12-1902

CAUSE NO. 12-1902

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

JOANN EVELYN SCHULTZ
Individually and as Personal Representative
Of the Estate of Donald Walter Schultz,

Appellant

v.

THE GLIDDEN COMPANY, et al.,

Appellees

On Appeal from the
United States District Court for the District of Wisconsin
Civil Action No. 2:08-cv-00919-RTR (Randa, J.)

AMICUS BRIEF FOR AMERICAN COATINGS ASSOCIATION AND AMERICAN CHEMISTRY COUNCIL IN SUPPORT OF APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Amicus curiae American Coatings Association, Inc. ("ACA") does not have any parent corporation and is not a publicly traded entity. Likewise, amicus curiae American Chemistry Council ("ACC") does not have any parent corporation and is not a publicly traded entity. ACA and ACC are both represented in this matter by Eric Lasker, a partner in the law firm Hollingsworth LLP. In addition, ACA is represented in this matter by its General Counsel, Thomas J. Graves, and ACC is represented in this matter by its Deputy General Counsel, Donald D. Evans.

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The American Coatings Association ("ACA") is a voluntary, nonprofit trade association representing some 300 manufacturers of paints, coatings, adhesives, sealants and caulks, raw materials suppliers to the industry, and product distributors. Collectively, ACA represents companies with greater than 95% of the country's annual production of paints and coatings, which are an essential component to virtually every product manufactured in the United States. ACA is actively involved in supporting its members' interests though *amicus curiae* briefing in courts across the country. *See* ACA's website, http://www.paint.org.

The American Chemistry Council ("ACC") represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The business of chemistry is a $760 billion enterprise and a key element of the nation's economy. ACC frequently submits *amicus curiae* briefs on issues of importance to its membership. *See* ACC's website, http://www.americanchemistry.com.

Amici curiae ACA and ACC respectfully submit this *amici curiae* brief in support of the Appellees, on behalf of themselves and their membership, because the present appeal raises fundamental legal issues regarding a toxic tort plaintiff's use of scientifically unreliable expert testimony to avoid her burden of proving that

the cancer was caused by exposure to the defendant's product.[1] Under the no-threshold, non-differential "methodology" espoused by the Appellant's expert, Dr. Gore, a plaintiff's causation burden in a cancer case would be reduced to a singular inquiry: Has the plaintiff ever been exposed at any non-trivial level to a carcinogen? If so, that plaintiff must be allowed to present his or her claim to a jury, even if (1) there is no scientifically reliable evidence that the plaintiff was exposed above a threshold level shown to cause cancer, (2) the timing of the plaintiff's exposure is outside of the known latency period for his cancer, or (3) the cancer can be attributed to a known alternative cause, *i.e.*, a cause that cannot be ruled out by a reliable differential diagnosis.

As the district court recognized in its proper exercise of its gatekeeping discretion, Dr. Gore's failure to properly consider the importance of dose or timing of exposure is scientifically unsound and, given the widespread (albeit low level) presence of carcinogens in our environment, would effectively do away with a toxic tort plaintiff's general causation burden. And Dr. Gore's non-differential diagnosis methodology – whereby admitted alternative causes (like smoking) have no impact on his causation opinions with respect to an alleged toxic exposure – would mean that plaintiffs need not prove specific causation either. Simply stated,

[1] No entities other than the identified *amici curiae* have contributed to the funding of this amicus brief, which was drafted by the counsel for *amici* identified herein. All of the parties in this appeal have consented to the filing of this brief.

if the mere existence of exposure to a carcinogen is sufficient for a plaintiff to reach a jury, then every cancer patient in the United States would be a potential plaintiff, and the court system would be inundated with speculative claims unsupported by reliable scientific evidence, in violation of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Amici* urge the Court to affirm the district court's discretionary ruling below and reaffirm the toxic tort plaintiff's traditional burden to present scientifically reliable expert evidence of causation.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issue before the Court is whether the district court acted within its discretion in excluding the expert testimony of the Appellant's sole causation expert, Dr. Steven Gore.[2] Dr. Gore's methodology in opining that the Mr. Schultz's AML was caused by exposure to trace amounts of benzene in the Appellees' paints rested upon the three-legged foundation that: (1) there is no threshold for the carcinogenic effect of benzene and (2) the known latency period (*i.e.*, period between exposure and manifestation of cancer) for the carcinogenic effect of benzene can be ignored, and (3) undisputed existence of known alternative causes of a patient's cancer is irrelevant to the causation analysis. Each of these legs is necessary to support Dr. Gore's causation opinion. But none of

[2] *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) ("the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable").

these methodological legs has the scientific reliability required to survive scrutiny under *Daubert*. Accordingly, the district court's ruling should be affirmed.

