No. 24-9176

IN THE

Supreme Court of the United States

October Term 2024

Mednology, Inc.,

Petitioner,

— versus —

United States Ex Rel. Riley Ortega,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Seventeenth Circuit

BRIEF FOR RESPONDENTS

Team 3304

Attorney for Respondent

QUESTIONS PRESENTED

I. Federal preemption does not apply to areas traditionally regulated by the States. Transylvania's statutory exceptions to manufacturer immunity are narrowly tailored to address concerns of manufacturers fraudulently obtaining FDA approval or failing to comply with FDA requirements. Does federal law preempt these carefully crafted exceptions that aim to protect public health and safety?

II. This court has clarified the demanding materiality standard. With this in mind, can Riley rely on the Implied False Certification theory for her FCA claim against Mednology, when Mednology immediately recalled Sleepternity, the FDA did not investigate, and the CMS neither continued nor withdrew payment?

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The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2-24, where the District Court DENIED Mednology's motion to dismiss Riley's state law claims and GRANTED Mednology's motion to dismiss Riley's claim under the False Claims Act. The opinion of the United States Court of Appeals for the Seventeenth Circuit is unreported but appears on pages 25-42, where the court AFFIRMED the District Court's denial of Mednology's motion to dismiss Riley's state law claims and REVERSED the District Court's grant of Mednology's motion to dismiss Riley's claim under the False Claims Act.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

At the federal level, this case involves Art. VI, cl. 2 of the United States Constitution. This case also involves United States Code 21 U.S.C. § 360k(a) and 21 U.S.C. § 337(a). It also involves 31 U.S.C. § 3729(a)(1)(A) and (B) under the False Claims Act as well as § 3730(b)(1) regarding who may bring such civil action under the False Claims Act.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

Riley Ortega's medical journey unknowingly began during her service as an artillery officer in the United States Army. Record at 3. Her traumatic experiences in that role caused her post-traumatic stress disorder diagnosis ("PTSD") and the development of insomnia and sleep apnea symptoms. *Id*. Under the medical guidance of a Somnologist, Riley was prescribed Sleepternity, a state-of-the-art continuous positive airway pressure ("CPAP") machine. *Id*. Sleepternity featured an automatic pressure adjustment system, a heated humidifier, a smartphone app, and noise-canceling sleep headphones that sent gentle pulses to the user's brain to promote sleep. *Id*. Unlike ordinary CPAP machines, these features allowed the medical device to reduce insomnia and sleep apnea, making it an ideal fit for patients like Riley. *Id*.

At first, Sleepternity seemed promising for Riley. *Id*. On December 30, 2022, the FDA approved Sleepternity for marketing as a Class III medical device. *Id.* at 4. Soon after, the Centers for Medicare and Medicaid Services ("CMS") started covering Sleepternity's costs since it received FDA approval for marketing. *Id.* But soon after, things took a turn for the worst. *Id.*

Riley experienced asthma attacks and was transported to the emergency room, where the physician suggested Riley stop using Sleepternity. *Id*. After, Riley's primary care physician confirmed her asthma attacks were unknown side effects of Sleepternity. R. at 5. When considering possible triggers, neither Riley nor her physician considered Riley's allergy to isocyanate because Sleepternity's warnings contained zero acknowledgment of the presence of isocyanate. *Id*. Despite Riley's asthma symptoms subsiding after she stopped using Sleepternity, the asthma attacks left her with chronic lung inflammation, and her sleep apnea symptoms resurfaced. *Id*. Although she

still uses the Sleepternity headband to manage her insomnia, her sleep apnea persists, even with the use of various medications. *Id*.

It was not until Riley's brother, an assembly manager at Mednology, told Riley that Mednology used polyester-based polyurethane ("PE-PUR") foam in their headphones instead of the silicone-based foams they used to get approval. *Id*. Further research explained that PE-PUR foam breaks down over time and leaves CPAP users at risk of breathing in or swallowing invisible volatile organic compounds ("VOC"s) like isocyanate, presenting significant health risks. *Id*. Riley's brother further confirmed that this decision was made to save manufacturing costs before packaging and sending Sleepternity to its distributors. *Id*.

Riley, the FDA, and the CMS were unaware that Mednology had altered their noise-canceling headphones. R. at 4. Menology replaced its silicone-based foam with PE-PUR foam without informing the FDA or warning users to reduce manufacturing costs. *Id.* They understood the health risks of this decision. *Id.* These health risks prompted another company, Philips Respironics ("Philips"), to recall their CPAP devices containing PE-PUR foams in June 2021. *Id*. Not only did Philips replace their PE-PUR foams, but they replaced them with silicone-based foams to increase safety. *Id*.

