No. 24-9176

IN THE

Supreme Court of the United States

October Term 2024

MEDNOLOGY, INC.,

Petitioner,

— versus —

UNITED STATES EX REL. Riley ORTEGA

Respondent.

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

BRIEF FOR PETITIONER

Team 3303

Attorneys for Petitioner

QUESTIONS PRESENTED

I. Whether federal law preempts statutory exceptions to a manufacturer's state-recognized immunity when the exceptions are based on the manufacturer fraudulently obtaining approval or failing to comply with requirements under the FDA, without a federal finding of fraud or failure to comply?

II. Does the fraud-on-the-FDA theory satisfy the materiality and causation elements for a False Claims Act claim against a medical device manufacturer under the Act's *qui tam* provision?

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The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2-24 of the record where the district court DENIED the Defendant's motion to dismiss Plaintiff's state law claims but GRANTED Defendant's motion to dismiss Plaintiff's False Claims Act ("FCA") claim. The opinion of the United States Court of Appeals for the Seventeenth Circuit is also unreported but appears on pages 25-38 of the record where the circuit court AFFIRMED in part and REVERSED in part. The concurring in part and dissenting in part opinion of Judge Ruzich appears on pages 38-42 of the record.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves provisions of the United States Code 21 U.S.C. § 360k(a) and 21 U.S.C. § 337(a). This case also involves Art. VI, § 2 under the United States Constitution.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves the federal preemption of immunity provision exceptions found in Transylvania's product liability statute and the failure to state a claim for relief under the False Claims Act using a fraud-on-the-FDA theory. The district court granted Petitioner Mednology, Inc.'s motion to dismiss Respondent Riley Ortega's claims under the False Claims Act and denied Mednology's motion to dismiss Ortega's state law claims brought under Transylvania's product liability statute. R. at 24. Mednology appeals the United States Court of Appeals for the Seventeenth Circuit's ruling to uphold the district court's denial of Mednology's motion to dismiss the state law claims and the circuit court's ruling to reverse the district court's grant of Mednology's motion to dismiss Ortega's FCA claim. R. at 38.

Riley Ortega. Riley Ortega is a recently retired United States Army artillery officer. R. at 3. Ortega is diagnosed with post-traumatic stress disorder (PTSD) because memories of events encountered during her military service interferes with her daily life. R. at 3. Her PTSD contributes to her sleep apnea symptoms. R. at 3. Ortega visited her somnologist seeking alleviation of her sleep apnea and insomnia symptoms and was prescribed a sleep-inducing medical device called Sleepternity. R. at 3.

Sleepternity. Sleepternity is a "state-of-the-art" continuous positive airway pressure (CPAP) machine equipped with several high-tech features. R. at 3. Among these features are an automatic pressure adjustment system that increases therapy comfort, a heated humidifier which reduces dryness and irritation, and a smartphone app that allows users to customize various settings on their Sleepternity device. R. at 3. Additionally, Sleepternity comes with noise-canceling sleep headphones that emit gentle pulses which help users relax and fall asleep quickly. R. at 3. These additional features are unique to Sleepternity, making the device "revolutionary" in both reducing the occurrence of sleep apnea and effectively reducing insomnia. R. at 3. On December 30, 2022, the FDA approved Sleepternity for marketing as a Class III medical device. R. at 3-4. With the FDA approval of Sleepternity, the Centers for Medicare and Medicaid Services (CMS) began providing coverage to those prescribed Sleepternity. R. at 4.

Mednology, Inc. Mednology modified Sleepternity's sound-dampening foam by replacing the silicone-based foam with a polyester-based polyurethane (PE-PUR) foam and did not disclose this modification to the FDA. R. at 4. According to the FDA, PE-PUR foams present health risks due to a tendency for these foams to break down into volatile organic compounds (VOCs). R. at 4. VOCs have the potential to be breathed in or swallowed by CPAP users. R. at 4. In June 2021, Philips Respironics (Philips) recalled from the market certain CPAP machines that had PE-PUR foams and replaced those foams with silicone-based foams. R. at 4.

Ortega's Claim. After experiencing asthma attacks, Ortega was treated at an emergency room at a local hospital. R. at 4. Both the emergency room physician and Ortega's primary care physician recommended that Ortega stopped using Sleepternity, believing that the asthma attacks were unknown side effects of the device. R. at 5. Ortega is allergic to isocyanate, which is a VOC that comes from degraded polyurethane. R. at 5. After stopping her use of Sleepternity, Ortega's asthma symptoms subsided but with chronically inflamed lungs, her sleep apnea symptoms returned and are still persistent. R. at 5. Ortega continues to use the Sleepternity headband to treat her insomnia. R. at 5.

