10-21-2014

In re: Avandia Marketing

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 13-4323

_____

IN RE: AVANDIA MARKETING SALES PRACTICES
& PRODUCTS LIABILITY LITIGATION

RICHARD V. D'APUZZO, on behalf of himself
and all others similarly situated,
Appellant

_____

On Appeal from the District Court
for the Eastern District of Pennsylvania
D.C. Civil No. 2-07-cv-04963 and 2-07-md-01871
(Honorable Cynthia M. Rufe)

_____

Argued: April 7, 2014

Before: FISHER, SCIRICA, and COWEN, *Circuit Judges*

(Filed: October 21, 2014)

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OPINION OF THE COURT

SCIRICA, *Circuit Judge*.

At issue in this diversity action is whether plaintiff has stated a claim under Federal Rule of Civil Procedure 12(b)(6) for breach of express warranty under New Jersey law. The trial court granted defendant's motion to dismiss, and plaintiff appeals.[1] We will affirm.[2]

I.

Richard V. D'Apuzzo, who suffers from Type 2 diabetes mellitus, filed suit alleging GlaxoSmithKline LLC ("GSK") caused him economic harm by misrepresenting

[1] We exercise plenary review over a district court's ruling on a Rule 12(b)(6) motion to dismiss. *Byers v. Intuit, Inc.*, 600 F.3d 286, 291 (3d Cir. 2010). A federal court sitting in diversity must apply state substantive law and federal procedural law. *See Liggon-Redding v. Estate of Sugarman*, 659 F.3d 258, 262 (3d Cir. 2011) (citing *Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938)).

[2] The District Court had diversity jurisdiction under 28 U.S.C. § 1332. We have appellate jurisdiction under 28 U.S.C. § 1291.

the safety and efficacy of its diabetes drug Avandia.[3] D'Apuzzo does not allege Avandia harmed him physically or that he experienced any cardiovascular injury. Instead, D'Apuzzo contends he would have paid less for safer, more effective insulin had GSK not expressly warranted Avandia to be safe and effective in treating type 2 diabetes. App. 25, 80. Specifically, he contends Avandia was approximately twenty-two times more expensive than older available drugs, such as insulin, that were often more effective and better tolerated than Avandia. App. 23. D'Apuzzo seeks damages for the higher cost, including co-payments, he paid for Avandia as a result of GSK's warranty that the drug was safe and effective. D'Apuzzo claims GSK breached an express warranty because Avandia is neither safe nor effective in treating diabetic patients like him when taking into account glycemic control and risk factors. Yet D'Apuzzo does not allege that Avandia caused him harm or was ineffective for him.

D'Apuzzo filed his initial class action complaint[4] on July 13, 2007, and his first amended complaint on October 24, 2007, both in the U.S. District Court for the District of New Jersey. The case was then transferred to the U.S. District Court for the Eastern District of Pennsylvania as part of MDL No. 1871 pursuant to an order from the Judicial

[3] Approved by the Food and Drug Administration on May 25, 1999, as an oral antidiabetic agent, Avandia is recommended and prescribed for the management of type 2 diabetes mellitus (also referred to as non–insulin-dependent diabetes or adult-onset diabetes).

[4] D'Apuzzo sought to include in the class patients who were prescribed and purchased Avandia (rosiglitazone maleate) and two related pharmaceuticals manufactured by GSK—Avandamet (a combination of rosiglitazone maleate and metformin) and Avandaryl (a combination of rosiglitazone maleate and glimepiride)—in New Jersey after May 25, 1999. The District Court dismissed the case before making any decision on class certification.

Panel on Multidistrict Litigation.[5] On June 6, 2010, D'Apuzzo filed his second amended complaint, alleging violations of the New Jersey Consumer Fraud Act and unjust enrichment. On September 7, 2011, on GSK's motion, the District Court dismissed D'Apuzzo's second amended complaint without prejudice. On October 25, 2011, D'Apuzzo filed his third amended complaint, alleging violations of the New Jersey Consumer Fraud Act, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, negligence, and unjust enrichment. GSK moved to dismiss the third amended complaint under Rule 12(b)(6).

