Nos. 20-1774, 20-1776, 20-1777, 20-1780, 20-1781, 20-1782, 20-1783, 20-1784, 20-1785

United States Court of Appeals
for the Seventh Circuit

GLENN BURTON, JR., RAVON OWENS,
and CESAR SIFUENTES,
Plaintiffs-Appellees,

v.

ARMSTRONG CONTAINERS, INC.,
E.I. DUPONT DE NEMOURS & COMPANY, *and*
THE SHERWIN-WILLIAMS COMPANY,
Defendants-Appellants.

On appeal from final judgments of the U.S. District Court for the Eastern District of Wisconsin,
Nos. 07-303, 07-441, and 10-75 (consolidated)
Hon. Lynn S. Adelman, District Judge.

BRIEF OF AMICUS CURIAE PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF APPELLANTS AND REVERSAL

Alan J. Lazarus (SBN 129767)
alan.lazarus@faegredrinker.com
FAEGRE DRINKER BIDDLE & REATH LLP
Four Embarcadero Center, 27th Floor
San Francisco, California 94111
Telephone: +1 415 591 7500
Facsimile: +1 415 591 7510

David B. Sudzus
david.sudzus@faegredrinker.com
FAEGRE DRINKER BIDDLE & REATH LLP
191 N. Wacker Drive, Suite 3700
Chicago, Illinois 60606
Telephone: +1 312 569 1000
Facsimile: +1 312 569 3498

Counsel for Amicus Curiae
THE PRODUCT LIABILITY ADVISORY COUNCIL, INC.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, The Product Liability Advisory Council, Inc. ("PLAC") states it is a non-profit association with no parent or subsidiary corporations. No publicly held company owns 10% or more of its stock.

The law firm that appears for PLAC in this matter is Faegre Drinker Biddle & Reath LLP. PLAC did not appear in the proceedings before the district court.

Dated, July 24, 2020

FAEGRE DRINKER BIDDLE & REATH LLP

By: */s/ Alan J. Lazarus*

Alan J. Lazarus (SBN 129767)
alan.lazarus@faegredrinker.com
Four Embarcadero Center, 27th Floor
San Francisco, California 94111
Telephone: +1 415 591 7500
Facsimile: +1 415 591 7510

David B. Sudzus
david.sudzus@faegredrinker.com
FAEGRE DRINKER BIDDLE & REATH LLP
191 N. Wacker Drive, Suite 3700
Chicago, Illinois 60606
Telephone: +1 312 569 1000
Facsimile: +1 312 569 3498

Counsel for Amicus Curiae
THE PRODUCT LIABILITY
ADVISORY COUNCIL, INC.

Save As Clear Form

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: Nos. 20-1774, 20-1776, 20-1777, 20-1780, 20-1781, 20-1782, 20-1783, 20-1784, 20-1785

Short Caption: Glenn Burton, Jr., et al., v. Armstrong Containers, Inc., et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Product Liability Advisory Council, Inc., Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Faegre Drinker Biddle & Reath LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Alan J. Lazarus Date: July 31, 2020

Attorney's Printed Name: Alan J. Lazarus

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

Address: Faegre Drinker Biddle & Reath LLP

Four Embarcadero Center, 27th Floor, San Francisco, CA 94111-4180

Phone Number: (415) 591-7500 Fax Number: (415) 591-7510

E-Mail Address: alan.lazarus@faegredrinker.com

Save As Clear Form

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: Nos. 20-1774, 20-1776, 20-1777, 20-1780, 20-1781, 20-1782, 20-1783, 20-1784, 20-1785

Short Caption: Glenn Burton, Jr., et al., v. Armstrong Containers, Inc., et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Product Liability Advisory Council, Inc., Amicus Curiae

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Faegre Drinker Biddle & Reath LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ David B. Sudzus Date: July 31, 2020

Attorney's Printed Name: David B. Sudzus

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: Faegre Drinker Biddle & Reath LLP

191 N. Wacker Drive, Suite 3700, Chicago, IL 60606

Phone Number: (312) 569-1000 Fax Number: (312) 569-3498

E-Mail Address: david.sudzus@faegredrinker.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES, RULES & REGULATIONS

OTHER AUTHORITIES

IDENTITY AND INTEREST OF AMICUS CURIAE

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit professional association of corporate members representing a broad cross-section of American and international product manufacturers (including Defendant/Appellant The Sherwin-Williams Company).[1] On behalf of its members, PLAC seeks to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products and those in the supply chain.

