UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRIAN K. MILWARD and LINDA J. MILWARD,	)	
Plaintiffs,	)	CIVIL ACTION NO. 07-11944-DPW
v.	)	
ACUITY SPECIALTY PRODUCTS GROUP, INC., et al.	)	
Defendants.	)	

MEMORANDUM AND ORDER
September 6, 2013

Plaintiffs Brian Milward and his wife Linda brought this negligence action against makers of products containing benzene, exposure to which allegedly caused Brian Milward to develop Acute Promyelocytic Leukemia ("APL"), a rare subtype of Acute Myeloid Leukemia ("AML"), a disease rare in itself. Only the claims against Rust-Oleum Corporation ("Rust-Oleum") remain before me. Rust-Oleum has moved for summary judgment on grounds that Milward lacks the reliable expert testimony necessary to prove that benzene exposure caused his leukemia, that his claim is preempted by the Occupational Health and Safety Act ("OSHA"), 29 U.S.C. § 651 *et seq.,* and that there is no genuine issue of fact as to whether Rust-Oleum's failure to warn about benzene in its products proximately caused Milward's injury.

I. BACKGROUND

Brian Milward ("Milward") was diagnosed with APL in 2004. The cancer is characterized by a deficiency of mature blood cells in the "myeloid" cell line and an excess of immature cells called promyelocytes. APL is known to be caused in part by a genetic translocation on chromosome 17 but, despite extensive research, there is no scientific consensus as to the causes of the translocation. *Milward* v. *Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 16 (1st Cir. 2011).

Toxicologist Martyn Smith has offered his opinion that exposure to benzene can cause APL. Although Judge O'Toole, who was previously assigned to this matter, excluded Smith's testimony as unreliable, *Milward* v. *Acuity Specialty Products Group, Inc.*, 664 F. Supp. 2d 137 (D. Mass. 2009), the First Circuit reversed, finding Smith's testimony as to "general causation" admissible under Fed. R. Evid. 702. *Milward*, 639 F.3d at 14. The case was then transferred to my docket.

Primarily at issue now is the question of "specific causation": whether Milward's workplace exposures to benzene caused his leukemia, and whether benzene exposure attributable to Rust-Oleum paint products was a "substantial contributing factor" to the injury. *See generally In re Neurontin Mktg. & Sales Practices & Products Litig.*, No. 04-10981-PBS, 2010 WL 3169485, at *2 (D. Mass. Aug. 10, 2010) (applying Massachusetts law);

Matsuyama v. *Birnbaum*, 890 N.E.2d 819, 842 & n.47 (Mass. 2008); *Morin* v. *AutoZone Ne., Inc.*, 943 N.E.2d 495, 499 (Mass. App. Ct. 2011); *see also infra* note 5.

Milward alleges he was exposed to benzene from Rust-Oleum paint in the course of various jobs he held as a pipefitter and refrigerator technician from 1973 until his APL diagnosis in 2004. Most of his work involved installing pipe, repairing equipment and the like. In the early part of his career, however, Milward spent 10 to 15 percent of his workday painting steel beams and pipe. In the 1980s, the amount of time Milward spent painting decreased, and continued to decrease as he became more experienced and took on more supervisory responsibility. For one year, in 1996, Milward worked an office job and spent no time "in the field" painting. Although Milward primarily used brush paint, he used spray paint between 1 to 5 percent of the time, typically for smaller touch-up jobs. For both brush and spray paint jobs, Milward used "two main" brands of paint over the course of his career--Rust-Oleum and Sherwin-Williams.

Milward presents the testimony of James Stewart, an industrial hygienist, to quantify his exposure to benzene from Rust-Oleum paint and other products. Occupational medicine physician Sheila Butler then opines, based primarily on Stewart's exposure assessment, that there is a reasonable medical probability that exposure to benzene was a cause-in-fact of Milward's APL.

Rust-Oleum seeks to exclude the testimony of both experts. Contending that Milward cannot prove specific causation without the expert testimony, *Kerlinsky* v. *Sandoz Inc.*, 783 F. Supp. 2d 236, 242-43 (D. Mass. 2011) (applying Massachusetts law), Rust-Oleum anticipatorily styles its motion as a motion for summary judgment. I address these contentions in Section III. Rust-Oleum also makes arguments based on OSHA preemption and lack of proximate cause, which involve independent sets of issues that I discuss separately in Section IV.

II. STANDARD OF REVIEW

Fed. R. Civ. P. 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322 (1986). The question is whether, viewing the facts in the light most favorable to the nonmoving party, there is a "genuine dispute as to any material fact." Fed. R. Civ. P. 56(a); *Casas Office Machines, Inc.* v. *Mita Copystar Am., Inc.*, 42 F.3d 668, 684 (1st Cir. 1994).

III. EXPERT TESTIMONY

A. Legal Framework

I must determine whether the expert testimony proffered by Milward is sufficiently reliable to be admitted under Fed. R.

Evid. 702, which 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.