On October 15, 2013,[6] the District Court granted GSK's Rule 12(b)(6) motion to dismiss the entire complaint with prejudice, concluding it would be inequitable to permit D'Apuzzo a fourth opportunity to state a claim. The District Court dismissed all but one of D'Apuzzo's claims—for violations of the New Jersey Consumer Fraud Act, breach of implied warranty, fraud, negligent misrepresentation, negligence, and unjust enrichment—as barred by the New Jersey Products Liability Act ("PLA"), N.J. Stat. Ann. §§ 2A:58C-1 *et seq.*, which is the exclusive basis for any New Jersey products liability

[5] D'Apuzzo's case is one of approximately 4,900 Avandia lawsuits centralized in the United States District Court for the Eastern District of Pennsylvania under MDL No. 1871. In centralizing these suits, the Judicial Panel on Multidistrict Litigation noted the actions "arise from allegations that certain diabetes drugs manufactured by GSK—Avandia and/or two sister drugs containing Avandia (Avandamet and Avandaryl)—cause an increased risk of heart attack and other physical injury, and that GSK failed to provide adequate warnings concerning that risk." *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 528 F. Supp. 2d 1339, 1340–41 (J.P.M.L. 2007). As noted, D'Apuzzo does not allege he suffered physical injury as a result of taking Avandia.

[6] On July 10, 2013, the District Court issued a memorandum opinion and order dismissing D'Apuzzo's complaint. It vacated that order on July 24, 2013, and issued a revised memorandum opinion and order dismissing the case on October 15, 2013.

action, except for express warranty and environmental tort actions.[7] App. 3-4. D'Apuzzo does not appeal the dismissal of those claims.[8]

The District Court also dismissed D'Apuzzo's express warranty claim—which is explicitly exempt from the ambit of the PLA—for failure to allege the "exact text of the warranties, or the precise time periods these warranties were in effect." App. 5. D'Apuzzo filed this timely appeal, in which the only ruling he challenges is the dismissal of his express warranty claim.

D'Apuzzo contends GSK "expressly warranted on its labels and packaging to Plaintiffs, prescribers, and patients, that Avandia would provide assist [sic] 'in the

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[7] The PLA defines a "product liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C-1(b)(3). The PLA "is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 924 A.2d 484, 503 (N.J. 2007). A plaintiff cannot circumvent the PLA by asserting other causes of action stemming from harm caused by a product if those causes of action are not excluded from the PLA's ambit. *See, e.g.*, *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991) ("We . . . predict that the New Jersey Supreme Court would hold that the [PLA] generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to consumers injured by a defective product."); *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 702–04 (D.N.J. 2011); *Sinclair v. Merck & Co.*, 948 A.2d 587, 595–96 (N.J. 2008); *Bailey v. Wyeth, Inc.*, 37 A.3d 549, 582–84 (N.J. Super. Ct. Law Div. 2008), *aff'd sub nom. DeBoard v. Wyeth, Inc.*, 28 A.3d 1245 (N.J. Super. Ct. App. Div. 2011).

[8] The PLA requires a plaintiff to have suffered (a) physical damage to property (other than to the product itself), (b) personal physical injury, (c) pain and suffering or emotional harm, or (d) any loss of consortium or services deriving from these types of harm. N.J. Stat. Ann. § 2A:58C-1(b)(2). As noted, D'Apuzzo only alleges he suffered economic loss—the amount of money he paid for Avandia, including insurance co-payments—and does not allege he suffered any physical injury. *See Sinclair*, 948 A.2d at 595 (rejecting claim for economic loss under the PLA for failure to allege physical injury).

