited exposure.

Amici urge the Court to examine the theory closely, including the antecedents Dr. Brodkin claims to rely on for his opinion. That examination will reveal that the *any exposure* theory fails the *Daubert* test at every step. The theory is a litigation construct that is not found in any published and peer-reviewed article or textbook; it is irreconcilable with the fundamental toxicology principle known as *dose* – all substances are toxic if the dose is high enough, but nontoxic (or even

beneficial) if the dose is low enough. The *any exposure* theory is not generally accepted except in the minds of these experts. None of these experts have ever attempted to test the theory, and where it has been tested (in low-dose chrysotile epidemiology studies) it has found no support. The theory is pure speculation and has an unlimited rate of error. The methodologies behind the *any exposure* theory – extrapolation down from high dose and amphibole studies to assume low dose chrysotile exposures cause the same outcomes, and relying on regulatory findings of "no known safe level" to opine that all exposures are in fact causative – are unscientific and unreliable. *See* Mark A. Behrens & William L. Anderson, *The "Any Exposure" Theory: An Unsound Basis for Asbestos Causation and Expert Testimony*, 37 Sw. U. L. Rev. 479 (2008).

Since 2005, a wave of opinions has issued from courts around the country – at least twenty of them – which have rejected the *any exposure* theory or similar approaches in asbestos and other toxic tort litigation. The courts rejecting this theory include the Sixth Circuit Court of Appeals (three times), the highest courts of Texas, New York, and Pennsylvania, two Ninth Circuit district court cases, two state court judges in the state where this case arose (Washington), and trial and appellate courts in Texas, Florida, Delaware, Ohio, Louisiana, Mississippi, and

Pennsylvania.[4] Dr. Brodkin's own *any exposure* testimony has been excluded by a Washington state court judge, who concluded:

> Dr. Brodkin opined that … every biological significant exposure to asbestos, that is, every exposure above ambient levels … is a

[4] *See Pluck v. B.P. Oil Pipeline Co.,* 2011 WL 1794293 (6th Cir. May 12, 2011) (benzene) (Appx. #22); *Gregg v. V-J Auto Parts Co.,* 943 A.2d 216 (Pa. 2007) (Appx. #12); *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765 (Tex. 2007) (Appx. #4); *Parker v. Mobil Oil Corp.,* 857 N.E.2d 1114 (N.Y. 2006) (benzene) (Appx. #21); *Georgia-Pacific Corp. v. Stephens*, 239 S.W.3d 304 (Tex. App.-Houston 2007) (Appx. #10); *In re Friction Prods. Cases Involving Chrysler LLC,* No. 0001 (Pa. Ct. Com. Pl. Sept. 24, 2008) (Appx. #16); *In re W.R. Grace & Co*., 355 B.R. 462 (Bankr. D. Del. 2006) (Appx. #11), *appeal denied*, 2007 WL 1074094 (D. Del. Mar. 26, 2007); *Brooks v. Stone Architecture, P.A*., 934 So. 2d 350 (Miss. Ct. App. 2006) (Appx. #5); *Bartel v. John Crane, Inc*., 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004) (Appx. #2), *aff'd sub nom. Lindstrom v. A-C Prod. Liab. Trust*, 424 F.3d 488 (6th Cir. 2005) (Appx. #18); *Anderson v. Asbestos Corp., Ltd*., No. 05-2-04551-5 SEA (Wash. Super. Oct. 31, 2006) (Tr. of Bench Ruling at 144-45) (Appx. #1); *In re Asbestos Litig*., No. 2004-03964, 2004 WL 5183959 (11th Dist. Ct., Harris County, Tex. Jan. 20, 2004) (letter ruling) (Appx. #14); *In re Asbestos Litig. [Pena v. Bondex],* No. 2004-3,964, 2007 WL 5994694 (11th Dist. Ct., Harris County, Tex. July 18, 2007) (letter ruling) (Appx. #15); *In re Toxic Substances Cases*, 2006 WL 2404008 (Pa. Ct. Com. Pl. Aug. 17, 2006) (Att. Ex. 17), *rev'd sub nom Betz v. Pneumo Abex LLC,* 998 A.2d 962 (Pa. Super. Ct.), *appeal granted,* 9 A.3d 1134 (Pa. 2010); *Basile v. American Honda Motor Co*., 2007 WL 712049 (Pa. Ct. Com. Pl. Feb. 22, 2007) (Order Granting Caterpillar's Motion to Exclude Plaintiffs' Experts' Testimony) (Appx. #3); *Free v. Ametek*, No. 07-2-04091-9-SEA, 2008 WL 728387 (Wash. Super. Ct. King County Feb. 28, 2008) (trial order) (Appx. #9); *Martin v. Cincinnati Gas & Elec. Co*., 561 F.3d 439 (6th Cir. 2009) (Appx. #19); *Smith v. Kelly-Moore Paint Co., Inc.,* 307 S.W.3d 829 (Tex. App.-Fort Worth 2010) (Appx. #24); *Daly v. Arvinmeritor, Inc*., 2009 WL 4662280 (17th Jud. Cir., Broward County, Fla. Nov. 30, 2009) (trial order) (Appx. #7); *Butler v. Union Carbide Corp.*, No. 2008-CA-114, at 18 (Morgan County Super. Ct., Ga. June 29, 2010) (Order Granting Defendant's Motion to Strike Certain Testimony of Plaintiff's Pathologist Dr. John Maddox) (Appx. #6); *Degrasse v. Anco Insulations,* No. 2007-12736 (Orleans Civ. Dist. Ct., La. Sept. 13, 2007) (Appx. #8); *Robertson v. Ashby,* No. 532,769 (East Baton Rouge Parish, La. Jan. 19, 2010) (motion hearing tr.) (Appx. #23); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142 (E.D. Wash. 2009) (benzene) (Appx. #13); *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006 (E.D. Wash. 2010) (popcorn) (Appx. #20). These cases are included in the Appendix accompanying the brief [hereinafter Appx.]. Only a few state appellate courts have accepted *any exposure* testimony, and they did so (as the trial court did here) merely by parroting the expert's testimony and without any serious inquiry behind that testimony. *See, e.g., Buttitta v. Allied Signal, Inc.,* 2010 WL 1427273 (N.J. Super. Ct. App. Div. Apr. 5, 2010), *cert. denied,* 999 A.2d 462 (N.J. 2010). Using a similar cursory analysis, the federal district court in charge of federal asbestos MDL proceedings has also admitted any exposure testimony, but those decisions have not been subjected to appellate review.