The Supreme Court offered guidance in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and subsequent elaborations, *Gen. Elec. Co.* v. *Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co., Ltd.* v. *Carmichael*, 526 U.S. 137 (1999). *Daubert* suggests that judges measure the admissibility of expert testimony by such considerations as:

> (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline.

United States v. *Mooney*, 315 F.3d 54, 62 (1st Cir. 2002) (citing *Daubert*, 509 U.S. at 593-94). These considerations make clear that I must focus on the "principles and methodology" employed by an expert. *Daubert* 509 U.S. at 595. That said, "conclusions and methodology are not entirely distinct from one another," and I may exclude opinion evidence when "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

While a 2000 amendment to Fed. R. Evid. 702 codified a rigorous reliability test, the *Daubert* line of cases has been

read by the First Circuit as "demand[ing] only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *Ruiz-Troche* v. *Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). "So long as an expert's scientific testimony rests upon good grounds based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities." *Milward*, 639 F.3d at 15 (internal quotation and citation omitted).

B. Dr. James Stewart

The plaintiffs offer the testimony of Dr. James Stewart to quantify Milward's exposure to benzene. I find Stewart's opinion admissible.

I. Stewart's Opinion

Stewart is a certified safety professional and industrial hygienist with over 35 years of experience in environmental and health safety. He holds a doctorate in environmental health and toxicology, a master's degree in chemistry, and a bachelor's degree in public health. Stewart teaches courses in industrial hygiene and occupational safety at the Harvard School of Public Health.

Stewart modeled Milward's exposure to benzene using the Advanced REACH Tool ("ART"), which was developed by European government agencies and research institutions to measure

compliance with European Union chemical-exposure regulations. The tool is designed to utilize modeled predictions about inhaled benzene exposure, and to update them using actual exposure data when available--what is known as a Bayesian approach. The ART accounts for "specific input parameters such as ventilation rate, room size, orientation of spray operations, and secondary sources of exposure." Elizabeth Hofstetter, et al., *Evaluation of Recommended REACH Exposure Modeling Tools and Near-Field, Far-Field Model in Assessing Occupational Exposure to Toluene from Spray Paint*, Ann. Occup. Hyg., at 3 (2012). Stewart used the ART to estimate Milward's cumulative benzene exposure concentration, measured in parts of benzene per million parts of air ("ppm") multiplied by the length of exposure in years ("ppm-years").

Stewart estimated Milward's average painting activity from 1973 through 2004 at 48 minutes per day--45 minutes of brush paint and 3 minutes of aerosol paint--using 90% Rust-Oleum brand paint. Stewart also estimated the benzene concentration of various solvents in Rust-Oleum paints--most notably "mineral spirits," a common organic solvent. Based on various studies of mineral spirits and the paint products of other manufacturers, Stewart set the benzene concentration of mineral spirits in Rust-Oleum paints at 1% before 1978, at .1% from 1979-1992, and at .001% from 1993-2004. Stewart also included in his calculations what he considered an unduly high ventilation rate--given co-

worker complaints about feeling ill and excessive heat in work spaces--which he predicted would produce "conservatively low" exposure estimates.

Using those inputs, Stewart averaged the median and 95th percentile exposure estimates generated by the ART, which produced an estimate of benzene exposure attributable to Rust-Oleum paints of 6.57 ppm-years. Stewart also provided an assessment of other possible exposures.[1] For example, Milward frequently used a product called Liquid Wrench to clean rusted nuts and bolts; Stewart estimated Milward's benzene exposure attributable to Liquid Wrench at 7.71 ppm-years. Taking account of the various products Milward used, Stewart set the total benzene exposure assessment at 25.6 ppm-years.

ii. Factual Disputes

Rust-Oleum identifies several alleged flaws in Stewart's opinion that go to its weight rather than admissibility. For example, Stewart used the testimony of Milward's occasional co-worker, Arthur DeFranzo, to estimate the percentage of time Milward used Rust-Oleum paint. DeFranzo reported that 90% of the paint he used was Rust-Oleum brand, and that "[e]verybody uses the same products in the industry." Rust-Oleum complains that

[1]Rust-Oleum does not specifically challenge the estimates of benzene exposure from non-Rust-Oleum products, but presumably its general complaints about the inaccuracy of the ART, discussed in Part III.B.3 below, would apply to those calculations as well.

DeFranzo infrequently worked with Milward, and that Milward's testimony about the "two main" types of paint he used means that he used Rust-Oleum paint at most 50% of the time. But it could be fair to call Rust-Oleum and Sherwin-Williams the "two main" types of paint used even at a 90:10 ratio, and resolving this dispute about the factual underpinnings of Stewart's opinion is the province of the jury. *See Milward*, 639 F.3d at 22 ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." (internal quotation and citation omitted)).

Rust-Oleum also complains that Stewart failed to discount his exposure estimate for the period from 1993-2004, as he did for the period from 1978-1992, to better reflect declining exposure levels. But the estimated exposure levels were so low during the 1993-2004 period that the adjustment proposed by Rust-Oleum would not have changed Stewart's cumulative exposure estimate. To the extent there was any error, it goes to Stewart's general credibility in the eyes of the jury and not the admissibility of his testimony.