Ortega assumed that Sleepternity was not suitable for her sleep apnea problem until her brother Jim, a Mednology assembly manager, theorized that replacing silicone-based foam with PE-PUR foams contributed to Ortega's asthma attacks. R. at 5. Jim's belief was that Mednology initially used the silicone-based foams to secure FDA approval and switched to PE-PUR foams to save on manufacturing costs. R. at 5. Ortega believes PE-PUR foams degrade into certain forms of isocyanate that contributed to her asthma attacks and chronically inflamed lungs. R. at 5.

II. NATURE OF PROCEEDINGS

The District Court. On June 21, 2023, Riley Ortega filed a petition against Mednology in the United States District Court for the Southern District of Transylvania. R. at 6. Ortega brought both a products liability action under Transylvania's product liability statute and a False Claims Act (FCA) (31 U.S.C. §§ 3729-3733 (2024)) action under the FCA's *qui tam* provision (31 U.S.C. § 3730(b)). R. at 6. The United States declined to intervene in Ortega's FCA action. R. at 6. Mednology moved to dismiss both Ortega's products liability claim and FCA claim pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. R. at 9. On October 15, 2023, the district court granted dismissal of Ortega's FCA claim but denied dismissal of the state law claims. R. at 24.

Seventeenth Circuit Court of Appeals. Ortega appealed the dismissal of her FCA claim and Mednology appealed the denial of its motion to dismiss Ortega's state law claims. R. at 25. The Seventeenth Circuit affirmed the district court's ruling regarding the state law claims, finding that Ortega alleged sufficient facts to plausibly rebut a presumption of Mednology's compliance with FDA requirements. R. at 35. The Seventeenth Circuit reversed the dismissal of Ortega's FCA claim, believing that the fraud-on-the-FDA theory is a viable theory for a FCA claim. R. at 27.

SUMMARY OF THE ARGUMENT

I.

This Court should reverse the denial for motion to dismiss because federal and Transylvania law preempts Ortega's claims. Because of preemption principles, Ortega has failed to state a claim upon which relief can be granted.

First, federal law impliedly preempts subsection (b), which is an exception to the immunity statute that applies if a manufacturer intentionally withholds or misrepresents required information under the FDCA. This provision stands as an obstacle to the enforcement and regulation of the FDA. Because of the strenuous application process for Class III medical devices, the FDCA gives broad authority to the FDA to punish and deter fraud. This Court has interpreted Section 337(a) of the FDCA to provide clear evidence of Congress's intent for Class III medical devices to be enforced exclusively by the federal government. The FDA fully controls the approval process and is responsible for detecting, deterring, and punishing fraud. To allow state courts to determine fraud-on-the-FDA claims under subsection (b) would create an unacceptable obstacle for the FDA to police fraud. Therefore, without a federal finding of fraudulent conduct by the medical device manufacturer, subsection (b) is impliedly preempted by federal law.

Second, federal law impliedly preempts subsection (c), which applies when a manufacturer fails to warn about dangers of a medical device as required by the FDA. The exception was relied upon to neutralize Transylvania's immunity statute. However, federal law preempts state-law claims that seek to privately enforce the duties owed to the FDA. For subsection (c) to apply, a plaintiff must bring claims based on conduct that violates the FDCA but may not sue *because* the conduct violates the FDCA. That is because the FDA must be able to enforce federally mandated requirements, and policing medical devices goes beyond the scope of traditional state police power. Ortega's failure to warn claims do not stem from state common-law principles. But are based on conduct required by the FDA, making the claims impliedly preempted under federal law.

Finally, subsection (a) shields Mednology from product liability claims. Ortega never asserted any finding from the FDA or a federal agency regarding noncompliance with Sleepternity as required by the FDA. Although preemption principles do not preempt a state-law claim against a medical device manufacturer for noncompliance, Transylvania law does. The Transylvania immunity statute presumes compliance by a manufacturer that has FDA approval. Therefore, minus a finding by the FDA, any allegation regarding noncompliance would attack the FDA's risk/benefit analysis, which this Court has raised concerns about. Ortega never asserted a federal finding, thus Mednology has protection against product liability claims under the Transylvania immunity statute. Since Ortega has failed to state a claim upon which relief may be granted, this Court should reserve the denial for motion to dismiss.

II.

The Seventeenth Circuit improperly reversed the district court's dismissal of Ortega's FCA claim because Ortega's fraud-on-the-FDA theory fails to establish materiality and causation. A plaintiff must show that a false statement was material and caused the government to pay money.