management of type 2 diabetes mellitus' in a safe and efficacious manner."[9] App. 80. But D'Apuzzo does not allege GSK made unqualified or absolute guarantees of Avandia's safety and efficacy. Nor could he make such an allegation given that the "express warranty" contained in Avandia's "labels and packaging" consists of much more than "safe and effective." The Avandia label discloses contraindications, risk factors, and potential side effects of taking the drug, thereby warning it may not be safe under all circumstances for every person. The Avandia label in effect when D'Apuzzo started taking the drug in October 2002 warned, among other things, that (1) Avandia could exacerbate congestive heart failure, (2) patients at risk for heart failure should be monitored, and (3) Avandia was contraindicated for patients with New York Heart Association Class III and IV cardiac status.[10] The label was revised in 2003 to more prominently feature the cardiac side effects warning and to include data from clinical studies indicating that Avandia could increase the risk of cardiovascular events.[11] GSK later added to the label a black box warning of the risk of congestive heart failure and myocardial infarction (heart attack).[12] Even with these potential side effects, Avandia

[9] D'Apuzzo's factual allegations are taken from his third amended complaint.

[10] *See Avandia Approval History*, NDA 021071, Apr. 3, 2000, Label, FDA, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-071S001_Avandia_prntlbl.pdf.

[11] *See Avandia Approval History*, NDA 021071, Feb. 27, 2003, Label, FDA, http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/021071s004lbl.pdf.

[12] *See Avandia Approval History*, NDA 021071, Aug. 14, 2007, Feb. 3, 2011, Labels, FDA, www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf (Aug. 14, 2007, label), www.accessdata.fda.gov/drugsatfda_docs/label/2011/021071s038, 021410s026,021700s010lbl.pdf (Feb. 3, 2011, label).

remains on the market today.[13]

II.

A.

Under Federal Rule of Civil Procedure 12(b)(6), we assume plaintiff's well-pleaded, nonconclusory factual allegations to be true. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). D'Apuzzo contends he adequately pleaded his express warranty claim because (1) New Jersey law does not require the use of particular language for the creation of an express warranty and (2) his third amended complaint referenced general representations of safety and efficacy contained in Avandia's labeling and package inserts as the source of the express warranty. The District Court disagreed, concluding that D'Apuzzo's failure "to allege the exact text of the warranties, or the precise time periods these warranties were in effect" was fatal to his express warranty claim. App. 5. We agree with the District Court that D'Apuzzo's allegations were general and vague. But we need not decide whether D'Apuzzo was required to provide the exact text and time period of the warranties because we can decide this case on another ground—D'Apuzzo's failure to state an express warranty claim as a matter of New Jersey law. *See Brightwell v. Lehman*, 637 F.3d 187, 191 (3d Cir. 2011) ("We may affirm a district court for any reason supported by the record."). Our decision turns not on the federal pleading standard and whether D'Apuzzo adequately pleaded the content of the express warranty he alleged, but instead on whether the language of GSK's label creates an express

[13] *See Drug Details—Avandia*, FDA, www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=Avandia (last visited Sept. 12, 2014).

warranty under New Jersey law.[14] Because we conclude the statement that Avandia is "safe and effective" for its intended use contained on its label disclosing contraindications, risk factors, and potential side effects of the drug is not sufficient as a matter of law to state a New Jersey express warranty claim, we will affirm.

B.

D'Apuzzo must state a valid express warranty claim as a matter of New Jersey substantive law to avoid dismissal.[15] In order to state a claim for breach of express warranty under New Jersey law, plaintiff must allege (1) GSK made an affirmation of fact, promise, or description about the product; (2) this affirmation of fact, promise, or description became part of the basis of the bargain for the product; and (3) the product ultimately did not conform to the affirmation of fact, promise, or description. *See* N.J. Stat. Ann. § 12A:2-313. Under New Jersey law, "guarantees of future performance should be specific." *See Herbstman v. Eastman Kodak Co.*, 342 A.2d 181, 187 (N.J. 1975). To create an express warranty, the seller need not use formal words such as "warrant" or "guarantee" or have a specific intention to make a warranty. N.J. Stat. Ann. § 12A:2-313. But that does not mean D'Apuzzo is relieved from identifying the affirmation of fact, promise, or description he contends constitutes the express warranty

[14] Because D'Apuzzo's complaint explicitly refers to Avandia's "labels" and those documents are publicly available on the FDA's website, we may take judicial notice of the labels' content. *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426–27 (3d Cir. 1999); *see also, e.g., Pryor v. NCAA*, 288 F.3d 548, 559–60 (3d Cir. 2002). We do so here not in the ordinary course but because, for the reasons described below, D'Apuzzo's express warranty claim cannot proceed under New Jersey substantive law regardless of how it is pleaded.