Because the Appellant seeks to confuse the issue in her brief, it is important to focus on the exact scientific reasoning that Dr. Gore offered on each of these three points in support of his causation opinion in this case:

A. Dr. Gore relied on a no-threshold methodology of causation.

In his expert report, Dr. Gore explained his methodological approach in opining on causation in this case: "I have concluded to a reasonable degree of scientific and medical certainty that there is no established threshold of exposure to benzene below which AML cannot be caused by benzene. When no safe threshold of exposure to a carcinogen has been established, this means that each and every exposure to the chemical will increase the risk of development of the types of cancer that the carcinogen is capable of causing." App. 404 (Gore Report ¶ 26). Based on this no-threshold methodology, Dr. Gore opined that "every non-trivial exposure to benzene should be considered a substantial factor that contributed to [the Appellant's] AML." *Id.* ¶ 27.

As the district court correctly recognized (and as other courts have found in similar situations), Appellant's contention that Dr. Gore's opinion is admissible because he subsequently cited epidemiologic studies purportedly involving benzene exposure levels lower than those alleged by the Appellant "sidesteps the

basic thrust of Dr. Gore's opinion, which is that the amount of benzene exposure is irrelevant, so long as it is non-trivial." Br. App. at 8a.[3] Indeed, Dr. Gore readily acknowledged that dose is irrelevant under his methodology: "In assessing causation in my patients . . . I try to identify and qualitatively characterize any chemical exposures that the patients may have had, but I do not make any effort to *quantify* the level or dose of exposure that the patient may have had to particular chemicals." App. 397-98 (Gore Report ¶¶ 10-11).

Benzene causation opinions premised on Dr. Gore's same no-threshold methodology have been rejected repeatedly as unreliable under *Daubert*, and the district court did not abuse its discretion in reaching a similar conclusion here. *See Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679 (6th Cir. 2011) (affirming exclusion of causation expert who relied on theory that "there is no safe level for benzene in terms of causing cancer"); *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 49 (2d Cir. 2004) (affirming exclusion of expert testimony that was based on

[3] *See Henricksen v. ConocoPhillips*, 605 F. Supp. 2d 1142, 1165-66 (E.D. Wash. 2009) (noting plaintiff expert's concession that "the quantified dose of exposure [to benzene] 'takes on far less significance' in a cancer case, because when no safe-threshold of exposure to a carcinogen has been established, each and every exposure will increase the development of cancer" and excluding expert's testimony); *Wills v. Amerada Hess Corp.*, No. 98 Civ. 7126 (RPP), 2002 WL 140542, at *15 (S.D.N.Y. Jan. 31, 2002) ("Although Plaintiff tries to argue that she would use the accepted dose-response relationship if she had more discovery, that is not relevant to the issue whether the conclusion that Plaintiffs' expert has drawn [based upon a no-threshold benzene theory] is scientifically reliable under *Daubert*."), *aff'd*, 379 F.3d 32, 49 (2d Cir. 2004).

theory that cancer can be "caused by a single exposure – regardless of the quantity of the dosage – of toxic chemicals such as benzene and PAHs"); *Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 885 (S.D. Ohio 2010) ("the no threshold or one-hit theory is not an accepted causation theory under *Daubert*"); *Henricksen*, 605 F. Supp. 2d at 1166 ("[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'"); *Sutera v. The Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 666 (D. Mass. 1997) ("there is no scientific evidence that the linear no-safe threshold analysis [for benzene] is an acceptable scientific technique used by experts in determining causation in an individual instance").