The Seventeenth Circuit merely said that it was plausible that Ortega pleaded sufficient facts to establish these elements.

Even though the Seventeenth Circuit acknowledged the demanding nature of the materiality standard, it punted the question for another day saying that it is a matter of proof, and no longer a legal ground for dismissal. In doing so, the Seventeenth Circuit failed to employ the holistic analysis of materiality that this Court demands. False certification theories such as Ortega's have been dismissed in other circuits because they fail to satisfy the demanding standard.

The court below also erred in its reversal because the fraud-on-the-FDA theory fails to establish a causal link between Mednology's actions and the CMS's decision to reimburse for Sleepternity. Ortega must show that there is a nexus between Mednology's actions and the government's injury. The fraud-on-the-FDA theory does not satisfy causation because if the FDA approves Sleepternity regardless of alleged fraud, then the causal connection disappears.

Furthermore, the fraud-on-the-FDA theory presents practical problems of proof and regulatory oversight that is outside of the purview of the courts. Allowing such claims to go to trial will place the power of overturning FDA approval into the hands of a six-member jury. Additionally, it will transform the FCA into a mechanism to enforce regulatory compliance, instead of the tool it is designed to be in protecting the government from fraudulent conduct. Thus, Ortega's FCA claims should clearly be dismissed.

ARGUMENT AND AUTHORITIES

Standard of Review. This appeal raises two legal questions. The Supreme Court of the United States reviews questions of law de novo. *Pierce v. Underwood*, 487 U.S. 552, 558 (1988). This Court also reviews motions to dismiss for failure to state a claim *de novo*. Fed. R. App. P. 12(b)(6).

I. THE SEVENTEENTH CIRCUIT IMPROPERLY DENIED THE MOTION TO DISMISS BECAUSE FEDERAL LAW PREEMPTS BOTH EXCEPTIONS TO THE TRANSYLVANIA IMMUNITY

STATUTE AND MEDNOLOGY IS IMMUNE FROM ORTEGA'S STATE LAW CLAIMS WITHOUT A FEDERAL FINDING OF FRAUD OR A FAILURE TO COMPLY UNDER THE FDA REQUIREMENTS.

This Court should reverse the court of appeals and grant Mednology's motion to dismiss Ortega's product liability claims. Rule 12(b)(6) of the Federal Rules of Civil Procedure allows for dismissal if the complaint fails to state a claim upon which relief can be granted and the Food, Drug and Cosmetic Act (FDCA) preempts Ortega's claims. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007).

The claims brought against Mednology are for the alleged fraudulent production of Sleepternity, a continuous positive airway pressure (CPAP) machine, and the failure to disclose to the Federal Drug Administration (FDA) modifications made to Sleepternity after the FDA approved the medical device. R. at 6. Ortega mistakenly relies on subsections (b) and (c) of the Transylvania product liability statute to avoid the State's manufacturer's immunity statute because federal law preempts both subsections. R. at 9; *see also* Trans. Comp. Stat. §630.546 (2024).

The concept of preemption derives from the Supremacy Clause of the Constitution, which vests Congress with the power to preempt state law. *Jones v. Rath Packing Co*., 430 U.S. 519, 525 (1977). The Supremacy Clause states that federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, cl. 2. Preemption may either be express or implied and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. *Jones*, 430 U.S. at 527; *See Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018). Because the structure and purpose of the FDCA are uniquely federal in nature, there is no presumption against preemption in this case. *See Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341, 347 (2001).

This Court has refused to rely solely on the legislature's purpose and looks to the effects of a law. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105 (1992). If state law interferes with the methods designed by a federal statute to reach a certain goal, federal law will preempt that state law. *Id*. at 103.

Ortega based her claims on Mednology's alleged fraudulent actions against the FDA. R. at 6. However, "[p]olicing fraud against federal agencies is hardly a 'field which the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). For an issue to have a presumption against preemption, there must be a situation that implicates federalism concerns and State's regulation of health and safety matters. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Transylvania's product liability immunity statute deals with matters of health and safety. *See* 21 Trans. Comp. Stat. § 630.544 (2024). However, the FDA regulated how Mednology would obtain approval for marketing Sleepternity, and the duties derived. The relationship between Mednology and the FDA "is inherently federal in character because the relationship originates form, is governed by, and terminates according to federal law." *Buckman* 531 U.S. at 347. Because of the nature of the relationship between Mednology and the FDA, there is no presumption against preemption for the exceptions in Transylvania's product manufacturer's immunity statute.

