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 PETITIONER

Attorneys for Petitioner

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QUESTIONS PRESENTED

I. Whether the Transylvania statutes that Respondent relies on are preempted when liability is based on federal FDA findings or when the statutes seek to add additional requirements beyond what is imposed by the FDA?

II. Whether the Seventeenth Circuit made an error in reversing the trial court's dismissal of Riley's False Claims Act claim by concluding that Riley *could* plead facts sufficient for an FCA claim, despite the fact that Riley did not satisfy the materiality or causation requirements in her pleadings?

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The opinion and order of the United States District Court for the Southern District of Transylvania is unreported and set out in the record. R. at 2—24. The opinion and order of the United States Court of Appeals for the Fifteenth Circuit is also unreported and set out in the record. R. at 25—42.

CONSTITUTIONAL AND STATUTORY PROVISIONS

The following Constitutional provision is relevant to this case: U.S. Const. art. VI, cl. 2.

The following provisions of the Transylvania Code are relevant to this case: 21 Trans. Comp. Stat. §§ 630.544—46.

The following provisions of the United States Code are relevant to this case: The False Claims Act ("FCA") (31 U.S.C. §§ 3729—3733).

STATEMENT OF THE CASE

This case involves whether preemption prevents allegations that Mednology defrauded the FDA from being heard. It also involves whether the factual allegations are sufficient for fraud-on-the-FDA to constitute a viable FCA claim.

I. STATEMENT OF FACTS

Respondent Riley Ortega is a retired military servicemember with sleep apnea, insomnia, post-traumatic stress disorder, and allergies. R. at 3. She was prescribed a sleep inducing continuous positive airway pressure (CPAP) machine called Sleepternity. *Id*. It has several unique features that provide comfort and practical improvements to health. *Id.* Among those features are a pair of sleep headphones to help with insomnia. *Id.* Sleepternity was approved by the FDA on December 30, 2022, and the Centers for Medicare and Medicaid Services (CMS) began to provide coverage for the device shortly after. R. at 3-4.

Petitioner Mednology modified the sound-dampening foam in the headphones subsequent to gaining the FDA's approval of the device, making a switch from silicone-based foam to polyester-based polyurethane (PE-PUR) foam and did not alert the FDA. R. at 4. Mednology allegedly made this switch to save on manufacturing, however, PE-PUR may present health risks. *Id.*

In June 2021, Philips Respironics recalled some CPAP machines containing PE-PUR, not because the FDA told them to, but out of an abundance of caution. *Id.* The FDA has stated that PE-PUR foams *may* break down over time, producing volatile

organic compounds which *could* be breathed in or swallowed which can result in health risks. *Id.*

Riley experienced asthma attacks and had to be transported to the emergency room where she was recommended to stop using Sleepternity. R at 4-5. Her primary care physician agreed and believed the asthma attacks to be an unknown side effect of the device. R. at 5. Riley and her doctor knew that she was allergic to isocyanate, a VOC that comes from PE-PUR break down, however there was no information on the warning label about its presence in the device. *Id.* Once Riley stopped using Sleepternity, her asthma symptoms stopped. *Id.* However, her lungs became chronically inflamed and her sleep apnea symptoms returned. *Id.* Despite the fact that she was told not to use Sleepternity anymore, she uses the headband containing the sound-dampening PE-PUR foam to this day to treat her insomnia. *Id*. Her sleep apnea symptoms persist despite her usage of various medications. *Id.*

Riley's brother, Jim, currently works as an assembly manager at Mednology. *Id.* He informed Riley that Mednology made the switch in materials after securing FDA approval in order to save money, and he believed the PE-PUR foams that were used may have been what actually caused her asthma attacks. *Id.* After conducting her own research, Riley agreed and commenced this action. R. at 5-6.

II. Procedural History

Respondent is Riley Ortega, a citizen of the State of Wohio. R. at 2-3. She was prescribed a Sleepternity device, manufactured by Petitioner Mednology, to treat her insomnia. R. at 3.