> proximate cause of the disease…. Downward extrapolation[, however,] from the studies that establish levels of risk at doses at or above 10 fbrs/cc yr is ***not a sound scientific methodology and is not generally accepted in the field of epidemiology or occupational medicine***…. Dr. Brodkin's analogies ***are not good science and they do not make good law***.[5]

These courts are attempting to regain some control over an asbestos litigation in which "anything goes" is increasingly becoming "not in our courts."[6]

The trial court's cursory glance at Dr. Brodkin's opinions and methodologies are out of step with other authority and this Court's *Daubert* standards. The three opinions in which the court addressed expert testimony are extremely thin in analysis and in each instance defer to the jury to decide whether the experts' approach is sound or not.

Amici request that the Court reverse the ruling permitting *any exposure* testimony, reverse the verdict against Asten and Scapa, and ensure that experts in asbestos litigation must meet the same standards as experts in all toxic tort cases.

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[5] *Free*, *supra* (emphasis added). In a later federal MDL hearings, Dr. Brodkin (after having his "every exposure" opinion excluded in *Free*) changed his approach to the "cumulative dose" articulation used below in this action. On that basis the magistrate in the federal MDL proceedings, erroneously in *amici's* view, permitted Dr. Brodkin to testify. *See In re Asbestos Prods. Liab. Litig. (No. VI) [Anderson v. Saberhagen Holdings, Inc.],* 2011 WL 677290 (E.D. Pa. Feb. 16, 2011).

[6] *See* David E. Bernstein, *Getting to Causation in Toxic Tort Cases,* 74 Brook. L. Rev. 51, 59 (2008) ("The recent, increasingly strict exposure cases . . . reflect a welcome realization by state courts that holding defendants liable for causing asbestos-related disease when their products were responsible for only *de minimis* exposure to asbestos, and other parties were responsible for far greater exposure, is not just, equitable, or consistent with the substantial factor requirements of the *Restatement (Second)* and *Lohrmann* [*v. Pittsburgh Corning Corp*., 782 F.2d 1156 (4th Cir. 1986)].").

ARGUMENT

Trial judges occasionally shy away from looking closely at complex scientific evidence. The tendency to do so is understandable, and it is reflected in the trial court's cursory examination of Dr. Brodkin's theories and evidence here. That approach, however, is inconsistent with *Daubert* requirements. The Ninth Circuit has a long history of requiring serious examination of expert opinions under *Daubert*, going all the way back to the seminal opinion in the *Daubert II* case, *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1994) (reviewing studies in detail before excluding expert testimony as unreliable), *cert. denied*, 516 U.S. 869 (1995), in which this Court took on the challenging task required by the United States Supreme Court – in the process coining the often quoted "brave new world" language. As the Court said, "Our responsibility, then…is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise…and occasionally to reject such expert testimony because it was not "derived by the scientific method." *Id.* at 1316. The trial judge must not accept what the experts say at face value, or defer to a dispute between experts.[7]