Finally, Riley had an answer. Riley believed Isocyanate from Sleepternity's headphones likely caused her asthma attacks and lungs to be chronically inflamed. *Id.* at 5-6. To hold Mednology accountable for its fraudulent conduct, Riley served a summons and a copy of her complaint to Mednology. R. at 7. Shortly after, Mednology, pursuant to 21 C.F.R. § 7.40(b), voluntarily recalled Sleepternity from the market. *Id*. Because Mednology had recalled Sleepternity, the FDA decided to stop its investigation into Mednology's fraudulent conduct and

devote its time to other allegedly defective products in the marketplace that had yet to be recalled. *Id*.

II. NATURE OF PROCEEDINGS

The District Court. On June 21, 2023, Riley Ortega filed a complaint against Mednology in the Southern District of Transylvania. R. at 2. In her complaint, Riley brought a product liability action against Mednology for its fraudulent production of Sleepternity. *Id*. at 6. She asserted that Mednology breached (1) its duty of care and good faith, (2) its duty to disclose its modifications to the FDA, and (3) its duty to warn about the dangers and risks associated with the PE-PUR foams. *Id*. In addition to her state law tort claim, Riley brought 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, relying on a fraud-on-the-FDA theory. *Id*. The United States declined to intervene in Riley's claim against Mednology under the FCA. *Id*. Subsequently, Mednology filed a motion to dismiss Riley Ortega's state law claims and FCA claim for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *Id*. at 9.

On September 12, 2023, the District Court heard Mednology's arguments. *Id*. On October 15, 2023, the court issued a ruling, partially denying and partially granting Mednology's motion to dismiss. *Id*. at 24. In denying part of Mednology's motion, the District Court determined federal law did not preempt the exceptions to Transylvania's immunity statute listed in subsections (b) and (c). *Id.* However, the court granted Mednology's motion in part by dismissing Riley's claim under the FCA and concluded that Mednology's fraudulent conduct in obtaining FDA approval was insufficient for causation and, therefore, not a valid basis. *Id.*

The Seventeenth Circuit Court of Appeals. On appeal, Mednology urged the Seventeenth Circuit to reverse the District Court's ruling that federal law does not preempt the exceptions to

Transylvania's immunity statute, but the court declined to do so. *Id*. at 25. While the Seventeenth Circuit affirmed the holding, it did not adopt the District Court's reasoning. *Id*. Instead of focusing on preemption, the Court of Appeals determined Mednology could not invoke Transylvania's immunity statute because Sleepternity did not comply with the FDA's approval when it was marketed and sold. *Id*. at 38. Additionally, on appeal, Riley sought to reverse the District Court's ruling that reliance on Mednology's fraudulent conduct in obtaining FDA approval did not establish a valid basis to pursue her claim under the FCA. *Id*. at 25. In Riley's favor, the Seventeenth Circuit reversed and remanded the case for further proceedings. *Id*.

SUMMARY OF THE ARGUMENT

Transylvania's statutory exceptions to manufacturer immunity are a vital safeguard for public health, firmly rooted in the state's long-standing authority to protect its citizens. These carefully crafted provisions do not defy federal law; rather, they enforce it. By incorporating existing FDA requirements, these exceptions create a seamless regulatory framework that holds manufacturers accountable without imposing any additional burdens. The compliance provision, fraud exception, and failure to warn exception to work together with federal regulations, filing gaps that might otherwise leave consumers vulnerable. To preempt these exceptions would be to create a dangerous void in consumer protection, effectively granting manufacturers a shield against liability for even the most egregious misconduct. The evidence of Mednology's post-approval modifications to their device underscores the urgent need for these state-level protections. Without them, companies could exploit FDA approval as a free pass to endanger public health. Transylvania's exceptions represent a balanced, necessary, and legally sound approach to ensuring that innovation in medical devices does not come at the cost of patient safety. This Court should

deny Mednology's motion to dismiss and uphold the validity of Transylvania's statutory exceptions to manufacturer immunity.

The False Claims Act (FCA) is designed to protect the government from fraud, including the fraudulent conduct of Mednology. Riley filed her claim under the FCA, relying on the false certification theory, which this Court has recognized as a valid basis for liability. Riley's claim requires meeting two conditions to satisfy the four elements of the FCA. However, Riley's claim is not automatic; she must satisfy two conditions to meet the four elements required under the FCA. First, the claim must not merely request payment but make specific representations about the goods or services provided. Second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements must render those representations misleading half-truths. Riley has fulfilled both conditions by pointing to Mednology's payment requests, initial FDA approval, and subsequent modifications.

The District Court ruled that Riley could not rely on the implied false certification theory due to a failure to establish causation. This conclusion was flawed because the District Court did not apply this Court's clarifications in *Escobar*. Had it done so, it would have found that Riley raised a genuine issue of material fact as to whether the government would have refused payment if it had known about Mednology's fraudulent conduct, thus satisfying the materiality requirement, which includes causation.

