UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Larry Patterson and Tammy Patterson v. Covidien, Inc., et al.

Patterson · No. 22-cv-10153-PBS; MDL No. 22-md-03029-PBS · Decided April 28, 2026

OPINION

Patterson

PER CURIAM.

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

_____)

IN RE: COVIDIEN HERNIA MESH)

PRODUCTS LIABILITY LITIGATION) MDL

NO. II) No. 22-md-03029-PBS _____))

LARRY PATTERSON and TAMMY)

PATTERSON,)

) Plaintiffs,)) Civil Action v.) No. 22-cv-10153-PBS) COVIDIEN, INC., et al.,)) Defendants.))

MEMORANDUM AND ORDER

April 28, 2026 Saris, J.

INTRODUCTION

This multidistrict litigation involves hernia mesh products manufactured by Defendants Covidien LP and Sofradim Production SAS (together, "Covidien"). In the first bellwether case, Plaintiff Larry Patterson ("Plaintiff") alleges that he was implanted with a Symbotex Composite Mesh ("Symbotex") during a 2017 hernia repair operation and that the Symbotex adhered to his bowel and eventually caused a bowel obstruction and hernia recurrence necessitating another operation in 2020. Plaintiff brings products liability claims against Covidien under Alabama law, including claims under the Alabama Extended Manufacturer's Liability Doctrine and for negligence, breach of warranty, and negligent and fraudulent concealment and misrepresentation. The parties have filed motions to exclude the testimony of eleven expert witnesses under Federal Rule of Evidence 702. This opinion addresses Covidien's motion to exclude the testimony of Dr. Laura Plunkett, a pharmacology, toxicology, and U.S. Food and Drug Administration ("FDA") regulatory expert offered by Plaintiff to opine on the relevant FDA regulatory scheme and the adequacy of Covidien's warnings, marketing, and complaint handling for Symbotex. The Court assumes familiarity with its opinion resolving Covidien's motion to exclude the testimony of Dr. Stephen Ferzoco and incorporates the background and legal standards from that opinion here. See In re

Covidien Hernia Mesh Prods. Liab. Litig. No. II, __ F. Supp. 3d __, __ (D. Mass. 2026) [2026 WL 1129617, at
*1-4].

After hearing, the Court ALLOWS IN PART and DENIES IN PART Covidien's motion to exclude the testimony of Dr. Plunkett (Dkt. 43).

DISCUSSION

The Court begins by summarizing Dr. Plunkett's qualifications and opinions. The Court then turns to the specific challenges Covidien raises to the admissibility of Dr. Plunkett's testimony. I. Dr. Plunkett's Qualifications and Opinions Dr. Laura Plunkett is a pharmacologist, toxicologist, and FDA regulatory specialist. She has a Ph.D. in pharmacology and is board-certified in toxicology. During her more than thirty years as a consultant, she has advised various drug and medical device manufacturers on FDA regulatory issues, labeling requirements, and the design of preclinical and clinical studies. She has worked with medical device manufacturers to analyze safety data for their products, prepare § 510(k) submissions for Class II medical devices, and conduct postmarket surveillance for safety concerns. Although Covidien criticizes Dr. Plunkett's lack of experience working for the FDA, Covidien does not contest her qualifications. The Court finds that Dr. Plunkett is qualified to opine as a toxicologist on Covidien's animal studies on the porcine collagen barrier and as an FDA regulatory expert to opine on the relevant regulatory scheme and the adequacy of Covidien's labeling, marketing, and postmarket surveillance. In forming her opinions, Dr. Plunkett reviewed scientific literature on the safety and efficacy of surgical mesh devices, FDA regulations and guidance, labeling and other marketing materials for Symbotex, deposition testimony from Covidien employees and representatives, and documents produced during the litigation. She states that she used the weight-of-the-evidence methodology to analyze this information and reach her conclusions. Dr. Plunkett's report first provides background on the FDA's regulation of medical devices, the § 510(k) process, medical device labeling requirements, and postmarket surveillance reporting of adverse events. She expresses general criticisms of the § 510(k) process and the FDA's postmarket surveillance programs. She describes Symbotex's physical attributes and intended uses. She then summarizes FDA guidance and best practices on safety testing for a § 510(k) submission. She notes that the FDA requires testing showing a medical device's biocompatibility, i.e., an ability to perform its functions without a toxic or injurious effect. She provides general information on tissue responses to implanted medical devices, emphasizing that the body may react to a device's implantation with a foreign body response and chronic inflammation and that one goal in designing a device is to avoid such a reaction while allowing for tissue repair. Dr. Plunkett then turns to the testing Covidien performed for Symbotex and other of its hernia meshes. She explains that Covidien's § 501(k) submission for Symbotex included data on biocompatibility and toxicity testing on the mesh's materials and on the composite mesh itself, including animal studies with up to a thirteen-week follow-up period. She opines that this submission "failed to address long-term tissue reactions with implantation of