Another alleged shortcoming is that Stewart did not vary the estimated amount of time Milward spent painting per day over the course of his career. Stewart also did not assign different benzene concentrations to Rust-Oleum brush and spray paint. For

its part, Rust-Oleum provided the testimony of its own industrial hygienist, John Spencer, who attempted to provide a more nuanced breakdown of Milward's painting habits and corresponding benzene exposures.[2] But, again, it is for the jury to decide whether Stewart's overall averages or Spencer's more specific breakdown provides a better approximation of Milward's work habits.

iii. The Advanced REACH Tool

More fundamental, but still unavailing, are Rust-Oleum's arguments about the unreliability of the ART, particularly in the context of an individual exposure assessment.

Stewart's opinion benefits from the fact that the ART "was, in the course of the development, peer reviewed by independent, leading experts from the industry, research institutes, and public authorities." Erik Tielemans, et al., *Advanced REACH Tool (ART): Overview of Version 1.0 and Research Needs*, 55 Ann. Occup. Hyg. 949, 954 (2011).

Rust-Oleum nevertheless objects to the ART based on a study showing that in a simulated exposure scenario (*i.e.*, without actual exposure data), the ART overestimated exposure by a factor of 2.92. Hofstetter, *Evaluation of Modeling Tools*, at 8. The

[2]Spencer only assessed benzene exposure attributable to Rust-Oleum products. To rebut Stewart's testimony, Spencer modeled exposure using the ART and calculated Milward's cumulative benzene exposure from Rust-Oleum products at 2.11 ppm-years. Under a Near Field, Far Field ("NF-FF") model, discussed in more detail below, Spencer estimated Milward's cumulative benzene exposure from Rust-Oleum products at .197 ppm-years.

Hofstetter study, however, found that the model employed by Rust-Oleum's expert--known as the Near Field, Far Field ("NF-FF") model--also overstated exposure by a factor of 1.96. The study thus reflects the unremarkable proposition that the ART, apparently much like the NF-FF model, is less precise when actual exposure data is unavailable. *Id.* at 10. The absence of actual exposure data is not fatal to the usefulness or reliability of either test. To the contrary, the ability to generate an exposure estimate in the absence of such data is part of the value of the ART to the scientific community. Tielemans, *Advanced REACH Tool*, at 950. Moreover, the Hofstetter study involved aerosol spray paints, which "have been noted to be more complex to model." Hofstetter, *Evaluation of Modeling Tools,* at 3. All agree that only a small portion of Milward's alleged benzene exposure came from aerosols.

Rust-Oleum also argues that the ART may be inappropriate for retrospective exposure assessment of a single individual, as opposed to a group of individuals or facilities. *See* Tielemans, *Advanced REACH Tool*, at 950, 955. But even a study that Rust-Oleum references to highlight uncertainty in the ART discusses use of the model for individual assessment, provided that the wide variability in exposure between workers is taken into account. Jody Schinkel, et al., *Advanced REACH Tool (ART):*

Calibration of the Mechanistic Model, 13 J. Envt'l Monitoring 1374, 1379 (2011).

Individual exposure variability of course means that precision in input parameters is all the more important; minor errors in modeling assumptions at the individual level could produce highly inaccurate exposure estimates. But the variability in individual exposure circumstances is inevitable. As discussed above, questions about the proper input parameters are questions about the factual underpinnings of the opinion, which are matters going to weight rather than admissibility. The ART may have room for improvement, and the NF-FF model may allow for more specificity in input parameters and a more precise exposure estimate, Hofstetter, *Evaluation of Modeling Tools*, at 10, but this does not mean the ART model is inadmissibly unreliable. Rather, the potential superiority of the NF-FF model will be one factor that the factfinder may consider in deciding whether and to what extent to credit Stewart and/or Spencer's exposure estimates.

iv. Summary

I thus find Stewart's exposure assessment using the ART admissible under Rule 702. The ART is peer-tested and produces fairly reliable exposure estimates. Concerns about over-estimation are apparently present in many exposure models, and individual assessment without actual exposure data may be

particularly difficult. But these are concerns going to weight rather than admissibility; they call for closer scrutiny by the factfinder as to estimated input parameters and adjustment of the resulting exposure estimate as necessary, but do not require exclusion of the evidence altogether.

C. Dr. Sheila Butler

The plaintiffs also rely on Sheila Butler to provide an opinion on specific causation. I find her opinion inadmissible.

i. Butler's Opinion

Butler is a physician with board certification in occupational medicine, as well as anatomic pathology, clinical pathology, and hematology. She has over 10 years of experience as a practicing diagnostic hematopathologist and as a consultant on occupationally-related malignancies. Butler currently conducts clinical assessment of environmental and occupational exposures in combat-exposed veterans at a VA medical center.

