IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: HAIR RELAXER MARKETING SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 3060
Case No. 23 C 818
Judge Mary M. Rowland

This document relates to:
23-cv-00818

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' MEDICAL MONITORING EXPERTS UNDER FEDERAL RULE OF EVIDENCE 702

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INTRODUCTION

Defendants' motion to exclude Drs. Amer Karam and Atul B. Shinagare is not a genuine methodological challenge; it is a merits argument dressed in the language of Rule 702. Dr. Karam is a board-certified, fellowship-trained gynecologic oncologist, a Clinical Professor at Stanford University, and Director of Robotic Surgery in Stanford's Division of Gynecologic Oncology, who cares for women at elevated risk of gynecologic cancer every day. Dkt. No. 1770-13 ("Karam Rep.") at 1. Dr. Shinagare is a board-certified diagnostic radiologist, Associate Professor of Radiology at Harvard Medical School, staff radiologist at Brigham and Women's Hospital, and Medical Director of Integrated Cancer Imaging for Mass General Brigham, with approximately 240 peer-reviewed articles focused on oncologic imaging. Dkt. No. 1770-14 ("Shinagare Rep.") at 1.

Asked to determine whether a structured medical-monitoring program is warranted for women who frequently used chemical hair relaxers, Dr. Karam examined the peer-reviewed epidemiology—which revealed a two- to two-and-a-half-fold increased risk of uterine and ovarian cancer among frequent users—grounded his protocol design in the accepted, decades-old DES exposure-based surveillance paradigm, and built a graduated, risk-stratified program using diagnostic tools the standard of care already endorses. Karam Rep. at 2, 4–19. Dr. Shinagare, in turn, evaluated the diagnostic performance and appropriate clinical use of established imaging modalities and described symptom-triggered clinical imaging pathways. Shinagare Rep. 2, 8, 18.

Defendants do not—and cannot—contend that either expert is unqualified or that the diagnostic modalities they recommend are unrecognized. Instead, they raise three arguments that collapse on inspection: (1) the experts' opinions rest on "insufficient data" because they depend on Plaintiffs' causation experts—but monitoring and imaging experts are *supposed* to rely on causation experts for causation, and Rule 703 expressly permits it; (2) the methods are unreliable

because no literature supports surveillance for hair-relaxer use alone—but the methodology is analogical reasoning from the accepted DES paradigm and the application of validated imaging-performance data; and (3) the opinions will not help the factfinder because clinical judgment is required—but that is true of every accepted monitoring program in medicine. Each argument is addressed in turn below.

The motion should be denied.

BACKGROUND

I. DR. KARAM'S QUALIFICATIONS AND ASSIGNMENT

Dr. Karam is board-certified in Obstetrics and Gynecology, in the subspecialty of Gynecologic Oncology, and in Hospice and Palliative Medicine. Karam Rep. at 1. He trained in obstetrics and gynecology at Johns Hopkins, completed a gynecologic-oncology fellowship at UCLA, and completed additional fellowship training at Memorial Sloan Kettering. *Id.* He is a Clinical Professor in Stanford's Division of Gynecologic Oncology and maintains an active clinical practice focused on gynecologic oncology, hereditary gynecologic cancers, and cancer surveillance in high-risk populations. Karam Rep. at 1–2. His assignment was to assess whether a structured medical-monitoring program for the exposed cohort is "reasonable, necessary, and appropriate" and to develop a reasonably tailored, actionable protocol for early detection of endometrial and ovarian cancers. Karam Rep. at 2.

II. DR. SHINAGARE'S QUALIFICATIONS AND ASSIGNMENT

Dr. Shinagare is a board-certified diagnostic radiologist who has interpreted or reviewed thousands of gynecologic imaging examinations, authored roughly 240 peer-reviewed articles on oncologic imaging, served on the ACR Appropriateness Criteria Panel on Women's Imaging, and chaired the Society of Abdominal Radiology's Uterine and Cervical Cancer panel. Shinagare Rep. 1–2. He offers a narrow, clearly bounded opinion: the diagnostic performance and appropriate

clinical use of established imaging modalities— in particular TVUS—and symptom-triggered clinical imaging pathways. Shinagare Rep. 2, 8, 18.