the Symbotex device." Dkt. 54-30 ¶ 74. She also expresses concern that certain of Covidien's in vivo studies involved use of anti- inflammatory drugs that may have masked any chronic inflammation from the device. Dr. Plunkett next canvasses Covidien's preclinical studies testing the resorption period of the collagen barrier on its hernia meshes. Her report includes a table listing twenty-four such studies and their follow-up period and findings. Citing Study #12778 and another study from 2003, she concludes that Covidien's "own animal study data had shown in 2003 that degradation or breakdown and disappearance of porcine collagen was complete or almost complete at the end of 1-week post-implantation in the abdominal area, while bovine collagen degradation was not as extensive at the 1-week time point." Id. ¶ 82. She continues: Importantly, after these 2003 studies were performed, most of the studies performed that monitored for collagen degradation focused on monitoring for degradation of porcine collagen at 4 weeks post- implantation, not at the shorter time point of one week. Regardless of the time point studied in rat and pig in vivo models, collagen degradation began in the first week post-implantation, and in Study [#]12778 was shown to be completely gone. Thus, as early as February of 2003, [Covidien] w[as] aware that porcine collagen almost completely degraded in vivo within 1 week in rats, and at a rate faster than bovine collagen (Study [#]12778). Id. (emphases omitted). She notes that Covidien submitted only a summary version of Study #12778 to the FDA in its § 510(k) submission seeking clearance for the new porcine barrier and that Covidien has never produced the full report. She adds that while a later study of the porcine barrier found less degradation of the barrier at one week than Study #12778, the later study involved a different implantation method. Dr. Plunkett cites an internal Covidien document discussing the reasons for using a four-week time period for preclinical studies on the collagen barrier, which includes as one reason "the time to formation of tissue attachments, reaching a plateau after two to three weeks." Id. ¶ 84 (emphasis omitted). Based on this document, Dr. Plunkett opines that Covidien was "aware that tissue attachments (adhesions) do not begin to plateau until two to three weeks after the mesh is implanted" even though "the degradation of the collagen film they used in their composite mesh devices (porcine collagen) actually was degrading at least to some appreciable extent within 1-2 weeks, if not sooner." Id. Dr. Plunkett then turns to Covidien's compliance with FDA regulations in connection with its labeling, marketing, and complaint handling for Symbotex. She explains that clearance of a medical device via the § 510(k) process does not entail an independent finding by the FDA that the device is safe and effective and that the manufacturer bears the responsibility to ensure the device's safety and efficacy. She notes that the regulatory scheme relies on manufacturers having effective methods of monitoring the postmarket safety and performance of their devices. With respect to Symbotex's Instructions for Use ("IFU"), Dr. Plunkett opines that Covidien "failed to provide physicians with clear, unambiguous, accurate and timely safety information" about Symbotex and, thus, that "physicians were not fully informed about the risks posed to their patients associated with use of" Symbotex. Id. ¶ 95. She points to the absence of a section entitled "Adverse Reactions," which "typically provides a listing of patient