In offering her opinion on specific causation, Butler relied on Stewart's quantitative exposure assessment, but made her own qualitative judgments as well. Her report, however, is relatively devoid of substantive content. Butler opined that there is a "reasonable medical probability that there is a direct causal association between Mr. Milward's APL and his excessive occupational exposure to benzene containing substances" based primarily on (1) the fact that his exposure to benzene preceded his development of APL, and (2) a survey of studies showing

increased AML risk following low average dose exposures to benzene.

A later-filed affidavit also includes a “differential diagnosis” analysis in which Butler eliminates other possible causes of Milward’s leukemia. For example, although Milward smoked about a pack of cigarettes per week for two years of his life, Butler ruled out smoking as a risk factor for AML generally, and deemed Milward’s smoking history insufficient to cause AML in any event.[3] Observing that Milward was “morbidly obese,” Butler opined that the weight of scientific evidence does not establish obesity as a risk factor for AML. Butler further states that even if smoking and obesity were contributing causes to Milward’s AML, she could not conclude they were the sole causes and would not rule out benzene as a probable cause.

Even taking into account the additional differential analysis provided in Butler's affidavit, I find that her opinion on specific causation must be excluded because it fails to meet the reliability requirements established by Rule 703.

ii. Differential Diagnosis

I begin with Butler's "differential diagnosis" analysis.

[3]Stewart discussed Milward’s smoking history, but did not provide an exposure assessment in ppm-years. He did opine, however, that “the work exposure to benzene for just one ppm-year is 137 times greater than the smoking of one pack of cigarettes a week, for one year.” Based on that estimate, Milward’s smoking habit contributed a benzene exposure of .00729 ppm-years for two years, for a total of .0146 ppm-years.

Differential diagnosis is a useful and accepted means of assessing causation, *Baker* v. *Dalkon Shield Claimants Trust*, 156 F.3d 248, 253 (1st Cir. 1998), particularly where an expert cannot provide epidemiological studies or well-established threshold exposure levels at which disease occurs, *cf. Hardyman* v. *Norfolk & W. Ry. Co.*, 243 F.3d 255, 262 (6th Cir. 2001). The parties dispute whether Butler competently ruled out smoking and obesity as the cause of Milward's APL. But, as Butler observes, that analysis is of little import given that benzene could be a substantial contributing factor to Milward's leukemia in addition to smoking and obesity.

The more fundamental problem with differential diagnosis in this context is that, as reported by plaintiff's expert Martin, between 70 and 80 percent of cases of AML are idiopathic--meaning they have no known cause. Here, even if Butler could rule out smoking and obesity as probable causes, the differential diagnosis analysis provides little information. When a disease has a discrete set of causes, eliminating some number of them significantly raises the probability that the remaining option or options were the cause-in-fact of the disease. *Restatement (Third) of Torts: Phys. & Emot. Harm* § 28, cmt. c(4) (2010) ("The underlying premise [of differential etiology] is that each of the[] known causes is independently responsible for some proportion of the disease in a given population. Eliminating one or more of these as a possible cause for a specific plaintiff's

disease increases the probability that the agent in question was responsible for that plaintiff's disease.”). The same cannot be said when eliminating a few possible causes leaves not only fewer possible causes but also a high probability that a cause cannot be identified. *Id.* ("When the causes of a disease are largely unknown . . . differential etiology is of little assistance.”). Butler cannot establish specific causation in this context using a differential diagnosis approach.

Butler answers that she “ruled out” an idiopathic origin of Milward’s leukemia by “ruling in” benzene. But this begs the question--namely, whether Butler was able to “rule in” benzene using other reliable scientific methods when a differential diagnosis approach was unavailable. Milward makes this very point, explaining that Butler can rule out an “idiopathic” origin of Milward’s APL only “to the extent that she identifies one or more causes of that patient’s leukemia that, to a reasonable degree of medical and scientific certainty, *did* contribute to his or her leukemia.”

Milward argues that the work of “ruling in” benzene was already done by general causation expert Martyn Smith. But this ignores the fact that Milward must demonstrate “the levels of exposure that are hazardous to human beings generally as well as the plaintiff’s actual level of exposure.” *Westberry* v. *Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) (internal quotation and citation omitted). In *Westberry*, it was undisputed that high

levels of the toxin at issue (talcum powder) could cause plaintiff's ailment (sinus problems), and there was evidence from which a factfinder could conclude plaintiff was exposed to such high levels. 178 F.3d at 264. In that context, differential etiology helped to distinguish among a discrete set of probable causes. Here, by contrast, an as-yet-unanswered and hotly disputed question is whether exposure to benzene *at Milward's alleged exposure level* could have caused him to develop APL.

