No. 24-9176

IN THE

Supreme Court of the United States

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 RESPONDENT

Attorneys for Respondent

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QUESTIONS PRESENTED

1. Whether the appellate court erred in holding that federal law preempts the immunity exceptions under 21 Trans. Comp. Stat. § 630.546(b) and (c), despite evidence that Mednology's failure to disclose material risks and provide adequate warnings aligns with the state's role in protecting health and does not conflict with federal regulatory standards?

2. Whether the trial court erred in dismissing Riley's False Claims Act claim under 31 U.S.C. § 3730(b) by concluding that Mednology's omissions and misrepresentations regarding the safety risks of the Sleepternity device did not constitute sufficient grounds for FCA liability, despite these actions misleading the federal government and influencing payment decisions?

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The opinion of the United States District Court for the Southern District of Transylvania is unreported but is set out in the record. R. at 24. The opinion of the United States Court of Appeals for the Seventeenth Circuit is also unreported but is set out in the record. R. at 5–43.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves Federal Food, Drug, and Cosmetic Act (FDCA). This case also involves 21 Trans. Comp. Stat. §§ 630.545 and 630.546 under Transylvania's Product Liability Statue.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves a retired United States artillery officer, Riley Ortega, who was physically injured by Sleepternity, a CPAP machine manufactured by Mednology. R. at 2. After a decision by the district court and the appellate court, the Supreme Court has granted certiorari. R. at 2—43.

Ms. Ortega's Health History. Ms. Ortega resides in the State of Owhio. R. at 3. Ms. Ortega is a retired United States artillery officer. R. at 2. While serving her country, Ms. Ortega experienced traumatic events. R. at 3. These traumatic events resulted in Ms. Ortega struggling with her day-to-day operations and the diagnosis of post-traumatic disorder. R. at 3. This diagnosis contributes to Ms. Ortega's insomnia and sleep apnea symptoms. R. at 3. Additionally, Ms. Ortega is "allergic to isocyanate, a volatile organic Compound (VOC) that comes from degraded polyurethane." R. at 5.

Ms. Ortega's Prescription for Sleepternity. As an attempt to alleviate her insomnia and sleep apnea symptoms, Ms. Ortega visited her somnologist. R. at 3. The somnologist prescribed Ms. Ortega Sleepternity, a sleep-inducing medical device manufactured by Mednology. R. at 3. Sleepternity is a "state-of-the-art continuous positive airway pressure

(CPAP) machine that provides several unique features." R. at 3. These features 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" and "noise canceling sleep headphones that can be attached to the mask." R. at 3. The sleep headphones "help users relax and fall asleep gently," by emitting "gentle pulses that travel to the user's brain." R. at 3. All combined, these features help to reduce sleep apnea and insomnia. R. at 3.

On December 30, 2022, Sleepternity was approved by the FDA to be marketed as a Class III medical device. R. at 3—4. Upon approval by the FDA, Centers for Medicare and Medicaid Services (CMS) provided "coverage to individuals who were prescribed Sleepternity for the costs of using the device." R. at 4.

Mednology's Alteration of Sleepternity Post-FDA Approval. Mednology altered the sleep headphones by replacing "the silicone-based foam with a polyester-based polyurethane (PE-PUR) foam." R. at 4. Ms. Ortega nor the FDA were notified of this alteration of the sleep headphones. R. at 4. Mednology was allegedly motivated to alter the sleep headphones to decrease the manufacturing costs because PE-PUR is "generally cheaper than silicone." R. at 4. Mednology did not change its labels on the CPAP machine to provide notice of this alteration in the sound abatement foam. R. at 5.

Health Risks Associated with PE-PUR Foam. The use of PE-PUR foam has caused health risks when it is used as sound abatement material in CPAP machines. R. at 4. The FDA has acknowledged that PE-PUR foams used in CPAP machines for sound abatement "can break down over time" and create pieces of PE-PUR foam or a chemical known as volatile organ compounds (VOCs). R. at 4. These byproducts can then "be breathed in or swallowed by CPAP users," unbeknownst to the users because the VOCs are invisible. R. at 4. The

harmful effects of PE-PUR foam in sound abatement material had been exposed before Mednology decided on the replacement. R. at 4. In June 2021, Philips Respironics, a medical device manufacturer, "recalled from the market certain CPAP machines that contained PE-PUR sound abatement foams" with the purpose of replacing the PE-PUR foam with a silicone-based foam. R. at 4.