injuries that can result from use of a medical device." Id. ¶ 98. She adds that Covidien's "[f]ailure to include discussion or description of the real-world experience about [its] polyester composite devices in the IFU[] . . . was a patient safety concern." Id. ¶ 99. Relatedly, she notes that while the IFU has a section called "Possible Complications," it does not "actually state what types of complications had been reported to [Covidien] over time," including adhesions and the rapid degradation of the barrier. Id. ¶ 105. Finally, she explains that "the information in the IFU was at best misleading as it relates to the likelihood that the collagen barrier would protect organs and tissues from adhesion formation" because Covidien was aware adhesions were forming during the month post-implantation. Id. Dr. Plunkett further opines that Covidien's marketing materials for Symbotex "failed to provide physicians with complete and accurate information" on certain topics. Id. ¶ 110. For example, Covidien "marketed the product as being able to minimize tissue attachment and to be used to prevent visceral adhesion formation" despite the company's awareness of the resorption period of the barrier and the risk of attachment and adhesions. Id. Symbotex's Value Analysis Committee Product Information Kit ("vac pac"), Dr. Plunkett continues, cites four clinical studies to support the product's safety and efficacy that all examined non-Symbotex meshes, most of which had the older bovine collagen barrier. Covidien's marketing materials also promoted Symbotex as minimizing tissue attachment and preventing adhesions even though the animal studies cited in support showed significant adhesion formation and the FDA prohibited Covidien from making such advertising claims. Lastly, Dr. Plunkett opines that Covidien "failed to adequately and timely investigate complaints" about Symbotex's performance as required by FDA regulations "and take actions such that surgeons could be informed about real-world experience with the devices." Id. ¶ 116. She does not, however, offer any explanation for this opinion that is specific to Symbotex. II. Analysis Covidien advances four sets of challenges to the reliability and relevance of Dr. Plunkett's testimony: (1) she does not reliably apply a weight-of-the-evidence methodology; (2) her opinions would not be helpful to the jury; (3) she improperly opines on Covidien's state of mind; and (4) she impermissibly offers legal conclusions. The Court addresses these issues seriatim. A. Weight-of-the-Evidence Methodology Covidien first argues that Dr. Plunkett's opinions are not based on a reliable application of the weight-of-the-evidence methodology. Covidien contends that Dr. Plunkett neither describes any steps she took in reaching her conclusions nor offers any scientifically reasonable explanation for how she assigned weight to the documents and information she considered. The weight-of-the-evidence approach "involves a mode of logical reasoning often described as 'inference to the best explanation,' in which the conclusion is not guaranteed by the premises." Milward v. Acuity Specialty Prods. Grp., 639 F.3d 11, 17 (1st Cir. 2011) (quoting Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1124 n.5 (10th Cir. 2004)). "The fact that the role of judgment in th[is] . . . approach is more readily apparent than it is in other methodologies does not mean that the approach is any less scientific." Id. at 18. The admissibility of an expert opinion based on the weight-of-the-evidence approach "turn[s] on the particular facts of the case." Id. at 19. A court must ask if the expert, "in

reaching h[er] opinion, applied the methodology with 'the same level of intellectual rigor' that [s]he uses in h[er] scientific practice." Id. (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999)). Covidien's methodological challenge focuses primarily on Dr. Plunkett's assessment of twenty-four Covidien preclinical studies testing the resorption period of the porcine collagen barrier. In Covidien's view, Dr. Plunkett gave undue weight to one preclinical study showing resorption of the barrier within seven days (Study #12778) and ignored other contrary preclinical studies without providing a methodologically sound basis for doing so. The Court disagrees. Based on her review of the preclinical studies and application of her expertise as a toxicologist, Dr. Plunkett opines that Covidien's "own animal study data had shown in 2003 that degradation or breakdown and disappearance of porcine collagen was complete or almost complete at the end of 1-week post- implantation" and that "collagen degradation began in the first week post-implantation, and in Study [#]12778 was shown to be completely gone." Dkt. 54-30 ¶ 82. This opinion reflects a straightforward assessment of the preclinical data laid out in Dr. Plunkett's summary table, which Covidien does not assert are inaccurate. All of the studies she cites that examined the porcine barrier at one week post-implantation found some degradation at that point. Covidien's criticisms of Dr. Plunkett's analysis are unpersuasive. Covidien complains that she omits certain relevant information from her analysis, including two preclinical studies on the porcine barrier specifically and all clinical studies on meshes with the porcine barrier. Covidien does not, however, argue that the two omitted preclinical studies change the overall picture painted by the twenty-four Dr. Plunkett examined. Nor are the clinical studies directly pertinent to Dr. Plunkett's assessment of the resorption period of the barrier, which for ethical reasons can only be directly studied in animal models. Covidien may challenge Dr. Plunkett's testimony based on the two omitted preclinical studies and, to the extent she opines more categorically that the barrier "only last[s] for 7 days" or is "mostly gone by 7 days," id. ¶¶ 105, 112, Covidien may cross-examine her with preclinical data showing only slight or moderate resorption at that stage. B. Helpfulness to the Jury Covidien next argues that Dr. Plunkett's opinions would not "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Covidien contends that Dr. Plunkett provides a meandering description of the regulatory background that is untethered to the facts of this case. Covidien also asserts that Dr. Plunkett does not tie her conclusions to Plaintiff's case by failing to opine on any causal relationship between Plaintiff's injuries and the deficiencies she identifies in Covidien's labeling, marketing, and complaint handling. In fact, Covidien continues, Dr. Newman's deposition testimony makes clear that his decision to use Symbotex for Plaintiff's hernia repair had nothing to do with Covidien's labeling, marketing, and complaint handling, as Dr. Newman testified that he could not recall ever reading Symbotex's IFU or marketing materials related to Symbotex, that he was aware of the risks of Symbotex's use for a hernia repair, and that he discussed those risk with Plaintiff. The Court rejects Covidien's effort to bar Dr. Plunkett's regulatory background testimony. Dr. Plunkett may provide background on the applicable regulatory schemes, which are relevant to the jury's