Since the Court of Appeals correctly applied the clarifications from *Escobar*, which treat causation as a matter of proof, this Court should affirm the Court of Appeals' decision. However, if the Court feels that the majority opinion did not adequately address causation, Mednology's motion to dismiss should still be denied, and this Court should adopt the concurrence's reasoning.

ARGUMENT AND AUTHORITIES

Standard of Review. Both issues before this Court pose questions of law, which are reviewed de novo. *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 572 U.S. 559, 563 (2014).

I. FEDERAL LAW DOES NOT PREEMPT THE STATUTORY EXCEPTIONS TO MANUFACTURER IMMUNITY UNDER TRANSYLVANIA'S PRODUCT LIABILITY STATUTE.

The balance between state and federal law is delicate. The Supremacy Clause of the United States Constitution crowns federal law as 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 creates the basis for the doctrine of federal preemption, which allows Congress to "preempt, *i.e.*, invalidate, a state law through federal legislation." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015).

Preemption can be 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." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Neither of these apply here to preempt Transylvania's statutory exceptions.

The federal law in question is the Food and Drug Claims Act ("FDCA"), which contains an express preemption that prohibits states from establishing requirements "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). The FDCA also contains an implied preemption because "Congress intended that the [Act] be enforced exclusively by the Federal Government." 21 U.S.C. § 337(a); *see Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017) (finding private enforcement of duties owed to the FDA are impliedly preempted).

However, federal law does not preempt state law when an individual 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)." *Mink*, 860 F.3d at 1327.

In the present case, Riley's state claims are not preempted for two reasons. First, Riley's claim is based on Mednology violating FDA requirements. Second, Riley is not suing *only* for these violations but instead is suing under Transylvania's Product Liability statute that states:

> 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) (emphasis added). Therefore, the question before this Court is not whether Riley's state law claims are preempted but whether the immunity exceptions are preempted under § 630.546. Respondents respectfully request that this Court deny Mednology's motion to dismiss and uphold the validity of Transylvania's statutory exceptions to manufacturer immunity.

A. The Presumption Against Preemption Applies Because States Have Traditionally Regulated Matters of Health and Safety.

Before Mednology can argue that the immunity exceptions are preempted, they must overcome the presumption against preemption. The presumption against preemption lays its roots in areas where "[s]tates have traditionally occupied." *Rice v. Santa Fe Elevator Corp.*, 331 U.S 218, 230 (1947). This Court has long recognized a presumption against preemption regarding a state's police powers regulating its citizens' health and safety. *Medtronic, Inc. v. Lohr*, 518 U.S.

470, 485 (1996). This is because states have "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons." *See Lohr*, 518 U.S. at 475 (stating health and safety concerns are "matters of local concern").

Therefore, courts "start with the assumption that the historic police powers of the states were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. The FDCA does not supersede Transylvania's statutes.

1. Transylvania's Product Liability Statute and immunity exceptions regulate health and safety matters.

Transylvania's Product Liability statute imposes a "duty of care and good faith" on Mednology and includes duties to warn, comply with laws and regulations, and disclose product modifications. 21 Trans. Comp. Stat. § 630.545 (2024). These duties were created by the Transylvania legislature with the expressed goal of "encourage[ing] manufacturers . . . to prioritize the health and safety of its consumers. 21 Trans. Comp. Stat. § 630.544 (2024). These regulations are well within Transylvania's traditional police powers, and the immunity exceptions are an extension of these powers.

Mednology relies on *Buckman* to show that the presumption against preemption does not apply here, but *Buckman* is distinguishable. *See generally Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiff brought a claim solely based on the defendant's fraudulent misrepresentations to the FDA. *Id.* at 344. The court held the claim to be preempted by the FDCA because "[p]olicing fraud against federal agencies is hardly a field which the states have traditionally occupied." *Id.* at 347.

Unlike in *Buckman*, where the plaintiff's claim was solely based on the defendant's fraudulent conduct, Riley's state claims are not solely based on policing fraud against the FDA. Instead, Riley's claims are within Transylvania's broader state tort law scheme, created to give

consumers a legal remedy when dangerous products injure them. The exceptions let Riley overcome statutory immunity in certain situations and do not interfere with or undermine the FDA's ability to police fraud against them, a significant concern of this Court in *Buckman*.

The Seventeenth Circuit below, similar to Mednology, over-relied on *Buckman* and found the presumption against preemption did not apply because "the relationship between a federal agency and the entity it regulates is inherently federal in character [since] the relationship originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347 (2001); R at 7. This overreliance fails to consider the consumer's relationship with a manufacturer. In this case, while Mednology and the FDA's relationship is federal in nature, the relationship between Mednology and Riley, who was injured by their product, is traditionally governed by state tort law. The immunity exceptions are not solely based on the manufacturer-FDA relationship but instead consider the manufacturer-consumer relationship.

