NO. 24-9176

IN THE

Supreme Court of the United States

NOVEMBER 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 RESPONDENT

TEAM 3315

Attorneys for Respondent

QUESTIONS PRESENTED

I. Whether the Federal Drug and Cosmetic Act (FDCA) preempts the immunity exceptions to Transylvania's product liability statute, despite the State exercising its historic police powers to regulate matters concerning the health and safety of its citizens and the plaintiff asserting claims to comply with the statutory requirements?

II. Whether this Court should adopt a broader interpretation of fraud-on-the-FDA as a valid basis for liability under the False Claims Act (FCA), given Riley has alleged sufficient facts demonstrating Mednology's misrepresentations to the FDA were material to the government's payment decision and led the Centers for Medicare and Medicaid Services (CMS) to reimburse claims for a device it might not have otherwise covered?

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The unreported Opinion of the United States District Court for the Southern District of Transylvania, *In re United States Ex rel. Riley Ortega*, *United States Ex rel. Riley Ortega v. Mednology, Inc.*, Case No. 24-cv-12121 (Oct. 12, 2023), is contained in the Record of Appeal at Pages 1-24 where the District Court DENIED the Defendant's motion to dismiss in Part and GRANTED Defendant's motion to dismiss in Part. The unreported Opinion of the United States Court of Appeals for the Seventeenth Circuit, *In re United States Ex rel. Riley Ortega*, *United States Ex rel. Riley Ortega v. Mednology, Inc.*, Case No. 24-100 (Apr. 1 2001), is contained in the Record of Appeal at Pages 25-42. The Appellate Court AFFIRMED the District Court's decision in Part and REVERSED the District Court's decision in Part.

STATUTORY PROVISIONS INVOLVED

The following provisions of the United States Code are relevant in this proceeding: 21 U.S.C. § 360k(a), 355(e), and § 337(a); 21 U.S.C. §§ 301-399i; and 31 U.S.C. §§ 3729-3733. Also relevant is the following statutes of the State of Transylvania: 21 Trans. Comp. Stat. §§ 630.544-.546.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case revolves around Riley Ortega's (Respondent) claims under The Federal Claims Act (FCA) and the State of Transylvania's product liability statute. Riley pursued an action against Mednology (Petitioner) for its fraudulent conduct and breaches of legal duties in connection with the manufacturing and marketing of its

Sleepternity device — a state-of-the-art continuous positive airway pressure (CPAP) machine. R. at 4.

June 2021, Philips Recalls Their CPAP Devices. Philips Respironics (Philips), another medical device company not party to this action, manufactures their own version of CPAP machines which treat sleep-related disorders. R. at 4. Initially Philips's CPAP machines were manufactured with polyester-based polyurethane (PE-PUR) foams. The addition of PE-PUR foams helps to abate sleep apnea by reducing the sounds and vibrations from these machines. R. at 3. However, in 2021, the Federal Drug Administration (FDA) formally disclosed that PE-PUR foams can break down over time and release invisible volatile organic compounds (VOCs). R. at 4. If breathed in or swallowed, VOCs can cause serious health risks. R. at 4. In response to the FDA's disclosure and to protect their consumers, Philips recalled certain CPAP devices which contained PE-PUR foams and sought to replace it with silicone-based foams as a safer alternative. R. at 4.

December 2022, The FDA approves Sleepternity. In 2022, the company Mednology created its own version of the CPAP machine with several unique features: an automatic pressure adjustment system, a heated mask humidifier, a smartphone app, and noise canceling headphones that attach to the mask. R. at 3. These additional features not only help to reduce the occurrence of sleep apnea like traditional CPAP machines but can also help users to effectively reduce insomnia. R. at 3. Mednology presented Sleepternity to the FDA for approval under its design

using silicone-based foam. R. at 4. On December 30th, 2022, the FDA approved their device as a Class III medical device. R. at 4.

After FDA Approval, Mednology Changes Their Material. Shortly after the Centers for Medicare and Medicaid Services (CMS) began providing coverage to individuals prescribed Sleepternity, Mednology changed the design of their device. R. at 4. Without informing the FDA, CMS, or any of the device users, Mednology replaced its silicone-based foam with the cheaper PE-PUR alternative. R. at 4.

Riley's Suffering. Riley Ortega, a United States Army veteran, was prescribed Sleepternity by her somnologist to treat her sleep apnea and chronic insomnia. R. at 3. The Post Traumatic Stress Disorder (PTSD) she developed after her years of service in the military exacerbated these two conditions. R. at 3. Due to Sleepternity's unique features in treating *both* sleep apnea and insomnia, Riley turned towards the device as her panacea. R. at 3. Little did she know, this device would worsen her conditions. R. at 4.

Riley has long been allergic to isocyanate, a VOC that comes from degraded polyurethane (PE-PUR). R. at 5. Soon after using Sleepternity, she began experiencing severe asthma attacks which resulted in an emergency hospitalization. R. at 4. Both the emergency room physician and Riley's primary care physician recommended she stop using Sleepternity after concluding that her asthma attacks constituted unknown side effects. R. at 5. It was not until Riley's brother Jim – an assembly manager at Mednology – revealed the switch to PE-PUR foam that the suspected link between Sleepternity and her asthma attacks became more apparent.

R. at 5. According to Jim, Mednology made this change to save on manufacturing costs before packaging and distributing Sleepternity. Mednology failed to inform the public, the FDA, or CMS of this change, and neglected to mention the presence of isocyanates on Sleepternity's warning label. R. at 4-5.

After further research, Riley was able to discover that PE-PUR foams break down into certain forms of isocyanate and likely caused her asthma attacks. R. at 5. This knowledge came too late, however, as the damage had already been done. To this day, Riley's lungs are chronically inflamed, and her sleep apnea symptoms have returned despite her use of various medications. R. at 5.

II. NATURE OF PROCEEDINGS

The District Court. On June 21, 2023, after reporting Mednology's fraudulent conduct to the FDA, Riley brought a products liability action in the United States District Court for the Southern District of Transylvania. R. at 6. Riley asserts that Mednology breached its duty of care and good faith, duty of disclosure to the FDA, and duty to warn about the dangers and risks associated with the presence of PE-PUR foams in the Sleepternity device. R. at 6. Riley also brought a False Claims Act (FCA) Action under the qui tam provision, relying on the fraud-on-the-FDA theory. R. at 6. The United States declined to intervene in Riley's FCA action. R. at 6. In response, Mednology filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. R. at 2. Mednology claims that federal law preempts Riley's state law claims, and that fraud-on-the-FDA cannot serve as a valid basis for Riley's FCA claim. R. at 2. The District Court GRANTED Mednology's motion to dismiss in Part finding that an FCA claim cannot be based on fraud-on-the-

FDA. R. at 2. The court also DENIED in Part holding that federal law does not preempt the exceptions under Transylvania's product liability statute. R. at 2.