Ms. Ortega Using Sleepternity. After Ms. Ortega began using Sleepternity, she suffered from asthma attacks. R. at 4. These asthma attacks led to Ms. Ortega being transported to the emergency room at a nearby hospital. R. at 4. The emergency room physician recommended that Ms. Ortega stop using Sleepternity. R. at 5. Ms. Ortega's primary physician echoed this recommendation as this physician concluded that Ms. Ortega's asthma attacks were an "unknown side effect of the medical device. R. at 5. The primary physician and Ms. Ortega were aware of Ms. Ortega's allergy to isocyanate; however, the label on the Sleepternity did not state that isocyanate was present in the device. R. at 5. Ms. Ortega followed the advice of the emergency room and primary physician and stopped using Sleepternity.

Ms. Ortega's Health Decline Post-Sleepternity. The use of Sleepternity has physically injured Ms. Ortega. R. at 5. Ms. Ortega now has chronically inflamed lungs because of her asthma attacks while using Sleepternity. R. at 5. Additionally, Ms. Ortega continues to suffer from her sleep apnea symptoms "notwithstanding her use of various sleep apnea medications." R. at 5.

Ms. Ortega Became Aware of Mednology's Alteration of Sleepternity and Health Risks of PE-PUR Foam. Ms. Ortega became aware of Mednology's alteration of Sleepternity from her brother, Jim. R. at 5. Mednology employs Jim as an assembly manager. R. at 5. Jim informed Ms. Ortega that Mednology used the "silicone-based foams to secure marketing approval from the FDA and replaced the foam with PE-PUR foam to save on

manufacturing costs before packing and sending Sleepternity to its distributors. R. at 5. Ms. Ortega then conducted her own research and found that PE-PUR foams can degrade types of isocyanates. R. at 5. Ms. Ortega realized that the PE-PUR foam likely caused her to experience asthma attacks, resulting in her chronically inflamed lungs. R. at 5.

II. NATURE OF PROCEEDINGS

United States District Court for the Southern District of Transylvania. On June 21, 2023, Ms. Ortega brought a product liability action against Mednology under Transylvania's Statutory Law and a False Claims Act (FCA) claim. R. at 6. Mednology filed a motion to dismiss Ms. Ortega's claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. R. at 2. Ms. Ortega requested that the district court deny the motion to dismiss. R. at 2. The district court entered a judgment denying Mednology's motion to dismiss in part and granting Mednology's motion to dismiss in part. R. at 2. The district court denied the motion to dismiss, holding that Ms. Ortega's claims under statutory law were not preempted by federal law. R. at 2. In contrast, the district court affirmed Mednology's motion to dismiss by holding that Ms. Ortega's FCA claim under the fraud-on-the-FDA theory was not a viable basis. R. at 2.

United States Court of Appeals for the Seventeenth Circuit. On April 1, 2024, the case reached the Seventeenth Circuit Court. R. at 25. The circuit court entered a judgment affirming in part and reversing in part the district court's holding. R. at 25. The circuit court affirmed the district court's decision, holding that although the statutory law was preempted by federal law, Ms. Ortega pleaded sufficient facts to avoid a dismissal. R. at 28—33. In contrast, the circuit court reversed and remanded the district court's decision regarding the FCA claim, holding that fraud-on-the-FDA was a viable basis for Ms. Ortega's claims. R. at 35—38.

United States Supreme Court. On August 1, 2024, a petition for writ of certiorari was granted and 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? R. at 43.

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? R. at 43.

SUMMARY OF THE ARGUMENT

I.

Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546 are not preempted by federal law. Instead, Transylvania's Product Liability Statutes complement the regulatory framework established by the Federal Food, Drug, and Cosmetic Act (FDCA). Grounded in long-standing state tort law principles, Riley's state law claims are designed to protect public health and safety. Transylvania's Product Liability statutory scheme provides manufacturers with immunity under § 630.546(a) but includes exceptions outlined in § 630.546(b) and (c), which apply when manufacturers fail to disclose material risks or provide adequate warnings. Mednology's failure to disclose the use of PE-PUR foam, a material with known health risks, triggers these exceptions. Transylvania's role in regulating public health through state tort law aligns with and reinforces federal standards, ensuring manufacturers are held accountable by offering remedies to consumers harmed by defective products.

II.