A. Federal Law Impliedly Preempts the Subsection (b) Exception to Transylvania's Immunity Statute

1. State law fraud-on-the-FDA claims interfere with the FDA's responsibility and objectives to police fraud

Ortega asserts that Mednology intentionally misrepresented the materials found in Sleepternity's sound abatement foams to the FDA, and therefore, subsection (b) of Transylvania's manufacturer immunity statute applies. This is incorrect. Subsection (b) states:

> The immunity granted under subsection (a) does not apply if the defendant, at any time before the event that allegedly caused the injury, intentionally withholds

> from or misrepresents to the United States Food and Drug Administration information concerning the drug or the medical device that is required to be submitted under the federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301-399i) and the drug or medical device would not have been approved, or the United States Food and Drug Administration would have withdrawn approval for the drug or medical device if the information were accurately submitted.

21 Trans. Comp. Stat. § 630.546(b). In *Buckman*, this Court held that state-law fraud-on-the-FDA claims conflict with federal law. 531 U.S. at 348. And this conflict impliedly preempts state fraud-on-the-FDA claims. *Id.* The FDCA gives the FDA broad authority "to punish and deter fraud against the Administration." *Id*. This Court interpreted Section 337(a) of the FDCA as providing "clear evidence that Congress intended that the [Act] be enforced exclusively by the Federal Government," which impliedly preempts state law. *Id.* at 352; *See* 21 U.S.C. § 337(a) ("all proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.").

Claims based on fraud-on-the-FDA are impliedly preempted because the claims would conflict and interfere with the FDA's responsibility and objectives to police fraud. *Id.* at 350. These policy concerns are particularly true for Class III medical devices, which are defined as “devices that present a potentially unreasonable risk of illness or injury or which are purported or represented to be for use in supporting or sustaining human life for the use of substantial importance in preventing impairment of human health”. § 360(a)(1)(C); *See Lohr*, 518 U.S. at 477.

To get approved for a Class III medical device by the FDA is a rigorous process. *Id.* at 447. A manufacturer must submit a multivolume application that includes complete reports of all studies on the device's effectiveness and safety, fully describe all components, the manufacturing and processing methods, proposed labeling, and more. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). The FDA also has the authority to request additional information and may counsel a panel of outside experts. *Id.* The FDA grants approval only after reasonable assurance that the

medical device is safe and effective. *Lohr*, 518 U.S. at 477. On average, the FDA spends 1,200 hours reviewing each application. *Id.*

The FDA not only controls the approval process, but the FDCA has provisions that help detect, deter, and punish suspected fraud. *See Buckman*, 531 U.S. at 349. The FDA has a wide range of avenues for enforcement for suspected fraudulent medical devices. The Administration may seek general criminal proscription and prosecution, injunctive relief, civil penalties, or the FDA may seize the device. *Id.* Therefore, any state law fraud-on-the-FDA based claims would disrupt the FDA's objectives. *Id.* This Court has held that Federal law impliedly preempts state law if the state's laws create an unacceptable obstacle to the execution of Congress's full purposes and objectives. *See Wyeth v. Levine*, 555 U.S. 555, 563-64 (2009). The purpose of Congress is the "touchstone" in every preemption case; however, a medical device manufacturer "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA…" *Buckman*, 531 U.S. at 350. This Court in *Buckman*, worried that manufacturers would file "a deluge of information" not required by the FDA that would substantially burden the Administration. *Id.* at 351.

To allow Ortega to assert her state-law fraud-on-the-FDA claims under Subsection (b) would create an unacceptable obstacle for the FDA to police fraud and is impliedly preempted.

2. Subsection (b) is Preempted Without a Federal Finding of Fraudulent Conduct

The Seventeenth Circuit correctly decided that subsection (b) of Transylvania's immunity statute is impliedly preempted under federal law because the FDA never found Mednology had committed fraud. R. at 29; *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004). Michigan has a strikingly similar exception to subsection (b) of the products liability immunity statute. *See* Mich. Comp. Laws § 600.2946(5)(a) (1995). This statute has created a circuit split

among the courts of appeals. *See Garcia*, 385 F.3d at 967; *see also Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006).

In *Garcia*, the Sixth Circuit held that the plaintiff's claims were preempted by federal law, following this Court's reasoning in *Buckman*. *Garcia*, 385 F.3d at 967. The plaintiff brought a claim against a medication manufacturer after suffering liver failure caused by the medication, which the FDA had approved. *Id*. at 963. The court found that the claims were essentially an attempt to enforce the FDCA through state law, which federal law preempts. *Id*. at 965. The court emphasized that allowing such claims would interfere with the FDA's regulatory authority and create a patchwork of state regulations that could undermine the uniformity of federal laws and regulations. *Id*. at 967.