[7] *See, e.g.*, *Avila v. Willits Envtl. Remediation Trust,* 633 F.3d 828, 837-840 (9th Cir. 2011) (close analysis of science); *Morin v. United States*, 244 Fed. Appx. 142, 143 (9th Cir. 2007) (cited studies did not support expert's conclusions), *cert. denied*, 552 U.S. 1185 (2008); *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1422-23 (9th Cir. 1998) (same); *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 501 (9th Cir. 1994) ("the district court was both authorized and obligated to scrutinize carefully the reasoning and methodology underlying the [expert] affidavits"); *United States v. Rincon,* 28 F.3d 921, 924 (9th Cir.) (expert did not provide sufficient detail regarding

Here, the trial court performed none of the gatekeeping steps this Court requires. If the trial court had undertaken the type of careful review this Court requires, it would have excluded the expert testimony related to the *any exposure* theory. The court's contrary opinion should be reversed.

I. The *Any Exposure* Theory Is Not Based on a Scientific Methodology

A. The *Any Exposure* Theory Ignores Any Consideration of Dose

Dr. Brodkin's "everything is cumulative" theory does not comport with the most fundamental principle of the science of toxicology – the requirement of a sufficient dose for a substance to be toxic. The human body is capable of defending itself against an array of daily exposures to known toxins, up to a point. Disease results when those exposures reach a level that overwhelms the body's defenses, called the "threshold" point. Aspirin, alcohol, sunlight, even known "poisons" like arsenic, are only poisonous if the dose is high enough, and are otherwise harmless or even beneficial at lower doses.

Toxicology rests on the "fundamental tenet"[8] that the dose makes the poison. "Dose is the single most important factor to consider in evaluating whether an

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studies to allow court to test their reliability), *cert. denied*, 513 U.S. 1029 (1994); *Domingo ex rel. Domingo v. T.K.,* 289 F.3d 600, 607 (9th Cir. 2002) (closely examining evidence on which expert relied).

[8] Federal Judicial Center, *Reference Manual on Scientific Evidence, Reference Guide on Toxicology* 403 (2d ed. 2000).

alleged exposure caused a specific adverse effect."[9] This principle holds true for asbestos just as much as any other toxin.[10]

The *any exposure* theorists ignore the principle of dose, substituting instead an illogical artifice designed to capture low-dose defendants in litigation. These experts simply claim that all exposures contribute to causation, with the notable and illogical exception that background exposures are somehow *not* cumulative – only occupational exposures.[11]

Dr. Brodkin departs from scientific principles in refusing to ascertain or identify whether Mr. Barabin's dryer felt chrysotile exposures reached a harmful level. He did not present evidence to suggest that Mr. Barabin's alleged exposures to dryer felts exceeded the levels his body could process without toxicity, or that those exposures would produce a different result than exposure to background fibers.

Many federal courts, including this one, have acknowledged the primacy of dose and the need to develop a dose assessment to support a toxic tort case.[12]

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[9] *See* David L. Eaton, *Scientific Judgment and Toxic Torts –A Primer In Toxicology For Judges and Lawyers*, 12 J.L. & Pol'y 5, 11 (2003) (Appx. #26).

[10] *Id.* at 13.

[11] Dr. Brodkin also agrees that up to 90% of fibers are removed from the body (*id.* at 740) (Appx. #40), but does not take into account the differential removal of chrysotile fibers. The removal half-life of chrysotile is a matter of months, whereas amphiboles take many years to clear. *See Free, supra*.

[12] *See, e.g., Avila*, 633 F.3d at 840 (affirming exclusion of expert testimony based on unreliable dose estimates); *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002) (proof of causation requires evidence that exposure to the challenged substance "at the level of exposure alleged by the plaintiffs is capable of causing the alleged injuries"); *accord*

Most recently, for example, in *Pluck v. B.P. Oil Pipeline Co.,* 2011 WL 1794293 (6th Cir. May 12, 2011) (Appx. #22), the Sixth Circuit Court of Appeals rejected another *any exposure* theorist who, without conducting any dose assessment, nevertheless opined that benzene in well water was the cause of plaintiff's non-Hodgkin's lymphoma. The Sixth Circuit noted, "it is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff's symptoms." *Id.* at *6. The court rejected the expert's reliance on a "no safe dose theory" that "had been discredited by other courts as a basis for establishing specific causation." *Id.* at *2. The Sixth Circuit has also twice rejected the *any exposure* theory as a basis for asbestos causation, in the process explicitly rejecting the "no safe dose" basis which would render the substantial factor test "meaningless."[13] Other district courts in this circuit have rejected the notion that dose does not matter and required reliable scientific evidence linking plaintiff's alleged exposure to a dose that has been shown to cause the alleged injury.[14] The trial court here departed

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McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241-42 (11th Cir. 2005); *Mitchell v. Gencorp*, 165 F.3d 778, 781 (10th Cir. 1999); *Wintz v. Northrop Corp.*, 110 F.3d 508, 513 (7th Cir. 1997); *Allen v. Penn. Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996).

