PANEL 3
New Developments in Tort Litigation

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **THIS DOCUMENT RELATES TO:** **All Cases** **and** *The County of Summit, Ohio, et al., v. Purdue Pharma L.P. et al.,* Case No. 18-op-45090	**Case No. 1:17-MD-2804** **Judge Dan Aaron Polster** **MEMORANDUM OPINION CERTIFYING NEGOTIATION CLASS**

Before the Court is Plaintiffs' Renewed and Amended Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class. Doc. #: 1820. Various Defendants and a handful of putative class members oppose the motion, as do 37 State Attorneys General and the Attorneys General of Guam and the District of Columbia. After consideration of all of the briefing on this motion, and oral argument held on August 6, 2019, and all of the prior proceedings herein, the Plaintiffs' Motion is **GRANTED-IN-PART**. This Memorandum opinion explains the Court's reasoning. An Order will issue separately.

I. THE NEGOTIATION CLASS CERTIFICATION MOTION

A. Background

On December 12, 2017, the Judicial Panel on Multidistrict Litigation (JPML) transferred all opioid-related litigation pending in federal courts throughout the United States to this forum for consolidated pretrial proceedings. Doc. #: 1. At present, this multidistrict litigation (MDL) encompasses more than 2,000 individual actions. Most of these constituent cases have been filed

by cities and counties throughout the United States seeking, *inter alia,* reimbursement for monies they have expended – and continue to spend – addressing the opioid crisis. The Defendants include numerous manufacturers, distributors, and pharmacies. Beyond the thousands of cases pending here, many other municipalities are litigating similar opioid-related lawsuits in state courts throughout the United States.

From the outset of this MDL, the Court has encouraged the parties to settle the case. Settlement is important in any case. Here, a settlement is especially important as it would expedite relief to communities so they can better address this devastating national health crisis. A Court-appointed Special Master (Professor Francis McGovern) has overseen extensive settlement negotiations. The Defendants have insisted throughout on the need for a "global settlement," that is, a settlement structure that resolves most, if not all, lawsuits against them arising out of the opioid epidemic. This has created an obstacle to settlement. In a standard settlement class action, the class members can opt out of the class after the settlement is reached. With thousands of counties and cities already litigating, the Defendants in this MDL are concerned that many of these Plaintiffs could opt out. The Defendants would then have paid a lot of money to settle non-litigating claims but would still have to litigate a host of potentially significant claims. This situation required creative thinking. The Special Master, in conjunction with experts and the parties in the case, developed an innovative solution: a new form of class action entitled "negotiation class certification."[1]

[1] The Special Master and Professor Rubenstein, the Court's expert in this matter, have produced a scholarly version of the idea. *See* Francis E. McGovern & William B. Rubenstein, *The Negotiation Class: A Cooperative Approach to Class Actions Involving Large Stakeholders* (Duke Law Sch. Pub. Law & Legal Theory Series, Paper No. 2019-41, 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3403834.

The idea is to undertake the class certification and opt-out process prior to a settlement being reached, as is done in a normal class action geared toward trial. This will fix a class size and provide the Defendants a sense of the precise scope of the group with whom they are negotiating. The class members' rights are protected in several critical ways. At the front end, before having to make the opt-out decision, the class members can calculate their share of any future settlement; here, groups of Plaintiffs and Plaintiffs' attorneys have worked together to establish a public health-based settlement allocation plan, the details of which are all made available to the Class and public at a case website, www.opioidsnegotiationclass.info. At the back end, each class member will be entitled to vote (yes or no) on whether a proposed settlement amount is sufficient, and no settlement will be deemed accepted unless it garners a supermajority (75%) of those voting; here, a proposal will need to secure approval from six separate supermajority vote counts, reflecting different slices of the class. Additionally, of course, the Court protects the absent class members: Rule 23 requires that the Court make specific determinations before permitting a class action to go forward, Fed. R. Civ. P. 23(a), (b)(3), (c), (g), and similarly requires that the Court – independent of the class's vote – approve any proposed settlement and attorney's fees, Fed. R. Civ. P. 23(e), (h).

As discussed more fully below, the Court is mindful of the fact that this is a novel procedure and one opposed by the vast majority of State Attorneys General, who themselves are actively pursuing important State opioid litigation. The Court has determined that the procedure is a legitimate one, that certification is warranted based on the facts of the case, and that the whole process is more likely to promote global settlement than it is, as the Attorneys General argue, to impede it. Regardless, there is nothing coercive about this process: no Defendant has to employ it. There is nothing exclusive about this process: it does not interfere with the States settling their

own cases any way they want, and it does not stop parties in the MDL from settling in other ways. And there is nothing intrusive about this process: it does not stop any litigation from continuing and in no way interferes with the upcoming bellwether trials in this MDL. This process simply provides an option – and in the Court's opinion, it is a powerful, creative, and helpful one. The Court therefore grants certification of the negotiation class but, mindful of the objections that have been mounted against it, upon terms more carefully prescribed and delimited than those proposed by the Plaintiffs.

B. The Motion

By motion dated June 14, 2019, the Plaintiffs' leadership team in this MDL filed a motion on behalf of 51 cities and counties entitled, Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class, Doc. #: 1683; Doc. #: 1690 (corrected version). A variety of parties responded to this motion, including a group of Distributor Defendants, Doc. #: 1720, and a group of Pharmacy Defendants, Doc. #: 1723, but no Manufacturer Defendants. Moreover, two sets of State Attorneys General – representing 30 States, the District of Columbia, and Guam – sent letters to the Court registering their disapproval of the proposed motion. Doc. ##: 1726, 1727. The Court held a hearing on the initial motion on June 25, 2019, and at that time adopted a briefing schedule enabling the Plaintiffs to re-brief the motion in light of the filed oppositions. Accordingly, on July 9, 2019, the Plaintiffs filed a Renewed and Amended Motion for Certification of Rule 23(b)(3) Cities/Counties Negotiation Class. Doc. #: 1820; *see also* Doc. #: 2135 (Statement of City of Manchester, New Hampshire Supplementing Plaintiffs' Renewed Motion). On July 23, a set of nine Distributor and Pharmacy Defendants filed a brief opposing the motion, Doc. #: 1949, while a group of Manufacturing Defendants filed a brief asking the Court to clarify

the relationship of negotiation class certification to *American Pipe* tolling, Doc. #: 1952;[2] other Defendants subsequently noted their joinder in these responses, Doc. ##: 1954, 2057. A group of six (6) Ohio cities filed a brief in opposition, Doc. #: 1958, later joined by a seventh city, Doc. #: 2064, while another putative class member (City of Fargo, North Dakota) filed a brief asking the Court to clarify the end date for inclusion in a particular sub-group of the proposed negotiation class, Doc. #: 1953. A letter to the Court joined by 37 State Attorneys General, as well as the Attorneys General of the District of Columbia and Guam, strongly urged the Court to reject the motion. Doc. ##: 1951, 1955. The Ohio Attorney General, who signed that letter, also filed a separate letter of his own registering further opposition. Doc. #: 1973. On July 30, 2019, the Plaintiffs filed a reply to these oppositions. Doc. #: 2076. On August 6, 2019, this Court held a hearing on the motion.

C. The Proposed Process

The negotiation class certification process unfolds in five stages:

1. *Allocation/Voting*. Class members first develop a plan for allocating a lump sum settlement among the class and a plan for voting on the reasonableness of any lump sum settlement that is achieved. This enables each class member to know its settlement share and franchise prior to the opt-out deadline. Here, the MDL Plaintiffs' leadership has met with numerous groups of Plaintiffs and public health experts to create the allocation plan. Doc. #: 1820-1 at 49. The plan proposes distributing 75% of the lump sum to counties, with each county's share calculated according to three equally-weighted public health factors. *Id.* at 48–49, 55–60. The county's share is then divided among the county and its constituent cities, ideally through negotiated agreement.

[2] Movants disclaim any tolling effect of their motion, Doc. #: 2076 at 19, so the Court need not address this issue at this time.

Id. at 60. Of the remaining 25%, 10% is set aside for a "Private Attorneys' Fee Fund," from which private attorneys – defined as any counsel with representation agreements with one or more Class members executed as of June 14, 2019 – could seek fees in lieu of enforcement of private contingency fee contracts with their clients. *Id.* at 49–50. Finally, 15% is set aside for a "Class Members' Special Needs Fund," to cover the special needs and expenditures of any Class member that are not addressed by the class-wide allocation formula, including expenses associated with litigation. *Id.* at 96. All of these amounts are subject to Court approval and any of this 25% (the Private Attorneys' Fee Fund and the Class Members' Special Needs Fund) not so distributed is then re-distributed across the class according to the allocation plan. *Id.* at 95, 97.

The voting model is both simple and complex. Doc. #: 1820 at 8–9. If a lump sum settlement is reached with a Defendant, each class member will be given the opportunity to cast a single, simple, yes/no vote as to whether the size of the lump sum settlement is sufficient. The votes will then be counted to ensure the settlement is accepted by 75% of all voting entities by number, 75% of all voting entities by population, and 75% of all voting entities by allocation; each of those three types of votes will be counted twice, once among jurisdictions that had filed lawsuits as of June 14, 2019 ("litigating entities") and once among jurisdictions that had not ("non-litigating entities"). The various counts ensure that: (1) the plethora of smaller counties cannot alone control an outcome (the population vote guards against that); (2) the plethora of small-recovery counties cannot alone control an outcome (the allocation vote guards against that); and that (3) neither the litigating nor non-litigating entities alone can control an outcome.

Part IV of this Memorandum analyzes the equities of the allocation and voting plans.

2. *Class Certification.* With the allocation and voting plans in place, plaintiffs move for certification of the negotiation class, as have the present movants.

3. *Notice and Opt-Out Period.* If the Court approves the motion, the class members are given notice of class certification and an opportunity to opt out. Here, movants propose a 60-day opt-out period. During that time, class members can assess their share of a lump sum settlement and the proposed voting structure at the class website to determine whether they want to be part of this negotiating group.

4. *Lump Sum Settlement Negotiation.* At the conclusion of the opt-out period, with the size of the class set, the class is ready to negotiate a settlement with one or more defendants. No defendant is required to negotiate with the class and the underlying litigation activities continue unabated.

5. *Judicial Approval, Including Class Vote.* If a settlement is reached, the parties move for judicial approval, as required by Rule 23(e). That process encompasses three parts: (a) the Court must preliminarily approve the settlement, Fed. R. Civ. P. 23(e)(1); (b) class members are then given their opportunity to vote on the settlement, and they may file objections with the Court, Fed. R. Civ. P. 23(e)(5); and (c) if the Class votes to accept the settlement, class counsel moves for final approval. The Court would then make the same determination as to the settlement's reasonableness as Rule 23 requires it to do in any class action. Fed. R. Civ. P. 23(e)(2).

II. RULE 23 AUTHORIZES NEGOTATION CLASS CERTIFICATION

Rule 23 authorizes a court to certify a case, or issues within a case, for class treatment if certain requirements are met. Since adoption of the current version of Rule 23 in 1966, courts have generally certified two types of class actions: trial class actions and settlement class actions. The present motion asks this Court to certify a "negotiation class action." The concept and

procedure are set forth above. The question addressed here is whether Rule 23 authorizes this procedure. The Court finds that it does.

An important starting point is that the text of Rule 23 does not dictate, nor therefore limit, the uses to which the class action mechanism can be applied. Rule 23(a) and (b) set forth the requirements that must be met before a court can certify a class, but neither specifies that the class to be certified is for "trial" or "settlement" purposes. Defendants point to the fact that several passages in Rule 23 specifically reference settlement, as opposed to trial, classes. Doc. #: 1949 at 7. They argue that these passages demonstrate that the Rule authorizes only trial and settlement classes. *Id.* Their argument is not convincing. The passages they reference were not added to Rule 23 until December 2018, yet 21 years before that – when Rule 23 contained no explicit reference to settlement class actions – the Supreme Court affirmed courts' use of the settlement class action device. *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 618 (1997). Moreover, the passages that were added in 2018 do not authorize settlement classes but simply identify certain procedures relevant to those types of class actions.

The history of class action law provides further support for this new use of the class action procedure. Soon after Rule 23's adoption in 1966, parties began asking courts to certify settlement class actions, that is, cases that had already been settled prior to the court's certification of a class. *See, e.g.*, *Philadelphia Hous. Auth. v. Am. Radiator & Standard Sanitary Corp.*, 323 F. Supp. 364 (E.D. Pa. 1970), *aff'd and modified sub nom. Ace Heating & Plumbing Co. v. Crane Co.*, 453 F.2d 30 (3d Cir. 1971). This development was deemed novel and had its share of detractors. *See Manual for Complex Litigation* § 1:46 (4th ed. 1977) ("There is, to say the least, serious doubt that this practice is authorized by Rule 23 as amended, even if it is conceded that the courts are expected to develop new methods of employing the amended Rule 23."). Many critics made the same

argument then that detractors of the proposed negotiation class make now: that the use is not authorized by the rule. The lower courts rejected this argument, and in its 1997 decision in the *Amchem* case, the Supreme Court affirmed that Rule 23 authorized settlement class actions. *Amchem*, 521 U.S. at 618 (noting that "all Federal Circuits recognize the utility of Rule 23(b)(3) settlement classes" and approving use of the device). The Defendants' reliance on *Amchem* for the proposition that "in recent years [the Supreme Court has] repeatedly warned that new innovations that go beyond the express scope of Rule 23 are prohibited," Doc. #: 1949 at 8 n.8, is therefore unpersuasive and inapposite.

Finally, it is not surprising that the history of Rule 23 supports different uses of the class action device, and the text does not prohibit these, because Rule 23 is equitable in nature and its purpose is to provide practical means for addressing complex litigation problems. Myriad judicial decisions have accordingly supported liberal application of Rule 23. *See, e.g.*, *Schneider v. Elec. Auto-Lite Co.*, 456 F.2d 366, 370 (6th Cir. 1972) ("[T]he District Court was correct in liberally interpreting Rule 23 in order to avoid burdensome litigation and to give efficient disposition to this action.").

One aspect of the negotiation class action process that differs from a settlement class action is that class members must make their decision whether to opt out before knowing the size of the settlement. Some argue this violates the Due Process Clause. Doc. #: 1958 at 8–12. It does not. In a normal trial class action, class members must make their opt-out decision at the outset of the suit, before the result is known, and no one argues that process is unconstitutional. Moreover, in that process, if their trial attorneys later settle the case, Rule 23 enables a Court to offer a second opt-out opportunity but does not require it to do so. Fed. R. Civ. P. 23(e)(4). If there were a constitutional right to opt out once the outcome was known, Rule 23 would require a second opt-

out opportunity, not just authorize it. Here, class members are given sufficient information to make an informed decision about whether they want to bind themselves to a negotiation process, from which they will receive a known portion of the outcome and in which they will get a right to vote on the settlement. Moreover, the Court always retains the option of enabling a second opt-out opportunity if circumstances require.

The Defendants also note that a few courts have rejected the 75% voting idea when employed outside the class action context, Doc. #: 1949 at 25–26 (citing *Tax Auth., Inc. v. Jackson Hewitt, Inc.*, 898 A.2d 512, 521 (N.J. 2006); *Hayes v. Eagle-Picher Indus., Inc.*, 513 F.2d 892, 894–95 (10th Cir. 1975)), and argue that the voting process therefore cannot be employed within the class action context. But the two contexts are distinct: class members in class actions, unlike individual mass tort plaintiffs, are not given individualized settlement approval rights. All class members are automatically bound unless they can and do opt out. Moreover, in a normal settlement class action, class members may either object or opt out, but if they object and lose their objection, they cannot then opt out: they are instead bound to a settlement with which they disagree. The voting process is therefore consistent with the class action mechanism.

More generally, the Defendants argue that a negotiation class violates Article III because it is somehow unrelated to a judicial function. Doc. #: 1949 at 7–8. They concede, as they must, that a settlement class is legitimate, noting that it assists a court in its judicial function of "entering a judgment of approval on a class settlement." *Id.* at 8. But negotiation class certification serves an even more important judicial function at an even more important juncture in the litigation: in certifying a negotiation class, the Court undertakes the familiar judicial function of ensuring that the class certification requirements are met and the absent class members' interests are protected by those who purport to represent them, *prior to those agents negotiating a settlement for the*

absent class members. Negotiation class certification therefore corrects one of the long-standing concerns of settlement class actions: that un-approved agents have settled un-certified claims. *See, e.g.*, *Ace Heating & Plumbing Co. v. Crane Co.,* 453 F.2d 30, 33 (3d Cir. 1971) (examining argument that lawyer, "having bargained the settlement terms with defendants prior to his official designation by the court as class representative . . . may be under strong pressure to conform to the defendants' wishes"). Moreover, assisting parties in creating a settlement, particularly in a large case of this type with contested liability and adversarial litigation, is itself a meaningful judicial function. *See, e.g.*, *In re Nat'l Prescription Opiate Litig*., 927 F.3d 919, 923 (6th Cir. 2019) (noting, without censure, that "[t]he district court presiding over this potentially momentous MDL has repeatedly expressed a desire to settle the litigation before it proceeds to trial").

III. THE REQUIREMENTS OF CLASS CERTIFICATION ARE MET

A. The Claims and Issues

Rule 23(c)(1)(B) states that: "An order that certifies a class action must define the class and the class claims, issues, or defenses, and must appoint class counsel under Rule 23(g)." Fed. R. Civ. P. 23(c)(1)(B). The Defendants argue that the movants have failed to proffer sufficient evidence in support of their motion and/or that the motion is not tethered to a particular complaint. Doc. #: 1949 at 9–13. (Defendants also complain about a lack of discovery concerning the class representatives. *Id*. at 12 n.13. They filed two briefs in response to movants' original proposal, Doc. ##: 1720, 1723, and appeared at the June 25, 2019 hearing on the motion, yet never asked for or filed a motion seeking discovery).

The current motion does not arise in a factual vacuum. This MDL has been pending for nearly two years. The Court has undertaken extensive review of the factual and legal issues in the case. Several bellwether trials will commence shortly and the Court has ruled on critical motions

to dismiss, myriad discovery matters, and a variety of complex and voluminous summary judgment motions. The Court and parties are deeply steeped in the legal and factual issues in the case, and the extensive record of the case – now over 2,500 entries on the MDL docket alone – provides more than sufficient factual and legal context for a decision on class certification. The Defendants' concern that the present motion is not tethered to a specific complaint implies that there is an absence of relevant pleading in this matter. If there is a problem in this case, however, it is one of glut, not famine: there are more than 2,000 complaints pending here, many of which exceed 300 pages in length. Although parties sometimes make class allegations in their complaint, Defendants point to no precedent holding that class allegations in a complaint are a necessary prerequisite to a class certification motion under Rule 23; similarly, although in MDLs of this type there are sometimes master complaints, there is no MDL-specific (or any other) rule requiring such a complaint and, absent specific agreement to the contrary, such complaints are typically purely administrative in nature. *See* William B. Rubenstein, 3 *Newberg on Class Actions* § 10:15 (5th ed. 2019) [hereinafter *Newberg on Class Actions*].

Contrary to the Defendants' assertions, the movants specifically point the Court to the allegations contained in Cuyahoga County, Ohio's pleadings. Doc. #: 1820-1 at 78 n.40. Given the Court's extensive knowledge of the heavily-developed legal and factual record in this matter, and the discretion Rule 23 delegates to it, the Court adopts movants' approach but utilizes as its reference the allegations in substantially similar complaints filed by Summit County, Ohio (Doc. ##: 513, 1466). The Court references the Summit County pleadings for several inter-related reasons: (1) Summit County is one of two bellwether cases set for trial in the coming month, with its facts and legal allegations well-known to the Court and litigants; (2) Summit County's complaint was extensively tested through motions to dismiss covering thousands of pages of

documents and nearly a year of litigation, Doc. #: 1203; (3) Summit County's complaint was the basis of a "short form complaint" process that enabled all plaintiffs in this MDL to incorporate by reference certain of the legal and factual allegations therein, Doc. #: 1282; (4) the vast bulk of the 49 putative class representatives – and numerous other plaintiffs – have accordingly adopted the Summit County pleadings.[3]

The Summit County complaint and related short-form complaint enabled MDL plaintiffs – by checking a few boxes – to adopt two federal RICO claims and a set of factual allegations encompassing, *inter alia*, issues arising out of the federal Controlled Substances Act. The first RICO claim, levelled against manufacturers labelled "RICO Marketing Defendants," alleges the manufacturers engaged in a variety of activities that misled physicians and the public about the need for and addictiveness of prescription opioids, all in an effort to increase sales. *See* Summit County Pleadings, Doc. #: 513, ¶¶ 814–48 (facts), ¶¶ 878–905 (law), Short Form Complaint Ruling, Doc. #: 1282-1 at 3 ¶3, at 3–4, ¶5. The second RICO claim, levelled against manufacturers and distributors labelled "RICO Supply Chain Defendants," alleges these defendants ignored their responsibilities to report and halt suspicious opioid sales, all in an effort to artificially sustain and increase federally-set limits (quotas) on opioid sales. *See* Summit County Pleadings, Doc. #: 513, ¶¶ 849–77 (facts) ¶¶ 906–38 (law), Short Form Complaint Ruling, Doc. #: 1282-1 at 3 ¶3, at 3–4, ¶5. The complaints also allege that the Controlled Substances Act required the manufacturers,

[3] The Court is aware that as Summit County's bellwether trial has approached, the County has settled with some defendants and that the County is no longer proposed as a class representative. Doc. #: 2583 at 5. However, using its complaints as the reference for analysis of the claims and issues suitable for class certification remains appropriate given that so many other plaintiffs here have adopted those same claims and issues through the short-form process and/or have filed complaints that are substantially identical in relevant passages to the Summit County complaint. *See, e.g.*, Second Amended Complaint of Cabell County Commission (W.Va.), Doc. #: 518; Second Amended Complaint of County of Monroe, Michigan, Doc. #: 522; Second Amended Complaint of Broward County, Florida, Doc. #: 525.

distributors, and pharmacies to create internal systems to identify, report, and suspend unlawful opioid sales, and that defendants failed to meet those obligations; these factual allegations underlie the second RICO claim above and are also pertinent to adjudication of myriad state-based legal claims, from public nuisance to negligence. *See* Summit County Pleadings, Doc. #: 513, ¶¶ 504, 506–659, Short Form Complaint Ruling, Doc. #: 1282-1 at 3 ¶ 3.

Based on these pleadings, which are common across many, if not most, of the MDL litigants and putative Class Representatives, the Court will analyze the movants' request to certify for class treatment:[4]

1. a RICO claim arising out of the alleged Opioid Marketing Enterprise, as against five (5) named Defendants – Purdue, Cephalon, Janssen, Endo, and Mallinckrodt – under Rule 23(b)(3) (Doc. #: 1820-1 at 83);

2. a RICO claim arising out of the alleged Opioid Supply Chain Enterprise, as against eight (8) named Defendants – Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen – under Rule 23(b)(3) (Doc. #: 1820-1 at 84); and,

3. two issues related to Defendants' obligations under the Controlled Substances Act, against thirteen (13) named Defendants – Purdue, Cephalon, Endo, Mallinckrodt, Actavis, Janssen, McKesson, Cardinal, AmerisourceBergen, CVS Rx Services, Inc., Rite-Aid Corporation, Walgreens, and Wal-Mart – under Rule 23(c)(4) (Doc. #: 1820-1 at 91 n.46 & at 84–86):

    a. What are the specific obligations of each defendant under the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*. and its implementing regulations, 21 C.F.R. § 1301 *et seq*., arising out of the requirement that registrants "provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 C.F.R. § 1307.71(a)?

    b. Did each defendant's action satisfy these obligations with respect to prescription opioids?

[4] The Court uses simple names for the 13 Defendants listed in the following numbered paragraphs, but adopts the definitions of the related Defendant entities set out in the Summit County Complaint, Doc. #1466 at 13–35.

B. The Class Certification Standard

The Sixth Circuit has held that: "Any class certification must satisfy Rule 23(a)'s requirement of numerosity, commonality, typicality, and adequate representation [and] fit under at least one of the categories identified in Rule 23(b)." *Clemons v. Norton Healthcare Inc. Ret. Plan*, 890 F.3d 254, 278 (6th Cir. 2018). Under Rule 23(b)(3), class certification is appropriate if (1) "the questions of law or fact common to class members predominate over any questions affecting only individual members," and (2) class resolution "is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Additionally, Rule 23(c)(4) states that "[w]hen appropriate, an action may be . . . maintained as a class action with respect to particular issues." Fed. R. Civ. P. 23(c)(4). The Sixth Circuit recently affirmed the utility of such "issue certification," explaining that Rule 23(c)(4) "contemplates using issue certification to retain a case's class character where common questions predominate within certain issues and where class treatment of those issues is the superior method of resolution." *Martin v. Behr Dayton Thermal Prod. LLC*, 896 F.3d 405, 413 (6th Cir. 2018), *cert. denied*, 139 S. Ct. 1319 (2019). After confirming existence of a cognizable class, this Court will accordingly consider all of the factors of Rule 23(a) and 23(b)(3) as they apply to both the RICO claims and the CSA issues, as against each relevant Defendant.

C. The Class is Ascertainable

Rule 23(b)(3) classes must be ascertainable. *Cole v. City of Memphis*, 839 F.3d 530, 541 (6th Cir. 2016). For a class to be ascertainable, the "class definition must be sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member of the proposed class." *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537–38 (6th Cir. 2012) (citation omitted). It is administratively feasible for the Court to determine class

membership if the class is defined by reference to objective criteria, and with reasonable accuracy. *See id.* at 538–39; *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525 (6th Cir. 2015).

The present motion seeks certification of a single national class, defined as:

> all counties, parishes, and boroughs (collectively, "counties"); and all incorporated places, including without limitation cities, towns, villages, townships, and municipalities, as defined by the United States Census Bureau (collectively "cities") as listed on the Opioids Negotiation Class website, opioidsnegotiationclass.com.

Doc. #: 1820 at 3. The class definition is based on purely objective criteria and is accompanied by an Excel spreadsheet at the website that lists the names of each of the proposed class members in 34,458 rows. The class is therefore not only ascertain***able***, its membership has been ascertain***ed***. Defendants argue that the complexity of governmental structures across the country creates some ambiguous situations and they provide a single such example. Doc. #: 1949 at 3 n.3. Such minor technical issues can be worked out going forward. For purposes of class certification, the Court finds that the class is adequately defined.

D. Rule 23(a)(1): The Class is So Numerous That Joinder is Impracticable

Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). The Sixth Circuit has held that "no strict numerical test exists to define numerosity," *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 722 F.3d 838, 852 (6th Cir. 2013), but that "'substantial' numbers . . . are sufficient to satisfy this requirement." *Id.* The proposed class consists of 34,458 public entities dispersed throughout the entire United States. Defendants explicitly concede that "numerosity is self-evident here." Doc. #: 1949 at 13. The Court finds that the class is so numerous that joinder of all members would be impracticable and thus that this requirement has been satisfied.

E. Rule 23(a)(2): There are Common Questions of Law or Fact

Rule 23(a)(2) requires plaintiffs to prove that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). Despite the Rule's use of the plural "questions," the Supreme Court has held that a single common question will suffice. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 359 (2011). Yet, "because the commonality requirement is qualitative, not quantitative," 1 *Newberg on Class Actions* § 3:22, at least one common issue must be central to the litigation, *see Wal-Mart*, 564 U.S. at 350 ("That common contention, moreover, must be of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.").

This putative class action occurs within a multi-district litigation (MDL). In creating this MDL, the Judicial Panel on Multidistrict Litigation (JPML) has steered thousands of individual actions pending throughout the nation to this Court. Its authority to do so turns on the presence of common questions. 28 U.S.C. § 1407(a) ("When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings."). In initiating this MDL, the JPML held:

> All actions involve common factual questions about, *inter alia*, the manufacturing and distributor defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs. Both manufacturers and distributors are under an obligation under the Controlled Substances Act and similar state laws to prevent diversion of opiates and other controlled substances into illicit channels. Plaintiffs assert that defendants have failed to adhere to those standards, which caused the diversion of opiates into their communities.

Doc. #: 1 at 3. Rejecting the argument that uncommon issues would generate inefficiencies if an MDL were formed, the JPML concluded: "All of the actions can be expected to implicate common

fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation . . . ." *Id.*

While commonality for pre-trial centralization purposes under § 1407 may not be precisely the same test as commonality for class certification purposes under Rule 23, it is close[5] and, regardless, the JPML's recitation, like the movants' papers, Doc. #: 1820-1 at 64–66, 81, identifies common issues that are qualitatively decisive for Rule 23 purposes. Moreover, there is direct evidence of the commonality of the claims and issues in this matter given that the short-form complaint process enabled MDL plaintiffs to adopt these specific claims and issues, and many did so. The Court finds that there are questions of both law and fact, as to the specified claims and issues, common to the class with respect to each relevant Defendant; the discussion in sub-section I, below, concerning whether these common questions predominate, sets forth with more particularity the specific common RICO and CSA issues.

F. Rule 23(a)(3): The Class Representatives' Claims are Typical of Those of the Class

Rule 23(a)(3) requires that "the claims or defenses of the representative parties [be] typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "Typicality is met if the class members' claims are 'fairly encompassed by the named plaintiffs' claims'" such that "by pursuing their own interests, the class representatives also advocate the interests of the class members." *In re Whirlpool Corp.*, 722 F.3d at 852–53 (6th Cir. 2013) (quoting *Sprague v. Gen. Motors Corp.*,

[5] Defendants rely on *In re Saturn L-Series Timing Chain Prod. Liab. Litig.*, No. 8:07CV298, 2008 WL 4866604, at *25 n.21 (D. Neb. Nov. 7, 2008) to argue that "[c]lass certification thus cannot be bootstrapped from the existence of an MDL." Doc. #: 1949 at 27. But the footnote that they reference distinguished the JPML's finding of *commonality* from Rule 23's finding of *predominance*. Moreover, in referencing the JPML's commonality finding as a good description of the common issues in this case, the Court is not "bootstrapping" on those findings; it is making its own independent determination of the presence of these findings and using the JPML's recitation as a descriptor.