2. Congress did not intend to preempt all state law claims related to medical devices.

Congress' language in the FDCA shows no clear intent to preempt all state law claims relating to medical devices. It does not specifically address state law defenses or exceptions to those defenses. The FDCA prohibits states from creating requirements "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). However, the immunity exceptions do not differ from or create new requirements for Mednology. Instead, the exceptions establish situations where Mednology may be held liable under state tort law for injuries caused by their products.

Therefore, since there is a lack of clear congressional intent to preempt Transylvania's statutes, and this Court's precedent supports the presumption against preemption in areas traditionally regulated by the states, this Court should find the presumption against preemption

applies in the present case. *See Lohr*, 518 U.S. at 485 ("[W]e have long presumed that Congress does not cavalierly pre-empt state-law cause of action.").

B. The Seventeenth Circuit Correctly Held That the Presumption of Compliance Under Transylvania's Immunity Statute Was Plausibly Rebutted.

The Transylvania legislature created the immunity statute because they recognized that medical device manufacturers required immunity from product liability claims "as long as the FDA had approved the . . . medical device in question." R. at 8. However, immunity only applies if (1) "the . . . medical device was approved for efficacy and safety by the [FDA]" and (2) "the . . . medical device was in compliance with the [FDA's] approval at the time the . . . medical device left the control of the manufacturer." 21 Trans. Comp. Stat. § 630.546(a).

There is no question that the FDA approved Mednology's Sleepternity device. R. at 3-4. The issue arises when looking at the second requirement for immunity. Though the FDA approved Mednology's device, the device did not leave Mednology's control in compliance with the approval that the FDA granted.

1. Evidence that Mednology modified its device after FDA approval rebutted the presumption of compliance.

The immunity statute was written in favor of manufacturers because a "medical device is *presumed* to have been in compliance with the [FDA's] approval" when it left the manufacturer's control. 21 Trans. Comp. Stat. § 630.546(a). Since Riley is challenging Mednology's immunity, she "bears the burden of rebutting this presumption." *Id.* A burden that Riley satisfies when looking at the standard that must be met.

Riley must allege sufficient 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 there is "factual content that allows the court to draw the *reasonable inference* that the defendant is liable

for the misconduct alleged." *Id.* at 556. Here, there are sufficient facts for this Court to draw a reasonable inference that Mednology's device did not comply with the FDA's approval when the device was sent out.

The FDA only approved Mednology's device when it contained sound-dampening foam made of silicone. R. at 3-4. After FDA approval, Mednology replaced the silicone with a PE-PUR foam. R. at 4. The FDA was not aware of the device's modification. Still, they were aware that polyester-based polyurethane foam "can break down over time [and] . . . if the foam breaks down, then volatile organic compounds (VOCs) that are not visible could be breathed in or swallowed . . . resulting in health risks." R. at 4. Health risks that forced a different medical device company, Philips Respironics, to recall their device containing the same toxic foam. *Id*. at 4.

These facts together are enough to reasonably infer that the device approved by the FDA was not the same device that was sent to Riley. Mednology performed a bait-and-switch that placed their device outside of compliance, which ultimately led to Riley's injuries. Therefore, the presumption of compliance has been rebutted, and Mednology cannot use the immunity statute to shield its wrongful conduct.

2. The compliance provision is not preempted by federal law because it incorporates existing federal requirements.

Mednology claims the provision is preempted as a last-ditch effort to get around the compliance provision of Transylvania's immunity statute. R. at 34. The provision does not infringe on federal law but instead incorporates existing federal requirements as a condition for state law immunity. *See Lohr*, 518 U.S. at 496 (finding that state law claims are not preempted when based on violations of federal requirements). The compliance provision simply allows state law liability when these requirements are violated.

Mednology relies on *Marsh v. Genentech* but fails to recognize the difference between the procedural compliance at issue in *Marsh* and the substantive compliance at issue here. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 552 (6th Cir. 2012).

In *Marsh*, a state immunity statute had the same compliance provision found in the present case. *Id.* at 549. The plaintiff brought a claim for injuries caused by a manufacturer's drug. *Id.* at 548. The plaintiff alleged that the manufacturer "did not comply with the terms of the FDA approval by failing to update its application or submit safety reports, not that the drug and its labeling did not comply. *Id.* at 552 (internal quotations omitted). The court held that the plaintiff's claims were preempted because they "did not constitute non-compliance within the meaning of the Act." *Id.* at 553. The court reasoned that the language of the compliance provision "suggests that immunity requires substantive compliance with FDA approval, but [the plaintiff] allege[d] procedural non-compliance." *Id.* at 552. The court continued that the plaintiff did not "allege that the dose of [the drug] . . . was adultered or that its label varied from the label that the FDA approved." *Id.* at 552-53.