The Sixth Circuit reasoned that *Buckman* stands to prohibit a plaintiff from invoking the immunity exceptions through state court findings of fraud on the FDA because of federal and state branch meddling concerns. *Id.* However, these concerns dissipate when the FDA itself determines that a fraud has been committed. *Id.* Therefore, the subsection in the Michigan statute, much like the Transylvania subsection (b), is preempted when a plaintiff asks a state court to find bribery or fraud on the FDA, but not when a claim is based on a federal finding that bribery or fraud occurred on the FDA. *Id*. at 966.

In contrast, the Second Circuit in *Desiano* held that federal law did not preempt the plaintiff's state law claims and reasoned that there was a presumption against preemption because the issue dealt with an area of health and safety traditionally regulated by the states. 467 F.3d at 93. The plaintiff sued a drug manufacturer after suffering liver damage. *Id*. 88. However, this case is not dispositive to the issue at hand because the claims brought by the plaintiff differ significantly from those brought by Ortega. *Id; See* R. at 6.

Ortega's cause of action is fraud-based claims against the FDA, and she is attempting to use state court to prove them. The claims brought by the plaintiff in *Desiano* are traditional state law claims, such as negligence or breach of implied and express warranties. 467 F.3d at 88. The claims arose from the alleged failure to use reasonable care in producing the product and not solely due to violations of the FDCA. *Id*. at 96.

Subsection (b) would not be preempted if the claims relied on federal findings to prove the fraudulent conduct. *See Garcia*, 385 F.3d at 967. However, Ortega did not allege that the FDA found Mednology fraudulently obtained marketing approval. R. at 29. The FDA has not confirmed any fraudulent behavior on the part of Mednology and further, stopped investigating Mednology once Mednology voluntarily recalled Sleepternity from the market after receiving a complaint from Ortega. *Id*. Ortega cannot use subsection (b) to bring her fraud-on-the-FDA claims against Mednology because without a federal finding, Ortega is attempting to find fraud-on-the-FDA through state court, and therefore, federal law impliedly preempts subsection (b).

B. Federal Law Impliedly Preempts Subsection (c) Exception for Failure to Warn Claims

1. State Law Failure to Warn Claims Based on Requirements by the FDA are Preempted

The Seventeenth Circuit correctly found that subsection (c) was preempted by federal law because the FDA did not find that Mednology failed to warn. R. at 31. Subsection (c) of Transylvania's immunity statute states: "The immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the drug or medical device as *required* by the FDA." 21 Trans. Comp. Stat. § 630.546(c) (emphasis added). Circuit courts have again split on whether a state-law failure to warn claim is preempted by federal law. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017) (holding that federal law preempts a failure to report claims); *see also Bryant v. Medtronic, Inc*, 623 F.3d 1200, 1204 (8th Cir. 2010) (holding failure to warn claims were preempted by § 36(k) because of specific language set for

Class III device warnings); *see also Hughs v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) (holding that a failure to warn claim is not expressly or impliedly preempted); *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (holding state-law failure to warn claims were not preempted because the state law duty to warn paralleled a federal duty). However, whether federal law preempts a state-law failure to warn is not the issue; instead, it is whether it preempts subsection (c) of Transylvania's immunity statute.

For Ortega to avoid preemption, she must have carefully pleaded a claim that implicated the safety or effectiveness of a federally regulated medical device that was parallel to the FDCA. *Id.* Preemption of state common law actions involving Class III preapproved medical devices may be expressed or implied. The FDCA includes an express preemption clause that states:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement- 1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and 2) which related to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The preemption statute demonstrates the concern that competing state requirements could unduly interfere with the market for medical devices. However, the court in *Lohr* made it clear that § 360k(a) did not preempt all state-law claims. 518 U.S. at 495. In *Riegel*, this Court clarified that duties imposed by state law are expressly preempted only to the narrow extent that they add different or extra requirements to the medical device beyond those required by the federal scheme. 522 U.S. at 330. In contrast, implied preemption prohibits state-law claims that seek to privately enforce the duties owed to the FDA. *See Buckman*, 531 U.S. at 348-49 (concluding that § 337(a) to bar claims by private litigants for noncompliance with the medical device provisions).

Therefore, a plaintiff has a narrow gap through which a state law claim must fit if the claim is to escape both types of preemption. *Bryant*, 623 F.3d at 1204. A plaintiff must sue for conduct

that violates the FDCA to avoid express preemption but may not be suing *because* the conduct violates the FDCA to avoid implied preemption. *Id.*

Ortega again relies on a subsection of Transylvania's product liability immunity statute to avoid Mednology's immunity for failure to warn. R. at 17; *see also* 21 Trans. Comp. Stat. § 630.546(c). Because of the assertion that Mednology failed to warn about the dangers as required by the FDA, that claim escapes express preemption. *See Riegel*, 522 U.S. at 330.