Respondent filed a products liability suit against Petitioner in the United States District Court for the Southern District of Transylvania on June 21, 2023. R. at 6. In Respondent's complaint, she alleged Petitioner breached their duty of care and good faith, Petitioner failed to disclose modifications to the FDA, and Petitioner's fraudulent conduct to the FDA enables her claim under the False Claims Act ("FCA") (31 U.S.C. §§ 3729-3733 (2024)). *Id.* Petitioner responded to the action with a motion to dismiss under Fed. R. Civ. P. 12(b)(6). R. at 9, 25. Petitioner argues both that fraud-on- the-FDA is not a viable basis for an FCA claim and that Respondent's reliance on Transylvania's product liability immunity exceptions does not provide a valid basis for a claim upon which relief can be granted because the immunity exceptions are preempted. R. at 9. The district court heard arguments on September 12, 2023. *Id.* The district court granted a motion to dismiss in part, dismissing Respondent's FCA claim for being on Petitioner's fraud towards the FDA. R. at 24. The district court denied the motion to dismiss in part as to subsections (b) and (c) of Transylvania's immunity statute, ruling that they were not preempted by federal law. *Id.*

Petitioner appealed the action to the United States Court of Appeals for the Seventeenth Circuit. R. at 25. Heard by a three-judge panel, the Seventeenth Circuit ruled on the district court's decision with Justice Ruzich writing separately concurring in part and dissenting in part. *Id.* The Seventeenth Circuit affirmed, on different grounds, the district court's denial of Petitioner's motion to dismiss as to Respondent's claims under Transylvania's product liability statute. *Id.* The Seventeenth Circuit reversed the district court's granting of Petitioner's motion to

dismiss Respondent's FCA claim. *Id.* Justice Ruzich concurred as to the Seventeenth Circuit's decision to reverse the dismissal of Respondent's FCA claim, emphasizing that Respondent should be able to offer proof as to the causation element of her claim. R. at 39–40. However, Justice Ruzich disagreed in part with the Seventeenth Circuit, arguing that he did not believe the either the compliance portion of the Transylvania product liability provision or the Transylvania immunity exceptions could survive preemption. R. at 40–42. On August 1, 2024, Petitioner's writ of certiorari was granted and limited to the following issues: 1) whether federal law preempts a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer's fraud on the FDA or failure to comply, and 2) whether a claimant can rely on fraud-on-the-FDA as the basis for bringing a False Claims Act claim against a medical device manufacturer. R. at 43.

SUMMARY OF THE ARGUMENT

I. Preemption

Preemption by federal law is based on the Supremacy Clause of the United States Constitution. While respecting federalism, the Federal Government may enact laws that take precedence over the Several States's laws to avoid confusing or conflicting requirements and responsibilities that such laws may impose. The Food and Drug Administration ("FDA") is a derivative department of the executive branch which acts as a federal regulatory agency in matters involving healthcare, food, cosmetics, and non-healthcare related drugs. The FDA is a federal agency, so it acts as the enforcement arm of the Federal Government, which enforces internal regulations or related codified statutes passed by Congress. Therefore, in this case, when there is conflict between state and federal laws, the federal laws should preempt the conflicting state law provisions.

As the formation, grants of authority, and the inherent nature of the FDA being a federal entity, state legislatures may easily preempted by the FDA when states attempt to impose their own regulations over healthcare industry. The Supreme Court recognized in *Buckman* that there are numerous public policy rationales for prohibiting additional restrictions beyond what is already enforced by the FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Specifically, the Supreme Court analyzed increased restrictions imposed by fraud-on-the-FDA claims. *Id.* Among the rationales supporting preemption are the historic nature of policing fraud on the FDA being a responsibility of the FDA as well as the adverse

effects on healthcare manufacturers in providing upwards of fifty (50) different legal obligation codes for manufacturers to tiptoe around. *Id.* at 347, 349, 351. Therefore, it was error by the lower courts to hold that preemption did not apply to the immunity exceptions provided by the Transylvania Legislature.

II. False Claims Act

The False Claims Act (FCA) imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States government. 31 U.S.C.S. § 3729(a)(1)(A). An FCA claim has four elements including "(1) a false statement of 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." *U.S. ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017) (quoting *U.S. ex rel. Hendow v. Univ. of Phx.,* 461 F.3d 1166, 1174 (9th Cir. 2006)). All four must be satisfied to establish liability.

Causation and materiality are both at issue in this case, and Riley has not pled sufficient allegations under Federal Rule of Civil Procedure 9(b) with the required particularity to support either one. As a result, her claim should be dismissed. Allowing her claim to continue on would also present an issue of public policy for the courts.