III. THE EPIDEMIOLOGY SUPPORTING AN AT-RISK COHORT

Dr. Karam's opinion rests on three large, peer-reviewed prospective cohort analyses. Chang (2022) followed 33,947 women over 10.9 years and found frequent use of straightening products (more than four applications per year) was associated with a hazard ratio of 2.55 for uterine cancer (95% CI 1.46–4.45; P*trend* = 0.002). Karam Rep. at 2, 9–10. Bertrand (2023) followed 44,798 Black women and found that among postmenopausal women, frequent relaxer use was associated with HR 2.52 (95% CI 1.39–4.55), with dose- and duration-related signals. Karam Rep. at 3, 10–11. White (2021) followed 40,559 women and found frequent straightener/relaxer use associated with HR 2.19 for ovarian cancer (95% CI 1.12–4.27; P*trend* = 0.03). Karam Rep. at 11–12.

IV. THE DES MONITORING PARADIGM AND DR. KARAM'S PROTOCOL

Dr. Karam drew on the DES model—a decades-old, accepted example of exposure-based gynecologic-cancer surveillance that he personally works with and on which he co-authored clinical guidance with Dr. Elizabeth Hatch, the principal researcher behind the foundational DES cohort. Karam (CV) at 17; Ex. 1, Karam Dep. 40:17–40:22. Applying that model, Dr. Karam proposed a protocol that (1) defines an objective exposed cohort—adult women with more than four applications of chemical hair relaxer within twelve months who have not been diagnosed with endometrial or ovarian cancer; (2) stratifies that cohort into moderate-, high-, and very-high-risk tiers based on established cancer risk factors; (3) prescribes baseline evaluation and a risk-adapted surveillance schedule using pelvic examination and TVUS; and (4) makes endometrial tissue sampling available through a symptom-triggered track and a fully informed, opt-in elective track. Karam Rep. at 14–19.

V. DR. SHINAGARE'S IMAGING FRAMEWORK

Dr. Shinagare describes a tiered and symptom-driven framework consistent with the medical monitoring protocol presented by Dr. Karam: Tier 1 is patient education and annual clinical evaluation, not routine imaging; and Tier 2 is first-line ultrasound "[i]n the presence of symptoms." For completeness, Dr. Shinagare further provides helpful information on advanced imaging beyond the scope of Dr. Karam's proposed surveillance: Tier 3 is escalation to MRI only "when there are abnormal or concerning ultrasound findings," with MRI "not proposed for routine screening in asymptomatic individuals"; and Tier 4 reserved for CT and PET for staging suspected metastatic or recurrent disease. Shinagare Rep. 19–21. His opinions are grounded in peer-reviewed diagnostic-performance literature and published professional-society guidelines (ACR, SAR, NCCN, ACOG). Shinagare Rep. 8, 23, 27.

LEGAL STANDARD

"Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) govern the admissibility of expert testimony." *Chartwell Studio, Inc. v. Team Impressions, Inc.*, 2023 WL 1992180, at *3 (N.D. Ill. 2023) (Rowland, J.). This Court has distilled the inquiry into three questions: "(1) whether the witness is qualified; (2) whether the expert's methodology is scientifically reliable; and (3) whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* The gatekeeping inquiry "must be 'tied to the facts' of a particular case," and the reliability factors are "flexible." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 780 (7th Cir. 2017) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)).

Reliability turns on methodology, not conclusions. "[R]eliability . . . is primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Pa.*, 732

F.3d 796, 806 (7th Cir. 2013). A court "usurps the role of the jury . . . if it unduly scrutinizes the quality of the expert's data and conclusions rather than the reliability of the methodology the expert employed." *Id.* "[T]he key to the gate is not the ultimate correctness of the expert's conclusions[,] . . . [but] the soundness and care with which the expert arrived at [his] opinion." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013). This Court has repeatedly held that challenges to an expert's perceived misinterpretation of evidence go to weight and do not warrant exclusion. *Chartwell Studio*, 2023 WL 1992180, at *5; *see Africano v. Atrium Med. Corp.*, 561 F. Supp. 3d 772, 778 (N.D. Ill. 2021) (Rowland, J.). Even "shaky" testimony "may be admissible, assailable by its opponents through cross-examination." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010).

