SOUTHERN ILLINOIS UNIVERSITY
2024 INTRAMURAL MOOT COURT COMPETITION

Docket No. 24-9176

MEDNOLOGY, INC.,
Petitioner,
v.
UNITED STATES EX REL. Riley ORTEGA,
Respondent.

Transcript of Record

In conjunction with the
National Health Law Moot Court Competition
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THE UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF TRANSYLVANIA

UNITED STATES EX REL. RILEY ORTEGA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	ORDER
	)	
MEDNOLOGY, INC.,		CASE No. 24-cv-12121
	)	
Defendant.	)	
_____	)	_____

MARCUS BURNS, UNITED STATES DISTRICT JUDGE

This case comes before this Court on Defendant Mednology, Inc.'s (hereinafter "Mednology") motion to dismiss Plaintiff Riley Ortega's state law claims along with her claim under the False Claims Act. Mednology seeks to dismiss Riley's claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. Specifically, Mednology asserts that its alleged fraudulent conduct toward the Food and Drug Administration (FDA) cannot serve as a valid basis for Riley's False Claims Act claim and that federal law preempts the pertinent state laws Riley relies on to bring her state law claims. Riley challenges these assertions and asks this Court to deny Mednology's motion to dismiss.

After considering the parties' competing positions, this Court concludes that Mednology's motion to dismiss should be denied in part and granted in part. Specifically, Mednology's motion to dismiss Riley's state law claims shall be denied because federal law does not preempt any provision that would neutralize Mednology's immunity under the State of Transylvania's immunity statute. On the other hand, Mednology's motion to dismiss Riley's claim under the False Claims Act shall be

granted because her False Claims Act action cannot be based entirely on Mednology's conduct of fraudulently obtaining FDA approval for its medical device.

FACTUAL BACKGROUND

The following facts are taken from the pleadings and are assumed true only for the purposes of the motions that are before this Court.

Riley Ortega is a citizen of the State of Wohio. She recently retired from military service as an artillery officer for the United States Army. Because memories of traumatic events she encountered during her military service disrupt her day-to-day functioning, she is diagnosed with post-traumatic stress disorder (PTSD). Such traumatic memories contribute to her insomnia and sleep apnea symptoms. When she visited her somnologist to find out if there was a way for her to alleviate her sleep apnea and insomnia symptoms, her somnologist prescribed to her a sleep-inducing medical device called Sleepternity.

Sleepternity is a state-of-the-art continuous positive airway pressure (CPAP) machine that provides several unique features. Some features this medical device provides include an automatic pressure adjustment system that can increase therapy comfort, a heated humidifier attached to the mask that helps to reduce dryness and irritation, and a smartphone app that enables Sleepternity users to customize various machine settings. Additionally, the device comes with noise-cancelling sleep headphones that can be attached to the mask. The sleep headphones emit gentle pulses that travel to the user's brain and are ultimately designed to help users relax and fall asleep gently. Since CPAP machines are generally used to reduce the occurrence of sleep apnea, the additional features unique to Sleepternity make the medical device revolutionary in that it can also help users to effectively reduce insomnia. Sleepternity was recently approved for marketing as a Class III medical

device by the FDA on December 30, 2022. Shortly afterwards, the Centers for Medicare and Medicaid Services (CMS) began to provide coverage to individuals who were prescribed Sleepternity for the costs of using the device, since the device was approved for marketing by the FDA.

Unbeknownst to the FDA or Riley, Mednology modified the sound-dampening foam contained in the Sleepternity machine after receiving FDA approval for marketing the device. Specifically, the corporation replaced the silicone-based foam with a polyester-based polyurethane (PE-PUR) foam and did not disclose such modification to the FDA. Sleepternity allegedly made the modification to reduce manufacturing costs, since polyurethane is generally cheaper than silicone. At the same time, PE-PUR foams can present significant health risks, and in June 2021, Philips Respironics (Philips), another medical device company, recalled from the market certain CPAP machines that contained PE-PUR sound abatement foams. According to the FDA, PE-PUR foams used in these devices to reduce sound and vibration can break down over time. If the foam breaks down, then volatile organic compounds (VOCs) that are not visible could be breathed in or swallowed by CPAP users. Since breathing in VOCs or swallowing small pieces of foam can result in health risks, Philips recalled their CPAP devices containing PE-PUR foams and sought to replace such foams with silicone-based foams as a safer alternative.[1]

Riley was not aware of the presence of PE-PUR foams in Sleepternity until after she experienced asthma attacks and had to be transported to the emergency room at a nearby hospital. After stabilizing her conditions and inquiring whether she was on any prescriptions, the on-call

[1] For more information about Philips Respironics recalling its CPAP machines containing PE-PUR-based foams, see *Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/foam-testing-summary-recalled-philips-ventilators-bipap-machines-and-cpap-machines#:~:text=Following%20the%20initial%20recall%20in,2021%20on%20the%20new%20foam (last updated Apr. 10, 2024).

emergency room physician recommended that she stop using Sleepternity. Her primary care physician agreed after concluding that her asthma attacks constituted unknown side effects of the medical device. At the time, Riley and her physician knew she was allergic to isocyanate, which is a VOC that comes from degraded polyurethane.[2] However, they did not consider her isocyanate allergy to be behind her asthma attacks because Sleepternity's warning label did not contain any information about the presence of isocyanates in the device. Although Riley's asthma symptoms subsided once she discontinued her use of Sleepternity, her asthma attacks caused her lungs to be chronically inflamed, and her sleep apnea symptoms returned.[3] Although she continues to use the Sleepternity headband to treat her insomnia, her sleep apnea symptoms persist to this day notwithstanding her use of various sleep apnea medications.

Initially, Riley assumed that Sleepternity was simply not a suitable device for treating her sleep apnea problem. However, her brother Jim, who works as an assembly manager at Mednology, thought that the corporation's replacement of silicone-based sound abatement foams with PE-PUR foams in Sleepternity may have contributed to the asthma attacks she suffered from. Jim ultimately informed her that the corporation initially utilized silicone-based foams to secure marketing approval from the FDA and that it replaced such foams with PE-PUR foams to save manufacturing costs before packaging and sending Sleepternity to its distributors. The information Jim provided to Riley led her to realize, after further research, that the PE-PUR foams, which could degrade into

[2] Specifically, polyurethane is typically produced by reacting polymeric isocyanate with polyol. *See Polyurethane*, AM. CHEMISTRY COUNCIL, https://www.americanchemistry.com/chemistry-in-america/chemistries/polyurethane (last visited June 2, 2024).

[3] Under the Honoring our Promise to Address Comprehensive Toxics (PACT) Act, chronic inflammation of the lungs is one of the conditions that are presumed to have been caused by the veteran's service in the military. *See* Honoring our PACT Act of 2022, Pub. L. 117-168, 136 Stat. 1759. However, for this competition, you are prohibited from raising any arguments that address the PACT Act, since the Act is not one of the principal issues in the competition problem.

certain forms of isocyanate,[4] likely contributed to her asthma attacks that caused her lungs to be chronically inflamed.

PROCEDURAL BACKGROUND

On June 21, 2023, Riley Ortega brought a products liability action against Mednology for its fraudulent production of Sleepternity soon after reporting Mednology's alleged fraudulent conduct to the FDA. Among other things, she asserts that Mednology breached its duty of care and good faith in violation of Transylvania's product liability statute. Under the same statute, she asserts that Mednology breached its duty to disclose to the FDA the modifications it made to the sound abatement foams in Sleepternity and its duty to warn about the dangers and risks associated with the presence of PE-PUR foams in the Sleepternity device. Finally, she relies on the fraud-on-the-FDA theory to bring a False Claims Act (FCA) (31 U.S.C. §§ 3729–3733 (2024)) action under the Act's *qui tam* provision (31 U.S.C. § 3730(b)) against Mednology. The United States declined to intervene in her FCA action against Mednology.

Because another medical device company recalled its CPAP devices due to the health risks associated with PE-PUR sound abatement foams, Riley asserts in her complaint that the FDA would not have approved Sleepternity if the device contained PE-PUR foams instead of silicone foams. Under this assertion, she contends that Mednology fraudulently obtained FDA approval for its Sleepternity device by utilizing silicone-based foams only to obtain such approval and by not disclosing to the agency its use of PE-PUR foams in the devices that were marketed and sold to consumers.

