UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

In re Flint Water Cases.

Judith E. Levy United States District Judge

This Order Relates To:

Carthan, et al. v. Snyder et al. Case No. 16-10444

OPINION AND ORDER GRANTING DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH AMERICA, INC., AND VEOLIA WATER NORTH AMERICA OPERATING SERVICES, LLC'S MOTION TO EXCLUDE THE TESTIMONY AND <u>REPORTS OF DR. ROBERT A. MICHAELS [2456]</u>

This opinion is the final one in a series addressing the admissibility

of the testimony and reports of nine experts retained by Class Plaintiffs¹

¹ See ECF No. 2454 (VNA's motion to exclude opinions and testimony of Dr. Larry Russell); ECF No. 2455 (VNA's motion to exclude opinions and testimony of Dr. Clifford P. Weisel); ECF No. 2456 (VNA's motion to exclude testimony and reports of Robert A. Michaels); ECF No. 2458 (VNA's motion to exclude opinions and testimony of Dr. David Keiser); ECF No. 2459 (VNA's motion to exclude opinions and testimony of Dr. David Keiser); ECF No. 2459 (VNA's motion to exclude opinions and testimony of Dr. David Keiser); ECF No. 2460 (VNA's motion to exclude opinions and testimony of Dr. Paolo Gardoni); ECF No. 2461 (VNA's motion to exclude opinions and testimony of Dr. Howard Hu); ECF No. 2483 (VNA's motion to exclude opinions and testimony of Dr. Panagiotis (Panos) G. Georgopoulos); and ECF No. 2462 (VNA's motion to exclude opinions and testimony of Dr. Robert A. Simons) (in ECF Nos. 2606 and 2617 the Court inadvertently failed to include the motion related to Dr. Simons' testimony in this list).

in anticipation of the issues class trial, currently set to begin on February 13, 2024. Defendants argue that none of these experts can meet the standards set by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Currently before the Court is the motion by Veolia North America, LLC, Veolia North America, Inc., and Veolia Water North America Operating Services, LLC (collectively "VNA") to exclude the testimony and report of Dr. Robert Michaels. (ECF No. 2456.) For the reasons set forth below, VNA's motion to exclude is GRANTED.

I. Background

Dr. Michaels is the president of RAM TRAC Corporation, a company that provides health risk assessment and management services. He holds an M.S. in Environmental Ecology and a Ph.D. in Environmental Toxicology. His qualifications as an expert are not in dispute.

Plaintiffs retained Dr. Michaels to evaluate whether, as a matter of general causation, the corrosive water conditions to which VNA allegedly contributed were capable of causing certain types of bodily harm to Flint residents. Specifically, Dr. Michaels considered whether exposure to corrosive water can lead to skin rashes and hair loss. To do so, Dr. Michaels primarily reviewed the Unified Coordination Group's Flint Rash Investigation (2016). That report arose from a collaboration between local, state, and federal agencies and focused on "rash-related concerns associated with . . . water quality" after Flint's return to Lake Huron (DWSD) water. (See ECF No. 2456-6, PageID.78344.) With respect to skin rashes that began during the Flint Water Crisis, the report concluded that inconsistent water quality at the time "may have contributed to the onset or worsening of irritant effects among individuals using the water," though a causal link could not be confirmed. (See ECF No. 2456-5, PageID.78366). The report further found no relationship between Flint water and hair loss—whether before or after the return to DWSD. (Id. at PageID.78368.)

After reviewing the Coordination Group's data, Dr. Michaels concluded that Flint's corrosive water very likely could cause both skin rashes and hair loss, and that the Coordination Group had been mistaken in concluding otherwise. (*See* ECF No. 2456-3, PageID.78243– PageID.78245 (Dr. Michaels's discussion of "imperfect" and "questionable" elements in Coordination Group report).). On May 19, 2023, VNA filed this motion seeking to exclude Dr. Michaels's opinions. (ECF No. 2456.)