B. Dr. Gore disregarded the fact that Appellant's benzene exposure was outside the latency window for AML.

Dr. Gore relied on similar "no threshold" reasoning in concluding that the timing of the Mr. Schultz's benzene exposures was irrelevant to causation. As also correctly noted by the district court, the small number of epidemiologic studies cited by Dr. Gore for purported increased risks of AML from low-level benzene exposures reported associations *only* for exposures with latency periods shorter that the 16 year span between Mr. Schultz's last alleged exposure to benzene and his cancer. Br. App. at 8a.; *see also* App. 376 (Dr. Gore deposition testimony agreeing that one of the studies he cited found that "exposures [to benzene] more than 15 years before diagnosis made little contribution to risk"). When confronted

with this fact at deposition, Dr. Gore testified that he had "discounted that" because he didn't believe the studies had sufficient numbers to reliably answer the question. App. 374 (Gore Dep. at 29). Of course, Dr. Gore cannot discount the parts of studies he does not like (regarding latency) while at the same time now assert that he is relying on other parts of those studies (regarding dose) in reaching his causation opinions. In any event, the district court was plainly within its discretion in finding that Dr. Gore's failure to account for the fact that Mr. Schultz's benzene exposures were outside the known latency period for AML rendered his opinion inadmissible. *See* Reference Manual on Scientific Evidence (3d ed. 2011), *Reference Guide on Epidemiology*, at 601 ("exposure outside a known latency period constitutes evidence, perhaps conclusive evidence, against the existence of causation").

C. Dr. Gore failed to rule out alternative causes for the Appellant's AML.

Finally, Dr. Gore avoided any meaningful analysis of potential alternative causes of Mr. Schultz's AML by adopting a methodology in which the existence of such alternative causes is irrelevant. Dr. Gore explained that under his causation methodology, "the mere fact that genetics or other environmental risk factors (in the broad sense of that term) have been identified as probable causes of a particular cancer in no way refutes the possibility that the chemical exposures being investigated have also played a substantial contributing role at one or more stages

of the development of that person's cancer." App. 399-400 (Gore Report ¶ 15). Thus, Dr. Gore readily acknowledged that Mr. Schultz's 40-year history of smoking a pack of cigarettes a day (*i.e.*, 40 pack-years) was an alternative cause of his AML, but concluded that "[t]he fact that Mr. Schultz's cigarette smoking may have contributed to his AML in no way undermines my conclusion that his benzene exposure played a substantial role in the development of the disease." App. 399-400 (Gore Report ¶ 16). Again, as the district court correctly held, this methodological approach is inadmissible under *Daubert*. *See Guinn v. Astrazeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (a "differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation") (citing cases); *see also Pluck*, 640 F.3d at 680 (holding that expert's failure to rule out smoking as an alternative cause of plaintiff's cancer was a "fatal flaw" in expert opinion that cancer was caused by benzene); *Wills*, 379 F.3d at 50 (same).

In sum, under Dr. Gore's causation methodology, exposure to benzene at any level and at any time must be considered a cause of a plaintiff's AML, even if the plaintiff's AML can be attributed to other causes. This is not a reliable scientific methodology for causation; it is a methodology by which plaintiffs can avoid their causation burden of proof altogether. The district court acted within its

discretion in finding Dr. Gore's causation opinion inadmissible under *Daubert*, and its ruling should be affirmed.

ARGUMENT

"An essential element of [Appellant's] negligence claim is proof of causation." *Harris v. Owens-Corning Fiberglas Corp.*, 102 F.3d 1429, 1431 (7th Cir. 1996). "[I]f the possibility of a causal connection is equivocal, the [plaintiff] has failed to meet the burden posed by the preponderance standard and an adverse summary judgment must be rendered as a matter of law." *Id.* (quoting *Porter v. Whitehall Labs., Inc.*, 791 F. Supp. 1335, 1346 (S.D. Ind. 1992), *aff'd*, 9 F.3d 607 (7th Cir. 1993)). "Expert testimony is needed to establish causation in cases alleging an adverse health effect when the 'medical effects [of exposure to the toxin] are not within the ken of the ordinary person.'" *Korte v. ExxonMobil Coal USA, Inc.*, 164 F. App'x 553, 556 (7th Cir. 2006).

In this case, Appellant seeks to avoid her causation burden by relying on an expert methodology that would transform their required proof of causation into a mere checklist finding of an exposure. Because Dr. Gore's causation methodology fails to properly account for either the dose or timing of Mr. Schultz's exposure to benzene or for potential alternative causes of his cancer, the district court's discretionary exclusion of Dr. Gore's testimony plainly was not "fundamentally

wrong" or "manifestly erroneous,"[4] and the district court's grant of summary judgment to the Appellees should be affirmed.