[15] Following oral argument, plaintiff requested we certify the question to the Supreme Court of New Jersey. We denied the motion.

under New Jersey law. *Id.*

For the first time on appeal—but in none of his complaints—D'Apuzzo focuses on one statement from a 2007 Avandia label that he alleges created an express warranty: "The 8 mg daily dose has been shown to be safe and effective in clinical studies as monothereapy [sic] and in combination with metformin, sulfonylurea, or sulfonylurea plus metformin."[16] Appellant Br. 21.[17]

This statement asserts only that a particular dose of Avandia has been shown to be safe and effective in clinical studies.[18] FDA regulations required GSK to disclose the highest dose for which the safety and efficacy of Avandia had been established in clinical trials. *See* 21 C.F.R. § 201.57(c)(3)(i)(B) (noting prescription drug labeling must identify an upper limit dose beyond which the safety and effectiveness of the drug have not been

[16] Two cases on which D'Apuzzo relies serve only to highlight his failure to identify with specificity the affirmation of fact, promise, or description he contends is the express warranty. *See Stewart v. Smart Balance, Inc.*, No. 11-6174, 2012 WL 4168584, at *11–12 (D.N.J. June 26, 2012) (refusing to dismiss breach of express warranty claim alleging defendants sold milk labeled "fat free" that failed to meet federal regulations for fat-free milk); *In re Ford Motor Co. E-350 Van Prods. Liab. Litig. (No. II)*, No. 03-4558, 2008 WL 4126264, at *3–5 (D.N.J. Sept. 2, 2008) (refusing to dismiss breach of express warranty claim alleging Ford marketed vans as "15-passenger" that could not safely transport 15 passengers). Unlike D'Apuzzo's general allegations against GSK, plaintiffs in these cases pointed to specific affirmations of fact or descriptions—"fat free" and "15-passenger"—that they alleged constituted express warranties.

[17] Typically, D'Apuzzo's citation to this passage for the first time in his appellate brief would be improper and we would decline to consider it. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 303 (3d Cir. 2011) ("[O]rdinarily a court of appeals should not take judicial notice of documents on an appeal which were available before the district court decided the case but nevertheless were not tendered to that court."). But in this case we will consider the passage because it comes from a 2007 Avandia label of which we have taken judicial notice.

[18] Plaintiff's complaint fails to specify the particular dose of Avandia he took.

established or increased doses do not result in increased effectiveness).[19] And the statement D'Apuzzo cites, when considered alone, does not claim Avandia will be safe and effective in every case for every consumer.

Nor could it be read to make that claim when considering the entirety of the Avandia label. *See Gladden v. Cadillac Motor Car Div., Gen. Motors Corp.*, 416 A.2d 394, 397 (N.J. 1980) (determining whether an express warranty was created by evaluating an owner's guide and guarantee document in its entirety). Crucially, Avandia's labeling discloses contraindications, risk factors, and possible side effects of the drug, thereby indicating the drug might prove dangerous or ineffective for some people. The August 14, 2007 Avandia label discloses, among other things, that Avandia is contraindicated for patients with New York Heart Association Class III or IV heart failure, may increase the risk of cardiac failure or other cardiac effects, should be used with caution in patients with edema, may increase the risk of hypoglycemia, may cause weight gain, may increase the risk of bone fractures in women, and may increase the risk of pregnancy. *See Avandia Approval History*, NDA 021071, Aug. 14, 2007, Label, FDA, www.accessdata.fda.gov/drugsatfda_docs/label/2007/021071s028lbl.pdf. These contraindications, risk factors, and possible side effects are the primary reasons D'Apuzzo required a prescription to obtain Avandia. Because GSK disclosed Avandia's contraindications, risk factors, and possible side effects on the drug's label, the statement

[19] The FDA regulates the approval and labeling of new drugs. As part of the approval process, the FDA evaluates a new drug's safety and effectiveness as well as its proposed labeling. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470–71 (2013); *see also* 21 U.S.C. § 355; 21 C.F.R. § 201.5.

on that same label that the 8 mg dose of Avandia has been shown in clinical trials to be "safe and effective" for its intended use cannot be read as an unqualified guarantee that Avandia would be safe and effective for all consumers.