The Seventeenth Circuit Court of Appeals. On appeal to the United States Court of Appeals for the Seventeenth Circuit, Riley argued the district court erred in holding that she could not rest her FCA claim on fraud-on-the-FDA. R. at 25. Mednology argued that the district court erred in its finding that federal law does not preempt subsection (b) and (c) of Transylvania's immunity statute. R. at 25. The Court of Appeals AFFIRMED the district court's decision to deny Mednology's motion to dismiss Riley's state law claims. R. at 25. The court found that while federal law does preempt subsections (b) and (c) of Transylvania's immunity statute, Riley had pleaded sufficient facts to rebut the presumption that Sleepternity complied with FDA requirements under subsection (a). R. at 35. The Court of Appeals REVERSED the district court's granting of Mednology's motion to dismiss Riley's FCA claim finding that Riley had alleged sufficient facts to plausibly satisfy the materiality element of the FCA claim. R. at 38.

SUMMARY OF THE ARGUMENT

This Court should affirm the holding of the Seventeenth Circuit Court of Appeals, but on the grounds that federal law does not preempt the immunity exceptions to Transylvania's product liability statute. This Court should also affirm the appellate court's holding that FDA approval does not preclude False Claims Act liability, particularly where the alleged false claims were the basis for obtaining that approval

in the first place. Riley has plead sufficient factual material to survive Mednology's motion to dismiss.

I.

The United States Court of Appeals for the Seventeenth Circuit improperly found the Federal Food, Drug, and Cosmetic Act (FDCA) preempts subsections (b) and (c) of Transylvania's product liability statute. However, the appellate court properly held that Riley may pursue her claims under subsection (a) of the statute. This Court should find that the FDCA does not preempt any of the immunity exceptions to Transylvania's product liability statute.

First, the Seventeenth Circuit violated fundamental notions of federalism when it failed to apply the presumption against preemption to Transylvania's product liability statute. This doctrine must be applied in this instance because Transylvania is exercising its historic police powers to provide relief for victims of improperly designed or fraudulently approved medical devices. The States have a long history in regulating matters concerning public health and safety; failure to adhere to this principle directly infringes upon their sovereignty.

The FDCA does not preempt the immunity exceptions to Transylvania's product liability statute because the statute parallels federal requirements and therefore does not interfere with the FDA's regulatory ability. To neutralize Mednology's immunity, Riley is asserting common law claims as required under 21 Trans. Comp. Stat. § 630.546. The State of Transylvania enumerated that violations of FDA regulatory requirements would reinstate medical device manufacturer liability under state law.

While Riley is suing Mednology because the corporation's conduct violated federal law, she is not suing Mednology solely because of this violation.

Petitioner's attempts to characterize these claims as policing fraud-against-the-FDA is not only inaccurate, but it would also create a scenario where Mednology would be completely immune to product liability suits in the State of Transylvania. For the foregoing reasons, the appellate court should have found the FDCA does not preempt any of immunity exceptions provided under Transylvania's product liability statute. This Court should affirm the denial of Mednology's motion to dismiss on that basis.

II.

The Seventeenth Circuit Court of Appeals correctly reversed the district court's dismissal of Riley's FCA claim, finding that she alleged sufficient facts showing that Mednology's fraudulent conduct caused CMS to make payments it otherwise would not have made. Riley relies on the implied false certification theory under the FCA, asserting that Mednology not only requested payment but also misled the government by failing to disclose noncompliance with material requirements.

Mednology knowingly presented false information by switching from FDA-approved silicone to PE-PUR foam and failing to disclose this change. It thereby satisfies the FCA's "knowingly" standard, which includes actual knowledge, deliberate ignorance, or reckless disregard. Mednology should have pursued the appropriate approval pathways under 21 U.S.C. § 360(k) and § 360e but failed to do

so. Its actions show willful disregard for the FDA's regulatory process, warranting FCA liability.

Furthermore, CMS's reliance on FDA approval for Medicare reimbursement makes Mednology's fraud material to the government's payment decision, particularly since the FDA likely would not have approved the device had it known about the substitution. This connection satisfies the FCA's materiality requirement.

And finally, Riley has shown a plausible link between Mednology's fraud and the government's payment decision. The sequence of events clearly establishes that CMS's payment was contingent on FDA approval, which was fraudulently obtained. Causation may be found here to present a matter of proof for later stages of litigation, not a reason for dismissal at the pleading stage. Therefore, Riley's claim is sufficiently pleaded under Rule 12(b)(6) and should proceed to discovery.

ARGUMENT

Standard of review. This appeal raises two issues that warrant *de novo* review as questions of law: federal preemption and FCA viability. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012); *see also United States ex rel. Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019). The Court also applies a *de novo* standard when considering a Rule 12(b)(6) motion to dismiss for these issues, since the question of whether a complaint states a plausible claim is a legal question. *Calogero v. Shows, Cali & Walsh, L.L.P.*, 970 F.3d 576, 580 (5th Cir. 2020).

I. THE FDCA DOES NOT PREEMPT THE IMMUNITY EXCEPTIONS TO TRANSYLVANIA'S PRODUCT LIABILITY STATUTE BECAUSE TRANSYLVANIA IS

EXERCISING ITS HISTORIC POLICE POWERS TO REGULATE THE HEALTH AND SAFETY OF ITS CITIZENS AND RILEY IS ASSERTING CLAIMS TO NEUTRALIZE MEDNOLOGY'S IMMUNITY.

This Court should affirm the denial of Mednology's motion to dismiss. However, this court should do so on the basis that the FDCA does *not* preempt the immunity exceptions under Transylvania's product liability statute. This is because the presumption against preemption applies to Transylvania's statute and the exceptions work to neutralize a manufacturer's immunity under state law; they do not police fraud against the FDA. *Desanio v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2nd Cir. 2006).

A. This Court Must Adhere to Fundamental Principles of Federalism and Begin Its Analysis by Applying the Presumption Against Preemption to Transylvania's Product Liability Statute.