133 F.3d 388, 399 (6th Cir. 1998)). "The test for typicality is not demanding . . . . [T]he plaintiffs' claims need not be identical to those of the class; typicality will be satisfied so long as the named representatives' claims share the same essential characteristics as the claims of the class at large." 1 *Newberg on Class Actions* § 3:29 (internal quotation marks and footnotes omitted).

As to the claims and issues identified for class treatment, the Court finds that the Class Representatives' claims are typical of those of the Class. The movants propose a total of 49 different counties and cities – from 30 states – to serve as Class Representatives.[6] The Court has reviewed the complaints (and where filed, short-form complaints) of each of the 49 proposed Class Representatives. These complaints demonstrate that the Class Representatives and the absent Class Members share an identity of interests. All are cities or counties, and are all generally interested in the same end: recouping money they have been forced to pay to address the opioid epidemic and ameliorating that epidemic. If the Class Representatives pursue their own interests identified in these complaints, they will necessarily be pursuing the interests of the absent class members. There is nothing unique about any of the proposed Class Representatives that would set them apart in meaningful ways from the absent class members.

The Defendants set forth a list of contentions to the contrary, Doc. #: 1949 at 38–39, but most are either irrelevant, recede in importance given the Court's adoption of the short-form complaint claims and issues for certification ("Differences in the causes of action asserted in the complaints . . . Differences in the identities of the defendants . . . Differences in the nature and quality of evidence available . . . ."), or are differences that do not defeat typicality ("Differences in the . . . scope of opioid-related harms . . . ."), *see Daffin v. Ford Motor Co.*, 458 F.3d 549, 553

[6] The movants initially proposed 51 class representatives, Doc. #: 1820 at 2, but later withdrew two (Cuyahoga County, Ohio and Summit County, Ohio). Doc. #: 2583 at 5.

(6th Cir. 2006) (finding typicality requirement met where class representative's and "other class members' claims arise from the same practice . . . [and] the same defect . . . and are based on the same legal theory. Typicality is satisfied despite the different factual circumstances regarding the manifestation of the [defect] . . ."); 1 *Newberg on Class Actions* § 3:43 ("Courts routinely find that the proposed class representative's claims are typical even if the amount of damages sought differ from those of the class or if there are differences among class members in the amount of damages each is claiming.").

As to the RICO claims and CSA issues, the proposed Representatives' claims align with those of the class. The Court therefore finds that the claims of the 49 proposed Class Representatives are typical of those of the Class, as to the specified claims and issues, with respect to each relevant Defendant.

G. Rule 23(a)(4): The Class Representatives Will Adequately Represent the Class

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The Court looks to two criteria in determining adequacy of representation: "1) the representative must have common interests with unnamed members of the class, and 2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel." *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 543 (6th Cir. 2012) (quoting *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1083 (6th Cir. 1996)).

Movants propose 49 Class Representatives. In their moving brief, movants describe each entity and briefly summarize how the opioid epidemic has impacted it. Doc. #: 1820-1 at 19–46. As above, the Court has also reviewed all of the relevant complaints and short-form complaints. Those documents demonstrate that each of the proposed Class Representatives is a member of the Class and each shares the same overriding interests as the other members of the Class in addressing

the consequences of the opioid epidemic. Moreover, as each of these entities is a governmental unit – some, like Chicago, enormous – the Court is confident that the representatives have the capacity to perform the functions of being actively engaged in the litigation, assisting Class Counsel with settlement negotiations, and, importantly, monitoring Class Counsel to ensure that the Class's interests remain paramount.

Most, if not all, of the proposed Class Representatives are entities that have been active in opioid litigation prior to the filing of the class action motion ("litigating entities"). This of course is of great value to the class: the litigating entities understand the case best and have been expending their own resources for years in a way that may now benefit the whole class. Many are large counties or cities with significant resources, skilled counsel, and enormous expertise as to the opioid epidemic. Who better to serve as representatives of a class? Defendants latch on to the fact that the allocation mechanism favors class representatives that primarily seek monetary relief for past damages over non-litigating entities that may be more interested in non-monetary relief, Doc. #: 1949 at 21–22, and that the voting scheme requires separate sets of approval from litigating and non-litigating entities, Doc. #: 1949 at 23–25. Below, the Court addresses the fairness of the allocation mechanism and finds no immediate fault. For present purposes, it reveals no fundamental conflict between litigating and non-litigating entities as to pursuit of this case against the Defendants that would render the list of 49 proposed representatives inadequate. *See* 1 *Newberg on Class Actions* § 3:58 ("Only conflicts that are fundamental to the suit and that go to the heart of the litigation prevent a plaintiff from meeting the Rule 23(a)(4) adequacy requirement."). Similarly, the Court rejects the Defendants' contention that there is a fundamental conflict between counties as a group and cities as a group that would require separate counsel and sub-classing. Doc. #: 1949 at 19–21, 25. It is true that if a settlement is reached, each county and

its constituent cities will need to work together – or, arguably, negotiate against one another – to divide the county-level allocation amongst themselves. But these negotiations are local in nature, will vary county to county, and, contrary to the Defendants' assertions, there is not one set of interests shared by all counties that fundamentally conflicts with one set of interests shared by all cities.

Lesser concerns are as easily dismissed. The State Attorneys General suggest that the range of Class Representatives is incomplete because it does not encompass representatives from each of the 50 states nor, they allege, from "smaller counties and cities." Doc. #: 1951 at 7; *see also* Doc. #: 1973 at 5. Here, the Court has considered for certification two federal (RICO) claims and several issues related to federal law (CSA) that are similar across the country and class. This is not a situation requiring class representatives from each of the 50 states. Moreover, the list of Class Representatives encompasses smaller areas such as Cass County, North Dakota; City of Concord, New Hampshire; County of Fannin, Georgia; and County of Gooding, Idaho. Doc. #: 1820 at 1. Importantly, as discussed more fully below, the allocation formula rebuts any concerns that hard-hit small counties are disadvantaged in some way by the movants' proposal. Finally, some of the Class Representatives are individually represented by lawyers who simultaneously represent States that are objecting to certification of this Class. Doc. ##: 1949 at 17; 1949-2 at 16–17. The Court finds that this situation does not disqualify these entities from serving as Class Representatives.[7] The Class Representatives themselves have no conflict and, as generally large governmental units, they have the capacity to balance advice they might get from their individual

[7] Defendants' citation to the Seventh Circuit decision in *Culver v. City of Milwaukee*, 277 F.3d 908, 913 (7th Cir. 2002), on this point is inapposite. Doc. #: 1949 at 18. That case did not deal with the question of a class representative's separate lawyer, but rather with the class representative's lawyer as (former) class counsel. *Culver*, 277 F.3d at 913.

lawyers against their responsibilities to the whole Class. The Court's conclusion is buttressed by the fact that there are both dozens of other Class Representatives and a set of experienced Class Counsel, each of whom represents only counties and cities, not States.

Like the putative Class Members, the 49 proposed Class Representatives have allegedly been adversely impacted by the Defendants' actions with regard to the manufacturing and distribution of opioids and they seek to be compensated for their losses. The Court finds that the Class Representatives, individually and as a group, will adequately represent the interests of the class members, as to the specified claims and issues, with respect to each Defendant.

H. Rule 23(g): Class Counsel Are Adequate

Rule 23(g) states that "a court that certifies a class must appoint class counsel." Fed. R. Civ. P. 23(g). In undertaking this appointment, the Rule directs the Court to consider: "(i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class." *Id.*

Movants propose the "the appointment of Jayne Conroy and Christopher Seeger as Co-Lead Negotiation Class Counsel and Gerard Stranch, Louise Renne, Zachary Carter, and Mark Flessner as Negotiation Class counsel," Doc. #: 1820 at 2, and have submitted Declarations from five of these lawyers, and a letter from one other, attesting to their experience, knowledge of the case, and willingness to commit resources. Doc. ##: 1820-1, Ex. A; 1821. As this Court has already held in appointing Interim Class Counsel:

> These documents demonstrate that Seeger is a very experienced and successful class action attorney, fully qualified to represent the Class. Two of the remaining five (Conroy and Stranch) have significant and impressive experience in leadership roles in mass tort MDLs in particular, Doc. #: 1820-1, Ex. A, while the remaining

> three are or were legal counsel for large cities (Renne/San Francisco; Carter/New York; and Flessner/Chicago), Doc. #: 1820-1 at 52. All have been involved in opioid-related litigation. Applying Rule 23(g)'s four factor test, the Court finds that these lawyers are well-situated to represent the Class.

Doc. #: 2490 at 3.

In its Orders regarding appointment of Interim Class Counsel, Doc. ##: 2490, 2493, the Court acknowledged the significant contributions to date of the MDL Negotiation Committee, the members of which are identified in Doc. #: 118. While most of these lawyers will not serve as Class Counsel for the Negotiation Class, their depth of knowledge about this case and their general expertise can continue to provide significant benefit for the Class. Accordingly, the Court's Order will clarify that there is no bar to Class Counsel working with the MDL Negotiation Committee members in negotiating with Defendants, nor is there any bar to these MDL lawyers applying to share Class Counsel duties in the future should their representational situations change. However, as the Court's order appointing interim Class Counsel clarified, only Class Counsel will "(a) represent the Class in settlement negotiations with Defendants; (b) sign any filings with this or any other Court made on behalf of the Class; (c) assist the Court with functions relevant to a class action, such as but not limited to maintaining the Class website and executing a satisfactory notice program; and (d) speak on behalf of the Class in Court." Doc. #: 2490 at 5. Thus, only Class Counsel can bind the Class and Class Counsel must independently approve all final decisions concerning any Class-based settlement and be the sole signatories on behalf of the Class of all Class-based term sheets, settlement agreements, or similar documents.

With these clarifications in the final certification order, the Court finds that the proposed Class Counsel will alone act for the Class and will fairly and adequately represent the interests of the class.

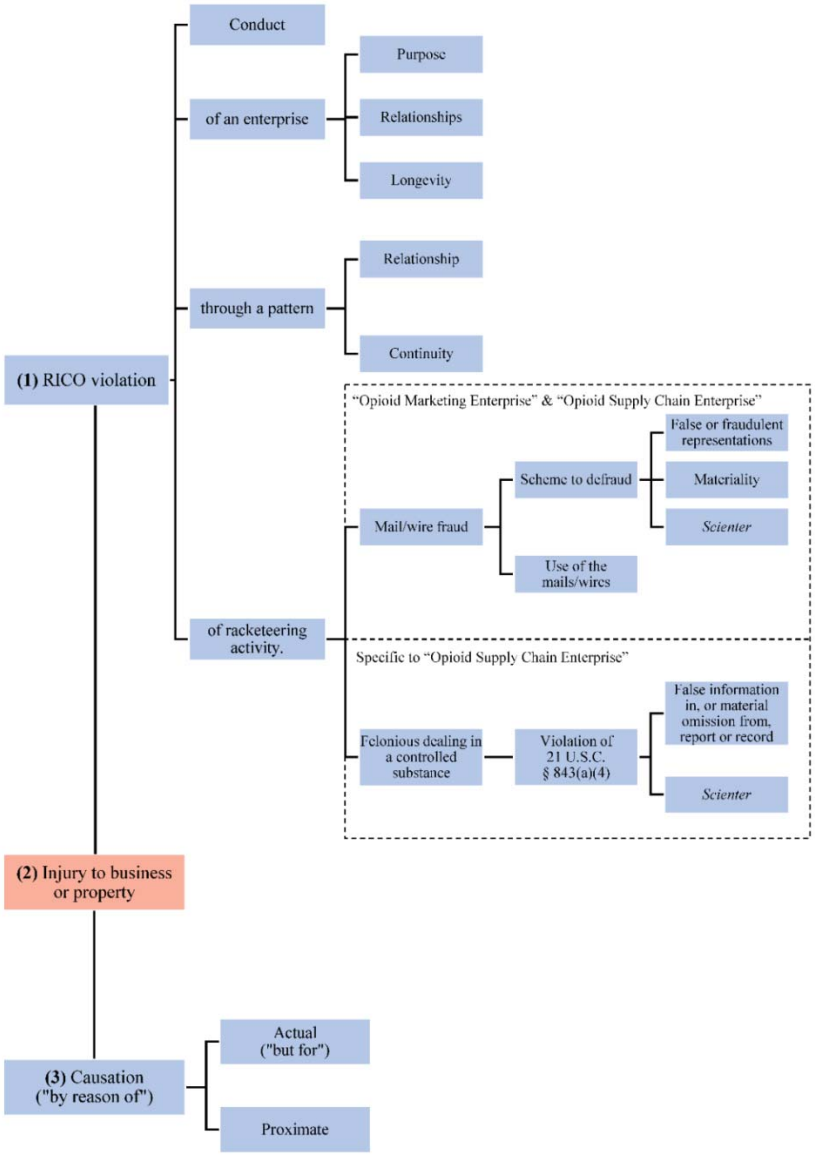
I. Rule 23(b)(3): Common Questions of Law or Fact Predominate

Rule 23(b)(3) requires that "questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). The predominance inquiry consists of two steps: "[a] court must first characterize the issues in the case as common or individual and then weigh which predominate." *Martin v. Behr Dayton Thermal Products LLC*, 896 F.3d 405, 413 (6th Cir. 2018) (alteration in original) (quoting 2 William B. Rubenstein, *Newberg on Class Actions* § 4:50 (5th ed. 2010)). Common questions are those where "the same evidence will suffice for each member to make a prima facie showing." *Sandusky Wellness Ctr., LLC v. ASD Specialty Healthcare, Inc.*, 863 F.3d 460, 468 (6th Cir. 2017) (citation and internal quotation marks omitted).

1. *RICO Claims*

To prevail on their federal civil RICO claims, the Plaintiffs will have to establish that (1) the defendants committed a RICO violation, (2) there was an injury to the Plaintiffs' businesses or properties, and (3) said injury occurred "by reason of" the RICO violation. *See Aces High Coal Sales, Inc. v. Cmty. Bank & Tr. of W. Georgia*, 768 F. App'x 446, 453 (6th Cir. 2019). In turn, the elements of a RICO violation are "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 483 (6th Cir. 2013) (citation omitted). Each of these prongs then breaks down into various elements. In the diagram below, the Court sets forth these elements and sub-elements and characterizes each as either common (blue) or individual (orange).

RICO ELEMENTS: COMMON (BLUE) vs INDIVIDUAL (ORANGE)



As is visually evident, there are a host of issues and sub-issues within the RICO claims. As applied to Plaintiffs' allegations concerning the existence of two national enterprises that disseminated a set of standard falsehoods in marketing and distributing opioids, all of the elements except injuries are common, not individual. Many courts have so held in similar circumstances. *See, e.g.*, *Just Film, Inc. v. Buono*, 847 F.3d 1108, 1121 n.3 (9th Cir. 2017) (noting that the issues involved in proving a RICO violation "are appropriate for classwide litigation because they focus on" the defendants' conduct); *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 118 (2d Cir. 2013) ("[F]raud claims based on uniform misrepresentations . . . are appropriate subjects for class certification.") (citation and internal quotation marks omitted); *McMahon Books, Inc. v. Willow Grove Assocs.*, 108 F.R.D. 32, 39 (E.D. Pa. 1985).

Defendants argue that causation should be characterized as an individual issue, Doc. #: 1949 at 37, but in this case – as to these RICO claims – the characterization of causation as common, not individualized, is supported by law and fact. Legally, plaintiffs alleging RICO claims predicated on mail and wire fraud may show third-party reliance and "need not show, either as an element of [their] claim or as a prerequisite to establishing proximate causation, that [***they***] relied on the defendant's alleged misrepresentations." *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 661 (2008); *see also Brown v. Cassens Transp. Co.*, 546 F.3d 347, 357 (6th Cir. 2008). Factually, this Court has already held that the "[p]laintiffs have alleged sufficient facts to support a . . . direct chain of causation" involving third-party reliance. Doc. #: 1203 at 9–10 (listing steps in chain). Specifically, the Plaintiffs argue they suffered injuries because others (doctors, patients, etc.) relied on the Defendants' misrepresentations, enabling the Defendants to sell more opioids than the legitimate medical market could support. Whether there was such third-party reliance is a question susceptible to class-wide proof, justifying characterization of this issue as common.

The numerous common issues obviously predominate. The fact that the "injury" prong alone is plausibly individualized does not alter this conclusion. Predominance does not require that *every* element can be established by class-wide proof, *see Sandusky*, 863 F.3d at 468, and the predominance requirement is satisfied "when liability can be determined on a class-wide basis, even when there are some individualized damage issues," *Beattie v. CenturyTel, Inc.*, 511 F.3d 554, 564 (6th Cir. 2007) (citation and internal quotation marks omitted). Similarly, the fact that affirmative defenses may arise, and apply only to some class members, "does not compel a finding that individual issues predominate over common ones." *Bridging Communities Inc. v. Top Flite Fin. Inc.*, 843 F.3d 1119, 1125 (6th Cir. 2016) (citations and internal quotation marks omitted).

Given this analysis, it is not surprising that many courts within this Circuit have found that common issues predominate in the adjudication of specific RICO claims. *See Williams v. Duke Energy Corp.*, No. 1:08-CV-46, 2014 WL 12652315 at *14 (S.D. Ohio Mar. 13, 2014); *Lauber v. Belford High Sch.*, No. 09-CV-14345, 2012 WL 5822243 at *9 (E.D. Mich. Jan. 23, 2012) (bifurcating issues of liability and damages); *Gokare v. Fed. Express Corp.*, No. 2:11-CV-2131-JTF-CGC, 2013 WL 12094870 at *14 (W.D. Tenn. Nov. 22, 2013) (for settlement purposes). This Court also so concludes.

2. *CSA Issues*

The pleadings in this case, as discussed above, raise several specific issues arising out of the Controlled Substance Act for which movants seek certification: the nature of each Defendant's obligations under the Act and the question of whether each Defendant complied with those obligations. Doc. #: 1820-1 at 84. These issues may arise in the adjudication of a federal (RICO) claim and of various state-law claims. The Court finds that common issues predominate in the resolution of these two specific issues, standing alone. Applying the Sixth Circuit's holding in

Martin, the Court finds that both issues are "capable of resolution with generalized, class-wide proof" and "need only be answered once because the answers apply in the same way" across the Class. *Martin*, 896 F.3d at 414. The fact that these issues may be relevant to the pursuit of state-based legal claims that vary across the class, or to legal claims that entail the resolution of individualized issues of causation or damages, "does not mean that [these] individualized inquiries taint the certified issues." *Id.* On the contrary, the certified issues can be addressed without overlapping with other issues that may or may not be common. For example, the Summit County complaint sets forth that the CSA issues are relevant to, *inter alia*, its common law absolute public nuisance claim, Doc. #: 513 at ¶ 1010, and its negligence claim, *id.* at ¶¶ 1042, 1045, 1060. Resolution of the certified issues would speak to the duty and breach elements of a negligence claim, for example, without pretermitting non-class resolution of the causation and damage elements. Moreover, since the Court is certifying for classwide treatment only the specific issues identified, there are no "individualized inquiries that outweigh the common questions prevalent *within each issue*." *Martin*, 896 F.3d. at 414 (emphasis added).[8]

In sum, the Court finds that common issues predominate over individualized issues with respect to both the RICO claims and the CSA issues, with respect to each specifically-identified Defendant.

[8] Heeding the Sixth Circuit's guidance, the Court is aware of the potential Seventh Amendment concerns raised by issue class certification and "will take care to conduct any subsequent proceedings in accordance with the Reexamination Clause." *Id*. at 416–17. Of course, since the Court is certifying the class solely for purposes of negotiation, these concerns are not present. Nonetheless, the Court notes the Sixth Circuit's conclusion that, "if done properly, bifurcation will not raise any constitutional issues." *Id*. at 417 (citations and internal quotation marks omitted).

J. Rule 23(b)(3): A Class Action is a Superior Method of Adjudication

For a class action to be maintained, Rule 23(b)(3) requires the Court to determine that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). This requirement "is designed to achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Pipefitters Local 636 Ins. Fund v. Blue Cross Blue Shield of Michigan*, 654 F.3d 618, 630 (6th Cir. 2011) (alteration in original) (internal quotation marks omitted) (quoting *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 615 (1997)). Rule 23(b)(3) itself further enumerates four specific factors speaking to the desirability of a class suit. Fed. R. Civ. P. 23(b)(3)(A)–(D). Here, all cut in favor of certification of both the two RICO claims and two CSA issues as against all Defendants:

1. *The class members' interests in individually controlling the prosecution or defense of separate actions*. This MDL consists of nearly 2,000 individual actions by class members. That would appear to cut against class certification, as it seems that many class members are capable of, and are, litigating individually. However, the proposed class consists of more than 34,000 entities, meaning that a small fraction of them (fewer than 6% here in federal court) are litigating individually. The vast bulk of class members are not actively involved in opioid litigation. This factor cuts in favor of certifying a nationwide class. This is particularly true in the negotiation class certification context for two reasons: (a) any litigant interested in individually controlling its action can opt out and the proposed procedure will in no way interfere with that individual litigation, yet (b) negotiation class certification simultaneously engages absent class members in the negotiation and voting process. To the extent this factor favors individual control and involvement, the Court finds that the negotiation class will further that end, not impede it.

2. *The extent and nature of any litigation concerning the controversy already begun by or against class members*. As just noted, there are about 2,000 individual cases within this federal MDL and many more filed in state courts. Among those in coordinated pre-trial proceedings in this forum, a few have advanced toward bellwether trials, but all others are at earlier litigation phases. The proposed negotiation class will not displace or interfere with any of this on-going litigation. At the same time, this on-going litigation will resolve only a small quantity of the class's claims, as noted above, meaning that the extent of the on-going litigation is limited compared to the size of the class. This factor cuts in favor of certifying a nationwide negotiation class.

3. *The desirability or undesirability of concentrating the litigation of the claims in the particular forum*. The JPML has already coordinated the many pending cases in this forum. This factor therefore cuts in favor of certifying a negotiation class, as a class approach is an efficient means of handling the 2,000 individual matters that are here.

4. *The likely difficulties in managing a class action.* This prong is inapplicable to the proposed negotiation class, as the proposal is not for litigation or trial, but simply for settlement negotiations. *Amchem*, 521 U.S. at 620 (holding that where the plaintiffs' class certification "proposal is that there be no trial," it is unnecessary to "inquire whether the case, if tried, would present intractable management problems").

The Attorney General of the State of Ohio argues that a class action is not a superior form of adjudication because the claims are more properly the province of the States, not the cities and counties. Doc. #: 1973 at 4. The letter joined by roughly 40 Attorneys General implies the same point without explicitly saying so. Doc. #: 1951 at 3–4. If the Attorneys General believe they control their local governments' litigation, then they can attempt to foreclose it directly. To date,

they have made no effort in this Court to shut down their constituent entities' cases. Until they do so, this Court remains vested with more than 2,000 separate actions by cities and counties from throughout the United States. The Court cannot pretend these cases do not exist. The Judicial Panel on Multidistrict Litigation has ordered it to coordinate pretrial litigation in most of these cases and Article III requires it to resolve those directly filed here.

* * *

For the foregoing reasons, the Court finds that all of the class certification requirements are met with respect to the two RICO claims and two CSA issues, as to each relevant Defendant on each claim or issue. In reaching these conclusions, the Court makes clear that it has not certified these claims or issues for trial. Because of the limited nature of negotiation class certification, including the fact that no defendant is required to utilize this process, many Defendants in this MDL did not even file opposition briefs. The analysis in this Memorandum Opinion is in no way meant to foreclose any Defendant from making any argument in opposition to a later motion for class certification, if such a motion is ever made here or in another forum. The Court's Order will so hold.

IV. THE COURT WILL LIKELY BE ABLE TO FIND THAT THE ALLOCATION AND VOTING PLAN TREAT CLASS MEMBERS EQUITABLY RELATIVE TO EACH OTHER

Rule 23 requires judicial approval of any proposed class action settlement. Fed. R. Civ. P. 23(e). The Rule sets forth a two-step process whereby the Court first ascertains whether the settlement is sufficiently likely to be approved as to warrant sending notice of it to the class, Fed. R. Civ. P. 23(e)(1)(B)(i), and then, after a notice and objection period, the Court makes a final determination of whether the settlement is "fair, reasonable, and adequate," Fed. R. Civ. P. 23(e)(2). One of the factors the Court must consider in making these assessments is whether "the proposal treats class members equitably relative to each other." Fed. R. Civ. P. 23(e)(2)(D). This means that if a monetary settlement is reached, this Court will be required to find that the money is being allocated fairly among the class members.

At this stage in the case, no settlement has been reached. However, with the negotiation class certification proposal, the movants have identified the settlement allocation and voting plans up front. They have done so to provide information to each class member about its relative share of any settlements reached and its relative enfranchisement under this proposal, so as to make the class member's current opt-out opportunity as meaningful as possible. The allocation and voting plans are therefore fixed – class members will make opt-out decisions based on them – and they will not change if a settlement is reached. Given that this class certification order could set in motion an elaborate negotiation and settlement process, the Court has stated that it should make a preliminary determination of the equity of these plans, given that it "would be perverse – and an enormous waste of judicial and social resources – to launch this whole negotiation class only to later hold that the allocation scheme, identified at the outset, was inequitable *ab initio*." Doc. #: 2529 at 3.

The Court specifically focused on the fact that both the voting and allocation plans distinguish between: (1) putative class members that filed litigation arising out of the opioid epidemic by June 14, 2019 ("litigating entities"), Doc. #: 1820-1 at 52, and (2) those class members that had not filed such litigation ("non-litigating entities"). As noted above, 10% of any settlement achieved for the Class will be set aside to help defray the legal fees of the litigating entities alone, with any unused portion flowing back into the full class's recovery fund, Doc. #: 1820-1 at 95–96; another 15% of any settlement is set aside for two purposes, one of which is to help defray the litigation expenses of the litigating entities alone, with, again, any unused portion flowing back into the full class's recovery fund, *id*. at 96; the proposed voting structure requires separate supermajority approvals from different sets of litigating class members and non-litigating class members, *id*. at 53-55; and litigating entities primarily drafted the proposal. To assist the Court in evaluating these distinctions, and in lieu of sending notice to and seeking reactions from the whole class at this stage in the proceedings, the Court asked Special Master Cathy Yanni to file a report analyzing whether the proposed allocation and voting plans treat the non-litigating class members equitably. Doc. #: 2529.

On September 10, 2019, Special Master Yanni filed a 17-page report in response to the Court's request. Doc. #: 2579. The Court has carefully reviewed Special Master Yanni's thoughtful and thorough report and adopts her findings. As to the allocation plan, the Court agrees with Special Master Yanni's conclusion that the method for allocating the core class recovery (75% of the fund) reflects a lot of hard work and is a significant and eminently fair step toward resolution of these many cases. Nothing in the allocation model appears to skew toward any group other than those hardest hit by the opioid epidemic. The Attorney General of Ohio argues that the model favors large cities (many of which serve as Class Representatives), as opposed to smaller

hard-hit counties he identifies by name, Doc. #: 1973 at 5, but his understanding is incorrect. A review of the allocations to the counties he identifies demonstrates that the smaller, hard-hit counties appropriately receive more recovery per capita than larger counties that have been less-severely impacted.[9] Similarly, a handful of counties filed an objection to the plan, arguing that the counties hardest hit by the epidemic, as measured by the allocation tool, are not necessarily the same counties that have been forced to expend the most resources combatting the epidemic. Doc. #: 1958 at 6–7. The model sets aside 15% of the class's recovery in its Special Needs Fund to, *inter alia,* address precisely these sorts of possible problems. There are a variety of intricacies of the model – how counties and cities will divide their county's recovery; how to deal with cities with recoveries so small as to be impractical to distribute; how the model works when a county opts out but its cities do not, etc. – but despite opponents' contentions, Doc. #: 1949 at 19–23, none of these is fatal and the movants' approach to each – as reflected in the updated notice and FAQ documents – is thoughtful and defensible.

Separate from the fairness of the allocation tool governing 75% of the class's recovery, the Court agrees with Special Master Yanni's conclusions that there is no inequity created by setting aside funds to address the litigation costs and legal fees of the parties that filed the early cases. As she notes, the "litigating class members are responsible for, *inter alia*, launching this litigation in state and federal courts, generating the establishment of this MDL, pursuing bellwether cases, uncovering critical facts through the discovery process, and creating significant negotiating

[9] Application of the allocation tool at the case website shows that the large counties the Ohio Attorney General identifies have per capita settlement values of $2.79 (Cuyahoga); $4.46 (Franklin); and $3.43 (Summit), for an average of $3.56; the smaller counties on whose behalf the Attorney General protests have settlement values of $4.64 (Adams); $6.08 (Jackson); $2.65 (Perry); $6.15 (Ross); $5.68 (Scioto) and $3.01 (Vinton), for an average of $4.70, or 32% greater than the large counties.

leverage." Doc. #: 2579 at 7. Given these facts, if a settlement is reached, these early champions of the class will likely be able to demonstrate that they are eligible for fees and costs from a common fund and, indeed, it may be unfair to them to force them to bear these costs alone. *Id.* at 7–8. Additionally, as Special Master Yanni notes, all fees and costs in a class action must be adjudicated according to the procedures set forth in Rule 23(h) and this Court will carefully scrutinize each fee request, as well as the total amount of fees paid from the class's recovery to all of the many attorneys involved here – Class Counsel, the MDL leadership, litigating-entity lawyers, etc. – to ensure that the Class is not unduly taxed. *Id.* at 8. Importantly, the model clarifies that any monies in these separate pools that are not distributed to litigating entities would revert to the entire class.