Rule 702's 2023 amendment clarified that the preponderance standard applies to reliability-based requirements but did not alter the governing standard. Fed. R. Evid. 702, 2023 Advisory Comm. Notes. *Daubert* is not a vehicle to resolve a "battle of the experts"—"it is left to the trier of fact . . . to decide how to weigh the competing expert testimony." *Morisch v. United States*, 653 F.3d 522, 529 (7th Cir. 2011). Under Rule 703, an expert may reasonably rely on facts, data, and opinions of other experts in the field. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 588 (7th Cir. 2000); *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).

ARGUMENT

I. DEFENDANTS' MOTION IS A MERITS AND CLASS-CERTIFICATION ARGUMENT MASQUERADING AS A DAUBERT MOTION.

This Court has already told the parties how it will decide Rule 702 motions. At the March 5, 2026 Case Management Conference, the Court explained that it is "not allowed to rule on the conclusions," and that it will not "strike experts' opinions unless they're either not qualified or . . . their methodology isn't sound." Dkt. 1746 at 14–16. The Court cautioned that "a lot of lawyers

file *Daubert* motions basically making arguments that courts say over and over . . . this is for cross-examination." *Id.* Defendants' motion is exactly the kind the Court described.

Stripped to its parts, the motion is a merits and class-certification argument dressed in Rule 702 language. Defendants' contention that the underlying science does not establish increased risk is an attack on general causation—separately briefed, assigned to Plaintiffs' causation experts, and a "factual underpinning" reserved to the trier of fact. *Manpower*, 732 F.3d at 806. Their contention that the protocols depend on "individualized considerations" is a predominance argument belonging to the class-certification opposition; every accepted screening program requires individualized clinical application. And their contention that monitoring "would likely place such women at risk for harm" rests entirely on their own expert, Dr. Shulman, invoking the paradigmatic "battle of the experts" that *Daubert* commits to the jury. *Morisch*, 653 F.3d at 529. None of these disputes impugns the reliability of Drs. Karam's or Shinagare's methodology.

II. DR. KARAM SHOULD NOT BE EXCLUDED.

A. Dr. Karam's Opinions Rest on Sufficient Facts and Data.

1. Reliance on Plaintiffs' general-causation experts is proper and is not a Rule 702 defect.

Defendants' lead argument is that Dr. Karam's opinion is "based on insufficient facts and data" because it "relies completely on Plaintiffs' general causation experts' opinions." Defs' Mot. at 8–9. That is not a flaw; it is the correct division of expert labor. Dr. Karam is a gynecologic oncologist offering a monitoring opinion, not a causation expert. He testified that he relies on the causation experts "[f]or causation," based on "their expertise and . . . their reports." Ex. 1, Karam Dep. 154:25–155:4. Rule 703 authorizes precisely that reliance, and the Seventh Circuit has repeatedly upheld it. *See Walker*, 208 F.3d at 588–89; *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).

Defendants' real quarrel is with the causation experts, whose reliability Plaintiffs defend

in the separate causation briefing. If those opinions are admitted, Dr. Karam's foundation stands. However, Dr. Karam did not accept causation blindly: he independently reviewed the primary epidemiology, read the published response to the principal methodological critique, and considered the mechanistic literature on endocrine-disrupting constituents. Karam Rep. at 2–4, 9–12; Ex. 1, Karam Dep. 38:2–38:18, 159:18–161:1.

a) The exposure definition is drawn directly from the epidemiology, not invented.

Defendants attack the "more than four applications in a year" enrollment criterion as arbitrary. Defs' Mot. at 10–11. In fact, that threshold is the exact "frequent use" metric the underlying studies used, and for which they reported the strongest, statistically significant associations. Chang defined "frequent use" as more than four applications in the prior twelve months and found HR 2.55 (P*trend* = 0.002); White used the same ">4 times/year" definition and found HR 2.19 (P*trend* = 0.03). Karam Rep. at 9, 12. Anchoring a monitoring cohort to the very exposure category the epidemiology found significant is the opposite of methodological caprice.

b) The absence of average-risk screening guidelines does not undermine—it confirms—the need for exposure-based monitoring of an above-average-risk cohort.