Unlike the plaintiff in *Marsh*, who did not allege that the drug or label had been changed from what the FDA had previously approved, Riley's claim here is based on substantive noncompliance. The FDA specifically approved Mednology's device containing silicone-based foam, but Mednology replaced the approved foam with a dangerous substitute that the FDA had not approved. R. at 4. This rendered the device substantively noncompliant with the prior FDA approval, which the court in *Marsh* stated is enough to work around a manufacturer's immunity.

Finding preemption of the compliance provision would render manufacturers invincible. Manufacturers, like Mednology, could get FDA approval for a device and then change it however they wanted. If manufacturers could change an FDA-approved device without losing their

immunity from state law claims, nothing would hold them accountable for complying with FDA requirements. This would disregard federal and state interests in protecting the health and safety of citizens.

Therefore, this Court should find that the compliance provision of Transylvania's Immunity statute has been rebutted and is not preempted by federal law. However, even if this Court finds that Riley has not rebutted the presumption of compliance or that it is preempted, the exceptions function as a method of stripping Mednology's immunity.

C. The Immunity Exceptions Remove Protection from Mednology Because Federal Law Does Not Preempt Them.

The immunity exceptions found in subsections (b) and (c) of Transylvania's statute allow state law liability when a manufacturer's device would not have been approved by the FDA absent fraud or when the manufacturer failed to warn as required by the FDA. Neither exception creates requirements different from or in addition to federal law.

1. The fraud exception under subsection (b) is not preempted because it does not interfere with FDA authority.

This Court should find that the fraud exception found under subsection (b) of the immunity statute is not preempted because it does not interfere with the FDA's power to regulate fraud against them. Subsection (b) provides that 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.

21 Trans. Comp. Stat. § 630.546(b). The main concern is state law undermining the "delicate balance of statutory objectives" that enable the FDA to "punish and deter fraud." *Buckman Co.*, 531 U.S. at 352. However, that balance is not affected by the fraud exception here. In *Buckman*, this Court addressed fraud-on-the-FDA claims based only on federal disclosure requirements. *Id.* at 352-53. *Buckman* does not apply to the present case because Transylvania's fraud exception does not create a new cause of action solely based on fraud-on-the-FDA claims but instead removes immunity from an existing state law claim when fraud on the FDA has occurred.

The Second Circuit upheld a similar fraud exception against a preemption challenge and explained why *Buckman* did not apply, as it should not here. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006). The court found the fraud exception did "not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*." *Id.* at 95. Like *Desiano*, the fraud exception here is only a part of Transylvania's state tort law scheme and does not solely police fraud on the FDA. The court went on to distinguish *Buckman* for reasons that also apply in the present case.

First, the court stated that unlike in *Buckman*, the plaintiffs in *Desiano* brought a traditional state law torts claim, not a freestanding fraud-on-the-FDA claim. *Id.* at 94. The fraud exception there simply removed a defense to those claims. The same is true here because Riley is bringing traditional product liability claims, and the fraud exception only takes away Mednology's immunity defense.

Second, the court in *Desiano* found that the immunity statute "cannot reasonably be characterized as a state's attempt to police fraud against the FDA," unlike the claim in *Buckman*, because the purpose was "to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Id.* at 94-95. The fraud exception ensured that

manufacturers committing fraud could not hide behind immunity. *Id*. at 87. Again, the same is true for Transylvania's fraud exception because the purpose was to ensure manufacturers engaged in fraud could not escape liability for injuries caused by their products. R. at 7-8.

To the contrary, the Sixth Circuit's holding in *Garcia*, which found a similar exception to be preempted absent prior FDA findings of fraud, should not guide this Court's analysis. *See generally Garcia v. Wyeth-Ayerst Labs.*, 385 F3d 961 (6th Cir. 2004). In *Garcia*, the court stated immunity exceptions "are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find . . . fraud on the FDA) but not in others (*e.g.,* claims based on federal findings of . . . fraud on the FDA)." *Id.* at 966.

The standard in *Garcia* fails to recognize the difference between a freestanding fraud-on-the-FDA claim and a fraud exception to immunity. This Court's holding in *Buckman* expressly preempts the former but does not necessarily preempt the latter. Under this approach, manufacturers would benefit from immunity against state law claims even when they have engaged in fraud simply because the FDA has not made any formal findings. This would incentivize manufacturers to conceal their fraudulent conduct from the FDA and potentially leave many injured consumers without a remedy.

In the present case, Mednology recalled their device shortly after Riley filed her lawsuit. R. at 7. At that point, "the FDA decided not to continue investigating Mednology's alleged fraudulent conduct" to focus their attention on other defective products in the market. *Id.* The issue with applying *Garcia's* standard is that even though the FDA declined to investigate further, the damage has already been done. If this Court were to apply *Garcia*, consumers like Riley would fall between the gaps and be left without an adequate remedy. Transylvania's fraud exception fills those gaps.