I thus turn to the other possible methods by which Butler might have "ruled in" Milward's level of benzene exposure as a probable cause of his leukemia.

iii. Threshold Level of Benzene Exposure

To the extent Butler seeks to establish specific causation based on the argument that any level of benzene is sufficient to cause leukemia--a so-called "no safe level," "no threshold," or "linear" model--her opinion is inadmissibly unreliable. Courts have found that "there is no scientific evidence that the linear no-safe threshold analysis is an acceptable scientific technique used by experts in determining causation in an individual instance." *Sutera* v. *Perrier Group of Am. Inc.*, 986 F. Supp. 655, 666 (D. Mass. 1997). The model is "merely a hypothesis," with "no known or potential rate of error." *Id.* (citing *Whiting* v. *Boston Edison Co.*, 891 F. Supp. 12, 25 (D. Mass. 1995)); *accord Henricksen* v. *ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1166 (E.D. Wash. 2009); *see generally* Federal Judicial Center,

Reference Manual on Scientific Evidence, at 643 n.28 (3d ed. 2011).

Although the EPA applies a linear dose-response curve for benzene, it apparently does so due to uncertainty about the shape of the dose-response curve below 40 ppm-years. EPA Office of Research and Development, *Carcinogenic Effects of Benzene: An Update*, at 38-39 (April 1998) ("EPA Report"). This is thus the classic example of a cautious prophylactic administrative rule; but it does not support the reliability of the linear, no-threshold model in establishing specific causation. *Cf*. *Sutera*, 986 F. Supp. at 664 (citing *Allen* v. *Pennsylvania Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir.1996)).[4]

Butler also points to a study concluding that there is "no clear evidence of a threshold below which benzene does not cause hematotoxicity in humans." Richard B. Hayes, et al., *Benzene and Lymphohemaptopoietic Malignancies in Humans*, 40 Am. J. Indus. Med. 117, 120 (2001). In context, however, it is clear that the study is referring to the lack of a hematotoxicity threshold for

[4]Earlier in this case, the First Circuit rejected defendant's attempt to *discredit* the "weight of the evidence" approach by arguing that regulatory agencies used the approach merely to craft prophylactic measures. *Milward*, 649 F.3d at 18 & n.9. But this does not mean that plaintiffs can rely on an agency's use of the "linear threshold model" to *confirm* its reliability. Use of the model by the EPA, especially given the EPA's professed uncertainty about its accuracy, cannot overcome the various ways in which use of the model to prove specific causation fails to meet the admissibility standards of Rule 702 and *Daubert*.

a low average dose of benzene. While it may be true that any given dose causes hematotoxicity, the study does not address whether there is a threshold *cumulative* benzene exposure level below which there is no significant chance of developing APL, or at least AML.

Given that Butler did not and could not quantify a threshold exposure level for benzene, Milward cannot posit that his cumulative exposure level crossed a relevant threshold.

iv. Relative Risk

Failure to identify a threshold level at which benzene exposure would not cause leukemia does not alone doom Butler's opinion. As an alternative to identifying a minimum threshold, a plaintiff may present evidence that the specific level of benzene exposure actually experienced caused plaintiff's illness--regardless of the existence of any minimum threshold. *See Schultz* v. *Akzo Nobel Paints, LLC*, 721 F.3d 426, 432 (7th Cir. 2013). Butler claims to have done precisely this by comparing Stewart's cumulative benzene exposure assessment of 25.6 ppm-years with quantities of benzene that, according to peer-reviewed epidemiological studies, significantly increase the risk of AML.[5]

[5]Determining only whether the cumulative benzene exposure (25.6 ppm-years) was a probable cause of Milward's leukemia--as opposed to the portion of that estimate attributable only to Rust-Oleum products (6.57 ppm-years)--is nonetheless consistent with Milward's eventual burden of proof as to causation. Milward need only show that benzene exposure from Rust-Oleum products was a "substantial contributing factor" to his disease, even if benzene exposure from Rust-Oleum products alone would have been

Such analysis of "relative risk" has been found an appropriate means of establishing specific causation. *See generally Reference Manual on Scientific Evidence*, at 611-612 (discussing propriety of using magnitude of relative risk to establish specific causation); *Restatement (Third) of Torts: Phys. & Emot. Harm* § 28, cmt. c(4) rprts. note (2010); *cf. City of Greenville* v. *W.R. Grace & Co.*, 827 F.2d 975, 980 n.2 (4th Cir. 1987) (linear no-threshold model used "in the absence of scientific studies concerning exposure to low levels of [toxin]").

The reliability of a relative risk approach here, however, is undermined by the fact that Butler conceded during her deposition that she is "not an epidemiologist" and "not a researcher," and that she did not intend to weigh different epidemiological studies. Butler is thus unqualified (and did not even attempt) to opine on how to choose among studies reaching dramatically different conclusions about what level of cumulative exposure significantly increases leukemia risk. *Cf. Schultz*, 721

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insufficient to cause the disease. *Cf. Restatement (Third) of Torts: Phys. & Emot. Harm* § 27, cmt. f (2010) ("The fact that an actor's conduct requires other conduct to be sufficient to cause another's harm . . . does not prevent the actor's conduct from being a factual cause of harm pursuant to this Section, if the actor's conduct is necessary to at least one causal set."). *See also Restatement (Third) of Torts: Phys. & Emot. Harm* § 36 (2010) ("When an actor's negligent conduct constitutes only a trivial contribution to a causal set that is a factual cause of harm . . . , the harm is not within the scope of the actor's liability); *id.* cmt. b (contemplating "submission of the case to the factfinder to decide if the actor's contribution was sufficiently trivial so as to be beyond the actor's scope of liability").