No New Jersey authority directly addresses the question of whether the statement that Avandia is "safe and effective" for its intended use—contained on a label disclosing contraindications, risk factors, and potential side effects—is sufficient to create an express warranty under New Jersey law. Accordingly, we interpret New Jersey law as we predict it would be interpreted by the Supreme Court of New Jersey. *See Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 244 (3d Cir. 2010). "In making such a prediction, we . . . consider relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would resolve the issue at hand." *Id.* (internal quotation marks and citation omitted).

New Jersey's express warranty statute follows section 2-313 of the Uniform Commercial Code. *Compare* N.J. Stat. Ann. § 12A:2-313, *with* U.C.C. § 2-313. Connecticut's and Ohio's express warranty statutes also follow section 2-313,[20] and courts interpreting the law of these states have refused to find the words "safe and effective" to create an express warranty in the absence of representations that a drug was free from all harmful side effects or was absolutely harmless. *See Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 428 (2d Cir. 1969) ("[W]e need say only that defendant did not represent either (1) that its drugs were free from all harmful side effects or (2) that its

[20] *See* Conn. Gen. Stat. Ann. § 42a-2-313; Ohio Rev. Code Ann. § 1302.26.

drugs were absolutely harmless."); *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 257–58 (D. Conn. 2012) ("[A] drug manufacturer's representation in advertising or a warning label that a product is safe and effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects."); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) (finding under Ohio law that "asserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty"). These authorities are consistent with the well-established principle that "safe and effective" are relative terms in the pharmaceutical industry—"safe" drugs harm some people and "effective" drugs do not work in every case. *See Bailey v. Wyeth, Inc.*, 37 A.3d 549, 554 n.8 (N.J. Super. Ct. Law Div. 2008) (noting the FDA concedes "no drug is absolutely safe [and] all drugs have side effects" and defines "safe" to mean "the benefits of the drug appear to outweigh the risks" (internal quotation marks omitted)); 21 C.F.R. § 201.57 (noting effective means there is substantial evidence of the drug's effectiveness based on adequate, well-controlled clinical studies).[21]

[21] These cases should not be read as foreclosing express warranty claims against pharmaceutical manufacturers or retailers. In certain circumstances, courts have found express warranties with respect to drug safety. *See Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 570–72 (Md. 2006) (concluding a package insert instructing patients to "[t]ake with food or milk if stomach upset occurs" could constitute an express warranty and noting that *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, "do[es] not support the proposition that there can never be an express warranty with respect to prescription drugs"); *Grinnell v. Charles Pfizer & Co.*, 79 Cal. Rptr. 369, 377–78 (Dist. Ct. App. 1969) (finding that a package insert indicating that "'[t]here are no known contraindications to oral polio virus vaccines" was an affirmation of fact that constituted an express warranty).

Our decision in *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 574–76 (3d Cir. 1990), *aff'd in part, rev'd in part on other grounds*, 505 U.S. 504 (1992), is consistent with these cases interpreting Connecticut and Ohio law. In *Cipollone*, the plaintiff cited specific representations made in Chesterfield cigarette advertisements. One advertisement stated, without qualification, that "NOSE, THROAT, and Accessory Organs [are] not Adversely Affected by Smoking Chesterfields." *Id.* at 575. Another advertisement cited a study that purportedly showed "proof" that Chesterfield cigarettes "never . . . did you any harm." *Id.* Other advertisements suggested consumers should "PLAY SAFE" and "Smoke Chesterfield" and described cigarettes as "just what the doctor ordered." *Id.* We concluded that under New Jersey law a "reasonable jury could infer that an unqualified representation that smoking is safe creates a warranty that smoking for a long period of time is safe." *Id.* at 576. Unlike the plaintiff in *Cipollone*, D'Apuzzo does not allege GSK made unqualified promises or affirmations of fact regarding Avandia.