II. Legal Standard

Federal Rule of Evidence 702 governs the admissibility of expert testimony and requires that experts are qualified, and that their testimony be both relevant and reliable. Fed. R. Evid. 702; *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008). As the Supreme Court explained in *Daubert*, Rule 702 imposes a "gatekeeping" obligation on the courts to ensure that the "reasoning or methodology underlying [the expert's] testimony is scientifically valid." *Daubert*, 509 U.S. at 589; *See also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

Daubert provides a non-exclusive list of factors courts may consider when evaluating reliability: (1) whether the theory or technique at the basis of the opinion is testable or has been tested, (2) whether it has been published and subjected to peer review, (3) what the known error rates are, and (4) whether the theory or technique is generally accepted. Daubert, 509 U.S. at 593; see also In re Scrap Metal, 527 F.3d at 529 (listing same factors). Not every factor needs to be considered in every instance, and courts may adapt them as appropriate for the facts of an individual case. *Kumho*, 526 U.S. at 150.

"Rejection of expert testimony is the exception, rather than the rule." United States v. LaVictor, 848 F.3d 428, 442 (6th Cir. 2017) (quoting In re Scrap Metal, 527 F.3d at 529–30)). But the burden is on Plaintiffs to show by a "preponderance of proof" that the proffered expert meets the standards of Rule 702 as interpreted by Daubert. Pride v. BIC Corp., 218 F.3d 566, 578 (6th Cir. 2000) (quoting Daubert, 509 U.S. at 592).

III. Analysis

VNA argues that Dr. Michaels' opinions as to both skin rashes and hair loss are inadmissible because he misapplied standard elements of causation analysis and relied on the wrong type of data. The Court considers each of Dr. Michaels' opinions in turn.

A. Skin Rashes

Dr. Michaels primarily focused his report on skin rashes and dermatological complaints. To consider whether corrosive water can cause skin rashes, Dr. Michaels applied Sir Bradford Hill's "weight of the evidence" guidelines. (ECF No. 2456-3, PageID.7823.) These guidelines,

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often referred to as the Bradford Hill criteria, "are metrics that epidemiologists use to distinguish a causal connection from a mere association." In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig., 858 F.3d 787, 795 (3d Cir. 2017). Sir Austin Bradford Hill, The Environment and Disease: Association or Causation?, 58 Proc. Royal Soc'y Med. 295 (1965) ("Hill, The Environment and Disease"). They consist of nine "viewpoints" or guidelines scientists can use to consider whether an association is best explained by a causal relationship or by something else. Hill, The Environment and Disease, 299; Milward v. Acuity Specialty Prod. Grp., Inc., 639 F.3d 11, 17–19 (1st Cir. 2011) (explaining Bradford Hill approach to causation). The first step in applying Bradford Hill's methodology is thus to "identify an association between an exposure and a disease." Milward, 639 F.3d at 17. After an association has been identified, epidemiologists consider the strength of that association; its consistency across different circumstances; its specificity; its temporality; whether there is an observable dose-response relationship; the scientific coherence and plausibility of the suspected causal relationship; whether the association can be replicated through experimentation; and whether the association can be supported by

analogy to similar exposures. Hill, *The Environment and Disease*, 297–99 (proposing these factors).

The parties agree—and many courts have held—that Bradford Hill's guidelines constitute a reliable method of inferring causation for purposes of Federal Rule 702. See, e.g., Milward, 639 F.3d at 18 ("no serious argument" that Bradford Hill methodology is unreliable); In re Zoloft, 858 F.3d at 795 (flexible methodologies such as Bradford Hill guidelines not unreliable); Hardeman v. Monsanto Comp., 997 F.3d 941 (9th Cir. 2021) (affirming admission of general causation testimony based on Bradford Hill guidelines). "Despite the fact that the methodology is generally reliable," however, "each application is distinct and should be analyzed for reliability" separately. In re Zoloft, 858 F.3d at 795. The question here is whether Dr. Michaels conducted his Bradford Hill analysis in a reliable way. To reliably apply this methodology, an expert must, at minimum, "explain 1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another." Id. at 796; cf. Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 671 (6th Cir. 2010) (expert must explain his analysis; *ipse dixit* alone not sufficient for admissibility).