[4] *See* Lena Låstbom et al., *Effects of thermal degradation products from polyurethane foams based on toluene diisocyanate and diphenylmethane diisocyanate on isolated, perfused lung of guinea pig*, 29 SCAND. J. WORK ENV. HEALTH 152, 154–56 (2003).

Shortly after Riley served a summons and a copy of her complaint to Mednology, Mednology voluntarily recalled Sleepternity from the market pursuant to 21 C.F.R. § 7.40(b). In response, the FDA decided not to continue investigating Mednology's alleged fraudulent conduct to focus on investigating other allegedly defective products in the marketplace that have not been recalled.

The State of Transylvania's legislature recognizes the importance of safeguarding the health and safety of its residents. Accordingly, it has codified various common law tort claims after finding that such claims are critical for facilitating its traditional ability to protect the health and safety of its citizens. *E.g.*, *Cipollone v. Liggett Grp.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part). Product liability claims are some of the common law tort claims it has codified. The State of Transylvania's product liability statute provides the following:

> Manufacturers and distributors of a product owe a duty of care and good faith to their consumers throughout the manufacturing and distribution of such product, including the duty to warn of any dangers or risks associated with the product, the duty to comply with all the state and federal laws and regulations governing the manufacturing and distribution of the product, and the duty to make disclosures to appropriate agencies or government officials about any modifications made to the product. Any resulting injury or death that would not have occurred but for the breach of any of the aforementioned duties shall serve as adequate basis for liability under this statute.

21 Trans. Comp. Stat. § 630.545 (2024). When the legislature codified this statute, it sought to protect the residents of Transylvania from any physical or emotional harm that would result from breaching the duty of care and good faith in manufacturing and distributing the product causing such harm. After all, its statement of purpose for enacting the product liability statute provides:

> It is the goal of the legislature to encourage manufacturers and distributors of various products to prioritize the health and safety of its consumers when manufacturing or distributing such products. It is also the goal of the legislature to encourage consumers who believe their injury resulted from a manufacturer and/or distributor's failure to exercise care, precaution, or good faith in manufacturing and/or distributing the product to bring a valid claim against the manufacturer and/or distributor.

Id. § 630.544.

At the same time, Transylvania's legislature intended to shield drugmakers or medical device manufacturers from product liability suits as long as the FDA had approved the drug or medical device in question. Thus, the pertinent provision states:

> In a product liability action against a manufacturer or distributor, a product that is a drug or a medical device is not defective or unreasonably dangerous, and the manufacturer or distributor is not liable, if the drug or medical device was approved for efficacy and safety by the United States Food and Drug Administration, and the drug or medical device was in compliance with the United States Food and Drug Administration's approval at the time the drug or medical device left the control of the manufacturer or distributor. Such drug or medical device is presumed to have been in compliance with the United States Food and Drug Administration's approval, and the party challenging a manufacturer's or distributor's immunity under this statute bears the burden of rebutting this presumption.

21 Trans. Comp. Stat. § 630.546(a). Nevertheless, the legislature enacted two critical exceptions to the immunity granted under subsection (a). The exception under subsection (b) provides:

> The immunity granted under subsection (a) does not apply if the defendant, at any time before the event that allegedly caused the injury, intentionally withholds from or misrepresents to the United States Food and Drug Administration information concerning the drug or the medical device that is required to be submitted under the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301–399i) and the drug or medical device would not have been approved, or the United States Food and Drug Administration would have withdrawn approval for the drug or medical device if the information were accurately submitted.

Id. § 630.546(b). Finally, the exception under subsection (c) provides: "The immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the drug or medical device as required by the FDA." *Id.* § 630.546(c). Because Riley contends that Mednology intentionally misrepresented to the FDA the materials contained in the sound abatement foams within the Sleepternity machine, she insists that the exception under subsection (b) applies in her product liability action against Mednology. Riley also contends that the exception under subsection

(c) applies because Mednology has failed to warn about the dangers or risks associated with the presence of PE-PUR foams in Sleepternity.

In its motion to dismiss, Mednology contends that the subsection (b) exception is preempted under the federal Food, Drug and Cosmetic Act (FDCA), meaning that the immunity provision under subsection (a) applies and ultimately shields it from Riley's claims under Transylvania's product liability statute. It also asserts that the same Act preempts the exception under subsection (c), which Riley relies on for her failure to warn claim. Finally, regarding her False Claims Act (FCA) claim, it insists that the fraud-on-the-FDA theory is not a viable basis for bringing such claim. For these reasons, it asserts that Riley has failed to state any claims upon which relief can be granted and that her product liability action should accordingly be dismissed. On September 12, 2023, this Court heard arguments on Mednology's motion to dismiss.

DISCUSSION

I. Riley's Claims Under Transylvania's Product Liability Statute

Even though Mednology is generally immune, under 21 Trans. Comp. Stat. § 630.546(a), from product liability lawsuits, Riley relies on two exceptions to such immunity that are provided under subsections (b) and (c). In its motion to dismiss, Mednology asserts that these two exceptions are preempted by the FDCA and that it is thus immune from Riley's claims brought under Transylvania's product liability statute. The Court will analyze the merits of Mednology's preemption arguments for subsections (b) and (c) separately.

To withstand a defendant's motion to dismiss, a plaintiff is required to plead "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when "the plaintiff pleads factual content that allows the

court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). When reviewing a defendant's motion to dismiss, the Court must accept all well-pled facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Crescent Plaza Hotel Owner, L.P. v. Zurich Am. Ins. Co.*, 20 F.4th 303, 307 (7th Cir. 2021). Moreover, dismissal of plaintiff's complaint is permitted only when "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) (citing *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957)).

With these standards in mind, the Court now reviews the merits of Mednology's argument that the FDCA preempts the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute.

A. The FDCA does not preempt the immunity exception provided in 21 Trans. Comp. Stat. § 630.546(b).

As inscribed in the Constitution's Supremacy Clause, the federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution *or Laws of any State to the Contrary notwithstanding*." U.S. Const. art. VI, cl. 2 (emphasis added). This language in the Constitution provides the foundation for the doctrine of federal preemption, where federal law supersedes conflicting state laws. *See Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018); *see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). The U.S. Supreme Court explained that "[p]re-emption may be either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Gade*, 505 U.S. at 98 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

Within the FDCA is an express preemption provision that applies to state laws or regulations governing medical devices. Specifically, the provision provides that states may not establish requirements that are "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). In addition, the Supreme Court has construed Section 337(a) of the FDCA to provide "clear evidence that Congress intended that the [Act] be enforced exclusively by the Federal Government," thereby impliedly preempting state law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Section 337(a) provides that "all . . . proceedings for the enforcement . . . of this Act shall be by and in the name of the United States." 21 U.S.C. § 337(a). Therefore, state law claims that are solely based on noncompliance with the FDCA are impliedly preempted because the authority to bring such claims rests with "the Federal Government rather than private litigants." *Buckman Co.*, 531 U.S. at 349 n.4. This means claims that "seek to privately enforce duties owed to the FDA" are impliedly preempted, regardless of how litigants label such claims. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). At the same time, a state law claim could survive both forms of preemption if the plaintiff sues "for conduct that violates a federal requirement (avoiding express preemption)" but does not sue "*only* because the conduct violated that federal requirement (avoiding implied preemption)." *Id.* (emphasis added) (citing *In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010)).

In its motion to dismiss, Mednology contends that because Riley's reliance on the subsection (b) exception is essentially equivalent to her suing Mednology only for the corporation's violation of a federal requirement (i.e., its misrepresentation to the FDA about the materials contained in Sleepternity's sound abatement foams), subsection (b) must be impliedly preempted by the FDCA. In other words, Mednology is arguing that subsection (b) serves as a means for private litigants to enforce duties strictly reserved to the FDA and is thus impliedly preempted under 21

U.S.C. § 337(a). *See Mink*, 860 F.3d at 1327. It insists that the Supreme Court's holding in *Buckman* controls in this case.