Marko v. Sears, Roebuck & Co., 94 A.2d 348 (N.J. Super. Ct. App. Div. 1953), similarly involved absolute assurances of safety. In that case, the plaintiff was injured when a lawnmower kept operating upon striking a rock despite a salesman's assurances the mower was "absolutely safe" and would stop operation upon contacting an obstacle. *Id.* at 349. The court found plaintiff made out a breach of express warranty claim because "[u]nder the warranty in question . . . plaintiff had a right to expect that when the mower struck the rock the blade would stop revolving and the machine would stop operating." *Id.* at 350. Unlike in *Marko*, D'Apuzzo has not alleged GSK promised

Avandia would be safe for all consumers, and GSK's disclosure of Avandia's contraindications, risk factors, and potential side effects on the drug's label indicates GSK did not make such an unqualified guarantee.

Although some courts have permitted express warranty claims based on the representation that a drug or medical device was safe and effective, these cases involved more substantial representations than those at issue here. *See, e.g.*, *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625–26 (E.D. Pa. 2008) (refusing to dismiss express warranty claim on summary judgment where plaintiff alleged manufacturer represented the drug to be safe and effective in "various articles, conferences, and journals presented to the medical community" and had made specific statements regarding the drug's safety and efficacy in a particular group); *Simonet v. SmithKline Beecham Corp.*, 506 F. Supp. 2d 77, 88–89 (D.P.R. 2007) (refusing to grant motion to dismiss where plaintiff alleged manufacturer made representations regarding its tablets' dissolution rate and controlled-release effect in numerous sources but defects in the tablets caused them not to function as described); *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 207–08 (Colo. 1984) (finding a jury could reasonably have concluded that manufacturer's representations regarding a medical device—including that it could "prevent pregnancy without producing any general effects on the body, blood or brain"—could constitute an express warranty). By contrast, D'Apuzzo alleges only that GSK represented Avandia as "safe and efficacious" in one source—Avandia's "labels and packaging"—and on appeal points to only one qualified statement on the label. *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d at 818 (determining under Ohio law that a manufacturer's representation of a drug as "safe

and effective"—without more substantial factual allegations by plaintiffs—did not constitute an express warranty).

Because GSK disclosed Avandia's contraindications, risk factors, and potential side effects and D'Apuzzo does not allege GSK made unqualified guarantees of safety or effectiveness, D'Apuzzo has failed as a matter of New Jersey law to state an express warranty claim.

C.

At oral argument, D'Apuzzo contended GSK also breached the alleged express warranty because the company failed to disclose or understated known cardiac risks that rendered Avandia potentially dangerous to consumers. This argument is unavailing because it is an attempt to argue a failure to warn cause of action in an express warranty appeal.

Failure to warn and express warranty are different causes of action. *See, e.g.*, *Cipollone*, 505 U.S. at 524–25 (analyzing failure to warn and express warranty claims as separate causes of action). A failure to warn claim is a type of product liability action governed by the New Jersey Products Liability Act. *See Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1055 (N.J. 2012) (noting the PLA defines an adequate product warning as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product" (internal quotation marks omitted)).

But D'Apuzzo's appeal is based on express warranty, which is specifically excluded from the scope of the PLA because it is not a product liability cause of action.

See N.J. Stat. Ann. § 2A:58C-1b(3) ("'Product liability action' means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty."). D'Apuzzo never raised a failure to warn claim, and he cannot raise that claim for the first time in this appeal of the dismissal of his express warranty cause of action. *See, e.g.*, *Freeman v. Pittsburgh Glass Works, LLC*, 709 F.3d 240, 249 (3d Cir. 2013) ("We generally refuse to consider issues that the parties have not raised below.").

Accordingly, we reject D'Apuzzo's attempt to advance a failure to warn cause of action in this express warranty appeal.

III.

Because D'Apuzzo has not stated a claim for breach of express warranty under New Jersey law, we will affirm the District Court's dismissal of D'Apuzzo's express warranty claim under Federal Rule of Civil Procedure 12(b)(6).