Riley's claims under §§ 630.545 and 630.546 aim to enforce duties manufacturers are already required to uphold—specifically, the need for transparency and accountability in marketing medical devices. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), the court

noted that nothing in the Medical Device Act (MDA) denied a state the right to provide traditional damage remedies for violations of common-law duties when those duties paralleled federal requirements. *Id*. at 487. Similarly, in *Wyeth v. Levine,* 555 U.S. 555, 573 (2009), the Court held that the FDA approval of a drug did not shield the manufacturer from liability under state tort law if inadequate warnings were given to consumers. These principles bolster Riley's claims because they enforce duties consistent with federal law while ensuring that consumers are protected and allowed compensation.

Importantly, Riley's claims are distinct from the decisions in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). *Buckman* and *Garcia* dealt with allegations consistent with fraud-on-the-FDA. Here, Riley's claims focus on Mednology's independent duty to disclose material risks and provide adequate warnings to consumers, claims that are firmly rooted in traditional state tort law. Unlike in *Buckman*, where the plaintiff's claims interfered with the FDA's authority, Riley's claims do not; they support the FDA's regulatory framework by enforcing existing obligations. The exceptions under § 630.546(b) and (c) align with federal objectives, aiding to ensure manufacturers uphold their responsibilities to consumers and protect public health.

III.

The trial court erred in dismissing Riley's False Claims Act (FCA) claim. Mednology's failure to disclose the substitution of PE-PUR foam in the Sleepternity devices misled the FDA and the government, leading to continued federal payments for non-compliant devices. This omission meets the FCA's materiality and scienter requirements, as Mednology knew that disclosing the foam's risks would have impacted government funding decisions. See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 193 (2016); *Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 907 (9th Cir. 2017). Unlike in *D'Agostino v. ev3,*

Inc., 845 F.3d 1, 7 (1st Cir. 2016). Riley's case involves explicit and documented fraudulent conduct directly affecting federal funding decisions. This distinction highlights that Riley's FCA claims are consistent with the Act's purpose—combatting fraud against the government.

IV.

For the reasons stated, this Court should AFFIRM the appellate court's dismissal of Mednology's motion to dismiss. Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546, alongside the False Claims Act claim, are well-founded and not preempted by federal law. These claims are essential in ensuring accountability, public health, and safety by aligning with state laws and federal regulations' objectives. Mednology's failure to disclose material risks and failure to warn justifies proceeding with the claims. The Court, by affirming the dismissal, will ensure consumer protections remain intact and that the balance of power between state and federal law is upheld.

ARGUMENT AND AUTHORITIES

Standard of Review. This appeal arises from questions of law. As such, the question of preemption is reviewed de novo. *Texas Midstream Gas Servs., LLC v. City of Grand Prairie*, 608 F.3d 200, 206 (5th Cir. 2010). Additionally, the validity of a claim is reviewed de novo. *Id*. As such, this Court reviews the lower court's determination de novo. *Id*.

I. Federal Law Does Not Preempt Riley's State Law Claims

Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546(a) operate within a statutory framework that grants conditional immunity to manufacturers of FDA-approved medical devices; however, it creates specific exceptions when manufacturers fail to meet their duty of care. While § 630.546(a) provides immunity to manufacturers whose products have received FDA approval, the protection is not absolute. The statute expressly allows for exceptions under § 630.546(b) and (c) when manufacturers fail to disclose material

modifications or fail to adequately warn consumers of risks that can/could affect the safety or effectiveness of the device. The duty of care under § 630.545 provides a backbone for these obligations by requiring manufacturers to disclose any modifications or risks, complying with state and federal regulations. Mednology's omission of critical information and failure to warn consumers violated these obligations by placing their conduct within the statutory exceptions to immunity under both § 630.546(b) and (c).

In this case, Mednology's substitution of PE-PUR foam—a material known to present significant health risks—without disclosure—triggers the exceptions outlined in § 630.546(c) for failure to warn about known risks. Furthermore, omitting this crucial information also implicates § 630.546(b), which applies when a manufacturer fails to disclose material modifications. Mednology breached its duty to inform and warn both the FDA and consumers about the dangers associated with the foam used in its Sleepternity device. This failure to disclose and warn directly removes the immunity provision granted under § 630.546(a).

Riley's claims are focused on Mednology's responsibilities to the consumer rather than challenging the FDA's decisions. Transylvania's Product Liability statutory scheme does not conflict with federal law. Instead, the statutes complement federal law by ensuring manufacturers are held accountable for failing to prioritize consumer safety. Therefore, Riley's state law claims are not preempted by federal law because they align with the federal regulatory scheme and assert traditional state law tort principles rather than fraud-on-the-FDA claims.