Applying *Desiano* rather than *Garcia* strikes a better balance between federal and state interests because it allows states to provide remedies for injured consumers while respecting the FDA's primary role in regulating medical devices. As this Court has expressed, states should not be prevented from their traditional role in regulating the health and safety of citizens. *Lohr*, 518 U.S. at 485.

2. The failure to warn exception under subsection (c) is not preempted because it parallels federal requirements.

Federal law does not preempt the failure to warn exception under subsection (c). Transylvania's failure to warn exception states "[t]he immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the . . . medical device as required by the FDA." 21 Trans. Comp. Stat. § 630.546(c). This exception removes immunity when the manufacturer fails to provide the FDA-required warnings and does not impose any additional or different warning requirements found in the FDCA. Mednology has failed to warn about the dangers associated with replacing the silicone-based noise-dampening foam with the dangerous PE-PUR foam.

Courts have consistently held that state law claims premised on violations of FDA requirements are not preempted. *See Lohr*, 518 U.S. at 495; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). The failure to warn exception operates in the same manner. It allows state liability when federal requirements are violated. It does not interfere with the FDA's authority to determine what warnings are required. *See Riegel*, 552 U.S. at 330 (finding that state failure to warn claims "would parallel, rather than [add] to federal requirements").

The Ninth Circuit and Fifth Circuit courts addressed similar failure to warn claims in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) respectively.

In *Stengel*, the plaintiff had a pain pump device implanted that ultimately left him paralyzed due to complications from the device. *Stengel*, 704 F.3d at 1227. The manufacturer "had become well aware of those risks but had failed to inform the FDA" even though they were required to do so by federal law. *Id.* The plaintiff sued under a state-law negligence claim, but the manufacturer argued the FDCA preempted the claim. *Id.* The court held that claims premised on a state law duty that mirrors a federal law duty are not preempted. *Id.* at 1233.

Similarly, in *Hughes*, the plaintiff received severe burns when hot liquid was released from a medical device. *Hughes*, 631 F.3d at 765. The plaintiff alleged the violation of a state law duty to warn. *Id.* The court held that state law failure to warn claims were not preempted "to the extent that [the] claim is predicated on [the manufacturer's] failure to comply with the applicable federal [laws]." *Id.* at 764. The court continued that failure to warn claims are "neither expressly nor impliedly preempted by [federal law] to the extent that [the] claim is premised on [the manufacturer's] violation of FDA regulations with respect to reporting burns caused by the [device]." *Id.* at 776.

Mednology relies on cases among the circuit courts that state the opposite of *Hughes* and *Stengel* by finding failure to warn claims are preempted by federal law. R. at 16. These cases include *Mink*, 860 F.3d 1319, and *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2017). However, relying on *Mink* and *Bryant* leads to a dangerous precedent that would leave injured plaintiffs without a remedy. The FDA has limited resources, and state law claims can help protect the integrity of the FDA approval process and help protect the public. *See Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992) (stating that a manufacturer satisfies their duty to warn if there is "reasonable assurance that the information will reach those whose safety depends on their having it"), *aff'd*, 44 F.3d 806 (9th Cir. 1995).

Riley's safety depended on Mednology's warning against the dangers of their device, yet it was blatantly disregarded. The failure to warn exception provides an additional mechanism for holding manufacturers liable and reinforces the FDCA's regulatory scheme of protecting the health and safety of consumers.

Even if this Court finds that *Stengel*, *Hughes*, *Mink*, and *Bryant* are factually distinguishable from the present case, as the District Court and Circuit Court found below, the fraud exception is still not preempted because *Desiano* swoops in to guide this Court's analysis as mentioned in section (c)(1) above. *See* R. at 17, 30 (stating the mentioned cases are different because they involved failure to warn claims, whereas the present case consists of a failure to warn exception to Transylvania's immunity statute). *Desiano* is clear that an immunity exception survives when it is premised on a defendant's violation of federal requirements. *Desiano*, 467 F.3d at 88; *see Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 87 (2006) (finding state law claims based on violations of federal disclosure requirements are not preempted in the area of securities law); *see also Her Majesty The Queen In Right of the Province of Ontario v. City of Detroit*, 874 F.2d 332, 342 (6th Cir. 1989) (finding state law claims based on violations of federal environmental law standards are not preempted).

The statutory exceptions to manufacturer immunity in Transylvania's product liability statute complement rather than conflict with the FDCA. The exceptions protect public safety and health without imposing additional requirements on manufacturers. Preempting these expectations would create a dangerous regulatory gap, leaving injured consumers to fend for themselves. This Court should find that federal law does not preempt these exceptions, thereby preserving the delicate balance between federal regulation and the state's traditional role in safeguarding their

citizen's health and safety. We respectfully ask that this Court affirm the Seventeenth Circuit's decision to deny Mednology's motion to dismiss for the abovementioned reasons.