In *Buckman*, the Supreme Court held the plaintiffs' claim to be preempted by the FDCA because such claim was based on the assertion that the defendant made fraudulent representations to the FDA. *See Buckman Co.*, 531 U.S. at 343–44. To justify its holding, the Court noted that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Buckman Co.*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). It thus concluded that the presumption against finding federal preemption of a state-law cause of action did not apply in its case. *Id.* at 347–48. To hold otherwise, it explained, would disrupt the "somewhat delicate balance of statutory objectives" that "amply empowers the FDA to punish and deter fraud against [it]." *Id.* Mednology emphasizes the need to maintain this balance of statutory objectives and urges this Court to find that the presumption against preemption does not apply to this case either.

When the Court in *Buckman* concluded that the presumption against preemption did not apply to its case, it distinguished its case from its prior case in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). It reasoned that the relationship between the FDA and the manufacturer in *Buckman* was inherently federal in character in that such relationship originated from, was governed by, and terminated according to federal law. *Buckman Co.*, 531 U.S. at 347–48. It thus concluded that the situation in *Buckman* contrasted "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,'" which was the case in *Medtronic*. *Id.* at 348 (quoting *Medtronic*, 518 U.S. at 485). In her response to Mednology's motion to dismiss, Riley urges this Court to adhere to the rule of presumption against preemption elaborated in *Medtronic* and hold that the essence of her claims brought under Transylvania's product liability statute does

not overcome this presumption. Because she is asserting claims that are based on traditional state tort law rather than "fraud-on-the-FDA" claims, the Court agrees with Riley that the presumption against preemption applies and has not been overcome in this case.

In *Medtronic*, the Supreme Court observed how states have, throughout our history, "exercised their police powers to protect the health and safety of their citizens." *Medtronic*, 518 U.S. at 475. It also recognized that "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* (quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)). Although the medical device manufacturer in *Medtronic* asserted that the express preemption provision under 21 U.S.C. § 360k(a)(1) preempted the plaintiffs' claims, the Court agreed with the plaintiffs that their claims that the manufacturer violated FDA regulations could be maintained without being preempted under Section 360k. *See id.* at 495. It concluded that the presumption against preemption approach "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485. This Court agrees and thus applies the presumption against preemption to the case at bar.

Moreover, the Court agrees with Riley that the Second Circuit's decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), is on point for resolving this case. Like the Supreme Court in *Medtronic*, the Second Circuit in *Desiano* applied the presumption against preemption approach to its case after noting that the cause of action recognized under Michigan's drugmaker immunity statute "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Desiano*, 467 F.3d at 94. Similarly, Transylvania's immunity statute does not necessarily reflect the Transylvania's attempt to police fraud against the FDA. *See* 21 Trans. Comp. Stat. § 630.546(a). Rather, Transylvania's legislature sought to minimize the liability drugmakers or

medical device manufacturers could otherwise face from various product liability lawsuits. Similarly, the legislative intent behind Michigan's drugmaker immunity statute was "to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Desiano*, 467 F.3d at 94. Because the presumption against preemption applied, the Second Circuit explained that its case required "an altogether different analysis from that made in *Buckman*." *Id.* Accordingly, this Court adopts *Desiano*'s rather than *Buckman*'s analysis to evaluate whether the FDCA preempts subsection (b), since the presumption against preemption applies.

In *Desiano*, the Second Circuit explained that the plaintiffs were asserting claims based on traditional state tort law rather than "fraud-on-the-FDA" claims because such claims were premised on traditional duties between the product manufacturer and consumers in Michigan. *Desiano*, 467 F.3d at 94. Moreover, it construed *Buckman* to stand for the proposition that "proof of fraud against the FDA is *alone sufficient* to impose liability" in fraud-on-the-FDA cases. *Id.* at 95 (emphasis in original). It then found the plaintiffs' claims to be distinguishable from the claims in *Buckman* because the plaintiffs' claims were not *solely* based on the wrongful conduct of defrauding the FDA. *Id.* Instead, the plaintiffs' claims in *Desiano* "allege[d] a wide range of putative violations of common law duties long-recognized by Michigan's tort regime." *Id.* Likewise, Riley is asserting several claims that are rooted in traditional common law duties, which Transylvania's product liability statute recognizes. *See* 21 Trans. Comp. Stat. § 630.545.

Furthermore, proof of fraud against the FDA does not constitute an element of Riley's product liability claims, just as the same proof was not even an element of the plaintiffs' product liability claim in *Desiano*. *See Desiano*, 467 F.3d at 96. Rather, Michigan's immunity statute allowed such proof of fraud to neutralize a drugmaker's reliance on compliance with FDA approval

as an absolute defense to product liability claims. *See id.* Specifically, the pertinent exception to the immunity statute provided:

> [The immunity provision] does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

Id. at 88 (quoting Mich. Comp. Laws § 600.2946(5)(a) (1995)). This exception to Michigan's immunity statute is substantially similar to the subsection (b) exception Riley relies on for her product liability claims. *See id.*; *see also* 21 Trans. Comp. Stat. § 630.546(b). Just like the plaintiffs in *Desiano*, Riley is asserting Mednology's fraudulent conduct to counter Mednology's reliance on Transylvania's immunity statute (i.e., 21 Trans. Comp. Stat. § 630.546(a)) rather than to establish a required element of her common law claims. *See Desiano*, 467 F.3d at 96.

Given the substantial similarity between the immunity exception in *Desiano* and the subsection (b) exception in this case, along with the fact that Riley is, like the plaintiffs in *Desiano*, asserting Mednology's fraudulent conduct to neutralize Mednology's immunity rather than to establish an element of her state common law claims, this Court follows the Second Circuit's approach in *Desiano* and holds that the FDCA does not preempt subsection (b). *See Desiano*, 467 F.3d at 96 (holding that federal law did not preempt the Michigan immunity exception). Additionally, subsection (b) requires Riley to establish that Mednology violated FDA's requirement of providing accurate information about its medical device as a condition for securing approval from the agency. *See* 21 Trans. Comp. Stat. § 630.546(b). Riley is relying on subsection (b) to neutralize the applicability of Transylvania's immunity statute and bring her state law claims against Mednology under Transylvania's product liability statute. *See id.* §§ 630.545–.546(a). Riley is thus

suing Mednology for its violation of a federal requirement in order to assert common law claims recognized under Transylvania's product liability statute. This is tantamount to a plaintiff suing "for conduct that violates a federal requirement (avoiding express preemption)" but not suing "*only* because the conduct violated that federal requirement (avoiding implied preemption)." *Mink*, 860 F.3d at 1327. For these reasons, Mednology's motion to dismiss Riley's claims shall be denied to the extent that it is based on the immunity exception in subsection (b) being preempted by federal law.

B. The FDCA does not preempt the immunity exception provided in 21 Trans. Comp. Stat. § 630.546(c).

Even if Mednology were correct to assert that the FDCA preempts the immunity exception provided in subsection (b), Riley can still bring her claims under Transylvania's product liability statute if she pleads facts to satisfy the immunity exception provided in subsection (c). Riley has done so by asserting that Mednology has failed to warn about the dangers or risks associated with the presence of PE-PUR foams in Sleepternity. Nevertheless, Mednology asserts that the FDCA also preempts the subsection (c) immunity exception. To support its argument, it draws this Court's attention to *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), and *Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. 2010). The courts in these cases held that federal law preempted failure to warn claims. *See Mink*, 860 F.3d at 1329 (concluding that the plaintiff's failure to report theory for his negligence claim was impliedly preempted by federal law); *see also Bryant*, 623 F.3d at 1205 (holding that federal law preempted the plaintiff's failure to warn and related claims). In response, Riley asserts that federal law does not preempt subsection (c), and she cites to *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), and *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013). These cases stand for the proposition that failure to warn claims are not impliedly preempted, thus conflicting with the Eleventh and Eighth Circuits' holdings in *Mink* and *Bryant*, respectively. *See Hughes*, 631 F.3d at 769, 776; *see also Stengel*, 704 F.3d at 1233.

