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File Name: 15a0290p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

STEPHANIE YATES,

Plaintiff-Appellant,

v.

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; ALZA CORPORATION; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.; JOHNSON & JOHNSON,

Defendants-Appellees.

No. 15-3104

Appeal from the United States District Court
for the Northern District of Ohio at Cleveland.
No. 1:09-oe-40023—David A. Katz, District Judge.

Argued: October 8, 2015

Decided and Filed: December 11, 2015

Before: GIBBONS and McKEAGUE, Circuit Judges; ANDERSON, District Judge.*

COUNSEL

ARGUED: Paul A. Woodard, CONNORS & VILARDO, LLP, Buffalo, New York, for Appellant. Irene C. Keyse-Walker, TUCKER ELLIS LLP, Cleveland, Ohio, for Appellees. **ON BRIEF:** Paul A. Woodard, Terrence M. Connors, CONNORS & VILARDO, LLP, Buffalo, New York, Daniel G. Tronolone, TRONOLONE & SURGALLA, P.C., Buffalo, New York, for Appellant. Irene C. Keyse-Walker, Robert C. Tucker, Julie A. Callsen, Michael J. Ruttinger, TUCKER ELLIS LLP, Cleveland, Ohio, Susan M. Sharko, Jennifer La Mont, DRINKER BIDDLE & REATH LLP, Florham Park, New Jersey, for Appellees.

*The Honorable S. Thomas Anderson, United States District Judge for the Western District of Tennessee, sitting by designation.

OPINION

JULIA SMITH GIBBONS, Circuit Judge. Stephanie Yates experienced a stroke while using the ORTHO EVRA® birth control patch, and she now seeks to hold the designers and manufacturers of the patch liable. Yates appeals the district court's award of summary judgment to defendants on all five of her claims. For the reasons set forth in this opinion, we affirm the district court's judgment.

I.

A.

Yates brought suit against Ortho-McNeil-Janssen Pharmaceuticals, Inc., Alza Corporation, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Johnson & Johnson ("defendants") in the New York State Supreme Court for Erie County in September 2008. Defendants then removed the case to the United States District Court for the Western District of New York, pursuant to 28 U.S.C. §§ 1332, 1441, and 1446. Thereafter, the case was transferred to the United States District Court for the Northern District of Ohio, pursuant to 28 U.S.C. § 1407, for consolidated pretrial proceedings in connection with *In re: Ortho Evra Products Liability Litigation*, MDL No. 1742. Judge David Katz has overseen product liability claims involving ORTHO EVRA® since March 2006, when the Judicial Panel on Multidistrict Litigation established MDL 1742. *See In re Ortho Evra Prods. Liab. Litig.*, 422 F. Supp. 2d 1379, 1381 (J.P.M.L. 2006).

In the district court, Yates alleged five causes of action against defendants: (1) strict liability in tort—failure to warn; (2) strict liability in tort—manufacturing defect; (3) negligence; (4) breach of implied warranty; and (5) breach of express warranty. On April 7, 2014, the district court granted summary judgment as to Yates's failure to warn claim. *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 3:09oe40023, 2014 WL 1369466 (N.D. Ohio Apr. 7, 2014). Thereafter, on January 5, 2015, the district court granted summary judgment as to Yates's remaining claims and entered final judgment dismissing the case. *Yates v. Ortho-McNeil*

Pharm., Inc., 76 F. Supp. 3d 680 (N.D. Ohio 2015). Yates timely appealed the district court's dismissal of all five of her causes of action.

B.

Yates first visited OB/GYN Associates of Western New York on May 20, 2004, for her first gynecological appointment. Yates again visited OB/GYN Associates on November 3, 2004, when she was seventeen years old, because she was sexually active and was suffering from severe menstrual cramps. During the November 3, 2004 appointment, a licensed physician assistant—Jennifer Smith—counseled Yates about a variety of contraceptives, as well as the risks and benefits accompanying each product. Smith discussed the risks, benefits, and side effects of several methods of birth control, including oral contraceptives, Depo-Provera, NuvaRing, and ORTHO EVRA®. Smith testified that it would have been her usual practice to advise Yates that all these methods of birth control carried risks, including breakthrough bleeding, moodiness, headaches, nausea, breast tenderness, blood clots, and stroke, and that the benefits included menstrual relief, and, obviously, birth control. Yates admits that she was counseled concerning the risk of a stroke and clotting associated with ORTHO EVRA®. At this time, Yates decided to try Depo-Provera, which requires injections at three-month intervals. Before this examination and consultation, Yates admittedly had never heard of ORTHO EVRA®.

Yates returned to OB/GYN Associates on March 3, 2005, because she wanted to discontinue the use of Depo-Provera due to weight gain. Yates did not want to take an oral contraceptive because she would have trouble remembering to take a pill every day. Yates elected to switch to the ORTHO EVRA® patch. Smith approved the change to ORTHO EVRA®, to begin on March 6, 2005. However, Yates was suffering from "constant heavy menses," which is a common side effect of Depo-Provera and which delayed her switch to ORTHO EVRA®. DE 48-6, Smith Dep., Page ID 286. Yates again visited OB/GYN Associates on March 18, 2005, March 29, 2015, and April 15, 2005. Smith testified that it would have been her custom and practice during the March 18, 2015 visit to again review with Yates the side effects and risks of ORTHO EVRA®. During the April 15, 2005 visit, Smith again discussed several side effects of ORTHO EVRA® with Yates. At some time during this visit, Yates was given a sample of ORTHO EVRA®. Although the sample patches came with a cardboard flyer, which listed a

phone number and website associated with ORTHO EVRA®, Yates never called the number or visited the website. Nor did Yates perform any Internet research on ORTHO EVRA® prior to using it. Yates further admitted that she would have used ORTHO EVRA® even if she had read the warnings, which included an increased risk of developing strokes and blood clots.

Yates first used the ORTHO EVRA® patch on April 17, 2005, and she suffered a stroke on April 24, 2005, while she was still wearing her first weekly patch. One of Yates's expert witnesses, Dr. Mary Elizabeth Roemholdt, a board-certified neurologist and neurophysiologist, opined that Yates's "use of the Ortho-Evra patch was the contributing cause of her stroke." DE 94-8, Roemholdt Aff., Page ID 4697.