STANDARD OF REVIEW

As this appeal raises both questions of law and questions of fact, questions of law are to be reviewed *de novo* while questions of fact are to be reviewed for clear error. *Monasky v. Taglieri*, 589 U.S. 68, 83—84 (2020). All issues of preemption in this case are to be reviewed *de novo*. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed de novo."). Whereas the review of claims under the False Claims Act may also be reviewed de novo. *Campie*, 862 F.3d at 898 (holding the dismissal of claims under the False Claims Act are reviewed *de novo*).

ARGUMENT

I. Preemption stands as an absolute bar against Respondent-Riley's claims as currently alleged, nullifying her reliance on the immunity exceptions and alleged non-compliance by Mednology.

The district court erred in denying Mednology's motion to dismiss when it ruled that the immunity exceptions under 21 Trans. Comp. Stat. §§ 630.546(b)–(c) were not preempted. A defendant's motion to dismiss is proper when the plaintiff has failed to plead sufficient facts upon which relief can be granted. *Haddle v. Garrison*, 525 U.S. 121, 126–27 (1998); *See also*, Fed. R. Civ. P. 12(b)(6). A plaintiff may overcome this burden by pleading "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Implicit in this requirement are the legal grounds on which the plaintiff's claims rest upon. *See generally*, Fed. R. Civ. P. 12(b)(6).

Preemption by a federal law of a state law is rooted in the Supremacy Clause of the Constitution, which states, "[t]his Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. With federal law being supreme over state law, when the two laws are in conflict, "the federal law takes precedence and the state law is preempted." *New Jersey Thoroughbred Horsemen's Ass'n v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018). This conflict with federal law can invoke preemption in three different ways: (1) express preemption, (2) implied preemption, and (3) actual conflict. *Id.* At 478—79; *Gibson v. Am. Bankers. Ins. Co.*, 289 F.3d 943, 948—49 (6th Cir. 2002). Express preemption applies when Congress has explicitly stated their enactments are to preempt state law. *Eng. v. Gen. Elec. Co.*, 496 U.S. 72, 78—79 (1990). Implied

preemption, also known as field-preemption, occurs when there is a federal regulation scheme that leaves "no room for the States to supplement it." *Id.* at 79 (citing, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Finally, actual conflict preemption can occur when the state law actually conflicts with federal law. *Id.* Another way this actual conflict can manifest itself is when the state law, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

In respecting federalism, there is a presumption against finding preemption of state laws. *See Bond v. U.S.*, 572 U.S. 844 (2014). However, when the nature of the action is one of a federal nature, the presumption against preemption does not apply. *Buckman*, 531 U.S. at 347; *Rice*, 331 U.S. at 230. Actions involving federal agencies such as the FDA are textbook style examples for situations where the presumption against preemption should not be applied. *Id.*

The Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §§ 301–399i) provides the procedural and substantive process by which medical inventions and innovations, including Class III medical devices, can enter the market. Included in this Act are prohibited actions by medical developers as well as penalties to be imposed against such violations. *See*, *Id.* § 331 (Prohibited Acts); § 333 (Penalties); § 335b (Civil Penalties). Additionally, § 360k(a) addresses the preemption of state laws which are different from or make additions to the rules provided by the FDCA. Furthermore, § 360k(b) outlines the specific process by which a state may make rules in addition to

those set out in the FDCA, whereby the State must both apply for and be approved by the Secretary of State for an exemption from the restrictions of § 360k(a).

A. By § 360k of the FDCA, the immunity exceptions of 21 Trans. Comp. Stat. §§ 630.546(b)–(c) are impliedly preempted.

In *Garcia v. Wyeth-Ayerst Laboratories*, the Court of Appeals for the Sixth Circuit analyzed a state statute from the Michigan Legislature that provided healthcare manufacturers with immunity while also providing for immunity exceptions. 385 F.3d 961 (6th Cir. 2004). The Michigan immunity exceptions provided that a manufacturer's shield from liability could be revoked if they "intentionally withheld or misrepresented material information" in the FDA's approval process, or "bribed an FDA official," or "if the drug was sold after the FDA withdrew approval or ordered the drug removed from the market." *Id.* at 964. The Sixth Circuit would go on to hold that the Michigan immunity exceptions ran afoul against federal law and were impliedly preempted. *Id.* at 965—66. The Sixth Circuit heavily relied on *Buckman Co. v. Plaintiffs' Legal Comm.*, which held that state common law fraud-on-the-FDA tort claims were "impliedly preempted by the FDCA." *Garcia*, 385 F.3d at 965 (citing *Buckman*, 531 U.S. at 350).

In *Buckman*, the Supreme Court faced a state tort action premised on a fraud-on-the-FDA claim and was tasked with determining if such a state law claim was prohibited by preemption. *Buckman*, 531 U.S. at 343. The Court would go on to hold that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre[empted] by, federal law." *Id.* at 348. The Court highlighted many practical hurdles and policy concerns that could result from all 50 states imposing their own

individual and unique burdens on manufacturers. *Id.* at 350. In combination with these practical hurdles, historically, policing fraud has never been "a field which the States have traditionally occupied." *Id.* at 347 (quoting *Rice*, 331 U.S. at 230). To accept that preemption does not apply would amount to denying the inherent federal characteristics of the FDA's authority over medical manufacturers, as the FDA's foundation, governance, and execution procedures are all sourced from federal law. *Id.*

The Respondents and District Court rely on *Desiano* for instruction on how to apply an immunity subsection against the same immunity statute in *Garcia*. R. at 15, 18; *Desiano v. Warner-Labert & Co.*, 467 F.3d 85, 88—90 (2nd Cir. 2006). In *Desiano*, the Michigan Legislature had a similar immunity statute as Transylvania's product liability immunity statute which would provide a shield from liability to a manufacturer if "the drug was approved for safety and efficacy by the [FDA] . . ." *Desiano*, 467 F.3d at 87. However, the immunity exception in countenance against the Michigan statute above would revoke this immunity shield if the manufacturer "intentionally withholds from or misrepresents to the [FDA]" information required under the FDCA." *Id.* at 88. The District Court attempted to draw similarities to subsection (c) of the Transylvania Statute which would revoke liability when a defendant "*fails to warn* about the dangers or risks of the drug or medical device as required by the FDA." 21 Trans. Comp. Stat. § 630.546(c) (emphasis added). However, the Court of Appeals of the Seventeenth Circuit addressed the district court's

splitting-hairs distinction of state law claims in *Desiano* and subsection (c), as Respondent would still need a federal finding to prove her claim. R. at 30—31.

Absent from the record of the lower courts was the impact of *Garcia's* on the Second Circuit's holdings in *Desiano*. As the two circuit cases came to opposite conclusions over the same statute, the framing by the Second Circuit hinged on working around *Garcia*. *Desiano*, 467 F.3d at 92. *Desiano* limited the weight of their sister jurisdiction to "whether [preemption applies,] is controlled by the decision in *Garcia only to the extent* that the Sixth Circuit's conclusion rested solely on findings as to state law." *Id.* at 91—92 (emphasis added). The Second Circuit in *Desiano* interpreted this holding to mean the Michigan statute's immunity exceptions "*[do] not* create a new cause of action for misleading the FDA." *Id.* at 92.

In analyzing *Desiano* more closely, its application to the case at hand only becomes further detached. Outside of the Second Circuit dicta which characterizes the controlling nature of *Buckman* as "underscoring" a "state regulation of matters of health and safety," the Second Circuit still recognized that implied preemption would exist when the cause of action bases its liability "*solely* on the basis of fraud against the FDA." *Id.* at 98. Additionally, the plaintiff in *Desiano* relied on "a wide range of putative violations of common law duties" in their complaint rather than relying on only fraud-on-the-FDA. *Id.* at 95.

These distinctions separate Riley's claims against Mednology from the plaintiff's in *Desiano*. Riley's claims hinge solely on whether fraud-on-the-FDA can be proven, and this was recognized by the Seventeenth Circuit through their

emphasis of the preemption of Transylvania's immunity statutes. R. at 30—31 ("After all, the issue in this case is whether federal law preempts the immunity exception provided under subsection (c), not whether it preempts Ruley's *state law claims* brought under Transylvania's product liability statute."). Without disrespecting the precedent set forth in *Buckman*, as well as the policy concerns that *Buckman* sought to remedy, this Court should find Transylvania's immunity exceptions to be impliedly preempted.

B. The compliance portion of Transylvania's Immunity Statute is also impliedly preempted under Federal Law, as it attempts to usurp powers which exclusively possessed by the FDA.

In *Marsh v. Genentech, Inc.*, the Sixth Circuit was faced with the same Michigan Products Liability statute as was addressed in both *Garcia* and *Desiano*. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 549—50 (6th Cir. 2012) (all cases ruling on Mich. Comp. Laws § 600.2946(5)). At issue in *Marsh* was whether the non-compliance with the FDA by the manufacturer would remove their statute-imposed immunity. *Id.* at 552. The Sixth Circuit emphasized that the product liability act did not define "compliance" with the FDA, and that making such a requirement was "arguably a species of fraud on the agency under the state Act." *Id.* at 552-53. While this determination alone could be sufficiently analogized to the previously ruled preempted fraud-on-the-FDA claims, the Sixth Circuit went on to flag such compliance requirements as relying on "federal enactments [a]s a critical element in [her] case." *Id.* at 553 (citing *Buckman*, 531 U.S. at 353). The Sixth Circuit concluded

the compliance portion would necessarily run afoul against the policy concerns raised in *Buckman*. *Id.*

The Seventeenth Circuit and the dissent by Justice Ruzich disagreed about the application of *Marsh* to the case at hand. R. at 34—35, 40—42. The Seventeenth Circuit ultimately concluded that *Marsh* was not instructive as *Marsh* had not dealt with fraud being the basis for non-compliance. R. at 34. This narrow distinction between the factual circumstances of *Marsh* compared to the facts of this case appeared to be heavily weighed by the other two justices. *Id.* However, Justice Ruzich found this factual distinction to be irrelevant in his dissent. R. at 41. Instead, Justice Ruzich emphasized the plaintiff's argument in *Marsh* being based solely on the non-compliance with the FDA, thus bringing *Marsh* directly on point for resolving this issue. *Id.*

Additionally, *Lohr* has already resolved the issue of preemption of state tort claims focusing on the "requirements" language set out in § 360k(a). *Medtronic, Inc. v. Lohr*, 815 U.S. 470 (1996). In *Lohr*, the Supreme Court was tasked with a Florida strict liability suit regarding a Class III medical device. *Id.* In its holding, the Court found the "requirements" language in § 360k(a) would close the door to state legislatures from "imposing a specific duty upon the manufacturer." *Id.* at 487 (referring to *Cipollone v. Leggett Group, Inc.*, 505 U.S. 504, 521—22 (1992)). However, this would be refined by the Court in *Riegel v. Medtronic, Inc.*, which held that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." 552 U.S. 312, 330 (2008). Thus, reinforcing

Petitioner's argument that Respondent needs a conclusive finding by the FDA in order to pursue any relief.

At the heart of the Seventeenth Circuit's ruling for allowing the compliance portion of the Transylvania immunity statute to remain were the factual allegations made by Respondent-Riley. R. at 33, 35. However, the factual allegations that are supposedly relied on are merely an inference based off of another inference. R. at 33 (first, inferring that a previous medical product was identical in application and operation as the Sleepternity and second, inferring that the mere presence of PE-PUR foams would be a dispositive factor in Mednology's non-compliance with the FDA's approval). Similar to the Seventeenth Circuit's previous comments of how "Riley is seeking to prove Mednology's fraudulent conduct solely through judicial fact-finding," this same objective of utilizing the courts to, not just rule, but also discover fault, goes beyond the scope of what Riley can validly bring. R. at 29; *See*, *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (2017) (state law claims that rely on violations against the FDA are impliedly preempted).

Respondent may attempt to argue that foreclosing their claims from relying on the same statute which provides manufacturers immunity, would prevent any claims surviving a motion to dismiss. *See* R. at 34—35 (Seventeenth Circuit claiming, "plaintiffs like Riley would then have no other alternatives for holding defendants like Mednology liable under Transylvania's product liability statute.") What this argument fails to consider is the liability that can be imposed by federal law rather than state law. *See generally*, FDCA § 360k. By holding that Respondent can bring a

valid claim under the Transylvania product liability statute would reverse course of the current trend of preemption of state regulation of Class III medical devices. *See* Kevin R. Costello, Christopher Q. Pham, *Regulatory Preemption of Medical Devices What Is the Boundary Between Federal and State Laws That Affect Medical Devices?*, L.A. Law., December 2003, at 10 ("Based upon a survey of current law. . . Class III devices marketed under the [pre-market approval] process, will generally be preempted from state regulations). Additionally, this sentiment was further supported by the FDA itself. *Id.* (referencing an amicus brief filed by the FDA in opposition to the plaintiffs in *Riegel*; "the Agency now advocated in favor of preemption of all state law tort claims"). Rather than attempt to bend the law against preemption, this Court should continue to allow Respondent and similar plaintiffs to seek their remedies properly through, and only through, federal law. Therefore, this Court should reverse the lower court's holding and remand this case.

C. Regardless of the application of Severability, Federal Preemption nullifies Riley's reliance on the Transylvania Immunity Exceptions.

Severability operates as a mechanism of judicial restraint to prevent courts from needlessly abolishing entire swaths of enacted statutes. However, when a portion of the statute is to be ruled unconstitutional or is preempted, it must be determined if the remaining portions of the statute can still exist consistent with the legislature's intent otherwise the entire statute must be abrogated. *See*, *Immigr. & Naturalization*

Serv. v. Chadha, 462 U.S. 919 (1983); *Moore v. Fowinkle*, 512 F.2d 629, 632 (6th Cir. 1975).

The Transylvania Legislature included in their statement of purpose that:

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

21 Trans. Comp. Stat. § 630.544.

1. The immunity exceptions can easily be severed from Transylvania's Immunity Statute while still respecting the intent of the Transylvania Legislature.

With the stated goal of the Transylvania Legislature being their desire to provide remedies for claims against medical manufacturers, it could be assumed that this intent could be insurmountable. 21 Trans. Comp. Stat. § 630.544. However, the Transylvania Legislature and Mednology can both have their cake and eat it too. Under 21 Trans. Comp. Stat. § 630.546(a) which provides immunity to manufacturers, potential plaintiffs would not be without a means for a remedy if they are able to prove that the manufacturers were not in compliance with the FDA. This solution to severability was addressed in *Garcia*, who had severed similar immunity exceptions on the grounds of preemption. *Garcia*, 385 F.3d at 967.

Following the spirit of preemption, the Sixth Circuit found it acceptable for the future claims of fraud on the FDA to be within the wheelhouse and responsibility of

the FDA to enforce. *Id.* Furthermore, the Sixth Circuit believed this solution would "not give license to drug manufacturers to use bribery or fraud as means of obtaining FDA approval," thereby ensuring the satisfaction of Transylvania Legislature's intent for harmed plaintiffs to still be able to receive proper remedies for their claims. *Id.* Therefore, since the intent of the Transylvania Legislature can still be upheld in light of severing the immunity exceptions, this Court should grant Petitioner's motion to dismiss.

2. The Compliance part of Transylvania's Immunity Statute can also be severed while still respecting the Transylvania Legislature's intent.

The Seventeenth Circuit rejected Petitioner's argument that the compliance portion of the immunity statute is preempted by federal law. R. 34—35. The Seventeenth Circuit believed that preemption of the compliance portion would leave plaintiffs with "no other alternatives for holding defendants like Mednology liable under Transylvania's product liability statute." *Id.* However, the absence of remedies under Transylvania's product liability statute should not be a dispositive factor in determining the statute's viability. As litigants who attempt to raise state law claims, which are contingent on violations against the FDA, will find they claims are impliedly preempted as a matter of law. *Mink*, 860 F.3d at 1327. To enable the compliance portion to act as an operative requirement of liability, Respondent's claims would necessarily be "premised on violation of federal law" and would in effect "[ask] the court to assume a rule usually held by the FDA—and thus is preempted." *Marsh*, 693 F.3d at 555. Furthermore, plaintiffs would not be without any remedies

as they would still be entitled to such actions upon the conclusive findings by the federal agency that was originally meant to regulate these manufacturers. *Id.* Therefore, this Court should grant Petitioner's motion to dismiss as Respondent cannot rely on the compliance portion of the Transylvania product liability statute.

II. THE DISTRICT COURT WAS CORRECT IN DISMISSING RILEY'S FALSE CLAIMS ACT CLAIM, AND THE APPELLATE COURT ERRED IN OVERTURNING IT.

The FCA holds liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). An individual, like Riley, may bring an action for an FCA violation for themselves and for the United States Government under the Act's *qui tam* provision. *Id.* § 3730(b)(1). If the government decides not to intervene, the individual has the "right to conduct the action." *Id.* § 3730(c)(3).

The district court dismissed Riley's FCA claim because it did not meet the standard for causation set forth by the First Circuit in *D'Agostino*. R. at 24. The appellate court utilized the *Escobar* analysis for materiality and deemed *Campie* more relevant because *Escobar* was utilized more heavily within it. R. at 36. Whether we consider *Campie, D'Agostino, Escobar,* or all of the above, Riley still fails to reach the heightened standard of pleading with "particularity" as required for cases alleging fraud under Federal Rule of Civil Procedure 9(b). *D'Agostino v. e3, Inc.*, 845 F.3d 1, 20 (1st Cir. 2016) (citing *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 123 (1st Cir. 2013). Dismissals of FCA claims are reviewed de novo. *United*

States ex rel. Campie v. Gilead Scis., 862 F.3d 890, 898 (9th Cir. 2017) (citing *Hendow* at 461 F.3d 1166, 1170).

A. The Appellate Court Made an Error in Their Application of the *Escobar* Test for Materiality, And Riley Did Not Satisfy the Requisite Elements in Her Pleadings to Meet the Heavy Burdens Required for an FCA Claim.

"[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." *Universal Health Servs. V. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). The FCA's materiality standard is "demanding." *Escobar* at 579 U.S. 193. FCA claims require a showing of "(1) a false statement of 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." *U.S. ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017) (quoting *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006)). When a complaint alleges fraud, it must also conform with both Federal Rules of Civil Procedure 8(a) and 9(b). *Wagh v. Metris Direct Inc.*, 363 F.3d 821, 828 (9th Cir. 2003). Rule 8(a) requires claims to be plausible, but FCA claims, along with other claims involving fraud or mistake, must also be pled with particularity under Fed. R. Civ. P. 9(b). *Cafasso v. Gen. Dynamics C4 Sys.*, 637 F.3d 1047, 1055 (9th Cir. 2011). "Materiality is a mixed question of law and fact that can be decided as a matter of law if reasonable minds could not differ on the question." *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 539 (10th Cir. 2020) (citing *Long v. Ins. Co. of N. Am.*, 670 F.2d 930, 934 (10th Cir. 1982)).

Riley did not plead with particularity facts that would establish that the usage of silicone-based materials and not polyurethane-based materials was material to the FDA's approval of Sleepternity and thus to CMS's payments and reimbursements for these devices. *Escobar* identified three factors that should be considered in determining whether a provision is material including: (1) whether the Government repeatedly refuses to pay similar claims based on noncompliance with the specific provision at issue or it continues to pay claims despite knowledge of the noncompliance, (2) whether the noncompliance goes to the "very essence of the bargain" or is simply "minor or insubstantial," and (3) whether the Government has expressly identified a provision as a condition of payment. *Escobar*, 579 U.S. at 196 & n.5. None of these standards alone are dispositive. *See United States v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

Applying this standard of materiality, Riley has failed to present sufficient evidence to raise a fact issue with respect to whether the switch from silicone-based foam to polyurethane-based foam was material to the Government's payment decision. *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 541 (10th Cir. 2020). The first *Escobar* factor considers the Government's past conduct and punitive actions, not only its payment history. *United States ex rel. Brooks v. Stevens-Henager Coll., Inc.*, No. 2:15-cv-00119-JNP-DAO, 2024 U.S. Dist. LEXIS 101358 at *31 (D. Utah Mar. 29, 2024). Once the Government found out about Mednology switching foam materials, the FDA did not take any action at all. Mednology voluntarily removed Sleepternity from the market, and no punitive

measures have been taken. R. at 7. The United States declined to intervene in Riley's action. R. at 6. As a result, this factor favors immateriality.

The second factor hinges on whether changing the type of foam was related to the "essence of the bargain" or it was "minor or insubstantial." *Escobar*, 579 U.S. at 196 & n.5. In this case, the type of foam was only one part of the product. The FDA's approval did not solely rest on the type of material used in the foam.

Finally, the Government did not expressly identify the silicone-based foam as a condition of payment. R. at 33 (the Seventeenth Circuit needed to draw inferences to determine whether PE-PUR based foams would have caused Sleepternity not to obtain FDA approval). This is not automatically dispositive, but when considered along with the other two factors, it is clear that the silicone-based foam was not material to the FDA's approval, and thus not material to CMS's payment of the claims either.

B. Riley cannot establish that had the FDA known Mednology was using polyurethane-based materials that it would revoke their approval, causing CMS to stop paying for claims.

In addition to materiality, causation must be established in FCA claims. The district court focused on causation and the appellate court focused on materiality; however, Justice Ruzich was correct in the dissent about the need to focus on both and not just one or the other. R. at 39 To establish causation, "the defendant's conduct must cause the government to make a payment or to forfeit money owed." *D'Agostino* 845 F.3d at 8 (citing *United States ex rel Westrick v. Second Change Body Armor Inc.*, 128 F.Supp. 3d 1, 18 (D.D.C. 2015)). In the absence of official FDA action to establish causation, a "fatal gap" is left in a complaint. *D'Agostino*, 845 F.3d at 17. In our case,

there was no action on the part of the FDA. In fact, the United States declined to intervene. R. at 6. In *Campie*, although the United States also declined to pursue the FCA claim, they did file a brief with the court supporting a reversal of the district court's dismissal of the claim. *Campie,* 862 F.3d at 898. This constitutes at least some action on the part of the government, whereas in our case there was none at all. As a result, there can be no establishment of causation and Riley's claim in precluded.

C. Riley Did Not Meet the Heightened Pleading Standard of Federal Rule of Civil Procedure 9(b) in Alleging Fraud on the Part of Mednology.

"The heightened pleading standard of Rule 9(b) governs FCA claims." *Cafasso*, 637 F.3d at 1054 (quoting *Bly-Magee v. California*, 236 Fl3d 1014, 1018 (9th Cir. 2001)). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). This includes the "who, what, when, where, and how of the misconduct charged." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (internal quotation marks omitted)).

In *Campie*, the allegations were a lot more specific as to how the company committed fraud against the FDA and CMS. *Campie*, 862 F.3d at 897. They did not merely fail to report a change in production materials, they actively concealed illicit ingredients manufactured in an unapproved facility by importing them through an approved facility, fraudulently labeling them, augmenting or obscuring paperwork, and crediting the ingredients to approved manufacturers. *Id.* When one of their employees tried to stop these practices, he was fired and asked to sign a document

promising not to bring forward an FCA claim. *Id.* at 898. These facts are significantly more particular than in the one currently at hand. Riley only alleges that Mednology utilized the silicone to obtain FDA approval before switching to the polyurethane foam to save money. R. at 6. This is far less specific than the claims in *Campie* and leaves out the "who, what, when, where, and how" of the allegedly fraudulent switch. *Vess*, 317 F.3d at 1106 (internal quotation marks omitted). Riley fails to meet the pleading standard set forth in FRCP 9(b), and therefore her claim should be dismissed.

D. A Myriad of Policy Concerns Exist in Allowing Claims Like Riley's to Go Forward Through the Courts, Including a Depreciation of the Value of the FDA and Other Federal Agencies as Well as Practical Problems for the Courts.

If jurors are able to decide what representations were essential to approval, which experts to trust, and how submissions were interpreted by the FDA, it could deter future applicants from securing approval for new products, and other future applicants may submit way more data than is necessary, undercutting the "FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *D'Agostino*, 845 F.3d at 8—9 (1st Cir. 2016) (quoting *Buckman*, 531 U.S. at 349—51). There also exist practical problems of proof. *D'Agostino*, 845 F.3d at 16. The problem is, absent a government action, there is no way to determine whether the FDA would or wouldn't have approved a device or medication without the fraudulent representations made by the applicant. *Id.* at 16—17. For these reasons, Respondent's FCA claim should be dismissed, and the appellate court's decision should be reversed.

CONCLUSION

The Supreme Court has made clear in their precedent set forth in *Buckman* that state laws can quickly run afoul when imposing requirements different from those imposed by the FDA. Such state laws run the risk of interfering with the federal nature of the FDA and the deference that must be shown to the FDA's independent enforcement of violations by manufacturers. This deference is based on the Supremacy Clause and is applicable through federal nature of the FDA. Also highlighted in *Buckman* are other significant policy concerns that lay the foundation for federal preemption of these state laws such as competing obligations imposed by the Several States. Because deference must be given towards preemption, the lower courts erred in ruling that preemption did not apply in their denial of Petitioner's motion to dismiss.

Several policy concerns have also been raised in case law related to allowing FCA claims where there has been no clear government response. Allowing laypeople to analyze FCA claims for whether they would or would not have been approved by the FDA absent certain regulations or standards is on its own problematic. It also runs the risk that the FDA's value and in turn the value of FDA approval would be diminished significantly. Because there is no set of facts that can conclusively prove whether or not the FDA would have approved the device with PE-PUR foam, the appellate court erred in reversing the district court's approval of Petitioner's motion to dismiss.

It is for these reasons that this Court should reverse the Seventeenth Circuit Court of Appeal's decision and remand the case for further proceedings.

Respectfully submitted,

/s/ 3308

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