Although *Mink*, *Bryant*, *Hughes*, and *Stengel*, respectively, provide some guidance for resolving whether federal law preempts the subsection (c) immunity exception, this case is different because Mednology is not arguing that the FDCA preempts Riley's failure to warn and failure to disclose claims brought under Transylvania's product liability statute. Instead, Mednology is arguing that the FDCA preempts the immunity exception provided under subsection (c), since it would receive protection from liability under the immunity statute if this Court were to hold that federal law preempted the immunity exceptions provided under both subsections (b) and (c). *See* 21 Trans. Comp. Stat. § 630.546(a)–(c). Accordingly, this case is more akin to *Desiano* than *Mink*, *Bryant*, *Hughes*, and *Stengel*, and the Court finds it appropriate to apply *Desiano*'s analysis to this case. After all, *Mink*, *Bryant*, *Hughes*, and *Stengel* unanimously recognize that a state law claim can survive both forms of preemption if the plaintiff alleges in his or her lawsuit that the defendant violated a federal requirement (thereby avoiding express preemption) but does not sue only on the basis that the defendant violated such federal requirement (thereby avoiding implied preemption). *See, e.g.*, *Mink*, 860 F.3d at 1327.

Like the plaintiffs in *Desiano*, Riley is relying on an exception to Transylvania's immunity statute to neutralize Mednology's immunity under the statute. The only difference between the immunity exception under subsection (c) and the exception provided in *Desiano* is when the exception applies. *See Desiano*, 467 F.3d at 88; *see also* 21 Trans. Comp. Stat. § 630.546(c). The immunity exception in *Desiano* applies whenever a defendant "intentionally withholds from or misrepresents to" the FDA any drug information that is required to be submitted under the FDCA. *Desiano*, 467 F.3d at 88. On the other hand, the immunity exception under subsection (c) applies whenever a defendant "fails to warn about the dangers or risks of the drug or medical device as required by the FDA." 21 Trans. Comp. Stat. § 630.546(c). Notwithstanding such difference,

however, both exceptions apply when a defendant violates a federal requirement. *See Desiano*, 467 F.3d at 88; *see also* 21 Trans. Comp. Stat. § 630.546(c). Thus, both exceptions survive express preemption under 21 U.S.C. § 360k(a). *See Mink*, 860 F.3d at 1327.

Furthermore, proof of defendant's fraudulent conduct toward the FDA did not serve as the basis of the plaintiffs' cause of action in *Desiano*, yet such proof was nevertheless necessary for negating limitation of defendant's liability under Michigan law. *See Desiano*, 467 F.3d at 97. Although Riley is bringing a duty to warn claim in addition to other state-law claims recognized under Transylvania's product liability statute, she is bringing her duty to warn claim under Transylvania's product liability statute, not under subsection (c). She is relying on subsection (c) to neutralize the applicability of Transylvania's immunity statute, so that she can assert her state law claims against Mednology under Transylvania's product liability statute. *See* 21 Trans. Comp. Stat. §§ 630.545–.546(a). Therefore, her assertion that Mednology failed to warn, as required by the FDA, about the dangers or risks of Sleepternity does not serve as the *sole basis* for her causes of actions against Mednology but is nevertheless necessary for negating the limitation of Mednology's liability under Transylvania's immunity statute. *See id.* § 630.546(a), (c).

Accordingly, this Court holds that the immunity exception provided under subsection (c) is not preempted under 21 U.S.C. § 337(a), just as the Second Circuit in *Desiano* held a similar immunity exception provision to not be preempted under federal law. *See Mink*, 860 F.3d at 1327; *see also Desiano*, 467 F.3d at 98. For these reasons, Mednology's motion to dismiss Riley's claims shall be denied to the extent that it is based on its assertion that federal law preempts the immunity exception in subsection (c).

II. Riley's Claim under the False Claims Act

Riley brings an FCA action under the Act's *qui tam* provision as an alternative way to hold Mednology liable. For her FCA claim, she relies on the fraud-on-the FDA theory by asserting that Mednology fraudulently obtained from the FDA pre-marketing approval for Sleepternity. Put another way, she contends that the FDA would have never allowed Mednology to sell Sleepternity in the market and that the CMS subsequently would have never covered the cost for using the medical device had Mednology disclosed to the FDA the presence of PE-PUR sound abatement foams in the devices that were to be distributed and sold. For the reasons explained below, such reliance on the fraud-on-the-FDA theory does not serve as a viable basis for bringing an FCA claim. Accordingly, Riley has failed to state a claim upon which a relief could be granted, and Mednology's motion to dismiss her FCA claim shall be granted.

A. Background of the False Claims Act

The FCA attaches liability to anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). Such individuals would be "liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." *Id.* § 3729(a)(1). An individual may bring a civil action for an FCA violation for themselves and for the United States Government. *Id.* § 3730(b)(1).

When an individual brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). If the United States Government elects to intervene, then it "shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the

action." *Id.* § 3730(c)(1). However, if the government decides not to intervene, then the individual who initiated the FCA action "shall have the right to conduct the action." *Id.* § 3730(c)(3). Riley is thus entitled to proceed with her FCA action against Mednology notwithstanding the United States Government's decision to not intervene in her case. *See id.* If she prevails in her FCA claim, then she would be entitled to "receive an amount which the court decides is reasonable for collecting the civil penalty and damages." *Id.* § 3730(d)(2). Such amount "shall not be less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds." *Id.* Before Riley can receive such amount, however, she must bring a valid FCA claim against Mednology.

B. Riley Cannot Rely on Her Fraud-on-the-FDA Theory to Maintain Her FCA Claim

In its motion to dismiss Riley's FCA claim, Mednology insists that Riley cannot utilize, as a basis for her FCA claim, the allegation that Mednology fraudulently obtained pre-marketing approval for Sleepternity from the FDA. To support its position, it cites *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). The facts in *D'Agostino* are somewhat analogous to the facts of this case. In *D'Agostino*, the relator brought an FCA action against the defendant corporation that discovered, developed, manufactured, and marketed medical devices. *See id.* at 3. The defendant[5] sought FDA's pre-market approval for Onyx,[6] which was an artificial liquid material used to treat malformed blood vessels in the brain. *Id.*

The First Circuit in *D'Agostino* explained that the defendant's conduct must "cause the government to make a payment or to forfeit money owed." *D'Agostino*, 845 F.3d at 8 (citing *United*

[5] It was actually the defendant's subsidiary that sought pre-market approval for Onyx. *D'Agostino*, 845 F.3d at 4. However, for the sake of simplicity, the defendant and the defendant's subsidiary will be referred to as "defendant."
[6] There was another medical device at issue in *D'Agostino*. However, it is not essential to analyze the relator's claims regarding that other device, since such claims were not based on the allegation that the defendant fraudulently induced the FDA to grant its pre-market approval request for that device. *See D'Agostino*, 845 F.3d at 5, 11–12.

States ex rel. Westrick v. Second Change Body Armor Inc., 128 F. Supp. 3d 1, 18 (D.D.C. 2015); *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005)). For example, if the FDA would have approved the defendant's medical device despite the alleged fraudulent representations, then the causal connection between the fraudulent representations to the FDA and CMS's payment that is contingent on FDA approval disappears. *Id.* Since the FDA did not demand either recall or relabeling of Onyx in the six years since the relator alleged the defendant's fraudulent conduct, the First Circuit concluded that the FDA's failure to actually withdraw its approval of Onyx foreclosed the relator's ability to base his FCA claim on the assertion that the FDA's approval was fraudulently obtained. *Id.*

Likewise, this Court finds that Riley has failed to establish the causation element of her FCA claim. Since CMS's decision to provide coverage for Sleepternity was based on the FDA's approval of the medical device, Riley must establish that the FDA would have recalled the device from the market had they known about Mednology fraudulently replacing the PE-PUR foams with the approved silicone-based foams. The allegations in Riley's complaint does not indicate that the FDA demanded such recall of Sleepternity once Riley reported to the administration about Mednology's fraudulent conduct. This Court finds such inaction by the FDA to preclude Riley from resting her FCA claim on her allegation that Mednology fraudulently obtained pre-marketing approval for Sleepternity, just as the First Circuit in *D'Agostino* found that the FDA's failure to withdraw its approval of Onyx precluded the relator from basing his FCA claim on the allegation that the FDA's approval was fraudulently obtained. *See D'Agostino*, 845 F.3d at 8. In other words, Riley has failed to establish the causation element of her FCA claim, just like the relator in *D'Agostino*. *See id.* at 10. Therefore, this Court holds that Mednology's fraudulent conduct toward the FDA cannot serve as a viable basis for Riley's FCA claim.