Smith began working at OB/GYN Associates in 2001. As a physician assistant, Smith sees patients for routine checkups, gynecological problems, diagnosis, and treatment, and she is authorized to prescribe medications. According to her deposition testimony, Smith prescribes medications based on her knowledge, training, and experience, as well as her assessment of the patient and her own clinical experience. Smith learns about the risks of medications that she prescribes from a variety of sources, including pharmaceutical sales representatives, medical journals, continuing medical education classes, and discussions with other doctors, physician assistants, and nurse practitioners in her office. Smith's custom is to prescribe contraceptives that, in her independent medical judgment, will be safe and effective for the particular patient. With regard to ORTHO EVRA®, Smith knew that the warnings for the patch included increased risks of thromboembolism and stroke. Smith also acknowledges that she tells her patients that one of the risks of using ORTHO EVRA® is the risk of developing a blood clot or a thromboembolism. Smith further testified that she still prescribes ORTHO EVRA® for her patients.

C.

As with other hormonal contraceptives, ORTHO EVRA® prevents pregnancy by delivering higher and more consistent levels of estrogen and progestin than present in normal menstrual cycles. Strokes are a well-known potential side effect associated with hormonal contraceptives. The ORTHO EVRA® package insert in use at the time Yates used the patch

contained information about the drug for prescribing physicians to review, and included the following warnings:

> The use of combination hormonal contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity and diabetes.
>
> . . .
>
> Hormonal contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, and smoking interacted to increase the risk of stroke.
>
> In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for normal normotensive users to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is reported to be 1.2 for non-smokers who used hormonal contraceptives, 2.6 for smokers who did not use hormonal contraceptives, 7.6 for smokers who used hormonal contraceptives, 1.8 for normotensive users and 25.7 for users with severe hypertension. The attributable risk is also greater in older women.

DE 48-8, Package Insert, Page ID 326–27.

The FDA requires that patient package inserts accompany each package of an estrogen drug product that the manufacturer or distributor intends to be dispensed to a patient. *See* 21 C.F.R. § 310.515. Accordingly, the patient package insert for ORTHO EVRA® included the following warning:

> RISKS OF USING HORMONAL CONTRACEPTIVES, INCLUDING ORTHO EVRA®
>
> . . .
>
> 2. Heart attacks and strokes
>
> Hormonal contraceptives, including ORTHO EVRA®, may increase the risk of developing strokes (blockage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability.

> Smoking and the use of hormonal contraceptives including ORTHO EVRA® greatly increase the chances of developing and dying of heart disease. Smoking also greatly increases the possibility of suffering heart attacks and strokes.

DE 48-8, Package Insert, Page ID 330.

II.

Because this is a diversity case, we apply New York substantive law, *Kepley v. Lanz*, 715 F.3d 969, 972 (6th Cir. 2013), meaning we "'follow the decisions of the state's highest court when that court has addressed the relevant issue.'" *Savedoff v. Access Grp., Inc.*, 524 F.3d 754, 762 (6th Cir. 2008) (quoting *Talley v. State Farm Fire & Cas. Co.*, 223 F.3d 323, 326 (6th Cir. 2000)). If the New York Court of Appeals has not directly addressed the issue, we must "anticipate how the relevant state's highest court would rule in the case." *In re Dow Corning Corp.*, 419 F.3d 543, 549 (6th Cir. 2005). "Intermediate state appellate courts' decisions are also viewed as persuasive unless it is shown that the state's highest court would decide the issue differently." *Id.*

"The Federal Rules of Civil Procedure are the rules of practice which apply to civil actions in the federal courts, regardless of whether jurisdiction is based on federal question or diversity of citizenship." *Hayes v. Equitable Energy Res. Co.*, 266 F.3d 560, 566 (6th Cir. 2001).

We review the district court's grant of summary judgment *de novo*. *Laster v. City of Kalamazoo*, 746 F.3d 714, 726 (6th Cir. 2014). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). When determining whether the movant has met this burden, we view the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in the movant's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Smith Wholesale Co. v. R.J. Reynolds Tobacco Co.*, 477 F.3d 854, 861 (6th Cir. 2007). A genuine issue of material fact exists when "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson*, 477 U.S. at 249. "The ultimate question is 'whether the evidence presents a sufficient disagreement to require submission to a jury or

whether it is so one-sided that one party must prevail as a matter of law.'" *Back v. Nestle USA, Inc.*, 694 F.3d 571, 575 (6th Cir. 2012) (quoting *Anderson*, 477 U.S. at 251–52).

III.

A. Failure to Warn

The district court granted defendants' motion for summary judgment on Yates's strict liability failure to warn claim, holding that defendants provided adequate warnings to Yates's prescribing medical provider regarding the risk of stroke associated with ORTHO EVRA®. *Yates*, 2014 WL 1369466, at *6. On appeal, Yates contends that the district court erred in dismissing her failure to warn claim for two reasons. First, Yates argues that defendants' warnings were inadequate because they failed to convey the level of risk of stroke that ORTHO EVRA® carries. Second, Yates asserts that defendants had a duty to warn her directly pursuant to FDA regulations.

1.

To establish a claim against a drug manufacturer for failure to warn under New York law, "'a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries.'" *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992) (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (App. Div. 1990)). The manufacturer's duty to warn extends to the treating physician, and not directly to the patient. *Glucksman*, 553 N.Y.S.2d at 726. "It has long been the law in New York that prescription medicine warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 96–97 (App. Div. 1979)). "[W]here the warning given to the prescribing physician by the manufacturer through the Physician's Desk Reference (PDR), package inserts and other literature gives specific detailed information on the risks of the drug, the manufacturer has been held absolved from liability as a matter of law." *Wolfgruber*, 423 N.Y.S.2d at 97. "Except where FDA regulations otherwise provide, the manufacturer's duty is to warn the doctor, not the patient. The doctor acts as an 'informed

intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use." *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (quoting *Wolfgruber*, 423 N.Y.S.2d at 96).