A fundamental concept to the United States Constitution is the careful balance of power that exists between the States and the federal government. Since "the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). A court must begin with the assumption that the historic police powers of the States are not to be superseded unless clearly expressed by Congress. *Id.* The presumption against preemption "is heightened 'where federal law is said to bar state action in fields of traditional state regulation.'" *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334 (2008) (Ginsburg, J., dissenting) (quoting *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

States traditionally have great latitude under their police powers when they are legislating over matters concerning the "lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). The historic primacy of state regulation in matters of health and safety contrasts with situations in which a State attempts to police fraud against federal agencies. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001). The presumption against preemption will not apply in such a situation because "the relationship between a federal agency and the entity it regulates is inherently federal in character." *Id.* at 347. However, this Court has long recognized that the presumption against preemption is at its strongest when a State is working to regulate "matters of health and safety." *Lohr*, 518 U.S. at 485.

1. The presumption against preemption applies to this case because Transylvania is exercising its historic police powers to regulate the health and safety of its citizens.

The State of Transylvania's product liability statute does not interfere with the regulatory ability of FDA, rather it regulates and restricts when victims can recover under the State's product liability law – a matter of traditional state regulation. Transylvania enacted its product liability statute with the goal of encouraging "manufacturers and distributors of various products to prioritize the health and safety of its consumers when manufacturing or distributing such products." 21 Trans. Comp. Stat. § 630.544 (2024). The statute grants immunity to manufacturers from *state law claims* so long as their products are approved by the FDA and in compliance with this approval at the time the product left the manufacturer's control. *See* 21 Trans. Comp. Stat. § 630.546(a) (2024) (emphasis added).

The appellate court prematurely concluded that this case is analogous to *Buckman*, incorrectly determining that the presumption against preemption does not apply on the basis that Mednology's relationship with the FDA is federal in character. R. at 3. While the relationship between the FDA and Mednology is certainly "federal in character," such a lackluster analysis completely disregards the concerns of this Court in *Lohr*. *See Lohr*, 518 U.S. at 485 (finding that the presumption against preemption applies to state-law causes of actions to be consistent with both federalism and the historic primacy of state regulation in matters of health and safety). *Buckman* considered whether state-law claims against a manufacturer for fraud-on-the-FDA interfered with the FDA's ability to regulate the entity. *Buckman*, 531 U.S. at 347. Since the plaintiff was asserting state-law claims based on the defendant's alleged violation of a federal statute, the *Buckman* Court held that the presumption against preemption did not apply because there were no concerns of federalism or the historic primacy of state regulation. *Id.* at 348. This is comparatively different from the present action because Riley is asserting claims to comply with the requirements of Transylvania's law in order to neutralize Mednology's immunity. R. at 15.

2. Fundamental principles of federalism are directly implicated here.

The relationship at issue in this case is between the FDCA and the exceptions under subsections (b) and (c) of Transylvania's immunity statute. That relationship is *not* "federal in character," rather it concerns the States' independent sovereignty – the very reason the presumption against preemption doctrine exists. *See Lohr,* 518

U.S. at 485. Therefore, "federalism concerns and the historic primacy of state regulation" is directly implicated. *See Buckman*, 531 U.S. at 348.

The Second Circuit relied on this analysis when it found that the presumption against preemption applied to the State of Michigan's product liability statute. *Desanio*, 467 F.3d at 94. In *Desanio*, the court held the Michigan legislature was "squarely within its prerogative to 'regulate matters of health and safety'" when it reined in state-based tort liability for drug manufacturers under M.C.L. § 2945(5). *Id.* Similarly, the State of Transylvania was "squarely within its prerogative" when it enacted its product liability statute with the goal of encouraging "manufacturers and distributers of various products *to prioritize the health and safety* of its consumers when manufacturing or distributing such products." 21 Trans. Comp. Stat. § 630.544 (emphasis added). Therefore, this Court should find the presumption against preemption applicable since Transylvania is regulating and restricting when victims can recover under state product liability law, a matter of traditional state regulation.

B. Subsections (b) and (c) of Transylvania's Product Liability Statute are Not Preempted by the FDCA.

This Court should affirm the denial of Mednology's motion to dismiss by finding that the FDCA does not preempt subsections (b) and (c) of Transylvania's product liability statute. The Supremacy Clause of the Constitution provides the foundation for federal preemption since federal law is "the supreme Law of the Land" and the "Laws of any State" shall be bound by it. *See* U.S. Const. art. VI, cl. 2. This is not an independent grant of legislative power to Congress, rather it provides the rule for a specific situation: when federal and state law conflict, federal law prevails, and state

law is preempted. *New Jersey Thoroughbred Horsemen's Ass'n v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 471 (2018). In the present action, federal and state law do not conflict because Transylvania's immunity exceptions parallel federal requirements to provide relief for victims of manufacturer negligence. *Desanio*, 467 F.3d at 97.

Preemption may be either expressed or implied. *Gade v. Nat'l Solid Wastes Mgmt* Ass'n, 505 U.S. 88, 98 (1992). Express preemption occurs when Congressional intent is "explicitly stated in the statutory language" and implied preemption occurs when the intent is "implicitly contained in [the statute's] structure and purpose." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). The FDCA does not expressly bar a State from providing a damages remedy for claims which are based on a violation of federal regulation because state duties parallel rather than add to or differ from federal requirements. *Riegel*, 552 U.S. at 330. However, state-law claims which interfere with the FDA's authority to regulate an entity are impliedly preempted by the FDCA. *Buckman*, 531 U.S. at 347-48. When read together, *Buckman* and *Riegel* create a narrow pathway for a plaintiff's state-law claim to follow: the plaintiff must be suing for conduct that *violates* the FDCA but cannot be suing *because* the conduct violates the FDCA. *In re Medtronic*, 623 F. 3d 1200, 1204 (8th Cir. 2010) (emphasis added).

1. Transylvania's product liability statute does not add to or differ from federal law requirements, it parallels them.

Transylvania enacted their product liability statute with the goal of minimizing "the liability drugmakers or medical device manufacturers could otherwise face from

various product liability lawsuits." R. at 13-14. Subsection (b) of the statute serves as an exception and reinstates liability 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) (emphasis added). Subsection (c) reinstates liability when the 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). The legislature expressly conveyed, in both subsections, that the immunity exceptions are only applicable when the defendant does not comply with the requirements set forth by the FDA or the FDCA. This language makes clear that neither subsection imposes requirements which are "different from, or in addition to" those set by federal law; instead, they "parallel federal safety requirements." *Lohr*, 518 U.S at 495. The statute simply ties a manufacturer's duty of care to the requirements already established by the FDA. 21 Trans. Comp. Stat. § 630.546. To argue that state law counters or conflicts with federal law here would completely misread the clear text.