[13] *See Martin,* 424 F.3d at 488; *Lindstrom*, 424 F.3d at 493.

[14] *See, e.g.*, *Henricksen*, 605 F. Supp. 2d at 1157 (expert must pay careful attention to dose-response relationship); *In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1174-5 (N.D. Cal. 2007) (studies did not show that dose at issue could cause the alleged injury; "The Court finds that dose matters."); *O'Hanlon v. Matrixx Initiatives*, 2007 WL 2446496, at *3-4 (C.D. Cal. Jan. 3, 2007) (expert failed to establish dose-response relationship).

substantially from this law by allowing Dr. Brodkin to testify with no assessment of dose.[15]

B. The *Any Exposure* Theory Ignores Differences in Fiber Potency

The proponents of the *any exposure* theory not only fail to account for the dose received but also fail to address differences in potency of fiber types. Not all asbestos is the same.[16] The fibers involved in dryer felts are chrysotile, a form of asbestos that is widely acknowledged as less potent than amphibole fibers. Unlike amphibole fibers found in insulation, chrysotile is not rigid, breaks down easily in the body, and much of it is quickly removed.[17] Cohorts exposed chiefly or only to chrysotile fibers show very few mesotheliomas, if any, even when the doses are much higher than the current OSHA limit (in contrast, there is no evidence that working with dryer felts in a paper mill setting would exceed today's OSHA

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[15] It is a fallacy to suggest, as the trial court did here, that requiring plaintiffs to demonstrate a harmful dose is too burdensome because it would require "precise quantification." A lot of ground exists between "precise quantification" and "every dose is a cause," and within that ground is the space where scientists estimate or assess past doses from known exposure studies and exposure circumstances.

[16] *See, e.g.*, *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1145 (5th Cir. 1985) ("all asbestos products cannot be lumped together in determining their dangerousness").

[17] *See* United States Envtl. Protection Agency, *Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk* vii (May 30, 2003) ("The panelists unanimously agreed that the available epidemiology studies provide compelling evidence that the carcinogenic potency of amphibole fibers is two orders of magnitude greater than that for chrysotile fibers."), *available at* http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf; Christine Rake *et al.*, *Occupational, Domestic and Environmental Mesothelioma Risks in the British Population: A Case Control Study*, 100 Brit. J. Cancer 1175, 1182 (2009), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2669989/ (Appx. #37).

standard).[18] More specifically, the studies of workers exposed to *low doses* of chrysotile have found that their disease incidence is no different than that in professions with little or no opportunity for asbestos exposure, such as teachers, accountants, or farmers.[19]

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[18] *See, e.g.*, David Rees *et al*., *Case-Control Study of Mesothelioma in South Africa*, 35 Am. J. Indus. Med. 213, 220 (1999), *available at* http://www.ehrn.co.za/publications/download/27.pdf (no reports of mesothelioma from chrysotile exposure found despite substantial numbers of miners in chrysotile mines from the 1930s to 1980s exposed to intense concentrations of dust) (App. Ex.33); H.F. Thomas, *Further Follow-Up Study of Workers from an Asbestos Cement Factory*, 39 Brit. J. Indus. Med. 273, 275 (1982), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1009023/pdf/brjindmed00059-0065.pdf (study of 1261 workers at asbestos cement plant using only chrysotile asbestos after 1936 found only two cases of mesothelioma, both in employees who worked at the plant prior to 1936 when the plant was using amphibole asbestos) (Appx. #39); M. Neuberger and M. Kundi, *Individual Asbestos Exposure: Smoking and Mortality – A Cohort Study in the Asbestos Cement Industry*, 47 Brit. J. Indus. Med. 615, 619 (1990), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1035247/pdf/brjindmed00045-0039.pdf (finding no incidence of mesothelioma among 2861 cement plant employees exposed only to chrysotile, some with exposures in excess of 50 f/ml) (Appx. #35); Misty Hein *et al*., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Exposure-Response*, 64 Occup. Envir. Med. 616, 618, Table 2, 620 (2007), *abstract available at* http://oem.bmj.com/content/64/9/616.abstract (finding only three mesotheliomas in workers employed in higher exposure jobs out of a cohort of 3,072 workers exposed to chrysotile of up to 700 f/cc years in an asbestos textile plant) (Appx. #28); *see also* John M. Dement *et al*., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Case-Control Analyses*, 26 Am. J. Indus. Med. 431, 437-38 (1994), *abstract available at* http://www.ncbi.nlm.nih.gov/pubmed/7810543 (Appx. #25).