Defendants make much of Dr. Karam's acknowledgment that no USPSTF or ACOG guideline recommends routine screening for "average-risk" women. Defs' Mot. at 1, 9. That point cuts the other way. Average-risk guidelines are designed for the general population; by the causation evidence, frequent relaxer users are an elevated-risk, exposure-defined cohort. The relevant clinical analogues are guidelines governing above-average-risk populations—DES-exposed women and carriers of Lynch and BRCA syndromes—for whom enhanced surveillance is recommended even absent randomized trials. Ex. 1, Karam Dep. 69:2–69:17, 75:6–75:20. Faulting a monitoring opinion for departing from average-risk guidance mistakes the entire premise of medical monitoring, which exists precisely because an exposure has moved a

population above baseline risk.

The authorities Defendants marshal do not help them. *Allgood v. Gen. Motors Corp.*, 2006 WL 2669337, at *31 (S.D. Ind. Sept. 18, 2006), excluded a monitoring expert who could not show alignment with generally accepted practices—but general acceptance is not a prerequisite under *Daubert*, and the building blocks of Dr. Karam's protocol are generally accepted standard of care. *Baker v. Chevron U.S.A. Inc.*, 533 F. App'x 509, 524–26 (6th Cir. 2013), involved an individualized specific-causation inquiry at the merits stage, not a class-wide monitoring-framework opinion.

2. Dr. Karam's Methodology Is Reliable.

a) Dr. Karam factors in dose-response; Defendants' cited authorities are inapposite.

Defendants lean heavily on *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), and *Mahler v. Vitamin Shoppe Industries, Inc.*, 2023 WL 6141369 (N.D. Ill. Sept. 20, 2023), contending that Dr. Karam ignored dose-response and thus opined that "exposure is exposure." Defs' Mot. at 10–11. Each of those cases excluded a *causation* expert—not a monitoring expert. Dose-response is a general-causation question assigned to Plaintiffs' causation experts, and Dr. Karam expressly deferred to them. Ex. 1, Karam Dep. 39:21–39:24, 154:24–155:4. A monitoring expert who reasonably relies on established general causation is not required to re-prove the dose-response curve.

Moreover, the epidemiology Dr. Karam relied upon does reflect an exposure-response relationship: Chang reported a statistically significant test for trend (P*trend* = 0.002), and Bertrand reported duration- and frequency-related gradients. Karam Rep. at 9, 11. Defendants' "exposure is exposure" soundbite also mischaracterizes the cohort definition. Dr. Karam defined the exposure by chemical mechanism—products that "use the pH to alter the keratin structure of the hair"—expressly excluding physical straighteners. Ex. 1, Karam Dep. 58:8–58:13. That the enrollment

gate applies regardless of brand mirrors the exposure classification used by Chang, White, and Bertrand—a matter for cross-examination, not exclusion.

b) Analogical reasoning from the DES paradigm is a recognized medical method.

The heart of Dr. Karam's method is analogical reasoning from the DES paradigm—an accepted, published model of exposure-based gynecologic-cancer monitoring that he personally works with and on which he co-authored clinical guidance with Dr. Elizabeth Hatch, the principal DES-cohort researcher. Karam (CV) at 17; Ex. 1, Karam Dep. 40:17–40:22, 99:2–99:24. As Dr. Karam explained, this is how monitoring science ordinarily develops: "research showing an increased risk"—"that's the DES"—"then it trickles down into the societies . . . and then national programs and public health programs." *Id.* at 147:21–148:4.

c) Defendants' attempt to distinguish DES fails on the record.