II. THIS COURT SHOULD AFFIRM THE SEVENTEENTH CIRCUIT'S DECISION AND DENY MEDNOLOGY'S 12(B)(6) MOTION TO DISMISS BECAUSE THE COURT APPROPRIATELY RELIED ON *CAMPIE* INSTEAD OF THE *D'AGOSTINO*.

A. The Ninth Circuit's Analysis in *Campie* Applies This Court's Precedent to A Case Asserting the Implied False Certification Theory and Therefore Is More Appropriate.

The False Claims Act ("FCA") has the same purpose now as it did when it was enacted during the Civil War: to protect the government from fraud. Accordingly, the FCA's *qui tam* provisions incentivize private individuals aware of fraudulent conduct to bring an action in the name of the United States. 31 U.S.C. § 3730(b)(1). In alignment with the Act's purpose, Riley filed a *qui tam* suit, alleging Mednology had violated the FCA. R. at 6. Under the FCA, 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," is subject to liability. 31 U.S.C. § 3729(a)(1)(A), (B). For purposes of this statute, a claim includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 181(2016).

To bring a claim under the FCA, there must be "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." *United States ex rel. Campie v. Gilead Scis.,* 862 F.3d 890, 899 (9th Cir. 2017) (citing *United States v. Univ. of Phx*., 461 F.3d 1166, 1174 (9th Cir. 2006)). Because Riley relies on the False Implied Certification Theory, encountered in *Campie* but not in *D'Agostino*, the Ninth Circuit's analysis in *Campie* is more appropriate. R at 36.

Riley's reliance on the fraud-on-the-FDA theory, commonly referred to as the false implied certification theory, is appropriate here. *Escobar*, 579 U.S. at 186. While circuits split for years over the validity of the implied false certification theory, this Court held it could be a basis for liability. *Id*. However, the theory is only appropriate where 1) the claim does not merely request payment, but also makes specific representations about the goods or services provided and 2) the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths. *Id.* at 191. Since Riley's facts plausibly satisfy both requirements, she can rely on her false implied certification theory as a valid basis to bring her claim under the FCA. R. at 36. *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009).

To start, Mednology knew the Food and Drug Administration (FDA) was aware of PE-PUR foam's health risks because another company had previously recalled its CPAP devices. R. at 6. That company even replaced PE-PUR foam with silicone-based foam as a safer alternative. Knowing this, when Mednology sought the approval of Sleepternity for marketing, it used silicone-based foams instead. R. at 4. Then, Mednology ditched the safer alternative and reverted to using PE-PUR foams to reduce manufacturing costs. *Id.*

Further, it was no secret that the Centers for Medicare and Medicaid Services (CMS) began providing coverage to individuals for the cost of using Sleepternity since the FDA approved the device for marketing. R. at 4. Accordingly, each time Mednology sought payment or reimbursement, it knowingly represented to the CMS, and ultimately the government, that Sleepternity complied with its FDA approval, though it did not. *Id*. Like Gilead's conduct in *Campie*, this went beyond a mere request for payment. *Campie,* 862 F.3d 890at 904 (determining requests for payment for re-labeled, unapproved drugs were more than a mere request for payment).

Further, Mednology failed to disclose it was using PE-PUR foams instead of silicone-based foams, in contrast to its FDA approval. R. at. 4. This misled the CMS, the FDA, and consumers like Riley. R. at 4. Like Gilead's failure to disclose its distribution of unapproved drugs, Mednology's conduct also fell "squarely within the rule that half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information– can be actionable misrepresentations." *Escobar*, 579 U.S. 176 at 189.

Unlike Riley and the claimant in *Campie*, D'Agostino's primary claim is fraudulent inducement. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 6 (1st Cir. 2016). Further, D'Agostino relies on three express representations, including 1) a narrow indication for Onyx's use, which it did not follow; 2) testimony that training would be rigorous, which they did not provide; and 3) the assistance of an experienced proctor for a physician's first use which often was not the case. *Id.* This is not like Riley's claim. Riley does not rely on misrepresentations. R. at 36. Instead, she points to the CMS's reliance on FDA approval and Mednology's subsequent conduct to show false statements were implied. *Id*. Because *D'Agostino* is factually different, and *Campie* is more similar to this case, reliance on *D'Agostino* would be inappropriate. *Id*.

B. Because The Ninth Circuit Properly Applied This Court's Clarifications from *Escobar* Regarding Materiality, Unlike the First Circuit, The Seventeenth Circuit's Reliance on The Ninth Circuit Analysis Was Proper.

1. Since there is a factual dispute as to whether the government would have continued to provide payment once it knew of such violations, materiality presents a matter of proof, and dismissal would be inappropriate.

To be considered material under the False Claims Act, a misrepresentation must have "a natural tendency to influence, or be capable of influencing, the payment of receipt of money or property." 31 U.S.C. § 3729(b)(4). While this standard is demanding, this court provided clarifications as to what does and does not constitute materiality. *Escobar*, 579 U.S. at 193.