I. The District Court Acted Within Its Discretion in Rejecting Dr. Gore's No-Threshold Methodology.

A. Dr. Gore's No-Threshold Methodology Fails to Properly Address the Issue of Dose.

In accord with courts across the country, this Court repeatedly has explained that an expert seeking to satisfy a toxic tort plaintiff's burden on causation must first determine "whether the dose to which the plaintiff was exposed is sufficient to cause the disease." *Korte*, 164 F. App'x at 557 (quoting *Wintz ex rel. Wintz v. Northrop Corp.*, 110 F.3d 508, 513 (7th Cir. 1997)); *see also Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) ("In order to carry this burden, 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.") (quotation marks omitted). "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

[4] *Lapsley v. Xtec, Inc.*, __ F.3d __, No. 11-3313, 2012 WL 3055865, at *5 (7th Cir. July 27, 2012) ("Provided the district court adhered to *Daubert's* parameters, we will not disturb the district court's findings unless they are manifestly erroneous."); *Chavez v. Ill. State Police*, 251 F.3d 612, 628 (7th Cir. 2001) ("The district court's decision must strike us as fundamentally wrong for an abuse of discretion to occur.")

plaintiffs' burden in a toxic tort case." *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 397 F. App'x 797, 800 (3d Cir. 2010) (citation omitted); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005) (same); *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996) (same); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107-08 (8th Cir. 1996). "Without this testimony, 'a plaintiff's toxic tort claim will fail.'" *Pluck*, 640 F.3d at 677 (to same effect).

By relying on a no-threshold theory of causation, Dr. Gore seeks to sweep away this well-settled causation requirement. As Dr. Gore readily admits, under his causation methodology, he "do[es] not make any effort to *quantify* the level or dose of exposure that the patient may have had to particular chemicals." App. 398 (Gore Report ¶ 11). That is because, as Dr. Gore maintains, "in the context of chemically-caused cancers generally, and exposure to benzene specifically, the absence of a safe 'threshold' level of exposure to the cancer-causing substance substantially alters the nature of the causation inquiry." App. 400 (Gore Report ¶ 17). "When no safe threshold of exposure to a carcinogen has been established, this means each and every exposure to the chemical will increase the risk of development of the types of cancer that the carcinogen is capable of causing." App. 403 (Gore Report ¶ 25).

Dr. Gore's no-threshold causation methodology has been squarely rejected in every reported benzene opinion in which it has been asserted. *See Pluck*, 640

F.3d at 679; *Wills*, 379 F.3d at 49; *Baker*, 680 F. Supp. 2d at 885; *Henricksen*, 605 F. Supp. 2d at 1166; *Sutera*, 986 F. Supp. at 666. Dr. Gore's "theory would lead to an impossible link of causation. If one exposure is sufficient for causation, there would be no way to determine which exposure caused a particular cancer since we are exposed to carcinogens to some degree in the ambient environment on a daily basis." *Wills*, 2002 WL 140542, at *15. Indeed, "since benzene is ubiquitous, causation under the one-hit theory could not be established because it would be just as likely that ambient benzene was the cause of Plaintiffs' illnesses." *Baker*, 680 F. Supp. 2d at 878 n.9.

In order to better understand the implications of Dr. Gore's reasoning in this case, it is useful to consider the following undisputed or judicially noticeable facts:

1. It is estimated that 13,780 men and women will be diagnosed with AML in 2012. *See* SEER Stat Fact Sheets: Acute Myeloid Leukemia, available at http://seer.cancer.gov/statfacts/html/amyl.html.

2. Only one percent of AML cases are benzene-induced, and the large majority are idiopathic, meaning that they have no known cause. App. 225; App. 319, Smith Dep. p. 33, l. 15-18; App. 323, Pyatt Dep. p. 48, l. 2-11.

3. However, all 13,780 of the individuals diagnosed with AML in 2012 will have been exposed to benzene in their past, likely through a variety of different environmental sources. *See* Lance A. Wallace, Environmental Exposure to Benzene: An Update, 104 (suppl. 6) Environmental Health Perspectives 1129 (Dec. 1996), available at http://www.biomedsearch.com/attachments/00/09/11/88/9118882/envhper00349-0019.pdf (reporting results of U.S. EPA Total Exposure Assessment Methodology (TEAM) studies on population exposures to benzene).

Thus, while the scientific evidence suggests that benzene (at sufficiently high exposure levels) might properly be associated with fewer than 140 of these new cases of AML, under Dr. Gore's no threshold theory, all 13,780 AML patients would have a legal cause of action sufficient to reach a jury blaming benzene for their cancers.