In this case, the "precise malady incurred" was a stroke, and the risk of stroke "was communicated in the prescribing information." Defendants mentioned the risk of stroke associated with ORTHO EVRA® several times in the package inserts. The ORTHO EVRA® label specifically stated that "[t]he use of combination hormonal contraceptives is associated with increased risks of several serious conditions including . . . stroke" and that "[h]ormonal contraceptives, including ORTHO EVRA®, may increase the risk of developing strokes (blockage or rupture of blood vessels in the brain)." DE 48-8, Package Insert, Page ID 326, 330. Smith's deposition testimony makes clear that she was well aware of the risk of stroke at the time she counseled Yates, and Yates admitted to being counseled about the risk of stroke associated with ORTHO EVRA®. There is no genuine issue of material fact for a jury on the issue of whether defendants failed to adequately warn Yates, through her prescribing medical provider, of the risk of stroke associated with ORTHO EVRA®.

Yates cites *Hollister v. Dayton Hudson Corp.*, 201 F.3d 731, 741 (6th Cir. 2000), for the proposition "that a warning must adequately convey the *degree* of risk, rather than just the existence of risk." Appellant Br. at 21. However, Yates overstates this court's holding in *Hollister*, as well as its relevance to the instant case. In *Hollister*, the clothing manufacturer had provided no warning whatsoever that the shirt at issue, which was found to burn twice as quickly as other comparable shirts, was flammable. 201 F.3d at 741. In that case, this court reversed the district court's "oversimplified" determination "that the danger inherent in having clothing come into contact with a hot stove is 'open and obvious,'" because the shirt was so much more combustible and flammable than a comparable shirt made out of similar material. *Id.* *Hollister* addresses the necessity for a warning in the first place, not the adequacy of a warning already given. Contrary to Yates's assertions, *Hollister* does not demand that this court reverse the district court's determination that defendants satisfied their duty to warn regarding the risk of stroke. In this case, the district court did not find that the risk of stroke associated with ORTHO EVRA® was "open and obvious," but instead found that the ORTHO EVRA® label explicitly

warned of the risk of stroke, thereby complying with its duty under New York law to adequately warn of the "precise malady incurred."

Yates next cites *DiBartolo v. Abbott Laboratories*, 914 F. Supp. 2d 601, 613 (S.D.N.Y. 2012), for the proposition that under New York law, a drug manufacturer does not "satisf[y] its duty to warn of a drug's side effects simply by mentioning those side effects in the drug's label." Reply Br. at 2. Indeed, New York law requires consideration of "not merely the existence of a pertinent warning, but also the qualitative adequacy of the warning." *DiBartolo*, 914 F. Supp. 2d at 613. Therefore, "a court deciding a failure-to-warn claim under New York law must consider not merely the existence of a relevant warning, but also the qualitative adequacy of that warning." *Id.* The plaintiff in *DiBartolo* survived the defendant's motion to dismiss on her failure to warn claim on the grounds that while the Humira label "stat[ed] the level of risk faced by Humira patients generally," it "did not specify the higher level of risk faced by patients with a history of PUVA treatment." *Id.* at 619. The court concluded that the Humira label, therefore, was not "'correct, fully descriptive and complete.'" *Id.* (quoting *Martin v. Hacker*, 628 N.E.2d 1308, 1313 (N.Y. 1993)). Yates essentially claims that the ORTHO EVRA® label should have stated that the risk of stroke was higher than other methods of birth control, namely than birth control pills. *DiBartolo* does not support such a proposition. If Yates were arguing that the ORTHO EVRA® label was deficient for not advising that smokers have a greater risk of stroke than nonsmokers, then *DiBartolo* might support her argument. *DiBartolo*'s requirement of comparative risks extends to patients with different underlying risk factors, not to different drugs treating the same ailment. The ORTHO EVRA® label provided more than adequate information to medical practitioners regarding the risk of stroke; its label was "correct, fully descriptive and complete." *See Martin*, 628 N.E.2d at 1313.

Yates further argues that the fact that the FDA subsequently required defendants to change ORTHO EVRA®'s warning regarding the risk of stroke is evidence of the insufficiency of the label in effect when she was prescribed ORTHO EVRA®. However, Yates cites no authority for the proposition that the subsequent improvement to a label, even a change that is required by the FDA, is probative evidence of the label's previous failure to warn. Absent any such authority, we will not consider evidence of a subsequent improvement to a drug label as

evidence of prior failure to warn, even in cases such as this in which the FDA mandated the change in labeling. *See* Fed. R. Evid. 407 ("When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . . a need for a warning or instruction."). As defendants contend, "Warnings can always be made 'better,' but 'better' is not the standard New York law requires—adequacy is. If the stroke warning was adequate to inform PA Smith when she prescribed ORTHO EVRA® to Plaintiff, then any subsequent updates made to that warning are not relevant." Appellee Br. at 27. Quite simply, the ORTHO EVRA® warnings in effect when Yates was prescribed the patch adequately warned her prescribing medical provider—Smith—of the risk of stroke.

2.

Yates next argues that her case presents an exception to the learned intermediary doctrine, and that FDA regulations required defendants to warn her, as the consumer, directly regarding ORTHO EVRA®'s risks. Under New York law, there is an exception to the informed intermediary doctrine "where FDA regulations otherwise provide." *Lindsay*, 637 F.2d at 91. In this case, however, there is no exception to the informed intermediary doctrine such that defendants owed a duty to Yates to warn her directly of the risk of stroke associated with ORTHO EVRA®.