The failure to warn claim, however, does not escape implied preemption. Ortega relies on subsection (c) to "neutralize" the immunity statute to bring her state-law claims. The alleged failure to warn by Mednology is a failed reporting requirement to the FDA under the FDCA and not a breach of the common-law duty to use reasonable care. *Marsh v. Genentech, Inc.*, 693 F.3d 546 (6th Cir. 2012). Since Ortega brings the failure to warn claim because the conduct violates the FDCA, federal law impliedly preempts the subsection (c) exception to immunity.

2. Subsection (c) Allows State Courts to Interfere With the FDA's Authority and Discretion to Police Medical Device Manufacturers

Subsection (c) should be preempted under federal law because Ortega seeks to have a state court find wrongdoing against the FDA to bring her claims. Like subsection (b), subsection (c) is preempted without a finding from the FDA that Mednology violated requirements to warn about the dangers or risks of the medical device. *See Garcia*, 385 F.3d at 966. To hold otherwise would directly interfere with the FDA's authority to regulate and police medical device manufacturers.

Throughout the nation's history, The States have exercised police powers to protect the health and safety of their citizens. *Lohr*, 518 U.S. at 475. However, the States dealt with "primarily, and historically, … matter[s] of *local* concern." *Id*. (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985)). (emphasis added). In recent decades, the

Federal Government has stepped in and played an increasingly significant role in the protection of the health of all citizens. *Id.*

The first enactment by Congress occurred in 1906 with the Food and Drug Act, which prohibited the manufacturing and shipment in interstate commerce of any adulterated and misbranded food or drugs. *Id*. As technology improved, so did the proliferation of medical devices. *See Riegel*, 552 U.S. at 316. Medical devices now play a critical role in delivering quality healthcare and constitute a significant portion of the costs incurred by the nation's healthcare system. Daniel W. Whitney, *Guide to preemption of state-law claims against class III medical devices*, 65 FOODDLJ 113, 113 (2010). Before the enactment of the FDCA, medical devices were left up to the supervision of the States as they saw fit. *Riegel*, 552 U.S. at 315. However, in the 1960s and 1970s, as medical devices became more complex, devices would fail, leading to severe injuries. *Id*. at 316. Congress stepped in and passed the Medical Device Amendments after the continued failures of medical devices. *Id.* The "aftermath demonstrated the inability of the common-law tort system to manage the risks associated with [medical] devices." *Id.*

Federal law dictates not only what information a manufacturer must produce but also that the FDA is responsible for imposing penalties for omissions and misrepresentations. *Buckman, 531* U.S. at 347-48. This means that disclosures to the FDA are uniquely federal and, therefore, beyond a state's traditional police power. *Id.*

The FDA must have the ability to enforce its federally mandated requirements, and without a finding from the FDA that Mednology breached its federal requirement for failure to warn, subsection (c) is preempted. *See Garcia*, 385 F.3d at 967. Therefore, Ortega may not bring her failure to warn claims against Mednology because of Transylvania's manufacturer immunity statute.

C. Without a Federal Finding of Noncompliance With the FDA, Subsection (a) Preempts Ortega's State Law Claims.

The Seventeenth Circuit denied Mednology's motion to dismiss because it incorrectly held that subsection (a) did not protect the manufacturer against Ortega's claims despite the determination that the two exceptions to the statute did not apply. R. at 32. Subsection (a) of Transylvania's immunity statute states that a manufacturer will not be liable if, "[the] 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). Medical devices that are approved by the FDA are presumed to be in compliance under the statute. *Id.*

If Transylvania did not have an immunity statute, Ortega could bring her claims based on noncompliance with the FDA. *See Marsh*, 693 F.3d at 554. Without the immunity statute, for Ortega to succeed on a motion to dismiss, the complaint must contain sufficient factual allegations, that when accepted as true state a claim for relief that is plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is considered plausible if the allegations assert "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id. (*quoting *Twombly* 550 U.S. at 556*)*.