As have the other courts before it, the district court below properly concluded that Dr. Gore's no-threshold theory for benzene causation was scientifically unreliable and, thus, inadmissible under *Daubert*. "The linear non-threshold model cannot be falsified, nor can it be validated. To the extent it has been subjected to peer review and publication, it has been rejected by the overwhelming majority of the scientific community. It has no known or potential rate of error. It is merely an hypothesis." *Henricksen*, 605 F. Supp. 2d at 1166 (quoting *Whiting ex rel. Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 25 (D. Mass. 1995); *Sutera*, 986 F. Supp. at 667 (same); *see also Pluck*, 640 F.3d at 679 (plaintiff's expert's "opinion that Mrs. Pluck's 'low-level exposure' to benzene caused her NHL is not grounded in 'sufficient facts or data,' nor does it reflect the 'reliable principles and methods' required by Rule 702. It is, instead, pure conjecture.").

Appellant's attempted reliance on EPA regulatory standards as support for her expert's no-threshold methodology is unavailing. App. Br. at 20-21. As

explained in the Reference Manual on Scientific Evidence, reliance on such regulatory positions is "[p]articularly problematic . . . in personal injury litigation . . . Regulatory standards are set for purposes far different than determining the preponderance of evidence in a toxic tort case." *See* Reference Manual on Scientific Evidence (3d ed. 2011), *Reference Guide on Toxicology*, at 665. The EPA's regulatory classification of carcinogens "results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances [and] [t]he agencies threshold of proof is reasonably lower than that appropriate in tort law." *Mitchell*, 165 F.3d at 783 n.3. Thus, "[w]hile the one-hit theory has been accepted for purposes of establishing regulatory safety standards, it has not been accepted as a reliable theory for causation under *Daubert* standards." *Baker*, 680 F. Supp. 2d at 878 n.9.[5]

B. Appellant's Post-Hoc Doubling-of-the-Risk Argument Does Not Salvage Dr. Gore's Methodology.

Appellant's defense of Dr. Gore's causation methodology is somewhat schizophrenic. Appellant devotes much of her brief to a full-throated defense of

[5] *See also, e.g., Parker v. Mobil Oil Corp.*, 16 A.D.3d 648, 653 (N.Y. App. Div. 2005) ("Furthermore, the plaintiff's reference to regulatory standards regarding benzene exposure was not compelling evidence, as such standards are not measures of causation but rather are public health exposure levels determined by agencies pursuant to statutory standards set by the United States Congress."), *aff'd*, 7 N.Y.3d 434, 450 (2006) ("[S]tandards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation.").

Dr. Gore's no-threshold theory. *See* App. Br. at 51-52 (arguing that the overwhelming judicial rejection of the no-threshold theory of causation in benzene litigation reflects an "overreaching approach to judicial gatekeeping"); *see generally id.* at 19-23, 50-53. But perhaps recognizing the weakness of this defense, Appellant then argues that Dr. Gore "did not need to reach the 'no-threshold' determination to find that Mr. Schultz's AML was caused by his benzene exposure, because quantified estimates of Mr. Schultz's exposures exist, and comparisons of those estimates with epidemiological literature show that his exposures more than doubled his risk." *Id.* at 45. Appellant carefully does not state that Dr. Gore himself relied on this so-called "doubling dose" analysis because this analysis does not appear anywhere in his expert report or deposition testimony.[6] Rather, Appellant seeks to salvage Dr. Gore's no-threshold

[6] Dr. Gore did note, as "further support" for his opinion, that there was some published literature associating benzene with AML at exposure levels similar to those alleged by the Appellant here. App. 404 (Gore Report at ¶ 28). However, because his causation opinion rested on his no-threshold theory, Dr. Gore did not conduct a full analysis of the scientific literature so as to reliably opine on the level of benzene exposure necessary to cause AML. As the district court correctly noted below, Dr. Gore cited these studies solely to establish that Appellant's exposures were not trivial, which, under his no-threshold theory, was all that was necessary for his causation opinion. Br. App. at 7a. In any event, as discussed *infra*, the studies cited in Dr. Gore's report cannot support his causation opinion because, as the district court also correctly noted, these studies report that any association between benzene exposure and AML disappears after 15 years. Br. App. at 8a. Mr. Schultz's AML became manifest 16 years after his last possible exposure to benzene in the Appellees' products.

methodology by proffering this new theory of causation through her counsel's briefing on appeal.