In determining whether defendants had a duty to warn Yates directly of the known side effects and possible risks of ORTHO EVRA®, first, FDA regulations must provide otherwise. *See id.* Second, the exception to the informed intermediary doctrine will apply only if "an in-depth analysis of the benefits and risks to the individual of the [drug's] administration appears to be unlikely." *See Samuels v. Am. Cyanamid Co.*, 130 Misc.2d 175, 184 (N.Y. Sup. Ct. 1985). In *Samuels*, the trial court concluded that the informed intermediary doctrine would not apply in a case involving tetanus toxoid, typhoid, and cholera vaccines, because the vaccines were administered in a company clinic "without any meaningful appraisal by an 'informed intermediary.'" *Id.* The *Samuels* court explained that "the resolution of the issue here must turn on the patient's opportunity to make an informed decision whether or not to receive a vaccine, or alternatively, to rely on an informed intermediary to make that decision for him, analyzing his needs and the possible risks and side effects of the vaccine." *Id.*

In this case, the applicable FDA regulations require that "each estrogen drug product restricted to prescription distribution, including products containing estrogens in fixed combinations with other drugs, shall be dispensed to patients with a patient package insert containing information concerning the drug's benefits and risks." 21 C.F.R. § 310.515(a). Thus, Yates has satisfied the first requirement for an exception to the learned intermediary doctrine.

As to the second requirement, however, we find that Yates was counseled meaningfully by her prescribing medical provider, such that no exception to the informed intermediary doctrine applies here. The facts of this case clearly demonstrate that Smith adequately counseled Yates regarding her different birth control options. Smith was aware of several personal matters that affected Yates's birth control selection, such as her apprehension about remembering to take an oral contraceptive daily. OB/GYN Associates is not a clinic designed to quickly process patients; rather, Smith testified that it is her custom to use her independent medical judgment when prescribing birth control products to patients, and she specifically testified that she discussed the risks and benefits of several different forms of birth control with Yates. The mere fact that Smith gave Yates options and a voice in determining which method of birth control would best fit her needs and lifestyle does not remove Smith from her status as a learned intermediary. There may be cases in which a prescriber of birth control medication does not function as a learned intermediary, but this is not such a case.[1]

B. Preemption

The district court concluded that, by virtue of the FDA's approval of ORTHO EVRA®, Yates's state law design defect claims are preempted under *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), and *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164 (W.D.N.Y. 2014). *See Yates*, 76 F. Supp. 3d at 687–88. Yates contends that "defendants had a duty under New York law to design Ortho Evra safely in the first instance, *before* submitting its new drug

[1]In her Reply brief, Yates requests this court certify to the New York Court of Appeals the question of whether New York law recognizes an exception to the informed intermediary doctrine under these circumstances. Certification is inappropriate where a federal court "believes that it can resolve an issue of state law with available research materials already at hand, and makes the effort to do so." *Lehman Bros. v. Schein*, 416 U.S. 386, 395 (1974) (Rehnquist, J., concurring). Yates has not sufficiently argued that New York law is unclear on whether such an exception exists, or that the available research materials are insufficient for the federal courts to determine this issue of state law, and, accordingly, there is no need for certification.

application to the FDA," and that "no federal law prohibited defendants from adopting a safer design at that time." Appellant Br. at 36, 38. We find that defendants owed Yates no duty to design the FDA-approved ORTHO EVRA® differently in the first instance. Consequently, we find that Yates's design defect claim is preempted under *Bartlett*.

1.

The doctrine of conflict preemption has its roots in the Supremacy Clause, which states that federal law "shall be the supreme Law of the Land . . . any thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. State-law claims can be preempted expressly in a federal statute or regulation, or impliedly, where congressional intent to preempt state law is inferred. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Without an express provision for preemption, "state law must yield to a congressional Act . . . [w]hen Congress intends federal law to 'occupy the field,'" or "to the extent of any conflict with a federal statute." *Id.* (internal citations omitted). "Conflict preemption" exists where (1) "it is impossible for a private party to comply with both state and federal law," and (2) the state law is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 372–73.

"Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). We "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 565 (citations omitted). Then, we identify the defendant's duties under state law. *Bartlett*, 133 S. Ct. at 2473. Next, we ascertain whether federal law expressly prohibits the defendant from complying with state law. *Id.* at 2476. If federal law does not expressly prohibit the defendant from complying with state law, then we determine whether the defendant has presented "clear evidence" that the FDA would have prohibited the defendant from taking the necessary steps under state law. *See Levine*, 555 U.S. at 571.

As a general matter, plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law. *See generally Levine*, 555 U.S. 555. The issue in this case is whether defendants could have complied with their alleged duty under

New York law to have designed a safer drug before submitting ORTHO EVRA® for approval to the FDA or to change its formulation post-approval, while simultaneously complying with federal law.

The Supreme Court has provided guidance in three recent opinions on federal preemption in pharmaceutical products liability suits. In *Levine*, the plaintiff suffered an arm amputation following an injection of Phenergan, a drug that was administered to curb her nausea from a migraine headache. 555 U.S. at 558–59. She alleged that Phenergan's warning label was defective and inadequate because it did not instruct medical clinicians to use the IV-drip method of intravenous administration rather than the higher-risk IV-push method, which was used to administer the drug to her. *Id.* at 560. "More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug's therapeutic benefits." *Id.* Wyeth asserted that Levine's claims were preempted because Wyeth could not comply simultaneously with the duties imposed upon it by state tort laws and federal labeling laws. *Id.* at 568. The Supreme Court held that "Wyeth could have analyzed the accumulating data" on the frequency of amputations and "added a stronger warning about IV-push administration of the drug" under FDA regulations. *Id.* at 569–70. The Court rejected Wyeth's arguments that to add a stronger warning without first obtaining the FDA's approval would violate federal misbranding laws, because strengthening the warning would not make Phenergan a "new drug" distributed without FDA authorization nor would such a warning misbrand the drug. *Id.* at 570. Rather, the FDA's "changes being effected" ("CBE") regulation permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety. *Id.* at 568. Although the FDA can reject labeling changes made under the CBE regulation, "absent clear evidence that the FDA would not have approved a change to Phenergan's label," the Supreme Court declined to "conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.* at 571.