A. The Presumption Against Preemption

State law claims are strongly presumed not to be preempted by federal law. The Tenth Amendment provides that all the powers not delegated to the federal government be reserved to the states. These powers are the states' historic police powers, allowing them to enact laws and regulations to safeguard their citizens' health, safety, and welfare. State tort law is

unique because it aligns with the broader conceptualization of the state police powers; it addresses health and safety concerns by allowing for direct compensation to victims while deterring misconduct. Additionally, states are better equipped to understand the dangers affecting their citizens locally. This does not denigrate the importance of a larger federal objective, but it is essential to note the strong presumption against preemption given the delicate balance of state and federal oversight.

To establish federal preemption, Congress must enact legislation that expressly limits the state's ability to regulate—expressly preempting the state law. Or state law must obstruct or conflict with an existing federal regulatory scheme—impliedly preempting state law. In the present case, express preemption does not apply because Congress has not explicitly displaced state authority over medical devices. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (noting the MDA does not expressly preempt state law claims). Moreover, Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546 are not impliedly preempted because they do not obstruct or conflict with federal regulations. Each statute imposes clear duties on manufacturers. These duties include warning, disclosing information, and complying with federal law. Neither statute imposes additional burdens on manufacturers beyond what federal law requires. Instead, §§630.545 and 630.546 reinforce existing obligations, ensuring that manufacturers remain accountable for the safety of consumers. This cooperative regulatory structure supports federal objectives and respects the constitutional balance between state sovereignty and federal oversight. Riley's claims are rooted in traditional state tort law principles—principles firmly held within the state's traditional police powers—and are not expressly or implicitly preempted by federal law.

1. The Preservation of Separation of Powers

The separation of powers is a cornerstone of the American constitutional system and is designed to safeguard liberty by ensuring that no single branch holds unchecked authority.

As Grace M. Zogaib highlights, the Founding Fathers intentionally structured this system to include non-delegation of powers, the separation of functions within branches, and clear political accountability for government officials. Despite occasionally leading to inefficiencies, this framework prevents branches of government and federal agencies from overstepping their bounds. Grace M. Zogaib, *Preemption After Buckman: State Tort Failure to Warn Claims Based on Lack of Disclosure to FDA*, 57 N.Y.U. Ann. Surv. Am. L. 417, 436–38 (2000).

Serious concerns arise when federal agencies, like the FDA, wield significant regulatory power without political accountability. Zogaib notes that FDA scientists operate outside of direct political accountability to the people, creating a risk of regulatory overreach and encroachment on state sovereignty. *Id.* at 440. Additionally, the FDA's assertion of broad preemptive authority over state law further centralizes control at the federal level, potentially undermining the states' traditional role in protecting public health. Richard C. Ausness, *After You, My Dear Alphonse!: Should the Courts Defer to the FDA's New Interpretation of 360k(a) of the Medical Device Amendments?*, 80 Tul. L. Rev. 727, 729 (2006).

The dangers of unchecked federal preemption are compounded by the fact that agencies, as William D. Rubenstein points out, are "purely national, unelected institutions" with limited accountability to the public. William D. Rubenstein, *The FDA and the Tort System: Post-Levine Reflections on Preemption, Jurisprudence, and Safety Concerns*, 65 Food & Drug L.J. 325, 333 (2010). Federal preemption that is too far-reaching risks allocating too much power to these unelected bodies, eroding state authority, and limiting the state's ability to safeguard public health.

2. The Role of State Tort Law in Safeguarding Public Health

The decisions in *Medtronic, Inc. v. Lohr* and *Wyeth v. Levine* establish that state tort law, in parallel with federal regulations, creates a comprehensive system for protecting public

health. In *Lohr*, the Court considered whether the MDA to the FDCA preempted state common-law claims. It ruled that the MDA's preemption clause, 21 U.S.C. § 360k(a), did not eliminate state law claims that mirror federal requirements. The Court emphasized that Congress intended for the MDA to *supplement*—not displace—state tort law. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The reasoning in *Lohr* directly applies to Riley's claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546. These claims merely reinforce duties already imposed by federal regulations, such as the duty to disclose material risks and modifications. By affirming the validity of state law claims, *Lohr* underscores the essential role of state tort law in compensating individuals harmed by defective products. *Lohr*, 518 U.S. at 495.