1. Association

As explained above, a Bradford Hill analysis must begin with evidence of an association. Milward, 639 F.3d at 17. Epidemiologists can then use the Bradford Hill criteria to consider whether the association is causal. For instance, one could use them to infer from studies showing that smokers are more likely to die of lung cancer (association) that smoking causes lung cancer—which was what Bradford Hill himself used his guidelines to do. Bradford Hill's approach thus works only when there is preexisting evidence of an association. See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig, 174 F.Supp.3d 911, 924–25 (D.S.C. 2016) (epidemiological studies required for Bradford Hill approach); see also Richard Wakeford, Association and Causation in Epidemiology—Half a Century Since the Publication of Bradford Hill's Interpretational Guidance, J. Royal Soc'y Med., vol. 108, no. 1, at 5 (2015) ("What Bradford Hill produced was a framework for a structured approach to the interpretation of epidemiological findings.").

VNA argues that Dr. Michaels lacks evidence of an association here because he relied exclusively on the Coordination Group's report—which never aimed to establish a correlation between corrosive water and dermatological conditions, and which did not follow the parameters of an epidemiological study. Indeed, the Coordination Group used self-reported information rather than a random sample, did not use a control group, and focused primarily on complaints postdating the Flint Water Crisis.

Dr. Michaels nevertheless concluded that there is "evidently" strong evidence for an association between corrosive water and skin rashes, because the Coordination Group found more reports of skin rashes with onset dates before October 2015 (the switch back to DWSD) than afterwards. (ECF No. 2456-3, PageID.78234.) But in drawing that conclusion, Dr. Michaels failed to provide any explanation for his choice to use the Coordination Group's nonrandom sample, rather than scientific studies of the relationship between corrosive water and dermatological complaints. That choice is particularly puzzling given Dr. Michaels' focus on general causation—which involves the causal relationship between corrosive water and skin rashes generally and is not specific to Flint. See Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 677-78 (6th Cir. 2011) (explaining general and specific causation); Powell-Murphy v. Revitalizing Auto Comm's Envir. Resp. Trust., 333 Mich. App. 234, 249-50 (Mich. App. 2020) ("General causation pertains to whether a toxin is capable of causing the harm alleged") (quoting Lowery v. Enbridge Energy Ltd. P'ship, 500 Mich. 1034, 1043 (2017) (Markman, J., concurring)). Under Daubert, Dr. Michaels was—at the very least required to explain his use of a single, non-random sample to apply the Bradford Hill analysis, particularly when it deviated so substantially from standard scientific practice. See In re Zoloft, 858 F.3d at 796. Yet he failed to do so here.

Plaintiffs a Bradford Hill dispute that analysis requires epidemiological studies. But the case they cite for that proposition holds only that evidence of *statistical significance* is not required. In re Tylenol (Acetominophen) Marketing, Sales Practices & Prod. Liab. Litig., 2016 WL 4039286, at *7 n.19 (E.D. Pa. July 28, 2016). That much is clear from Bradford Hill's own explanation. Hill, The Environment and Disease at 299 ("No formal tests of significance can answer [the causation question] ... Such tests ... contribute nothing to the 'proof' of our hypothesis."). But as In re Tylenol itself recognizes, "an association is needed first to apply Bradford Hill." In re Tylenol, 2016 WL 4039286 at *7 n.19. And the problem with the Coordination Group's study is not that it fails tests of statistical significance but that it is unclear whether it establishes any

relevant association in the first place. Without a reasoned argument for this study's significance as evidence of an association between corrosive water and skin rashes, Dr. Michaels and Plaintiffs have offered very little basis to find that the subsequent Bradford Hill analysis could meet the reliability requirement of *Daubert*. *In re Lipitor*, 174 F.Supp.3d at 924– 25 ("the Bradford Hill analysis used by epidemiologists does require that an association be established through [epidemiological] studies") (collecting cases).