F.3d at 430 (plaintiff's expert discussed and distinguished studies contradicting opinion that benzene exposure levels of 24 ppm-years were insufficient to cause AML). She is thus equally unqualified to draw reliable conclusions about whether a cumulative exposure of 25.6 ppm-years can result in significantly increased risk.[6] *Compare* Deborah C. Glass, et al., *The Health Watch Case--Control Study of Leukemia and Benzene*, 1076 Ann. N.Y. Acad. Sci. 80, 85 (2006) (finding significantly increased risk of AML in group with cumulative benzene exposures greater than 8 ppm-years), *and* Richard B. Hayes, et al., *Benzene and the Dose-Related Incidence of Hematologic Neoplasms in China*, 89 J. Nat'l Cancer Inst. 1065, 1068 (1997) (finding significantly increased risk of AML in group with cumulative benzene exposures less than 40 ppm-years), *with* EPA Report at 6 (finding no increase in relative risk of leukemia in cumulative benzene exposure less than 40 ppm-years, primarily based on Robert A. Rinsky, et al., *Benzene and Leukemia: An Epidemiologic Risk Assessment*, 316 New England J. Med. 1044 (1987)), *and id.* at 14 (questioning reliability of Hayes 1997 study).

The mere lack of consensus as to the benzene exposure level

[6] Thus, the qualifications of the expert to engage with the relevant scientific literature can be decisive on the question of admissibility. Dr. Gore, whose testimony was found admissible in *Schultz* v. *Akzo Nobel Paints*, 721 F.3d 426, 428-34 (7th Cir. 2013), appears to have been fully able not merely to identify but to evaluate the relevant literature. Here, Dr. Butler concedes she is not.

at which leukemia risk significantly increases might not, on its own, disqualify a relative risk approach to establishing specific causation. In fact, I would arrogate more than is entailed in my "role as gatekeeper" by "[taking] sides on questions that are currently the focus of extensive scientific research and debate--and on which reasonable scientists can clearly disagree." *Milward*, 639 F.3d at 22. But to the extent Butler's opinion requires taking sides in a debate within the epidemiological literature, it lacks the "rigor that characterizes the practice" of an epidemiological expert. *Kumho Tire*, 526 U.S. at 152. Butler's professed inability to engage with the conflicting epidemiological literature makes her opinion based on that literature unreliable and unhelpful to a jury. Without the ability to explain how and why the epidemiological literature favorable to Milward should be trusted over conflicting views, Milward cannot meet his burden to show that Butler's opinion on specific causation premised on increased relative risk "has been arrived at in a scientifically sound and methodologically reliable fashion." *Milward*, 639 F.3d at 15 (internal citations and quotations omitted).[7]

[7] Following the hearing on the summary judgment motion before me now, Milward moved to supplement the summary judgment record with two documents meant to support Butler's qualifications to evaluate epidemiology studies. One document is a printout from the website of the American Board of Preventive Medicine ("ABPM"), which represents that preventive medicine specialists have "core competencies" in, among other things, "epidemiology" and "environmental and occupational medicine." The

Milward might meet his burden of production as to specific causation by relying upon findings of significantly increased relative risk such as those contained in the Glass 2006 and Hayes 1997 studies, independent of Butler's opinion as to specific causation. Such hearsay statements are admissible under the so-called "learned treatises" exception to the hearsay rule if "the publication is established as a reliable authority by [an] expert's admission or testimony, by another expert's testimony, or by judicial notice." Fed. R. Evid. 803(18).

Butler's mere identification and endorsement of the studies

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other document, from the website of the American College of Occupational and Environmental Medicine ("ACOEM"), states that occupational medicine physicians are competent to "[i]nterpret exposure data in the context of the scientific literature (human and animal" and the patient's presentation" and to "[u]se occupational and environmental information resources to conduct a literature search or to research the health effects of a chemical substance."

These generalities are insufficient to overcome Butler's explicit disavowal of the requisite epidemiological expertise and any ability or willingness to weigh the epidemiological studies potentially relevant to this case. In any event, the representations in these newly submitted documents are consistent with Butler's testimony about (the limits of) her own qualifications. There is little doubt that Butler can and did "conduct a literature search" to find epidemiology studies, and that she is capable of reading, understanding, and even applying those studies. This does not mean, however, that she can evaluate the relevant studies with the "rigor that characterizes the practice" of an epidemiological expert, *Kumho Tire*, 526 U.S. at 152, such that she can meaningfully attest to their reliability, or distinguish more reliable studies from those less reliable. As discussed above, without the qualifications to do so, Butler cannot demonstrate that her opinion as to specific causation has a reliable scientific foundation in the relevant epidemiology studies.

favorable to Milward is insufficient to establish their reliability and thus admissibility. As the Advisory Committee observed:

> testing of professional knowledge [is] incomplete without exploration of the witness' knowledge of and attitude toward established treatises in the field. The process works equally well in reverse and furnishes the basis of [Rule 803(18)].