[19] *See, e.g.*, Kay Teschke *et al*., *Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos*, 88 Can. J. Pub. Health 164, Table II (1997), *available at* http://journal.cpha.ca/index.php/cjph/article/view/945/945 (Appx. #34); Alison D. McDonald & J. Corbett McDonald, *Malignant Mesothelioma in North America*, 46 Cancer 1650, 1653-54, Table II (1980), *abstract available at* http://onlinelibrary.wiley.com/doi/10.1002/1097-0142 (19801001) 46:7%3C1650::AID-CNCR2820460726%3E3.0. CO;2-Y/abstract (Appx. #32). For example, there are at least 17 studies related to automotive mechanics, another population of workers exposed to low-dose chrysotile, conducted over the last 30 years, almost all published in peer-reviewed articles, and performed in seven different countries by over 60 researchers – none of which found an excess of mesothelioma in this worker group. *See* Francine Laden *et al., Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review*, 19 Revs. on Envtl. Health 39 (2004), *abstract available at* http://www.ncbi.nlm.nih.gov/pubmed/15186039 (Appx. #31); Michael Goodman *et al*., *Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: A Meta-analysis*, 48 Ann. Occup. Hyg. 309 (2004), *available at* http://annhyg.oxfordjournals.org/content/48/4/309.full.pdf+html (Appx. #27); *see also* Julian Peto *et al.*, *Occupational, Domestic and Environmental Mesothelioma Risks in Britain: A Case-Control Study*, UK Health and Safety Exec. (2009), *available at* http://www.hse.gov.uk/research/rrpdf/rr696.pdf; Rake, *supra*, at 1182 (Appx. #36).

The *any exposure* theorists typically agree that chrysotile fibers are significantly less potent but then fail to take that difference into account in their opinions. Medically, it is obvious that a less potent substance requires a higher dose to have any effect – e.g., it would require a much greater quantity of beer to have the same impact as drinking a bottle of 180 proof whiskey. A scientific approach to asbestos, then, requires an estimate of the different doses of fibers of different toxicity to determine whether they contributed to disease. Dr. Brodkin does not do this. He agrees chrysotile is less potent (at least *three times* less) but does not assess, e.g., whether Mr. Barabin's exposures were at least three times the level of amphibole exposures known to cause disease. There is no scientific principle that would permit an expert to opine that all exposures with different potency are equally causative, but that is a fundamental underpinning of the *any exposure* theory.

C. The *Any Exposure* Theory is an Untested and Speculative Hypothesis

Dr. Brodkin and the other *any exposure* experts have repeatedly agreed that the theory is just that – an unproven hypothesis. Dr. Brodkin, for instance, admits that there is no scientific evidence that establishes the dose above which a person is at risk for asbestos disease:

> Those studies have not identified a specific dose below which we can say this person is at no risk and above which this person [is] at some risk. ***Medical science hasn't come up with that kind of dose, which***

> ***we call a threshold dose. It's not to say there isn't one, but science has not determined that at this point***.[20]

In *Free v. Ametek*, 2008 WL 728387 (Wash. Super. Ct. King County Feb. 28, 2008) (Appx. #9), the experts *admitted* that the *any exposure* theory was an uproven hypothesis, and the court rejected the testimony on that and other grounds:

> The assumption that every exposure to asbestos over a life's work history, even every exposure greater than 0.1 fbrs/cc yr, is a substantial factor contributing to development of an asbestos-related disease, is not a scientifically proved proposition that is generally accepted in the field of epidemiology, pulmonary pathology, or any other field relevant to this case.

Id. Unproven hypotheses should not form the basis for courtroom expert testimony.[21]

No studies in the peer-reviewed literature state as scientific fact that every occupational exposure to asbestos – no matter how brief or small – must be considered a cause of mesothelioma. Any such statement would run counter to the established principles of cancer causation, as set forth in the seminal article on toxic tort causation, David L. Eaton, *Scientific Judgment and Toxic Torts – A Primer In Toxicology For Judges and Lawyers*, 12 J.L. & Pol'y 5 (2003) (Appx. #26). Dr. Brodkin himself has never published this conclusion or submitted it for

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[20] Brodkin Trial Tr. 714 (Appx. #41).