Not only would the appellate court's interpretation of Transylvania's immunity exceptions be grossly inaccurate, but it would also create a strange situation in which medical device or drug manufacturers would effectively become immune to product liability suits. *See Lohr*, 518 U.S. at 487 (finding that the lower court's construction

of § 360k(a) has the "perverse effect" of granting broad immunity to an entire industry which in the view of the Congress needed stronger regulations). Holding that the FDCA preempts subsections (b) and (c) of Transylvania's product liability statute would permit state-law tort claims under subsection (a) alone. Plaintiffs would therefore only be able to access relief when the defendant failed to comply with the FDA's approval at the time the product left the defendant's control. 21 Trans. Comp. Stat. § 630.546(a). Such a narrow interpretation would directly contradict *Riegel*'s unequivocal holding that a state may impose additional "damages remedy for claims premised on violations of FDA regulations." *Riegel*, 552 U.S. at 330.

2. Riley is asserting common law claims to comply with Transylvania's statute in order to neutralize Mednology's immunity.

As already established, subsections (b) and (c) of Transylvania's product liability statute serve the purpose of reinstating liability for manufacturers of drug and medical devices. Pursuant to these requirements, Riley is asserting state common law claims of a breach of duty of care, duty to disclose, and duty to warn in order to neutralize Mednology's immunity under the statute. R. at 6. In other words, she is not suing solely because Mednology violated a federal requirement, rather she is using the failure to meet FDA requirements to remove Mednology's immunity under state law.

The appellate court correctly identified this very factor as distinguishable from *Buckman* in which the plaintiff was asserting a state-law fraud-on-the-FDA claim. *See* R. at 28 (citing *Buckman*, 531 U.S. at 346-47). And yet, the appellate court then declares that *Garcia*– rather than *Desanio* – is on point for resolving this case despite

the *Garcia* court's substantial reliance on *Buckman*. *See Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 966 (6th Cir. 2004) (finding the differences between the plaintiff's claims under Michigan's immunity exceptions and the claims in *Buckman* to be "immaterial" in light of the Supreme Court's ruling in *Buckman*).

The Sixth Circuit's opinion in *Garcia* is not on point for resolving this case because the Sixth Circuit does not adhere to the Supreme Court's precedent regarding federal preemption of the "historic police powers of the States." *See Cipollone*, 505 U.S. at 516. The statute at issue in *Garcia* disclaimed liability for drug and medical device manufacturers but provides an exception when "the manufacturer intentionally withheld or misrepresented material information that is required to be submitted under the Food and Drug Cosmetics Act and the drug would not have been approved, or the FDA would've withdrawn approval if the information was accurately submitted…" *Garcia*, 385 F.3d at 963. This statute is nearly identical to subsection (b) of Transylvania's product liability statute. *See* 21 Trans. Comp. Stat. § 630.546(b). Neither statute "invent[s] new causes of action premised on fraud against the FDA," rather the goal is to reinstate liability under state law for manufacturers who do not comply with requirements which have been previously established by the FDA. *Desanio*, 467 F.3d at 94.

This is precisely the issue in the current action: Riley is asserting state common law tort claims under the State of Transylvania's immunity exceptions to neutralize Mednology's immunity. R. at 6. As the district court correctly noted, the analysis should parallel the Second Circuit's reasoning in *Desanio* for both subsections. R. at

13-14, 17. Fraudulent conduct towards the FDA does not serve as the basis for Riley's claims like the plaintiff's claims in *Buckman*, it is merely a condition that Riley must satisfy in order reinstate liability for Mednology. *Desanio*, 467 F.3d 97-98.

C. Mednology's Argument that Riley's Claims Are Equivalent to Suing Mednology Solely for Violations of a Federal Requirement is Not Persuasive.

In response to the foregoing arguments, Mednology asserts that Riley's claims are equivalent to suing Mednology solely for violations of FDA regulations and therefore the immunity exceptions are impliedly preempted by the FDCA. R. at 11. Under this interpretation, *Buckman* would govern because the litigant is seeking to privately enforce a duty owed to the FDA. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). But as already established, Riley is not attempting to enforce a duty to the FDA, she is satisfying a requirement to Transylvania's product liability statute to pursue state common law claims against Mednology. Further, a plaintiff's state common law claims are based on the traditional duties between a manufacturer and that State's consumers. *Desanio*, 467 F.3d at 94. "None of them derives from, or is based on, a newly concocted duty between a manufacturer and a federal agency." *Id.* at 95.

Claims based on traditional state tort law do not conflict with federal requirements, they merely provide another reason for manufacturers to comply with the requirements. *Lohr*, 518 U.S at 495. Even *Buckman* recognized the distinction between claims which rely on traditional state tort law and fraud claims which "exist solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353. Riley's claims fit squarely into the pathway of suing for conduct that violates the

FDCA but not *solely* because that conduct violates the FDCA. *In re Medtronic*, 623 F. 3d at 1204. Mednology's argument is not only incorrect, but also a gross infringement upon Transylvania's police powers to regulate matters of health and safety in order to protect their citizens. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013).

D. Even if the FDCA Preempts Subsections (b) and (c) of Transylvania's Immunity Statute, the FDCA Does Not Preempt Subsection (a).

Even assuming *arguendo* that the FDCA preempts subsections (b) and (c), this Court should still affirm the appellate court's ruling because Riley can proceed with her claims under subsection (a) of Transylvania's product liability statute. R. at 34. In addition to the other immunity exceptions included in Transylvania's product liability statute, subsection (a) disclaims liability for medical device manufacturers or distributors if "the drug or medical device was in compliance with the United States Food and Drug Administration's approval at the time the drug or medical device left the control of the manufacturer or distributor." 21 Trans. Comp. Stat. § 630.546(a). As the appellate court noted, Riley bears the burden of rebutting the presumed compliance within the statute since she is challenging Mednology's immunity. R. at 32.

1. Riley can bring her state common law claims under subsection (a) of Transylvania's product liability statute.

Mednology argues that *Marsh v. Genetech, Inc.*, 693 F.3d 546 (6th Cir. 2012) should be decisive on this issue. R. at 34. In *Marsh*, the Sixth Circuit considered a compliance exception to the State of Michigan's product liability statute which was

very similar to the Transylvania's exception. *Compare Marsh*, 693 F.3d at 550 with 21 Trans. Comp. Stat. § 630.546(a). The Sixth Circuit, relying on its ruling in *Garcia*, found that the plaintiff could not bring her claims under the compliance exception because they interfered with the FDA's regulatory ability and therefore were impliedly preempted by federal law. *Marsh*, 693 F.3d at 553. Once again, the Sixth Circuit overextends the application of *Buckman* from claims which originate solely on the basis of violating federal law to claims which parallel federal law requirements and are asserted to reinstate liability under state law. *See Desanio*, 467 F.3d at 97.