More importantly, the First Circuit expressed several concerns about allowing the relator to base his FCA claim on the alleged fraudulent representations made by the defendant to obtain FDA approval for Onyx. *See D'Agostino*, 845 F.3d at 8–9. For example, it was concerned that the FCA could transform into a mechanism "with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id.* In other words, it explained, the purpose of the FCA is "to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." *Id.* Moreover, it was concerned about the practical problems of proof courts would have to face if the relator's FCA claim were permitted. *See id.* at 9. It questioned how the relator in its case or other relators under the FCA would "prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind? Whose? What if former officials no longer in government were of one view, and current officials of another?" *Id.*

This Court shares the same concerns behind allowing an FCA claim to be based on an allegation that the defendant fraudulently induced the FDA to grant pre-marketing approval for its medical device. The Court agrees that the purpose of the FCA is "to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." *D'Agostino*, 845 F.3d at 8. By bringing her FCA claim against Mednology on the theory that Mednology fraudulently induced the FDA to grant pre-marketing approval of Sleepternity, Riley is asking this Court to determine whether the FDA would have rescinded its approval of Sleepternity had the administration known that Mednology was planning to include PE-PUR foams rather than silicone-based foams inside the devices that were to be sold. Even if such fact were known, there is a possibility that the administration would still have proceeded to approve

Sleepternity for marketing. In any event, this Court, like the First Circuit in *D'Agostino*, does not find it appropriate to second-guess the administration's judgment in such manner. *See id.*

Riley asserts that this Court should adhere to the Ninth Circuit's reasoning in *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890 (9th Cir. 2017), that "[m]ere FDA approval cannot preclude False Claims Act liability, especially where, as here, the alleged false claims procured certain approvals in the first instance." *Id.* at 905. However, it is unclear whether Mednology's false claims that all the marketed Sleepternity devices were to contain silicone-based foams procured FDA approval. Riley has failed to establish the causation element of her claim, and she would need to do so before it can reasonably be concluded that the alleged false claims made by Mednology procured approval from the FDA. Until it is established that the FDA would not have approved Sleepternity in such situation, it is unclear at best whether the requirement that "the alleged false claims procured certain approvals" has been met in this case.

Moreover, the Ninth Circuit in *Campie* outlined the following essential elements of liability under the FCA: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, *causing* (4) the government to pay out money or forfeit moneys due." *Campie*, 862 F.3d at 902 (emphasis added) (citing *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 188–93 (2016)). Given the uncertainty as to whether the FDA would not have approved Sleepternity if it had known about the presence of PE-PUR foams in the medical device, Riley has failed to link the causation chain between Mednology's fraudulent conduct and CMS's decision to cover the cost of using Sleepternity for those prescribed with the medical device. Therefore, assuming that Mednology's fraudulent conduct satisfied the materiality element of liability under the FCA, Riley's alleged facts do not indicate that the same fraudulent conduct actually caused the FDA to approve Sleepternity, which CMS relied on to issue reimbursements for

the use of the medical device. Consequently, even if this Court were to adopt the standards set forth by the Ninth Circuit in *Campie*, Riley cannot rely on Mednology's alleged fraudulent conduct as a viable basis for bringing her FCA claim against Mednology, since the causation element has not been met. *See id.*

For the foregoing reasons, this Court holds that Riley's FCA claim cannot rest on Mednology's conduct of fraudulently obtaining FDA approval for Sleepternity. Accordingly, Mednology's motion to dismiss Riley's FCA claim shall be granted.

CONCLUSION

Because the immunity exceptions provided under subsections (b) and (c) of Transylvania's immunity statute are not preempted by federal law, Mednology's motion to dismiss Riley's state law claims shall be denied.[7] On the other hand, Mednology's motion to dismiss Riley's FCA claim shall be granted because her FCA claim cannot be based on Mednology's fraudulent conduct toward the FDA.

IT IS SO ORDERED.

Dated: October 15, 2023

MARCUS BURNS
United States District Judge

[7] Because this Court holds that subsections (b) and (c) of Transylvania's immunity statute are not preempted by federal law to where Riley is able to bring her state law claims under Transylvania's product liability statute, it does not need to address whether Riley has pled sufficient facts to overcome the presumption that Sleepternity was in compliance with the FDA's approval by the time the medical device left the control of Mednology. Accordingly, the Court does not need to evaluate the merits of Mednology's argument that federal law preempts the compliance part of Transylvania's immunity statute. *See* 21 Trans. Comp. Stat. § 630.546(a).

UNITED STATES COURT OF APPEALS FOR THE SEVENTEENTH CIRCUIT

UNITED STATES EX REL. Riley ORTEGA,
Appellant / Cross-Appellee,

v.

MEDNOLOGY, INC.,
Appellee / Cross-Appellant.

No. 24-1000 April 1, 2024

Before: Joanna Phillips, Thurston Wells, and Trevor Ruzich, Circuit Judges.

OPINION

Phillips, J., delivered the opinion of the Court in which Wells, J., joined.

Ruzich, J., filed an opinion concurring in part and dissenting in part.

Phillips, J.

This case comes to us on appeal of a judgment entered by the United States District Court for the Southern District of Transylvania granting in part and denying in part the Appellee/Cross-Appellant Mednology, Inc.'s Rule 12(b)(6) motion to dismiss Appellant/Cross-Appellee Riley Ortega's state law claims and False Claims Act (FCA) claim. Riley argues that the district court erred in holding that she could not rest her FCA claim on Mednology's fraudulent conduct toward the Food and Drug Administration (FDA). Mednology argues that the district court erred in holding that federal law does not preempt the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute.

We AFFIRM, albeit on different grounds, the district court's denial of Mednology's motion to dismiss Riley's state law claims brought under Transylvania's product liability statute. However, we REVERSE the district court's granting of Mednology's motion to dismiss Riley's FCA claim. We REMAND the case for further proceedings consistent with this opinion.

Standard of Review

Generally, we review any questions of law *de novo* and any questions of fact for clear error. *Monasky v. Taglieri*, 140 S. Ct. 719, 730 (2020). We thus review the issue of whether federal law preempts subsections (b) and (c) of Transylvania's immunity statute *de novo*. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed *de novo*."). Finally, we review the dismissal of any claims under the False Claims Act *de novo*. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017).

Discussion

The following questions are presented before us: (1) Whether federal law preempts the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute, thereby protecting a manufacturer or distributor of a drug or medical device from any liability under Transylvania's product liability statute; and (2) Whether a defendant's fraudulent conduct toward the FDA is a valid basis for bringing an FCA claim against the defendant. We hold that federal law does preempt the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute. Nevertheless, we AFFIRM the district court's denial of Mednology's motion to dismiss Riley's state law claims because Mednology cannot seek protection under Transylvania's immunity statute if Sleepternity was not in compliance with the FDA's approval when it was marketed and sold to consumers. In other words, the district court should be allotted the opportunity to determine whether the medical device was in fact not in compliance with such approval.

Finally, we REVERSE the district court's granting of Mednology's motion to dismiss Riley's FCA claim. This is because the district court failed to analyze whether the Supreme Court's

precedent in *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), permits plaintiffs like Riley to base their FCA claims on a defendant's fraudulent conduct toward the FDA. After reviewing how the Ninth Circuit applied *Escobar* to a case that is somewhat like ours in *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890 (9th Cir. 2017), we conclude that Riley's FCA can be based on Mednology's fraudulent conduct toward the FDA. Since Riley's reliance on this fraud-on-the-FDA theory was the sole basis for Mednology's motion to dismiss her FCA claim, the district court should not have granted Mednology's motion to dismiss.

I. Preemption Issue

We first address whether federal law, specifically the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 301–399i), preempts the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute. The district court below was correct to note that there are two general types of preemption: express preemption and implied preemption. *See, e.g.*, *Barnett Bank, N.A. v. Nelson*, 517 U.S. 25, 31 (1996).