However, because of the state immunity statute, for Ortega to successfully bring her claims against Mednology, she must show that the medical device was not in compliance at the time the device left the control of Mednology. *See* Trans. Comp. Stat. § 630.546(a). Medical devices that are approved by the FDA are presumed to be complying under the statute and therefore, Ortega bears the burden of rebutting this presumption. *Id.*

The issue at hand is similar to *Marsh*, where the plaintiff brought a product liability suit against a drug manufacturer alleging that the manufacturer knew of dangerous side effects prior to and after FDA approval of the drug. 693 F.3d at 548. The state of Michigan has an immunity statute almost identical to Transylvania's. *See* Mich. Comp. Laws § 600.2946(5); *see also* 21

Trans. Comp. Stat. § 630.546(a). The plaintiff alleged that the drug manufacturer was not entitled to Michigan's immunity statute after it failed to submit updated safety information to the FDA or comply with various FDA requirements. *Id.* The Sixth Circuit disagreed, holding that federal law preempted the plaintiff's ability to assert that the manufacturer's drug did not comply with the FDA's approval. *Id*. at 554. Which allowed the manufacturer to remain protected under the state immunity statute. *Id.*

The Seventeenth Circuit attempted to differentiate *Marsh* from case at hand because Ortega alleged that Mednology adulterated the medical device. R. at 34. Although the plaintiff in *Marsh* did not allege the drug was changed after FDA approval, the allegation was that the drug manufacturer was not in compliance with the FDA before or after the drug was approved. 693 F.3d at 548. Despite any differences in the basis of the allegation, both parties brought their claims based on noncompliance with the FDA.

FDA approval of a drug or medical device does not always preempt a state common-law premised on noncompliance with the FDA. *See Wyeth*, 555 U.S. at 558-59. The Sixth Circuit held that absent Michigan's immunity statute, the plaintiff could bring such a claim. *Marsh*, 693 F.3d at 554.

The Seventeenth Circuit held that Ortega had plead sufficient facts to plausibly rebut the presumption that Mednology complied with the FDA when the medical device left the manufacturer. R. at 35. However, this goes against the holdings with *Buckman* and *Garcia*. *See Buckman*, 531 U.S. at 348; see also *Garcia*, 385 F.3d at 967. Absent any concrete allegations that the product was not in compliance with the FDA the claims are not parallel and are impliedly preempted. *See Marsh*, 693 F.3d at 554. Instead, the allegations are an "attack[] on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device." *Id.* Such claims

are preempted minus a federal finding that Mednology was not in compliance. *Garcia*, 385 F.3d at 967.

Because Ortega did not assert or plead any facts regarding a federal finding of non-compliance, she is barred from bringing her claims against Mednology under the Transylvania's manufacturer's immunity statute. Although the preemption principles do not prevent state-law claims against a medical device manufacturer for noncompliance with the FDA, Transylvania law does. Therefore, Mednology is protected under the immunity statute and this Court should grant the motion to dismiss for failure to state a claim.

II. THE SEVENTEENTH CIRCUIT ERRONEOUSLY REVERSED THE DISTRICT COURT'S DISMISSAL OF RESPONDENT'S FCA CLAIMS BECAUSE RESPONDENT'S FRAUD-ON-THE-FDA THEORY FAILS TO ESTABLISH CAUSATION.

For Respondent to succeed on her FCA claim, she must establish the following elements: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis*., 862 F.3d 890, 902 (9th Cir. 2017) (citing *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 188-93 (2016)). The Seventeenth Circuit erred in its analysis of both the materiality and causation elements. Even if this Court finds that all the elements are satisfied, it is clear that as a final matter, the purpose of the FCA is "not to second-guess agencies' judgments about whether to rescind regulatory rulings." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016).

A. Respondent's FCA Claim Should be Dismissed Because it Fails to Meet *Escobar's* Demanding Materiality Standard.

In *Escobar*, this Court held that "the materiality standard is demanding." *Universal Health Servs. v. United States ex rel. Escobar,* 579 U.S. 176, 194 (2016). FCA plaintiffs must plead facts that support allegations of materiality. *Id.*, at 195 n. 6. This Court has also stated that the FCA is

not "an all-purpose antifraud statute." *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). Nor is the FCA a "catch-all statute for targeting weaselly behavior." *United States ex rel. Crocano v. Trividia Health Inc.*, 616 F. Supp. 3d 1296, 1310 (S.D. Fla. 2022) (citing *Escobar*, 579 U.S. at 194).

Any alleged misconduct is not deemed material merely because the Government requires compliance with a regulatory requirement as a condition of payment. *Escobar*, 579 U.S. at 194. It is also not sufficient to satisfy the materiality standard that the Government has the option to decline to pay a claim if it knew of the defendant's noncompliance with a statutory or regulatory requirement. *Id*. If the federal agency pays a particular claim in full even with actual knowledge that certain requirements were violated, "that is very strong evidence that those requirements are not material." *Id*, at 195. Similarly, when a federal agency pays a certain type of claim despite its actual knowledge of a violating of certain requirements, and has not changed its position, that also serves as strong evidence that the requirements are not material. *Id*. In sum, the FCA is not a means of punishing corporations for "insignificant regulatory" violations but is a vehicle for addressing fraud. *Id.*, at 196.