Two years later, in *PLIVA, Inc. v. Mensing*, the Supreme Court applied the impossibility preemption framework set forth in *Levine* and found that the plaintiff's state law claim was preempted. 131 S. Ct. 2567, 2581 (2011). State law would have required the generic manufacturer to add a warning to its label, while federal law required the generic drug

manufacturer to "ensur[e] that its warning label is the same as the brand name's." *Id.* at 2574. Additionally, "the CBE process was not open to [generic manufacturers] for the sort of change required by state law." *Id.* at 2575–76. Therefore, the generic drug manufacturer could not have changed its label without prior FDA approval, which it could have obtained only by proposing that the FDA require a change in the corresponding brand name label. *Id.* at 2576. Importantly, the Court explained that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579 (citing *Levine*, 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 2581. The Court thus limited *Levine* to situations in which the drug manufacturer can, "of its own volition, . . . strengthen its label in compliance with its state tort duty," but the Court did not overturn or radically alter the impossibility preemption framework as stated in *Levine*. *See id.*

Another two years later, in *Bartlett*, the Supreme Court applied the *Levine* and *Mensing* preemption analyses to a generic design defect case. The plaintiff was given a generic form of the anti-inflammatory pain reliever sulindac, and as a result, she developed an acute case of toxic epidermal necrolysis. *Bartlett*, 133 S. Ct. at 2471–72. The sulindac label did not specifically warn that the drug could cause toxic epidermal necrolysis. *Id.* at 2472. At trial, the plaintiff prevailed on a design defect claim, and the court of appeals affirmed, finding that the FDA's regulations did not preempt that claim, because the generic manufacturers could comply with both federal and state law by choosing not to make the drug at all. *Id.* The Supreme Court reversed, holding that impossibility preemption barred the plaintiff's claims. *Id.* at 2473. It found that state law imposed a duty "to ensure that the products [manufacturers] design, manufacture, and sell are not 'unreasonably dangerous,'" and that duty could be satisfied "either by changing a drug's design or by changing its labeling." *Id.* at 2474. As for drug redesign, the Court found that was impossible for two reasons: (1) the FDCA requires generic drugs to have "the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"; and (2) sulindac is "chemically incapable" of being redesigned. *Id.* at 2475. The Court then concluded, as in *Mensing*, that "federal law prevents

generic drug manufacturers from changing their labels." *Id.* at 2476. The Court explicitly rejected the lower court's conclusion that the defendant could have complied with both state and federal law by simply exiting the market, holding that, "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* at 2477 (quoting *Mensing*, 131 S. Ct. at 2579).

2.

There is some disagreement between the parties about whether Yates pleaded design defect under strict liability or negligence theories. However, since New York law treats claims of design defect sounding in negligence as "functionally synonymous" to claims for design defect based on strict liability, we analyze the claims identically. *Cavanagh v. Ford Motor Co.*, No. 13-cv-4584, 2014 WL 2048571, at *5 (E.D.N.Y. May 19, 2014).

As an initial matter, the district court oversimplified the impossibility preemption analysis as stated in *Levine*, *Mensing*, and *Bartlett*. The district court seemingly concluded, and defendants encourage this reading on appeal, that the *Bartlett* Court's finding of impossibility preemption extends to all design defect claims for both generic and brand-name drug manufacturers, based on the following sentence: "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). We do not read *Bartlett* as broadly as the defendants. As noted above, the *Bartlett* Court did not reach the sweeping conclusion that all design defect claims are preempted by federal law, but rather applied the impossibility preemption analysis to the plaintiff's design defect claim regarding a generic drug, and clarified that preemption cannot be avoided if the only way a manufacturer can comply with both federal and state law is to exit the market. *See id.* at 2477. Additionally, the above-quoted material from *Bartlett* is dicta, written in a section explaining the general approval process that manufacturers must go through to gain approval from the FDA before marketing any drug in interstate commerce. *See id.* at 2470–71. The district court's, and defendants', reliance on this statement is misplaced.

Important to the preemption findings in *Bartlett* and *Mensing* is the fact that generic drug manufacturers are prohibited from making any unilateral changes to the drug's composition or label, which is known as the "sameness" requirement. *Bartlett*, 133 S. Ct. at 2471; *Mensing*, 131 S. Ct. at 2575–76. Therefore, in *Mensing*, the Supreme Court determined that the plaintiffs' state law failure to warn claims regarding the generic drug were barred by impossibility preemption because the duty of sameness prohibited the generic manufacturers from unilaterally strengthening the drug's label so as to comply with their state-law duties. *See* 131 S. Ct. at 2577–78. Likewise, in *Bartlett*, the Court found that the plaintiff's state law design defect claim regarding the generic drug was barred by impossibility preemption because the sameness requirement prohibited the manufacturer from unilaterally changing the composition or labeling of the drug, as state law required. *See* 133 S. Ct. at 2475–76. The Court in *Mensing* clarified that "[i]t is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers," and such "different federal statutes and regulations may . . . lead to different pre-emption results." 131 S. Ct. at 2567. Therefore, contrary to Yates's contention that the impossibility preemption in *Mensing* and *Bartlett* is limited to generic drugs, we view *Levine*, *Mensing*, and *Bartlett* as together stating the same test for impossibility preemption. Because the federal statutes and regulations for brand-name and generic drugs are sometimes different, however, brand-name and generic drugs may face different impossibility preemption results in some circumstances.

Further, both the district court and defendants improperly rely on *Amos*, 28 F. Supp. 3d 164, for the proposition that New York design defect claims are preempted as a matter of law. The district court in *Amos* did not conduct the relevant impossibility preemption inquiry. Instead its decision was based only on the plaintiffs' concession that their design defect claims were preempted under federal law, and its conclusion that "such claims are preempted as a matter of law" is not persuasive. *Id.* at 169.

3.

Applying the federal impossibility preemption analysis to this case, we must first determine what duties New York law placed on defendants in designing ORTHO EVRA®.

See Bartlett, 133 S. Ct. at 2473. New York law provides that a product is defectively designed if "the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." *Doomes v. Best Transit Corp.*, 17 N.Y.3d 594, 608 (2011) (internal quotation marks and citation omitted). "In design defect cases, the alleged product flaw arises from an intentional decision by the manufacturer to configure the product in a particular way." *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 257 n.3 (1995). "[A] drug manufacturer, like any other manufacturer, can be held liable for a defective product under the theory of strict products liability." *Lindsay*, 637 F.2d at 90 (citing *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 84 (App. Div. 1979)). New York follows a "risk-utility" approach to determining whether a product is not reasonably safe, which calls for consideration of several factors:

> (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product—that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread any cost related to improving the safety of the design.

Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 109 (1983). "The purpose of risk/utility analysis is to determine whether the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design." *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997). "Brand-name drug manufacturers can thus avoid liability under New York law by choosing a safer design for a drug." *Sullivan v. Aventis, Inc.*, No. 14-cv-2939, 2015 WL 4879112, at *5 (S.D.N.Y. Aug. 13, 2015).[2]

Brand name drug manufacturers can also avoid liability by strengthening a drug's warning label. *See id.* The strength of the drug's warnings directly impacts one of the risk-utility factors, namely "the degree of awareness of the potential danger of the product which

[2]In her Reply brief, Yates contends that "if this Court is unconvinced that New York recognizes a pre-approval duty to safely design prescription drugs," that the following question be certified to the New York Court of Appeals: "Does New York recognize a drug manufacturer's duty to safely design a prescription drug before the FDA approves the drug for marketing?" Reply Br. at 22 n.3. For the reasons stated in this opinion, such certification is unnecessary. *See Lindsay*, 637 F.2d at 90–91; *supra* note 1.

reasonably can be attributed to the plaintiff." *See Voss*, 59 N.Y.2d at 109. "Moreover, for drugs that are unavoidably unsafe, drug manufacturers have an affirmative defense to liability if the drugs are 'properly prepared, and accompanied by proper directions and warning.'" *Sullivan*, 2015 WL 4879112, at *5 (quoting *Martin*, 83 N.Y.2d at 8); *see also Lindsay*, 637 F.2d at 90–91 (noting that drugs which "may cause untoward side effects despite the fact that they have been carefully and properly manufactured" are deemed "unavoidably unsafe products" that "are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects").

Second, we must determine whether federal law expressly prohibits defendants from complying with state law. *Id.* at 2476. Stated another way, we ask "whether this state-law duty makes compliance with any federal law impossible." *Sullivan*, 2015 WL 4879112, at *6.

Yates's post-approval design defect claim is clearly preempted by federal law. FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i). Moderate changes must be reported to the FDA "at least 30 days *prior to* distribution of the drug product made using the change." *Id.* § 314.70(c) (emphasis added). Minor changes need only be reported in an annual report to the FDA. *Id.* § 314.70(d)(3). Although Yates asserts that to "reduc[e] the amount of estrogen from 0.75 mg/patch to 0.6 mg/patch" "would be minimal," we disagree. Appellant Br. at 45. Based on the plain meaning of the regulation, we are convinced that defendants could not have altered the dosage of estrogen in ORTHO EVRA® without submission to the FDA and the agency's "approval *prior to* distribution of the product made using the change." *See* 21 C.F.R. § 314.70(b)(2)(i) (emphasis added). Among the enumerated "minor changes" that do not require prior notification to and/or approval from the FDA, are "[t]he deletion or reduction of an ingredient intended to affect only the color of the drug product" and "[a] change in the size and/or shape of a container containing the same number of dosage units." 21 C.F.R. § 314.70(d)(2)(ii), (iv). A "moderate change," for example, is "[a] change in the container closure system that does not affect the quality of the drug product." We think it clear that

changing the dosage level of the active ingredient of ORTHO EVRA® constitutes a "major change," such that prior FDA approval is necessary. *Id.* § 314.70(b)(2)(i) (stating that "major changes" include "changes in the qualitative or *quantitative formulation* of the drug product) (emphasis added)). Therefore, to the extent Yates argues that defendants should have altered the formulation of ORTHO EVRA® after the FDA had approved the patch, we find this claim clearly preempted. Quite simply, federal law prohibited defendants from decreasing the dosage of estrogen post-approval.[3]

Yates also contends, however, that there is no federal law that would have prohibited defendants from designing a different drug in the first instance. Specifically, Yates asserts that "when defendants first decided how to configure Ortho Evra and before defendants ever obtained FDA approval to market the drug—no federal law prohibited defendants from adopting a safer design." Appellant Br. at 38. Indeed, counsel for defendants has cited no federal law that restricts a brand-name drug manufacturer from designing a reasonably safe product prior to FDA approval. *See Sullivan*, 2015 WL 4879112, at *6. A brand-name manufacturer is not restricted to the "sameness" requirement, which prohibits generic manufacturers from redesigning the drug either prior to or after seeking FDA approval. *See Mensing*, 131 S. Ct. at 2575. Furthermore, Yates argues that the existence of the contraceptive Evra, which is chemically distinct from ORTHO EVRA® and was marketed in Canada and Europe, shows that redesign of ORTHO EVRA® was possible prior to submitting for FDA approval. Defendants have offered no evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval. *See Levine*, 555 U.S. at 571.

But Yates's argument regarding defendants' pre-approval duty is too attenuated. To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed ORTHO EVRA® differently, the FDA would have approved the alternate design. Next, we would have to assume that Yates would have selected this method of birth control. Further

[3]Yates further claims that her post-approval design defect claim parallels the federal Food, Drug, and Cosmetic Act ("FDCA"), and as such, is not preempted. Pursuant to the FDCA, manufacturers may not sell a drug that is "deemed to be misbranded" because it is "dangerous to health" when used in the dosage or manner called for in the drug's label." *See* 21 U.S.C. § 352(j). The FDCA requires "new and scientifically significant information that was not before the FDA," *Bartlett*, 133 S. Ct. at 2477 n.4, and Yates has not cited any such scientific evidence. Therefore, her mention of the FDCA in her brief is not enough to stave off preemption.

yet, we would have to suppose that this alternate design would not have caused Yates to suffer a stroke. This is several steps too far. Even if New York law requires defendants to produce and market a different design, the ultimate availability to Yates is contingent upon whether the FDA would approve the alternate design in the first place. In *Mensing*, the plaintiffs argued that "if the Manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires." 131 S. Ct. at 2578. In regard to that claim, which mirrors Yates's speculative claim about defendants' pre-approval duty to design ORTHO EVRA® with a different estrogen dosage, the Supreme Court opined as follows:

> The Manufacturers "freely concede" that they could have asked the FDA for help. If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide.