Defendants argue that DES is too different because it involved a single chemical, a known dose, a defined cohort, a rare cancer, and a very high relative risk. Dr. Karam's testimony refutes each: both DES and chemical hair relaxers involve exposure to endocrine-disrupting chemicals, *Id.* at 100:3–100:10; the DES dose was not precisely known ("a lot of the time it was yes-or-no exposure," *Id.* at 101:2–101:7); the DES cohort was itself not comprehensively identifiable, with many DES progeny who "never knew they were exposed," *Id.* at 103:10–103:21; and both data sources were prospective longitudinal registries. Karam Rep. at 3–4, 9–13.

As to relative risk, the DES 40.7 standardized incidence ratio reflects an extraordinarily rare cancer with a lifetime risk of only 0.1–0.2%. Hair-relaxer users, by contrast, face "absolute risks that are now north of 6 percent potentially over their lifetime," so the "burden of the disease is much, much higher." Ex. 1, Karam Dep. 112:24–113:5. Moreover, ACOG placed DES-exposed women in its "high-risk" category because of "a doubling in the risk of . . . high-grade cervical dysplasia—just a doubling of the risk." *Id.* at 172:19–172:23. A doubling is squarely within the 2-

to 2.5-fold range identified for hair relaxers.

d) That no society has yet adopted this precise protocol, and that no RCT has proven a mortality benefit, do not render the method unreliable.

Under *Daubert* and *Kumho*, general acceptance and formal testing are non-dispositive factors, not threshold requirements. Dr. Karam's protocol is founded upon universally accepted clinical modalities—ACOG guidance on evaluating abnormal uterine bleeding and pelvic pain, transvaginal ultrasonography, endometrial tissue sampling, and DES-style surveillance. Karam Rep. at 4–7. That no professional society has adopted this precise combination is unsurprising: professional associations like ACOG often do little more than provide a clinical comment or historical reference to existing surveillance protocols. Ex. 5, Shulman Dep. 118:17–118:20, 127:25–128:20. As for the absence of an RCT, clinicians already recommend surveillance for defined high-risk populations (e.g., Lynch syndrome) absent RCTs. Ex. 1, Karam Dep. 73:6–73:20. No RCT was required for the DES protocol or the Pap smear test; ACOG acknowledges that "[b]ecause of bioethical considerations, the efficacy of the Pap test has not been proved by prospective, randomized studies." Ex. 5, Shulman Dep. 114:11–115:1.

3. <u>Dr. Karam's Opinions Will Help the Trier of Fact.</u>

a) Individualized clinical application is inherent in every accepted monitoring program and is not a basis for exclusion.

Defendants' principal "helpfulness" argument is that Dr. Karam "concedes that there is no one-size-fits-all medical monitoring plan." Defs' Mot. at 11. But that is true of all of medicine—and of every recognized monitoring program. Dr. Karam testified: the need for individualized application "is true for every single monitoring program we have," including mammography. Ex. 1, Karam Dep. 51:7–51:12. Even the DES protocol "still required individualized physician care." *Id.* at 121:17–121:22. If clinical judgment disqualified a monitoring framework, no framework could ever be offered.

Moreover, Defendants' two attacks are mutually exclusive: in their reliability section they fault Dr. Karam for treating all exposed women alike—"exposure is exposure"—while in their helpfulness section they fault him for a protocol so individualized it cannot be uniformly applied. Both cannot be true. The reconciliation is straightforward: the enrollment gate is objective and uniform (frequent exposure to chemical hair relaxers, >4 applications/year), while surveillance intensity is calibrated to recognized cancer risk factors. *Id*. at 55:14–25; Karam Rep. at 14–15. The diagnostic decision points are binary: whether imaging is "reassuring and adequate or suspicious or inadequate." Ex. 1, Karam Dep. 81:5–81:14.

b) Dr. Karam was not required to examine individual plaintiffs to opine on a class-wide framework.

Defendants emphasize that Dr. Karam did not examine any individual plaintiff. Defs' Mot. at 11. But he was retained to opine on whether a structured monitoring framework is medically appropriate for the defined exposed cohort—not to diagnose individuals. To the extent Defendants invoke *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), that authority concerns experts offering specific-causation opinions in an individual-causation posture. *Id.* at 770. A class-wide framework opinion that presupposes causation established by other experts is wholly unlike an individual-causation opinion requiring chart review.