Fed. R. Evid. 803(18) advisory committee note. In other words, testing the reliability of proffered scientific literature is incomplete without exploration of an expert's knowledge of and attitude toward the scientific literature. Here, Butler disclaimed any willingness or ability to comment on the relevant scientific literature from an epidemiological perspective, and thus could not establish the reliability of the epidemiological studies favorable to Milward's position.

Although I may take judicial notice of the relevant studies and conclusions within those studies if I find them sufficiently reliable, courts have refused to do so when dealing with specific findings in scientific literature and no expert is available to vouch for the "authors' methodology or the accuracy of their results." *Gilhool* v. *Chairman & Comm'rs, Philadelphia County Bd. of Elections*, 306 F. Supp. 1202, 1208 (E.D. Pa. 1969), *aff'd*, 397 U.S. 147 (1970). *See also Meschino* v. *N. Am. Drager, Inc.*, 841 F.2d 429, 434 (1st Cir. 1988) (finding no error in exclusion of scientific article when no expert available to comment on its reliability); *United States* v. *Turner*, 104 F.3d 217, 221 (8th Cir.

1997) (finding no error in excluding medical texts when "there was no expert testimony establishing the texts as authoritative"). Judicial notice of reliability is usually better reserved for "standard reference works," *e.g., Application of Hartop*, 311 F.2d 249, 253 (C.C.P.A. 1962), or cases in which the judge has other indicia of reliability--for example, an implicit concession of reliability by a competing expert, *see Costantino* v. *David M. Herzog, M.D., P.C.*, 203 F.3d 164, 172 (2d Cir. 2000).

I consider judicial notice of reliability particularly inappropriate here, given the conflicting strands of scientific literature--and especially because the EPA Report specifically calls into doubt Hayes 1997, one of the main studies favorable to Milward's position. This case clearly calls for an expert witness to "explain and assist in the application" of conflicting strands of scientific literature. Fed. R. Evid. 803(18) advisory committee note; *see also Anderson* v. *United States*, 571 F. Supp. 2d 202, 212 (D. Me. 2008) ("The Rule's constrained use of learned treatises imposes a valuable discipline on the factfinder, whether jury or judge, to avoid playing expert and restricts the factfinder to those technical matters that have been illuminated by expert testimony."). This is something Butler has admitted she cannot do. It is not something the Court should do on its own or leave to an unassisted factfinder.

Given Butler's limitations as an expert, Milward lacks the reliable scientific evidence necessary to send the issue of

specific causation to a jury based on the theory that his alleged level of benzene exposure resulted in a significantly increased relative risk of APL.

v. Latency Period

Butler found a satisfactory "temporal relationship" between benzene exposure and the development of Milward's leukemia merely based on the fact that exposure "preceded" onset of the disease. But Butler failed to address potential complications posed by the latency period between exposure and development of AML. *See Henricksen*, 605 F. Supp. 2d at 1156 ("the chronological relationship between exposure and effect must be biologically plausible"). Butler testified to an "average" latency period of five to ten years. The *Reference Manual on Scientific Evidence* more charitably concludes that "the period of significantly higher risk [of AML] from the last exposure [to benzene] usually persists for no more than about 15 years." *Reference Manual on Scientific Evidence*, at 668-69.

By these estimates, the "last" exposure to benzene likely to have caused Milward's leukemia occurred somewhere between 1989 and 1999. All agree that his exposure levels declined over time, and thus the relevant period at which benzene might have triggered Milward's leukemia coincides with what all agree was a lower-exposure period of his life. For the entire 1993-2004 period, for example, Stewart estimated Milward's benzene exposure attributable to Rust-Oleum products at .032 ppm-years--and that is before the

50% reduction Stewart applied to other periods to account for declining exposure levels. The argument that benzene exposure was, in fact, the triggering event of Milward's leukemia is thus complicated by his especially low benzene exposure levels at the time necessary to make exposure consistent with the average latency period.

At her deposition, Butler expressed the opinion that the diminishing exposures into the latency period were unimportant because "cumulative effect" was what mattered. She theorized that "eventually maybe that more recent exposure is like the straw that breaks the camel's back," regardless of the age of earlier exposures. Perhaps so. But Butler also admitted she "ha[d] no way of proving this."