Similarly, in *Wyeth v. Levine*, the Court underscored the complementary role of state law in consumer protection. In *Wyeth*, The Court held that FDA approval did not preempt state law claims for failure to warn, stating that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety" and that FDA regulation "supplemented existing state law remedies." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Both *Lohr* and *Wyeth* demonstrate that state law claims that align with federal safety requirements are not preempted. These cases affirm that state tort law can provide additional oversight and remedies, enhancing consumer safety. Riley's claims under 21 Trans. Comp. Stat. § 630.545 aligns with this precedent, as it seeks to enforce Mednology's duties of transparency, accountability, and the obligation to warn.

Further supporting this view is *Montoya v. St. Joseph Health Care Sys.*, emphasizes the importance of preserving state law claims within the context of the MDA. The court held that the MDA did not preempt all state common-law causes of action arising from injuries related to Class III medical devices that had undergone the premarket approval process. The court noted that while the MDA contains an express preemption provision, legislative history

indicates no intent to preempt common-law tort actions. Instead, Congress understood that states would continue to regulate this traditional area, ensuring consumers had avenues for redress. As the court stated: "There was nothing in the record indicating Congress' intent to preempt common law tort actions by passing the legislation." *Montoya v. St. Joseph Health Care Sys.*, 1996-NMCA-067, 139 N.M. 418, 415 P.3d 1109. The court stressed the necessity of preserving remedies for injured parties, explaining that preempting state law claims would leave consumers with no recourse for redress, contravening Congress's intent to protect the public. As noted in the legislative record: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all, the consumer pays for medical device malfunctions with his health and his life." 121 Cong. Rec. S10688 (daily ed. Apr. 17, 1975) (statement of Sen. Kennedy).

Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546 align with this framework by holding manufacturers accountable for failing to meet state and federal obligations. Far from being preempted, these claims provide essential consumer protection, ensuring a comprehensive system of oversight and accountability. State tort law is essential for manufacturer accountability, victim compensation, and the health and safety of the consumer.

B. Riley's Claims Assert Traditional State Law Claims

The parallel nature between Riley's claims brought under 21 Trans. Comp. Stat. § 630.545, and the FDCA does more than suggest that Riley's claims should not be preempted. It highlights claims independent of Mednology's explicit fraud against the FDA. Riley's claims are not expressly preempted, given the regulatory framework, and they are not impliedly preempted by overstepping into the FDA's exclusive authority. Yes, the FDA was deceived, but so were consumers. The very nature of Riley's claims seeks to hold Mednology

accountable by asserting long-standing tort law principles independent of Mednology's fraud of the FDA.

1. The Distinction Between State Law Claims and Fraud-on-the-FDA

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court drew a line between claims that directly challenge the FDA's regulatory process—and traditional state tort claims. *Buckman* held that fraud-on-the-FDA claims are impliedly preempted due to the FDA's exclusive authority over its regulatory processes. However, the court recognized state tort law's essential role in consumer protection, understanding that these claims serve as an important check on corporate misconduct, providing a dual layer of oversight to preserve public health and safety. *Id.* at 348-49. This understanding is echoed in *Desiano,* where the court held that state tort claims were not preempted despite being brought against FDA-regulated drugs. In *Desiano*, the court recognized the presumption against preemption, emphasizing state tort law, which has a long-standing role in regulating health and safety, finding that the plaintiff's complaints alleged a wide range of violations of common law duties long recognized by state tort law and were not *solely* based on defrauding the FDA. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

In *Riegel v. Medtronic*, 552 U.S. 312 (2008), the Court held that the MDA to the FDCA preempted state law claims under 21. U.S.C. §360k(a), if the state law imposed different or additional obligations on device regulation, it did not prevent states from providing a remedy for claims premised on violating FDA regulations *Id.* at 336. The decision in *Riegel* and *Buckman* focuses on the stringent requirements of Class III medical devices as set out in the MDA, specifically the requirements in the FDA's Premarket Approval (PMA) process. Both decisions affirm the express preemption under §360k(a) of the MDA and assert implied preemption against state law claims that merely attempt to enforce the FDCA, interfering

with the FDA's exclusive domain. However, the Court has consistently not barred recovery for state tort law claims, leaving the door open for claims that align with the requirements of the FDCA and do not allege only fraud on the FDA.