Id. (internal citation omitted). In that case, the Supreme Court ultimately found that "[t]he only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern." *Id.* at 2581. So too in this case. Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing ORTHO EVRA®, and certainly prior to Yates's use of the drug.

Yates cites *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010) for the distinction between a manufacturer's pre-approval and post-approval duties. It is true that in *Wimbush*, this court stated that "as a general proposition, we can discern no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs," and that "we are not persuaded that it is always impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval." 619 F.3d at 643. However, Yates has not explained precisely what a pre-approval claim would look like in her case. And we are unable to conceive of any coherent pre-approval duty that defendants would have owed to Yates when it was developing ORTHO EVRA®. Moreover, the *Wimbush* opinion, which predates the Supreme Court's analyses in *Mensing* and *Bartlett*, contains a caveat: "This is not to

say that such a physical impossibility could never exist, for instance if a state duty required that the manufacturer do something that the FDA forbade or vice versa." *Id.* The facts of *Wimbush* are also distinguishable from the instant case. In *Wimbush*, the plaintiff's estate brought suit regarding a diet pill that was placed on the market in June 1996 and was taken off the market in September 1997, with the suit not being commenced until 2001. *Id.* at 635. In contrast to this case, ORTHO EVRA®, was first marketed in 2001, Yates used the patch in 2005, and today, medical providers continue to prescribe ORTHO EVRA® as a manner of birth control. *Wimbush* is still good law, but it does not mandate the relief Yates seeks.

Yates's pre-approval claim fails for another reason. In *Bartlett*, the Supreme Court held that "[t]he [First Circuit] Court of Appeals' solution—that [the manufacturer] should simply have pulled [the drug] from the market in order to comply with both state and federal law—is no solution." 133 S. Ct. at 2470. This "stop-selling" rationale is "incompatible with . . . pre-emption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 2477. In contending that defendants' pre-approval duty would have resulted in a birth control patch with a different formulation, Yates essentially argues that defendants should never have sold the FDA-approved formulation of ORTHO EVRA® in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale of the First Circuit.

In sum, both Yates's pre-approval and post-approval design defect claims are preempted by federal law.

C. Manufacturing Defect

As to Yates's manufacturing defect claim, the district court held that "[t]here is no evidence that the Ortho Evra® patches which Ms. Yates received differed from either the manufacturing specifications for that product or from other identical units. Therefore, the Defendants are entitled to summary judgment as a matter of law on this issue." *Yates*, 76 F. Supp. 3d at 686.

Under New York law, "[a] manufacturing defect claim is premised on the relevant product being defective because it was not manufactured as designed." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). "Consistent with that premise, a manufacturing defect claim is properly dismissed if a plaintiff has not alleged that the particular drug administered to her had a defect as compared to other samples of that drug." *Id.* (internal quotations marks and citation omitted). New York law recognizes a "circumstantial approach in products liability cases." *Speller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38, 41 (2003). "In a products liability case alleging a manufacturing defect, the existence of the defect may be inferred from circumstantial evidence, provided that the plaintiff has proven that the product has not performed as intended and has excluded all other possible causes of the defect not attributable to the defendant." *Sanchez v. Stanley-Bostitch, Inc.*, No. 98-cv-0494, 2000 WL 968776, at *2 (S.D.N.Y. July 13, 2000).

Yates contends that she has produced evidence that defendants used a "flawed manufacturing process to produce the drug" and that defendants had "major difficulties in scaling up the manufacture of Ortho Evra from clinical trials to commercial production." Appellant Br. at 47–48. The only evidence that Yates produced on this matter comes from an affidavit from an expert witness. Dr. Susan Parisian, a board-certified physician and a former chief medical officer with the FDA, opined that defendants failed to adhere to good manufacturing practices for commercial production of ORTHO EVRA®. Dr. Parisian stated that defendants experienced difficulties in scaling up the manufacture of ORTHO EVRA® from clinical trials to commercial production, apparently as evidenced by inter-lot variability with respect to estrogen release rates. Dr. Parisian further asserted that "*prior to commercial launch of April 2002*, [defendants] had not developed robust manufacturing release specifications and process validations necessary to ensure consistent release of safe and effective commercial ORTHO EVRA." DE 94-6, Parisian Aff., Page ID 4567 (emphasis added). Notably missing from Dr. Parisian's affidavit, or from any other evidence produced by Yates, is support for the claim that there were manufacturing irregularities *after* the commercial launch of ORTHO EVRA®.

> Defendants argue as follows:
>
> > Plaintiff cannot show that the product did not work as intended; ORTHO EVRA® did what it was prescribed to do—prevent her from becoming pregnant while using it. That she alleges that she experienced a known and warned-of side effect while using ORTHO EVRA® is not circumstantial evidence that the product did not perform as intended.

Appellee Br. at 51. We agree. If evidence of a known and warned-of side effect could be used as sufficient circumstantial evidence of a manufacturing defect, then every drug-user who suffered a known and warned-of side effect could state a claim for a manufacturing defect. Specifically, the fact that Dr. Roemholdt attributes Yates's stroke to her use of the ORTHO EVRA® patch is not evidence of a manufacturing defect, since the ORTHO EVRA® label and package insert explicitly warned of the risk of stroke. Further, Yates has produced no evidence, from Dr. Parisian or others, that any studies have revealed that the patches actually commercially produced and released to the public contained different estrogen amounts from either the FDA-approved design or each other. Allegations of problems in scaling up production from clinical trials to commercial distribution, however, simply are not circumstantial proof on the issue of whether the estrogen levels in ORTHO EVRA® patches commercially-distributed for public use differed from the FDA-approved design.

Drawing every reasonable inference in Yates's favor, as required on summary judgment, her manufacturing defect claim must fail. There is no evidence, direct or circumstantial, that the ORTHO EVRA® patch used by Yates, or anyone else, differed from the FDA-approved design.