However, the district court was incorrect to apply the presumption against preemption in this case. As the Supreme Court explained in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The Court in *Buckman* thus clarified that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* Such relationship exists in this case just as it did in *Buckman*. Just as *Buckman* involved the FDA regulating a corporation that manufactured orthopedic bone screws, the entity being regulated in this case by the FDA is Mednology. *See id.* at 343. As the FDA does in this case, the FDA in *Buckman* regulated how the corporation would obtain

approval for marketing the medical devices it manufactured. *See id.* at 343–44. Since the Court in *Buckman* concluded that the presumption against preemption did not apply to its case, we conclude that the presumption against preemption does not apply in this case. *See id.* at 348. With this presumption in mind, we now address whether the FDCA preempts the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute.

A. The FDCA preempts the immunity exception provided in subsection (b) of Transylvania's immunity statute.

What makes this case different from *Buckman* is that Riley is alleging Mednology's fraudulent representation to the FDA to neutralize Mednology's immunity rather than to bring a state-law fraud-on-the-FDA claim like the plaintiffs in *Buckman*. *See Buckman*, 531 U.S. at 346–47. Therefore, the district court was correct to note that the Second Circuit's decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), is on point for resolving this particular preemption issue, since that case involved an immunity exception provision that is strikingly similar to subsection (b) of Transylvania's immunity statute. *See id.* at 88. However, the Second Circuit was not the only one among our sister circuits to review whether such provision was preempted under federal law. The Sixth Circuit in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), reviewed the same immunity exception provision that was at issue in *Desiano* and ultimately concluded that federal law preempted the provision in some cases. *See id.* at 966.

Mednology argues that because the presumption against preemption does not apply in this case, the Sixth Circuit's decision in *Garcia* rather than the Second Circuit's decision in *Desiano* should guide our analysis of this case. We agree. After all, the Sixth Circuit in *Garcia* correctly applied the Supreme Court's precedent in *Buckman* by accounting for the policy concerns the Court in *Buckman* raised about state courts interfering with the FDA's responsibility to police fraud. *See id.* at 966. We share the same concerns given the federal regulatory nature of the relationship between

the FDA and Mednology. With such concern in mind, the Sixth Circuit in *Garcia* concluded that the immunity exceptions "are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.*, claims based on federal findings of bribery or fraud on the FDA). *Id.*

Like the Sixth Circuit in *Garcia*, we find it appropriate to construe the immunity exception under subsection (b) to be preempted whenever a plaintiff requests a state court to find defendant's fraudulent conduct toward the FDA. *See Garcia*, 385 F.3d at 966. Likewise, subsection (b) should not be preempted whenever a plaintiff relies on federal findings to prove the defendant's fraudulent conduct toward the FDA. *See id.* In this case, Riley has not alleged anywhere in her complaint that the FDA has officially found Mednology to have fraudulently obtained pre-marketing approval for its medical device. Moreover, the FDA terminated its investigation of Mednology's fraudulent conduct after Mednology voluntarily recalled Sleepternity from the market shortly after being served with Riley's complaint. There is no indication whatsoever that the FDA has confirmed that Mednology engaged in fraudulent conduct toward the FDA. Therefore, under *Garcia*, subsection (b) is preempted by the FDCA, since Riley is seeking to prove Mednology's fraudulent conduct solely through judicial fact-finding. *See id.*

B. The FDCA also preempts the immunity exception provided in subsection (c) of Transylvania's immunity statute.

Unlike subsection (b), subsection (c) does not concern whether a drug or medical device manufacturer committed fraud toward the FDA. Instead, it applies and thereby neutralizes a drug or medical device manufacturer's immunity from product liability suits if the manufacturer "fails to warn about the dangers or risks of the drug or medical device as required by the FDA." 21 Trans. Comp. Stat. § 630.546(c). Riley emphasizes this difference to support her argument that *Buckman*

should not be dispositive for determining whether the FDCA preempts subsection (c). However, we agree with Mednology that *Buckman* is dispositive for resolving this preemption issue.

Regarding the issue of whether federal law preempts failure to warn claims, the district court below noted the circuit split over this issue in *Mink v. Smith & Newphew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), *Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. 2010), *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), and *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013). *See* Grace M. Zogaib, Note, *Preemption After* Buckman*: State Tort Failure to Warn Claims Based on Lack of Disclosure to FDA*, 21 Ave Maria L. Rev. 236, 242–61 (2023) (reviewing the circuit split over the preemption of state law failure to warn tort claims and explaining how the split should be resolved). Nevertheless, we do not find *Mink*, *Bryant*, *Hughes*, and *Stengel*, respectively, to be dispositive for resolving the issue of whether the FDCA preempts subsection (c). While those cases focus on whether federal law preempts state law failure to warn claims, the issue in this case is whether federal law preempts a failure to warn provision that neutralizes a drug or medical device manufacturer's statutory immunity from product liability lawsuits. *See* 21 Trans. Comp. Stat. § 630.546(a), (c). Therefore, the district court was correct to find that the Second Circuit's precedent in *Desiano* is more analogous to the facts and circumstances of this case.

However, we disagree with the district court's application of *Desiano* to resolve the preemption issue regarding subsection (c). The district court incorrectly focused on Riley's breach of duty to warn claim when it reasoned, under *Desiano*, that Mednology's alleged violation of FDA's requirement of warning about the dangers or risks of Sleepternity did not serve as the only basis for her state law claims. After all, the issue in this case is whether federal law preempts the *immunity*

exception provided under subsection (c), not whether it preempts Riley's *state law claims* brought under Transylvania's product liability statute.

More importantly, our concern about state courts interfering with the FDA's discretion to police the conduct of regulated entities persuades us adopt the Sixth Circuit's analysis in *Garcia* rather than the Second Circuit's analysis in *Desiano*. After all, we find subsection (c) to directly invade the FDA's investigatory processes whenever the issue of whether a defendant has violated the FDA's warning requirements becomes a close question, just as the Fifth Circuit in *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), reasoned that "the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." *Id.* at 380. The Fifth Circuit's concern about the need "to preserve the agency's discretion to police the conduct of regulated entities" ultimately persuaded it to adopt *Garcia*'s approach rather than *Desiano*'s approach. *See id.* We do the same and hold that *Garcia* applies to situations where, as in this case, a plaintiff seeks to neutralize a defendant's immunity from product liability suits by relying on failure to warn immunity exceptions that are based solely on violations of FDA requirements.

Therefore, subsection (c) and other failure to warn immunity exceptions would be preempted unless a plaintiff relies on the FDA's independent finding that the defendant has violated requirements to warn about the dangers or risks of the drug or medical device. *See Garcia*, 385 F.3d at 966 ("[E]xemptions are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA)."). In this case, federal law preempts subsection (c) because Riley's reliance on the subsection is not based on the FDA's finding of Mednology's failure to warn.

C. Mednology's motion to dismiss should still be denied because Riley has alleged sufficient facts to plausibly rebut the presumption that Sleepternity complied with the requirements for FDA approval when it was distributed and sold to the market.

Even though we hold that subsections (b) and (c) are preempted by the FDCA, Mednology still has one more hurdle to clear before it can seek protection under Transylvania's immunity statute. That hurdle is the condition that "the drug or medical device was in compliance with the United States Food and Drug Administration's approval at the time the drug or medical device left the control of the manufacturer or distributor." 21 Trans. Comp. Stat. § 630.546(a). In other words, the immunity statute will not protect defendants like Mednology from any claims asserted under Transylvania's product liability statute if they fail to comply with all the requirements for obtaining the FDA's approval. *See id.* At the same time, such hurdle stands favorably toward defendants like Mednology because the drugs or medical devices they manufacture or distribute are "*presumed* to have been in compliance with the United States Food and Drug Administration's approval" to where "the party challenging a manufacturer's or distributor's immunity . . . bears the burden of rebutting this presumption." *Id.* (emphasis added). Accordingly, Riley bears the burden of rebutting the presumption that Sleepternity was in compliance with all the underlying requirements Mednology had to meet to secure the FDA's approval. *See id.*

In this case, the district court did not address whether Riley has alleged sufficient facts to plausibly rebut the presumption that Sleepternity was in compliance with the underlying requirements for obtaining the FDA's approval at the time the medical device left Mednology's control. Specifically, the district court did not find the need to determine this particular issue because it already concluded that Riley could rely on the immunity exceptions provided under either subsections (b) or (c) to destroy Mednology's immunity under Transylvania's immunity statute, regardless of whether Sleepternity was in compliance with the FDA's approval. Because we hold

that federal law preempts both subsections (b) and (c), we are now required to address this compliance issue before we can determine whether Mednology's motion to dismiss Riley's state law claims should be granted.