2. Distinguishing Riley's Claims from Fraud-on-the-FDA

In this context, the claims brought under 21 Trans. Comp. Stat. §§ 630.545 and 630.546 split the gap between being expressly preempted by the FDCA and impliedly preempted by the FDA's exclusive domain. Rather than undermining federal regulations, Transylvania's Product Liability statutes work in concert with federal requirements. Riley's claims are firmly grounded in traditional state tort principles, emphasizing Mednology's duty to warn and disclose material risks to consumers—duties that persist regardless of FDA approval. The responsibilities found within §§ 630.545 and 630.546 align with the requirements set forth by the FDCA, particularly under 21 U.S.C. § 360e, which requires manufacturers of Class III medical devices to disclose any material changes affecting the safety or effectiveness of their devices.

Mednology's failure to warn and disclose risks under §§ 630.545 and 630.546 is independent from FDA approval. Neither provision challenges the FDA's authority. This distinction is crucial: Riley's claims don't allege only fraud-on-the-FDA theories or add to or differ from federal requirements. This distinction is critical; Riley's claims focus on consumer protection and do not impede federal regulatory authority. Here, no conflict exists between state and federal requirements, and Riley's claims promote the shared goal of consumer safety, ensuring compliance with federal standards through traditional state tort law.

II. Immunity Exceptions Under 21 Trans. Comp. Stat. § 630.546 is Preempted by Federal Law

The United States Court of Appeals for the Seventeenth Circuit correctly held that the immunity granted under 21 Trans. Comp. Stat. §630.546(a) did not apply to Mednology's

defense. To this, we agree; however, if it is the case that the Court decides that immunity applies, then the exceptions to immunity under §630.546(b) and (c) apply with it.

A. Subsection (b) Reinforces Federal Law Ensuring Accountability for Fraudulent Conduct

The immunity exceptions under 21 Trans. Comp. Stat. § 630.546(b) are valid and enforceable. Subsection (b) states:

> "The immunity granted… does not apply if the defendant…intentionally withholds from or misrepresents to the United States Food and Drug Administration…information that would have affected approval or led to withdrawal of the device."

The appellate court erred in following the precedent set in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), rather than *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006). While it is true that there are ample concerns about state tort laws' interference with the FDA's ability to regulate, subsection (b) does not interfere; rather, it relies on the presumption that a manufacturer has intentionally withheld or misrepresented information that would have affected the approval process. Furthermore, subsection (b) does not impose any additional obligations; it aims to ensure manufacturers are held responsible to the consumer if they violate their federal and state responsibilities to disclose information pertinent to the consumer's health.

1. The reasons why a failure to warn claim should survive *Buckman*

A failure to warn claim should survive *Buckman* because the FDA is unable to properly monitor medical devices and the lack of remedy available to Riley. The FDA is not the same "sophisticated and expert regulator," as described in *Buckman*. Grace M. Zogaib, *Preemption After Buckman: State Tort Failure to Warn Claims Based on Lack of Disclosure to FDA*, at 253. In fact, recently the FDA was characterized as "underresourced agency unable to obtain the information it needs to monitor the multitude of drugs and devices on the

market." Id. at 253. Therefore, the FDA does not have the resources or manpower to effectively regulate medical devices in our modern times. Additionally, there is currently "no private right of action for a consumer injured by a medical device that has earned FDA approval." *Id*. at 251. Ultimately, without state law tort claims, the FDA will continue to fail to monitor medical devices and Riley, among other Americans, will continue to suffer injuries with no form of redress.

B. Subsection (c) and the Post-market Approval Process

Subsection (c) of 21 Trans. Comp. Stat. § 630.546 addresses the manufacturer's duty to warn consumers about the dangers or risks of a medical device after the FDA has approved its device. The provision states:

> "The immunity granted…does not apply if the defendant fails to warn about the dangers of or risks of the drug or medical device as required by the FDA."

Subsection (c) aligns with the FDA's post-market requirements, outlined in 21 U.S.C. § 360(h). §360(h) requires manufacturers to report any new risks, adverse events, or safety concerns arising post-market approval. The statutory language of Subsection (c) intends to mirror the federal requirements, as it specifically references compliance with the FDA as a prerequisite to liability. Manufacturers must continue to warn about risks their devices can pose post-market, especially in medicine, where scientific discoveries enhance our knowledge of potential health risks.