Even if the Coordination Group's data sufficed to establish an association for purposes of the Bradford Hill analysis, that association could only be between skin rashes and the Flint Water Crisis generally. After all, the only basis for the association is the date of onset: whether a rash began before or after Flint had switched back to DWSD water. Dr. Michaels' testimony is admissible only if it can support his conclusions about "corrosive Flint municipal water conditions." (ECF No. 2456-3, PageID.78254.) The Coordination Group data on which Dr. Michaels relies is not specific to the issue of corrosivity.² In relying almost

 $^{^2}$ Indeed, some of the Coordination Group's own hypotheses were directly inconsistent with attributing skin irritation to corrosive water. For instance, the

exclusively on the Group's report, Dr. Michaels wrongly conflates an association between rashes and the Flint Water Crisis with an association between rashes and *corrosive water*.

Plaintiffs point out that Dr. Michaels also cites studies showing that "metals . . . such as arsenic, chromium, cobalt, copper, nickel, silver, thallium, and zinc" are associated with contact dermatitis. (ECF No. 2508, PageID.83067 (citing ECF No. 2456-3).) But Class Plaintiffs never alleged that Flint's water contained any of these substances. (*See* ECF No. 1175-3 (Fifth Amended Class Complaint).) Nor did the Coordination Group. (*See* ECF No. 2456-5, PageID.78365.) Nor, for that matter, does Dr. Michaels. These associations thus form a weak alternative basis for the conclusion that "corrosive Flint municipal water conditions" could have caused skin rashes. (ECF No. 2456-3, PageID.78254.)

In any event, Dr. Michaels did not conduct his Bradford Hill analysis on any of these studies. As explained above, Hill's methodology

Coordination Group found that "during the period of using the Flint River water . . . pH increased significantly to an average of 7.7," and "Alkalinity is associated with skin dryness and irritation." (ECF No. 2456-5, PageID.78365.) But as Plaintiffs themselves explain in their Complaint, corrosivity is associated with *low* pH values. (ECF No. 1176-3, PageID.28667.) That is why Plaintiffs argued that VNA should have "advis[ed] that the pH of the water should be increased." (*Id.* at PageID.28663.)

is meant to help epidemiologists move from evidence of association to evidence of causation. Identifying an association is the beginning of that process-not its end. Milward, 639 F.3d at 17. Dr. Michaels could have proceeded by taking studies associating exposure to certain metals with skin irritation and asking-using Bradford Hill's guidelines-whether a causal relationship likely explained those associations. Instead, Dr. Michaels' analysis relied exclusively on the association contained in the Coordination Group's data. Other citations in his report were unaccompanied by any analysis and therefore would not suffice under Daubert even if they were consistent with the allegations in this case. See, e.g., Robison v. Continental Casualty Comp., No. 1:17-CV-508, 2022 WL 336900 at *9 (E.D. Tex., Jan. 6, 2022) ("It is only when the expert undertakes some independent investigation of the underlying opinions that his testimony may be considered reliable.") (quoting Hunt v. McNeil Consumer Healthcare, 297 F.R.D. 268, 275 (E.D. La. 2014)).

In sum, there are two problems with Dr. Michaels' choice to focus his analysis exclusively on the Coordination Group's report. First, the report did not follow standard scientific practices for assessing the presence of an association—such as creating a control group or selecting participants randomly—because it was never the Group's purpose to establish an association between the Flint Water Crisis and skin complaints. This means the report's data falls below the bar courts have generally set for evidence of association. *In re Lipitor*, 174 F.Supp.3d 911 at 924. Second, to the extent the report does sufficiently support finding an association, that association would encompass *every* aspect of the Flint Water Crisis—including the water quality before VNA's involvement, the stress associated with a crisis of this magnitude, and aspects of Flint River water for which Plaintiffs never sought to hold VNA responsible. So broad an association is too general to draw inferences about the corrosivity at issue in this litigation.