We conclude that Riley has pled sufficient facts to plausibly rebut the presumption of compliance and that Mednology's motion to dismiss her state law claims should thus be denied. For plaintiffs like Riley to survive a motion to dismiss, their complaints "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible whenever the plaintiff asserts "factual content that allows the court to draw the *reasonable inference* that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Conversely, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555).

Riley asserts that the FDA would not have approved Sleepternity if the medical device contained PE-PUR sound abatement foams rather than silicone-based foams. To support this assertion, she references a prior incident where another medical device company had to recall certain CPAP machines that contained PE-PUR foams because the FDA found that such foams presented health hazards when broken down. Under this reference, it can reasonably be inferred that a proper sound abatement foam that presented minimal health risks to CPAP machine users was required to be included within Sleepternity before the medical device could obtain pre-marketing approval from the FDA. From this inference, it can reasonably be concluded that Sleepternity was not in compliance with the FDA's approval when it contained the more hazardous PE-PUR foams instead of the much-safer silicone-based foams. Riley has thus pled sufficient facts that enable us to reasonably infer that Sleepternity was not in compliance with the FDA's approval by the time it left

Mednology's control. Therefore, Mednology cannot utilize Transylvania's immunity statute as a basis for dismissing Riley's state law claims. *See* 21 Trans. Comp. Stat. § 630.546(a).

In response, Mednology and our colleague Justice Ruzich in his dissenting opinion contend that federal law preempts, in this case, the compliance part of Transylvania's immunity statute. They draw our attention to the Sixth Circuit's decision in *Marsh v. Genentech, Inc.*, 693 F.3d 546 (6th Cir. 2012). In *Marsh*, the Sixth Circuit reviewed the compliance part of Michigan's immunity statute that is somewhat similar to that in Transylvania's immunity statute. *See Marsh*, 693 F.3d at 549; *see also* 21 Trans. Comp. Stat. § 630.546(a). The Sixth Circuit held that federal law preempted the plaintiff's ability to assert that the defendant's drug did not comply with the FDA's approval, thereby enabling the defendant to remain protected under Michigan's immunity statute. *See Marsh*, 693 F.3d at 555.

However, Mednology and the dissent overlook the difference between the plaintiff's assertion of the defendant's noncompliance in *Marsh* and Riley's assertion of Mednology's noncompliance. The plaintiff in *Marsh* did not allege that the drug she received from the defendant "was adulterated or that its label varied from the label that the FDA approved." *Marsh*, 693 F.3d at 552–53. On the other hand, Riley's assertion of Mednology's non-compliance is based on Mednology deliberately replacing the approved silicone-based foams with the unapproved PE-PUR foams in Sleepternity. This is analogous to a drug being adulterated. Thus, *Marsh* is not necessarily on point for resolving the issue of whether federal law preempts Riley's ability to assert Mednology's non-compliance with the FDA's approval. *See id.* at 554 n.9.

In the end, it would be an anomaly to find the compliance part of Transylvania's immunity statute to be preempted because plaintiffs like Riley would then have no other alternatives for

holding defendants like Mednology liable under Transylvania's product liability statute.[8] When Congress enacted the FDCA, it did not intend to completely shield drug or medical device manufacturers from any form of liability. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996). Rather, its primary goal was to ensure the safety of these health-related products. *See id.* at 490–91. Therefore, it cannot be reasonably deduced that Congress wanted defendants like Mednology to be completely immune from suits brought by plaintiffs like Riley. *See id.* Unless there is direct authority that requires us to hold that federal law preempts Riley's assertion of Mednology's non-compliance, we will not construe federal law to preempt the compliance part of Transylvania's immunity statute.

Since we hold that federal law does not preempt the compliance part of Transylvania's immunity statute, Riley can rebut Mednology's presumed compliance with FDA's approval to prevent Mednology from seeking protection under Transylvania's immunity statute. *See* 21 Trans. Comp. Stat. § 630.546(a). Since we find that Riley has pled facts that are sufficient for us to reasonably infer that Sleepternity was not in compliance with the FDA's approval by the time it left Mednology's control, we rule that Mednology's motion to dismiss Riley's state law claims shall be denied.

II. False Claims Act Issue

Riley also brings a FCA action against Mednology on the theory that the United States government, through the Centers for Medicare and Medicaid Services (CMS), would not have provided payments or reimbursements for the use of Sleepternity but for Mednology's conduct of fraudulently obtaining FDA approval for the medical device. The district court's analysis of Riley's

[8] Of course, this would only be the case where both subsections (b) and (c) are also preempted under federal law. Otherwise, a plaintiff could rely on either of these subsections to neutralize a defendant's immunity under Transylvania's immunity statute. *See* 21 Trans. Comp. Stat. § 630.546(a)–(c).

FCA claim inevitably led to its encountering a split between the First Circuit and the Ninth Circuit over the issue of whether the fraud-on-the-FDA theory can serve as a valid basis for bringing an FCA claim. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (explaining that the relator's allegation fell "short of pleading a causal link between the representations made to the FDA and the payments made by CMS"); *see also United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 907 (9th Cir. 2017) (holding that the relators have alleged, as part of their reliance on the implied false certification theory, sufficient facts to state a claim for relief under the FCA that is plausible on its face). Unsurprisingly, Riley urges us to side with the Ninth Circuit's decision in *Campie* while Mednology urges us to side with the First Circuit's decision in *D'Agostino*.

Because we find the Supreme Court's decision in *Universal Health Services v. United States ex rel. Escobar*, 579 U.S. 176 (2016), to be instructive for resolving the FCA issue before us, we side with the Ninth Circuit for this issue. After all, the Ninth Circuit in *Campie*, unlike the First Circuit in *D'Agostino*, applied *Escobar*'s clarifications of the FCA to a case that is like ours.[9] *See Campie*, 862 F.3d at 906–07. We find *Escobar* to be instructive because Riley appears to be relying on an implied false certification theory to bring her FCA claim against Mednology. Because she alleges that Mednology replaced the approved silicone-based foams with the unapproved PE-PUR foams and that CMS's decision to pay or reimburse for the use of Sleepternity was based on the FDA approving the medical device for marketing and distribution, it can reasonably be inferred that Mednology falsely certified to the payor that it had complied with all the requirements for obtaining the FDA's approval. Therefore, our task is to determine, under the clarifications set forth in *Escobar*,

[9] The First Circuit in *D'Agostino* did cite to *Escobar* along with some other authorities when it explained that a relator could allege, in appropriate circumstances, factual or statistical evidence that would strengthen the inference of fraud beyond mere possibility. *D'Agostino*, 845 F.3d at 10–11. However, that was the only time the court referenced *Escobar*.

whether such false certification was material to CMS's payment decision. *See Escobar*, 579 U.S. at 181.

In *Escobar*, the Supreme Court cautioned that the materiality standard is demanding. *Escobar*, 579 U.S. at 194. At the same time, it explained that "proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 194–95. Although the defendant in *Campie* relied on these clarifications to assert that its violations of FDA requirements were not material to the government's payment decision since the government continued to provide such payment notwithstanding such violations, the Ninth Circuit noted that there was factual dispute over whether the government knew of such violations and whether it would have continued to provide such payment once it knew of such violations. *See Campie*, 862 F.3d at 906–07. Accordingly, the court considered such issue of materiality to present a matter of proof rather than a legal ground to dismiss the relators' complaint. *Id.* at 907.