assessment of Symbotex's safety and the adequacy of Covidien's warnings about Symbotex's risks. Contrary to Covidien's argument, an expert may offer this type of regulatory background testimony without running afoul of the principle that experts may not opine on the law. See United States v. Galatis, 849 F.3d 455, 462 (1st Cir. 2017); Tang Cap. Partners, LP v. BRC Inc., 757 F. Supp. 3d 363, 391 (S.D.N.Y. 2024); see also Nieves- Villanueva v. Soto-Rivera, 133 F.3d 92, 101 (1st Cir. 1997) (allowing for expert testimony on legal issues in "highly complex and technical matters"). As Plaintiff concedes, however, Dr. Plunkett may not offer opinions criticizing the FDA, its regulations, or the § 510(k) process. Dr. Plunkett also may opine on the adequacy of Covidien's preclinical testing, labeling, and marketing of Symbotex. Her opinions that Covidien did not perform adequate testing before seeking § 510(k) approval for Symbotex, provided misleading information about Symbotex's collagen barrier and ability to prevent adhesions, and failed to sufficiently warn about the efficacy of the barrier and resulting risks are plainly relevant to the jury's assessment of Symbotex's safety and Plaintiff's failure to warn claim. And as the Court explained in its opinion on Covidien's motion to exclude the testimony of Dr. Ferzoco, Dr. Plunkett "need not point to evidence of, or opine on, causation for h[er] testimony on the adequacy of the warnings to be admissible under Rule 702." In re Covidien, __ F. Supp. 3d at __ [2026 WL 1129617, at *14]. The Court will address whether Plaintiff has put forth sufficient evidence to demonstrate causation for his failure to warn claim when resolving Covidien's motion for summary judgment.1 Moreover, Covidien's argument that Dr. Plunkett's testimony is "little more than a narrative summary of [Covidien's] internal documents" that "draws on little, if any, of h[er] regulatory expertise" is unpersuasive. In re Zofran (Ondansetron) Prods. Liab. Litig., No. 15-md-2657-FDS, 2019 WL 5685269, at *9 (D. Mass. 1 In seeking exclusion of Dr. Plunkett's testimony, Covidien relies heavily on Hunt v. Covidien LP, in which another session of this court excluded her opinions based on their "lack of any mooring in the facts of th[e] case." No. 22-cv-10697, 2024 WL 2724144, at *7 (D. Mass. May 28, 2024). This Court agrees with Hunt that Dr. Plunkett's critiques of various FDA processes and programs are "not of any help to the jury." Id. at *7. But unlike in Hunt, her opinions on Covidien's testing of the porcine collagen barrier and its labelling and marketing of Symbotex directly relate to Symbotex and the injuries Plaintiff suffered. Nov. 1, 2019). Rather, Dr. Plunkett uses her toxicological expertise to analyze Covidien's preclinical studies on the porcine collagen barrier and then applies her knowledge of the regulatory scheme to form opinions on the adequacy of Covidien's preclinical testing, labelling, and marketing. The Court will, however, preclude Dr. Plunkett from opining on the adequacy of Covidien's postmarket surveillance and complaint handling. In support of this opinion, Dr. Plunkett relies on (1) an extensive discussion of the regulatory scheme for reporting adverse events to the FDA and the general problems of underreporting and inadequate monitoring of adverse events;

(2) evidence of complaints of mesh degradation, testicular pain,

and mesh tearing with a different hernia mesh product; and (3) a 2019 report Covidien prepared

on complaints about an unspecific product. She does not cite any evidence regarding postmarket surveillance or complaints about Symbotex or issues relating to collagen barrier such as adhesions. Plaintiff emphasizes that Dr. Plunkett testified at her deposition about a 2012 FDA inspection report raising concerns about complaint handling at a Covidien facility in North Haven, Connecticut, but she did not provide any specifics about this report, which predated Symbotex's § 510(k) clearance in 2013. Without any evidence on this issue related to Symbotex or the collagen barrier specifically, Dr. Plunkett lacks "sufficient facts or data" to opine on the adequacy of Covidien's postmarket surveillance and complaint handling for Symbotex, and any testimony about Covidien's deficiencies in this domain with respect to other products would not "help the trier of fact to understand the evidence or to determine a fact in issue" in this case. Fed. R. Evid. 702(a)-(b). C. State-of-Mind Testimony Covidien next argues that Dr. Plunkett should be precluded from opining on the company's knowledge or awareness of various information based on scientific data or physician reports in its possession. For example, Dr. Plunkett opines that "as early as February of 2003, [Covidien] w[as] aware that porcine collagen almost completely degraded in vivo within 1 week in rats, and at a rate faster than bovine collagen," based on its preclinical studies. Dkt. 54-30 ¶ 82. She similarly opines that Covidien "knew that adhesions were forming over an initial period of a month." Id. ¶ 105. It is well established that a "party's intent or state of mind is not the proper subject of expert testimony." Doe ex rel. Pike v. Pike, 405 F. Supp. 3d 243, 250 (D. Mass. 2019) (quoting OneBeacon Am. Ins. Co. v. Com. Union Assurance Co. of Can., 804 F. Supp. 2d 77, 85 (D. Mass. 2011)); see Williams v. Poulos, 11 F.3d 271, 282 n.20 (1st Cir. 1993). Nonetheless, "an expert may indicate what information was in [a] [d]efendant['s] possession, which oftentimes is referred to synonymously as knowledge." In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig., No. 18-md-2846, 2021 WL 3617152, at *7 (S.D. Ohio Aug. 16, 2021); see In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 479 (S.D.N.Y. 2016) (permitting expert testimony "on what documents in [the defendant]'s possession said -- in other words, on what [the defendant] 'knew' in the sense of what information was in its possession"). To police the boundary between proper and improper testimony in this area, Dr. Plunkett "should refrain from using words like 'knew' or 'aware' and should use . . . language[] such as possessing information or acknowledging information." In re Davol, 2021 WL 3617152, at *7. D. Legal Conclusions Finally, Covidien seeks to bar Dr. Plunkett from testifying to legal conclusions. "[E]xpert testimony on . . . purely legal issues is rarely admissible," as "[e]xpert testimony that consists of legal conclusions cannot properly assist the trier of fact." Nieves-Villanueva, 133 F.3d at 99-100 (quoting Burkhart v. Wash. Metro. Area Transit Auth., 112 F.3d 1207, 1212 (D.C. Cir. 1997)); see In re Zofran (Ondansetron) Prods. Liab. Litig., 57 F.4th 327, 340 (1st Cir. 2023); Birkenstock US BidCo, Inc. v. White Mountain Int'l LLC, 806 F. Supp. 3d 156, 162 (D. Mass. 2025). Dr. Plunkett may describe the relevant regulatory requirements and explain any deficiencies she identifies in Covidien's preclinical data, labelling, and marketing for Symbotex. She may not, however, testify that Covidien violated any regulatory requirements in

connection with its § 510(k) submission for Symbotex or its labelling and marketing of the product.

ORDER

For the foregoing reasons, Covidien's motion to exclude the testimony of Dr. Plunkett (Dkt. 43) is ALLOWED with respect to her opinions about the adequacy of Covidien's postmarket surveillance and complaint handling and otherwise DENIED. SO ORDERED.

/s/ PATTI B. SARIS_____

Hon. Patti B. Saris United States District Judge