Courts around the country have correctly rejected this type of back-filling argument. As the Supreme Court made clear in *Daubert*, '[t]he focus [of the inquiry envisioned by Rule 702] must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. Thus, Appellant must show that the methodology that Dr. Gore in fact used in reaching his causation opinion was reliable; Appellant cannot defend Dr. Gore's opinion based on a methodology he did not use. *See Rondigo v. Casco Twp., Mich.*, 537 F. Supp. 2d 891, 896 (E.D. Mich. 2008) (rejecting "Plaintiff's attempt to defend their [expert's] report by arguing what the report *does not* rely on instead of what it actually does rely on").[7]

If Dr. Gore had, in fact, based his causation opinion upon a "doubling dose" analysis, he would have been required to explain through scientifically reliable evidence how that analysis accounts for the prevailing contrary trend of medical and scientific literature, which holds that the minimum exposure level necessary

[7] *See also, e.g., Mause v. Global Household Brands, Inc.*, No. Civ.A. 01-4313, 2003 WL 22416000, at *2 (E.D. Pa. Oct. 20. 2003) (rejecting new "reference to the Bradford Hill [causation] criteria [as] an after the fact attempt to buttress an opinion that was not formed as a result of any scientific methodology"); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1049 n.5 (S.D. Ill. 2001) ("Justifying a conclusion after the fact by applying a [new] methodology does not generally lead to reliable scientific knowledge").

for benzene to cause AML – let alone double the risk – is 40 ppm-years, far higher than the Appellant alleges here. *See* App. 224 (Report of David Pyatt at 8). In so doing, Dr. Gore could not – as Appellant does in her brief – rely on cherry-picked findings of increased risk in two isolated epidemiologic studies. *See* App. Br. at 16-17 nn. 8-10; *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (an expert opinion based on "cherry-picking observational studies that support [the expert's] conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion . . . does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science;' it is therefore inadmissible"); *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 850 (W.D. Tex. 2005) (rejecting testimony of expert who "sifted through the literature to pick and choose positive relative risks between ionizing radiation (of any type, source, and dose) and a particular Plaintiff's cancer"). Rather, Dr. Gore would have been required to account for the full body of epidemiologic and scientific research on benzene, which informs the consensus view contrary to his purported "doubling dose" argument. The district court then could have reviewed that explanation to determine whether the "doubling dose" analysis was admissible under *Daubert*.

Moreover, Dr. Gore would have been required to square his "doubling dose" approach with the fact that Mr. Schultz had an independent exposure to an

alternative cause of AML through his 40 pack-year smoking history. As explained in The RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL, § 28 COMMENT C (2010), the use of a "doubling dose" approach depends upon "the plaintiff's similarity to those included in the group study . . . includ[ing] whether . . . the plaintiff was not differentially exposed to other potential causes of disease." *See also In re Silicone Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 894 (C.D. Cal. 2004) ("'doubling risk' approach . . . to proving specific causation assumes that the plaintiff is comparable to the subjects of the epidemiological study and that there were no other causal agents present in the plaintiff's case not accounted for by the study"). Where, as here, a plaintiff has an independent exposure to an alternative cause of the disease, his background risk of that disease is higher than the control group in an epidemiologic study, and the logic behind the "doubling dose" methodology falls apart. *See* RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARMS, § 28 COMMENT C (2010) ("Depending on the other factors detailed above, an increase of the incidence of disease less than a doubling may be sufficient to support a finding of causation, while in another case, even an increased incidence greater than two may not be sufficient.").[8]

[8] For example, if one were to assume that benzene exposure at a level that could be reliably calculated for Mr. Schultz was associated with a doubling of AML risk but that a 40-year smoking history was associated with a *tripling* of AML risk, the "doubling dose" approach would point to smoking as a more likely cause of Mr. Schultz's disease. Dr. Gore did not present any evidence on this issue.

But Dr. Gore did not rely on a doubling-dose methodology, and he did not present any such scientific explanations of the application of such a methodology here in support of his causation opinion. Instead, Dr. Gore relied upon the no-threshold theory, and the district court correctly held that his causation methodology could not withstand scrutiny under *Daubert*.

II. The District Court Acted Within Its Discretion in Holding that Dr. Gore Failed to Reliably Account for the Fact That Appellant's Exposure Was Outside the Latency Period for Benzene-Induced AML.

The district court was well within its discretion in concluding that Dr. Gore's causation methodology also fails because he ignored the crucial issue of latency. It is undisputed that Appellant's most recent possible exposure to the Appellees' paint occurred 16 years before his diagnosis with AML. However, the only studies cited by Dr. Gore in his report as "further support" for his causation opinion reported that the association between benzene exposure and AML disappeared after 15 years.