The Court also accepts Special Master Yanni's conclusion that the voting plan – requiring separate sets of votes from litigating entities and non-litigating entities – does not treat the non-litigating counties unfairly. As she concluded:

> (1) all class members have the same franchise (one vote); (2) the vote-counting mechanism understandably ensures that any settlement is approved by a majority of the class, counted by head, by population, and by impact; (3) the vote-counting mechanism further ensures against the non-litigating class members approving a low settlement unacceptable to the litigating class members; (4) that assurance is defensible on the grounds that the litigating entities are the most knowledgeable about the value of the class's claims; and (5) the fact that nonlitigating entities must separately approve the settlement tempers concerns that the litigating entities will settle low to recover their costs, as does the fact that the litigating entities are likely to be able to spread their costs across the whole class as described above.

Id. at 13.

Finally, having found that neither the allocation nor voting mechanisms enshrine any fundamental intra-class conflict between litigating and non-litigating entities, Special Master Yanni concluded that a single set of class representatives and class counsel could represent the whole class, without the need for sub-classes. *Id.* at 13–17. The Court agrees.

V. THE NOTICE AND EXCLUSION PLANS ARE SUFFICENT

A. Notice

The moving parties submitted proposed notices and a notice plan, Doc. #: 1820-2, Ex. A, and Interim Class Counsel subsequently submitted updated versions of these documents. Doc. ##: 2583, 2583-1, 2583-2. The Court has carefully reviewed these documents and finds that they comply with the requirements of Rule 23 and that, as due process requires, they are "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections [or otherwise safeguard their interests]." *Vassalle v. Midland Funding LLC*, 708 F.3d 747, 759 (6th Cir. 2013) (citation and internal quotation marks omitted).

Rule 23(c) requires the Court in a class action under Rule 23(b)(3) to "direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort," and notes that such notice may be "by one or more of the following: United States mail, electronic means, or other appropriate means." Fed. R. Civ. P. 23(c)(2)(B). Here the notice will be sent by first-class United States mail to all class members. Doc. #: 2583 at 3–4. It will also be posted at the class website. *Id.* at 4. The notice will also be emailed to that sub-set of the class for which the notice administrator has email addresses. *Id*. at 4 n.1. The *method* requirements of Rule 23(c)(2)(B) are met.

The Rule further requires that the notice "clearly and concisely state in plain, easily understood language: (i) the nature of the action; (ii) the definition of the class certified; (iii) the class claims, issues, or defenses; (iv) that a class member may enter an appearance through an attorney if the member so desires; (v) that the court will exclude from the class any member who requests exclusion; (vi) the time and manner for requesting exclusion; and (vii) the binding effect

of a class judgment on members under Rule 23(c)(3)." Fed. R. Civ. P. 23(c)(2)(B)(i)–(vii). The notice packet contains a two-page notice along with a 13-page set of Frequently Asked Questions (FAQs), Doc. #: 2583-1, in a format recommended by the Federal Judicial Center, *see* Fed. Judicial Ctr., *Judges' Class Action Notice and Claims Process Checklist and Plain Language Guide* 8–9 (2010), https://www.fjc.gov/sites/default/files/2012/NotCheck.pdf. The two-page notice alone contains each of the seven pieces of information required by Rule 23 and the FAQs provide even more detailed information as to most. The *content* requirements of Rule 23(c)(2)(B) are met.

Beyond the basics, the Court notes, as discussed above, that the moving parties have gone to great lengths to make transparent the various aspects of this unique procedure – the allocation formula and its underlying components, the voting plans, etc. A class website, active since June, has provided a wealth of information to the putative class members and will continue to do so following certification. The moving parties have done a commendable job making transparent all of the moving parts of this novel procedure. The Court finds that the class members have been provided a wealth of pertinent information that will enable them to make informed decisions about whether to remain in or opt out of this Negotiation Class.

B. Exclusion

Rule 23(c)(2)(B) requires, for any class certified under Rule 23(b)(3), that the district court send notice to class members informing them "that the court will exclude from the class any member who requests exclusion," Fed. R. Civ. P. 23(c)(2)(B)(v), and specifying "the time and manner for requesting exclusion," Fed. R. Civ. P. 23(c)(2)(B)(vi). The Federal Judicial Center recommends that a form be provided to class members, *see Manual for Complex Litigation* (*Fourth*) §§ 21.311–21.312 (2004) [hereinafter *Manual for Complex Litigation*], and instructs that the form should "clearly and concisely explain the available alternatives and their consequences,"

id. at § 21.321. Exclusion notices should require "that class members (1) mail a letter or post card; (2) by a date certain; (3) to a specific address; (4) clearly identifying themselves and/or some information demonstrating their membership in the class" but "[c]lass members are not required to give reasons for opting out." 3 *Newberg on Class Actions* § 9:46. Rule 23 does not mandate a time period within which class members must exercise their exclusion right, but the *Manual for Complex Litigation* suggests that class members be given a "reasonable time" and states that courts "usually establish a period of thirty to sixty days (or longer if appropriate) following mailing or publication of the notice for class members to opt out." *Manual for Complex Litigation* § 21.321.

The movants propose that Class Members be required to fill out a designated Exclusion Request Form, Doc. #: 2583-2, and be given 60 days (until a date certain – November 22, 2019) to do so. Doc. #: 2583 at 5. The movants explain that the "form can be submitted to the Notice Administrator via either first-class mail or email." Doc. #: 2583 at 3. The Exclusion Request Form is part of the Notice packet and will be posted and distributed in the same manner as the Notice packet. *Id.* The movants further explain that:

> Exclusion Request Forms would not have to be notarized but, instead, would have to be executed with an averment, pursuant to 28 U.S.C. § 1746, that the city or county official has the authority to submit the exclusion request. Also, the form would contain an express acknowledgment of the consequences of opting out (including that the city or county will not share in any recovery achieved by the Class and that it may not be afforded an opportunity at a later date to revoke its opt-out request). Mandating use of a specific form for opting out should sharply reduce, if not eliminate altogether, both disputes as to whether opt-out requests comported Court-directed requirements as well as potential arguments about whether optouts genuinely understood the ramifications of their exclusion requests.

Id.

The Court has reviewed the Exclusion Request Form and finds that it meets the requirements of Rule 23. It clearly explains the ramifications of exclusion, and it provides exact

instructions about how and when to execute and return the form. The plan sufficiently protects the absent-class members' right to exclude themselves from this Class.

CONCLUSION

For the foregoing reasons, the Court certifies a Negotiation Class on the claims and issues identified, against the Defendants identified, and appoints Class Counsel. The Negotiation Class is authorized to negotiate settlements with any of the 13 sets of Defendants identified herein, on any of the claims or issues identified here, or those arising out of a common factual predicate. *See Moulton v. U.S. Steel Corp.*, 581 F.3d 344, 349 (6th Cir. 2009) ("The question [of whether a subsequent claim is barred] is not whether the definition of the claim in the complaint and the definition of the claim in the release overlap perfectly; it is whether the released claims share a 'factual predicate' with 'the claims pled in the complaint.'" (quoting *Olden v. Gardner*, 294 F. App'x 210, 220 (6th Cir. 2008))). *See generally* 6 *Newberg on Class Actions* § 18:19. If Class Counsel seek to utilize the Negotiation Class to negotiate against any other Defendants, they may later make a formal motion to amend the class certification order accordingly. As set forth in an accompanying Order, this Court does ***not*** authorize the Negotiation Class to negotiate on behalf of cities and counties against their State governments, as its proponents suggested. Doc. #: 1820-1 at 53. This puts to rest a concern raised by the Attorneys General. Doc. #: 1951 at 3.

As noted throughout, an Order accompanies this Memorandum Opinion.

/s/ Dan Aaron Polster
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

Dated: September 11, 2019

Outgunned No More? Reviving a Firearms Mass Tort Litigation

Professor Linda S. Mullenix
University of Texas School of Law

Precipitating Event

- U.S. Supreme Court, certiorari denied, *Remington Arms Co., L.L.C. v. Soto*
  - ___S.Ct. ___, 2019 WL 5875142(Mem.)(Nov. 12, 2019)
- On appeal from Connecticut Supreme Court:
  - *Soto v. Bushmaster Firearms Int'l LLC*
  - 331 Conn. 53, 202 Atl. Rptr. 3d 262 (March 19, 2019)
- Trial court: *Soto v. Bushmaster Firearms Int'l LLC*
  - No. FBT-CV-15-6048103-S (Conn. Super Ct. 2016)

Significance of Supreme Court Cert. Denial

- (1) Signaled non-engagement by Supreme Court in Second Amendment gun-related litigation
- (2) Allowed Connecticut *Sandy Hook* litigation to proceed
- (3) Exposed narrow ground upon which victims of gun violence might pursue relief
- (4) Resuscitated possibility of a mass tort litigation against the firearms industry

The Sandy Hook Litigation: Trial Court

- 2014 litigation by estate administrators of Sandy Hook elementary school massacre
- Wrongful death claims
- Seeking damages and injunctive relief
- Defendants: various Bushmaster Firearms and Remington Arms entities
  - Manufacturers, distributors, and retailers of Bushmaster XM15-E2S semiautomatic rifle used in the shooting
- Defendants invoked preemption immunity under the Protection of Lawful Commerce in Arms Act (PLCCA)

The Sandy Hook Litigation: Trial Court

- ***Ps claimed two exceptions under PLCCA***:
  - Negligent entrustment of a firearm to a civilian consumer an AR-15 style assault weapon suitable for use only by military or law enforcement personnel
  - Knowing violation of a predicate statute:
    - Connecticut Unfair Trade Practices Act (CUTPA)
    - Remington defendants knowingly marketed, advertised, and promoted the XM15-E2S for civilians to carry out military-style actions against perceived enemies
    - Offending marketing materials unethical, immoral, oppressive, unscrupulous

The Sandy Hook Litigation: Trial Court

- ***Granted defendants' motion to strike Ps' allegations***:
  - Allegations did not fit within common law theory of negligent entrustment
  - PLCCA barred Ps' claims sounding in negligent entrustment
  - Ps lacked standing to bring wrongful death claims predicated on CUPTA violations
    - Ps never entered into business relationship with Ds

The Sandy Hook Litigation: Connecticut Supreme Court

- ***Holdings***:
- 4 -3 decision, affirming in part and reversing in part (88 page opinion)
- Rejected Ps' theories resting on negligent entrustment
- Ps' claims generally precluded by Connecticut and PLCCA
- Ps had standing to prosecute claims under Connecticut law (CUPTA):
  - Connecticut law did not permit advertisements that promote or encourage violent criminal behavior
  - Legislature did not intend to bar Ps from recovering damages for personal injuries resulting from unfair trade practices

The Sandy Hook Litigation: Connecticut Supreme Court

- ***Connecticut Supreme Court on PLCCA preemption:***
  - PLCCA did not bar Ps' claims
  - Text and legislative history: no Congressional intent to extinguish traditional authority of Connecticut legislature or its courts
  - Core exercise of state police power: regulation of advertising that threatens public health, safety, and morals
  - CUPTA qualified as a "predicate statute" under PLCCA's third exception to blanket immunity
  - CUPTA general unfair trade practices statute of broad scope

Implications

- Expansive reading of PLCCA's "predicate statute" exception
- Opened the possibility of similar gun lawsuits based on state consumer protection and unfair trade practices statutes
- "Because all states have analogous unfair trade practices laws, the decision below threatens to unleash a flood of lawsuits nationwide that would subject lawful business practices to crippling litigation burdens"
  - Remington Arms, Petition for a Writ of Certiorari, No. 19-168, *Remington Arms Co., LLC v. Soto* (Aug. 1, 2019) at 4.

Firearms Litigation in Context

First Wave Gun Litigation 1990s-2005

- Suits by individuals and municipalities
- ***Claims***:
  - negligent distribution or marketing
  - making and selling defective firearms
  - deceptive advertising
  - contributing to a public nuisance
- ***Track record***:
  - Dismissals prior to trial
  - Few favorable jury verdicts
  - All but one overturned on appeal

Impact of the Big Tobacco Settlement (1998)

- State AG multistate settlement with Big Tobacco Ds in 1998
- Inspired filing of firearms litigation by 30+ municipalities against firearm Ds
- Growing concern by firearms industry re vulnerability to litigation
- Forecast of "next big mass torts":
  - Fast industry
  - Lead paint manufacturers
  - Firearms industry

Industry Reaction to Increasing Gun Litigation: Statutory Immunity from Suit

- Congressional enactment of Protection of Lawful Commerce in Arms Act (2005)(PLCCA)
  - Pub. L. No. 109-2, 119 Stat. 2095 (2005), codified at 15 U.S.C. § 7903
  - Broad protection to firearms Ds from liability to suit for crimes committed with their products
- 34 states enacted statutes providing blanket immunity to gun industry, in ways similar to PLCCA

PLCCA's Six Exceptions to Immunity

- **15 U.S.C. § 70903(5)(i)-(vi):**
- (1) knowing transfer of a firearm to be used in a crime of violence;
- (2) negligent entrustment or negligence per se by a seller;
- (3) knowingly violation a state or federal statute applicable to the sale or marketing of a product, manufacturer or seller of a product;
- (4) breach of contract or warranty in connection with purchase of the product;
- (5) defect in design of manufacture of the product;
- (6) Attorney General action to enforce the Gun Control Act or the National Firearms Act

Post-PLCCA Gun Litigation

- **<u>Plaintiff unsuccessful invocation of PLCCA exceptions, post-2005:</u>**
  - Negligent entrustment
  - Negligence per se
  - Design defects
  - Failure to warn
  - Breach of implied warranty of merchantability

PLCCA's Third "Predicate Statute" Exception

- **15 U.S.C. § 70903(5)(iii):**
- Permits actions "in which a manufacturer or seller of a [firearm or ammunition] knowingly violated a State or Federal statute *applicable* to the sale or marketing of the product, and the violation was a proximate cause of the harm for which relief is sought."
- P must present cognizable claim with knowing violation of a predicate statute: that is, statute that is *applicable* to the sale or marketing of firearms

Circuit Conflict in Interpretation of "Predicate Statute" Requirement

- **Broad interpretation: Second Circuit**
  - *City of New York v. Beretta*, 524 F.3d 384 (2d Cir.2008), *cert. denied*, 129 S. Ct. 1579 (2009)
  - Upheld constitutionality of PLCCA
  - PLCCA's predicate statute exception did not apply to New York Penal Law § 240.45
  - ***However***: nothing in PLCCA required any express language regarding firearms to be included in a statute in order for that statute to fall within the predicate exception
- **Connecticut Supreme Court reliance on *Beretta* in *Soto***

Circuit Conflict in Interpretation of "Predicate Statute" Requirement

- **Narrow Interpretation: Ninth Circuit**
  - *Ileto v. Glock, Inc.*, 565 F.3d 1126 (9th Cir. 2009)
  - PLCCA preempts general tort theories of liability, regardless of whether such theories are codified
  - Predicate exception did not apply to claims under Cal. Civil Code pertaining to nuisance, public nuisance, and negligence
  - "Applicable statute" language in PLCCA should be given narrow construction
- **Connecticut Supreme Court on *Ileto*:**
  - Rejected Ds' reliance on Ileto as dispositive of predicate exception issue in *Soto*
  - Ninth Circuit recognized that other statutes that regulate sale and manufacturing activities could qualify as predicate statutes

Modeling Mass Tort Litigation

Will Soto v. Remington Arms Revive the Possibility of a Firearms Mass Tort Litigation?

Sign-Posts of a Developing Mass Tort Litigation

- (1) Developments or changes in the law
- (2) Regulatory alerts, notices, or product recalls
- (3) Establishment of a winning track record of litigation and settlement awards
- (4) Increase in interest among the plaintiffs' bar in pursuing litigation
- (5) Emergence of a critical mass of similarly-situated claimants
- (6) Docket congestion

Sign-Posts of a Developing Mass Tort Litigation

- (7) Judicial receptivity towards aggregating and managing multiple claims litigation
- (8) Discovery of underlying facts and public dissemination of discovery materials
- (9) Development or maturation of underlying scientific or expert testimony in support of claims
- (10) Interest of state attorneys generals in pursuing relief on behalf of their citizenry
- (11) Agile strategic lawyering in response to changing litigation developments
- (12) Willingness of putative defendants and their insurers to come to the negotiation table

Modeling Mass Tort Litigation

Will Soto v. Remington Arms Revive the Possibility of a Firearms Mass Tort Litigation?

Factors Supporting Emergence of a Firearms Mass Tort

- (1) Developments and Changes in the Law
  - Liberal interpretation of PLCCA's predicate statute exception
  - Application to Connecticut consumer and unfair trade practices statute
- (2) Agile Strategic Lawyering in Response to Changing Litigation Developments

Factors Militating Against Emergence of a Firearms Mass Tort

- (1) Absence of Regulatory Alerts, Notices, or Recalls of a Defective or Harmful Product
- (2) Lack of a Winning Track Record of Firearms Litigation and Settlements
- (3) Absence of Docket Congestion
- (4) Absence of Judicial Interest in Aggregating and Managing Multiple Gun Litigation Claims
- (5) Unwillingness of Putative Defendants and Insurers to Come to the Negotiation Table

Factors Not Relevant or Not Yet Relevant

- (1) Questionable Interest of the Plaintiffs' Bar in Pursuing Gun Litigation
- (2) Absence of a Critical Mass of Similarly-Situated Claimants
- (3) Absence of Public Dissemination of Discovery Materials
- (4) Lack of Development of Probative Scientific or Expert Testimony in Support of Claims
- (5) Lack of Interest of States' Attorney Generals in Pursuing Relief on Behalf of their Citizenry

Conclusions

Will Soto v. Remington Arms Revive the Possibility of a Firearms Mass Tort Litigation?

- Curb your enthusiasm – at best, a very nascent (embryonic) mass tort litigation
- Connecticut has led the way to overcoming PLCCA's broad immunity to the firearms industry under PLCCA's third exception to blanket immunity
- Expansive application of predicate statute exception may open door to similar lawsuits under state consumer protection and unfair trade practice statutes
- Mass torts take a long time to develop
- Watch for settlement with municipalities in the Opiate MDL: a model for reviving municipal lawsuits against the firearms industry?

The End (Or Not)

Nos. 19-16636, 19-16708

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

EDWIN HARDEMAN,
Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court for the Northern District of California, Nos. 16-cv-00525 & 16-md-02741 (Chhabria, J.)

BRIEF OF *AMICI CURIAE* STATES OF NEBRASKA, IDAHO, LOUISIANA, NORTH DAKOTA, SOUTH DAKOTA, TEXAS, AND UTAH IN SUPPORT OF DEFENDANT-APPELLANT/CROSS-APPELLEE MONSANTO COMPANY SEEKING REVERSAL

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

RULES

OTHER AUTHORITIES

The States of Nebraska, Idaho, Louisiana, North Dakota, South Dakota, Texas, and Utah ("*amici* States") file this *amicus curiae* brief in support of Defendant-Appellant/Cross-Appellee Monsanto Company seeking reversal of the judgment of the U.S. District Court for the Northern District of California. In particular, the *amici* States' brief focuses on the district court's Pretrial Orders Denying Monsanto Company's Summary Judgment and *Daubert* Motions on General Causation (ER49) and Motion for Summary Judgment on Specific Causation (ER33).[1]

IDENTITY AND INTEREST OF THE *AMICI* STATES

Amici are the States of Nebraska, Idaho, Louisiana, North Dakota, South Dakota, Texas, and Utah. Agriculture is important in these States. The *amici* States are home to over 400,000 farms and ranches covering over 280 million acres. Last year, their farmers produced more than three billion bushels of corn and over 800 million bushels of soybeans adding billions to the economy. These farmers and

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the *amici* States are permitted to file an amicus brief without consent of the parties to the appeal or leave of the Court. All citations to the record are designated by "ER" and pertain to the Excerpts of Record filed by Monsanto Company in this appeal.

the crops they grow help feed a growing population, contribute to rural, state, and national economies, and directly and indirectly employ millions of people. The herbicide at issue in this case—glyphosate—helped farmers in these States, and across the country, accomplish these feats.

Glyphosate is an essential herbicide for farmers in the *amici* States. Glyphosate can control 300 different weeds and can be applied directly to growing crops engineered to be resistant to it. With glyphosate, farmers can manage weeds more effectively in less time and for less money. Better weed management also positively impacts crop yields by allowing the growing crops to reach yield potential. Producing higher yields with fewer costs not only benefits farmers in the *amici* States, but also related industries and downstream consumers. The *amici* States benefit because of the impact of agriculture on their economies and, especially, the economies in their rural areas.

Glyphosate also benefits the environment in the *amici* States. Glyphosate paired with glyphosate-resistant crops encourages the adoption of conservation tillage by farmers. The *amici* States benefit from conservation tillage because there is less soil erosion and runoff

from fields into surface waters of the States. Glyphosate is also less toxic and harmful than many other herbicides. Simply, glyphosate greatly benefits agriculture in the *amici* States and, in turn, the economies, environment, and people in those States.

Glyphosate has been used safely and effectively as a weed management tool in agriculture for over forty years. The overwhelming consensus from research and regulatory bodies is that glyphosate does not cause cancer or non-Hodgkins lymphoma ("NHL") in humans. The U.S. Environmental Protection Agency ("EPA") has repeatedly determined glyphosate is not likely to be carcinogenic to humans and is in the process of again renewing that determination. Regulatory bodies in other countries have reached similar determinations. But in 2015, the International Agency for Research on Cancer ("IARC")—seemingly out of nowhere—classified glyphosate as "probably carcinogenic to humans" and precipitated this case and thousands like it.

In this case, the plaintiff, Hardeman, presented experts who opined that glyphosate not only causes NHL in humans, but specifically caused Hardeman's NHL. The district court was skeptical and called these opinions "rather weak" and "shaky" but nonetheless found them

admissible under Federal Rule of Evidence 702 and the *Daubert* standard. The jury heard this expert evidence and, ultimately, rendered a verdict for Hardeman and against Monsanto Company.

Although the overwhelming evidence from national and international research and regulatory bodies shows glyphosate is not carcinogenic to humans, the judgment in this case threatens to undermine that evidence and curtail glyphosate from agricultural use in the *amici* States and the Nation. In response, farmers may have to resort to less effective, more expensive, and more toxic herbicides. This could impact crop yields, the economy, and the environment in the *amici* States. For these reasons, the *amici* States request this Court reverse the district court's judgment.

ARGUMENT

I. THE DISTRICT COURT ERRED WHEN IT MISAPPLIED THE *DAUBERT* STANDARD AND ALLOWED THE JURY TO HEAR UNRELIABLE EXPERT OPINIONS.

Production agriculture makes up the vast majority of glyphosate usage because of the economic, environmental, and time-saving benefits. If glyphosate were curtailed, agriculture in the *amici* States would be adversely impacted. The district court's decisions on the

admissibility of expert testimony on glyphosate being carcinogenic go beyond just this case because other users, like farmers in the *amici* States, greatly rely on glyphosate.

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) ("*Daubert I*"). Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. District courts play an important role in analyzing the relevancy and reliability of expert evidence before a jury hears the evidence at trial. *See Daubert I*, 509 U.S. at 589, 595.

In the case below, the district court engaged in two *Daubert* analyses at the general causation and specific causation phases. The district court repeatedly recognized the uphill battle Hardeman faced given the substantial evidence showing glyphosate was not carcinogenic to humans. Yet, each time, the district court opened the door for

Hardeman to present "shaky" and "rather weak" expert opinions to the jury. As demonstrated below, the district court erred at the general and specific causation phases based on the misapplication of the *Daubert* standard in this Circuit. If the district court's erroneous decisions admitting unreliable expert evidence are allowed to stand, then agriculture in the *amici* States will bear the brunt of these errors.

A. The District Court Erroneously Admitted "Shaky" And "Rather Weak" Expert Evidence On General Causation.

To determine the admissibility of expert testimony, the district court analyzes whether the expert testimony is sufficiently relevant and reliable under Federal Rule of Evidence 702 and the *Daubert* standard. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("*Daubert II*"). Although Federal Rule of Evidence 702 "*should* be applied with a 'liberal thrust' favoring admission", it "*requires*" that expert testimony "be both relevant and reliable." *Messick v. Novartis Pharmaceuticals Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (internal quotations omitted) (all emphasis added). Determining whether expert evidence is both relevant and reliable is key because "[e]xpert evidence can be both powerful and quite misleading because of

the difficulty in evaluating it." *Daubert I*, 509 U.S. at 595 (internal quotations omitted). In this regard, the district court "act[s] as a gatekeeper to exclude junk science that does not meet Federal Rule of Evidence 702's reliability standards." *Messick*, 747 F.3d at 1197.

This Circuit recognizes the importance of the task a district court confronts in determining whether scientific expert testimony is relevant and reliable. *See Daubert II*, 43 F.3d at 1315. Reliability requires the district court to "determine … whether the experts' testimony reflects 'scientific knowledge,' whether their findings are 'derived by the scientific method,' and whether their work product amounts to 'good science.'" *Id.* (quoting *Daubert I*, 509 U.S. at 590). This task may be more difficult when "the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability." *Daubert II*, 43 F.3d at 1316. Nonetheless, this Court explained:

> Our responsibility … is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not "good science," and occasionally to reject such expert testimony because it was not "derived by the scientific method."

Id. In a post-*Daubert* world, a federal judge's duty to act as a gatekeeper is essential.

This case, however, does not present a difficult dispute over a matter at the "very cutting edge of scientific research" or without "scientific consensus." Glyphosate has been "commercially available" since 1974 and is "widely used across the United States and much of the world." ER52. There have been a large number of scientific studies on the carcinogenicity of glyphosate—from case-control studies and meta-analyses to laboratory studies to a large cohort study. *See* ER62-ER73. The most recently published studies, the 2005 study and 2018 update to the Agricultural Health Study ("AHS"), which was a cohort study of more than 57,000 licensed pesticide applicators, found no association between glyphosate and NHL. *See* ER73 & ER88-ER89. The EPA also "does not currently consider glyphosate likely to cause cancer" and neither do other regulatory bodies, including those in Canada and parts of Europe.[2] The overwhelming majority of studies and regulators have found glyphosate is not carcinogenic to humans.

[2] *See* U.S. Environmental Protection Agency, *Glyphosate—Human Health*, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last visited Dec. 20, 2019).

Yet, the IARC classified glyphosate as "probably carcinogenic to humans" in 2015, which spawned the current litigation and thousands of other cases. *See* ER52-ER53. In this case, Hardeman relied "heavily" on this IARC classification and the district court recognized such reliance as problematic. ER49 & ER57. The district court explained IARC's classification of glyphosate as "probably carcinogenic to humans" meant there was only "limited" evidence that glyphosate causes cancer in humans and "sufficient" evidence in animals. ER58-ER59. Given the IARC classification was "too limited" and "too abstract," the district court correctly closed the gate to Hardeman's experts who only parroted the IARC's examination. ER60-ER61. The district court, however, further analyzed Hardeman's three remaining experts on the basis that these experts "went beyond" the IARC classification. ER51.

After the expert reports were exchanged but a few months before the *Daubert* hearing on general causation, the 2018 update to the AHS was published. *See* ER74. With this update, the district court had even greater evidence of "scientific consensus." As the district court stated, the update showed glyphosate was not likely causing NHL in humans:

> There is one large cohort study (the AHS), with results recently published in a well-regarded scientific journal, suggesting no association between glyphosate use and NHL. There is a series of case-control studies arguably suggesting an association, but a fairly weak one. There are limited data indicating that the association strengthens with greater exposure to glyphosate, but also data to the contrary. And there are legitimate concerns about the reliability of the data from all the studies. *Under these circumstances, all one might expect an expert to conclude is that glyphosate exposure is cause for concern, but not that glyphosate is likely causing NHL at realistic human exposure levels.*

ER88-ER89 (emphasis added). With regard to the evidence as a whole, the district court stated "the evidence of a causal link between glyphosate exposure and NHL in the human population seems rather weak" and "[t]he evidence, viewed in its totality, seems too equivocal to support any firm conclusion that glyphosate causes NHL." ER50. Because of this, the district court correctly described Hardeman's expert evidence as "shaky" and "rather weak". ER50, ER88-ER89, ER115.

The district court further described Hardeman's experts' opinions as being based on their identification of "at least a few statistically significant elevated odds ratios from case-control studies and meta-analyses" and "what they deem to a be a pattern of odds ratios above 1.0 from the case-control studies, even if not all are statistically significant[.]" ER116. Yet somehow, the district court called

admissibility a "close question" and admitted the expert testimony because Federal Rule of Evidence 702 "should be applied with a liberal thrust." *Messick*, 747 F.3d at 1196 (internal quotations omitted); ER56-ER57, ER115.

The district court misapplied this Court's *Daubert* standard, thereby lowering the bar for reliability. When there is only a "scintilla of evidence" or "a few statistically significant" studies that support a position, a district court should, as a gatekeeper, exclude those expert opinions as junk science—especially when the district court finds such opinions to be rather weak and shaky. *See Daubert I*, 509 U.S. at 596 ("[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment … and likewise grant summary judgment …."); Fed. R. Evid. 702 (requiring expert testimony to be based on "sufficient" data). The district court should have excluded all of Hardeman's expert testimony at the general causation phase as unreliable based on the overwhelming evidence showing no association between glyphosate and NHL. The district court's error gave credibility

to these unreliable expert opinions thereby threatening the agricultural use of glyphosate in the *amici* States.

B. The District Court Erroneously Admitted Expert Opinions On Specific Causation By Wrongly Elevating Art Over Science.

By opening the gate for junk science on glyphosate at the general causation phase, Hardeman's experts were able to "rule-in" glyphosate as a potential cause of his NHL at the specific causation phase. ER34-ER35. The district court, then, lowered the reliability bar even more at the specific causation phase.

At the specific causation phase, the district court again voiced skepticism and called it a close question that glyphosate caused Hardeman's NHL. ER33, ER38. And yet again the district court concluded the expert testimony was admissible:

> The Court may be skeptical of [Hardeman's experts'] conclusions, and *in particular of the assumption built into their opinions from the general causation phase about the strength of the epidemiological evidence*. But their core opinions—that [Hardeman has] no other significant risk factors and w[as] exposed to enough glyphosate to conclude that it was a substantial factor in causing [his] NHL—are admissible.

ER38 (emphasis added). The district court relied on *Messick* and *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017) as the

basis for admitting the expert evidence. ER36-ER37. The district court explained that while Hardeman presented "borderline expert opinions" such opinions were admissible in the Ninth Circuit because of a tolerance for specific causation opinions that "lean strongly toward the 'art' side of the spectrum" rather than the science side. ER37. The district court, however, misapplied *Messick* and *Wendell*.

Messick and *Wendell* dealt with different scenarios than the case at hand. In *Messick*, the expert relied "on his extensive clinical experience[,]" as well as "examination of the [plaintiff's] records, treatment, and history" to determine whether the plaintiff's condition met the "unique features" defining that particular medical condition. 747 F.3d at 1196-98. In reversing the district court's exclusion of this expert's testimony, this Court stated "[m]edicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a differential diagnosis." *Id.* at 1198.

In *Wendell*, the plaintiff had "an exceedingly rare cancer, with only 100 to 200 cases reported since it was first recognized." 858 F.3d at 1236. Moreover, this type of cancer was not widely studied. *Id.* ("It

is not surprising that the scientific community has not invested substantial time or resources into investigating the causes of such a rare disease."). In reversing the district court, this Court explained that sometimes there may not be "a plethora of peer reviewed evidence" especially with a "rare disease" and, thus, *Daubert* should not bar the testimony of "two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease at issue …." *Id.* at 1238.

Unlike the scenarios in *Messick* and *Wendell*, NHL is not a rare disease—there were over 74,000 new cases in 2019.[3] NHL is, unfortunately, a common type of cancer and has a number of known risk factors.[4] Moreover, unlike *Wendell*, glyphosate is a well-studied herbicide and there is a "plethora of peer reviewed evidence" that glyphosate does not cause cancer or NHL. *See* ER65-ER82, ER88-ER89.

The district court misapplied this Circuit's *Daubert* standard at both phases. The district court was not presented with a case where the

[3] American Cancer Society, *Key Statistics for Non-Hodgkin Lymphoma*, https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/key-statistics.html (last visited Dec. 20, 2019).

[4] *Id.*

disease was unique or rare or did not have a number of peer reviewed studies finding no association between glyphosate and NHL and, in turn, Hardeman's NHL. There was no reason for an expert's "art" to take precedence over "science" or "scientific consensus". The district court should have excluded Hardeman's expert testimony instead of opening the gate to shaky, weak, and unreliable opinions that glyphosate causes NHL and, more specifically, caused Hardeman's NHL. By admitting this unreliable expert testimony, the district court failed to protect the jury from misleading expert evidence and, thus, has adversely affected agriculture and farmers in the *amici* States.

II. THE DISTRICT COURT'S MISAPPLICATION OF THIS COURT'S *DAUBERT* STANDARD WILL HAVE REAL WORLD IMPACTS ON AGRICULTURE.

The district court's errors in admitting unreliable expert evidence that glyphosate causes cancer in humans has real world effects. The use of glyphosate paired with glyphosate-resistant crops is critically important as a weed control tool in agriculture. As demonstrated below, agriculture is vital to the country and the *amici* States. Because the district court let the jury be misled by unreliable expert testimony that

glyphosate causes cancer, agriculture and farmers in the *amici* States will bear the costs of the district court's erroneous evidentiary decisions.

A. Agriculture Is Important To The *Amici* States And Abroad.

From coast to coast, America's farmers and ranchers produce and raise crops and livestock on over 2 million farms covering more than 900 million acres.[5] Every person living in the United States benefits from agriculture and the industries related to it. The benefits of agriculture are many and far-reaching—from the economy to the kitchen table.

Agriculture significantly contributes to the national economy. In 2017, America's farmers contributed $132.8 billion to the United States' gross domestic product.[6] This number, however, does not include related industries. Related industries range from food and beverage manufacturers, retailers, and restaurants to textiles and apparel

[5] U.S. Dep't of Agric., 2017 Census of Agriculture, 7 (Table 1).

[6] U.S. Dep't of Agric., Econ. Research Serv., *Ag and Food Sectors and the Economy*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/ (last visited Dec. 20, 2019).

manufacturers and stores.[7] If these related industries are included, the overall contribution of the agricultural sector is higher—$1.053 trillion in 2017.[8] In turn, if America's farmers and ranchers are doing well, then the downstream consumers and their pocketbooks benefit.[9]

Likewise, agriculture benefits the global economy. In 2018, the United States exported $140 billion in agricultural products.[10] These exports resulted in a trade surplus, which has been ongoing since 1960.[11] The majority of agricultural goods exported are grains/feed, soybeans, livestock products, and horticulture products.[12]

There is also room for increases in agricultural exports. The world's population is expected to continue to increase from 7.7 billion

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[7] *Id.*

[8] *Id.*

[9] In 2018, Americans spent 12.9% of their household expenditures on food. *See id.*

[10] U.S. Dep't of Agric., Econ. Research Serv., *Agricultural Trade*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-trade (last visited Dec. 20, 2019).

[11] *Id.*; U.S. Congress, Joint Econ. Comm., *The Economic Contribution of America's Farmers and the Importance of Agricultural Exports*, 1 (Sept. 2013).

[12] *Supra* note 10.

persons today to 9.7 billion persons in 2050.[13] Due to the increases, there will likely be a larger demand for agricultural products and, thus, an increase in exports to those growing countries.[14]

Agriculture also creates and supports millions of employment opportunities in many different areas. These areas include insurance, transportation, technology, engineering, sales, repairs, and the food industry. In 2017, 21.6 million jobs were related to the agriculture and food sectors, which amounted to 11.0% of all employment in the United States.[15] This number includes approximately 2.6 million on-farm jobs.[16]

States also depend on agriculture for their economies. Every state has some type of agricultural production. Crop production, however, is

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[13] Press Release, Dep't of Econ. & Soc. Affairs, Growing at a slower pace, world population is expected to reach 9.7 billion in 2050 and could peak at nearly 11 billion around 2100, U.N. Press Release (June 17, 2019).

[14] *Supra* note 11 at 1 ("Ninety-five percent of the world's potential consumers live outside of the United States, and population growth in the decades ahead will be concentrated in developing countries. As these countries grow and their citizens' incomes rise, their demand for meat, dairy and other agricultural products will increase.").

[15] *Supra* note 6.

[16] *Id.*

mostly centered in the Midwest.[17] The top five States with the most crop sales are California, Iowa, Illinois, Minnesota, and Nebraska.[18] California's crop sales mostly come from horticulture, while the Midwest's crop sales mostly come from grains and oilseeds—corn and soybeans.[19] These crops also support livestock and poultry production by providing feed.[20] The top five States with the most livestock sales are Texas, Iowa, California, Nebraska, and Kansas.[21]

Agriculture is particularly important in the *amici* States. Nebraska, known as the Cornhusker State and the Beef State, is defined by agriculture.[22] Nebraska is home to 47,400 farms and ranches covering 91% of the State's total land area.[23] In 2017, Nebraska farmers and ranchers contributed $21 billion to the state's

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[17] U.S. Dep't of Agric., Econ. Research Serv., *Agricultural Production and Prices*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-production-and-prices/ (last visited Dec. 20, 2019).

[18] *Id.*

[19] *Id.*

[20] Nebraska Dep't of Agric., Nebraska Ag Facts Brochure, 17, https://nda.nebraska.gov/publications/ne_ag_facts_brochure.pdf.

[21] *Supra* note 17.

[22] *Supra* note 20 at 14.

[23] Nebraska Dep't of Agric., Nebraska Agriculture Fact Card (Feb. 2019), https://nda.nebraska.gov/facts.pdf.

economy, which was 5.7% of the United States' total.[24] Nebraska also had $6.4 billion in agricultural exports, which translated into $8.9 billion in additional economic activity.[25] Nebraska agriculture also supports 1 in 4 jobs in the state.[26]

Nebraska's top agricultural commodities are corn and cattle, which go hand in hand—corn is used as feed for many cattle operations.[27] Corn is an important feed for finishing cattle before processing because it improves the final beef product.[28] Iowa, Illinois, Nebraska, Minnesota, Kansas, and Indiana had the largest corn area forecasted to be planted and harvested in 2019.[29]

Like corn and cattle, soybeans are an important commodity. For 2019, Illinois, Iowa, Minnesota, North Dakota, Indiana, and Missouri had the largest soybean area forecasted to be planted and harvested.[30]

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[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Supra* note 20 at 12.
[29] U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., Acreage (June 2019), 6 (June 28, 2019).
[30] *Id.* at 15.

Soybeans are not only used in human food products, but also as feed for livestock and poultry.[31]

Another important crop is sugar beets. Sugar beets are used for sugar production.[32] Over half of the sugar produced in the United States comes from sugar beets.[33] Minnesota, North Dakota, Idaho, Michigan, Nebraska, and Montana are the largest sugar beet producers in the country producing millions of tons of sugar beets every year to be used in a wide range of products.[34]

Agriculture plays not only an important role in our country's history, but is essential to our country's and the *amici* States' futures. Agriculture and related industries in the *amici* States put food on the table, employ millions, and significantly contribute to the economy at all levels. It is imperative that agriculture and the inputs that fuel it be protected.

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[31] *Supra* note 20 at 18.
[32] *Supra* note 20 at 24.
[33] *Id.*
[34] *Supra* note 29 at 23.

B. Glyphosate Provides Numerous Benefits To Agriculture In The *Amici* States.

Glyphosate benefits agriculture in a substantial number of ways. Glyphosate was commercially introduced in 1974 and is now the most widely used herbicide in the world.[35] Part of its success has been the development of transgenic, glyphosate-resistant crops, which were introduced in 1996.[36] Glyphosate-resistant crops include alfalfa, canola, corn, cotton, soybeans, and sugar beet varieties.[37] Glyphosate-resistant crops allow a farmer to spray glyphosate on his or her fields to manage weeds without damaging the crops.[38] Weed management is essential to good and sustainable agriculture because pests, like weeds, "can reduce

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[35] Stephen O. Duke & Stephen B. Powles, *Mini-review Glyphosate: a once-in-a-century herbicide*, 64 Pest Mgmt. Sci. 319, 319 (2008).

[36] *Id.*

[37] U.S. Dep't of Agric., ERR-184, The Economics of Glyphosate Resistance Management in Corn and Soybean Production, 1 (April 2015).

[38] U.S. Dep't of Agric., EIB-208, Agricultural Resources and Environmental Indicators, 2019, 30 (May 2019) ("Herbicide-tolerant … crops are not damaged when they are sprayed with broad-spectrum herbicides (such as glyphosate or glufosinate) that damage most conventional varieties. Planting [herbicide-tolerant] crops allows farmers to use nonselective, broad-spectrum herbicides throughout the growing season (even after crop emergence).").

crop yields or the quality of production ...."[39] Weeds reduce crop yields or quality by competing with crops for the same resources of water, nutrients, sunlight, and space. The development of glyphosate-resistant crops "made weed management easy, efficient, economical and environmentally compatible—exactly what growers wanted."[40] Due to these benefits, the vast majority of the corn and soybeans planted are glyphosate-resistant.[41] For example, Nebraska farmers used some form of glyphosate on 85% of the area planted with corn and 92% of the area planted with soybeans in 2018.[42] And, most if not all, sugar beets planted are glyphosate-resistant.[43]

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[39] *Id.* at 35.

[40] Jerry M. Green, *The benefits of herbicide-resistant crops*, 68 Pesticide Mgmt. Sci. 1323, 1323 (May 2012).

[41] *Supra* note 38 at v & 30.

[42] U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Soybeans-Treated, Measured in Percentage of Area Planted, Average (2018)*, https://quickstats.nass.usda.gov/data/printable/3496DCDD-6C83-3E4F-A4E1-AAF41FC5DC78 (last visited Dec. 20, 2019); *see also* U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Corn-Treated, Measured in Percentage of Area Planted, Average (2018)*, https://quickstats.nass.usda.gov/data/printable/A18FA0E1-F27F-350E-B3B7-3B52B69B4B0C (last visited Dec. 20, 2019).

[43] Memorandum from Caleb Hawkins, Charmaine Hanson, & Dexter Sellers, EPA, to Khue Nguyen, EPA, 7 (Apr. 18, 2019), https://www.epa.gov/sites/production/files/2019-04/documents

Glyphosate paired with glyphosate-resistant crops has helped increase yields and lower production costs. The use of glyphosate-resistant crops allowed for easy, effective weed control and, in turn, resulted in better yields.[44] For example, Nebraska farmers harvested 111 bushels/acre of corn and 33 bushels/acre of soybeans in 1995 (prior to glyphosate-resistant crop introduction) compared to 182 bushels/acre of corn and 57 bushels/acre of soybeans in 2019, which is attributable to glyphosate and other variables.[45] Sugar beet yield increased 30% since glyphosate-resistant sugar beets were introduced.[46] These yield increases support more livestock and poultry to feed a growing world and, also, are used to make other human food products.

/glyphosate-response-comments-usage-benefits-final.pdf.

[44] U.S. Dep't of Agric., ERR-162, Genetically Engineered Crops in the United States, 12 (Feb. 2014) ("[B]y protecting the plant from certain pests, [genetically engineered] crops can prevent yield losses to pests, allowing the plant to approach its yield potential."); *supra* note 38 at 32.

[45] U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Corn, Grain & Soybeans-Yield, Measured in Bushels/Acre (1995)*, https://quickstats.nass.usda.gov/results/A3BAB75C-BEFF-3665-8DEF-8D0CBB7674D4 (last visited Dec. 20, 2019); U.S. Dep't of Agric., Nat'l Agric. Statistics Serv., *Quick Stats for Nebraska Corn, Grain & Soybeans-Yield, Measured in Bushels/Acre (2019)*, https://quickstats.nass.usda.gov/results/A490EBB2-26AD-383A-87F2-0944B690543B (last visited Dec. 20, 2019).

[46] *Supra* note 43 at 7.

Prior to glyphosate-resistant crops, glyphosate could not be directly sprayed onto growing crops because it would not only kill the weeds, but the crops.[47] Direct spraying of glyphosate onto glyphosate-resistant crops enabled farmers to better control weeds in an economical and environmentally-friendly way.[48] Farmers using this method saved money and time because glyphosate could be applied to control "essentially all weeds—300 weed species—at a wide range of growth stages with no recropping restrictions."[49] When the patent for glyphosate expired, the price fell as generics came on the market thereby resulting in more savings for farmers.[50]

Moreover, farmers saved on fuel and equipment. Because glyphosate covers a broad spectrum of weeds, farmers were able to

[47] *Supra* note 40 at 1324.

[48] For example, farmers are able to use spraying equipment to apply glyphosate after the crop has emerged from the soil instead of only being able to spray prior to crop emergence or having to use row cultivators after crop emergence.

[49] *Supra* note 40 at 1325.

[50] *Supra* note 38 at 38; *supra* note 37 at 1.

control weeds with "a single timely application …."[51] As such, the use of glyphosate may save passes over a field,[52] but even if:

> [Glyphosate-resistant] crops do not necessarily save passes over a field, … they do substitute herbicide applications for more expensive and more fuel intensive methods of weed management, such as intensive tillage practices or the use of herbicides that require physical incorporation into the soil. Also, with potentially fewer passes over the field, tractor and spraying equipment lasts longer, and this results in savings in machinery and equipment costs over the long term.[53]

These cost-savings are, in turn, passed down to other consumers and users. For example, "[l]ivestock producers constitute a large percentage of corn and soybean buyers and therefore are major beneficiaries of any downward pressure on crop price due to adoption of [genetically-engineered] crops."[54] If farmers have cost-savings, then those cost-savings are passed on to livestock producers and consumers.

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[51] Nat'l Research Council, The Impact of Genetically Engineered Crops on Farm Sustainability in the United States, 32 (The National Academies Press, 2010).

[52] Passes over a field refers to the number of times a farmer uses machinery—whether spraying or tilling—to accomplish a task. For example, spraying machinery may cover more ground than cultivators (spray booms versus cultivator wings), which means fewer passes over a field and less soil compaction or a farmer may have to be in the field fewer times to manage weeds.

[53] *Supra* note 51 at 151-52.

[54] *Supra* note 51 at 11, 166.

This is particularly important because, on average, Americans spend 12.9% of their household expenditures on food.[55]

The use of glyphosate-resistant crops has also benefited the environment. Glyphosate-resistant crops "have had fewer adverse effects on the environment than non-[glyphosate-resistant] crops produced conventionally."[56] By being able to spray glyphosate directly on glyphosate-resistant crops, farmers are able to eliminate the use of row cultivators to control weeds during the growing season and reduce the use of intensive cultivation practices after harvest or before planting.[57] Rather, farmers can engage in conservation tillage:

> Conservation tillage maintains a soil cover with crop residues, which has many positive environmental benefits, including reduced soil erosion and water pollution from nutrient and sediment run-off, protection from wind erosion and improved habitat for birds, mammals and microorganisms, as well as less consumption of fossil fuels and lower carbon dioxide emissions.[58]

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[55] *Supra* note 6.

[56] *Supra* note 51 at 3.

[57] Supra note 51 at 64 ("[T]he use of glyphosate allowed weeds to be controlled after crop emergence without the need for tillage to disrupt weed development before or after planting."). If a farmer could not directly spray crops after emergence, then row cultivators would be used to break up the soil between the rows of crops thereby uprooting weeds.

[58] *Supra* note 40 at 1326.

One form of conservation tillage is no-till, where "the soil and surface residue from the previously harvested crop are left undisturbed as the next crop is seeded directly into the soil without tillage."[59] The crop residue leftover, by conservation tilling, "builds organic matter, and there is less soil compaction because [herbicide-resistant] crop growers make fewer passes through the field with tractors than non-[herbicide-resistant] crop growers."[60] Conservation tillage "reduces soil loss from erosion, increases water filtration, and can improve soil quality and moisture retention …."[61] By increasing water filtration, conservation tillage reduces the amount of sediment and chemicals that runoff into surface waters.[62] Conservation tillage is used on 70% of soybean acres and 65% of corn acres.[63] Glyphosate and glyphosate-resistant crops have helped increase the use of conservation tillage, as well as crop production.[64]

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[59] *Supra* note 51 at 63.
[60] *Supra* note 40 at 1326.
[61] *Supra* note 51 at 68.
[62] *Supra* note 51 at 69.
[63] *Supra* note 38 at VI.
[64] *Supra* note 40 at 1326.

An added benefit of less tilling is using less fuel resulting in fewer emissions.[65] For example, moldboard plowing may use 5.29 gallons per acre of fuel whereas no-till practices may use 1.40 gallons per acre of fuel.[66] On a 120-acre field, moldboard plowing may use 635 gallons of fuel and no-till practices may use 168 gallons.

Glyphosate has other environmental benefits. Glyphosate is "more environmentally benign than the herbicides that it has replaced …."[67] It has "very low toxicity to mammals, birds, and fish" because "they do not have a shikimate pathway for protein synthesis …."[68] Glyphosate also "has low soil and water contamination potential because it binds readily to soil particles and has a relatively short half-life in soil …."[69]

Glyphosate is an important tool as part of an integrated and diverse weed management system.[70] Even with the emergence of

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[65] *Id.*

[66] *Id.*; *see also supra* note 51 at 151. A moldboard plow is a piece of equipment with curved metal plates pulled by a tractor to turn over the soil.

[67] *Supra* note 51 at 62.

[68] *Supra* note 51 at 29, 62.

[69] *Supra* note 51 at 29 & 70.

[70] *Supra* note 40 at 1328.

relatively few glyphosate-resistant weeds, glyphosate-resistant crops will be a mainstay because "[w]eeds that have evolved resistance to glyphosate have not eliminated the ability of glyphosate to control other weeds."[71] Because of its effectiveness on a broad spectrum of weeds, glyphosate will continue to be an herbicide that is part of a weed management system where resistance can be slowed or removed for the remaining 200+ weeds that glyphosate covers.[72] It is also cheaper and environmentally safer. Glyphosate will remain an important and effective weed management tool for farmers in the *amici* States.

Glyphosate has a beneficial impact on farmers, the economy, the environment, and the way of life in the *amici* States. If glyphosate were curtailed as a result of this case and the thousands of cases like it, there would be a palpable and adverse effect on agriculture in the *amici* States and abroad.

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[71] *Supra* note 40 at 1329.

[72] *Supra* note 44 at 32; Univ. of Nebraska-Lincoln, Inst. of Agric. & Nat. Res., *Multiple Herbicide Resistant Weeds and Challenges Ahead*, https://cropwatch.unl.edu/multiple-herbicide-resistant-weeds-and-challenges-ahead#:~:targetText=By%202014%2C%2029%20weed%20species,species%20in%20the%20United%20States (last visited Dec. 20, 2019) (providing there were 15 weed species resistant to glyphosate in the United States in 2014).

C. The District Court's Erroneous Evidentiary Decisions Threaten To Curtail The Important Use Of Glyphosate In Agriculture.

The importance of glyphosate in agriculture is undeniable. The beneficial impacts of glyphosate not only accrue to farmers and the *amici* States, but to the country and the world as a whole. The shelf life of glyphosate, however, may be limited if the district court's decisions to open the gate to unreliable and misleading expert testimony on the carcinogenicity of glyphosate on humans is left standing. As demonstrated below, the curtailment of glyphosate from agriculture will have real impacts not only to farmers and agriculture in the *amici* States, but the ripple effects of these impacts will be felt by every person.

Glyphosate is the most widely used herbicide in the country and the *amici* States. Because of its broad applicability, effectiveness, price, and environmental benefits, it is the herbicide of choice for most farmers in the United States. In 2018, farmers used some form of glyphosate on the vast majority of the areas planted with corn and soybeans.[73]

[73] *E.g.*, *supra* note 42.

Many herbicide-resistant crops, like corn and soybeans, are engineered to be resistant to only glyphosate.[74] Without glyphosate as a weed management tool, farmers in the *amici* States will have to resort to another herbicide or more likely a mixture of herbicides. These herbicides may be less environmentally-friendly and less effective on a broad spectrum of weeds, meaning farmers may need to use more herbicides to fill the gap left by glyphosate or make additional passes in the field. These other herbicides may also be more expensive and more difficult to use than glyphosate. This is because choosing "[glyphosate] often means reducing the use of less effective, more costly, and possibly more toxic herbicides although exceptions occur …. That substitution effect can produce cost savings as well as reductions in environmental and human health risks associated with chemical applications …."[75]

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[74] *Supra* note 51 at 29; *but see supra* note 38 at 33 ("Recently, new varieties of [genetically engineered] seeds that are tolerant of the herbicidal active ingredients dicamba and 2,4-D have been commercialized. It remains to be seen how the introduction of these technologies will affect the herbicide use and weed control decisions of U.S. farmers.").

[75] *Supra* note 51 at 149; *see also, supra* note 44 at 25 ("[G]lyphosate is significantly less toxic and less persistent than traditional herbicides …."); U.S. Dep't of Agric., AER-801, Adoption of Bioengineered Crops, 28 (May 2002) ("The herbicides that glyphosate replaces are 3.4 to 16.8 times more toxic" and "glyphosate has a half-life in the environment of

Additionally, farmers will have to change up their weed management program, which may take additional time and cost additional money.

The change to other herbicides may not only impact the environment, but also the economy. Farmers would likely need to spend more on herbicides for weed management, which in turn impacts downstream consumers of agricultural products, such as livestock and poultry producers, manufacturers, and supermarkets. In the alternative, if the market would not adjust to the increased costs of farmers' inputs, then the economies in the *amici* States—especially in the rural areas—may suffer.

Agriculture in this country, and the *amici* States, plays a prominent role in feeding the world and conserving the environment. "Agriculture must take advantage of any technology that provides more food to a hungry world by enabling better control of weeds and does not hurt the environment or human health."[76] Glyphosate is a jack of all trades in that regard—yields have increased since the introduction of glyphosate-resistant crops, the environment has benefitted, the

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47 days … compared with 60-90 days for the herbicides it commonly replaces.").

[76] *Supra* note 40 at 1330.

economy has benefited, and it is safer than other herbicides. All of these benefits are important to the *amici* States where agriculture is a valuable component of their identities.

Glyphosate is one of the most studied herbicides. It has repeatedly been found not likely to be carcinogenic to humans by the EPA, other regulatory bodies, and many scientific researchers. Tens of thousands of farmers have been using glyphosate as their herbicide of choice for over twenty years and maybe longer. Farmers in the *amici* States should not have to worry that glyphosate will disappear because the district court and the jury in this case bought into junk science. The district court's erroneous evidentiary decisions threaten the continued vitality of agriculture in the *amici* States. This Court should reverse the district court's judgment and exclude Hardeman's expert testimony on general and specific causation.

CONCLUSION

The district court's judgment should be reversed.

Dated: December 20, 2019.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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s/ *Maegan L. Woita*
MAEGAN L. WOITA

No. 19-16636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Monsanto Company,
Defendant/Appellant,

v.

Edwin Hardeman,
Plaintiff/Appellee.

Appeal from the United States District Court
for the Northern District of California
Nos. 3:16-cv-00525 (Hon. Vince Chhabria)

BRIEF OF THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF MONSANTO

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Court Rules

Regulations

Other Authorities

INTRODUCTION

The district court in this case erred. When regulating pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), EPA has long declared, "The label is the law."[1] For "[i]t is a violation of Federal law to use [a pesticide] in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). *See also* 40 C.F.R. § 156.10(i)(2)(ii). Every time EPA reviews and approves the label for a registered pesticide, it is making federal law. EPA's decisions must also run a gauntlet of judicial review. And the outcome of that administrative law and judicial-review process then applies to a pesticide's users. It also applies to a pesticide's manufacturer and sellers. It is unlawful for manufacturers and sellers to make claims on their labels that differ from what EPA approves. 7 U.S.C. § 136j(a)(1)(B).

States can generally restrict the sale or use of pesticides. But they cannot "impose or continue in effect any requirements ***for labeling*** or packaging ***in addition to or different from*** those required under this subchapter." 7 U.S.C. § 136v(a), (b) (emphasis added). Through its application of state common law, Plaintiff did exactly that. He claimed that Monsanto failed a legal duty to make additional statements on the label about alleged cancer risks associated with Monsanto's glyphosate

[1] *See, e.g.*, *EPA, Pesticide Registration Manual* (last updated April 2017), *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

pesticide—cancer risks that EPA has for decades concluded science does not support.

EPA reviewed and approved Monsanto's glyphosate pesticide label. That approved label was the law tailored to Monsanto's product. Yet Plaintiff asserted safety labeling requirements exist under California law in addition to and different from that required, reviewed, and approved by EPA. Plaintiff is wrong and his lawyers sailed directly into preempted territory in how they opted to try this case.

INTEREST OF THE UNITED STATES

The United States, through the Environmental Protection Agency (EPA), has responsibility for implementing and enforcing the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y. FIFRA generally requires that EPA must register a pesticide and approve its label before that pesticide may be distributed, sold, or used in any State. 7 U.S.C. § 136a. That label, once reviewed and approved by EPA, is controlling. States retain the power to restrict the sale, or use of pesticides within their borders, but they cannot "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(a), (b).

Plaintiff here sued the manufacturer of the pesticide Roundup®. This pesticide contains an active ingredient called glyphosate, which Plaintiff alleges

causes cancer. Plaintiff alleged state law causes of action relating to the manufacturer's failure of the common law legal duty to warn of the alleged risk.

Roundup is registered under FIFRA and its EPA-approved label does not contain a cancer warning. The United States has a strong interest in preserving Congress's express delineation of federal versus state authority, which ensures that the federal government can establish and maintain nationally uniform requirements for the labeling and packaging of pesticides.

The United States files this brief as of right pursuant to Federal Rule of Appellate Procedure 29(a)(2).

STATEMENT OF THE CASE

A. FIFRA

Congress created FIFRA through a series of enactments to regulate the labeling, sale, and use of pesticides, including herbicides. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991). As originally enacted in 1947, *see* ch. 125, 61 Stat. 163, FIFRA "was primarily a licensing and labeling statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). In 1972, Congress "significantly strengthened FIFRA's registration and labeling standards" in response to "environmental and safety concerns." *Id.*; *see also* Federal Environmental Pesticide Control Act of 1972 (1972 Amendments), Pub. L. No. 92-516, 86 Stat. 973. The 1972 Amendments effectively "transformed FIFRA

from a labeling law into a comprehensive regulatory statute." *Mortier*, 501 U.S. at 601 (quoting *Ruckelshaus*, 467 U.S. at 991). Congress has continued to amend FIFRA in response to experience gained in regulating pesticides. *See, e.g.*, Federal Pesticide Act of 1978 (1978 Amendments), Pub. L. No. 95-396, 92 Stat. 819; Food Quality Protection Act of 1996 (1996 Amendments), Pub. L. No. 104-170, Tit. II, 110 Stat. 1489.

Section 136a(c)(5) of FIFRA provides that EPA "shall register a pesticide" if the agency determines, in light of any restrictions placed on the pesticide's use, that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5). EPA has promulgated FIFRA regulations establishing the registration process. *See* 40 C.F.R. § 152 et seq. As part of that process, EPA must and does review and approve of the statements manufacturers propose to make on a label. *See* 40 §§ C.F.R 152.40-152.55. If EPA has reason to believe a pesticide product violates FIFRA's provisions, EPA may issue "stop sale, use, or removal" orders, 7 U.S.C. § 136k(a), the offending products may be seized and condemned, 7 U.S.C. § 136k(b), and the pesticide manufacturer may be subject to civil and

criminal penalties, 7 U.S.C. § 136l. *See* 7 U.S.C. 136j (identifying "[u]nlawful acts").

EPA is required to review each pesticide registration every fifteen years to ensure that each registration continues to satisfy FIFRA's standards. 40 C.F.R. § 155.40(a). EPA also must review and approve any significant change to the labeling or packaging of a FIFRA-registered product. *See* 7 U.S.C. § 136a(c); 40 C.F.R. § 152.44(a).

FIFRA establishes a program for federal-state cooperation in regulating pesticides. *See Mortier*, 501 U.S. at 601-602. Section 136v, captioned "Authority of States," sets forth key principles of that relationship. *See* 7 U.S.C. § 136v. Section 136v(a) recognizes that, as a general matter, States retain their historic authority to regulate pesticide sale or use, provided that a State does not permit a sale or use that FIFRA, or EPA's implementing regulations, prohibit:

> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

7 U.S.C. § 136v(a).

Nevertheless, to ensure a uniform nationwide regulation of pesticide labeling, Section 136v(b) forbids a State from imposing any additional or different requirements on pesticide labeling or packaging than those imposed by FIFRA:

> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v(b). Sections 136v(c)(1) through (c)(4) set out additional limitations on state-issued registrations. 7 U.S.C. § 136v(c)(2)-(4). In short, Section 136v provides that a State may prohibit the sale or use of any pesticide within its borders. Under specified conditions, a State may also allow a pesticide to be used within its borders for purposes other than those provided in the federal registration.

FIFRA defines the term "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." *Id.* § 136(p)(1). FIFRA defines "labeling" more broadly as:

> [A]ll labels ***and all other written, printed, or graphic matter***: (A) ***accompanying the pesticide or device at any time***; ***or*** (B) to which reference is made on the label or ***in literature accompanying the pesticide*** or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, and the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

Id. § 136(p)(2) (emphasis added).

FIFRA prohibits the sale and distribution of misbranded, unregistered, or adulterated pesticides and the use of any registered pesticide in a manner inconsistent

with its labeling. 7 U.S.C. § 136j(a)(1). One way a pesticide may be misbranded is if its label bears a statement that "is false or misleading." 7 U.S.C. § 136(q)(1)(A).

B. California's Proposition 65

Under California's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5–25249.14, known as Proposition 65, the Governor of California is required to publish a list of chemicals said to be known to the State to cause cancer. The contents are determined by certain identified entities, including EPA and the International Agency for Research on Cancer. Proposition 65 also prohibits any person in the course of doing business from knowingly and intentionally exposing anyone to the listed chemicals without a prior "clear and reasonable" warning. Cal. Health & Safety Code § 25249.6. This means that the warning must: (1) clearly say that the chemical involved is known to the State of California to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed to that chemical. 27 Cal. Code Regs. § 25601. California recognizes several ways to provide the mandated warning. Cal. Code Regs. § 25602.

C. History of Glyphosate Review and California's Glyphosate Listing[2]

EPA first reviewed the potential carcinogenic effects of glyphosate in 1985.[3] The reviewing panel concluded that glyphosate, was "possibly carcinogenic to humans," though this conclusion was subsequently amended to a lower risk category after the original data was reassessed. *Id.* at 1. In 1991, EPA reviewed additional glyphosate studies and concluded that the substance should be classified as having "non-carcinogenicity for humans." This designation supported EPA's re-registration of glyphosate in 1993.[4] EPA relied on this 1991 review in a series of glyphosate tolerance rulemakings occurring from 1997 to 2008. *See i.e.*, 62 Fed. Reg. 17,723 (1997); 67 Fed. Reg. 60,936 (2002); 69 Fed. Reg. 65,083 (2004).

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[2] In recounting the history of EPA's glyphosate review the United States cites to government reports and records. This Court may take judicial notice of such reports and records. *See Interstate Natural Gas Co. v. Southern California Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953) (recognizing that government records and reports are generally appropriate for judicial notice); Fed. R. Evid. 201(b)(2) (The court may judicially notice a fact that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

[3] *See* EPA Office of Pesticides & Toxic Substances, "Second Peer Review of Glyphosate," at 3 (Oct. 30, 1991), available at https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/417300-1991-10-30a.pdf.

[4] EPA Office of Pesticides and Toxic Substances, "Reregistration Eligibility Decision Glyphosate," (September 1993), available at https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf.

EPA revised its carcinogen risk assessment guidelines in 2005. The lowest risk category under the 2005 guidelines is "not likely to be carcinogenic to humans."[5] In 2015, during the last Administration, EPA's Cancer Assessment Review Committee reevaluated available glyphosate data, and classified glyphosate as "not likely to be carcinogenic to humans."[6] On December 12, 2017, EPA's Office of Pesticide Programs issued a paper entitled "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential."[7] EPA undertook this evaluation as part of its 15-year registration review. *Id.* at 12. The 2017 evaluation includes review of existing studies that registrants had not previously submitted to the Agency, as well as a comprehensive literature review. *Id.* at 20-22. In 2017, EPA concluded that "the strongest support" was for a conclusion that glyphosate is "not likely to be carcinogenic in humans." *Id.* at 143. This 2017 paper is part of EPA's glyphosate registration review process—a process that remains ongoing.

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[5] EPA Risk Assessment Forum, "Guidelines for Carcinogen Risk Assessment," at 2-57 (March 2005), available at https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.

[6] EPA Office of Chemical Safety & Pollution Prevention, "Glyphosate: Report of the Cancer Assessment Review Committee," at 10 (October 1, 2015), available at https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/EPA-HQ-OPP-2009-0361-0057.pdf.

[7] EPA Office of Pesticide Programs, "Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential," (Dec. 12, 2017), available at https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=OPP&dirEntryId=337935.

On July 7, 2017, California listed glyphosate as a substance regulated under Proposition 65, based on the International Agency for Research on Cancer's classification of the pesticide as "probably carcinogenic to humans." Because this listing triggered Proposition 65's warning requirements, many manufacturers that had been registered to use glyphosate reached out to EPA for guidance. Some specifically sought EPA's approval to amend their product labels to satisfy Proposition 65. EPA did approve a limited number of applications allowing the addition of a Proposition 65 glyphosate cancer warning to pesticide labels when requested. EPA did not, however, consider these statements to be "Human Hazard and Precautionary Statements" as administered in 40 C.F.R. § 152.156 Subpart D (156.60 *et seq.*). Because the statement was not a FIFRA required statement, and because it was framed as a statement about California's assessment, it did not receive the same level or review as other parts of the label. These label-change approvals, however, were erroneous because the proposed edits warned of a cancer risk that, according to EPA's assessment, does not exist.[8]

As a result, such a warning instead constituted prohibited misbranding. *See* 7 U.S.C. § 136(q)(1)(A) (defining "misbranded" to include representations that are "false or misleading in any particular"); § 136j(a)(1)(E) (establishing that it is illegal to sell a misbranded pesticide). *See generally* 40 C.F.R. § 152.112(f) (allowing EPA

[8] *See* n.6, *supra*.

approval of an application under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), only where "[t]he Agency has determined that the product is not misbranded").

In an August 7, 2019 letter, EPA informed all glyphosate registrants that EPA had concluded glyphosate is "not likely to be carcinogenic to humans."[9] EPA then stated that products bearing a Proposition 65 warning statement due to the presence of glyphosate are misbranded under FIFRA because such a statement is "false and misleading." *See* EPA August 7 Letter at 1. In support of the representation that glyphosate is "not likely to be carcinogenic," EPA cited to its 2017 glyphosate evaluation. *Id.*

D. Facts and District Court Proceedings

Plaintiff, Edwin Hardeman, who regularly used Roundup for many years beginning in the 1980's, was diagnosed with cancer in 2015. ER2294.[10] In 2016, Mr. Hardeman filed a complaint against Monsanto seeking compensatory, economic, and punitive damages. Mr. Hardeman brought common law claims based on Monsanto's alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing,

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[9] EPA Office of Chemical Safety & Pollution Prevention, Letter from Michael L. Goodis, Director, Registration Division to registrants of glyphosate (Aug. 7, 2019), available at https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf (EPA August 7 Letter).

[10] ER refers to the Excerpts of Record filed with Monsanto's Opening Brief. SER refers to the Supplemental Excerpts of Record filed with this brief.

advertising, distribution, labeling, and sale of Roundup. ER2280; ER2294. Plaintiff filed claims for (1) negligence; (2) design defect; (3) failure to warn; and (4) breach of implied warranty. ER2296-2306.

Monsanto filed a motion to dismiss, arguing that the first three claims were essentially "warnings-based" claims that were expressly preempted by FIFRA. *See Hardeman v. Monsanto Co.*, 216 F. Supp. 3d 1037, 1037-39 (N.D. Cal. 2016), ER117. Monsanto argued that Plaintiff's state-law claims sought to compel a labeling requirement that differed from the label approved by EPA. *Id.* The District Court denied the motion to dismiss, holding that none of the claims were preempted. The district court reasoned that Plaintiff's claims were not preempted because they were consistent with FIFRA. Because FIFRA requires a pesticide label to contain warnings adequate to protect health and the environment, California law similarly requiring warnings of risks is permissible. *Id.*

The district court then conducted a 19-day jury trial. Plaintiff dropped his implied warranty claim prior to trial and tried only his negligence, design defect, and failure to warn claims. During the course of trial, the Court held that Plaintiff's design defect claim relied solely on a consumer expectations test. *See* SER001. This had the effect of converting the design claim to a "warnings-based" claim. *Id.* As a result, all three claims that went to trial were based on a failure to warn theory.

Phase I of the trial concluded with the jury finding that Plaintiff had proved that his exposure to Roundup was a substantial factor in causing his cancer. Phase II concluded with the jury finding that Plaintiff proved "that Roundup's design was defective"; "that Roundup lacked sufficient warnings of the risk of [cancer]," and that "Monsanto was negligent by not using reasonable care to warn about Roundup's [cancer] risk." ER1680-1681. The jury awarded $5,267,634.10 in compensatory damages and $75,000,000 in punitive damages. *Id.* The Court subsequently reduced the punitive damages award to $20,000,000. ER10.

SUMMARY OF ARGUMENT

FIFRA prohibits States from imposing "any requirements" for pesticide labeling that are "in addition to or different from" those required under FIFRA. 7 U.S.C. § 136v(b). Federal law can preempt not only state statutes and regulations, but state common law claims based on duties sounding in tort. The plain terms of FIFRA's prohibition expressly preempt state pesticide labeling requirements, regardless of whether those requirements are expressed through positive enactments or common-law duties.

Under FIFRA, the label is the law. EPA approved the label for the pesticide/herbicide at issue here, Roundup, through a registration process that did not require a cancer warning. In fact, EPA has never required a labeling warning of a cancer risk posed by Roundup, and such a warning would be inconsistent with the

agency's scientific assessments of the carcinogenic potential of the product. Mr. Hardeman nevertheless sought damages under California common law, alleging that Monsanto had failed to adequately warn consumers of cancer risks posed by the active ingredient in Roundup. FIFRA therefore preempts Mr. Hardeman's claims to the extent that they are based on the lack of a warning on Roundup's labeling.

ARGUMENT

FIFRA preempts state tort claims that would subject pesticide manufacturers to inconsistent and additional product labeling requirements.

A. Section 136v(b) preempts State common-law duties that would impose requirements for labeling "in addition to or different from" those required under FIFRA.

Section 136v(b) broadly and expressly prohibits "any requirements for labeling" that are "in addition to or different from" those that FIFRA imposes. 7 U.S.C. 136v(b). Section 136v(b)'s plain text does not distinguish among state labeling requirements based on their origin in a state legislature's enactment of statutes, a state agency's promulgation of rules, or a state court's articulation of common-law standards of care. *See Bates v. Dow Agrosciences LLC*, 544 U.S., 431, 443 (2005). And thus a court's articulation of common-law standards of care can be preempted just like a legislative or regulatory labeling requirement. *Id.*

Mr. Hardeman's failure to warn claims fall within the express preemptive scope of FIFRA. This scope is defined through a two-part test. *See id.* at 444. ***First***,

the state law "must be a requirement ***'for labeling or packaging'***; rules governing the design of a product, for example, are not preempted." *Id.* (quoting 7 U.S.C. § 136v(b)). ***Second***, the state law "must impose a labeling or packaging requirement that is '***in addition to or different from*** those required under [FIFRA].'" *Id.* (quoting 7 U.S.C. § 136v(b)). Thus, although FIFRA does not prevent a State from making the violation of federal labeling requirements a state offense and imposing separate sanctions, States cannot impose distinct labeling requirements. *See id.* at 442. Mr. Hardeman's nevertheless based his failure to warn claims on the existence of just such preempted requirements.

First, Monsanto notes that Mr. Hardeman argued to the jury throughout the District Court trial that Monsanto's common law duty included labeling obligations. Monsanto Opening Br. at 25-26. This representation comports with the United States' review of the closing arguments.[11] During his closing statement, counsel declared:

> And one of those requests for admission is that Monsanto says - - they admit, they have never warned that Roundup causes cancer. It's not on the label, Ladies and Gentlemen.

SER28. During his recitation of the scientific evidence counsel followed with:

> Let's go to the animal [studies]. We heard - - remember Dr. Portier testified in Phase One about the mice and rats? The first one, *Knezevich*

[11] The United States has not reviewed all 21 volumes of the trial transcript but our spot review of the record has revealed nothing that would seem to undermine the basic parameters sketched above as to how this case was tried.

> *& Hogan*, 1983 - - this is before Mr. Hardeman ever started spraying Roundup - - when that study came out originally in 1983, if Monsanto had done the right thing and put a warning on the label, we wouldn't be here. We wouldn't be here. Instead, they didn't.

SER30. And finally, when discussing how Monsanto should react to those studies counsel said:

> What is Monsanto's response when they are told that it is - - it is a Category C oncogene[12]? A responsible company would first say, should we take this off the market? Or should we test it? Or should we put a warning on it that it is an oncogene? It is going to cause cancer. They don't do anything.

SER35.

Second, FIFRA defines "label" to include "written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." 7 U.S.C. § 136(p). This definition clearly includes the warnings that counsel referenced at trial. Indeed, in its closing argument, Mr. Hardeman's counsel did not advance any specific examples, ***other than a label warning***, to illustrate how Monsanto could have warned Mr. Hardeman of the cancer risk allegedly posed by Roundup. *See* SER28, 30, 35; https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

Third, even if Mr. Hardeman did raise an argument that Monsanto might have provided a warning someplace other than Roundup's labeling, that does not save Mr.

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[12] An "oncogene" is "a gene found in the chromosomes of tumor cells whose activation is associated with the initial and continuing conversion of normal cells into cancer cells." https://medical-dictionary.thefreedictionary.com/oncogene.

Hardeman's case from preemption. Where a claim relies, even in part, on a prohibited argument, this raises questions of whether the trial record was so infected that the case must be remanded for retrial. *See Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 733 (9th Cir. 1999) (remanding jury award of damages for tortious interference where two of the three statements Plaintiff relied upon could not violate the Lanham Act or state defamation standards as a matter of law, and damages based on the third statement could not be isolated in the record), *overruled on other ground by Lexmark, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). Even if alternate, non-"label" or non-"labeling" warnings could satisfy Monsanto's common-law duties, remand and retrial is still appropriate. Plaintiff's label theory is inextricably intertwined with the evidence relied on by the jury to establish the elements of Plaintiff's claims.

Notably, Mr. Hardeman did not merely seek a label warning that is "different from" EPA's labeling requirements for glyphosate. He added a glyphosate cancer warning to Roundup that EPA rejects. Following California's Proposition 65 listing in 2017, certain companies that were registered to sell and distribute glyphosate sought EPA's approval to amend the labels of their products to include a Proposition 65 cancer warning. Though there were implementation mistakes at an earlier stage, EPA ultimately rejected those warnings. On August 7, 2019, EPA sent a letter to all glyphosate registrants reiterating its disagreement with the International Agency for

Research on Cancer's assessment. A 2017 evaluation of glyphosate by EPA scientists continues to conclude it is "not likely to be carcinogenic to humans." *See* August 7, 2019 letter.

In the 2017 evaluation, EPA specifically considered and rejected the International Agency for Research on Cancer's assessment.[13] Thus, in its August 7 letter, EPA warned that any pesticide products with labels ***bearing*** the Proposition 65 warning due to the presence of glyphosate ***would be deemed misbranded*** pursuant to section 2(q)(1)(A) of FIFRA. The Proposition 65 warning therefore makes a product misbranded because it is misleading.

Mr. Hardeman's alleged legal duty to warn nevertheless required a glyphosate cancer warning on a Roundup label. That not only required a different label (a requirement preempted by FIFRA)—it would almost certainly compel Monsanto to produce a misleading label warning very much at odds with EPA's scientific assessment of the carcinogenic potential of glyphosate, similar to the Proposition 65 warning already rejected by EPA.[14] There is no dispute—nor could there be any

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[13] *See* n.7, *supra*; 2017 study at 13, 23, 32-33, 63-64, and 146.

[14] Distinct from express preemption, implied preemption occurs where "it is impossible for a private party to comply with both state and federal law." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372–373 (2000) (internal quotation marks omitted). Implied preemption would also bar Mr. Hardeman's tort theory, to the extent his theory is based on a labeling requirement. *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (discussing implied preemption standard). We acknowledge, however, that even in the face of EPA's consistent historic assessment of the cancer

dispute—that FIFRA does not require a warning on Roundup's label that glyphosate causes cancer. To the extent that Mr. Hardeman's theory at trial was tied to Monsanto's failure to include a mandatory state-law-based glyphosate cancer warning on Roundup labels, such a warning is different from the requirements that FIFRA imposed for the labeling and packaging of this product and therefore a legal nullity.

B. The District Court's analysis is erroneous.

In denying Monsanto's motion to dismiss, the District Court held that a state-required glyphosate cancer warning was essentially no different from FIFRA's requirement that label warnings are "adequate to protect health and the environment." *Hardeman v. Monsanto Co.*, 216 F.Supp.3d 1037, 1038 (N.D. Cal.). The District Court compared this general FIFRA standard to California's general strict liability and negligence standards that require a manufacturer to warn of known risks. *Id.* This comparison misses the thrust and full import of FIFRA's preemption provision. It also ignored the fact that EPA had many times addressed the carcinogenic potential of glyphosate ***in particular*** and determined that glyphosate is not likely to be carcinogenic to humans.

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risk posed by glyphosate, EPA mistakenly approved glyphosate cancer warnings on at least two prior occasions. This Court does not need to reach implied preemption, however, because the claims as to labeling and packaging are expressly preempted.

First, in order to avoid federal preemption under FIFRA, it is not enough for a state law merely to be advancing ***similar*** policies or interests. 7 U.S.C. § 136v. Instead, where California general common-law standards impose any inconsistent labeling or packaging requirement, the California common-law claims are be preempted, ***even if the standard supporting those claims is phrased similarly to the standard imposed by Congress through FIFRA***.

Moreover, the potential that glyphosate is carcinogenic to humans is not something that EPA has ignored. EPA has studied and expressly addressed the carcinogenic potential of glyphosate a number of times over the past three decades, *see supra* Statement of the Case § C. And EPA continues to assess it. *See* Glyphosate Proposed Interim Registration Review Decision; Notice of Availability, 84 Fed. Reg. 19782 (May 6, 2019). Through FIFRA, Congress determined that EPA should make these scientific judgments for the nation as a whole. States may, of course, restrict or prohibit the sale or use of pesticides in the State if they disagree with EPA's assessment. But States are prohibited from second-guessing EPA's determination of what risks should be reflected on pesticide labeling. 7 U.S.C. § 136v(a), (b).

Second, the District Court also suggested that EPA's actions under FIFRA were insufficiently formal to trigger preemption. *Hardeman*, 216 F.Supp.3d at 1038-39. That is incorrect. The EPA approved label is a very formal affair that is

the foundation of any FIFRA preemption argument, and that label (and the associated registration process) establishes "requirements" sufficient to support a preemption analysis. The process of registering a pesticide is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide, where it will be used, the amount, frequency, and timing of its use and storage-related issues. *See* 40 C.F.R. § 152.40-152.55 (Registration Procedures). This process includes evaluation of human health risks, including review of aggregated risks through food, water and residential exposure as well as occupational risks. *See* 40 C.F.R. § 152.112; Pesticide Registration Evaluation Process available at https://www.epa.gov/pesticide-registration/about-pesticide-registration#label; *see also* EPA Pesticide Registration Manual available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

Every pesticide product label, including the Roundup label, is reviewed, and must be approved, as part of this process. And EPA seeks to ensure that labels provide clear directions for effective product performance while minimizing risk to human health and the environment. Once a product is registered, EPA posts the approved labels. *See* https://www.epa.gov/pesticide-labels/pesticide-product-label-system-ppls-more-information. Thereafter, "[t]he label is the law." *See, e.g., Introduction to EPA, Pesticide Registration Manual* (last updated April 2017), *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-

manual. And the Supreme Court has recognized that such premarket agency approvals are sufficient to trigger preemption. *See generally Riegel v. Medtronic, Inc.*, 552 U.S. 320, 323 (2008) (holding that premarket approval of individual medical devices were "requirements" sufficient to trigger preemption under the Federal Food, Drug, and Cosmetic Act (FDCA).

Third, the District Court incorrectly stated that Mr. Hardeman's complaint was based on "Monsanto's alleged violation of FIFRA." *Hardeman*, 216 F.Supp.3d at 1038. This is incorrect, too. Mr. Hardeman alleged neither a FIFRA claim nor a claim under the Food, Drug, and Cosmetic Act.

Congress provides for such challenges to the EPA-approved tolerance levels and labels of any Roundup ingredient. For example, individuals may file a petition challenging a pesticide registration action in federal district court. 7 U.S.C. § 136n(a). The label approval is part of such a registration action. EPA must determine that the human dietary risk from pesticide residues in food is consistent with safety standards from the FDCA. *See* 7 U.S.C. 136(bb)(2). And the tolerance is the maximum residue of a pesticide that can legally be present in food or feed. 21 U.S.C. § 346a(a). At the conclusion of these processes, glyphosate labels could have been challenged through FIFRA's judicial review process. Individuals might also petition to request amendment of a tolerance level. *See* 21 U.S.C. § 346a(d); 40

C.F.R. § 180.7. But Mr. Hardeman did not allege either a FIFRA or an FDCA violation regarding glyphosate—neither before EPA nor the district court.

C. FIFRA's preemption of state-law labeling requirements is broad and no exception applies here that would allow Mr. Hardeman's claims to proceed.

With respect to registered product labels, the FIFRA preemption provision is sweeping. It preempts any state law that "would impose a labeling requirement inconsistent with those established by FIFRA." *Worm v. American Cyanimid Co.*, 970 F.2d 1301, 1308 (4th Cir. 1992). A state may impose different or additional ***remedies—or bar or restrict a pesticide use entirely***—but it may not impose different or additional labeling requirements. *Bates*, 544 U.S. at 448.

Despite this broad scope, the Supreme Court has recognized that the FIFRA preemption provision is not unlimited. It did not reach state-law design-defect claims where the particular claim "was not a 'requirement for labeling or packaging' for purposes of FIFRA and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case." *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 491 (2013), citing *Bates*, 544 U.S. at 431, 443–444. But that is inapplicable here.

In *Bates*, a group of farmers brought claims under Texas law. They alleged that a pesticide had damaged their crop. On that issue, Congress's 1978 FIFRA amendment had allowed EPA to ***waive*** data requirements pertaining to efficacy and

so approve labels without examining efficacy claims. *Bates*, 544 U.S. at 440. *See also* 7 U.S.C. § 136a(c)(5). EPA invoked this authority, and announced it was waiving efficacy review. *See* 44 Fed. Reg. 27,932 (1979); 40 C.F.R. § 158.640(b) (2004).

When reaching its decision, the Court recognized that FIFRA did not preempt the state-law claims seeking an efficacy-based warning, in part, because EPA did not evaluate the efficacy of the product at issue. *Id.* at 450. So EPA had not—by its non-review of the pesticides' efficacy claims—established a legal standard for state law to conflict with. Here, by contrast, Mr. Hardeman seeks to apply state law to impose a human-health warning. And carcinogenicity is a risk that EPA indisputably ***does (and did)*** evaluate under FIFRA. *See supra* Statement of the Case § C. That is why the farmers' claims were not preempted. *Id.* at 447.

This distinction between efficacy-related label statements and health-related label statements is consistent with other Supreme Court decisions. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497-498 (1996), the Court considered the reach of a similar preemption provision in part of the FDCA. The FDCA, too, provides that no State may establish any requirement relating to the safety or effectiveness of a medical device "which is different from, or in addition to" a requirement mandated by the FDCA. 21 U.S.C. § 360k(a). In *Lohr*, the Court concluded that "general federal regulations governing the labeling and manufacture of all medical devices"

under the FDCA did not necessarily preempt all state tort claims of general applicability. *Id.* at 497-98. But that state tort requirements would be preempted when inconsistent with the FDA's "'specific counterpart regulations or . . . other specific requirements applicable to a particular device'" and its safety. 518 U.S. at 497-498 (quoting 21 C.F.R. § 808.1(d)).

In another case, the Court applied that rule. It held that the FDCA preempted state claims when the "Federal Government ha[d] established requirements applicable to" the particular medical device in question. *Riegel*, 552 U.S. at 321. Thus, under both statutes, the Court has recognized that where the agency had not established specific standards on point, state law claims were not preempted. Nevertheless, in the sphere of regulation where an agency has acted, states cannot impose additional requirements.

As previously noted, EPA has authority over pesticide labels and packaging. *See* 7 U.S.C. §§ 136a, 136q. EPA is required to ensure that labels are not misbranded, and was required by Congress to protect the public from the dissemination of false or misleading information. *See* 7 U.S.C. § 136(q)(1)(A); 40 C.F.R. § 152.112(f). EPA may not approve a pesticide's introduction into commerce unless the Administrator finds that the pesticide "will not generally cause unreasonable adverse effects on the environment" when used in accordance with any EPA-imposed restrictions and "with widespread and commonly recognized

practice." 7 U.S.C. § 136a(c)(5)(D). "Unreasonable adverse effects on the environment" are defined to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). And there is no exception to the bedrock requirement that EPA assess health impacts during the pesticide registration process—unlike EPA's ability to opt out of efficacy review.

In fact, forty-four versions of the label for the original formulation of Roundup have been accepted by EPA since 1991. EPA most recently approved the Roundup label in 2009.[15] In EPA's August 7, 2019 letter to glyphosate registrants, EPA clearly expressed its position that a strong glyphosate cancer warning on a pesticide label is misbranding.

Finally, legislative history reveals no Congressional intent to preserve tort actions related to labeling requirements that address the health effects of a product. To the contrary, the Committee Reports supporting Congress's 1972 overhaul of FIFRA contain statements expressing an intent to provide for broad preemption of state requirements respecting pesticide labels. The House Committee Reports states, with reference to Section 136v(b), that "the Committee has adopted language which is intended to completely preempt State authority in regard to labeling and

[15] A list of approved labels is available by searching the "Product" field of EPA's Pesticide Product and Label System for "Roundup." *See* https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

packaging." H.R. Rep. No. 511, 92d Cong., 1st Sess. 16 (1971). The Senate Committee Report expresses a similar intent, stating "[Section 136v(b)] preempts any State labeling or packaging requirements differing from such requirements under the Act." S. Rep. No. 838, 92d Cong., 2d Sess. Pt. 1, at 30 (1972). Those statements suggest that Congress envisioned that all state labeling or packaging "requirements"—whatever the form—would be preempted.

CONCLUSION

For all of the foregoing reasons, Mr. Hardeman's claims of failure to warn in Monsanto labeling are preempted. The judgment of the district court should be reversed and this case should be either dismissed or, in the alternative, remanded.

Respectfully submitted,

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THE "ANY EXPOSURE" THEORY: AN UNSOUND BASIS FOR ASBESTOS CAUSATION AND EXPERT TESTIMONY

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Over the years asbestos litigation has morphed into a tort world all of its own.[1] Courts developed entire sets of rules in an attempt to manage efficiently their substantial asbestos dockets,[2] in the process dispensing with

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1. *See* Griffin B. Bell, *Asbestos Litigation and Judicial Leadership: The Courts' Duty to Help Solve the Asbestos Litigation Crisis*, BRIEFLY, June 2002, at 1, 4; Mark A. Behrens, *Some Proposals for Courts Interested in Helping Sick Claimants and Solving Serious Problems in Asbestos Litigation*, 54 BAYLOR L. REV. 331, 336-42 (2002); Paul F. Rothstein, *What Courts Can Do in the Face of the Never-Ending Asbestos Crisis*, 71 MISS. L.J. 1, 4-9 (2001).

2. *See In re* Combustion Eng'g, Inc., 391 F.3d 190, 200 (3d Cir. 2004) ("For decades, the state and federal judicial systems have struggled with an avalanche of asbestos lawsuits."). The United States Supreme Court has described the litigation as a "crisis." Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 597 (1997). Through 2002, approximately 730,000 claims had been filed. STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION xxiv (RAND Inst. for Civil Justice 2005), *available at* http://www.rand.org/pubs/monographs/2005/RAND_MG162.pdf. "In August 2005, the Congressional Budget Office estimated that there were about 322,000 asbestos bodily injury cases pending in state and federal courts." AM. ACAD. OF ACTUARIES' MASS TORTS SUBCOMM., OVERVIEW OF ASBESTOS CLAIMS ISSUES AND TRENDS 5 (2007), *available at* http://www.actuary.org/pdf/casualty/asbestos_aug07.pdf.

many standard venue, discovery, and trial consolidation requirements.[3] The changes almost universally favored plaintiffs and instead of affecting a reduction in congested dockets, the litigation became so malleable and lucrative that plaintiff attorneys have spent the last decade searching for the "next asbestos." Practitioners in this field have come to know these asbestos rules well, whereas newcomers are often astounded to discover that their tort law frame of reference means little in the alternative universe of asbestos litigation.

One of the most substantial departures from black letter tort law is the *any exposure* theory of causation, sometimes referred to as the *any fiber* theory.[4] In a nutshell, the *any exposure* theory contends that because asbestos disease is a cumulative, dose-response process, each and every exposure to asbestos during a person's lifetime, no matter how small or trivial, substantially contributes to the ultimate disease (e.g., asbestosis, lung cancer, or mesothelioma).[5] There is an important caveat, however, in that most proponents of this theory agree that *background* exposures to asbestos, even though they may contribute millions of fibers to an individual's lungs over a lifetime, do *not* contribute to the development of disease.[6] Only occupational or para-occupational (e.g., home remodeling or "shade tree" automotive brake repair) exposures count.[7] The theory allows plaintiffs' counsel to sue thousands of defendants every year whose "contribution" to disease is trivial and far below the type of doses actually known to cause disease, while at the same time excluding from causation another source of millions of fibers (i.e., background exposures).

In the last three years, more than a dozen courts in multiple jurisdictions have excluded or criticized *any exposure* causation testimony, either as unscientific under a *Daubert*[8]/*Frye*[9] analysis or as insufficient to support causation.[10] This pattern of decisions includes:

- the Texas Supreme Court in a mechanic/asbestosis case,

3. *See* Victor E. Schwartz & Rochelle M. Tedesco, *The Law of Unintended Consequences in Asbestos Litigation: How Efforts to Streamline the Litigation Have Fueled More Claims*, 71 MISS. L.J. 531, 542-47 (2001); Victor E. Schwartz & Leah Lorber, *A Letter to the Nation's Trial Judges: How the Focus on Efficiency Is Hurting You and Innocent Victims in Asbestos Liability Cases*, 24 AM. J. TRIAL ADVOC. 247, 256-58 (2000).

4. *See, e.g.*, *infra* notes 26, 30-31.

5. *See, e.g.*, *infra* note 50.

6. *See* Bartel v. John Crane, Inc., 316 F. Supp. 2d 603, 607-08 (N.D. Ohio 2004), *aff'd sub nom.* Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488 (6th Cir. 2005).

7. *See, e.g.*, Borg-Warner Corp. v. Flores, 232 S.W.3d 765, 773 (Tex. 2007), *reh'g denied* (Oct. 12, 2007).

8. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

9. *See* Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

10. *See, e.g.*, *infra* notes 11-19.

rejecting the testimony of Dr. Barry Castleman and another expert that mere proof of exposure is sufficient for causation;[11]

- a Texas appellate court in a mesothelioma case, rejecting the testimony of Dr. Samuel Hammar that any dry wall exposures above 0.1 fibers/cc year would be a substantial contributing factor;[12]
- the Texas Multi-District Litigation ("MDL") court, rejecting the testimony of Dr. Eugene Mark in a friction product case and other experts in an electrician/dry wall exposure case;[13]
- the Pennsylvania Supreme Court in a mesothelioma case against an auto parts company, rejecting the position espoused in affidavits by Drs. Richard Lemen, James Girard, and Arthur Frank;[14]
- an Ohio federal district court and the Sixth Circuit Court of Appeals in a gasket and packings case, rejecting the testimony of Drs. Arthur Frank and Yasunosuki Suzuki;[15]
- three Pennsylvania state trial courts, rejecting the *any exposure* testimony of Drs. John Maddox, Eugene Mark, William Longo, Jonathan Gelfand, and Arthur Frank in friction product cases and criticizing the theory's application in a pleural disease case;[16]
- a federal bankruptcy court in litigation involving asbestos in vermiculite insulation, rejecting Dr. Henry Anderson's *any exposure* approach;[17]
- a Mississippi appellate court, rejecting a medical monitoring class for persons allegedly exposed in a school building;[18] and
- two Washington State trial court decisions by different judges, rejecting the opinions of Drs. Samuel Hammar and Carl

11. *See Flores*, 232 S.W.3d at 774.

12. *See* Georgia-Pac. Corp. v. Stephens, 239 S.W.3d 304, 320-21 (Tex. App. 2007), *reh'g overruled* (Oct. 13, 2007), *review denied* (Feb. 22, 2008).

13. *See* Letter Ruling, *In re* Asbestos Litig., Cause No. 2004-03964 (Tex. Dist. Ct. Jan. 20, 2004); Letter Ruling, *In re* Asbestos, Cause No. 2004-3,964 (Tex. Dist. Ct. July 18, 2007).

14. *See* Gregg v. V-J. Auto Parts, Inc., 943 A.2d 216, 218, 223, 226-27 (Pa. 2007).

15. *See Bartel*, 316 F. Supp. 2d at 611.

16. *See In re* Toxic Substance Cases, No. A.D. 03-319, 2006 WL 2404008 at *7-8 (Pa. Ct. Com. Pl. Aug. 17, 2006); Basile v. Am. Honda Motor Co., No 11484 CD 2005 (Pa. Ct. Com. Pl. Feb. 22, 2007); *In re* Asbestos Litig., Certain Asbestos Friction Cases Involving Chrysler LLC, No. 0001 Control #084682 (Pa. Ct. Com. Pl. Sept. 24, 2008); Summers order v. Certainteed Corp., 886 A.2d 240, 244 (Pa. Super. Ct. 2005), *appeal granted*, 897 A.2d 460 (Pa. 2006).

17. *See In re* W.R. Grace & Co., 355 B.R. 462, 474, 478 (Bankr. D. Del. 2006), *leave to appeal denied*, No. 07-MC-0005 RLB, 01-1139, 2007 WL 1074094 (D. Del. Mar. 26, 2007).

18. *See* Brooks v. Stone Architecture, P.A., 934 So. 2d 350 (Miss. Ct. App. 2006).

Brodkin in heavy equipment mechanic cases.[19]

These are not insignificant courts—they include two state supreme courts, one federal appellate court, a federal bankruptcy court, and state appellate and trial courts in several jurisdictions.[20] In addition, the breadth of alleged exposures and diseases covered by these cases demonstrates that the *any exposure* theory is failing across the spectrum of asbestos cases, regardless of disease and type of exposure. Perhaps most remarkably, the experts whose testimony is being excluded are veterans in the litigation who have supported plaintiff cases for many years with little or no interference from the judiciary.[21] The rejection of these experts' causation testimony, while a significant departure from past practice, reflects the sound application of standard causation rules to asbestos testimony[22]—something that should have happened years ago and is finally gaining traction. These rulings also likely reflect a growing skepticism of many asbestos claims in the wake of findings of massive fraud in federal court silica litigation.[23]

This Article discusses the underpinnings of the *any exposure* causation theory and why recent courts that have examined the theory more carefully

19. *See* Anderson v. Asbestos Corp., No. 05-2-04551-5SEA, slip op. at 144-45 (Wash. King County Super. Ct. Oct. 31, 2006) (transcript of bench ruling) (Erlick, J.); Free v. Ametek, No. 07-2-04091-9-SEA (Wash. King County Super. Ct. Feb. 29, 2008) (Barnett, J.) (ruling on motion *in limine*).

20. *See supra* notes 11-19 and accompanying text.

21. *See infra* notes 50-53.

22. *See, e.g.*, *Flores*, 232 S.W.3d at 770 (discussing the "substantial factor" test in causation); David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 BROOK. L. REV. 51, 59 (2008) (stating that "[t]he 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)]."); *cf.* Lee S. Siegel, Note, *As the Asbestos Crumbles: A Look at New Evidentiary Issues in Asbestos-Related Property Damage Litigations*, 20 HOFSTRA L. REV. 1139, 1146 (1992) ("There is no merit to the one fiber theory, and the myth is slowly being dispelled.").

23. *See In re* Silica Prods. Liab. Litig., 398 F. Supp. 2d 563, 635 (S.D. Tex. 2005); Lester Brickman, *Disparities Between Asbestosis and Silicosis Claims Generated by Litigation Screenings and Clinical Studies*, 29 CARDOZO L. REV. 513 (2007); Lester Brickman, *On the Applicability of the Silica MDL Proceeding to Asbestos Litigation*, 12 CONN. INS. L.J. 289 (2006); *see also* Editorial, *Screening for Corruption*, WALL ST. J., Dec. 2, 2005, at A10, *abstract available at* 2005 WLNR 19447615; Editorial, *Silicosis, Inc.*, WALL ST. J., Oct. 27, 2005, at A20, *abstract available at* 2005 WLNR 17413061; Editorial, *The Silicosis Sheriff*, WALL ST. J., July 14, 2005, at A10, *abstract available at* 2005 WLNR 11084626; David Hechler, *Silica Plaintiffs Suffer Setbacks: Broad Effects Seen in Fraud Allegations*, NAT'L L.J., Feb. 28, 2005, at 1; Roger Parloff, *Diagnosis for Dollars: A Court Battle Over Silicosis Shines a Harsh Light on Mass Medical Screeners–The Same People Whose Diagnoses Have Cost Asbestos Defendants Billions*, FORTUNE, June 13, 2005, at 96, *available at* 2005 WLNR 8694138; Jonathan D. Glater, *Companies Get Weapon in Injury Suits Many Silica-Damage Plaintiffs Also Filed Claims Over Asbestos*, N.Y. TIMES, Feb. 2, 2005, at C1, *available at* 2005 WLNR 1415209.

have decided to reject it. These decisions reflect a proper assessment of the *dose requirement* of toxicology.[24] On the other hand, courts that continue to allow *any exposure* testimony to proceed unchallenged run the risk of encouraging a flood of speculative or trivial claims at a time when the litigation environment for asbestos claims appears to be regaining some semblance of control.[25] Such an outcome would reflect poor science and even poorer public policy.

I. THE TOXICOLOGICAL REQUIREMENT OF DOSE AND ITS APPLICATION IN THE TOXIC TORT CONTEXT

The *any exposure* theory can only be understood against the backdrop of widely accepted tort and medical causation principles because the theory departs so dramatically from those principles. Ordinarily, under long-standing rules of tort law, courts should require asbestos plaintiffs to demonstrate that each defendant's product was either a "but-for" cause or a "substantial factor" in the cause of plaintiff's disease.[26] In the typical tort case, such a showing would require not only proof of exposure to the defendant's product, but also exposure to *enough of a dose* of the defendant's product to actually cause disease.[27] The concept of a necessary dose goes back to the sixteenth century, when the "father of toxicology," physician and philosopher Paracelsus, first articulated the principle that the dose makes the poison: "All substances are poisonous—there is none which is not; the dose differentiates a poison from a remedy."[28] Examples are

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24. *See* David E. Bernstein, *Keeping Junk Science Out of Asbestos Litigation*, 31 PEPP. L. REV. 11, 28 (2003) ("There is clearly some relationship between asbestos and diseases. The effects of exposure to asbestos on a particular individual, however, depend on the level of exposure and what type of asbestos one was exposed to and for how long.").

25. *See* Mark A. Behrens & Phil Goldberg, *The Asbestos Litigation Crisis: The Tide Appears to Be Turning*, 12 CONN. INS. L.J. 477 (2006); James A. Henderson, Jr., *Asbestos Litigation Madness: Have the States Turned a Corner?*, MEALEY'S TORT REFORM UPDATE, vol. 3:6, Jan. 18, 2006, at 23; Patti Waldmeir, *The Americas: Asbestos Litigation Declines in Face of US Legal Reforms*, FIN. TIMES, July 24, 2006, at 2, *available at* 2006 WLNR 12719566; Martha Neil, *Backing Away from the Abyss: Courts May Be Starting to Get a Grip on Asbestos Litigation*, A.B.A. J., Sept. 2006, at 26.

26. *See* RESTATEMENT (SECOND) OF TORTS §§ 431, 433 (1965).

> The word "substantial" is used to denote the fact that the defendant's conduct has such an effect in producing the harm as to lead reasonable men to regard it as a cause . . . rather than in the so-called "philosophical sense," which includes every one of the great number of events without which any happening would not have occurred.

Id. at § 431cmt. a.

27. *See infra* notes 29-31 and accompanying text.

28. David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & POL'Y 5, 11 (2003) (emphasis omitted) (internal quotation marks omitted)

commonplace—alcohol, aspirin, sunlight, even basic substances we eat in food and vitamins like zinc are not harmful at low levels, but can cause harm at higher doses.[29]

This dose concept is widely recognized in both science and courts as the foundation of causation and the basis for many medical tort decisions.[30] Courts around the country, including at least five federal circuit courts, have recognized the necessity of proving an actual toxic dose in medical tort cases.[31] As one leading researcher recently wrote: "Dose is the single most

(quoting CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS, Chs. 1, 4 (Curtis D. Klaassen ed., McGraw Hill 6th ed. 2001)).

29. A fundamental tenet of toxicology is that "the dose makes the poison." Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in* FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 401, 403 (West Group 2d ed. 2000) (1994) (internal quotation marks omitted). Thus, courts routinely require plaintiffs to demonstrate not just some exposure, but "evidence from which the trier of fact could conclude that the plaintiff was exposed to levels of toxins sufficient to cause the harm complained of." Nelson v. Tenn. Gas Pipeline Co., No. 95-1112, 1998 WL 1297690, slip op. at *6 (W.D. Tenn. Aug. 31, 1998), *aff'd*, 243 F.3d 244 (6th Cir.), *cert. denied*, 534 U.S. 822 (2001) (citing Wintz v. Northrop Corp., 110 F.3d 508, 513 (7th Cir. 1997) (internal citation omitted)); *see also* Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1107 (8th Cir. 1996). This is as true for asbestos as for any other potentially toxic substance. *See Bartel*, 316 F. Supp. 2d at 611 (rejecting "one-fiber" asbestos theory as not supported by medical literature); *In re Toxic Substance Cases*, 2006 WL 2404008 at *7-8 (criticizing plaintiffs' experts for failing to assess the dose for mechanic exposure).

30. *See, e.g.*, McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005) ("In toxic tort cases, '[s]cientific *knowledge of the harmful level of exposure* to a chemical, plus knowledge that [the] plaintiff was exposed to *such quantities*[,] are minimal facts necessary to sustain the plaintiff's burden . . . .'") (emphasis added) (quoting Allen v. Pa. Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996)).

31. *See, e.g.*, *id.* (explaining that plaintiffs must establish the level at which substance is harmful and that their exposures were of that level); *Nelson*, 1998 WL 1297690 at *6 (excluding opinion of expert who did not assess dose because "[a]n appropriate methodology requires evidence from which the trier of fact could conclude that the plaintiff was exposed to levels of toxin sufficient to cause the harm complained of."); Mitchell v. Gencorp, Inc., 165 F.3d 778, 781 (10th Cir. 1999) ("[A] plaintiff must demonstrate 'the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.'") (quoting *Wright*, 91 F.3d at 1106); Moore v. Ashland Chem., Inc., 151 F.3d 269, 278 (5th Cir. 1998) ("Because he had no accurate information on the level of Moore's exposure to the fumes, Dr. Jenkins necessarily had no support for the theory that the level of chemicals to which Moore was exposed caused RADS."), *cert. denied*, 526 U.S. 1064 (1999); *Allen*, 102 F.3d at 199 ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."); Cano v. Everest Minerals Corp., 362 F. Supp. 2d 814, 825 (W.D. Tex. 2005) (quoting Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 720 (Tex. 1997)) ("[A] claimant must not only introduce sufficient epidemiological evidence, he must also show that he is similar to those in the studies."); Nat'l Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1524 (E.D. Ark. 1996) (explaining plaintiff must provide evidence of level of exposure and show that the dose was likely to produce harm of the type experienced by plaintiff); Louderback v. Orkin Exterminating Co., Inc., 26 F. Supp. 2d 1298, 1305 (D. Kan. 1998) ("[T]o recover in a toxic tort case, the plaintiff must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of

important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect."[32]

Parker v. Mobil Oil Corp.,[33] a recent non-asbestos case involving benzene, illustrates the point and the reasoned approach of many courts. In *Parker*, a gas station attendant alleged that he developed acute myeloid leukemia ("AML") from low level benzene exposures in gasoline.[34] Epidemiology studies have demonstrated that high exposures to pure benzene, typically in factory settings, can cause AML, but studies have not demonstrated the occurrence of disease from low-exposure gas station work where the exposures involved only a small amount (usually two to five percent) of benzene in gasoline.[35] Plaintiff's experts, Drs. Phil Landrigan and Bernard Goldstein, extrapolated down from the high-dose, factory benzene exposure studies and cited to government regulations and mathematical modeling studies to opine that low level exposures would likewise cause the disease.[36] They did so, however, without any assessment of the actual dose from gas station work; they could not present any evidence that the plaintiff's dose approached those shown to cause disease in the epidemiology studies of high-dose workers.[37] Instead, they expressed their opinions in subjective terms, referring to the plaintiff's exposures as "substantial" or "significant" with no grounding in actual dose calculations or comparisons.[38]

The New York Court of Appeals rejected this methodology as unreliable under New York's general requirements for reliability and proper foundation to support an evidentiary submission.[39] The decision focused on the flawed approach to dose and unsupported assumptions that low doses produce the same effects as high doses:

> The experts, although undoubtedly highly qualified in their respective fields, failed to demonstrate that exposure to benzene as a component of gasoline caused Parker's AML. Dr. Goldstein's general, subjective and

exposure to the toxic substance.") (quoting *Wright*, 91 F.3d at 1106); Mancuso v. Consol. Edison Co., 967 F. Supp. 1437, 1453 (S.D.N.Y. 1997) (explaining that expert's testimony that plaintiffs' ailments were caused by exposure to PCBs was inadmissible because, *inter alia*, expert "did not make sufficient determinations of environmental PCB levels, nor of the extent of the plaintiffs' exposure thereto.").

32. Eaton, *supra* note 28, at 11.

33. 857 N.E.2d 1114 (N.Y. 2006), *reargument denied*, 861 N.E.2d 104 (N.Y. 2007).

34. *Id.* at 1116.

35. *Id.* at 1117.

36. *Id.* at 1122.

37. *Id.*

38. *Id.* at 1121-22.

39. *Id.* at 1120-22.

> conclusory assertion—based on Parker's deposition testimony—that Parker had "far more exposure to benzene than did the refinery workers in the epidemiological studies" is plainly insufficient to establish causation. It neither states the level of the refinery workers' exposure, nor specifies how Parker's exposure exceeded it, thus lacking in epidemiologic evidence to support the claim.[40]

The New York court thus rejected the notion that low level, unquantified exposures to a known harmful substance necessarily suffices as proof of causation of a disease the substance is known to produce at much higher exposure levels.[41] This is classic toxicology, applied properly in the courtroom setting.

Parker has many antecedents similarly rejecting *assumed* causation at low levels, including, for instance, the United States Supreme Court's *General Electric Co. v. Joiner* ruling,[42] which rejected alleged PCB injury without a dose assessment,[43] and the Sixth Circuit's *Nelson v. Tennessee Gas Pipeline Co.* decision,[44] which likewise rejected alleged environmental harm from PCB exposure without any assessment of the actual dose.[45] The concept of a sufficient dose to cause disease is fundamental to both science and tort law, and should not be jettisoned in favor of a mere "exposure only" approach.

II. THE ASBESTOS *ANY EXPOSURE* THEORY

In contrast to the traditional tort approach requiring some assessment of dose, some courts presiding over asbestos cases have permitted plaintiffs to demonstrate merely that they were *exposed* to a defendant's product, rather than require proof that any particular exposure was high enough to cause a plaintiff's disease.[46] The result is that the causation dose requirement—real *exposure*, at *quantities* known to cause disease—was reduced to an exposure test, and a minimal one at that. Some verdicts have stretched the

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40. *Id.* at 1121-22.

41. *Id.* at 1122.

42. 522 U.S. 136 (1997).

43. *Id.* at 144-47.

44. 243 F.3d 244 (6th Cir.), *cert. denied*, 534 U.S. 822 (2001).

45. *Id.* at 252-54.

46. *See, e.g.*, Jones v. John Crane, Inc., 35 Cal. Rptr. 3d 144, 151-52 (Ct. App. 2005) (finding evidence of exposure to defendant's asbestos products, regardless of level of exposure, was sufficient to establish causation); Celotex Corp. v. Tate, 797 S.W.2d 197, 203 (Tex. App. 1990), *writ dismissed by agreement* (Aug. 16, 1996); *see generally* Steven D. Wasserman et al., *Asbestos Litigation in California: Can it Change for the Better?*, 34 PEPP. L. REV. 883, 897-99 (2007) (discussing California cases involving *de minimis* exposures).

concept so far that virtually any exposure, regardless of degree or frequency, suffices.[47]

The foundation for these opinions is the *any exposure* theory, sometimes called the *any fiber* theory.[48] Rather than assess dose, the experts who support this theory simply opine that any occupational or product-related exposure to asbestos fibers is sufficient—there is no minimum.[49] As a result, they regularly opine that every exposure a plaintiff received from any occupational or hobby-related work is a substantial factor in causing disease.[50] The opinions will encompass all such activities,

47. Some examples include a verdict upholding a $4 million judgment against Union Carbide, based on the *any exposure* theory, when plaintiff could not even recall using defendant's product, *see California Court: Conflicting Evidence Could Have Resulted in Verdict for Asbestos-Exposed Man*, MEALEY'S LITIG. REP.: ASBESTOS, vol. 22:22, Dec. 12, 2007, at 4; a $5 million verdict against John Crane based on any exposure to rope and gaskets without any assessment of the dose or fiber release from those products, *see Judge: Daughter's Showing That Father was Exposed, Product was Present Sufficient*, MEALEY'S LITIG. REP.: ASBESTOS, vol. 22:22, Dec. 12, 2007, at 5; a $35 million verdict for "exposure" to Leslie Control's "small pump and valve components" in the Navy, ignoring large-scale exposure to Navy insulation, *see $35.1M Awarded to Couple for Exposure to Asbestos in Navy*, MEALEY'S LITIG. REP.: ASBESTOS, vol. 22:19, Nov. 1, 2007, at 3; and a verdict of $3.92 million against General Electric alleging exposure from brakes in cranes and a mill motor, apparently with no assessment of the minimal dose those exposures likely would produce, *see Maryland Asbestos Jury Awards $3.92 Million to 3 Steelworkers' Families*, MEALEY'S ASBESTOS. BANKR. REP., vol. 7:1, Aug. 1, 2007, at 12. *See also* Flores v. Borg-Warner Corp., 153 S.W.3d 209, 214 (Tex. App. 2004) (finding a product "emitting" dust or "working in the presence of" dust deemed sufficient for causation), *rev'd*, 232 S.W.3d 765 (Tex. 2007), *reh'g denied* (Oct. 12, 2007).

48. Some plaintiff experts have testified that breathing even a single fiber of asbestos could cause disease. When this approach began to be criticized, the theory became more commonly articulated as "every exposure," "any exposure," "every breath," or similar phrases. Some plaintiffs' experts state simply that any exposure above background is sufficient, while others attach a number as a cutoff (e.g., Dr. Samuel Hammar's 0.1 fibers/cc year level, or Dr. John Maddox's 0.0003 fibers/cc single exposure cutoff), but the result is usually the same—most if not all occupational exposures are captured. *See infra* notes 50-51 and accompanying text.

49. *See Gregg*, 943 A.2d at 226 ("We recognize that it is common for plaintiffs to submit expert affidavits attesting that any exposure to asbestos, no matter how small, is a substantial contributing factor in asbestos disease."); *Georgia-Pac. Corp.*, 239 S.W.3d at 308 (stating plaintiffs relied on "expert testimony that any exposure to asbestos contributes to cause mesothelioma"); *Lindstrom*, 424 F.3d at 498 (stating plaintiff experts contended that "[o]nce mesothelioma is diagnosed, it is impossible to rule out any of Mr. Lindstrom's exposures as being substantially contributory.").

50. *See Georgia-Pac. Corp.*, 239 S.W.3d at 315 (stating opinion of plaintiffs' expert Jerry Lauderdale was "that every exposure does contribute to the development of potential to develop mesothelioma."); *Summers*, 886 A.2d at 244 (quoting plaintiffs' expert Dr. Jonathan Gelfand stating, "Each and every exposure to asbestos has been a substantial contributing factor to the abnormalities noted."); *Bartel*, 316 F. Supp. 2d at 611 (criticizing testimony of Drs. Arthur Frank and Yasunosuke Suzuki "that every exposure to asbestos [plaintiff] had during his working career, no matter how small, was a substantial factor in causing his peritoneal mesothelioma"); *In re Toxic Substance Cases*, 2006 WL 2404007 at *1 (rejecting testimony of plaintiffs' experts, Drs. Maddox and Laman, who opined that "every single exposure to every asbestos product is a

regardless of duration or dose—a single backyard brake job, one remodeling job using asbestos-containing joint compound, walking by a gasket repair job on an engine—all have been targeted by plaintiffs' experts as the cause of mesothelioma.[51]

The *any exposure* plaintiffs' experts typically make the following arguments to support their position:

(a) A single fiber of asbestos can generate mesothelioma. The exact mechanism by which asbestos causes cancer, including mesothelioma, is not known, but one theory is that the cancer is believed to be the result of inflammation or other factors that disrupt a cell's DNA and cause the cell to begin replicating out of control.[52] The *any exposure* experts rely on this hypothesis to testify that exposure to a single fiber could, in theory, start the disease.[53] Once an individual has mesothelioma, these experts contend that we do not know and cannot determine which fiber (or more importantly, which *defendant's* fiber) caused the disease, and thus must assume that any and all exposures are the potential cause.[54] The experts exclude,

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proximate cause of a subsequently diagnosed asbestos-related disease.").

51. For instance, Dr. Arthur Frank, a proponent of the *any exposure* theory, has testified that a single brake job should be identified as a substantial factor in causing asbestos disease. *See* Lulich v. Rapid Am. Corp., No. 2005 L004323 (Cir. Ct. Cook County, Ill.) (Deposition of Arthur Frank, Feb. 1, 2005, at 111 ("[S]omeone removing a set of brakes that contain brake dust where there is some percentage of untransformed chrysotile . . . I would say yes, it was a contributing factor to his mesothelioma."). The other examples are representative of allegations and expert testimony in numerous other cases. *See, e.g.*, Chavers v. General Motors Corp., 79 S.W.3d 361, 370 (Ark. 2002) ("The competent medical evidence presented in this case does not support the conclusion that a one-time exposure to asbestos-containing brakes was a substantial cause of Mr. Chaver's mesothelioma."); Wilson v. A.P. Green Indus., Inc., 807 A.2d 922, 926 (Pa. Super. Ct. 2002) (affirming summary judgment for manufacturer where decedent was merely exposed to dust from defendant's product "at one time or another.").

52. *See, e.g.*, Hamilton v. Asbestos Corp., 998 P.2d 403, 407 (Cal. 2000) (describing mesothelioma disease process); Cheryl L. Fattman et al., *Experimental Models of Asbestos-Related Disease*, *in* PATHOLOGY OF ASBESTOS-ASSOCIATED DISEASES 256, 285 (Victor L. Roggli et al. eds., Springer Sci.+Bus. Media, Inc. 2d ed. 2004) (1992) (citing studies by Moalli).

53. *See, e.g.*, *Bartel*, 316 F. Supp. 2d at 605 (Dr. Arthur Frank testified that a single fiber could cause disease); *Gregg*, 943 A.2d at 223 (stating plaintiffs' expert Dr. Richard Lemen opined that there is no "safe" level of exposure to asbestos and that any level of exposure will place an individual at risk for developing asbestos-related conditions); Bonnette v. Conoco, Inc., 837 So. 2d 1219, 1232 (La. 2003) (stating plaintiff's expert Dr. Richard Lemen "testified that any level of exposure to asbestos will place an individual at risk for developing asbestos-related conditions."); *Basile*, No 11484 CD 2005, slip. op. at 9-12 ("The 'single fiber' theory [presented by plaintiff's expert] holds that exposure to a single asbestos fiber can cause mesothelioma and other disease processes."); *Georgia-Pac. Corp.*, 239 S.W.3d at 320 ("[T]he experts posited that all asbestos fibers cause mesothelioma because all asbestos fibers have the ability to cause cancer-inducing mutations in the cells and it is not possible to pinpoint which particular fibers actually caused the mutations."); *In re Toxic Substance Cases*, 2006 WL 2404008 at *6 (stating plaintiff experts testified that a "single exposure" can cause disease).

54. *See, e.g.*, *Georgia-Pac. Corp.*, 239 S.W.3d at 314-15, 320; *Gregg*, 943 A.2d at 223;

incongruously, background fibers as the potential initiating source, and they do not address or account for the body's defensive mechanisms that actually protect against cancer caused by just one fiber or even many fibers entering the body.[55]

(b) Asbestos is a cumulative dose disease. Asbestos disease is generally believed to result from the cumulative total dose of asbestos received over time rather than from an instantaneous exposure.[56] The *any exposure* proponents rely on the cumulative dose principle to conclude that every occupational exposure contributes to the disease, from the very smallest to the very highest, much like every drop of water contributes to filling a glass.[57] They do not factor in, however, the established differences in fiber potency,[58] any differences in duration of exposure across jobs or the

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Bonnette, 837 So. 2d at 1232; *Basile*, No 11484 CD 2005, slip. op. at 9-12; *In re Toxic Substance Cases*, 2006 WL 2404008 at *6.

55. *See, e.g.*, *Flores*, 232 S.W.3d at 773 (stating expert acknowledged background fibers but did not suggest they were a cause of asbestosis); *Georgia-Pac. Corp.*, 239 S.W.3d at 315 (quoting Dr. Samuel Hammar's testimony that the "level of exposure it takes to cause mesothelioma 'could be any level above what is considered to be background . . . .'"); *In re Toxic Substance Cases*, 2006 WL 2404008 at *3 ("[B]ackground or ambient exposure is simply not sufficient to allow experts to causally attribute asbestos-related disease to it. Everyone, including the plaintiff's experts, agrees that something greater is required."). *Bartel*, 316 F. Supp. 2d at 607-08 (discussing background levels of asbestos).

56. National Cancer Institute, Fact Sheet, Asbestos Exposure: Questions and Answers 3 (Feb. 1, 2007), http://www.cancer.gov/images/Documents/5ac7d2fc-27df-4ecc-839f-dc5bc1909e01 /fs3_21.pdf.

57. *See, e.g.*, *Georgia-Pac. Corp.*, 239 S.W.3d at 320.

58. A great many studies and publications recognize that chrysotile is less potent in causing mesothelioma than the amphibole family of asbestos fibers, including amosite and crocidolite. *See Bartel*, 316 F. Supp. 2d at 606 ("[P]revailing scientific and medical view" supports lower chrysotile potency); Becker v. Baron Bros., Coliseum Auto Parts, Inc., 649 A.2d 613, 620 (N.J. 1994) (holding that trial court erred in instructing jury that all asbestos-containing friction products without warnings are defective as a matter of law: "Our courts have acknowledged that asbestos-containing products are not uniformly dangerous and thus that courts should not treat them all alike."); Gideon v. Johns-Manville Sales Corp., 761 F.2d 1129, 1145 (5th Cir. 1985) ("[A]ll asbestos-containing products cannot be lumped together in determining their dangerousness."); Celotex Corp. v. Copeland, 471 So. 2d 533, 538 (Fla. 1985) ("Asbestos products . . . have widely divergent toxicities, with some asbestos products presenting a much greater risk of harm than others."); Charles M. Yarborough, *Chrysotile as a Cause of Mesothelioma: An Assessment Based on Epidemiology*, 36 CRITICAL REV. TOXICOLOGY 165, 165 (2006); U.S. ENVTL. PROT. AGENCY, REPORT ON THE PEER CONSULTATION WORKSHOP TO DISCUSS A PROPOSED PROTOCOL TO ASSESS ASBESTOS RELATED RISK viii (2003), http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf; Andrew Churg, *Nonneoplastic Disease Caused by Asbestos*, *in* PATHOLOGY OF OCCUPATIONAL LUNG DISEASE 277, 314 (Andrew Churg & Francis H.Y. Green eds., 2d ed. 1998); B.T. Mossman et al., *Asbestos: Scientific Developments and Implications for Public Policy*, 247 SCIENCE 294, 296, 299 (1990), *available at* 1990 WLNR 2425147. The distinction is important for jobs such as automotive mechanics whose exposure is only to chrysotile fibers, because the difference in potency would indicate the need for a considerably higher dose to cause disease in that occupation.

dose of fiber received from any particular job, the removal of some fibers from the body,[59] or the frequency of exposure on any job. All asbestos types and all exposures are treated the same for purposes of their opinions.

(c) The "no safe dose" or "no threshold" approach. In keeping with the dose principle, virtually every toxin is believed to have a *threshold* level below which injury does not occur.[60] A dose of two aspirin, for instance, is below the threshold of injury for that drug.[61] It is exceedingly difficult, however, to establish with certainty the level at which asbestos exposures do not cause mesothelioma.[62] This is primarily because epidemiology studies—the "gold standard" for establishing causation—cannot easily identify differences in populations at low exposure levels approaching background. Because of the difficulty of proof that low exposures are safe, regulatory agencies such as OSHA have frequently stated that there is no *known* safe level of asbestos exposure and, therefore, set the regulatory limit at the lowest technologically feasible limit.[63]

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59. The body is capable of removing many inhaled fibers through defense mechanisms such as throat mucus, ciliary bodies, coughing and sneezing, the action of macrophage cells, and the lymph system. *See generally* Fattman, *supra* note 52, at 260-65. Chrysotile fibers, in particular, are removed fairly quickly, with a half life (the amount of time required to remove half the resident fibers from the body) of a few months for most fibers. The half life of amphibole fibers in contrast is measured in years or decades. *See* Churg, *supra* note 58, at 284-85; *Free*, No. 07-2-04091-9-SEA, slip op. at 2-3.

The notion that chrysotile fibers cause damage during their brief stay in the human body before their expulsion—known as the "hit and run" theory—is supported by plaintiff experts but rejected by many researchers. *See, e.g.*, Richard A. Lemen, *Asbestos in Brakes: Exposure and Risk of Disease*, 45 AM. J. INDUS. MED. 229, 234 (2004) (stating plaintiff testifying expert Dr. Lemen argued that fast clearance of chrysotile does not eliminate possibility it caused disease before being eliminated); Kelly J. Butnor et al., *Exposure to Brake Dust and Malignant Mesothelioma: A Study of 10 Cases with Mineral Fiber Analyses*, 47 ANNALS OCCUPATIONAL HYGIENE 325, 239 (2000) (explaining why "hit and run" theory is "flimsy" and not plausible); Richard A. Lemen, *Reply to Victor L. Roggli and Arthur M. Langer*, 47 AM. J. INDUS. MED. 278, 278-79 (2005) (criticizing Roggli's rejection of "hit and run" theory).

60. *See* Eaton, *supra* note 28, at 15.

61. Aspirin is a commonly-understood example. Others include alcohol, nitroglycerine, arsenic, and even water. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *7.

62. *Id.* at *8-9; *Free*, No. 07-2-04091-9-SEA, slip op. at 4.

63. *See, e.g.*, NIOSH-OSHA ASBESTOS WORK GROUP, WORKPLACE EXPOSURE TO ASBESTOS: REVIEW AND RECOMMENDATIONS DHHS (NIOSH) Pub. No. 81-103 3 (1980), www.cdc.gov/niosh/topics/asbestos/pdfs/81103.pdf ("Evaluation of all available human data provides no evidence for a threshold or for a 'safe' level of asbestos exposure."); 59 Fed. Reg. 40964-01, 40967 (Aug. 10, 1994) (stating OSHA believes that the regulatory limit of .1 fiber per cubic centimeter of air as an eight-hour time-weighted average is "the practical lower limit of feasibility for measuring asbestos levels reliably."), *available at* 1994 WL 413576 (F.R.).

> The basis for the 1975 proposal's reduction in the permissible exposure limit to 0.5 f/cc was OSHA's then-current policy for carcinogens that assumed that no safe threshold level was demonstrable and therefore that the Act required the Agency to set the PEL at a level as low as technologically and economically feasible.

51 Fed. Reg. 222612-01, 22614 (June 20, 1986), *available at* 1986 WL 103293 (F.R.).

The *any exposure* experts have converted this cautionary approach into an opinion that there *is* no safe dose of asbestos.[64] This conclusion, however, is clearly a non sequitur—the absence of conclusory proof as to *where* the threshold lies does not mean there is no threshold. These experts rely on, and often misstate, this concept to argue that since the safe level is unknown, then every exposure must be considered dangerous and contributory to disease.[65]

(d) The linear non-threshold theory and extrapolation down. The *any exposure* theorists are often confronted with the lack of any epidemiology studies reasonably demonstrating that low levels of asbestos exposure produce any increased incidence of disease.[66] Because the plaintiffs' experts have no such proof at the levels they claim are disease-inducing, they turn to an extrapolation methodology that relies on the assumption that high-dose studies can be used to estimate low-dose disease.[67] In the studies of high-incidence asbestos disease, typically in professions such as insulators, asbestos factory workers, miners, and textile workers, the disease follows a dose-response relationship that approaches, at least at the higher exposure levels experienced by those workers, a somewhat linear relationship between the lifetime fiber burden and the incidence of disease.[68]

That data, however, *does not exist* at lower levels of exposure.[69] The two most likely explanations are: (1) the exposures do not cause disease at

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64. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *11.

> While it may be a valid assertion that: if high dose asbestos exposure is bad for you, then low dose asbestos exposure may potentially be bad for you; it is not a valid assertion that because high dose exposure to asbestos is bad for you, then low dose exposure to asbestos is, in fact, bad for you, or that a specific plaintiff's exposure at an unknown low dose exposure level, in fact, contributed to that plaintiff's asbestos-related disease.

Id. (emphasis omitted).

65. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *11 ("[Drs. John Maddox and David Laman] offer not a shred of independent corroboration of their opinion that each and every fiber causes or contributes to a Plaintiff's disease process."); *Brooks*, 934 So. 2d at 355 (stating plaintiffs' expert Dr. Gaeton Lorino "was unable to cite a single study or publication to support his assertion" that mesothelioma is not a dose-related disease); *In re W.R. Grace*, 355 B.R. at 474-75 (discussing the fallacy of the "no safe dose" position).

66. *See, e.g.*, B.T. Mossman et al., *supra* note 58, at 294 ("There are no available data showing health hazards due to low-level exposure . . . .").

67. The extrapolation-down approach of plaintiff experts was specifically addressed and rejected by the courts in *In re Toxic Substance Cases*, 2006 WL 2404008 at *7-8, and *Free*, No. 07-2-04091-9-SEA, slip op. at 3-4.

68. *See* John T. Hodgson & Andrew Darnton, *The Quantitative Risks of Mesothelioma and Lung Cancer in Relation to Asbestos Exposure*, 44 ANNALS OCCUPATIONAL HYGIENE 565, 578 fig. 6 (2000); *Free*, No. 07-2-04091-9-SEA, slip op. at 3 n.5 (discussing slope in Hodgson article).

69. *See* Hodgson & Darnton, *supra* note 68, at 578 fig. 6, 580 fig. 9 (identifying data points above 10 fibers/ml years).

lower levels and there is, quite plainly, nothing to find, or (2) the exposures may cause very low levels of disease, so low that their occurrence is not distinguishable from other causes of the disease. The *any exposure* experts, relying on a theoretical approach sometimes used by regulators, *assume* that the latter explanation is true.[70] They adopt a linear dose-response curve that extends in a straight line all the way to zero exposure.[71] Most toxins do not follow such a line, but present a curvilinear relationship that drops to zero disease as the exposures approach the threshold (usually well above zero exposures).[72] The assumed linear relationship at low levels produces a *theoretical* level of mesothelioma at extremely low levels of exposure, but these are theoretical and assumed cases only since no study has ever identified real disease at such low levels that is distinguishable from idiopathic or spontaneous mesothelioma.[73] The experts nevertheless testify, through this extrapolation down methodology, that disease must exist at low levels and that their calculated estimates prove that an individual plaintiff's low exposures contributed to his disease.[74]

(e) Reliance on case reports. In some instances, lacking any supporting epidemiology, some *any exposure* experts resort to reliance on case reports of disease in persons exposed to low doses.[75] The most frequent application is in mechanic cases, where the epidemiology has consistently supported a *lack of disease* from chrysotile exposures, even among lifetime mechanics.[76] The experts reject the existing, contradictory epidemiology and rely on case reports instead.[77] "Case reports, by their

70. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *6-7.

71. *Id.* at *7.

72. *Id.* (discussing threshold effect for common substances); Eaton, *supra* note 28, at 15-17.

73. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *6; National Cancer Institute, *supra* note 56, at 3.

74. *See In re Toxic Substance Cases*, 2006 WL 2404008 at *7-8.

75. A case report is nothing more than an occurrence in which a person with a particular exposure also develops a particular disease. If epidemiology has established the link, a case report can potentially reflect a real causative source, for example, a heavy smoker who develops lung cancer. In most instances, however, case reports are at best suggestive of a possible link and frequently represent unrelated incidents. For example, case reports of coffee drinkers incurring pancreatic cancer a few years ago turned out to be false associations when epidemiology studies produced no evidence of a link. *See* American Cancer Society, *Pancreatic Cancer is Not Linked with Drinking Coffee or Alcohol* (July 17, 2001), http://www.cancer.org/docroot/NWS/content/NWS_1_1x_Pancreatic_Cancer_Is_Not_Linked_With_Drinking_Coffee_or_Alcohol.asp.

76. The studies are summarized and discussed in Francine Laden et al., *Lung Cancer and Mesothelioma among Male Automobile Mechanics: A Review*, 19 REV. ON ENVTL. HEALTH 39 (2004); Michael Goodman et al., *Mesothelioma and Lung Cancer among Motor Vehicle Mechanics: A Meta-analysis*, 48 ANNALS OCCUPATIONAL HYGIENE 309, 309 (2004); *see also* Yarborough, *supra* note 58.

77. *See, e.g.*, *In re Toxic Substance Cases*, 2006 WL 2404008 at *4-5.

very nature, can never prove causation."[78] Consequently, some courts routinely reject case reports as proof of causation.[79] Nevertheless, some courts allow experts to rely on case reports as evidence in asbestos courtrooms where these experts are permitted to testify.

The proponents of the *any exposure* theory make little or no attempt to segregate real exposures from trivial or nonexistent exposures. The types of exposures sufficient to name a defendant can involve either a small number of exposure experiences, or a longer series of low dose exposures, such as mechanics doing brake jobs.[80] The lifetime dose from either type of exposure is minimal and far different from the world of known asbestos disease generated typically in dusty trades involving amphibole fibers.

Through this testimony, the *any exposure* experts are helping to extend the asbestos litigation to any entity that had any connection to asbestos.[81] The "new" wave of asbestos cases, relying almost exclusively on the *any exposure* theory, typically involves a mesothelioma victim who, through attorney interviews, has identified any conceivable contact with asbestos in his or her lifetime.[82] The contact can include household members who had direct contact and then allegedly brought fibers home, or "bystander" or "pass-by" exposures allegedly resulting from just being in the same building or vicinity as asbestos-related work.[83] In each case, the attorneys

78. Robert N. Jones, *Asbestos Medicine II*, SJ031 ALI-ABA 29, 29, 35 (Nov. 13-14, 2003).

79. *See* Glastetter v. Novartis Pharms. Corp., 107 F. Supp. 2d 1015 (E.D. Mo. 2000), *aff'd*, 252 F.3d 986 (8th Cir. 2001); Hollander v. Sandoz Pharms. Corp., 95 F. Supp. 2d 1230, 1235-38 (W.D. Okla. 2000), *aff'd in part*, 289 F.3d 1193 (10th Cir.), *cert. denied*, 537 U.S. 1088 (2002); Brumbaugh v. Sandoz Pharm. Corp., 77 F. Supp. 2d 1153, 1157 (D. Mont. 1999); Willert v. Ortho Pharm. Corp., 995 F. Supp. 979, 981 (D. Minn. 1998); Boyles v. Am. Cyanamid Co., 796 F. Supp. 704, 708 (E.D.N.Y. 1992); Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995); *In re* Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., MDL 1203, 2001 WL 454586 at *15 (E.D. Pa. Feb. 1, 2001) (memorandum and pretrial order No. 1685) (unreported).

80. *See* Dennis J. Paustenbach et al., *An Evaluation of the Historical Exposures of Mechanics to Asbestos in Brake Dust*, 18 APPLIED OCCUPATIONAL & ENVTL. HYGIENE 786, 786-804 (2003) (stating average lifetime mechanic exposures calculated at 0.04 f/cc or less, below OSHA standard of 0.1 f/cc); Brent L. Finley et al., *Cumulative Asbestos Exposure for US Automobile Mechanics Involved in Brake Repair (circa 1950s-2000)*, 17 J. EXPOSURE SCIENCE & ENVTL. EPIDEMIOLOGY (2007) 644, 644 (stating cumulative lifetime average exposures for automobile mechanics "are all substantially lower than the cumulative exposure of 4.5 f/cm3 year associated with occupational exposure to 0.1 f/cm3 of asbestos for 45 years that is currently permitted under the current occupational exposure limits in the US.").

81. *See* Richard B. Schmitt, *Burning Issue: How Plaintiffs' Lawyers Have Turned Asbestos into a Court Perennial*, WALL ST. J., Mar. 5, 2001, at A1, *available at* 2001 WLNR 2021814; Susan Warren, *Asbestos Quagmire: Plaintiffs Target Companies Whose Premises Contained Any Form of Deadly Material*, WALL ST. J., Jan. 27, 2003, at B1, *available at* 2003 WLNR 3099209.

82. *See, e.g.*, *Chavers*, 79 S.W.3d at 370.

83. *See, e.g.*, *Georgia-Pac. Corp.*, 239 S.W.3d at 315 (stating plaintiffs' expert Dr. Samuel Hammer expressed opinion that "each and every exposure that an individual has in a bystander

then sue dozens of defendants associated with these contacts, many of whom have never made an asbestos product.[84] One-time contacts or events are treated equally as causes along with long-duration, high level exposures, such as Navy shipyard work.[85] Mesothelioma is particularly vulnerable, because it is readily associated with asbestos and, at least for amphiboles, requires a lower dose than other asbestos diseases.[86] Despite the wide agreement that a significant number (by some estimates, twenty to thirty percent) of mesotheliomas are not asbestos induced,[87] the *any exposure* theory is capable of converting every diagnosis of mesothelioma into an asbestos action. Countless individuals have had some contact with asbestos, either directly or through a family member, in their lifetime sufficient to satisfy the theory's minimal requirements. The *any exposure* cases are heavily weighted toward a handful of jurisdictions that continue to apply the "old" rules to all asbestos cases.[88]

The massive expansion of the number of asbestos defendants brought about by this theory is highly problematic. When asbestos litigation focused on actual producers of asbestos and asbestos-containing products, defendants numbered in the hundreds (in 1982, about 300 such defendant

occupational setting causes their mesothelioma."); *see also* Jackson v. Anchor Packing Co., 994 F.2d 1295 (8th Cir. 1993) (affirming dismissal of claimants who performed general "tireworker" duties and did not directly handle any of the defendant's asbestos products).

84. *See, e.g.*, Chavers v. Gatke Corp., 132 Cal. Rptr. 2d 198, 199 (Ct. App. 2003) (stating plaintiffs' complaint "joined as defendants scores of manufacturers, suppliers and distributors of friction brake products containing asbestos–59 named defendants and 800 'Doe' defendants . . . ."); Susan Warren, *Asbestos Suits Target Makers of Wine, Cars, Soups, Soaps*, WALL ST. J., Apr. 12, 2000, at B1, *available at* 2000 WLNR 2042486.

85. *See, e.g.*, *$35.1M Awarded to Couple for Exposure to Asbestos in Navy*, MEALEY'S LITIG. REP.: ASBESTOS, vol. 22:19, Nov. 1, 2007, at 3 (stating $35 million verdict for "exposure" to Leslie Control's "small pump and valve components" in the Navy, ignoring large-scale exposure to Navy insulation).

86. *See* 51 Fed. Reg. 22612-01, 22619 (June 20, 1986) (noting cases of mesothelioma, but not lung cancer, in low-exposed populations such as neighborhood and home exposures), *available at* 1986 WL 103293 (F.R.).

87. *See* Mayo Clinic Staff, *Mesothelioma* (Aug. 11, 2006), http://www.mayoclinic.com/health/mesothelioma/DS00779/DSECTION=4 ("Asbestos exposure plays a role in 70 percent to 80 percent of mesothelioma cases, though the actual percentage could be higher."); Lawrence G. Cetrulo, *Asbestos Litigation & Tort Reform: Health Hazards/Diseases*, 3 TOXIC TORTS LITIG. GUIDE § 33:3 (updated Oct. 2007) ("Asbestos exposure is the dominant cause of mesothelioma, and accounts for 70 to 80 percent of all mesothelioma cases."); B.T. Mossman et al., *supra* note 58 ("[A]pproximately 20 to 30% of mestheliomas occur in the general population in adults not exposed occupationally to asbestos."); Lester Brickman, *On the Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality*, 31 PEPP. L. REV. 33, 44 n.19 (2003) (stating that approximately twenty percent of malignant mesotheliomas have been attributed to causes other than exposure to asbestos).

88. *See* Wasserman et al., *supra* note 46, at 905-08 (discussing policy reasons why courts should reject *de minimis* and *any exposure* causation theories in asbestos litigation).

companies).[89] Now, over 8,500 defendants have been named,[90] as "the net has spread from the asbestos makers to companies far removed from the scene of any putative wrongdoing."[91] One well-known plaintiffs' attorney has described the litigation as an "endless search for a solvent bystander."[92] Once a company is caught in this net, unless courts are willing to reject *any exposure* testimony prior to trial, it is nearly impossible for a defendant to escape without serious financial consequences.

III. COURT RULINGS REJECTING OR CRITICIZING THE *ANY EXPOSURE* APPROACH

In the last three years, the *any exposure* approach has been criticized or found inadmissible under both the *Frye* and *Daubert* tests, and under general requirements of reliability and foundation, before over a dozen courts in multiple jurisdictions.[93] These courts have recognized the extreme position the plaintiffs' experts are taking, the lack of scientific proof supporting their theory, and the lack of logical or scientific support for their conclusions.[94]

The *any exposure* theory was first criticized in a 2005 Ohio federal court case, *Bartel v. John Crane, Inc.*[95] In *Bartel*, plaintiff's experts attempted to attribute plaintiff's mesothelioma to exposure from handling the defendant's gaskets and packing while in the Navy.[96] The plaintiff, like many Naval workers, had substantial exposure to large amounts of amphibole asbestos in ship insulation, but plaintiff either did not sue or had settled with the entities responsible for those extreme and clearly dangerous exposures.[97] Exposures from gaskets and packing, in contrast, are quite

89. *See* JAMES S. KAKALIK ET AL., VARIATION IN ASBESTOS LITIGATION COMPENSATION AND EXPENSES 5 (1984).

90. *See* Deborah R. Hensler, *California Asbestos Litigation—The Big Picture*, HARRISMARTIN COLUMNS: ASBESTOS, Aug. 2004, at 5.

91. Editorial, *Lawyers Torch the Economy*, WALL ST. J., Apr. 6, 2001, at A14, *available at* 2001 WLNR 1993314.

92. *'Medical Monitoring and Asbestos Litigation'—A Discussion with Richard Scruggs and Victor Schwartz*, MEALEY'S LITIG. REP.: ASBESTOS, vol. 17:3, Mar. 1, 2002, at 5 (quoting Mr. Scruggs); *see also* Steven B. Hantler et al., *Is the "Crisis" in the Civil Justice System Real or Imagined?*, 38 LOY. L.A. L. REV. 1121, 1151-52 (2005) (discussing spread of asbestos litigation to "peripheral defendants"). "Nontraditional [d]efendants [n]ow [a]ccount for [m]ore [t]han [h]alf of [a]sbestos [e]xpenditures." CARROLL ET AL., *supra* note 2, at 94.

93. *See supra* notes 11-19.

94. *See, e.g.*, *Flores*, 232 S.W.3d at 774.

95. 316 F. Supp. 2d at 611.

96. *Id.* at 604-05.

97. *Id.* at 604-06.

low—measured at 0.0062 fibers/cc in trial evidence.[98] Some of plaintiff's experts agreed that exposures approaching or below background, such as those from gasket work, would be insufficient for causation.[99] As to the remaining *any exposure* experts, who relied on this theory to point the finger at the minimal chrysotile exposures rather than plaintiff's insulation exposures, the court found their testimony unpersuasive:

> The two experts who disagreed, Dr. Frank and Dr. Suzuki, testified that every exposure to asbestos Lindstrom had during his working career, no matter how small, was a substantial factor in causing his peritoneal mesothelioma . . . . 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 . . . .
>
> In addition, the opinion of Dr. Frank, that every breath Lindstrom took which contained asbestos could have been a substantial factor in causing his disease, is not supported by the medical literature.[100]

This decision was upheld on appeal by the United States Court of Appeals for the Sixth Circuit: "[Plaintiff's expert argument] appears to be that a showing of any level of asbestos exposure attributable to John Crane's products was sufficient for the court to have entered a judgment in their favor. We reject plaintiffs-appellants' argument on this point."[101]

We believe the *Bartel* opinions were the first time that the *any exposure* theory was held insufficient to support causation. *Bartel* itself appears to have received little attention and did not quickly replicate itself in other courts. In the last two years, however, and largely independent of *Bartel*, the flawed *any exposure* approach has produced a raft of decisions that reject the theory as unscientific and/or exclude the expert testimony under *Daubert* or *Frye*.[102]

The first and most influential of these subsequent decisions was that of Judge Colville in a Pennsylvania case, *Betz v. Pneumo-Abex*.[103] *Betz* initially involved a group of automotive mechanic cases in which plaintiffs'

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98. *Id.* at 608. For comparison purposes, this figure is more than ten times *lower* than the current standard (0.1 fibers per cubic centimeter of air as an eight-hour time-weighted average) at which OSHA permits workers to be exposed every day for forty years without requiring any protection. *See* 29 C.F.R. § 1910.1001(c)(1) (2006).

99. *Bartel*, 316 F. Supp. 2d at 604-06.

100. *Id.* at 611.

101. *Lindstrom*, 424 F.3d at 498.

102. *See supra* notes 11-19.

103. The trial court opinion was entitled *In re Toxic Substances Cases*, 2006 WL 2404008 (Pa. Ct. Com. Pl. Aug. 17, 2006). The case has also been referred to as *Simikian* (another plaintiff), but on appeal the title changed to *Betz v. Pneumo Abex LLC*, No. 1058 WDA 2006 (Pa. Super. Ct. Jan. 16, 2007) (Betz is the administrator of the deceased plaintiff Vogelsberger's estate).

experts Drs. John Maddox and David Laman declared that the specific exposure facts of each mechanic were essentially irrelevant because any exposure was sufficient to support causation.[104] The experts thus rebuffed the need for any sort of dose assessment and opined that any level of mechanic work, regardless of duration, was sufficient to cause disease.[105] Judge Colville precluded this testimony, and in the process, addressed the key underpinnings of the theory and found each one illogical and unsupported.[106] We will cover Judge Colville's reasoning in some detail, because it remains today the seminal and best evisceration of the grounds asserted by *any exposure* approach experts. Decisions that followed largely repeated and elaborated on Judge Colville's arguments.

First, Judge Colville addressed the serious discrepancy between the claim that any exposure to an occupational fiber causes disease, and the experts' candid, albeit incongruent, admission that a lifetime of background exposures to asbestos fibers does not cause disease.[107] In modern industrial society, urban and sometimes rural air has historically contained asbestos at low levels (some of this from natural asbestos outcrops), and thus most individuals over fifty will have millions of "background" fibers in their lungs even without any known occupational or other direct exposure to asbestos.[108] These levels have never been known to cause disease, primarily because the human body is capable of ejecting, absorbing, or otherwise dealing with these low exposures.[109] Plaintiff experts almost without exception readily admit this and exclude background exposures from their cumulative dose opinions.[110] (This "admission" has the benefit for plaintiffs of preventing defendants from pointing to background exposures as contributory.) The fibers involved in these two types of exposures, however, are no different—only the dose distinguishes background from occupational exposures, and even then a low occupational exposure (such as the Crane gasket exposure of 0.0062 f/cc in the *Bartel* case above) can easily overlap or not exceed a higher background exposure.[111] Thus, there is no logic that permits these experts to categorically exclude background exposure, yet, at the same time,

104. *In re Toxic Substance Cases*, 2006 WL 2404008 at *1.
105. *Id.*
106. *Id.* at *11-12.
107. *Id.*
108. *Id.* at *3.
109. *Id.*
110. *Id.*
111. *Id.*

categorically include all occupational exposures as causative.[112]

Given the admission by plaintiff's experts that background exposures were not high enough to cause disease, Judge Colville recognized that it was incumbent on the experts to identify exactly *what dose would be sufficient* to cause disease:

> For instance, experts suggest that the average ambient exposure in Pittsburgh is approximately .0001 fibers per milliliter of air . . . . No one, including the plaintiff's experts, proffers an opinion that this level of exposure creates an increased risk of the development of any asbestos-related disease . . . . The argument in this Frye challenge, in part, revolves around the question of how much greater quantity of exposure is necessary to permit the causal attribution of an asbestos-related disease to a particular asbestos-related exposure.[113]

Plaintiff's experts made no attempt to measure or quantify the mechanics' occupational doses or show how they were sufficient to cause disease when background exposures clearly are not.[114] The court rejected the experts' complete failure to quantify or assess the mechanic's dose in any way because the lack of any measurement made it impossible for them to accurately distinguish low level occupational exposures from background exposures.[115]

Second, Judge Colville rejected the experts' attempt to "extrapolate down" from high-dose asbestos studies to prove that occupational exposures at low doses, above background or not, also must cause disease.[116] The amphibole form of asbestos is widely recognized to cause disease at significant doses (e.g., in the shipyard, insulator, and asbestos factory professions), but there are no low-dose response curves for asbestos exposure and no studies demonstrating an increase in actual disease at very low doses, particularly for chrysotile.[117] Drs. Maddox and Laman used the

112. *Id.* at *12.

113. *Id.* at *3 (emphasis added).

114. *Id.* at *6-7.

115. *Id.* at *6, 9, 11-13.

116. *Id.* at *6-7.

117. *Id.* at *6, 8. Whether chrysotile exposures cause mesothelioma at all is the subject of considerable debate currently in the scientific community. *See supra* notes 58-59; J. C. McDonald & A. D. McDonald, *Chrysotile, Tremolite and Carcinogenicity*, 41 ANNALS OCCUPATIONAL HYGIENE 699, 703 (1977); Thomas A. Sporn & Victor L. Roggli, *Mesothelioma*, *in* PATHOLOGY OF ASBESTOS-ASSOCIATED DISEASES 104, 108 (Victor L. Roggli et al. eds., Springer Sci.+Bus. Media, Inc. 2d ed. 2004) (1992) (stating the capacity of chrysotile to cause mesothelioma is "much debated"). Epidemiology studies have not demonstrated excess mesothelioma among populations exposed only to low levels of chrysotile. *See, e.g.*, *supra* note 58 (vehicle mechanic studies show no increased mesothelioma); Jennifer Pierce et al., *An Evaluation of Reported No-Effect Chrysotile Asbestos Exposures for Lung Cancer and Mesothelioma*, 38 CRITICAL REV. IN

"extrapolate down" methodology to assume, based on high-dose studies, that low-dose studies would also cause disease in a linear fashion.[118] Judge Colville rejected this approach:

> The fallacy of the "extrapolation down" argument is plainly illustrated by common sense and common experience. Large amounts of alcohol can intoxicate, larger amounts can kill; a very small amount, however, can do neither. Large amounts of nitroglycerine or arsenic can injure, larger amounts can kill; small amounts, however, are medicinal. Great volumes of water may be harmful, . . . moderate amounts of water, however, are healthful. In short, the poison is in the dose.[119]

Judge Colville recognized that when experts attempt this kind of extrapolation downward, they are engaged in both a logical falsehood and scientific error:

> [P]laintiffs have not proffered any generally accepted methodology to support the contention that a single exposure or an otherwise vanishingly small exposure has, in fact, in any case, ever caused or contributed to any specific individual's disease, or even less so, that in this case such a small exposure did, in fact, contribute to this specific plaintiff's disease.[120]

Finally, Judge Colville rejected the experts' reliance on the "no safe threshold" position.[121] The court noted the very large difference between stating that the threshold is not known and claiming that *there is no threshold at all*.[122] The court believed that such testimony improperly shifted the burden of proof to defendants when it is plaintiff's burden to establish the known toxic level of a substance and that plaintiff experienced a dose consistent with that level.[123]

Following Judge Colville's ruling, a second Pennsylvania trial judge rejected the *any exposure* testimony of Dr. Maddox on similar reasoning in a case involving heavy equipment mechanic exposures.[124] Judge Colville's decision is currently on appeal before Pennsylvania's intermediate appellate court. The Pennsylvania Supreme Court, however, recently issued a decision in *Gregg v. V.J. Auto Parts, Inc.*[125] that clearly rejects the *any exposure* theory and may well offer a glimpse into how the court would ultimately deal with *Betz*. *Gregg* involved allegations that personal car

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TOXICOLOGY 191 (2008) (identifying likely no-effect level in chrysotile studies).

118. *In re Toxic Substance Cases*, 2006 WL 2404008 at *7.
119. *Id.*
120. *Id.* at *8.
121. *Id.*
122. *Id.* at *8-9.
123. *Id.* at *8.
124. *See Basile*, No. 11484 CD 2005, slip op. at 5.
125. 943 A.2d at 226.

repair work on brakes and gaskets caused plaintiff's mesothelioma, resulting in a lawsuit against the auto parts store that sold Mr. Gregg the parts he used.[126] The primary holding in the case dealt with the application of the "frequency, proximity, and regularity" causation test, but in the course of the discussion the Court majority expressed a clear rejection of the *any exposure* approach:

> We recognize that it is common for plaintiffs to submit expert affidavits attesting that any exposure to asbestos, no matter how minimal, is a substantial contributing factor in asbestos disease. However, we share Judge Klein's perspective, as expressed in the *Summers* [*v. Certainteed Corp.*, 886 A.2d 240 (Pa. Super. 2005), *appeal granted*, 897 A.2d 460 (Pa. 2006)] decision, that such generalized opinions do not suffice to create a jury question in a case where exposure to the defendant's product is *de minimis*, particularly in the absence of evidence excluding other possible sources of exposure (or in the face of evidence of substantial exposure from other sources). As Judge Klein explained, one of the difficulties courts face in the mass tort cases arises on account of a willingness on the part of some experts to offer opinions that are not fairly grounded in a reasonable belief concerning the underlying facts and/or opinions that are not couched within accepted scientific methodology.[127]

While recognizing the occasional difficulty of proving which of plaintiff's exposures contributed to the disease, Pennsylvania's highest court nevertheless rejected the easy way out of simply stating that all exposures are responsible:

> [W]e do not believe that it is a viable solution to indulge in a fiction that each and every exposure to asbestos, no matter how minimal in relation to other exposures, implicates a fact issue concerning substantial-factor causation in every "direct-evidence" case. The result, in our view, is to subject defendants to full joint-and-several liability for injuries and fatalities in the absence of any reasonably developed scientific reasoning that would support the conclusion that the product sold by the defendant was a substantial factor in causing the harm.[128]

Thus, it now appears to be the law in Pennsylvania, as expressed by that state's highest court, that asbestos cases will have to follow the same dose and toxicity rules and proof as any other toxic tort case. A blanket assertion that each and every occupational exposure contributes to disease will no longer support an asbestos case in that state.

Pennsylvania's Supreme Court is not the only state supreme court to

126. *Id.* at 217-18.
127. *Id.* at 226 (citation omitted).
128. *Id.* at 226-27.

address this issue. Six months earlier, the Texas Supreme Court in *Borg-Warner Corp. v. Flores* became the first state court of last appeal to reject the *any exposure* theory.[129] The case involved a mechanic who worked most of his life doing brake and clutch jobs and claimed he developed asbestosis as a result of repeated, low-level exposures over a lifetime.[130] Following a line of Texas asbestos cases highly favorable to plaintiffs, the intermediate Corpus Christi appellate court had held that under Texas law it was sufficient for plaintiffs to show mere exposure to take a defendant to trial:

> In the context of asbestos-related claims, if there is sufficient evidence that the defendant supplied any of the asbestos to which the plaintiff was exposed, then the plaintiff has met the burden of proof . . . .
>
> . . . .
>
> [T]he plaintiffs offered evidence that the defendant's products emitted dust containing respirable asbestos fibers, which one of the plaintiffs had inhaled. On appeal, this Court held that the evidence was sufficient to prove the defendant's products injured both plaintiffs.
>
> . . . .
>
> "[W]ork[ing] in the presence of the asbestos-containing product" was "direct evidence" of causation and sufficient to uphold the jury's finding [of liability].[131]

These statements reflect the older, shortcut approach to causation in asbestos cases designed to expedite cases to trial and alleviate plaintiffs of the burden of proving which exposures actually contributed to their disease.[132] The Texas Supreme Court, however, rejected this approach as inconsistent with Texas tort and causation law:

> While science has confirmed the threat posed by asbestos, we have not had the occasion to decide whether a person's exposure to "some" respirable fibers is sufficient to show that a product containing asbestos was a substantial factor in causing asbestosis . . . . [W]e conclude that it is not . . . .[133]

The court's reasoning followed that of Judge Colville in recognizing the importance of dose, the need for a dose quantification, and the necessity of equating the plaintiff's dose to those in the epidemiological literature

129. 232 S.W.3d at 774.
130. *Id.* at 766.
131. *Flores*, 153 S.W.3d at 213-14 (citations omitted).
132. *See supra* notes 1-3 and accompanying text.
133. *Flores*, 232 S.W.3d at 765-66.

documenting disease.[134] Since *Flores*, other Texas courts have rejected the *any exposure* approach, including in mesothelioma cases.[135]

The federal bankruptcy court in Delaware (Judge Judith K. Fitzgerald) also rejected the *any exposure* theory in *In re W.R. Grace & Co.*[136] Plaintiff's experts contended that asbestos contamination in vermiculate attic insulation posed an unreasonable risk of harm to the homeowners because "any exposure to asbestos fibers is an unreasonable risk."[137] Their testimony was excluded under *Daubert*, however, because the experts failed to establish what level of exposure would actually cause disease and could not present any epidemiology studies demonstrating asbestos disease from exposure to vermiculite.[138] The court held, "[t]he use of the no safe level or linear 'no threshold' model for showing unreasonable risk 'flies in the face of the toxicological law of dose-response, that is, that 'the dose makes the poison . . . .'"[139]

Other courts in Mississippi and Washington State have similarly rejected *any exposure* testimony.[140] The Mississippi decision came in the context of an allegation that exposure to asbestos in a school justified a medical monitoring award, but the court of appeals rejected that approach

134. *Id.* at 770-74.

135. *See Georgia-Pac. Corp.*, 239 S.W.3d at 321; Letter Ruling, *In re Asbestos*, No. 2004-3, 964 (Tex. Dist. Ct., July 18, 2007). The Texas MDL judge actually presaged the *Flores* ruling in rejecting similar *any exposure* testimony in 2004. *See* Letter Ruling, *In re Asbestos*, No. 2004-03964 (excluding plaintiff expert Eugene Mark on "any exposure" theory).

136. 355 B.R. at 474-78.

137. *Id.* at 474.

138. *Id.* at 468.

139. *Id.* at 476. A Delaware state judge in charge of asbestos litigation, Judge Joseph R. Slights III, has rejected a broad motion by automotive defendants to dismiss all mechanic cases, filed largely on the ground that the epidemiology did not support such cases. Even in rejecting this argument, however, Judge Slights expressed considerable skepticism that a no threshold, *any fiber* theory would be viable:

> If, in a given case, a plaintiff must rely upon a no threshold theory to establish causation, the [c]ourt can determine the reliability of that testimony on a separate *in limine* motion. Suffice it to say, the testimony will be scrutinized carefully. *See Bartel v. John Crane, Inc.*, 316 F.[ ]Supp.[ ]2d 603, 611 (N.D. Ohio 2004) (finding Dr. Frank's single fiber theory to be inconsistent with prevailing scientific evidence, including the testimony of Drs. Lemen and Hammar).

In re Asbestos Litig., 911 A.2d 1176, 1209 n.202 (Del. Super. Ct.), *cert. denied*, 2006 WL 1579782 (Del. Super. Ct. June 7, 2006), *appeal refused*, 906 A.2d 806 (Del. 2006). The Michigan intermediate appellate court likewise failed to exclude the testimony of plaintiffs' expert Richard Lemen, but the decision turned on the vehicle mechanic epidemiology and not on a purported *any exposure* causation opinion. *See* Chapin v. A & L Parts, 732 N.W.2d 578, 587 (Mich. Ct. App.), *appeal denied*, 733 N.W.2d 23 (Mich. 2007), 733 N.W.2d 29 (Mich. 2007), *and* 733 N.W.2d 35 (Mich. 2007).

140. *See Brooks*, 934 So. 2d at 355-56; *Anderson*, No. 05-2-04551-5SEA, slip op. at 144-45 ("[T]his is not a theory which is generally accepted in the scientific community."); *Free*, No. 07-2-04091-9-SEA.

without some assessment that the dose was high enough to produce disease.[141] In one the Washington decisions, a state trial judge held that Dr. Samuel Hammar's testimony that any occupational exposure was sufficient to cause disease was "not a theory which is generally accepted in the scientific community" and thus prevented him from so testifying.[142] This case illustrates the extremes of the theory, as the case went to trial against Caterpillar, not in regard to plaintiff's extensive Navy exposures, but on the ground that plaintiff walked by Caterpillar engines while gaskets were being removed and thus must have breathed some asbestos fibers.[143] This ruling is believed to be the first substantive limitation on the testimony of Dr. Hammar, one of the most prominent of plaintiffs' testifying experts. Since then, Dr. Hammar's low dose testimony has been excluded by another Washington State trial judge (along with the testimony of another plaintiffs' expert, Dr. Carl Brodkin),[144] and in Texas in the *Georgia-Pacific Corp. v. Stephens*[145] mesothelioma case where Dr. Hammar testified that any exposure above 0.1 fibers/cc years would contribute to cause disease.[146]

One of the opinions criticizing the *any exposure* approach, *Summers v. Certainteed Corp.*,[147] directly addresses the illogic of the cumulative dose approach many of these expert use to include every exposure in causation:

> Dr. [Jonathan] Gelfand used the phrase, "Each and every exposure to asbestos has been a substantial contributing factor to the abnormalities noted." However, suppose an expert said that if one took a bucket of water and dumped it in the ocean, that was a "substantial contributing factor" to the size of the ocean. Dr. Gelfand's statement saying every breath is a "substantial contributing factor" is not accurate. If someone walks past a mechanic changing brakes, he or she is exposed to asbestos. If that person worked for thirty years at an asbestos factory making lagging, it can hardly be said that the one whiff of the asbestos from the brakes is a "substantial" factor in causing disease.[148]

The *Summers* statement proved influential in convincing the Pennsylvania Supreme Court to reject the *any exposure* approach in the recent *Gregg* ruling.[149]

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141. *See Brooks*, 934 So. 2d at 355-56.
142. *See Anderson*, No. 05-2-04551-5SEA, slip op. at 145.
143. *Id.* at 95.
144. *Free*, No. 07-2-04091-9-SEA, slip. op. at 4-5 (ruling on motion *in limine*).
145. 239 S.W.3d at 304.
146. *Id.* at 316.
147. 886 A.2d 240 (Pa. Super. Ct. 2005), *appeal granted*, 897 A.2d 460 (Pa. 2006).
148. *Id.* at 244 (emphasis omitted).
149. *See Gregg*, 943 A.2d at 226.

Experts who continue to assert the *any exposure* basis for medical causation in asbestos cases are carrying a torch that is being extinguished repeatedly in asbestos cases around the country. As courts have held, "each and every exposure" testimony is, at best, an unproven hypothesis that ignores scientific principles and should not suffice for causation in an asbestos case.[150]

IV. HOW THE *ANY EXPOSURE* THEORY FITS INTO THE SCIENTIFIC AND TORT LITIGATION WORLD

Plaintiffs' experts who support the *any exposure* approach to asbestos litigation can speak at great length and cite to many materials to justify their approach. The discussion is a siren song of epidemiology, animal studies, the history of asbestos, fear of cancer, case reports of persons with mesothelioma and a certain exposure, and mathematical predictions of thousands of mesothelioma cases at even the lowest of doses.[151] They can cite to a number of review articles and other published literature that support at least a portion of their approach, much of it written by other plaintiff testifying experts.[152] Government publications also offer tacit support, since regulators take highly conservative approaches and rarely, if ever, declare any form of asbestos exposure to be "safe," even when the literature supports an identifiable no-effect level.[153]

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150. *See, e.g.*, *In re Toxic Substance Cases*, 2006 WL 2404008 at *6; *Bartel*, 316 F. Supp. 2d at 611; *Georgia-Pac. Corp.*, 239 S.W.3d at 320-21.

151. *See, e.g.*, Lemen, *supra* note 59; David Egilman et al., *Exposing the "Myth" of ABC, "Anything But Chrysotile": A Critique of the Canadian Asbestos Mining Industry and McGill University Chrysotile Studies*, 44 AM. J. INDUS. MED. 540 (2003); Laura S. Welch, *Asbestos Exposure Causes Mesothelioma, But Not* This *Exposure: An Amicus Brief to the Michigan Supreme Court*, 13 INTL. J. OCCUPATIONAL & ENVTL. HEALTH 318 (2007).

152. *See, e.g.*, Lemen, *supra* note 59; *see also* Egilman et al., *supra* note 151; *see also* Welch, *supra* note 151; David S. Egilman, *Abuse of Epidemiology: Automobile Manufacturers Manufacture a Defense to Asbestos Liability*, 11 INT. J. OCCUPATIONAL & ENVTL. HEALTH 360 (2005); BARRY I. CASTLEMAN, ASBESTOS: MEDICAL AND LEGAL ASPECTS 539-80 (Aspen Publishers, Inc. 5th ed. 2005). All of these authors testify on behalf of plaintiffs in asbestos litigation.

153. *See, e.g.*, Pierce et al., *supra* note 117, at 205 (calculating no-effect level for chrysotile exposures). For example, despite the extensive growing evidence that chrysotile is less potent than amphiboles and that short fibers do not cause disease, neither OSHA nor EPA has ever made any distinctions between the different exposures in their regulatory requirements. There are practical reasons for this (the difficulty of separating exposures in a workplace), but the justification is usually, "since we don't know for sure we'll just be cautious and regulate everything the same way." While this approach may have some justification in the regulatory world, it should never serve as a basis for finding legal causation as to any exposure regardless of disease-inducing potency. EPA has announced the creation of a scientific advisory panel to assist

Nevertheless, despite these attempts to support it, the *any exposure* theory does not have any credible foundation in the scientific literature.[154] In fact, the *any exposure* theory is almost entirely a litigation construct and is not widely published or accepted in the peer-reviewed literature. Virtually nothing in the literature expressly states what these experts routinely say in court—that each and every occupational exposure, no matter how small, is a cause of disease.[155] There is great debate over related subjects such as whether chrysotile should be considered a cause of mesothelioma, whether short fibers contribute to disease, or whether occupations like vehicle mechanics are even subject to any asbestos disease at all, despite long-term, low-level exposures.[156] Even the most plaintiff-oriented of these articles, however, do not take the extreme position that there is no minimum. The litigation proponents of the theory themselves rarely, if ever, present the notion that *every occupational exposure is causative* to the general scientific community through publications or

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the agency in deciding whether its asbestos risk assessment process should be modified to reflect the growing literature and findings.

154. *See* cases cited *supra* note 65.

155. Perhaps the closest enunciation is that of the "Helsinki Criteria," a document generated by nineteen scientists in 1997 to develop their version of criteria for attributing lung cancer and mesothelioma to asbestos exposure. *See Asbestos, Asbestosis, and Cancer: The Helsinki Criteria for Diagnosis and Attribution*, 23 SCANDINAVIAN J. WORK ENV'T & HEALTH 311, 312-14 (1997). As to mesothelioma, the Helsinki Criteria states that a "significant occupational exposure" is adequate for attribution, but then later restates (confusingly) that "brief or low level exposures" are also sufficient. *Id.* at 313. There is no definition or even discussion of what would constitute a significant, brief, or low level exposure, and no justification provided for attributing disease to such exposures, particularly for chrysotile. Nor does the Helsinki Criteria document purport to provide any basis for determining *which* occupational exposures should be considered causative—it merely provides criteria for attributing a disease to occupational exposure generally. Even the Helsinki Criteria's extreme approach to mesothelioma attribution does not state that every occupational exposure, or every exposure above background, should be considered disease-inducing. Instead, it clearly implies a universe of occupational exposures that are too low to be included and some judgment about dose and duration must be exercised before attributing a disease to an occupational exposure. *See id.*

156. *Cf., e.g.*, Ronald F. Dodson et al., *Asbestos Fiber Length as Related to Potential Pathogenicity: A Critical Review*, 44 AM. J. INDUS. MED. 291 (2003); Phillip J. Landrigan et al., *The Hazards of Chrysotile Asbestos: A Critical Review*, 37 INDUS. HEALTH 271 (1999); William J. Nicholson, *The Carcinogenicity of Chrysotile Asbestos—A Review*, 39 INDUS. HEALTH 57 (2001); Gunnar Hillerdal, *Mesothelioma: Cases Associated with Non-Occupational and Low Dose Exposures*, 56 OCCUPATIONAL & ENVTL. MED. 505 (1999); *with* Hodgson & Darnton, *supra* note 68 (stating chrysotile far less potent than amphiboles); EASTERN RESEARCH GROUP, INC., REPORT ON THE EXPERT PANEL ON HEALTH EFFECTS OF ASBESTOS AND SYNTHETIC VITREOUS FIBERS: THE INFLUENCE OF FIBER LENGTH vi (2003), http://www.atsdr.cdc.gov/HAC/asbestospanel/final part1.pdf; EASTERN RESEARCH GROUP, INC., REPORT ON THE PEER CONSULTATION WORKSHOP TO DISCUSS A PROPOSED PROTOCOL TO ASSESS ASBESTOS RELATED RISK viii (2003), http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf; Churg, *supra* note 58, at 314.

scientific conferences where it could be scrutinized and likely debunked. Thus, the theory completely fails the *Daubert* "peer review and publication" test and the "general acceptance" test under either *Daubert* or *Frye*.[157]

The *any exposure* theory also does not fit well in the litigation world. It is largely an asbestos issue because in most toxic tort litigation the notion that any exposure to a toxin satisfies the substantial factor or but-for tests of causation would be considered so extreme that most experts would not have the temerity to present it. In the *Parker* case discussed previously, the plaintiff's experts testified that plaintiff's AML was caused by many years of gas station work exposures, not *any* exposure.[158] Imagine if they had been dealing with a long-time benzene factory worker—the exact population demonstrated by epidemiology to be at risk—but tried to blame the plaintiff's disease on the few times he put gas in his own car and thus breathed miniscule amounts of benzene in gasoline. This is the equivalent of the *any exposure* theory carried over to non-asbestos litigation.

At best, the *any exposure* approach is only a theory, an unproven hypothetical concept. At worst and carried to extremes, it is almost certainly erroneous and misleading, and would never be permitted as a basis for testimony in most toxic tort causation contexts. Only in the world of special asbestos rules can such a theory gain a foothold.

V. ASBESTOS JURISPRUDENCE IN LIGHT OF THE DECISIONS REJECTING THE *ANY EXPOSURE* THEORY

The above decisions rejecting the *any exposure* theory have the potential to affect a sea of change in asbestos litigation causation testimony. The issues they raise will likely come to be litigated at some point in virtually every asbestos jurisdiction.

Many of the courts that will have to address *any exposure* motions have managed asbestos cases for years and have seen some of the plaintiffs' experts testify perhaps hundreds of times without anyone challenging the scientific basis for their testimony. Some of these judges will be quite puzzled to understand why defendants are suddenly raising expert and

157. The *Daubert* test requires that the scientific methodology be reliable, one aspect of which is that the theory/methodology have been subjected to peer review and general acceptance in the scientific community. *See Daubert*, 509 U.S. at 593-94. The *Frye* test is more narrow, requiring simply that the theory be accepted in the scientific community before admission as evidence. *See id.* at 584-85. Both tests are designed to prevent theories from being presented as courtroom evidence before they have run the gauntlet of review and testing in the scientific community. *See id.* at 589-90.

158. *See supra* notes 33-41 and accompanying text.

causation issues not part of the previous asbestos landscape. For several reasons, courts should take a closer look at this causation testimony, even if they have not done so in the past.

A. *Courts Should Begin to Apply Standard Tort Principles and Causation Rules to Asbestos Cases*

For three decades, the special asbestos rules affecting causation created a unique opportunity for plaintiffs to prove their cases merely by identifying a defendant's product and asserting, through plaintiff's or co-workers' testimony, that some fibers from that product were in the plaintiff's breathing zone.[159] In the context of the "old" asbestos litigation, where, for example, an insulator might work with multiple insulation products but could not necessarily prove how much with each one, the rule served to overcome proof obstacles in occupations and industries clearly demonstrated through epidemiology to cause mesothelioma and other asbestos disease.[160]

Whether the relaxation of causation rules was justified in this circumstance or not, the justification no longer exists where most of the defendants are not asbestos companies or insulation suppliers, but are companies that only sold or used products with limited asbestos in them. Often the asbestos in the products used or sold by these defendants was sealed in resins or binders and thus would not ordinarily produce much, if any, exposure. Mechanic exposures, for example, have historically been in the range of half the current OSHA standard of acceptable exposures in the workplace.[161] Gaskets likewise produce very little exposure, as noted in the *Bartel* case.[162] Nevertheless, in the face of allegations that the plaintiff worker or co-worker witnessed visible dust while working with asbestos parts, or disrupted these products through grinding, sanding, cutting, or drilling, it is nearly impossible for such a defendant to claim *zero* fiber exposure—the only defense that could avoid a trial under an *any exposure* attack.

These cases fall squarely into the world of the New York *Parker* case, where the causation theory is highly speculative and theoretical, and is not supported by epidemiology showing disease from these exposures or

159. *See supra* notes 1-3, 46-47 and accompanying text.

160. *See id.*

161. *See* Paustenbach et al., *supra* note 80.

162. *See Bartel*, 316 F. Supp. 2d at 608.

occupations.[163] If plaintiff law firms wish to develop a new wave of asbestos litigation against *de minimis* exposure defendants, based on a theory that is not generally accepted in the scientific community, they should not be permitted to rely on the old rules to do so. Instead, the principles of *Parker* and other traditional toxic tort cases should apply, and the testimony must be tested under *Daubert*, *Frye*, or other state evidentiary and expert requirements before trial. Plaintiffs' experts should be required to assess the dose from an individual defendant's product or workplace and demonstrate that it is the kind of dose shown in established epidemiology studies to be capable of causing disease.

B. *The Expansion of Asbestos Litigation to a Wide Array of Minimal Exposure Defendants is Unjustified*

The effect of the *any exposure* theory can be exceptionally unfair when applied to defendants connected with extremely small exposures, especially when plaintiff experts ignore far more significant exposures that almost certainly caused the disease. The unfairness is only multiplied in jurisdictions that will not permit the defendants remaining at trial to point to the plaintiff's real asbestos exposures from other sources.[164] The courts discussed above have sometimes reacted to the perverse effect of the *any exposure* theory as applied to asbestos cases. The Pennsylvania *Summers* court, for example, noted the incongruity of blaming a single brake job for plaintiff's mesothelioma when he was a lifelong insulator.[165] The *Gregg* court questioned why plaintiffs were trying to take a brake parts supplier to trial when the complaint alleged a forty-year history of occupational exposure.[166] The *Bartel/Lindstrom* cases noted that the claim against the provider of gaskets and packings seemed trivial in comparison to the worker's extensive insulation exposure.[167]

These courts are recognizing that asbestos causation can get out of

163. *See Parker*, 857 N.E.2d at 1121-22.

164. In Illinois, for instance, the bizarre *Lipke v. Celotex Corp.*, 505 N.E.2d 1213 (Ill. App. Ct. 1987), rule, the only one of its kind in the country, prohibits a trial defendant from informing the jury about *any* of plaintiff's other asbestos exposures, even when those exposures were severe (e.g., in the Navy) and far more than sufficient to cause the disease. This rule, and others like it that prohibit references to bankrupt asbestos companies, leave the jury with few or no sources of asbestos to consider as the cause of the plaintiff's disease except for the minimal exposures of the remaining, low dose trial defendants. *See generally* Victor E. Schwartz et al., *Asbestos Litigation in Madison County, Illinois: The Challenge Ahead*, 16 WASH. U. J.L. & POL'Y 235 (2004).

165. *See Summers*, 886 A.2d at 244.

166. *See Gregg*, 943 A.2d at 226.

167. *See Bartel*, 316 F. Supp. 2d at 610-11.

control under the *any exposure* approach. Yet plaintiffs' experts refuse to acknowledge that their theory attaches causation to trivial exposures, nor do they even attempt to separate work experiences that truly cause asbestos disease from those that contribute nothing but isolated or inconsequential exposures. Put bluntly, there is likely to be a credibility issue for courts that allow experts to testify that a single breath of exposure justifies taking that defendant to trial.[168]

C. *The Science Requires More*

As documented in Judge Colville's analysis[169] and others above, the *any exposure* experts do not have epidemiology or other scientific proof that these low exposures cause anything. They are testifying to a theory, a hypothesis, an estimate of disease derived from assumptions that may or may not be true. Courts cannot be in the business of allowing cases to go forward with only theory and speculation to prove causation. Under either *Frye* or *Daubert*, and for that matter under basic evidentiary and reliability principles, there must be more.[170] Traditional industrial hygiene and toxicology principles and methodologies exist under which non-litigation professionals can assess whether past exposures were sufficient to cause disease.[171] The *Parker* opinion noted as much and found no merit to the contention that low dose cases cannot be proven unless plaintiffs are given the advantage of avoiding any dose assessment.[172] The reality is that such cases can and should only be proven if the dose can be reasonably and scientifically assessed and there is credible science supporting causation at such doses. Otherwise, the experts should be excluded and the cases should not go to trial.

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168. Virtually everyone who lives in an industrial society has been exposed to asbestos fibers and could be a potential plaintiff under the *any exposure* theory, even though there is no evidence low-level exposures consistent with background exposures actually cause disease.

> [Because asbestos] is one of the most ubiquitous of the Earth's minerals and in addition, millions of cars still spew thousands of asbestos fibers into the air each time a driver applies the brakes, many if not most adults in the general population have significant numbers of asbestos fibers in their lungs; however, despite breathing in millions of asbestos fibers annually, virtually none of the population thus exposed to ambient concentrations of asbestos fibers thereby suffer adverse effects on their health.

Brickman, *supra* note 87, at 49.

169. *See supra* notes 103-23 and accompanying text.

170. *See Frye*, 293 F. at 1013 (explaining admission of expert testimony depends on general acceptance within the scientific community); *see also Daubert*, 509 U.S. at 579 (explaining admission of expert testimony depends on reliability).

171. *See, e.g.*, *Parker*, 857 N.E.2d at 1114.

172. *See supra* notes 33-41 and accompanying text.

D. *It Is Not Sufficient to Let a Low-dose Case Simply Go to the Jury*

Some courts are proponents of letting expert disputes, such as the level of exposure required, go to the jury in every instance. Similarly, some of the *any exposure* experts, when confronted with their failure to separate significant from insignificant exposures, respond that they are unwilling to deal with differences among defendants and simply expect the jury to figure it all out. This is not an acceptable approach, scientifically or legally. Without any expert testimony separating the exposures likely to have caused the disease from those unlikely to have done so, the jury has no basis to make the decision. The attribution of disease among different fiber types and exposure experiences is not within the province of a lay person but must be supported by expert testimony. Experts who abdicate that exercise should not be permitted to testify that all exposures "contribute" and then hand it over to the jury.

Likewise, the subject of "how much is enough" is without question one that is subject to a *Daubert/Frye* review of the experts' methodology and testimony. Judges cannot abdicate their gatekeeping function on this critical expert issue,[173] but must determine whether the expert testimony and causation evidence pass scientific and legal muster. This is particularly true in complex science cases, in which juries of lay people are singularly ill-equipped to sort through the complex studies and scientific issues and instead often render decisions based on favorable reactions to witnesses, impressive testimony by the experts, and sympathy for a plaintiff who is likely to die soon (or already has) from a disease known to be caused by asbestos.

VI. CONCLUSION

Asbestos has for years held sway as perhaps the most feared of industrial exposures. At the same time, asbestos litigation has also earned a reputation as the most out-of-control of all tort litigation. The history of asbestos is indeed a terrible one, with great loss of life from exposures that predate the institution of OSHA workplace and other regulations. That history is not a basis for blaming every fiber and every breath for asbestos disease in today's litigation environment. Courts must exercise control over the current state of litigation and the assertion of the *any exposure* theory. In light of the array of recent decisions rejecting that theory, courts that do so are clearly in good company and have substantial support from their colleagues in other jurisdictions.

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173. *See, e.g.*, *Daubert*, 509 U.S. at 597.