4. <u>The Framework Is Objectively Testable and Replicable.</u>

Defendants invoke *Timm v. Goodyear Dunlop Tires N. Am., Ltd.*, 932 F.3d 986 (7th Cir. 2019), and *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416 (7th Cir. 2005), for the proposition that Dr. Karam's approach "cannot be objectively replicated." Those were engineering and technical cases involving idiosyncratic methods. Dr. Karam's framework is the opposite: the enrollment gate is a single, mechanical criterion that "can be applied based on just exposure alone" and by itself yields a complete monitoring recommendation. Ex. 1, Karam Dep. 186:10–186:14. Where individual risk factors exist, they elevate the tier from a published, closed list. Karam Rep.

at 14–15. Any qualified gynecologist given the same information would place the patient in the same tier. Karam Rep. at 17.

5. The opt-in endometrial-sampling component is reasonable and directly answers Defendants' "harm" argument.

Defendants argue the proposed monitoring will "harm women" through false positives. Defs' Mot. at 2. That argument—sourced to a defense rebuttal expert—is a classic battle of experts that goes to weight. In any event, endometrial tissue sampling proceeds on two tracks: a symptom-triggered diagnostic track (already standard of care under ACOG guidance) and an elective, risk-stratified opt-in track with standardized consent, disclosure that no RCT has established a mortality benefit, and annual reaffirmation. Karam Rep. at 18–19. This opt-in architecture tracks the accepted DES paradigm. Whether Defendants' competing expert disagrees about net benefit is a quintessential jury question. *See Wipf v. Kowalski*, 519 F.3d 380, 385 (7th Cir. 2008) ("Especially in a case of dueling experts, . . . it is left to the trier of fact . . . to decide how to weigh the competing expert testimony.").

III. DR. SHINAGARE SHOULD NOT BE EXCLUDED.

A. Dr. Shinagare's Opinions Rest on Sufficient Facts and Data and Are the Product of Reliable Methods.

Defendants contend that Dr. Shinagare's opinions are "based on insufficient facts and data" because he "assumes" class members are at increased risk, relies on other experts, and does not know hair-relaxer chemistry. Defs' Mot. at 12. Each point confirms Dr. Shinagare stayed within his expertise; none supports exclusion. Rule 703 permits an expert to rely on facts or data "of a type reasonably relied upon by experts in the particular field." Dr. Shinagare relied on the causation experts to identify the elevated-risk population. Shinagare Rep. 3, 5; Ex. 6, Shinagare Dep. 49:5–13. An imaging expert's opinions about the diagnostic performance of TVUS do not depend on the chemical composition of hair relaxers. Under settled law, any lack of specialization "goes to

the weight to be placed on that opinion, not its admissibility." *Gayton*, 593 F.3d at 617; *Hall v. Flannery*, 840 F.3d 922, 929 (7th Cir. 2016).

As to reliability, Dr. Shinagare's methodology is the application of established, peer-reviewed imaging-performance data and professional-society standards to a defined population, the same analysis radiologists perform every day. Shinagare Rep. 27. His opinions "do not rely on novel or experimental imaging techniques, nor do they propose a new standard of care or a screening paradigm in normal risk population." *Id.* at 27, 30. Defendants' assertion that "nothing in any literature supports surveillance for hair relaxer use" is, again, a causation argument that does not undermine the validity of the imaging methodology. *See In re Soc. Media Adolescent Addiction/Pers. Injury Prods. Liab. Litig.*, 2026 WL 775421, at *3 (N.D. Cal. Mar. 17, 2026).

Defendants' "first-time expert" theory—that Dr. Shinagare had never before designed a monitoring plan—misdescribes his role. Dr. Karam designed the monitoring program; Dr. Shinagare's assignment was to evaluate imaging modalities and describe the evidence-based sequence in which they are used. Shinagare Rep. 2, 8–27. Courts have rejected this theory: it "warrants no discussion whatsoever" because "[b]y that logic, no witness could ever qualify as an expert for the first time." *Schramm v. Peregrine Transp. Co.*, 2024 WL 2134253, at *5 (S.D. Ill. May 13, 2024). His deferral to Dr. Karam on clinical-management questions reflects the boundary between radiology and clinical practice; his imaging opinions are independent. Shinagare Rep. 8, 18; Ex. 6, Shinagare Dep. 113:3–114:2.