[21] *See Sanderson v. Int'l Flavors and Fragrances, Inc.*, 950 F. Supp. 981, 1003 (C.D. Cal. 1996) ("Plaintiff asks, 'Given the dearth of research on the neurotoxic effects of fragrances and fragrance chemicals, what is a plaintiff to do?' Unfortunately for plaintiff, the answer is: Wait. When a plaintiff can't prove her case with reliable scientific evidence, she can't prove her case.") (internal citation omitted).

peer review. As observed by this Court in *Daubert II*, "[i]t's as if there were a tacit understanding within the scientific community that what's going on here is not science at all, but litigation." *Daubert II*, 43 F.3d at 1318.

II. Plaintiffs' Experts Rely on Irrelevant and Misleading Materials to Support the *Any Exposure* Theory

Instead of providing scientific evidence of causation at low chrysotile doses,[22] Dr. Brodkin forwards three irrelevant lynchpins to support his theory.

1. *The No Safe Dose Theory*

The first is the "no safe dose" theory that the Sixth Circuit and other courts have repeatedly rejected as inappropriate for courtroom evidence. The genesis of this argument is the "linear no-threshold" approach to risk analysis used by regulators. Under this theoretical construct, regulators draw a line through the known doses that have caused a disease – ordinarily at the high end of the exposure range – and then *assume* that the line continues straight done to zero, rather than curving downward as any toxic substance with a threshold would do. Regulators, of course, operate under a different mandate than courts of law and frequently make decisions, in the interests of precaution, based on theory or uncertainty.[23]

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[22] *See Daubert II*, 43 F.3d at 1318; *see also In re Canvas Specialty, Inc.*, 261 B.R. 12, 20 (Bankr. C.D. Cal. 2001) (Rule 702 requires sufficient quantum of right kinds of data).

[23] *See, e.g., Allen,* 102 F.3d at 198 ("The agencies' threshold of proof is reasonably lower than that appropriate in tort law….") (quoting *Wright*, 91 F.3d at 1107); *see also Mitchell v. Gencorp Inc.*, 165 F.3d 778 (10th Cir. 1999) (same); *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1366 (N.D. Ga. 2001) (standard of proof "for agency determinations based upon a risk utility analysis" is lower than the standard required in tort cases), *aff'd sub nom. Rider v. Sandoz Pharms. Corp*., 295 F.3d 1194 (11th Cir. 2002).

The *any exposure* theorists convert the regulators' "there is no known safe dose" approach into something very different – "every dose is causative, no matter how small." Those statements are not the same and there is no reliable scientific evidence to bridge the gap between the two. As the *Free* court stated:

> There is no known threshold; there is no known safe level of exposure. That does not mean none exists; it simply means modern science has not and cannot , with current scientific expertise or relying on existing studies, determine what that level of exposure is.

Free, *supra* (Appx. #9). Another district court in this circuit has already recognized: "[The] no safe dose [premise] flies in the face of the toxicological law of dose-response, that is, that the dose makes the poison."[24]

2. *The High-Dose and Amphibole Epidemiology Studies*

Second, Dr. Brodkin relies on irrelevant epidemiology studies that do *not* address the effects of low exposures to chrysotile fibers. The chrysotile cohort studies that Dr. Brodkin cites (Brodkin Report, p. 26 (Appx. #40)), involved industries whose workers were exposed to high doses hundreds of times greater than anything dryer felts would produce – textile plants, mines, cement plants – and yet even these settings produced very few mesotheliomas. Rather than support Dr. Brodkin, these studies indicate, at most, that it *takes a massive dose of*

[24] *Henricksen*, 605 F. Supp. 2d at 1165-66 (the theory "has been rejected by the overwhelming majority of the scientific community").

chrysotile to cause anything. The trial judge never discussed these studies and apparently failed to review them or assess their lack of relevance.

Dr. Brodkin also relies on several paper mill studies, only some of which found excess mesothelioma. *See* Brodkin Report at 23-24. Even those instances were explained by work around insulation.[25] None of the authors of the paper mill studies ascribed those mesotheliomas to dryer felt exposure. Dr. Brodkin cites to only two studies that purport to find mesothelioma from low asbestos exposure – Iwatsubo[26] and Rödelsperger[27] – but both studies relate to *amphibole* exposures and state explicitly that their findings cannot be attributed to chrysotile exposures. Iwatsbu, for instance, concluded: "We could not examine mesothelioma risk according to fiber types because our study design … did not allow us to identify those subjects whose exposure was only to chrysotile fibers."[28] Rödelsperger likewise acknowledged that there is no reliable relationship observed for chrysotile, and the lung tissue portion of the study accounted for all of the results

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25 *See* Kjell Toren *et al*., *Health Effects of Working in Pulp and Paper Mills: Malignant Diseases*, 29 Am. J. Indus. Med. 123 (1996 (surveying eight studies, only two found increased mesothelioma, and 20 out of 21 such cases were in maintenance workers).