Although these questions about the temporal relationship between Milward's benzene exposure and his leukemia may not be insuperable, Butler has failed to answer them with reliable scientific evidence. Her treatment of the issue is thus an additional consideration I weigh in rejecting the reliability of her opinion.

vi. Clinical Judgment

Milward also makes something of an overarching defense of Butler's "clinical approach" to causation, seeking shelter in the First Circuit's recent treatment of the "weight of the evidence" approach. *Milward*, 639 F.3d at 17-19. The Court of Appeals, however, made clear that "admissibility must turn on the

particular facts of the case." *Id.* at 19. Here, it remains a mystery exactly what evidence Butler's "clinical approach" weighs without the benefit of established, tested, and reliable methods of analyzing specific causation discussed above--including differential etiology, safe threshold, and relative risk analyses. Butler's "clinical assessment" or "qualitative approach" thus appears to do nothing more than connect Milward's estimated benzene exposure to his APL "by the *ipse dixit* of the expert." *Cf. Joiner*, 522 U.S. at 146.

vii. Summary

I will exclude Butler's opinion as to specific causation. The "linear no-threshold" analysis has been rejected as a reliable means of proving specific causation. Moreover, Butler was unqualified to offer an opinion on specific causation by comparing Milward's quantified benzene exposure to epidemiological studies showing significant risk increases at similar exposure levels. By her own admission, she lacks the expertise to establish the reliability of the studies favorable to Milward over others reflecting significantly increased risk only at higher cumulative exposure levels. Neither a "safe threshold" or "relative risk" analysis would be necessary if Butler could form a reliable opinion on specific causation based on a "differential diagnosis" approach. But differential etiology is not possible here given the large percentage of idiopathic cases of AML. Any further "clinical" or "qualitative" assessment of causation

suggested by Butler has not been demonstrated to be anything more than exegesis by assertion.

D. Summary Judgment

Without Butler's testimony, Milward cannot establish it was more likely than not that his exposure to benzene was a cause-in-fact of his leukemia, let alone that benzene from Rust-Oleum products was a substantial contributing factor--issues on which he would bear the burden of proof at trial. Accordingly, summary judgment must enter for defendant Rust-Oleum. *Celotex*, 477 U.S. at 322; *Sutera*, 986 F. Supp. at 668.

IV. REMAINING ISSUES

In the interest of completeness, I will briefly address the remaining issues. In doing so, I conclude Rust-Oleum would not be entitled to summary judgment based on its preemption and proximate cause arguments.

A. Preemption

The relevant tortious conduct in this case is Rust-Oleum's alleged failure to provide adequate warnings about the presence of benzene in its products. Even plaintiff's expert Stewart said there was no data to show that benzene was present in Rust-Oleum products at a concentration exceeding the OSHA regulatory limit, above which Rust-Oleum would have been obligated to identify the presence of benzene. *See* 29 C.F.R. § 1910.12(g)(1) & (2). Rust-Oleum argues Milward's failure-to-warn claim is preempted because

the imposition of tort liability, despite regulatory compliance, would unduly interfere with federal law.

Although OSHA requires states to obtain approval to assert jurisdiction over occupational safety or health issues as to which a federal standard is already in place, 29 U.S.C. § 667(b), the statute also includes a "savings clause," which provides:

> Nothing in this chapter shall be construed . . . to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.

29 U.S.C.A. § 653(b)(4).

The First Circuit has explicitly held that the savings clause reflects Congress' intent not to preempt "enforcement in the workplace of private rights and remedies traditionally afforded by state laws of general application." *Pedraza* v. *Shell Oil Co.*, 942 F.2d 48, 53 (1st Cir. 1991). State law negligence actions fit comfortably within this category. *Id.* at 52. The OSHA standard may be relevant in establishing the standard of care in a negligence action, *id.*, but it is not determinative. The OSHA standard is prophylactic and does not mean a worker is necessarily left without a remedy when injury in fact occurs. *Id.* at 54 n.7.

OSHA's savings clause is clear enough, and *Pedraza* is binding authority. Preemption is not at play here.

B. Proximate Cause

Rust-Oleum also argues Milward cannot establish that the

failure to provide adequate warnings about benzene was the proximate cause of his injuries. The evidence is thin, but Milward produces testimony from Steven Giannelli, who was Milward's employer in both the late 1980s and late 1990s. Giannelli reviewed material safety data sheets for products used by his refrigeration technicians, and testified that none ever disclosed the presence of benzene in products his company was using. Giannelli also testified that if he had been aware that a product "ha[d] a chemical in it that could cause cancer" he would "look for alternative products to purchase." Milward similarly testified that he would not have used any product bearing a warning that "use of this product and inhalation of vapors may cause cancer."

Rust-Oleum responds that at least one of its products bore just such a warning. But the warnings appear to have been inconsistent across various products, and at least some did not warn of cancer risk at all. It would be better left to a finder of fact to consider the warnings on the products Milward used most frequently, to determine whether the warnings could have been improved, and to determine whether Rust-Oleum reasonably could have foreseen that its failure to change the warnings would have altered the behavior of users like Milward (or his employers) and prevented injury. *Nna* v. *Am. Standard, Inc.*, 630 F. Supp. 2d 115, 130 (D. Mass. 2009) ("The question of whether a risk of harm was reasonably foreseeable is ordinarily a matter for the jury.").

V. CONCLUSION

For the reasons set forth more fully above, defendant's motion for summary judgment is GRANTED on grounds that because Dr. Butler's opinion on specific causation is inadmissible, Milward has failed to proffer sufficient evidence to demonstrate that benzene from Rust-Oleum caused his leukemia.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE