IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

ANGELA LAUDERDALE,
Individually and as
Representative of the Estate
of Addison Cook, Deceased **PLAINTIFF**

V. **CASE NO. 5:21-CV-5200**

ORGANON USA, INC.;
MERCK & CO. INC.; and
MERCK SHARP & DOHME CORP. **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

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I. INTRODUCTION

This is a personal injury suit. Plaintiff Angela Lauderdale sues Defendants Organon USA, Inc., Merck & Co. Inc, and Merck Sharp & Dohme Corp. (collectively, "Defendants") in her personal capacity and as representative of the Estate of Addison Cook. *See* Doc. 2.

Ms. Lauderdale's daughter, Addison Cook, died at the age of 19 from a venous thromboembolism ("VTE") allegedly caused by Nexplanon, a prescription contraceptive manufactured by Defendants. Ms. Lauderdale contends Defendants failed to properly label Nexplanon, leaving doctors in the dark about the risks associated with the drug.

Defendants' Motion to Dismiss (Doc. 25) is now before the Court. Defendants argue Ms. Lauderdale's claims fail as a matter of law. They contend federal law preempts Ms. Lauderdale's "failure-to-warn" claims, and she fails to state sufficient facts to plausibly allege strict liability, fraud, negligence, or gross negligence under Arkansas law.

After considering the parties' briefing and for the below reasons, Defendants' Motion is **DENIED** in part and **GRANTED** in part.[1]

[1] In addition to Ms. Lauderdale's Complaint (Doc. 2) and Defendants' Motion to Dismiss (Doc. 25), the Court considered Ms. Lauderdale's Response in Opposition (Doc. 29), and Defendants' Reply (Doc. 33).

The Court also reviewed Defendants' Request for Notice (Doc. 26), Ms. Lauderdale's Conditional Motion for Leave (Doc. 34), and Defendants' Response in Opposition (Doc. 35). Both parties request the Court take notice of certain documents not attached to the Complaint but dispute which the Court may properly consider on a Rule 12(b)(6) motion. The Court considered those documents necessarily embraced by the Complaint. Those materials that constitute extrinsic evidence were not considered.

II. BACKGROUND

In February 2019, 18-year-old Addison Cook attended a medical appointment at Parkhill Clinic for Women in Fayetteville, Arkansas. She expressed an interest in obtaining contraception and asked about Nexplanon, an implant manufactured by Defendants and approved by the Food & Drug Administration ("FDA") to prevent pregnancy. In a follow-up visit a month later, Dr. Jason Hurt prescribed Nexplanon and implanted the small, flexible rod in Ms. Cook's arm the same day. *See* Doc. 2, pp. 6–7.

On December 6, 2019, Ms. Cook arrived at Washington Regional Medical Center's emergency room complaining of chest pain and shortness of breath. She was tachycardic and hypoxic. Lab results indicated a blood clot, and a CT scan showed a bilateral multiple pulmonary emboli with right lower lobe infarct and right ventricular strain. Doctors diagnosed Ms. Cook with a pulmonary embolism and infarction, acute cor pulmonale, and acute hypoxemic respiratory failure and admitted her for further treatment. She seemingly recovered and was discharged on December 10. *Id.* at p. 7.

Ms. Cook returned to Washington Regional on December 13—this time by ambulance. She was admitted to the ICU, where she died four days later from a fatal VTE. *Id* at pp. 7–8.[2]

Ms. Lauderdale believes Nexplanon caused her daughter's death. Ms. Cook was a young African-American woman with a history of severe morbid obesity. According to the Complaint, Nexplanon has a synergistic effect on those individuals with other risk factors for VTE, and both obese women and African-American women experience VTE and other related cardiovascular events at higher rates. *See id.* at pp. 13–14.

[2] "VTE" is an umbrella term that includes deep vein thrombosis ("DVT") and pulmonary embolism ("PE") events.

Ms. Lauderdale claims the Nexplanon label should have deployed stronger warnings about the risk of VTE—particularly with respect to obese and African-American women—and provided incidence data to allow prescribing physicians to place the increased risk of VTE in context when assessing Nexplanon's risk-benefit profile against safer contraceptive drugs. *See id.* at p. 4. If Defendants properly labeled Nexplanon, Ms. Lauderdale contends, Dr. Hurt would not have prescribed it to Ms. Cook. *See id.* at p. 29.

A. Nexplanon

Nexplanon is a small, flexible rod placed beneath the skin of a woman's inner-upper arm. *See* Doc. 27, p. 11. It is the newer, patent-protected version of Implanon. Because it is patent-protected, Nexplanon is considered a "brand-name" pharmaceutical product. (Doc. 2, p. 4). The FDA approved Implanon in 2006 and Nexplanon in 2011. *See id.* at pp. 11–12.

Implanon and Nexplanon are almost identical; they contain the same hormone, in the same quantity. *See id.* at pp. 4–5.[3] Both drugs are progestin-only products ("POPs") that release etonogestrel, a "progestin" or synthetic form of the female hormone progesterone.[4]

Etonogestrel is a biologically active metabolite of desogestrel, a progestin developed by Organon. *See* Doc. 2, p. 15. In 1992, Organon received FDA approval for

[3] Nexplanon, however, contains an additional ingredient to make the implant "radiopaque," or visible on an x-ray. *See* Doc. 27, p. 13. Neither party suggests Nexplanon's radiopaque nature impacts the drug's safety or how it functions when implanted in a woman's arm.

[4] POPs differ from combination hormonal contraceptives ("CHCs"), which contain both estrogen and progestin.

its first desogestrel-based contraceptive, Desogen. Organon has since introduced several other desogestrel-based products, including Mircette, NuvaRing, and, eventually, Implanon and Nexplanon. *Id.*

The Nexplanon label acknowledges the drug may increase the risk of VTE. The Prescribing Information cautions physicians that women with a "current or past history of thrombosis or thromboembolic disorders" should not use Nexplanon. *See* Doc. 26-5, p. 7. The "Warnings and Precautions" section also provides a more fulsome warning for doctors:

> **WARNINGS AND PRECAUTIONS**
>
> **The following information is based on experience with the etonogestrel implants (IMPLANON and/or NEXPLANON), other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives.**
>
> . . .
>
> **5.4 Thrombotic and Other Vascular Events**
>
> The use of combination hormonal contraceptives (progestin plus estrogen) increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism). NEXPLANON is a progestin-only contraceptive. It is unknown whether this increased risk is applicable to etonogestrel alone. It is recommended, however, that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed.
>
> There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using the non-radiopaque etonogestrel implant. NEXPLANON should be removed in the event of a thrombosis.
>
> Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions.

> Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

(Doc. 26-10, pp. 10–11 (emphasis in original)).

The Nexplanon Patient Information likewise discusses a risk of VTE associated with Nexplanon:

> **WARNINGS AND PRECAUTIONS**
>
> **The following information is based on experience with the etonogestrel implants (IMPLANON and/or NEXPLANON), other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives.**
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> Evaluate for retinal vein thrombosis immediately if there is unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions.
>
> Consider removal of the NEXPLANON implant in case of long-term immobilization due to surgery or illness.

(Doc. 26-10, pp. 10–11 (emphasis in original)).

The above reproduction derives from the first Nexplanon label, approved in 2011. According to Defendants, the FDA again approved the label in 2015 (Doc. 26-10) and in 2018 (Docs. 26-1 & 26-2). A review of the labels suggests neither the 2015 nor 2018 revision substantively changed the VTE-related warnings.[5] In addition, all three iterations of the Nexplanon label largely resemble the label used for Implanon, Nexplanon's nearly identical predecessor drug.

B. Regulatory Regime

The Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, empowers the FDA to regulate pharmaceutical products in the United States. The FDCA requires drug manufacturers to obtain FDA approval before marketing or distributing a new drug in interstate commerce. 21 U.S.C. § 355(a). Drug manufacturers may do so by submitting a new-drug application ("NDA"), or, in some circumstances, a supplemental new-drug application ("sNDA"). The same requirements govern both the NDA and the sNDA. *See* 21 C.F.R. § 314.1 *et seq*.

The NDA or sNDA must include "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A)(i). The FDA will not approve the application absent "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." *Id.* § 355(d)(5). ‼

[5] With one exception, the 2011, 2015, and 2018 include the same language regarding the risk of VTE. The 2011 Prescribing Information states: "There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and strokes, in women using the ***non-radiopaque*** etonogestrel implant." (emphasis added). The 2015 and 2018 versions exclude the term "non-radiopaque."

Showing "substantial evidence" requires the drug manufacturer to "submit[] the results of 'adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.'" *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 36 (1st Cir. 2015) (quoting 21 U.S.C. § 355(d)(7)). This includes:

> (ii) A description and analysis of each controlled clinical study pertinent to a proposed use of the drug[.]
>
> (iv) A description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, . . . including information derived from clinical investigations, including controlled and uncontrolled studies of uses of the drug other than those proposed in the NDA, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

21 C.F.R. § 314.50.

Following NDA or sNDA approval, the manufacturer must notify the FDA about any change made to the product. Certain changes—such as to the manufacturing process—require the manufacturer to undergo additional review processes. *See id.* § 314.70.

The FDA also regulates the safety information that appears on the drug's label.[6] As part of the NDA and sNDA process, drug manufacturers must propose and receive approval for the label. 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.50(c)(2)(i), (e). The label itself must contain information directed to both the prescribing physician ("Prescribing Information") and the patient ("Patient Warnings").

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[6] The drug "label" refers to "the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (citing 21 U.S.C. § 321(m)).

Once the FDA approves an NDA or sNDA, federal law generally prohibits the manufacturer from materially changing the label without submitting an additional sNDA for the FDA's advance approval. 21 C.F.R. § 314.70(b). A limited exception exists under 21 C.F.R. § 314.70(c)(6)(iii), also known as the "Changes Being Effected" (CBE) regulation, which allows a brand-name drug manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to reflect "newly acquired information" without advance FDA approval.

The FDCA does not entirely supplant state tort law. *See Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (While Congress "enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, [it] took care to preserve state law." (internal quotation marks and citation omitted)). "[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Id.* at 570–71. The manufacturer, not the FDA, "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.*

III. LEGAL STANDARD

Defendants move to dismiss the suit pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted.

A. Pleading

To survive a 12(b)(6) motion, the "complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). This standard governs Ms. Lauderdale's failure-to-warn claims under both strict liability and negligence theories.

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Glick v. W. Power Sports, Inc.*, 944 F.3d 714, 717 (8th Cir. 2019) (quoting *Iqbal*, 556 U.S. at 663)). In ruling, the Court must "accept as true all facts pleaded by the non-moving party and grant all reasonable inferences from the pleadings in favor of the nonmoving party." *Gallagher v. City of Clayton*, 699 F.3d 1013, 1016 (8th Cir. 2012) (quotation marks omitted).

Still, the complaint must contain sufficient facts "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Pleadings that contain mere "labels and conclusions" or "a formulaic recitation of the elements of the cause of action will not do." *Id.* A court is not required to "blindly accept the legal conclusions drawn by the pleader from the facts." *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990).

B. Matters Considered

The parties dispute the materials appropriate for consideration. On a motion to dismiss, the district court "primarily consider[s] the allegations in the complaint." *Zean v. Fairview Health Servs.*, 858 F.3d 520, 526 (8th Cir. 2017) (quoting *Miller v. Redwood Toxicology Lab, Inc.*, 688 F.3d 928, 931 n.3 (8th Cir. 2012)). If the court considers "matters outside the pleadings[,] . . . the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d).

However, "documents necessarily embraced by the complaint are not matters outside the pleading." *Zean*, 858 F.3d at 826 (quoting *Enervations, Inc. v. Minn. Min. & Mfg. Co.*, 380 F.3d 1066, 1069 (8th Cir. 2004)). As a result, the Court may properly consider such documents without converting the motion into one for summary judgment.

"Materials embraced by the complaint" include "matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint whose authenticity is unquestioned." *Id.* (quoting *Miller*, 688 F.3d at 931 n.3).

Defendants filed 20 exhibits, over 570 pages, to the docket in support of their Motion to Dismiss, which they urge the Court to consider when deciding the pending motion. *See* Doc. 26. Defendants argue the exhibits constitute either public records or matters incorporated by reference in the Complaint. Ms. Lauderdale disagrees. She characterizes the documents as matters outside the pleadings. Furthermore, she argues, regardless of how the Court characterizes the exhibits, the Court may decline Defendants' request for notice. Ms. Lauderdale urges the Court to exercise that discretion and confine its review to the four corners of the Complaint. But should this Court grant Defendants' request, Ms. Lauderdale asks the Court to also take notice of additional documents cited in the Complaint (but which Defendants did not necessarily request the Court take notice of), *see* Doc. 29-1, and Dr. Jason Hurt's Declaration stating that Defendants failed to disclose material safety data and that he would not have prescribed Nexplanon to Ms. Cook had he received such data, *see* Doc. 34-1.

"[T]he purpose of a Rule 12(b)(6) motion is to test the sufficiency of the complaint." *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 433 (W.D. Ark. 2020)). At this point in litigation, the objective "is to weed out cases that do not warrant reaching the (oftentimes) laborious and expensive discovery process because, based on the factual scenario on which the case rests, the plaintiff could never win." *Foley v. Wells Fargo Bank, N.A.*, 772 F.3d 63, 71–72 (1st Cir. 2014).

Accordingly, the Court will take notice of those documents cited in or relied on by the Complaint. But it will confine its examination to the face of these materials. The Court will not rely on them to make factual determinations.[7] For example, if Ms. Lauderdale's Complaint incorrectly states the warning label text—an error the Court may observe while reviewing the label itself—the Court may take notice of that fact. The Court will not, however, examine the scientific literature cited in the Complaint and determine which party more persuasively identifies the appropriate conclusions to draw from a given study.

IV. DISCUSSION

Ms. Lauderdale levies four causes of action against Defendants: (I) Strict Products Liability / Failure to Warn; (II) Fraud / Fraudulent Inducement; (III) Negligence; and (IV) Gross Negligence. With respect to failure-to-warn, Ms. Lauderdale alleges Defendants could have adopted an adequate warning label prior to FDA approval in 2011 (a "pre-approval" claim), as well as in the period between approval and Ms. Cook's death in 2011 (a "post-approval" claim).

Defendants present two grounds for dismissal. Defendants first contend federal law preempts Ms. Lauderdale's pre-approval and post-approval failure-to-warn claims—an affirmative defense. Second, Defendants argue, Ms. Lauderdale fails to plausibly allege sufficient facts to state a claim for each cause of action under Arkansas law.

[7] In *LeMay v. Mays*, the Eighth Circuit held that while courts may consider "materials necessarily embraced by the pleadings, including exhibits attached to the complaint and matters of public record, [s]uch evidence may not . . . be viewed for the truth of the matters asserted." 18 F.4th 283, 289 (8th Cir. 2021) (internal citations and quotation marks omitted).

A. Preemption

The Supremacy Clause provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." Art. VI, cl. 2. Accordingly, "[w]here state and federal law 'directly conflict,' state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). Such a conflict—termed "impossibility preemption"—occurs when it is "impossible for a private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990)).

The preemption analysis here focuses on the intersection between the state and federal law governing prescription drug warning labels. Arkansas law requires drug manufacturers to ensure that the warning label "puts a reasonably prudent physician on notice of a particular risk that the manufacturer has actual or constructive knowledge of at the time of distribution." *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 433 (W.D. Ark. 2020). But federal statutory and regulatory law also governs the information that appears on the label. Where the labeling requirements conflict such that it is impossible for Defendants to comply with both, federal law preempts the state-law failure-to-warn claim. For preemption purposes, a conflict arises when a party cannot independently satisfy its state law duties without seeking special permission or assistance from the federal government.

Defendants contend revising the Nexplanon label to comply with Arkansas law would force them to do just that. They argue any change to the Nexplanon label would

ultimately require advance permission from the FDA. Ms. Lauderdale disagrees. She asserts Defendants could have proposed a stronger Nexplanon label when initially seeking FDA approval and that, after FDA approval, federal regulation would have allowed Defendants to unilaterally strengthen the Nexplanon label in these circumstances.

1. Framework

The Court begins its analysis with a presumption that federal law accommodates, rather than supersedes, state law. "[T]he purpose of Congress is the ultimate touchstone," *Wyeth*, 555 U.S. at 565 (internal quotation marks and citations omitted), and significant evidence suggests Congress did not intend for the FDCA to displace state tort law. In *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court explained:

> Congress enacted the FDCA to bolster consumer protection against harmful products; that Congress provided no *federal* remedy for consumers harmed by unsafe or ineffective drugs; that Congress was aware of the prevalence of state tort litigation; and that, whether Congress' general purpose was to protect consumers, to provide safety-related incentives to manufacturers, or both, language, history, and purpose all indicate that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

139 S. Ct. 1668, 1677–78 (2019) (internal quotation marks and brackets omitted) (emphasis in original) (citing *Wyeth*, 555 U.S. at 574–575). Moreover, the states have long exercised police power to protect the health and safety of their citizens by providing tort remedies. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). Especially when "Congress legislated in a field which the States have traditionally occupied"—like here—the Court will not find "the historic police powers of the States . . . superseded by the

Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565 (internal quotation marks and citations omitted).

In the context of prescription drugs, four recent Supreme Court cases suggest that "[a] drug manufacturer may establish preemption by showing federal law prevented it from independently adopting a label that complied with state law, or by presenting clear evidence the FDA would have rejected such a label." *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 821 (N.D. Cal. 2019) (internal citation omitted). "If independent action is not possible, then the state-law claims are preempted. If independent action is possible, then the claims are preempted only if there is clear evidence that the FDA would not grant approval." *Id.*[8]

The first case, *Wyeth v. Levine*, turned on the FDA's "Changes Being Effected" or "CBE" regulation. After FDA approval, most labeling changes require advance FDA permission. 21 C.F.R. § 314.70(b)(2)(v)(A). "The CBE regulation [provides] an exception," *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 806 (7th Cir. 2018), by allowing brand-name drug manufacturers to unilaterally add or strengthen the drug's warning label without advance FDA approval. Manufacturers may act pursuant to CBE rule, however, only if newly acquired information supports the label change.

Wyeth held state-law claims based on labeling deficiencies are not preempted if the manufacturer could have relied on the CBE regulation to unilaterally strengthen the label. 555 U.S. at 573. Because the CBE regulation allowed the drug manufacturer to

[8] At the present stage of litigation, the analysis turns on whether Defendants could have independently made the revisions allegedly required under state law. Because Defendants do not argue the FDA would have rejected those changes, the Court does not consider that argument here.

act without the FDA's prior permission, the Court explained, it was not impossible for the manufacturer to comply with both federal and state requirements.

The FDA "retains authority to reject labeling changes made pursuant to the CBE regulation," *id.* at 571, but the mere "possibility of impossibility" is insufficient to establish preemption. However, "if a manufacturer can provide 'clear evidence' that the FDA would have rejected the label, then the manufacturer can show that it would have been impossible to amend the label in compliance with state law while simultaneously complying with federal law." *Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 339 (D.N.J. 2021) (citing *Wyeth*, 555 U.S. at 571). In these circumstances, the drug manufacturer has demonstrated impossibility and the state law claim is preempted.

The next case, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), distinguished between brand-name and generic drug manufacturers. Because federal law imposes a "sameness requirement" on generic drug manufacturers—i.e., the generic drug label must mirror the brand-name label—it was impossible for generic drug manufacturers to simultaneously comply with a state-law duty to revise the warning label and the federal-law duty to keep the label the same. The Court recognized that the generic manufacturer could seek FDA assistance to persuade the brand-name manufacturer to revise the label but refused to find that sufficient to defeat preemption. The Court emphasized that preemption analysis turns on "whether the private party could *independently* do under federal law what state law requires of it." *PLIVA*, 564 U.S. at 620 (emphasis added) (quoting *Wyeth*, 555 U.S. at 573). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance,

which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623–24.

Mutual Pharmaceutical Company, Inc. v. Bartlett applied the same rationale to a state-law design defect involving a generic drug. 570 U.S. 472, 480 (2013). "[B]ecause a generic drug's composition (like its label) cannot differ from that of the brand-name drug[,] [i]t was therefore impossible for the manufacturer to redesign the drug in accordance with state law, while simultaneously complying with the federal prohibition against redesigning the drug." *Gaetano*, 529 F. Supp. 3d at 340. Furthermore, the Court held, forcing a drug manufacturer to choose between a direct conflict—with only the "possibility of possibility" that compliance with federal and state law would eventually prove possible—and exiting the market represents an "impossible choice" that state law may not impose on drug manufacturers.

Finally, in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), the Supreme Court reaffirmed *Wyeth*'s holding and elaborated on its requirements. The Court reiterated that "'clear evidence' that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." *Id.* at 1672. It also explained that "clear evidence that FDA would not have approved a change to a drug's label" requires "evidence that the manufacturer fully informed FDA of justifications for warning required by state law and that FDA, in turn, informed manufacturer that FDA would not approve a change to drug's label to include that warning." *Id.*

2. Analysis

As a general rule, manufacturers must warn users about the risks associated with their product. *See Lee v. Martin*, 74 Ark. App. 193, 199 (2001). In Arkansas, the warning associated with a particular drug must "put[] a reasonably prudent physician on notice of a particular risk that the manufacturer has actual or constructive knowledge of at the time of distribution." *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 433 (W.D. Ark. 2020). Ms. Lauderdale argues that, under this standard, Defendants had a duty to provide a stronger warning about VTE risk, highlight which populations were most at risk, and include VTE incidence data.

At the present posture, Defendants fail to establish the affirmative defense of impossibility preemption. The Court finds Ms. Lauderdale's failure-to-warn allegation survives the Rule 12(b)(6) challenge based on a post-approval theory.[9]

According to Ms. Lauderdale, between 2011 and Ms. Cook's death in 2019, new scientific literature, clinical studies, and adverse event reports emerged (1) confirming a causal relationship between Nexplanon and VTE risk, and (2) demonstrating the risk of VTE was particularly high among obese women and African-American women using Nexplanon. Ms. Lauderdale contends the CBE regulation would have allowed Defendants to revise the Nexplanon label to accurately reflect this information. Defendants argue this post-approval claim is preempted because the information cited in the Complaint is neither newly acquired nor capable of supporting strengthened or

[9] Because the Court finds Ms. Lauderdale's failure-to-warn allegation is not preempted on at least one basis (post-approval), the Court need not reach the parties' pre-approval arguments. The distinction between pre- and post-approval does not create two separate causes of action, and the Court declines to reach non-dispositive issues at the present juncture.

additional warnings about VTE. As a result, Defendants contend, they cannot rely on the CBE regulation and thus lack any mechanism to independently revise the label.

The CBE regulation allows drug manufacturers to unilaterally revise the drug label if there exists (1) newly acquired information about the drug "(2) that showed a causal association (3) between the drug and an effect that warranted a new or stronger warning." *Dolin*, 901 F.3d at 806.

The FDA defines "newly acquired information" as:

> [D]ata, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3. Notably, "[n]ewly acquired information is not limited to new data. It includes new analysis of old data." *Dolin*, 901 F.3d at 815. This reflects "the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments." *Wyeth*, 555 U.S. at 569. For example, "[i]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for newly acquired information." *Id.* at 573. The FDA's 2008 final rule, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, adds that "information . . . previously known to the manufacturer, but not submitted to FDA" also constitutes "'newly acquired information' that may qualify for inclusion in a CBE supplement." 73 Fed. Reg. 49603.

Defendants fail to establish that no "newly acquired information" exists so as to necessarily prevent Defendants from relying on the CBE regulation to amend the Nexplanon label. Ms. Lauderdale cites specific data and research studies that plausibly qualify as "newly acquired," and, taken together, plausibly justify inclusion of additional and/or stronger warnings about the risk of VTE pursuant to the CBE regulation.

Impossibility preemption is an affirmative defense. The "burden for demonstrating impossibility rests with the party asserting preemption." *Holley*, 379 F. Supp. 3d at 819. "[I]f [preemption] is to be the basis for a Rule 12(b)(6) dismissal," *MHA, LLC v. Amerigroup Corp.*, 539 F. Supp. 3d 349, 364 (D.N.J. 2021), Defendants "must show that the defense is apparent on the face of the complaint and documents relied on in the complaint," *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018) (internal quotation marks omitted). *See also ABF Freight Sys., Inc. v. Int'l Bhd. of Teamsters*, 728 F.3d 853, 861 (8th Cir. 2013) (finding the basis for dismissal must be "apparent on the face of the complaint"). Moreover, "the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015). *See also Ideus v. Teva Pharms. USA, Inc.*, 2017 WL 6389630, at *2 (D. Neb. Dec. 12, 2017) (quoting *Galper* and stating the same).

Defendants clearly disagree with the factual conclusions that Ms. Lauderdale draws from the research cited in her Complaint. While Defendants attempt to frame their motion as one grounded in the law, their post-approval preemption theory ultimately turns on questions of fact. Defendants argue Ms. Lauderdale overstates the research's

significance—i.e., Nexplanon is not as dangerous as Ms. Lauderdale claims—and the Court should dismiss the matter on that ground.

Defendants urge this Court to analyze the evidence and conclude Defendants' proposed interpretation of the data prevails. Defendants will have an opportunity to conduct discovery, assemble evidence, and present the Court with a factual record that proves as much, but a Rule 12(b)(6) motion is not the proper vehicle.

a. *Scientific Studies Published After 2011*

Ms. Lauderdale alleges that "[a]fter Nexplanon was approved in 2011, several scientific studies identified an increased risk of VTE from Nexplanon." (Doc. 2, p. 22). Defendants dispute the conclusions Ms. Lauderdale draws from those studies, arguing the research does not justify strengthening the Nexplanon label.

Ms. Lauderdale cites two meta-analyses that examined the risk of VTE associated with progestin-only contraception products ("POCs"), as well as a third publication comparing the VTE risk associated with contraceptives containing desogestrel with those containing different types of progestins. According to Ms. Lauderdale, these studies demonstrate a higher risk of VTE among users of contraceptive products similar to Nexplanon.

Defendants argue Ms. Lauderdale's reliance on these studies is misplaced. Defendants claim that Ms. Lauderdale "erroneous[ly] assum[es] that Nexplanon's safety profile mimics that of other forms of hormonal birth control," (Doc. 27, pp. 26–27), and "[s]tudies of VTE risks associated with other hormonal contraceptives are plainly not 'newly acquired information' with respect to Nexplanon," *id.* at p. 27.

The Court disagrees with Defendants. Two of the studies examined progestin-only products, a category of contraception that includes Nexplanon. The third study analyzed desogestrel products. Etonogestrel, the progestin used in Nexplanon, is a biologically active metabolite of desogestrel. The Court cannot find it implausible, as a matter of law, that research into similar drugs provide no information about Nexplanon's safety.

Defendants next argue that while these products may contain similar ingredients, the research also shows that the "route of administration" (e.g., oral, intrauterine, injection, implant, etc.) impacts the level of VTE risk. Thus, they assert, because the studies cited by Ms. Lauderdale examine drugs with a route of administration different from that used by Nexplanon, the findings do not bear on Nexplanon's safety profile. The relationship between route of administration and VTE risk presents a factual issue that the Court cannot resolve on a motion to dismiss. Defendants provide no basis upon which the Court may conclude, as a matter of law, that the increased VTE risk associated with progestin-only *injections*, for example, cannot plausibly support an allegation of increased VTE risk associated with progestin-only *implants*.

Furthermore, as a general matter, it appears the FDA itself considers information about closely-related drugs relevant to a drug's safety profile. Ms. Lauderdale notes that the FDA's guidance documents expressly encourage drug manufacturers to consider information stemming from research into drugs in the pertinent drug class. Defendants' own 2004 submission to the FDA specifically references research into the effects associated with oral desogestrel as relevant to the Implanon safety profile. *See* Doc. 26-7, p. 111. Even the Nexplanon warning label *itself* expressly acknowledges that

research into other contraceptives may bear on Nexplanon's safety profile. The Prescribing Information, section 5, "WARNINGS AND PRECAUTIONS" states: "The following information is based on experience with the etonogestrel implants (IMPLANON and/or NEXPLANON), *other progestin-only contraceptives, or experience with combination (estrogen plus progestin) oral contraceptives*." (Doc. 26-1, p. 16 (emphasis added)).

Defendants also urge this Court to disregard two other studies cited by Ms. Lauderdale because they fail to demonstrate a statistically significant relationship between Nexplanon and VTE risk. One meta-study, for instance, states, "[t]he progestogen only implants (etonogestrel) had a nonsignificant increase at 1.4 with confidence intervals of 0.6–3.4." (Doc. 26-17, p. 5). However, the same article also found, "[a]ll studies showed an increased risk of hormonal contraceptives to nonusers except the levonorgestrel releasing intrauterine device (IUD)," and "[w]ith the growing rate of obesity in the United States, many [individuals] would fall in the category of a sixfold increased risk [of VT associated with hormonal contraceptive] due to BMI above thirty." *Id.* at p. 7. Clearly, the findings are nuanced. The Court will not attempt to parse them on a motion to dismiss.

In sum, the research studies identified in Ms. Lauderdale's Complaint plausibly constitute newly acquired information that justifies a stronger warning regarding the risk of VTE associated with Nexplanon.

b. Implanon Clinical Trial Data

Ms. Lauderdale also contends Defendants failed to disclose all clinical trial cases of VTE to the FDA. Defendants refute this allegation on the facts, claiming that "[t]he

clinical and post-market data identified in the Complaint were submitted to and reviewed by FDA—on multiple occasions—before the agency approved Nexplanon's VTE warnings." (Doc. 27, p. 25). Thus, according to Defendants, "[t]hose data were not 'newly acquired' under federal law, and Plaintiff thus cannot rely on them to state a valid claim for relief." *Id.*

Ms. Lauderdale's Complaint identifies specific VTE events in 2004 and 2005 that she alleges Defendants failed to report to the FDA during the Implanon approval process. She cites to Defendants' 2004 FDA submission, which would seem to indicate Defendants did in fact alert the agency. That's what Defendants argue, pointing to adverse events referenced in the 2004 and 2005 submissions that appear similar to those events Ms. Lauderdale claims were never reported.

The Court has no way to validate whether the adverse events referenced in the Complaint represent the same adverse events referenced in the FDA submissions. The Court will not conduct its own factual investigation at this juncture, particularly because the Complaint cites other sources of newly acquired information sufficient to satisfy the CBE regulation.

c. Other Clinical Study Data & Post-Market Adverse Events

Ms. Lauderdale cites three clinical studies published after 2011 that she contends contain additional reports of VTE-related events. For example, in the NORA study, which occurred between 2011 and 2017, "there were eight reports of women who suffered deep venous thrombosis, three of whom also suffered pulmonary embolism." (Doc. 2, p. 21).[10] Furthermore, "[s]everal of the cases of VTEs and pulmonary embolus

[10] Etonogestrel Implant/MK-8415, Protocol No: P08290 – NORA Final Study, May 2013.

were in obese and young patients who were first time users of Nexplanon." *Id.* Ms. Lauderdale also alleges post-market reports of adverse events related to VTE have substantially increased since 2011. *See id.* at 24–25.

According to Defendants, however, Ms. Lauderdale fails to demonstrate "that those reports communicated meaningfully different safety information than the earlier ones—reporting the same conditions in users of the same product—that were previously submitted to FDA. (Doc. 27, p. 17).

The Supreme Court has expressly held that "accumulating data" may justify a stronger warning. In *Wyeth*, the plaintiff presented evidence of similar adverse events that occurred before her own injury. The Court explained, "[a]fter the first such incident came to Wyeth's attention in 1967, it notified the FDA and worked with the agency to change Phenergan's label. In later years, as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug." 555 U.S. at 569–70. The Court concluded the accumulation of adverse events constituted "newly acquired information."

In sum, Defendants fail to establish that the accumulation of adverse event reports, coupled with peer-reviewed scientific literature documenting a causal relationship between drugs similar to Nexplanon and VTE risk, provide insufficient evidence such that Defendants could have plausibly relied on the CBE regulation to amend the Nexplanon label. The Court **DENIES** Defendants' motion with respect to preemption.

B. Failure to State a Claim Upon Which Relief May Be Granted

Ms. Lauderdale's Complaint contains four counts: Strict Products Liability / Failure to Warn (Count I); Fraud / Fraudulent Inducement (Count II); Negligence (Count III); and Gross Negligence (Count IV). Defendants argue that even if this Court does not find Ms. Lauderdale's claims preempted, the Court should nevertheless dismiss the case because the Complaint fails to state sufficient facts upon which relief may be granted under state law.

1. Failure-to-Warn

Arkansas law requires Defendants to an adequate warning regarding the dangers associated with use of their product. *See Boehm v. Eli Lilly & Co.*, 747 F.3d 501, 505 (8th Cir. 2014). Ms. Lauderdale alleges a breach of this duty under both a strict-liability theory (Count I) and a negligence theory (Count III).

Generally, product liability law requires the manufacturer to warn the ultimate *user* of such risks. *See Thomas v. Borg-Warner Morse TEC LLC*, 362 F. Supp. 3d 610, 615 (E.D. Ark. 2018). However, in the context of prescription drugs, Arkansas recognizes that physicians play a critical mediating role between drug manufacturer and patient. *See Wilichowski v. Bos. Sci. Corp.*, 2021 WL 798869, at *3 (W.D. Ark. Mar. 2, 2021) (explaining that "medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and manufacturer, the information regarding risks is often too technical for a patient to make a reasonable choice, and it is virtually impossible in many cases for a manufacturer to directly warn each patient" (cleaned up)). Accordingly, Arkansas has adopted the "learned intermediary rule," which "assumes that it is reasonable for a manufacturer to rely on the prescribing physician to

forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects." *Hill v. Searle Lab'ys, a Div. of Searle Pharms., Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989).

"[A] drug warning is adequate so long as it puts a reasonably prudent physician on notice of a particular risk that the manufacturer has actual or constructive knowledge of at the time of distribution." *Stube*, 446 F. Supp. 3d at 433 (quoting *Bell v. PLIVA, Inc.*, 845 F. Supp.2d 967, 970 (E.D. Ark. 2012)). Defendants were "legally obligated to provide 'meaningful and complete' warnings" to Dr. Hurt, but not to Ms. Cook directly. *Sharp v. Ethicon, Inc.*, 2020 WL 1434566, at *3 (W.D. Ark. Mar. 24, 2020); *see also Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) ("[A] warning to the physician is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of" pharmaceutical products.).

a. Strict Liability

Under the Arkansas product liability statute, the "supplier of a product is strictly liable for an injury caused by the product if (1) the product is in a defective condition that rendered it unreasonably dangerous, and (2) the defective condition was a proximate cause of the injury." *Harrell v. Madison Cnty. Miss. Mote Co.*, 370 F.3d 760, 762 (8th Cir. 2004) (quoting *Boerner v. Brown & Williamson Tobacco Co.,* 260 F.3d 837, 842 (8th Cir.2001)). An inadequate warning may render the product "defective" for the purpose of strict liability. *See Hill*, 884 F.2d at 1070.

Defendants argue Ms. Lauderdale "cannot state a plausible claim based on conclusory risk allegations without scientific support or other factual enhancement." (Doc. 27, p. 35). That mischaracterizes the Complaint. Ms. Lauderdale cites scientific

literature, clinical studies, and adverse event reports, all seemingly available in the public domain, that suggest a causal relationship between Nexplanon and VTE risk. As explained, Defendants may disagree with those factual allegations but that is not relevant at the present posture. Ms. Lauderdale states sufficient facts to plausibly allege Defendants knew or should have known that Nexplanon poses a higher risk of VTE than the label currently reflects. That is enough under Rule 12(b)(6).

Defendants also assert Ms. Lauderdale "has not plausibly alleged that Organon failed to adequately warn of the risks of which it did know." (Doc. 27, p. 35). In other words, Defendants argue Ms. Lauderdale fails to state a claim because the existing Nexplanon label accurately reflects all that Defendants know or should know about VTE risk associated with their product. That is also a factual question. The Court will not resolve it on a Rule 12(b)(6) motion.

To find a "defective condition" (here, an allegedly inadequate warning label) unreasonably dangerous, the defect "must pose an actual danger to person or property, which exceeds 'that contemplated by the ordinary and reasonable buyer, taking into account any special knowledge of the buyer concerning the characteristics, propensities, risks, dangers, and proper and improper uses of the product.'" *J&B Tankers, Inc. v. Navistar Int'l Corp.*, 539 F. Supp. 3d 955, 959 (E.D. Ark. 2021) (quoting *Purina Mills, Inc. v. Askins*, 317 Ark. 58, 66 1994)). Ms. Lauderdale alleges the Nexplanon label fails to adequately state the potential for VTE, a serious and sometimes fatal condition. This risk goes far beyond that which an ordinary and reasonable patient might contemplate in considering contraception.

Proximate cause requires that "the defective aspect of the product [to] cause the injury." *Sharp v. Ethicon, Inc.*, 2020 WL 1434566, at *3 (W.D. Ark. Mar. 24, 2020) (quoting *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014)). Defendants argue the allegations fail on this basis. *Id.* at p. 39 ("'[T]he non-disclosed risk [must] manifest itself into actual injury,' and the plaintiff [must] 'demonstrate that [she] suffered from the precise injury that the manufacturer allegedly failed to disclose.'") (quoting *Cochran v. Wyeth*, 3 A.3d 673, 679-81 (Pa. Super. Ct. 2010)). This (again) mischaracterizes the Complaint. Ms. Lauderdale alleges (1) Defendants failed to adequately warn Ms. Cook's physician about the relationship between Nexplanon and VTE risk, especially among certain populations; (2) had Defendants provided a warning label that reflected the true nature of the risk, Dr. Hurt would not have prescribed Nexplanon; (3) Ms. Cook experienced, among other things, VTE; and (4) Nexplanon caused the VTE.

Under the learned intermediary rule, "[a] manufacturer's inadequate warning is not a proximate cause of a plaintiff's harm [if] the prescribing physician had independent knowledge of the risk that the inadequate warning should have communicated." *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013). But while the doctrine applies here, it does not defeat Ms. Lauderdale's claim. The Complaint expressly alleges the label failed to adequately warn *Dr. Hurt* of the dangers associated with Nexplanon. There is no indication Dr. Hurt possessed independent knowledge regarding the degree of risk Nexplanon posed to Ms. Cook.

Discovery will surely yield more insight into the precise nature of Ms. Cook's injuries. Should evidence show Ms. Cook experienced harm attributable to Nexplanon but that the label already sufficiently warned of, that might provide a basis for dismissal.

But we're not there yet, and Defendants do not explain why Ms. Lauderdale's allegations fail to plausibly support proximate cause as a matter of law.

b. Negligence

The evidence cited in support of Ms. Lauderdale's strict liability claim also supports a negligence claim.[11]

Ms. Lauderdale alleges Defendants were negligent; she sustained damages; and such negligence was the proximate cause of her damages. An inadequate warning may provide "evidence of negligence on the part of the manufacturer," *Hill v. Searle Lab'ys, a Div. of Searle Pharms., Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989), and, per the above discussion, Ms. Lauderdale states sufficient facts to allege the inadequate warning caused Ms. Cook's injuries.

Accordingly, the Court concludes Ms. Lauderdale adequately pleads a failure-to-warn claim under both strict liability and negligence theories. Defendants motion is **DENIED** as to Count I and Count III.

2. Fraud

Arkansas recognizes, as relevant here, two variations of fraud liability: (1) fraudulent misrepresentation, and (2) fraudulent omission or concealment.

To state a claim, the Complaint must plead the requisite elements with particularity. *See* Fed. R. Civ. P. 9(b). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9. Put simply, "the complaint must identify the 'who, what, where, when, and how' of the

[11] *See Wilichowski*, 2021 WL 798869, at *4 ("According to the Arkansas Supreme Court, "negligence and strict liability are not mutually exclusive claims. More than one theory of liability is permissible in a products liability claim." (internal brackets omitted) (citing *Nationwide Rentals Co. v. Carter*, 765 S.W.2d 931, 933 (Ark. 1989))).

alleged fraud." *Johnson v. Gilead Scis., Inc.*, 563 F. Supp. 3d 981, 990 (E.D. Mo. 2021) (quoting *U.S. ex rel. Joshi v. St. Luke's Hosp.*, Inc., 441 F.3d 552, 556 (8th Cir. 2006)).

For the below reasons, the Court concludes Ms. Lauderdale fails to plead sufficient facts to state a claim under either theory of fraud.

a. Fraudulent Misrepresentation

Under Arkansas law, fraudulent misrepresentation consists of the following five elements:

> (1) that the defendant made a false representation of material fact; (2) that the defendant knew that the representation was false or that there was insufficient evidence upon which to make the representation; (3) that the defendant intended to induce action or inaction by the plaintiff in reliance upon the representation; (4) that the plaintiff justifiably relied on the representation; and (5) that the plaintiff suffered damage as a result of the false representation.

KBX, Inc. v. Zero Grade Farms, 2022 Ark. 42, 16 (2022).

As an initial matter, the Court limits Ms. Lauderdale's fraud claim to one premised on the warning label. References to "DHCP letters," "promotional materials," and "sales representative detail efforts," "direct-to-physician communications," "press releases, patient information leaflets, medication guides, . . . [or] other risk communication mediums" lack the requisite specificity to support a claim for fraud under Rule 9(b). *See Allstate Indem. Co. v. Dixon*, 304 F.R.D. 580, 584 (W.D. Mo. 2015) ("A plaintiff need not plead every alleged misrepresentation but must provide some representative examples in order to enable defendant to respond."). Ms. Lauderdale generally alleges these materials contain misleading and false statements, but she does not point to any specific document or identify the false or misleading statements such materials contain.

Ms. Lauderdale characterizes her claim as one for both fraudulent misrepresentation and fraudulent omission. For the most part, Ms. Lauderdale alleges the Nexplanon label is misleading because it omits, rather than affirmatively misrepresents, critical information. But the Complaint does seem to point to at least one plausible affirmative misrepresentation: The Nexplanon label states that the relationship between an increased risk of VTE and "etonogestrel alone" is unknown. As explained *supra*, the Court finds Ms. Lauderdale plausibly alleges Defendants knew or should have known at least some relationship exists between etonogestrel and VTE, thereby plausibly rendering the label's determination that the relationship is "unknown" to be false.

Ms. Lauderdale's fraudulent misrepresentation claim, however, fails with respect to the second and third prong. The Complaint does not allege sufficient facts to plausibly conclude Defendants knew the representation to be false and intended to deceive physicians.

Fraudulent misrepresentation, unlike failure-to-warn, requires scienter. *See In re Neurontin Mktg., Sales Pracs. & Prod. Liab. Litig.*, 618 F. Supp. 2d 96, 113 (D. Mass. 2009). Some jurisdictions distinguish between fraudulent misrepresentation and negligent misrepresentation, thereby recognizing gradations in a defendant's mental state and corresponding culpability. Arkansas does not. *S. Cnty., Inc. v. First W. Loan Co.*, 315 Ark. 722, 725 (1994). According to the Arkansas Supreme Court, "[m]isrepresentation, also commonly referred to as deceit or fraud, has [long] been an *intentional* tort in Arkansas." *Id.* (emphasis added). The Eighth Circuit, applying Arkansas law, explained that "negligent misrepresentation is an unintentional tort" that

does not require scienter but instead simply requires that the "defendant 'fail[ed] to exercise reasonable care or competence in obtaining or communicating the information.'" *Receivables Purchasing Co. v. Eng'g & Pro. Servs., Inc.*, 510 F.3d 840, 843 (8th Cir. 2008) (quoting Restatement (Second) of Torts § 552(1)).

There is some nuance here. The Eighth Circuit has distinguished between negligent misrepresentation, which alleges "the defendant 'should have known' that the representation was false, regardless of what the defendant actually knew," and "knowingly ignorant" misrepresentations, finding the Arkansas Supreme Court would likely recognize liability for the latter. *Id.* The court concluded, "[w]e therefore believe that the Arkansas Supreme Court would hold that liability for fraud attaches in cases where a defendant lacked knowledge that his or her representation was false but did not know whether it was true or not." *Id.* The Eighth Circuit later added additional gloss, finding that Arkansas law extends tort liability to "*recklessly* false statements." *Curtis Lumber Co. v. Louisiana Pac. Corp.*, 618 F.3d 762, 775 (8th Cir. 2010) (emphasis added).

Nevertheless, while Ms. Lauderdale adequately alleges Defendants *should have known* the label misrepresented the risk, she does not provide any facts that would allow the Court to infer Defendants affirmatively developed a label they knew contained false statements, or remained knowingly or recklessly ignorant of that fact, for the purpose of inducing physicians to prescribe Nexplanon to a wider array of individuals. Put differently, the facts alleged with respect to failure-to-warn plausibly establish negligence. But Ms. Lauderdale does not allege any additional facts to support her

claim for fraud. The Complaint simply contains no more than conclusory allegations with respect to Defendants' knowledge.

b. Fraudulent Omission or Concealment

"Fraud also extends to concealment of material information and nondisclosure of certain pertinent information." *Curtis*, 618 F.3d at 772. However, "[t]he law distinguishes between . . . mere silence and the suppression or concealment of a fact." *Farm Bureau Pol'y Holders & Members v. Farm Bureau Mut. Ins. Co. of Ark.*, 335 Ark. 285, 302 (1998) (quoting 37 AM. JUR.2d Fraud and Deceit § 145). The law does not impose an affirmative duty to speak in every circumstance but instead narrows the duty's application to facts in which "equity and good conscience" render disclosure necessary. *See Loughridge v. Goodyear Tire & Rubber Co.*, 192 F. Supp. 2d 1175, 1184 (D. Colo. 2002). Accordingly, many courts hold silence, in order to be actionable, "must relate to a material matter known to the party and which it is his legal duty to communicate," *Farm Bureau*, 335 Ark. at 302, because "[w]here there is no obligation to speak, silence cannot be termed 'suppression,' and therefore is not a fraud." *Id.*

But this Court does not believe that this standard for fraudulent concealment disposes of the scienter element. *See In re Neurontin Mktg.*, 618 F. Supp. 2d at 113 ("In contrast to failure to warn claims, though, claims based on a fraudulent concealment or misrepresentation require scienter."). Fraud requires some affirmative act done with intent to deceive, and liability for fraudulent omission is no different. *See Farm Bureau*, 335 Ark. at 302 ("The law distinguishes between passive concealment and active concealment, or in other words, between mere silence and the suppression or concealment of a fact, the difference consisting in the fact that concealment implies a

purpose or design, while the simple failure to disclose a fact does not."). "To prevail in a case of fraudulent nondisclosure, the plaintiff must prove that the defendant *concealed* a material fact known to it." *Hobson v. Entergy Arkansas, Inc.*, 2014 Ark. App. 101, 11–12 (2014) (emphasis added) (citing *Downum v. Downum,* 101 Ark. App. 243 (2008)).

For example, in *In re Neurontin Marketing*, the court upheld some of the plaintiffs' fraudulent concealment claims. There, the defendant drug manufacturer actively sought to promote off-label use of the drug Neurontin yet failed to warn of its side effects. Moreover, the company continued to promote it as such even while its own research indicated the drug was not safe and effective for off-label use.

There is no comparable allegation in the present matter. Even if this Court were to assume Defendants possessed certain knowledge of the VTE risk associated with Nexplanon, Ms. Lauderdale does not allege any affirmative act to conceal that information. As with fraudulent misrepresentation, Ms. Lauderdale plausibly alleges negligence. But fraud requires some greater degree of intentionality, and Ms. Lauderdale does not cite any facts in support.

Accordingly, Defendants' Motion to Dismiss is GRANTED as to Count II.

3. Gross Negligence

In Count IV of the Complaint, Ms. Lauderdale alleges liability under a "gross negligence" theory.

The concept of "gross negligence" arises in very discrete circumstances under Arkansas law. For example, to sustain recovery under the Arkansas "Guest Statute," a plaintiff must plead "wilful negligence," which the Arkansas Supreme Court defines as "the same as gross negligence with the added factor that the actor knows, or the

situation is so extremely dangerous that he should know, that his act or failure to act will probably cause harm." *Spence v. Vaught*, 236 Ark. 509, 513 (1963). It also arises with respect to licensing decisions made by the Arkansas State Medical Board:

> The authorizing statute for the board's action, Ark. Stat. Ann. § 72–613, provides that the board may revoke or suspend a license if the holder has committed any acts or offenses defined to be unprofessional conduct. Included in the list of definitions is "(g) grossly negligent or ignorant malpractice."

Livingston v. Ark. State Med. Bd., 288 Ark. 1, 4 (1986) (internal citation omitted). However, "gross negligence" does not constitute an independent cause of action. Arkansas tort law recognizes a cause of action for negligence. It requires the plaintiff to prove the same elements, regardless of whether the breach of duty is characterized as "ordinary" or "gross." *See Cross v. W. Waste Indus.*, 2015 Ark. App. 476, 7 (2015) (finding negligence and gross negligence require proof of the same elements). To that extent, the premise of Count IV (gross negligence) is no different than the premise of Count III (ordinary negligence).[12] Count IV is superfluous. Defendants' Motion is therefore **GRANTED** with respect to Count IV.

V. CONCLUSION

Defendants' Motion to Dismiss is **DENIED** as to Counts I and III. It is **GRANTED** as to Counts III and IV.

IT IS SO ORDERED on this ____ day of August, 2022.

_____
TIMOTHY L. BROOKS
UNITED STATES DISTRICT JUDGE

[12] See Ark. Model Jury Instr., Civil AMI 301, which provides an instruction for negligence—not gross negligence.