2. Bradford Hill Analysis

The problems discussed above independently render Dr. Michaels' work on skin rashes inadmissible in this case. Fed. R. Evid. 702. But the remainder of his analysis is also problematic. With respect to Hill's second guideline, the consistency of the association, Dr. Michaels finds a "consistent" association because "association of rashes and Flint water was at least qualitatively consistent among groups." (ECF No. 2456-3, PageID.78235). But Hill's "consistency" factor looks to "similar findings

generated by several epidemiological studies involving various investigators." In re Mirena Ius Levonorgestrel-Related Prod.'s Liab. Litig. II, 341 F. Supp.3d 213, 250 (S.D.N.Y. 2018) (citing Reference Manual on Scientific Evidence at 604); Hill, The Environment and Disease, 296 (explaining that an association is consistent if it "has . . . been repeatedly observed by different persons, in different places, circumstances and times"). A single study of a single incident is by definition insufficient to establish consistency.

Dr. Michaels' analysis of the "analogy" factor is even further afield. Analogies can support a finding of causation when a very similar causal relationship to the one at issue has already been established. For instance, as Bradford Hill explained, if there is a great deal of evidence that some medication causes rubella, then "we would surely be ready to accept slighter but similar evidence with another drug or another viral disease." Hill, *The Environment and Disease*, 299. Dr. Michaels, by contrast, relies on examples involving lethal poisonings and house fires to establish that it may be appropriate to infer causation even where the causal mechanism is "incompletely characterized." (ECF No. 2456-3, PageID.78242.) These analogies certainly do not support the conclusion that the Flint River water caused skin rashes.

Dr. Michaels' analysis of the other Bradford Hill factors does not fare better. For instance, his analysis of the association's temporality meaning whether observed rashes started soon after exposure to corrosive water—consists exclusively of the statistic that "over 77% of respondents [to the Coordination Group] reported that they noticed changes . . . in the tap water at the time their symptoms began." (ECF No. 2456-3, PageID.78238.) That statistic includes everyone whose rashes started only *after* Flint's return to DWSD water, so it is not necessarily tied to corrosive water. Yet Dr. Michaels again failed to provide any substantive analysis or explanation for his conclusions. *In re Zoloft*, 858 F.3d at 796; *Tamraz*, 620 F.3d at 671.

B. Hair Loss

Dr. Michaels separately concluded that corrosive Flint water could cause hair loss. But that conclusion depends entirely on his opinion that corrosive water could cause skin rashes. As he explains in his report:

Corrosive water conditions evidently can cause skin rashes at multiple places on the body, presumably including the scalp. Also presumably, such rashes on the scalp would cause itching, as elsewhere, and could stimulate scratching, as elsewhere, constituting a potential cause of scalp irritation and of (at least temporary) hair loss . . .

(ECF No. 2456-3, PageID.78227). Because Dr. Michaels' conclusion that corrosive water causes skin rashes is inadmissible, so are his conclusions about hair loss.

None of this is to say, importantly, that Dr. Michaels' (and Plaintiffs') conclusions about Flint's water are incorrect, and this Opinion should not be read as a rejection of Plaintiffs' view that the Flint Water Crisis caused dermatological issues or hair loss. As the Court has emphasized previously, its "role here is not to evaluate experts' conclusions," so it may well be that the Flint Water Crisis caused skin rashes and hair loss. (ECF No. 2649, PageID.86532.) But in evaluating whether a particular expert's opinion is reliable under *Daubert*, "the task for the district court . . . is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation." In re Scrap Metal, 527 F.3d at 517. Here, Dr. Michaels repeatedly deviated from the Bradford Hill methodology without providing adequate explanation for his choice to do so. That means Plaintiffs have not shown

by a preponderance of the evidence that Dr. Michaels' testimony is reliable. *Daubert*, 509 U.S. at 589, 592.

IV. Conclusion

For the reasons set forth above, VNA's motion to exclude Dr. Michaels' opinions and testimony is GRANTED.

IT IS SO ORDERED.

Dated: January 2, 2024 Ann Arbor, Michigan <u>s/Judith E. Levy</u> JUDITH E. LEVY United States District Judge

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was served upon counsel of record and any unrepresented parties via the Court's ECF System to their respective email or first-class U.S. mail addresses disclosed on the Notice of Electronic Filing on January 2, 2024.

> <u>s/William Barkholz</u> WILLIAM BARKHOLZ Case Manager