PLAC's perspective derives from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product litigation defense attorneys are sustaining (non-voting) members of PLAC.

Since 1983, PLAC has filed more than 1,100 briefs as amicus curiae in both state and federal courts. PLAC briefs support its members' interests, present the broad perspective of product manufacturers, and seek fairness and balance in the application and development of the law as it affects product liability and risk management.

PLAC's interest in this action arises from the interest of its members. PLAC's members frequently are involved in product liability litigation featuring

[1] *See* https://plac.com/PLAC/Membership/Corporate_Membership.aspx (listing the corporate members of PLAC).

the testimony of expert witnesses, including experts testifying on complex topics of medical causation that implicate the reliability of the jury's fact finding. PLAC's members often litigate issues involving the admissibility of expert opinion testimony under Federal Rule of Evidence 702 and state counterpart rules.

Further, PLAC's members are occasionally confronted with theories of causation and injury which seek to stretch the bounds of substantive tort law, such as expansive theories of what qualifies as a compensable injury under state tort law. These companies and the attorneys that represent them have an interest in avoiding the expansion of the scope of liability where it is not warranted by law and public policy, and assuring that juries are adequately instructed on the boundaries of tort liability, so that its members can avoid excessive liabilities and unfair economic burdens.

INTRODUCTION

This case presents issues of importance to the operation of Federal Rule of Evidence 702 (Rule 702) in the context of testimony asserting the existence of brain damage and its causal connection to toxic exposures, and the foundation required for reliable conclusions on the subject. In light of the way scientists approach causal assessments, and measured against applicable standards for the admission of expert testimony, the testimony of Doctors Trope and Besunder lacked a reliable foundation and should have been excluded. To allow the jury to hear it was an abuse of the district court's discretion as a gatekeeper.

The district court declined to instruct the jury and provide substantive guidance on how to decide the issues of injury and the causal relationship required between the claimed injury and the alleged tortious conduct. The Court should clarify district courts' obligation to give appropriate guidance to jurors on the sometimes complicated, obscure issues they are called upon to decide.

DISCUSSION

A. The District Court Erred By Admitting Unreliable Expert Testimony on the Issues of Injury and Causation

The district court's application of Rule 702 to admit or exclude expert testimony is reviewed for abuse of discretion. *General Elec. Co. v. Joiner*, 522 U.S. 136, 142-43 (1997). This Court bifurcates the analysis: It first reviews *de novo* the district court's application of the framework established in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). It then reviews for abuse of discretion the district's court determination to admit or exclude the testimony under Rule 702. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 804 (7th Cir. 2007).

1. Proof of Causation in Toxic Tort Cases

Decades of toxic tort and product liability litigation, scientific development, and judicial opinions have produced a recognized consensus methodology of scientific proof in cases like this one. M. Green, et al., *Reference Guide on Epidemiology* 551 & n.2, in **Reference Manual on Scientific Evidence** (Fed. Judicial Ctr. 3d ed. 2011) ("*Green Reference Guide*"). That experience reveals

conspicuous foundational flaws in the testimony of Drs. Trope and Besunder.

Epidemiology plays an important role in reaching valid scientific conclusions as to the causation of latent injuries in toxic tort litigation. Epidemiology is the study of disease in the general population. *Green Reference Guide* at 551-52. Through experimental statistics-based studies, it examines the question of whether an agent or class of agents can produce a certain medical outcome in the population.

If a statistical association between exposure to an agent and an outcome is found in at least one study, the scientist then proceeds to evaluation of all the available epidemiological data and other relevant scientific evidence (such as toxicology data based on animal and in vitro experiments) applying established analytical guidelines, to determine whether the totality of the evidence supports an inference of general causation (that exposure to the agent can cause the disease in the general population). *Id.* at 597-600; *In re Lipitor (Atorvastatin Calcium) Marketing, Sales, Practices and Prods. Liab. Litig*, 892 F.3d 624, 640 (4th Cir. 2018). [2] If the evaluation of the totality of the evidence under the causation guidelines produces a scientifically sound conclusion that the association is probably causal in nature, then the epidemiological evidence has established

[2] There are several sets of guidelines used by scientists to assess the evidence and evaluate general causation. The most well-known in the scientific community are the Bradford Hill guidelines. *Green Reference Guide* at 598-600 & n.141.

general causation. *Green Reference Guide* at 597-600.

General causation (increased risk of the endpoint in the population) establishes only a *possibility* of specific causation, meaning causation as to a specific exposed individual (e.g., a plaintiff).[3] *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005) (a finding of general causation is a prerequisite to specific causation, because only if the substance *can* cause the disease *in the population* is it possible that it caused the plaintiff's disease); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1238, 1253 (11th Cir. 2005) (same); *Green Reference Guide* at 611 ("An agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general.").

Whether that possibility of causation crosses over into probability (more likely than not) of causation in the individual ordinarily requires further analysis of additional factors and additional evidence. How closely does the individual's exposure resemble the exposure characteristics identified in the epidemiology studies as variables associated with the endpoint? *Green Reference Guide* at 552, 613-14. What dose or level of exposure to the agent, under what circumstances, has been shown to produce the endpoint? *Id.* at 603; *see McClain*, at 1241-42.

[3] *See, e.g., In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1129 (9th Cir. 2002) ("'Generic causation' has typically been understood to mean the capacity of a toxic agent … to cause the illnesses complained of by plaintiffs. If such capacity is established, 'individual causation' answers whether that toxic agent actually caused a particular plaintiff's illness.").

What demographic characteristics are associated with or excluded from the risk? *Green Reference Guide* at 552, 613. What comorbidities or risk factors must be present and what protective characteristics have to be absent? *Id.* at 613. What is the range of established latency periods between the exposure and the manifestation of signs or symptoms? *Id.* at 601.

As part of this evaluation, the scientist then compares the causation scenario supported by the epidemiology evidence to the circumstances of the plaintiff and his or her exposure. If they sufficiently match that of the population shown in the studies to develop the endpoint from exposure to the agent, including in particular the dose, then an expert may be justified in "ruling in" the exposure as a potential cause of the endpoint in the individual. *Id.* at 613-14 & n.194. *See Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010).

After the exposure has been scientifically ruled in as a potential cause, an expert can then proceed to determine specific causation, evaluating whether the individual plaintiff's condition was actually caused by the exposure, or rather by something else. This ordinarily involves a comparison of the various potential etiological explanations for the injury and their likelihood, ruling out the ones that are not supported. J. Wong, et al., *Reference Guide on Medical Testimony* 690 n.8 in **Reference Manual on Scientific Evidence** (Fed. Judicial Ctr 3d ed. 2011). *See Tamraz*, at 674 (requiring a reliable specific causation conclusion to be based on

(1) an accurate diagnosis of the condition, (2) a reliable determination ruling in the exposure as a possible cause, and (3) a reliable determination ruling out the rejected alternative causes); *Claussen v. M/V New Carissa*, 339 F.3d 1049, 1058 (9th Cir. 2003) (requiring that the exposure be reliably ruled in and the alternative causes be reliably ruled out using scientific methods and procedures).

But in all cases, under Rule 702, the expert's causality methodology, foundation, and reasoning must be reliable, scientifically valid, and intellectually rigorous. It must not be speculative. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("the courtroom is not the place for scientific guesswork, even of the inspired sort").

As these principles demonstrate, epidemiological studies play an important role in causal assessments, but that role ordinarily is limited to evaluating general causation and cannot be used to draw direct inferences about the existence of specific causation. "Epidemiology focuses on the question of general causation (i.e., is the agent capable of causing disease?) rather than that of specific causation (i.e., did it cause disease in a particular individual?)." *Green Reference Guide* at 552. *See also id.* at 553 ("employing the results of group-based studies of risk to make a causal determination for an individual plaintiff is beyond the limits of epidemiology"); *id.* at 608:

> **Epidemiology is concerned with the incidence of disease in populations, and epidemiological studies do not address the**

> **question of the cause of an individual's disease. This question, often referred to as specific causation, is beyond the domain of the science of epidemiology. Epidemiology has its limits at the point where an inference is made that the relationship between an agent and a disease is causal (general causation) and where the magnitude of excess risk attributed to the agent has been determined; that is, epidemiologists investigate whether an agent can cause a disease, not whether an agent did cause a specific plaintiff's disease.**

Thus, drawing conclusions about an individual's condition and its cause based on population studies is not a scientifically sound and valid methodology. And misusing epidemiological evidence in this way fails to meet the level of scientific rigor expected of experts in the field. *See, e.g.*, *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321-22 (9th Cir. 1995) (on remand from the Supreme Court; absent consistent epidemiological studies demonstrating more than doubling of the risk in exposed subjects similar to plaintiffs, epidemiology studies cannot support an inference of individual causation, and expert's testimony to that effect would be inadmissible under *Daubert*).

2. Dr. Trope's Testimony was Inadmissible and Should Have Been Excluded

Against this backdrop and measured against Rule 702 standards, Dr. Trope's testimony was inadmissible and its admission an abuse of discretion.

Dr. Idit Trope, a neuropsychologist, told the jury that each plaintiff had

incurred brain damage caused by their exposure to lead. DJA2648/2994. She based her opinion primarily on each plaintiff's performance on a battery of neuropsychological tests conducted long after their exposure, during the litigation. DJA2677-78/3122, 3125. But cognitive performance tests can demonstrate no more than the level of existing function at the time of testing; as a single data point, they cannot reveal any *change* in capability or function, unless paired with comparative evidence of pre-exposure baseline function. And even if reliable comparable evidence of previous function could support a finding of diminution in performance or capability, cognitive tests are incapable of proving what agents or influences produced the change.

The snapshot Dr. Trope obtained of the plaintiffs' performances and capabilities is not evidence a neuropsychologist or other medical expert could use reliably to prove injury, much less the cause of an injury. And the insistence she can do so reflects both an unsound and scientifically unacceptable methodology and a lack of requisite intellectual rigor. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (the purpose of gatekeeping is to guarantee that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

Cognitive performance tests can perhaps contribute to understanding whether plaintiff has a deficit compared to the average score, and prompt a further

investigation into whether there is a neurological injury and its possible causes. But it ordinarily cannot be the sole or primary basis to establish the existence of an injury and its cause. There has to be a "before" counterpart to the test's "after" to establish a decline in function, and there must be some independent reliable evidence supporting a causal link. In the absence of that baseline and non-speculative linkage, there is simply too great an analytical gap between the data and the conclusion that there is causation and an injury. *See Joiner*, 136 U.S. at 146.

Dr. Trope's opinion testimony also committed one of *Daubert*'s cardinal sins – it is fundamentally subjective. *See Daubert*, 509 U.S. at 590 (distinguishing admissible scientific knowledge from inadmissible subjective belief and unsupported speculation). The Rule 702 case law repeatedly warns against medical causation opinions based heavily on the expert's impressionistic judgments and personal opinion because they defy one of the hallmarks of the scientific method, verification or falsification. *See Daubert*, 509 U.S. at 593-94 (one criteria for reliability is whether or not the expert's opinion or theory can be tested or verified). Dr. Trope finds brain damage based on her interpretation of the "pattern of performance" on each plaintiff's separate cognitive tests. DJA2677/3122. She cited no set of published professional guideposts or objective criteria that would permit another neuropsychologist or other expert to say she is right or wrong. In *Daubert*-speak, there is no known error rate, no peer-reviewed methodology, and

no generally accepted method or standard. Even "a supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999).

There may be other areas of expertise where experience and personal impression can provide a sufficiently reliable foundation, but a determination that an individual has experienced brain damage, and particularly a determination as to the source of that damage, is not one of them. Dr. Trope's injury and causation opinion testimony is too subjective, standardless and unverifiable to qualify as scientific knowledge and assist the trier of fact.

In sum, the district court's rejection of the defense *Daubert* challenges to Dr. Trope's opinion testimony cannot be sustained as a reasonable exercise of discretion. Testimony drawing subjective conclusions about diminished function and its cause based solely on the interpretation of a plaintiff's performance on subsequent cognitive tests is not a scientifically sound and valid methodology and fails to demonstrate the level of intellectual rigor employed by experts in the field.

3. Dr. Besunder's Testimony was Inadmissible and Should Have Been Excluded

Dr. James Besunder, an M.D. toxicologist, was allowed to tell the jury that each plaintiff had sustained a brain injury caused by lead exposure producing a loss of IQ of "at least 10 points." DJA2570/2619, 2590/2715, 2594/2731, 2597/2742.

This injury and causation testimony should have been excluded because he testified to specific causation but he relied on epidemiological studies that can support only general causation. The studies were capable of proving, at most, no more than lead exposure under certain circumstances is capable of causing brain injury and variable loss of IQ – not that it did so, or did so at any particular level in these plaintiffs. Admission of his epidemiological testimony to prove something it could not was an abuse of discretion.[4]

Dr. Besunder's testimony runs afoul of the recognized scientific limitations of epidemiology evidence outlined above. Nothing in the population studies he relies on scientifically justify his transition from the general to the particular, from general causation to specific or individual causation.[5]

Dr. Besunder failed to lay any foundation to fit any of the plaintiffs squarely within a profile that could reliably apply the study population data to the individual plaintiffs, and no basis appears in the record to do so. All of the plaintiffs appear to

[4] Dr. Besunder also based his opinion testimony in large part on Dr. Trope's unreliable opinion testimony, a second, independent ground for exclusion.

[5] The effort to draw an individualized inference from population data is reminiscent of logically flawed efforts to reach conclusions that a particular product subject to a recall is defective. Courts consistently find that mere inclusion of a product within a recall population does not prove the specific unit is defective or otherwise relieve a plaintiff of the burden of proving the defect exists in that unit. Rather, the plaintiff must produce independent evidence that the unit contains the defect. *See, e.g., Vockie v. General Motors Corp.*, 66 F.R.D. 57, 61-62 (E.D. Pa. 1975), *aff'd mem.*, 523 F.2d 1052 (3d Cir. 1976); *Landry v. Adam*, 282 So.2d 590, 596 (La. Ct. App. 1973).

have characteristics or conditions which would have excluded them from the study populations and confound any efforts to apply the data to them directly – in other words, they do not fit the study profile. DJA2140-41/575-581. *See Green Reference Guide* at 552, 613-14.

The reliability of Dr. Besunder's testimony is also undermined by the same methodological flaws as Dr. Trope. Dr. Trope lacked any objective basis to support her "pattern of performance" method. Likewise, Dr. Besunder identified no objective basis in the scientific literature authorizing his raw extrapolation from an epidemiological study to determine a loss of IQ and its extent on a patient he never met, let alone examined. DJA2591/2717, 2603-04/2786-88, DJA2621/2858. Just as the lack of a baseline robbed Dr. Trope of necessary foundation for her opinions, Dr. Besunder's opinions were also unfounded and methodologically improper. In the terms of Rule 702, Dr. Besunder (and Dr. Trope) lacked sufficient facts or data to reach a reliable conclusion, and his (their) opinion testimony was not the product of reliable principles and methods. Rule 702. It suffers from an excessive analytical gap, rendering it speculative and inadmissible.

Further, the record is devoid of any reasonable explanation for how Dr. Besunder reliably ruled in lead exposure as a cause of any plaintiff's supposed loss of IQ, based on the epidemiology studies; nor how he could reliably rule out any potential alternative explanations, based on the studies. That is not surprising, as

the studies had nothing to do with the plaintiffs. There was no basis to apply them to the plaintiffs, other than impermissible subjective belief and unsupported speculation. *Claussen*, 339 F.3d at 1058. And, epidemiological studies associate lower IQ or cognitive deficits with heredity and myriad medical conditions, environmental, educational, and social factors, and substances other than lead.

B. The District Court Erred By Failing to Give the Jury Adequate and Accurate Guidance on How to Decide the Issues of "Injury" and Causation

The district court also erred when it failed to instruct the jury so as to require a legally sufficient causal connection between the defendants' alleged delict and a cognizable injury.[6] This Court reviews jury instructions *de novo* to determine whether they fairly and accurately describe the law, and it reviews for abuse of discretion the decision whether the court should have instructed on an issue. *Green v. Junius*, 937 F.3d 1009, 1013 (7th Cir. 2019).

The misleading and unfounded evidence of "injury" and causation the jury received from the experts was exacerbated by the district court's failure to adequately inform the jury that asymptomatic elevated blood lead levels by

[6] We recognize that this appeal also raises the issue of whether the risk-contribution causation theory was properly applied in this case. That issue is beyond the scope of this amicus brief. However, "[e]ven under the risk-contribution theory, the plaintiff still retains a burden of establishing causation" and the burden of proving his "injury" was caused by lead exposure is not relieved or relaxed. *Thomas v. Mallett*, 701 N.W.2d 523, 563-64 (Wis. 2005). Accordingly, resolution of that issue does not affect this one.

themselves, which plaintiffs called "lead poisoning," cannot constitute a legally actionable "injury" – a subject well beyond the understanding of lay jurors. They needed guidance from the court to avoid being further misled regarding whether plaintiffs were injured. That guidance was not provided, allowing the jury to fill the void with speculation.

The jury also needed to know what kind of connection the law requires between the tortious act and the "injury." But the district court merely instructed the jury to decide whether the injury was caused by "ingestion of white lead carbonate." DJA3450/6855. The jury was therefore not required to find that the tortious conduct of the defendant or a defect in the product caused the injury, only that the injury was caused by the product. Under applicable law and basic principles of product liability law, it should have been.

1. Failure to Instruct the Jury on the Definition of "Injury."

Under what circumstances exposure to a toxic substance develops into a compensable "injury" is not an intuitive matter. But the district court declined to instruct on how "injury" is defined under Wisconsin tort, leaving counsel an open field for argument and leaving the jury to speculate.

The law generally recognizes that mere increase in a risk that plaintiff will suffer an adverse medical outcome is not an injury. *See, e.g.*, *Daubert*, 43 F.3d at 1321; *In re Baycol Prods. Liab. Litig.*, 596 F.3d 884, 889 (8th Cir. 2010); *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 216 (Wis. Ct. App. 2011). Under Wisconsin law,

mere exposure to a toxic substance without any manifestation of "actual injury or damage" is not an actionable injury. *Alsteen*, at 216. The exposure or increase in risk is therefore no more than a threshold step, a link in the chain of causation that may ultimately lead to an actionable manifested injury, but it is not a compensable injury by itself. The jury needed to know this to properly decide whether to hold defendants liable for exposures which may have done no more than temporarily elevate plaintiffs' blood lead levels without producing any physical harm.

Wisconsin law spoke clearly to the injury issue, in *Alsteen*, 802 N.W.2d 212. The plaintiffs alleged they were exposed to carcinogenic chemicals released from a nearby factory and that they were injured by the toxins "affront to the body." They sought to recover for their increased risk of developing cancer. The trial court dismissed and the court of appeal affirmed, rejecting the argument that the absorption of carcinogens was itself an actionable injury. Rather, the plaintiff must prove "actual damage." Indeed, in *Alsteen*, even the increased risk of a potentially *fatal* future illness was not an "injury." Wisconsin tort law requires a *present* injury; plaintiff must *actually develop the threatened disease.* 802 N.W.2d at 216-17 (emphasis added).

Rejecting the argument that toxic exposure is itself a sufficient "affront to the body" to constitute an "actual injury," the court held that in "cases involving exposure to environmental contaminants,", "asymptomatic plaintiffs who are merely

exposed to toxic chemicals do not suffer a corresponding physical injury." *Id.* at 217-18. Because "most people are exposed to a wide variety of environmental contaminants, including carcinogens, on a daily basis," "if mere exposure to a contaminated source were sufficient to state an actual injury in the toxic tort context, the number of potential claimants would be enormous." *Id.* at 218.

Accordingly, *Alsteen* stands for the proposition that "mere exposure to a dangerous substance does not constitute an actual injury." *Ibid. See also id.* at 220 (citing with approval *Metro-North Commuter Railroad Co. v. Buckley*, 521 U.S. 424, 442 (1997) for the proposition that permitting a medical monitoring claim for exposure to asbestos fibers without any present illness "could lead to unlimited and unpredictable liability").

Given the clarity of the law and the likelihood that the jury did not understand it, it was incumbent on the district court to educate the jury about how this essential element of the claim was to be evaluated. A party is entitled to an instruction if there is any direct or circumstantial evidence to support it. *Cameo Convalescent Center, Inc. v. Senn*, 738 F.2d 836, 841 (7th Cir. 1984).

2. Failure to Require a Causal Connection Between the Conduct and the Injury.

It is a fundamental principle of tort law that a defect in the product or a specific act of negligence must be causally connected to the plaintiff's injury for liability to be imposed. *See Clark v. Leisure Vehicles, Inc.*, 292 N.W.2d 630, 635

(Wis. 1980); *Tanner v. Shoupe*, 596 N.W.2d 805, 812 (Wis. Ct. App. 1999). It is not sufficient to show that the plaintiff was injured by the *product*, even if the product is proven to be defective in some respect.[7]

The established rule in products liability cases is that the design, warning or manufacturing flaw alleged must cause the injury. *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) (liability for failure to warn requires finding that a proper warning would have avoided the injury). *See also In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 752-53 (7th Cir. 2018) (Wisconsin law) (summary judgment proper where plaintiff failed to present evidence that failure to warn his physician was a proximate cause of his injuries); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1016-17 (7th Cir. 2020) (Indiana law) (plaintiff's failure to warn claim required proof that Doctor would not have prescribed the product if defendant had supplied adequate warnings). *See generally*

[7] The concept is well-illustrated by a California case, *Whiteley v. Philip Morris Co.*, 117 Cal.App.4th 635, 696 (2004). A smoker developed lung cancer and sued the tobacco manufacturer for negligent design, arguing that the presence of excessive nicotine and toxic additives in defendant's cigarettes was a design defect. The plaintiff proved the product was defective and more dangerous due to the defect. The court reversed a verdict for plaintiff because there was no proof that the increased toxicity had caused him any injury above and beyond the injury from the cigarettes themselves, and plaintiff therefore had not established that the design defect had contributed to his injury. "Plaintiff's expert witnesses did not attempt to quantify the likelihood that the asserted design defect of cigarettes, as distinguished from smoking cigarettes in general, contributed to Whiteley's developing lung cancer." 117 Cal.App.4th at 701-03. *See also Werner v. Pittway Corp.*, 90 F.Supp.2d 1018, 1028 (W.D. Wis. 2000) (causation lacking where smoke alarm woke plaintiffs in time to escape the fire, whether or not it sounded in a timely manner).

Piltch v. Ford Motor Co., 778 F.3d 628, 632 (7th Cir. 2015) (Indiana law) (plaintiff is required to prove his injuries were caused by the alleged manufacturing, design or warning defect).

The district court justified its overly general causation instruction by reasoning that application of risk-contribution theory eliminated any requirement that the jury tie a specific breach of a duty of care to plaintiffs' injuries, citing *Thomas*, 334 F.Supp.3d at 958. But as previously explained, *Thomas* does not alter the burden of proving causation; it merely relaxes the burden of showing that the plaintiff's exposure to defendant's specific *product* was the exposure that produced the injury. It does not eliminate the need for plaintiff to tie his injury to the common defect in the supposedly fungible products.

CONCLUSION

The jury received unfounded and misleading expert testimony that plaintiffs had sustained brain damage and loss of IQ caused by lead exposure; that testimony should have been excluded under Rule 702.

The jury needed guidance from the district court on the law, explaining what constituted a legally cognizable injury and the nature of the causal connection needed between the defendants' products/conduct and the plaintiffs' injuries. That guidance was not provided.

For these reasons, the judgment should be reversed.

Dated, July 24, 2020

FAEGRE DRINKER BIDDLE & REATH LLP

By: */s/ Alan J. Lazarus*

Alan J. Lazarus (SBN 129767)
alan.lazarus@faegredrinker.com
Four Embarcadero Center, 27th Floor
San Francisco, California 94111
Telephone: +1 415 591 7500
Facsimile: +1 415 591 7510

David B. Sudzus
david.sudzus@faegredrinker.com
FAEGRE DRINKER BIDDLE & REATH LLP
191 N. Wacker Drive, Suite 3700
Chicago, Illinois 60606
Telephone: +1 312 569 1000
Facsimile: +1 312 569 3498

Counsel for Amicus Curiae
THE PRODUCT LIABILITY
ADVISORY COUNCIL, INC.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) and Circuit Rule 32(c).

1. Exclusive of the exempted portions of the brief, as provided in Seventh Circuit Rule 32, the brief contains 4,711 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft 2016 in 14-point plain roman font (Times New Roman) using Microsoft Word, as permitted by Circuit Rule 32(b). As permitted by Federal Rule 32(a)(7)(B), the undersigned has relied on the word count feature of this word processing system in preparing this certificate.

/s/ Alan J. Lazarus