Like the Ninth Circuit in *Campie*, we consider the materiality issue in this case to present a matter of proof rather than a legal ground to dismiss Riley's FCA claim. Riley asserts that CMS's payment for Sleepternity was conditioned on the FDA's approval of the medical device and that the Center would have never provided such payments if they had known of Mednology's violation of FDA's requirements. These alleged facts are sufficient to transform the issue of materiality from a legal ground for dismissal to a matter of proof, since Riley could plausibly satisfy the materiality element of her FCA claim under these allegations. *See Ashcroft*, 556 U.S. at 678. Just as the Ninth Circuit held that such issue presented a matter of proof rather than a legal basis to dismiss the

relators' complaint, we hold the same and thereby deny Mednology's motion to dismiss Riley's FCA claim. *See Campie*, 862 F.3d at 907.

III. Conclusion

Although we hold that the FDCA preempts subsections (b) and (c), we AFFIRM the district court's denial of Mednology's motion to dismiss Riley's state law claims because Riley has alleged sufficient facts to plausibly rebut the presumption that Sleepternity was in compliance with FDA approval. We REVERSE the district court's granting of Mednology's motion to dismiss Riley's FCA claim because Riley has alleged sufficient facts to plausibly satisfy the materiality element of her FCA claim.

It is so ordered.

Affirmed in Part and Reversed in Part

Ruzich, J., concurring in part and dissenting in part.

I join the majority in their disposition of Mednology's motion to dismiss Riley's False Claims Act (FCA) claim. I write separately to emphasize that the causation element of her FCA claim should not be overlooked. However, I do not join the majority in their disposition of Mednology's motion to dismiss Riley's state law claims. Although I agree that the FDCA preempts subsections (b) and (c), I disagree with the majority that the FDCA does not preempt the compliance part of Transylvania's immunity statute. Accordingly, I concur with the majority on the FCA issue and dissent on the preemption issue.

I. Riley's FCA Claim

Because Riley asserts that CMS's payment for Sleepternity was conditioned on the FDA's approval of the medical device, I agree with the majority that she is ultimately relying on the implied

certification theory to sustain her False Claims Act (FCA) claim. I also agree that the clarifications provided in *Escobar* should be adhered to when evaluating the validity of Riley's FCA claim. I write separately to emphasize that the causation requirement emphasized by the district court below and the First Circuit in *D'Agostino* should also be met for Riley to prevail on her FCA claim.

The majority rightfully focuses on the materiality requirement that *Escobar* clarified and that the Ninth Circuit in *Campie* subsequently applied. However, implicit in *Escobar*'s clarification of the materiality requirement is the importance of establishing a *causal link* between a defendant's conduct of fraudulently obtaining FDA approval for its product and the government's decision to provide payment or reimbursement for the defendant's FDA-approved product. *See Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 194-95 (2016). The Supreme Court in *Escobar* explained that materiality can be proven through "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* At the same time, it provided some of the situations in which the materiality requirement is unlikely to be met:

> [I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 195. These explanations of the materiality element indicate that a defendant's fraudulent violation of a particular requirement must cause the government to withdraw its payment. *See id.* at 194-95. Put another way, the government's decision to withdraw payment for the defendant's product must be based on the defendant's violation of a particular requirement that serves as a condition for payment. Therefore, establishing causation between a defendant's conduct of fraudulently completing a requirement for receiving payment and a government's decision to

withdraw payment upon discovering such fraud is necessary for satisfying the materiality requirement clarified in *Escobar*. *See id.* Accordingly, the district court below correctly recognized the importance of establishing such causation.

However, I disagree with the district court's decision to grant Mednology's motion to dismiss Riley's FCA claim after it found that Riley had failed to establish causation. The Ninth Circuit in *Campie* considered the issue regarding the materiality requirement to present a matter of proof. *See Campie*, 862 F.3d at 907. Because establishing causation is necessary for satisfying the materiality element clarified in *Escobar*, the question of whether Riley has established causation in her FCA claim presents a matter of proof just as the majority has found the materiality issue in this case to present such matter. Because Riley has not indicated that she would be unable to prove causation between Mednology's fraudulent conduct and CMS's payment decision, I would grant her the opportunity to provide such proof. *See, e.g.*, *Barnett v. Centoni*, 31 F.3d 813, 816 (9th Cir. 1994) ("A complaint may not be dismissed unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief.") For these reasons, I concur with the majority in reversing the district court's granting of Mednology's motion to dismiss Riley's FCA claim.

II. Riley's State Law Claims

Riley relies on the immunity exceptions provided in subsections (b) and (c) to neutralize Mednology's presumed immunity under Transylvania's immunity statute. The majority correctly concludes that the FDCA preempts both subsections unless the FDA itself has found a defendant like Mednology to have engaged in any conduct covered in these subsections. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012). Since there is no indication of the FDA's finding that Mednology had engaged in any conduct that would trigger either subsection

(b) or (c), Riley may not utilize these subsections to neutralize Mednology's presumed immunity. *See id.* However, my agreement with the majority ends here.

The majority proceeds to hold that Riley has alleged enough facts to plausibly rebut the statutory presumption that Sleepternity was in compliance with all the FDA requirements by the time it left Mednology's control. Unlike the majority, I cannot allow the compliance part of Transylvania's immunity statute to stand because it is preempted under federal law. *See Marsh v. Genetech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012). The Sixth Circuit in *Marsh* focused on the compliance part of Michigan's immunity statute that is similar to the compliance part of Transylvania's immunity statute. *See id.* at 549, 552; *see also* 21 Trans. Comp. Stat. § 630.546(a). Just like Riley's assertion of non-compliance in this case, the plaintiff's argument in *Marsh* that immunity did not apply was based on the defendant's "alleged non-compliance with the terms of the FDA's approval of" the drug it manufactured and distributed. *Marsh*, 693 F.3d at 552. *Marsh* is thus on point for resolving whether federal law preempts the compliance part of Transylvania's immunity statute.

The Sixth Circuit in *Marsh* ultimately held that the compliance part of Michigan's immunity statute was preempted under federal law. *See Marsh*, 693 F.3d at 555. Although the majority on our panel tries to distinguish Riley's assertion of non-compliance from the plaintiff's assertion of non-compliance in *Marsh* by characterizing Riley's assertion of non-compliance to be more substantive, it overlooks the Sixth Circuit's view that the same preemption concerns would still be triggered. *See id.* at 553. The Sixth Circuit concluded that the plaintiff's assertion of non-compliance was "premised on violation of federal law, implicate[d] the relationship between a federal agency and the entity it regulate[d], and ask[ed] the court to assume a role usually held by the FDA." *Id.* at 555.

After noting *Buckman* and *Garcia*'s concerns about such inter-branch meddling, it held that federal law preempted the compliance part of Michigan's immunity statute. *Id.* at 553, 555.

Because I share the same concern about the inter-branch meddling between the court and the FDA, I would side with the Sixth Circuit's approach in *Marsh* and hold that federal law preempts the compliance part of Transylvania's immunity statute. After all, it is the FDA's expertise, not the court, that is best suited for determining whether Sleepternity was in compliance with the FDA's approval by the time it left Mednology's control. *See Marsh*, 693 F.3d at 553–54; *cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."). Since I would hold that federal law preempts the compliance part of Transylvania's immunity statute in addition to subsections (b) and (c), I would conclude that Riley cannot rely on any of those avenues to neutralize Mednology's immunity under Transylvania's immunity statute. *See* 21 Trans. Comp. Stat. § 630.546(a)-(c). Therefore, I would grant Mednology's motion to dismiss Riley's state law claims brought under Transylvania's product liability statute.

III. Conclusion

For the foregoing reasons, I would reverse the district court's granting of Mednology's motion to dismiss Riley's FCA claim, since the causation element in her FCA claim presents a matter of proof to where her claim should not be dismissed. I would affirm the district court's granting of Mednology's motion to dismiss Riley's state law claims, since federal law preempts all the provisions Riley relies on to neutralize Mednology's immunity. I respectfully concur in part and dissent in part.

IN THE SUPREME COURT OF THE UNITED STATES

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES EX REL. Riley ORTEGA,

Respondent.

Docket No. 24-9176

The petition for writ of certiorari to the United States Court of Appeals for the Seventeenth Circuit is granted limited to the following questions:

1. Does federal law preempt a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer fraudulently obtaining FDA approval or failing to comply with any FDA requirements?

2. May a relator rely on the fraud-on-the-FDA theory to bring a False Claims Act claim against a medical device manufacturer under the Act's *qui tam* provision?

Dated: August 1, 2024