B. Dr. Shinagare's Opinions Will Help the Trier of Fact.

How gynecologic imaging modalities work, when each is indicated, how they are sequenced, and their accuracy—these are not matters within the common knowledge of a lay jury. Shinagare Rep. 8, 18. Even Defendants' own expert describes this as Dr. Shinagare's proper role: he would "provid[e] important information to those clinicians who are determining the appropriate

surveillance, detection and management." Dkt. No. 1904-1 ("Shulman Rep.") at 22. Testimony that even the opposing expert concedes is useful to clinicians is, *a fortiori*, helpful to the trier of fact.

Defendants' invocation of *Timm* is misplaced. Dr. Shinagare's framework is not an ad hoc, unstated intuition; it is a defined, published sequence grounded in professional-society standards. His first-line modality, TVUS, is "probably one of [the] most standardized modalities in radiology." Ex. 6, Shinagare Dep. 108:10–25. The imaging protocols are "standardized, validated protocols supported by professional organizations including ACR, RSNA, SAR, and ESUR." Shinagare Rep. 4, 23. A framework whose decision rules are published, protocol-driven, and binding on the radiologists who apply them is the opposite of the unstated, unreplicable methodology at issue in *Timm*.

As with Dr. Karam, Defendants' two theories about Dr. Shinagare are mutually exclusive and cannot both be true: an expert cannot be excluded for supporting Dr. Karam's class-wide framework to individual patients *and* simultaneously excluded because the framework leaves tailoring to clinicians. The two theories describe the same feature of the testimony and Defendants have labeled it a defect twice, in opposite directions.

IV. DEFENDANTS' REMAINING OBJECTIONS GO TO WEIGHT, NOT ADMISSIBILITY.

Several of Defendants' remaining points are quarrels with the underlying epidemiology that are classic weight arguments. Defendants note that Bertrand found no statistically significant overall association "with the exception of postmenopausal women." Defs' Mot. at 4. But the postmenopausal subgroup is clinically relevant—endometrial cancer is overwhelmingly a postmenopausal disease—and the finding was significant (HR 2.52, 95% CI 1.39–4.55). Karam Rep. at 10–11. Whether that subgroup finding, together with significant results in Chang and

White, supports monitoring is a merits question for the factfinder.

That the studies examined "straighteners/relaxers" as a class rather than isolating a single ingredient, and that their authors called for further research, are ordinary features of observational epidemiology. Where a party contests an expert's "conclusions about what the overall body of literature indicates, that is a matter for cross-examination, not exclusion." *In re Soc. Media Adolescent Addiction*, 2026 WL 775421, at *3. Defendants' reliance on the SGO/OCRA Joint Statement is misplaced—the statement addresses routine screening in the general population, not targeted surveillance of an exposure-defined cohort, a distinction Dr. Shulman himself conceded. Ex. 5, Shulman Dep. 147:3–147:6.

The Seventh Circuit is emphatic that "the soundness of the factual underpinnings" and "the correctness of the expert's conclusions" are "factual matters to be determined by the trier of fact." *Manpower*, 732 F.3d at 806–08. Defendants are free to present their competing expert and test Drs. Karam and Shinagare on cross; they are not entitled to have the Court weigh that dispute on a Rule 702 motion.

CONCLUSION

Dr. Karam is a highly qualified gynecologic oncologist who applied a recognized method—reasoning from the accepted DES surveillance paradigm—to reliable peer-reviewed epidemiology, and produced a transparent, risk-stratified, patient-centered monitoring framework grounded in the standard of care. Dr. Shinagare is a preeminent radiologist offering a narrow, well-supported opinion about the diagnostic performance of established imaging modalities within a symptom-triggered, tiered framework grounded in peer-reviewed science and professional-society standards. Defendants' objections to both experts are merits disputes for cross-examination and the trier of fact. For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' motion to exclude the opinions of Drs. Amer Karam and Atul B. Shinagare.

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