Thus, while Dr. Gore references epidemiologic research by Dr. Glass at footnotes 6 and 7 of his report, App. 402-03 (Gore Report ¶ 23 nn.6-7), Dr. Glass has explained that her studies found that "exposures more than 15 years before diagnosis made little contribution to [cancer] risk." Deborah C. Glass, *et al.*. *Leukemia Risk and Relevant Benzene Exposure Period – Re: Follow-up Time on Risk Estimates*, 45 Am. J. Indus. Med. 222, 222 (2004); *see also id.* at 223 ("One

implication of our findings is that exposure estimates to investigate the risk of benzene-induced leukemia can be restricted to the period up to 15 years prior to diagnosis."). And while Dr. Gore cites to another study by Dr. Hayes at footnote 8 of his report, App. 403 (Gore Report ¶¶ 24 n. 8), that study reported increased risks of AML only in individuals who had been exposed to benzene within 10 years of diagnosis. Richard B. Hayes, *et al.*, *Benzene and the Dose-Related Incidence of Hematologic Neoplasms in China*, 89(14) J. Nat'l Cancer Institute 1065, 1067-68 (1997) ("risk of ANLL/MDS was significantly increased among those who had only recent [within 10 years] benzene exposure").[9]

"[E]xposure outside a known latency period constitutes evidence, perhaps conclusive evidence, against the existence of causation." Reference Manual on Scientific Evidence (3d ed. 2011), *Reference Guide on Epidemiology*, at 601. But when confronted with this evidence at deposition, Dr. Gore failed to provide any scientifically reliable explanation for his opinion that Mr. Schultz's exposure outside the known latency period for benzene-induced AML nonetheless was the cause of his cancer. App. 374 (Gore Dep. at 28-29). Dr. Gore testified that he

[9] Dr. Gore also cited in his report to a study by Dr. Patel (App. App. 403, Gore Report ¶¶ 24 n. 8), but as the court recognized in *Baker*, there are "some significant limitations of this study," including the fact that "the benzene exposure was not well characterized at an individual level" and that "Patel did not have an appropriate control group for this study." *Baker*, 680 F. Supp. 2d at 886 (internal quotation marks omitted). In any event, that study did not break down its findings based on latency period.

discounted the studies' findings regarding latency because the studies were too small to detect an effect from the more distant exposures, but Dr. Gore cannot support his opinion under *Daubert* by attacking the very same epidemiologic studies upon which he otherwise purports to rely. *See Siharath v. Sandoz Pharm., Corp.*, 131 F. Supp. 2d 1347, 1358 (N.D. Ga. 2001) (noting that even "well-taken criticisms of the epidemiologic studies does not satisfy [plaintiff's] burden of proof"), *aff'd sub nom. Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002). Nor can Dr. Gore rely on speculation that studies demonstrating a causal link with more distant exposures to benzene might emerge in the future. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("Law lags science; it does not lead it.").

Appellants' suggestion that Dr. Gore adequately supported his opinion based upon a purported longer latency period for radiation or therapy-related AMLs is also misplaced. Appellants do not argue that Mr. Schultz's AML was caused by radiation or therapy, and Dr. Gore presented no evidence that these different exposures would act in the body in the same way and with the same duration of latency as benzene. Courts have repeatedly held that expert opinions based on analogy even to closely related compounds are unreliable under *Daubert* because "small differences in chemical structure can make very large differences in the type of toxic response that is produced." *McClain*, 401 F.3d at 1246 (citing cases). Dr.

Gore's even larger speculative leap from radiation to benzene cannot provide any reliable support for his opinion.

III. The District Court Acted Within Its Discretion in Holding that Dr. Gore Failed to Reliably Exclude Alternate Causes for Appellant's AML.

Dr. Gore's causation methodology is also fatally flawed in its treatment of potential alternative causes of Mr. Schultz's AML. Dr. Gore readily concedes that Mr. Schultz's 40 pack-year smoking history is a significant contributing factor to his AML. App. 379 (Gore Dep. p. 47 l. 16 - p. 48 l. 3). But Dr. Gore obviates any need to exclude smoking as the potential sole cause of Mr. Schultz's AML by opining that "no case of cancer truly has only one cause" and that "because cancer development is a complex, multi-stage process where many factors work together to the ultimate emergence of a full blown malignancy, *each of those factors at each of the stages must properly be considered a cause of the ultimate cancer and a substantial factor in bringing it about.*" App. 399 (Gore Report at ¶ 13) (emphasis added). Thus, Dr. Gore concludes, "[t]he fact that Mr. Schultz's cigarette smoking may have contributed to his AML in no way undermines my conclusion that his benzene exposure played a substantial role in the development of the disease." App. 400 (Gore Report at ¶ 16).