1. Mednology's Breach of Post-Market Duty to Warn

Mednology's failure to disclose the substitution of PE-PUR foam represents a direct violation of its post-market duty to warn under state and federal law. Despite knowing the dangers associated with PE-PUR foam, Mednology did not inform the FDA or consumers of these risks. This omission violates the FDA's post-market surveillance requirements and triggers the exception to immunity under subsection (c) of § 630.546. The duty to warn post-

market is essential to ensuring that consumers are informed of risks that may only become apparent after a product is used. Mednology's failure to fulfill this duty eliminates its claim to immunity under § 630.546. Subsection (c) works harmoniously with federal regulations to safeguard public health by holding manufacturers accountable for failing to warn consumers of emerging risks.

Mednology's post-market failure to warn about the risks associated with PE-PUR foam negates its claim to immunity under § 630.546(a). Subsection (c) denies explicit immunity when a manufacturer fails to warn about known dangers, as required by the FDA's regulations. Mednology violated its duty to warn under state and federal law by not disclosing the risks associated with PE-PUR foam. This nondisclosure triggers the exception provided by § 630.546(c), preventing Mednology from claiming immunity. By aligning with federal post-market obligations, subsection (c) ensures that manufacturers remain accountable for the safety of their products after receiving FDA approval, supporting the ongoing responsibility of manufacturers to inform the public and the FDA of emerging risks. Therefore, Mednology's conduct falls squarely within the exceptions to immunity, ensuring that state law complements federal regulations to maintain robust consumer protection.

III. The Trial Court Erred in Dismissing Riley's False Claims Act

The trial court dismissed Riley's FCA claim by holding that the theory of fraud-on-the-FDA was not a viable basis for her claim as it did not fulfill the causation element established in *D'Agostino*. R. at 20-21. The element of causation required that Mednology's conduct caused "the government to make a payment or to forfeit money owed." R. at 20. This element is satisfied when the FDA withdraws its approval of the device or drug. R. at 21. The trial court found that Riley failed to establish the causation element because her complaint

"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." R. at 21.

Upon reviewing the trial court's decision, the appellate court used a different approach to analyze Riley's FCA claim and stated that the district court erred in dismissing the claim. R. at 35-38. At the start of its analysis, the appellate court classified the fraud-on-the-FDA theory as an implied false certification theory. R. at 36. The appellate court reasoning is asl follows: "Because [Riley] 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." R. at 36.

After this classification of the basis of Riley's FCA claim the appellate court used *Escobar* and *Campie* to analyze the claim. R. at 35-38. *Campie* required the following *Escobar* clarifications to establish a FCA claim: "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (citing *Universal Health Servs., Inc v. United States ex rel. Escobar*, 579 U.S. 176, 188-193 (2016). Regarding materiality, *Campie* held that the "issue of to present a matter of proof rather than a legal ground to dismiss the relators' complaint." R. at 39. Accordingly, the appellate court found that since "Riley assert[ing] 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 facts would be 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." R. at 37. As the materiality

element was satisfied by Riley's claim, the appellate court did not directly analyze the other Escobar clarifications prior to upholding Riley's FCA claim. R. at 35-38.

A. Mednology's Conduct Satisfies the Requirements for FCA Liability

Mednology's failure to disclose the substitution of PE-PUR foam in its Sleepternity devices is a crucial component of its FCA liability. By omitting this information, Mednology created the false impression that its devices complied with FDA standards—which were material for the approval of the device and continued government payments. The non-disclosure of PE-PUR foam misled the FDA and other stakeholders, allowing Sleepternity to be approved and purchased. This omission is significant, as it involves an essential safety component that could have affected the government's decision to disburse funds. Such omissions are actionable under the FCA because they create a falsehood that directly influences the approval and funding of the product.

1. Impact of Misrepresentation on Government Payments

Mednology's omission directly impacted the government's payment decisions, meeting the causation requirement under the FCA. By withholding information about the PE-PUR foam, Mednology induced the government to fund these devices through Medicare and Medicaid based on the mistaken belief that they complied with all safety and regulatory standards. The use of undisclosed, high-risk materials would have likely led to the withdrawal or denial of FDA approval, and consequently, the government would not have continued funding the devices. Mednology's failure to disclose these risks directly led to the government's disbursement of funds under false assumptions, thereby satisfying the materiality and causation requirements for FCA liability.

2. Precedent Supports FCA Liability

In *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Court clarified that liability under the FCA can arise from misleading omissions if they lead the government to make payments it would not have otherwise made. The Court stated: "Half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations." *Universal Health Servs., Inc v. United States ex rel. Escobar*, 579 U.S. 176, 200 (2016). *Escobar* establishes that overt false claims and omissions of critical information can trigger FCA liability if the omission is material to the government's payment decision.