26 *See* Y. Iwatsubo *et al*., *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-based Case-Control Study*, 148 Am. J. Epidemiology 133 (1998), *abstract available at* http://aje.oxfordjournals.org/content/148/2/133.short (Appx. #29).

27 *See* 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 (2001), *abstract available at* http://www.ncbi.nlm.nih.gov/pubmed/11241559 (Appx. #38).

28 Iwatsubo *et al*., *supra*.

through amphibole fiber and found no association with chrysotile in the lungs.[29] These are not studies that any reputable scientist would rely on in the scientific community to conclude that minor exposures to chrysotile cause or contribute to disease. But that is what Dr. Brodkin does in asbestos litigation.

Dr. Brodkin's reliance on these epidemiology studies is inappropriate and misleading – they are irrelevant to the proposition he must prove, that "any dose of chrysotile" should be considered a cause. Yet he relies on them as if they prove Mr. Barabin's slightest exposure to dryer felt contributed to his disease. Dr. Brodkin's methodology of "extrapolating down" from high dose studies to conclude that every exposure to fibers would contribute to disease is inherently unscientific, and has been rejected repeatedly by courts.[30] As noted, Dr. Brodkin's testimony was rejected by a Washington state court for this very reason: "Downward extrapolation[, however,] from the studies that establish levels of risk at doses at or above 10 fbrs/cc yr is not a sound scientific methodology and is not generally accepted in the field of epidemiology or occupational medicine."[31]

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29 *See* Rödelsperger *et al*., *supra*.

30 *See, e.g., Free, supra*; *Henricksen,* 605 F. Supp. 2d at 1156; *In re Bextra,* 524 F. Supp. 2d at 1181.

31 *Free*, *supra* (emphasis added). This type of extrapolation from irrelevant studies is classic *Daubert* error. *See Avila*, 633 F.3d at 839 n.8, 840 (affirming exclusion of expert testimony relying on studies involving other injuries or chemicals than at issue); *Cano v. Continental Airlines*, 193 Fed. Appx. 664, 666 (9th Cir. 2006) (affirming exclusion of expert opinion where "relationship between [expert's] conclusions and the scientific literature is tenuous at best"); *Domingo*, 289 F.3d at 606-07 (affirming exclusion of expert testimony that relied on faulty extrapolation from dissimilar studies); *Schudel v. General Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997) (excluding opinions extrapolating from studies of organic solvents

3. *The Welch Article and Helsinki Criteria*

Third, Dr. Brodkin relied heavily on two irrelevant opinion pieces, one by Dr. Laura Welch, an expert for asbestos plaintiffs' interests, and the other the "Helsinki criteria." Unlike the above studies, Judge Lasnik did comment on both of these, rejecting (appropriately) the Welch article as a legal memorandum. That should have been a red flag – the supposed "study" Dr. Brodkin "primarily" relied on was not a study but a legal advocacy piece. Scientists do not rely on legal briefs to reach medical conclusions.

Despite such a warning sign, the trial judge here nevertheless allowed Dr. Brodkin to testify partly because of his reliance on the Helsinki "consensus" criteria article. This article (whose "criteria" have never been adopted by a medical body) does not support an "each and every exposure" opinion – it requires a "significant" occupational dose for attribution.[32] The obvious corollary is that "insignificant *occupational* doses" are not a cause, and the expert must distinguish between occupational exposures that are "significant" and "insignificant" – exactly

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allegedly similar to chemicals in question), *cert. denied*, 523 U.S. 1094 (1998); *Newkirk*, 727 F. Supp. 2d at 1022-23 (rejecting extrapolation from higher doses and different settings); *In re Bextra*, 524 F. Supp. 2d at 1180 (rejecting expert's extrapolation from 400 mg/d dose studies of drug to opine regarding 200 mg/d doses).

[32] *See Asbestos, Asbestosis, and Cancer: the Helsinki Criteria for Diagnosis and Attribution*, 23 Scan. J. Work Environ. Health 311, 313 (1997), *available at* http://www.sjweh.fi/show_abstract.php?abstract_id=226 ("significant" exposures should be considered causative of mesothelioma) (Appx. #30). The criteria also state that "an occupational history of brief or low-level exposure" should be considered causative, but provide no guidance as to what this means or what fiber type is encompassed. The Helsinki Critieria can only be interpreted to mean that *some* occupational exposures are *not* causative – the opposite of Dr. Brodkin's "everything is cumulative" view.

what Dr. Brodkin did *not* do. If the trial judge had examined the Helsinki article as *Daubert* requires, the court would have discovered that Dr. Brodkin ignored its requirements and distorted its statements to fit his theory.