While Appellants argue that Dr. Gore's opinion was based on a reliable differential diagnosis, his opinion that every *potential* cause of Mr. Schultz's AML must be considered a substantial contributing factor negates the very essence of the

differential diagnosis methodology. As this Court has explained, "expert opinions employing differential diagnosis must be based on scientifically valid decisions as to what potential causes should be "ruled in" and "ruled out." *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007). But under Dr. Gore's methodology, every potential cause is "ruled in" and no potential cause is "ruled out." There is no differentiating between potential causes whatsoever.[10]

This type of *non*-differential diagnosis methodology repeatedly has been rejected as unreliable under *Daubert*, and the district court did not abuse its discretion in similarly holding here. "An expert . . . cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development." *Guinn*, 602 F.3d at 1255. "Although the differential diagnosis technique is well accepted . . . [, a finding] that all possible causes are causes does not appear to have gained general acceptance in the medical and scientific communities." *Id.* (alteration in original) (quoting *Cano*, 362 F. Supp. 2d at 846). Indeed, if Dr. Gore's methodology was accepted, plaintiffs' experts in toxic tort litigation would

[10] *See Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 645 (7th Cir. 2010) (affirming exclusion of plaintiff's causation experts who "did not use a differential etiology" because "[t]hey did not 'rule in' any potential causes or 'rule out' any potential causes."); *see also Fuesting v. Zimmer, Inc.*, 362 F. App'x 560, 563 (7th Cir. 2010) (affirming exclusion of expert witness who "did not rule out possible alternative methods of causation"); *Korte*, 164 F. App'x at 556 (same).

no longer have any need to consider potential alternative causes and another essential part of plaintiffs' causation burden of proof would be rendered moot.

Using a properly-applied differential diagnosis, Dr. Gore's inability to rule out smoking as a potential cause of Mr. Schultz's AML is a fatal flaw that, in and of itself, renders his causation opinion inadmissible. Under similar circumstances, both the Second and Sixth Circuits have affirmed the *Daubert* exclusion of plaintiff causation experts who failed to exclude smoking as a potential alternative cause for their alleged benzene-induced cancer. *Pluck*, 640 F.3d at 680; *Wills*, 379 F.3d at 50. In this case, Dr. Gore not only failed to rule out smoking as a potential cause of Mr. Schultz's AML, he affirmatively ruled it in. App. 379 (Gore Dep. p. 47 l. 16 - p. 48 l. 3). He also acknowledged that smoking causes up to 40 percent of all AMLs, a percentage that dwarfs the number of AMLs that might be caused by occupational exposures to benzene. App. 379 (Gore Dep. p. 46 l. 8-13). Appellants have presented no argument by which this Court could find that the district court was fundamentally wrong in concluding that Dr. Gore's failure to rule out smoking rendered his causation opinion "inherently unreliable," Br. App. at 9a, and the district court's exclusion of Dr. Gore's causation opinion should be affirmed on this independent ground as well.

CONCLUSION

In asking the Court for an abuse of discretion reversal, the Appellants are asking the Court to adopt a view of *Daubert* that would eviscerate a toxic tort plaintiff's causation burden of proof. Plaintiffs and their experts would no longer be required to establish an injurious level of exposure to a defendant's product or an exposure during a time period that could be reliably associated with disease. Nor would plaintiffs and their experts be required to account for other potential causes of the plaintiffs' diseases. Rather, if a plaintiff can show an exposure to a known toxin at any level at any time in the past, his or her expert's opinion that the exposure caused the plaintiff's illness *must* be admitted.

This is not the law, and it is exactly the type of unreliable science that *Daubert* mandates must be excluded. For the reasons set forth herein and in the Appellee's Opposition Brief, *Amici* urge the Court to affirm the district court's opinion.

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CERTIFICATE OF COMPLIANCE

I certify that this brief contains 6,351 words and therefore satisfies the type-volume limitation of Fed. R. App. P. 29(d).

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 28th day of August 2012, I caused this Amicus Brief in Support of Appellees to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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