Similarly, in *Campie v. Gilead Sciences, Inc.*, the Ninth Circuit held that Gilead made false representations to the FDA about the source of its active ingredients for HIV drugs manufactured in unregistered facilities. The court found that factual disputes over whether the government would have withheld payments had it known about these violations precluded dismissal at the pleading stage. *Campie* underscores that misrepresentations intended to maintain FDA approval and secure government payments create FCA liability. Mednology's failure to disclose the substitution of PE-PUR foam in the Sleepternity device creates a parallel scenario. *Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 907 (9th Cir. 2017).

Like in *Campie*, Mednology's undisclosed substitution of PE-PUR foam constitutes a factually false certification, as the Sleepternity devices did not comply with FDA standards. Mednology implicitly certified compliance with relevant regulations by seeking government reimbursement for these devices, creating an implied false certification—additionally, *United States ex rel. Hutcheson v. Blackstone* further broadens the materiality analysis under the FCA. In *Hutcheson*, the court held that materiality can be demonstrated by the implied expectations of compliance between contracting parties, even without explicit documentation

in the contractual language. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 626 F.3d 1257, 1269 (1st Cir. 2010). This precedent supports the argument that Mednology's omission of the risks associated with PE-PUR foam would have influenced the government's payment decisions.

Mednology's failure to disclose the use of PE-PUR foam, a material with known health risks, directly misled the FDA and the federal government, resulting in continued payments based on the false assumption of regulatory compliance. These omissions undermine the FDA's regulatory framework and demonstrate clear instances of misrepresentation, materiality, and scienter under the FCA, as supported by *Escobar*, *Campie*, and *Hutcheson*.

3. A Clear-Cut Case of Fraud and FCA Liability in Contrast to Speculative Claims

Unlike in *D'Agostino v. ev3, Inc.*, where the court hesitated to extend FCA liability due to concerns about undermining FDA authority, Riley's case presents a direct instance of fraud with clear consequences for government spending. In *D'Agostino*, the court expressed apprehension about using the FCA to challenge FDA regulatory decisions based on speculative outcomes, worrying that such claims could disrupt market stability. The court focused on the difficulty of proving that FDA approval would not have occurred without the alleged fraud, raising concerns about judicial interference with FDA decisions. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7, (1st Cir. 2016).

In contrast, Riley's case is grounded in tangible and established fraud committed by Mednology. Specifically, their failure to disclose the substitution of PE-PUR foam violated FDA safety standards. It directly influenced the government's decision to continue payments, believing the device was fully compliant. Unlike the speculative concerns in *D'Agostino*, Mednology's omission had immediate and clear financial implications for the government.

Precedents such as *Escobar* and *Campie* support the argument that FCA liability is warranted when fraud materially impacts government payments. Riley's claims focus on actual harm caused by Mednology's deception rather than hypothetical regulatory issues, making it a well-defined case of FCA liability.

This distinction from *D'Agostino* demonstrates that Riley's case is firmly rooted in established FCA principles. The case highlights blatant non-compliance with FDA regulations, leading to unnecessary federal expenditures, which fits within the clear boundaries of FCA liability. Given the Supreme Court's review, this case offers an opportunity to affirm legal standards regarding FCA liability in regulatory contexts and to ensure that fraud against the government is rigorously addressed. The decision will resolve the issues with Mednology and set a precedent for enforcing federal health and safety standards through the FCA, safeguarding public funds.

CONCLUSION

For the foregoing reasons, this Court should AFFIRM the decision of the Seventeenth Circuit Court of Appeals to deny Mednology's motion to dismiss, as federal law does not preempt Riley's state law claims under 21 Trans. Comp. Stat. §§ 630.545 and 630.546. Furthermore, the Court should reverse the appellate court's decision regarding the preemption of the immunity exceptions under 21 Trans. Comp. Stat. § 630.546(b) and (c).

By affirming the Appellate court's ruling on Riley's FCA claim and reversing its error on the preemption of state law immunity exceptions, this Court will maintain the delicate balance of powers between state and federal law. Upholding Riley's

claims ensures that state law plays a vital role in protecting public health, reinforcing the dual layer of oversight that holds manufacturers accountable for misconduct. This decision will preserve the integrity of the statutory scheme, ensuring that both federal and state regulations work in concert to safeguard the public.

Respectfully submitted,

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ATTORNEYS FOR RESPONDENT

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