The appellate court attempts to differentiate between the present case and *Marsh* by distinguishing between the allegations made by the plaintiff in *Marsh* and those made by Riley. R. at 34. Since the plaintiff in *Marsh* did not allege that the defendant altered their label after FDA approval, "*Marsh* is not necessarily on point for resolving the issue…" R. at 34. However, such a fragile distinction wouldn't be necessary if the appellate court would've recognized one simple notion: Riley is asserting state common law claims to comply with the exception requirements of Transylvania's product liability statute in order to neutralize Mednology's immunity. *Desanio*, 467 F.3d at 97. This interpretation is the correct application of *Riegel* and *Buckman* to subsection (a) and quells the appellate court's rightfully placed concerns about creating an absurd result in which Mednology has absolute immunity from products liability suits. *See In re Medtronic*, 623 F. 3d at 1204; *see also Lohr*, 518 U.S. at 487.

2. Riley's allegations provide sufficient factual matter to plausibly suggest that Mednology is not in compliance with FDA requirements.

As the appellate court correctly noted, Riley has plead sufficient factual material in her complaint to survive Mednology's motion to dismiss and to rebut Mednology's presumed compliance under subsection (a) of Transylvania's product liability statute. R. at 35. The Supreme Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) set the pleading requirements for a complaint to survive a motion to dismiss under Rule 12(b)(6). These standards require that a plaintiff's complaint must state a claim that is both "plausible on its face" and consisting of sufficient factual allegations that make a claim seem reasonable and likely to occur. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

Riley's factual allegations plausibly establish that Mednology knowingly changed the sound-insulating foam in its device from silicone to PE-PUR due to the significant manufacturing cost savings. R. at 4. Further, there is no indication that Mednology disclosed to the FDA the modifications after Sleepternity's approval nor any evidence that suggests Mednology warned consumers about the dangers of this material. In fact, the factual allegations as pleaded suggest the opposite: Mednology intentionally misled consumers and the FDA to save on manufacturing costs despite having knowledge of the dangers of PE-PUR foam.

These allegations fall squarely into the immunity exceptions under 21 Trans. Comp. Stat. § 630.546(a). If taken as true on their face, the facts plausibly allege that Sleepternity was *not in compliance* with FDA approval at the time it left Mednology's control. Facial plausibility requires only that the alleged facts allow "a court to draw

a reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Since it is reasonable to infer Sleepternity was not in compliance with the FDA's approval at the time the device left Mednology's control, Riley can therefore bring her claim under subsection (a) of Transylvania's product liability statute.

II. RILEY HAS ALLEGED ENOUGH FACTS TO BRING A FALSE CLAIMS ACT (FCA) CLAIM AGAINST MEDNOLOGY FOR FRAUD-ON-THE-FDA.

The Seventeenth Circuit Court of Appeals correctly reversed the district court's dismissal of Riley's FCA claim, determining Riley alleged sufficient facts supporting that Mednology's fraudulent conduct led CMS to make payments it otherwise would not have made. Under the *qui tam* provision, Riley relies on the implied false certification theory as a basis for liability under the FCA. R. at 36. She asserts that Mednology not only requested payment, but also made misleading representations about its goods by failing to disclose noncompliance with material statutory, regulatory, or contractual requirements. *See Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016). By obtaining FDA approval using one material, then switching to another without obtaining post-approval permission, Mednology's representation became an actionable half-truth: stating only part of the truth while omitting critical qualifying information. *Id.* at 188.

In determining that Riley's FCA claim should not be dismissed, this Court should consider the existing circuit split between the First and Ninth Circuit regarding the viability of fraud-on-the-FDA as a basis for FCA liability. This Court should align with the Ninth Circuit's approach rather than the First Circuit's narrower

interpretation. *Compare D'Agostino v. ev3, Inc.*, 845 F.3d 1, 3-10 (1st Cir. 2016) (limiting the viability of FCA claims based on fraud-on-the-FDA theories by focusing heavily on the FDA's post-approval conduct and the burden of proving materiality) *with U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 909 (9th Cir. 2017) (allowing FCA claims to proceed based on the potential influence of fraudulent statements on government payment decisions). The Ninth Circuit's approach incorporates a proper understanding of the relationship between the FDA and the FCA. The FCA is intended to address fraud on the federal government, not to second-guess regulatory decisions:

> Congress enacted the FCA to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy. The Act does so by aligning the interests of the government and that of the relator through a shared pursuit. That a relator seeks personal gain is embedded in the statute and should not, alone, cast doubt on his claims.

United States ex rel. Harman v. Trinity Indus., Inc., 872 F. 3d 645 (5th Cir. 2017). To succeed under the FCA pursuant to 31 U.S.C. § 3729, Riley must prove that (1) a false claim was made with (2) the requisite scienter (knowledge that it was false), which was (3) material to the government's payment decision, and (4) caused the government to disburse funds. 31 U.S.C. § 3729. Riley has sufficiently alleged each of these elements.

A. Mednology Knowingly Made False Representations.

Regarding the falsity of Mednology's claim, Riley needs only to prove that it was predicated upon a false representation of compliance with a material statutory, regulatory, or contractual term. 31 U.S.C. § 3729(b)(3). Simply put, Mednology

changed the composition of its device without obtaining subsequent FDA permission, as silicone and PE-PUR are not interchangeable materials. This element has been met.

As for the second element, the FCA holds individuals or entities liable if they knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a). To prove that Mednology knowingly presented its false claim for payment or approval by CMS, the term "knowingly" may be interpreted in an expansive manner in that it does not require proof of *specific intent* to defraud. 31 U.S.C. § 3729(b)(1)(B). Riley need only prove that Mednology (i) had actual knowledge of the information; (ii) acted in deliberate ignorance of the truth or falsity of the information; or (iii) acted in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). Mednology meets the "knowingly" standard under the FCA as Riley can assert sufficient facts which demonstrate that Mednology acted with one of the three specific states of mind and is therefore liable under the FCA for the submission of false claims to the government.

Mednology should have been fully aware of both Philips' recall and the FDA's warnings about PE-PUR foam when it applied for approval of Sleepternity in 2022. In 2021, Philips, another well-known medical device manufacturer, recalled its CPAP machines containing PE-PUR foam due to potential health risks. R. at 4. The FDA publicly announced these risks, and Philips took steps to correct their devices and offer safer alternatives to patients. R. at 4. Mednology's awareness of this would satisfy the actual knowledge requirement under the FCA. And, even if Mednology

claims it was unaware, it could still meet the knowledge requirement for acting with "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information it presented to the FDA. 31 U.S.C. § 3729(b)(1)(A). As the court in *Hendow* delineated, "so long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." *U.S. ex rel. Hendow v. Univ. Of Phx.*, 461 F.3d 1166, 1172 (9th Cir. 2006).

Mednology knowingly (with actual knowledge, deliberate ignorance, or reckless disregard) presented false information to the FDA regarding Sleepternity's foam composition – substituting PE-PUR foam for the FDA-approved silicone foam – and then submitted claims for reimbursement to CMS based on that information. Therefore, Mednology should be held liable under the FCA.

B. Mednology's Concealment Constitutes a False Claim.

The rationale Mednology proffered for its conduct, that it *modified* its device after receiving FDA approval to reduce manufacturing costs, is both overly simplistic and insufficient. R. at 4. Mednology did not merely modify its device; it replaced a material in Sleepternity with one the FDA had previously warned against. Before making this major change, Mednology had a responsibility to obtain FDA approval before distributing Sleepternity. *See Campie*, 862 F.3d at 890. No cost savings can justify such an alteration and Mednology's willful blindness to the gravity of it.

An actionable half-truth, such as the one committed by Mednology, constitutes fraud or misrepresentation because it presents information in a manner that is likely to deceive or mislead another party – especially when there is a duty to disclose the

omitted information. *See Escobar*, 579 U.S. at 188. Mednology had several avenues to obtain the required FDA approval for the change in Sleepternity's material composition but chose not to pursue any.

In the medical device industry, post-approval changes are classified as either major or minor, depending on their potential impact on the device's safety and efficacy. *Deciding When to Submit a 510(k) for a Change to an Existing Device*, The Food and Drug Administration, 32 (2017). Under the 510(k)-clearance process, medical device manufacturers must report any significant changes to their devices and provide evidence that such changes do not adversely affect the device's safety or effectiveness. 21 U.S.C. § 360(k). Major changes, such as alterations to the manufacturing process or material composition, require regulatory approval before implementation. 21 C.F.R. § 807.81(a)(3) (2024). In contrast, minor changes do not usually require prior approval but must still be reported to the relevant regulatory authorities. *Id.* Alternatively, a manufacturer may receive approval for a device change without a supplemental application by submitting a detailed written notice to the Secretary of Health and Human Services, describing the change, summarizing supporting data, and confirming compliance with § 360j(f). 21 U.S.C. § 360e.

While a 'swapping' of similar materials is typically considered a minor change, if the modification directly affects the health of users, it can no longer be classified as such. 21 C.F.R. § 807.81(a)(3) (2024) (requiring a premarket notification for any change or modification in a device that could significantly affect its safety or effectiveness). Given the detrimental impact PE-PUR can have on individuals like

Riley, Mednology was required to obtain regulatory approval before marketing Sleepternity in accordance with 21 U.S.C. § 360(n)(2)(A). Mednology's failure to pursue any of these approval pathways suggests it anticipated that Sleepternity, with its unapproved PE-PUR foam, would not withstand FDA scrutiny; the FDA has the authority to withdraw a previously approved application if the methods or facilities "are inadequate to preserve the device's identity, strength, quality, and purity." 21 U.S.C. § 355(d), (e). Rather than face this possibility, Mednology proceeded with a significant safety-related change and released Sleepternity for market distribution without securing the necessary FDA approval. Mednology committed fraud.

Mednology may argue that the material used in Sleepternity was not the decisive factor in the FDA's original approval and, consequently, a "modification" in a non-decisive factor would not preclude FDA approval. *See Campie*, 862 F.3d at 906 (acknowledging FDA approval decisions are based on multiple factors). However, this syllogistic logic overlooks the significance of the modification. Mednology switched from a safer silicone-based foam to a hazardous PE-PUR foam, which certainly provides the FDA with grounds to reconsider or withdraw approval. 21 U.S.C. § 355(e). Even if the change might seem minor to Mednology in theory, in practice it was significant enough to pose health risks that warranted disclosure to the FDA. The failure to report such a change undermines the entire basis of the FDA's approval and, by extension, CMS's decision to pay. In matters concerning public health and safety, it is indeed better to ask for permission rather than forgiveness.

C. Mednology's Misrepresentation Was Material to CMS Payments Under the Standards Set in *Escobar*.

After establishing that Mednology knowingly presented a fraudulent claim for approval, the key issue becomes whether this misrepresentation was material to the government's decision to pay for Sleepternity coverage. *Escobar*, 579 U.S. at 176. Manufacturing deficiencies become relevant when they affect the quality, safety, and efficacy of the affected products to the extent that the products would never have been approved or cleared by the FDA in the first instance. 21 U.S.C. § 351. Such claims involving those devices become an FCA violation because the product would not have been eligible for health care program reimbursement without the fraudulent FDA approval. *See Campie*, 862 F.3d at 907. Therefore, in evaluating Riley's FCA claim, materiality depends on whether Mednology's undisclosed substitution of materials in the Sleepternity device was capable of influencing the FDA's original decision to approve the device.

In *Escobar*, the Supreme Court emphasized that the materiality requirement is both "rigorous" and "demanding." *Escobar*, 579 U.S. at 193. However, it also clarified that materiality is not solely determined by whether the government continues to pay claims after learning of the alleged fraud. *Id.* at 194. Instead, it hinges on whether the false statement could naturally influence the payment decision. *Id.* Here, while it is unclear if CMS would have continued payment since Mednology voluntarily withdrew Sleepternity from the market, it *is* clear that CMS's payment decisions often depend on the FDA's initial approval of the device. *See Campie*, 862 F.3d at 905 ("FDA approval is the "*sine qua non*" of federal funding") (citing *Hendow*, 461 F.3d at 1176). This reliance is evident in the Medicare Benefit Policy Manual, Chapter 14, §

10, which lists only FDA approved devices as eligible for Medicare coverage. *Medicare Benefit Policy Manual*, Ch. 14, § 10 (2023) (citing eligible devices as those "approved by the FDA through the Pre-Market Approval process, cleared by the FDA through the 510(k) process, and FDA-approved Investigational Device Exemption Category B devices"). If the FDA would not have approved the device with PE-PUR, CMS likely would not have issued payments.

The *Escobar* ruling sets a materiality standard that is high enough to distinguish mere non-compliance from fraud, but not so high as to prevent individuals like Riley from presenting sufficient evidence to meet it. As the Department of Justice (DOJ) noted in its statement of interest regarding the defendant's motion to dismiss in *United States ex. rel. Patricia Crocano v. Trividia Health Inc.*, 615 F. Supp. 3d 1296 (S.D. Fla. 2022), "in deciding whether to pay for a drug or device, federal healthcare programs often rely on the FDA's decision as to whether the drug or device is sufficiently safe and effective to be sold in the United States." United States' Statement of Interest as to Defendant's Motion to Dismiss at 4, United States ex. rel. Patricia Crocano v. Trividia Health Inc., No. 22-CV-60160-RAR (S.D. Fla. Jun. 3, 2022). In essence, what is material to the FDA's approval decision is also material to a CMS repayment decision.

While FDA approval is "necessary, but not sufficient" for Medicare coverage — as Medicare must also determine if the device is "reasonable and necessary" for treatment —FDA approval remains the sole determinant of whether a device is safe and effective for marketing to the public. *International Rehab. Scis. Inc. v. Sebelius*,

688 F.3d 994, 1002 (9th Cir. 2012); 42 U.S.C. § 1395y(a)(1)(A). Since this case centers on the safety of the device, FDA approval is a key consideration for this Court. Moreover, even if Mednology argues that CMS does not rely solely on FDA approval, *Petratos* establishes that a violation can still be deemed material under the FCA if it is likely to affect payment, whether or not the violation is a violation of an express condition of payment (here — FDA approval). *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481 (3rd Cir. 2017).

1. The burden of proof on materiality should not be unreasonably high.

The standard for materiality under the FCA is based on the balance of probabilities. Riley needs only to demonstrate that it is more likely than not (more than a mere possibility) that the undisclosed information influenced the FDA's approval and subsequently CMS payment. 31 U.S.C. § 3729(b)(4). Proving a hypothetical outcome, such as what the FDA would have done, to a certainty is impractical and not required. Rather, materiality looks to the effect on the "likely or actual behavior" of the recipient of the alleged misrepresentation, not on the definite behavior. *Escobar*, 579 U.S. at 193. The materiality of the false statements to CMS's payment decision is established by their role in securing FDA approval. *See Campie*, 862 F.3d at 905.

In evaluating Riley's claim, this Court should reject the First Circuit's view. The First Circuit's dismissal of the "could-have-influenced" argument misinterprets the materiality standard by conflating it with causation. *D'Agostino,* 845 F.3d at 7 ("We reject this argument because alleging that the fraudulent representations 'could have'

influenced the FDA to approve Onyx falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS."). Materiality requires only that a false statement has the potential to influence the government's actions, while causation requires proving that the falsehood actually led to a payment or loss. *Campie*, 862 F.3d at 905-09. Materiality is a threshold issue that comes before causation. *See Escobar*, 579 U.S. at 178 ("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 FCA."). Thus, claims should not be dismissed at the "could-have-influenced" stage due to its suspected inability to satisfy causation. Here, Riley needs only to prove that Mednology's misrepresentation of Sleepternity's material composition had the ability to influence CMS's payment decision, not that it actually caused CMS to pay. 31 U.S.C. § 3729(b)(4). The Ninth Circuit's approach correctly distinguishes materiality from causation and should guide this Court's decision. *Campie*, 862 F.3d at 890.

Furthermore, under the FCA, liability for failing to disclose violations does not depend on whether those requirements were expressly identified as conditions of payment. *Escobar*, 579 U.S. at 178. Rather, CMS's payment decision was likely predicated on the assumption that the device met all FDA approval requirements, including the use of approved materials and adherence to safety standards. In this way, compliance with FDA approval requirements functions as an implied condition of payment. *See Campie*, 862 F.3d at 904 (holding that although the defendant Gilead Sciences used unapproved and contaminated ingredients in its HIV drugs and still

received payments from the Government, the case could proceed because those payments were based on the assumption that the drugs complied with FDA-approved specifications).

Mednology's misrepresentation of Sleepternity's foam composition should be considered material to CMS's reimbursement decisions, as it relied on FDA approval as a proxy for the safety and efficacy of Sleepternity. If Mednology had disclosed the use of a different, harmful material (the PE-PUR foam), the FDA might have made a different decision—such as not approving the device at all, requiring additional testing, or imposing stricter conditions. 21 U.S.C. § 355(e). Without FDA approval, CMS would not have made those payments. *Medicare Benefit Policy Manual*, Ch. 14, § 10 (2023).

2. The FDA's inaction does not diminish the materiality of Mednology's fraud.

As established, the FDA's decision-making process and the impact of the undisclosed substitution on that process are central to the materiality analysis. The FDA's failure to act after Mednology voluntarily recalled Sleepternity does not negate the fraud's materiality.

It is essential to distinguish between fact and conclusion; they are not interchangeable. It is a fact that shortly after Riley served a summons and complaint to Mednology, the company voluntarily recalled Sleepternity from the market as pursuant to 21 C.F.R. § 7.40(b). R. at 7. It is also a fact that following this recall, the FDA discontinued its investigation into Mednology's alleged fraudulent conduct. R. at 7. Yet, it cannot be conclusively determined that the FDA's inaction precludes Riley

from basing her FCA claim on the allegation that Mednology fraudulently obtained pre-marketing approval for Sleepternity. *See Campie*, 862 F.3d at 890 (holding that questions of materiality remained even where the FDA had continued to pay for the drug).

Courts have held that FDA inaction does not imply approval or validate the safety and efficacy of the product in question. In *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 774 (5th Cir. 2011), the court concluded that there is no case law establishing that the FDA's silence should be interpreted as approval of the fraud. In fact, some courts have explicitly rejected such arguments. In *Celebrex*, the court found that the defendant could not cite any authority to support its claim that the "FDA's silence as to a particular advertisement means that the FDA necessarily determined that the advertisement was not deceptive." *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742, at *11 (N.D. Cal Aug. 16, 2006).

However, the court in *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 3-10 (1st Cir. 2016) still held that the FDA's failure to withdrawal its approval of Onyx following D'Agostino's allegations suggested that the fraud was not material to the agency's regulatory decision. Yet, the court's reasoning relies on a conditional statement: if not A, then not B – if the FDA did not act, then the fraud was not material. *D'Agostino*, 845 F.3d at 8. This reasoning creates a significant barrier for FCA claims that are based on allegations of fraud on the FDA, as it ties materiality to the FDA's post-fraud actions or inaction. Instead, this Court should examine the events in reverse order, applying

the contrapositive; it should begin not with an examination of the FDA's subsequent inaction, but with the materiality of the fraud. *Escobar*, 579 U.S. at 196.

As Mednology's initial misrepresentation has been established as material, reliance on the FDA's inaction would be misplaced. That overlooks the possibility that the FDA's decision not to recall Sleepternity could be due to factors unrelated to the merits of the fraud allegations, such as resource allocation or public health concerns. *See Campie, Inc.*, 862 F.3d at 906 ("[T]here are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs."). The FDA's lack of swift action does not negate that the initial approval was based on incomplete or false information. The focus is not on the FDA's actions after approval, but on whether the initial approval was based on such information, which, as shown, it was. *See Escobar*, 579 U.S. at 190.

Allowing corporations to escape FCA liability merely because the FDA did not withdraw its approval would set a dangerous precedent. The FCA aims to protect the government from fraud. This purpose would be compromised if corporations could evade liability by relying on the inaction of an overburdened regulatory agency.

It cannot be conclusively determined that the concealed misrepresentation that led to FDA approval influenced CMS's decision to pay, but neither can it be definitively determined that it did not. Ergo, this Court should affirm the appellate court's denial of Mednology's motion to dismiss and allow Riley's claim to proceed, as she has pled sufficient facts to establish the plausibility of materiality. At this state,

she need not prove it with certainty. *Twombly*, 550 U.S. at 556 ("A well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

D. Mednology's Fraudulent Conduct Meets the Causation Standard as a Matter of Proof, Not Dismissal.

The fourth element of an FCA claim, causation, requires Riley to show that the fraudulent statement — or omission of a material change — caused CMS to pay out money. *See Campie*, 862 F.2d at 899. Just as the appellate court determined that the materiality requirement in Riley's FCA claim is a matter of proof, not a legal ground for dismissal, the same applies to causation. *Id.* at 907. The district court erred in granting Mednology's motion to dismiss based on a lack of proof of causation. R. at 23. The appellate court correctly reversed this decision, following the Ninth Circuit's approach in *Campie* rather than the First Circuit's in *D'Agostino*. R. at 36. While the district court focused on causation and found insufficient proof thereof, the appellate court focused on materiality and denied Mednology's motion to dismiss. This Court should affirm this holding, but on the grounds that Riley can satisfy *both* materiality and causation. The two elements, while distinct, are also interconnected and equally significant for establishing liability.

At the pleading stage, Riley is not required to prove causation to a certainty; she needs only to present sufficient evidence of a plausible link between the fraudulent act and the government's payment decision to survive a motion to dismiss *See Twombly*, 550 U.S. at 556. Establishing that Mednology's nondisclosure of the change to Sleepternity's material composition would have led the FDA — and subsequently

CMS — to alter their decisions is both straightforward and legally supported. Courts have consistently held that legal liability under the FCA extends to "any person who knowingly assisted in causing the government to pay claims grounded in fraud," regardless of the degree of separation between the falsehood and the payment decision. *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943), *superseded by* 31 U.S.C. § 3729(c). Mednology is precisely the type of actor the FCA intended to reach when fraud by one party causes another to unwittingly submit false claims to the government. 31 U.S.C. § 3729(a)(1)(A) and (B).

The sequence of events establishes a clear causal chain between Mednology's fraud and the government's payment. Mednology initially represented to the FDA that Sleepternity used silicone, a material with an FDA-accepted safety profile. However, after obtaining FDA approval, Mednology unilaterally changed the material to PE-PUR foam, which was associated with serious health risks. Despite this significant change, Mednology began to market Sleepternity as if it remained FDA-approved in its original form. Unaware of the material change, doctors prescribed the device, and CMS, relying on FDA approval, reimbursed claims for its use. When taken together, these factual allegations permit this Court to reasonably infer that, but-for Mednology's fraudulent conduct, CMS would likely not have extended coverage for Sleepternity. *See Campie*, 862 F.2d at 906; 31 U.S.C. § 3729(b)(4). Since Riley presents enough factual allegations to "nudge" her implied false certification and fraud-on-the-FDA theory "across the line from conceivable to

plausible," further argument over the causation element would be more appropriately addressed beyond the pleading stage. *Twombly*, 550 U.S. at 570.

1. Finding for Riley's FCA claim does not undermine the value of FDA approval.

"How would a relator under the FCA prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind?" *D'Agostino*, 845 F.3d at 9. Neither Riley, nor her experts, need know how to retroactively read minds to prove that the FDA would have denied approval but-for Mednology's fraudulent representations. Such an expectation is not required for a relator under an FCA claim. The requirement is simply to show that the false statement could have influenced the government's payment decision and that it actually caused the government to pay. 31 U.S.C. § 3729(a). This can be demonstrated through facts, not by speculating about the thoughts or motives that might have been percolating through one's mind. Indeed, telepathy belongs in fiction, not the courtroom.

The FCA exists to protect the government from paying fraudulent claims, not to second-guess the FDA's regulatory judgments about rescinding approvals. *See D'Agostino*, 845 F.3d at 8. ("Surely, where the FDA was authorized to render the expert decision on ... use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions" (quoting *King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir. 1993) (Aldrich, J., concurring)). Riley is not misusing the FCA to undermine FDA approval, she is using it as it was intended — to address fraudulent claims.

The FCA's focus is on whether fraud could have influenced the government's payment decisions, not on re-litigating the FDA's regulatory judgments. 31 U.S.C. § 3729(b)(4). In her FCA claim under the implied false certification theory, Riley is not asking the Court to question the FDA's decision-making, rather, she is arguing that Mednology misled the government into making payments by concealing facts material to reimbursement eligibility. In this case, the FCA complements the FDA's role by deterring fraud and promoting transparency, ensuring that federal agencies like the FDA can function effectively and public funds are properly used. *See United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (emphasizing that the objective of Congress in enacting the False Claims Act was broadly to protect the funds and property of the Government from fraudulent claims).

2. Riley's claims are not grounds for dismissal under Rule 12(b)(6).

Riley's FCA claim should survive Mednology's motion to dismiss because she has provided enough factual content in her complaint to make it plausible – rather than merely possible – that Mednology's actions led the government to make payments it otherwise would not have made. She has clearly outlined how the fraud ensued and how it impacted the FDA's and the government's payment decisions. Whether Mednology is actually liable is a determination for later stages of litigation, not for the motion to dismiss stage. *Iqbal*, 556 U.S. at 678 (holding that the focus is on the sufficiency of the allegations, not on whether the plaintiff will ultimately prevail). After all, "Rule 12(b)(6) does not countenance dismissals based on a judge's disbelief of a complaint's factual allegations." *Twombly*, 550 U.S. at 556.

CONCLUSION

This Court should AFFIRM the Seventeenth Circuit's holding on the basis that the FDCA does not preempt the exceptions to Transylvania's product liability statute. Riley may assert her state common law claims under any of the immunity exceptions to the statute to reinstate Mednology's liability. Additionally, fraud-on-the-FDA is a legally viable form of liability under the FCA. Riley has established all of the required elements and Mednology is therefore liable under federal law.

Respectfully submitted,

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ATTORNEYS FOR RESPONDENT