D. Negligence

The district court awarded summary judgment to defendants on Yates's negligence claim on the basis that "[t]he courts of New York have held that state law claims of negligence, negligence per se, and breach of implied warranty are pre-empted when the article in question is regulated by federal law." *Yates*, 76 F. Supp. 3d at 688 (citing *Mitaro v. Medtronic, Inc.*, 73 A.D.3d 1142 (N.Y. App. Div. 2010)). Yates argues that the district court's reliance on *Mitaro* was misplaced, because that case concerned claims regarding a defective medical device, not a defective drug. Yates's argument on the substance of her negligence claims is unclear. Regardless of the propriety of the district court's reliance on *Mitaro*, because New York law

treats products liability claims arising in negligence the same as products liability claims arising in strict liability, *Cavanagh*, 2014 WL 2048571, at *5, the court's decision on Yates's failure to warn, design defect, and manufacturing defect claims disposes of her claim that defendants "negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, researched, distributed, marketed, labeled, packaged, prepared for use and sold ORTHO EVRA and failed to adequately test and warn of the risks and dangers of ORTHO EVRA." DE 1, Compl., Page ID 24. Therefore, we find that the district court properly dismissed Yates's negligence claims.

E. Breach of Implied Warranty

The district court granted summary judgment to defendants on Yates's claim for breach of the implied warranty of merchantability because it is preempted by federal law on the basis of *Mitaro*. *Yates*, 76 F. Supp. 3d at 688. Defendants argue that because Yates's design defect claim is preempted under *Bartlett*, *Mensing*, and *Wyeth*, so too is her breach of implied warranty claim.

Under New York law, breach of the implied warranty of merchantability is a valid cause of action, separate and apart from strict liability in tort, though there is considerable overlap between them. *See Denny*, 87 N.Y.2d at 256. A manufacturer may be held liable for breach of implied warranty for marketing goods that are not "fit for the ordinary purposes for which such goods are used." *See* UCC § 2-314(2)(c). To establish that a manufacturer breached its implied warranty of merchantability, a plaintiff must show that "the product was not minimally safe for its expected purpose." *Denny*, 87 N.Y.2d at 259. The plaintiff must show "that a defect in the product was a substantial factor in causing the injury and that the defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued." *DiBartolo*, 914 F. Supp. 2d at 627 (internal quotation marks and citations omitted). Similarly to strict products liability or negligence claims, "[t]he defect may arise from a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product." *Id.* (internal quotation marks and citations omitted).

Even if *Mitaro* does not stand for the proposition that once a design defect claim is preempted under federal law, other state law claims are preempted as well, Yates's implied warranty claim fails on the merits. Because defendants adequately warned Yates's prescribing

medical provider of the risk of stroke, Yates has not proven her claim with respect to "a failure to provide adequate warnings." *See id.* Further, Yates failed to produce any evidence on whether there was a manufacturing defect that affected commercial production of ORTHO EVRA®. *See id.*

F. Breach of Express Warranty

The district court granted summary judgment to defendants on Yates's claim for breach of express warranty, because she "failed to perform any research regarding the Ortho Evra® patch because she trusted the medical advice she was given." *Yates*, 76 F. Supp. 3d at 688. Further, "Yates never received an affirmation of fact or promise from the Defendants, nor did she ever receive an expressed factual representation from the Defendants which induced her to use the Ortho Evra® patch." *Id.* at 689.

To state a claim for breach of express warranty under New York law, the "plaintiff must allege that 'there was an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the plaintiff's detriment.'" *DiBartolo*, 914 F. Supp. 2d at 625 (quoting *Weiner v. Snapple Beverage Corp.*, No. 07-cv-8742, 2011 WL 196930, at *5 (S.D.N.Y. Jan. 21, 2011)). "The affirmation of fact or promise must have been 'false or misleading when made.'" *Id.* (quoting *Shop Vac Corp. v. BCL Magnetics Ltd.*, No. 04-cv-262, 2005 WL 2739161, at *6 (N.D.N.Y. Oct. 24, 2005)). "Privity is not required in a personal injury action for breach of express or implied warranty (UCC 2-318)." *Cereo v. Takigawa Kogyo Co.*, 676 N.Y.S.2d 364, 365 (App. Div. 1998). Therefore, "[a] buyer may bring a claim against a manufacturer from whom he did not purchase a product directly, since an express warranty 'may include specific representations made by a manufacturer in its sales brochures or advertisements regarding a product upon which a purchaser relies.'" *Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014) (quoting *Arthur Glick Leasing, Inc. v. William J. Petzold, Inc.*, 858 N.Y.S.2d 405, 407 (App. Div. 2008)). Importantly, "a plaintiff complaining of breach of express warranty must 'set forth the terms of the warranty upon which he relied.'" *Id.* (quoting *Parker v. Raymond Corp.*, 930 N.Y.S.2d 27, 29 (App. Div. 2011)).

Yates contends that, even if she never received a representation from defendants to induce her to use ORTHO EVRA®, because New York does not require privity, her claim for breach of express warranty survives because "defendants falsely represented the level of estrogen in their product." Appellant Br. at 54. Defendants respond that they made no direct, affirmative representation to Yates.

We conclude that the district court properly awarded summary judgment to defendants on Yates's breach of express warranty claim. The record makes clear that defendants made no affirmation of fact or promise to Yates, and that therefore, Yates could not have relied on any such affirmation. In her testimony, Yates admitted that before her examination and consultation in November 2004, she had never heard of ORTHO EVRA®. Yates further testified that before she started using ORTHO EVRA®, she had not seen any advertising for it. Moreover, Yates performed no independent research on ORTHO EVRA® prior to her use. New York law does not require privity to state an express breach of warranty claim, but it certainly requires more than Yates's bare assertions, unsupported by citations to the record, that "defendants falsely represented the level of estrogen contained in their product" and that "plaintiff's prescribing healthcare provider [] relied on defendant's misrepresentations." Appellant Br. at 54. Put simply, Yates failed to "'set forth the terms of the warranty upon which [she] relied.'" *Goldemberg*, 8 F. Supp. 3d at 482 (quoting *Parker*, 930 N.Y.S.2d at 29). Accordingly, the district court properly dismissed Yates's breach of express warranty claim.

CONCLUSION

For the reasons discussed above, we affirm the district court's grant of summary judgment to defendants.