Relevant to this case, this court in *Escobar* stated proof of materiality may include evidence that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirements. *Id.* at 186. Riley alleged several facts showing the government consistently refuses to pay claims based on noncompliance with FDA approval. First, Riley alleged the CMS began providing coverage as a result of its FDA approval for marketing. R. at 7. More relevant to this case, because another company recalled its CPAP machines for its use of PE-PUR, the government would refuse to pay Sleepternity for its noncompliance and similar use of PE-UR. R. at 4. Lastly, Mednology's voluntary recall, shortly after Riley filed her lawsuit, indicates Mednology's awareness that the government would refuse to continue paying for the costs of Sleepternity. R. at 7.

That being said, if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong proof that those requirements were not material. *Escobar*, 579 U.S. 176, 186 (2016). In this case, there is no allegation that the CMS continued to pay for claims when it knew of Mednology's fraudulent conduct, especially considering Mednology's recall quickly followed Riley's lawsuit and Mednology's receipt of a summons. R. at 7.

Additionally, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, and the government has signaled no change in position, that is also strong evidence that those requirements were not material. *Escobar*, 579 U.S. 176, 186 (2016). Here it is important to acknowledge Mednology recalled Sleepternity under 21 C.F.R. § 7.40(b) which provides that "[r]ecall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations

and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled." 21 C.F.R. § 7.40(b).

Accordingly, Mednology's immediate recall did not allow the FDA the opportunity to decide whether to demand a recall. R. at 7. Therefore, the CMS could not signal a position as to whether it would have continued to pay for the costs of using Sleepternity. *Id.*

In analyzing materiality, when there are factual disputes as to whether the government was aware of certain FDA violations and whether the government would have continued to provide payment once it knew of such violations, the issue becomes a matter of proof. *Campie,* 862 F.3d at 906. For example, the defendants in *Campie* argued the government continued payments despite their violations, proving their violations were not material. *Id.* However, because the noncompliant drugs were no longer used when the government continued payment, it became a matter of proof because they raised genuine issues of material fact. *Id* at 907. Similarly, Riley raised a genuine issue of material fact when she alleged the CMS would not have continued paying for Sleepternity if it knew the device did not comply with the FDA because the CMS's coverage requires FDA approval. R. at 6. Since Riley's alleged facts could plausibly satisfy the materiality element, dismissal would be inappropriate. R. at 6.

2. Because this Court's clarifications in *Escobar* regarding materiality shifted the focus to the causal link between the fraudulent conduct and the government's decision to pay, adopting the concurrence is not necessary.

Dismissal for lack of causation would also be inappropriate because the Court's clarification in Escobar shifted the focus of materiality but kept causation at the forefront. *Escobar*, 579 U.S. at 191. In fact, right before clarifying how materiality should be enforced, this Court reiterated, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims

Act." *Id.* at 192. It makes sense that various ways to prove or disprove materiality revolve around the Government's decision to pay. *Id.* For this reason, because Riley alleged sufficient facts to plausibly satisfy materiality, she has done the same for causation. R. at 37.

3. Even if this Court is unsatisfied with the Seventeenth Circuit's coverage of causation, the Court should incorporate its concurrence instead of reverting to the District Court's holding.

Overall, the Seventeenth Circuit's concurring opinion agrees with the majority that Mednology's motion to dismiss Riley's False Claims Act action should be denied. R. at 38. The opinion approves of the Majority's determination that Riley is relying on the implied certification theory and that this Court's clarifications of materiality in *Escobar* should control. R. at 38. However, the concurrence writes to emphasize causation. R. at 39. The opinion agrees with the proposition that causation is implicit in *Escobar's* clarifications, but where it differs is in the length of its explanation or potential lack of emphasis. R. at 39. Despite its request, the concurrence still disagrees with the District Court's determination that Riley lacked causation. R. at 40.

The concurrence correctly stated, in light of Escobar, that causation is essential to establishing materiality. R. at 40. Given that the majority found materiality to be a matter of proof, the concurrence reasoned that causation should also. R. at 40. Specifically, because Riley had not indicated she was unable to prove a causal link between Mednology's fraudulent conduct and the government's decision to pay, the concurrence determined Riley should have the opportunity to do so. R. at 40.

CONCLUSION

It is for these reasons that we respectfully ask that this Court AFFIRM the Seventeenth Circuit's decision to deny Mednology's motion to dismiss and uphold the validity of Transylvania's statutory exceptions to manufacturer immunity.

We also respectfully request that this Court AFFIRM the Court of Appeals for the Seventeenth Circuit as to Riley's claim under the False Claims Act and REMAND the case for further proceedings. Should this Court find the Court of Appeals inadequately addressed causation in the majority opinion, this Court should still AFFIRM the Court of Appeals but incorporate its concurring opinion.

Respectfully submitted,

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ATTORNEYS FOR RESPONDENT