4. *Dr. Hammar's Testimony*

In the Order Denying New Trial (pp. 14-15) (E. R. 15-16), the trial court reverted to the cross-examination testimony of a defense expert, Dr. Hammar rather than examine the theory's reliability. Nowhere does *Daubert* allow a judge to relinquish the gatekeeping role simply because of testimony from another side's expert. It is still the court's job to investigate the theory, its viability, and the evidence supporting it.

Dr. Hammar did *not* testify that Dr. Brodkin's *any exposure* theory supported Mr. Barabin's case – he testified that dryer felts did *not* cause Mr. Barabin's disease. Dr. Hammar's recent attempts in other cases to use the *any exposure* theory have resulted in exclusion of his testimony, including twice by Washington courts.[33] If Washington courts would not permit this testimony, it was incumbent on the judge to examine its underpinnings and not simply defer to Dr. Hammar's comments on cross as conclusive evidence of the theory's reliability. Dr. Hammar's testimony at best merely confirms that he and Dr. Brodkin are both proponents of an unscientific theory.

[33] *See Anderson, supra* n.4 (Appx. #1); *Free*, *supra* n.4 (Appx. #9).

III. The *Any Exposure* Theory Fails the *Daubert* Criteria and Distorts Substantial Factor Causation

The *any exposure* theory fails *Daubert* on multiple grounds. As set forth above, it is based on an unreliable methodology of extrapolating down from irrelevant studies and ignores dose and potency. These experts rely on studies that do not "fit" the circumstances of this case, namely using amphibole and high-dose chrysotile studies to support a low-dose chrysotile opinion. The theory results in an infinite rate of error,[34] is not peer-reviewed, and is not generally accepted, as set forth in multiple court opinions, e.g.:

- The *any exposure* hypothesis "is not a theory which is generally accepted in the scientific community . . . [T]here are no techniques, experiments, or studies that are capable of producing reliable results or otherwise replicating that thesis." *Anderson, supra* n.4 (Appx. #1).
- "[T]he assumption that every exposure to asbestos … is a substantial factor contributing to development of an asbestos-related disease, is not a scientifically proved proposition that is accepted in the field of epidemiology, pulmonology, or any other field relevant to this case." *Free*, *supra* n.4 (Appx. #9).
- "If an opinion such as [this] would be sufficient for plaintiff to meet his burden, the Sixth Circuit's 'substantial factor' test would be meaningless…." *Bartel,* 316 F. Supp. 2d at 611 (Appx. #2).

Courts within the Ninth Circuit have also rebuffed attempts to export the *any exposure* theory to non-asbestos litigation. *See Henricksen v. ConocoPhillips Co.*,

[34] *See Total Containment, Inc. v. Dayco Prods., Inc.*, 2001 WL 1167506, *7 (E.D. Pa. Sept. 6, 2001) (if enough relevant data to support methodology are simply unavailable, methodology will have infinite error rate); *Siharath*, 131 F. Supp. 2d at 1372 (*Daubert* does not establish a "best efforts" test); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 452 (W.D. Pa. 2003) (excluding expert testimony where there was insufficient data on which expert could base causation opinion).

605 F. Supp. 2d 1142, 1165-66 (E.D. Wash. 2009) (holding in a benzene case that the theory "flies in the face of the toxicological law of dose-response.") (Appx. #13); *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006, 1024 (E.D. Wash. 2010) (rejecting plaintiffs' effort to apply the theory in popcorn diacetyl litigation) (Appx. #20). The degree of examination of expert evidence in these opinions is impressive – the judges read the studies, dissected the experts' reliance on them, examined illogical premises, and entered into the *Daubert* "brave new world" exactly as they were supposed to. Those opinions represent a dramatic contrast to the court's minimalist review below in this action.

Dr. Brodkin's approach, which is grounded in the ***absence*** of reliable testing and data to support a causation opinion, also makes Washington's substantial factor standard meaningless – every exposure becomes substantial, and none are insubstantial. That criticism is even more applicable where, as here, the expert Dr. Brodkin ascribes causation to minor chrysotile exposures when Mr. Barabin had significant amphibole insulation exposure that explains his disease.

The pernicious effect of the *any exposure* theory is to shift to defendants the burden of proving where actual harm would occur. There is no unfairness in requiring plaintiffs to meet the normal burden of demonstrating a harmful dose that is appropriate for all toxic tort litigation. Science has well-established mechanisms for determining exposures believed to be capable of causing human harm,

including primarily epidemiology studies of the relevant substance at exposures and doses relevant to the population in question. Plaintiffs call on irrelevant studies and principles like "no safe dose" to support the unsupportable proposition that everything is causative, rather than engage in any scientific process to determine whether in fact disease occurs because of exposures to chrysotile at levels generated by dryer felts.

CONCLUSION

For these reasons, the Court should reverse the decision below.

Respectfully submitted,

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