The analysis of materiality is "holistic." *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018) (quoting *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016)). Factors that are considered are: (1) "the Government's decision to expressly identify a provision as a condition of payment"; (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and (3) whether the "noncompliance is minor or insubstantial" or if it goes "to the very essence of the bargain. *Prather*, 892 F.3d 822, 831 (citing *Escobar*, 579 U.S.

176, 193 & n.5). None of these considerations is dispositive on its own, neither is the list exclusive. *Id*.

The court below erred when it decided that Respondent satisfied the materiality element of her FCA claim. One reason the Seventeenth Circuit sided with the Ninth Circuit is because "the Ninth Circuit in *Campie*, unlike the First Circuit in *D'Agostino*, applied *Escobar's* clarifications of the FCA." R. at 36. While the Seventeenth Circuit is right in deciding that its "task is to determine, under the clarifications set forth in *Escobar*, whether such false certification was material", the court below does no such thing. R. at 36-37. Despite its acknowledgment of *Escobar's* demanding materiality standard, the Seventeenth Circuit merely states that the materiality issue presents a matter of proof rather than a legal ground to dismiss Respondent's FCA claim. R. at 37. The Seventeenth Circuit does not consider any of the factors laid out by the Sixth Circuit in *Prather* in its materiality analysis.

Additionally, the Seventeenth Circuit gives Respondent the benefit of the doubt that she is using "an implied false certification theory to bring her FCA claim against Mednology." R. at 36. Even so, Respondent has failed to establish materiality. Multiple courts have dismissed FCA claims when the relator lies on a false certification theory because compliance with FDA regulations "is not required for payment by Medicare and Medicaid, [Defendant] has not falsely stated such compliance to the government." *Trividia Health Inc.*, 616 F. Supp. 3d at 1312 (quoting *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014)).

B. Respondent's Fraud-on-the-FDA Theory Fails Because it Cannot Establish a Causal Connection Between Mednology's Actions and the CMS's Decision to Reimburse Sleepternity.

Even if the Court determines that Respondent has plead sufficient facts to satisfy the materiality element, her FCA claims should be dismissed as she cannot rely on the fraud-on-the-FDA theory to establish causation. Implicit in the demanding materiality standard set forth in

Escobar is the necessity of establishing a causal connection between a defendant's conduct and CMS's decision to reimburse for the defendant's product. *Escobar*, U.S. 579 at 194-95. In its discussion of the materiality standard in *Escobar*, the Court indicated that alleged fraudulent conduct *must cause* the government to withdraw its payment. *Id.* Respondent has failed to establish the causal link the FCA requires.

A plaintiff proves causation when she "show[s] an element of causation between the false statements and the loss." *United States v. Miller*, 645 F.2d 473, 475 (5th Cir. 1981). This is because some courts apply the rule "that damages are limited to the amount that was paid out by reason of the false claim." *United States ex rel. Longhi v. Lithium Power Technologies, Inc.*, 575 F.3d 458, 473 (5th Cir. 2009). To show causation, a plaintiff must show that a nexus exists between the defendant's action and the government's injury to show causation. *Id.* (finding causation relationship between the false statements and the loss, even though the deceptive contracts produced no tangible injury to the government, as intangible benefit of "providing an 'eligible deserving' business with grants was lost as a result of the defendants' fraud"; also, direct causal connection existed between the defendants' false statements and the funds they received.) (citations omitted); *United States ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005) ("The FCA requires a causal rather than a temporal connection between fraud and payment. If a false statement is integral to a causal chain leading to payment, it is irrelevant how that federal bureaucracy has apportioned the statements among layers of paperwork.").

When a relator alleges that the defendant fraudulently induced the FDA to grant pre-market approval, the relator must show that the defendant's conduct "cause[d] the government to make a payment or to forfeit money owed." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) (citing *United States ex rel. Westrick v. Second Change Body Armor Inc.*, 128 F. Supp. 3d 1, 18 (D.D.C. 2015). The causal connection disappears if the FDA would have approved the medical device

despite the alleged fraudulent representations. *Id.* The district court was correct in its analysis that "until it is established that the FDA would not have approved Sleepternity in such situation, it is unclear at best whether the requirement that 'the alleged false claims procured certain approvals' has been met". R. at 23 (citing *Campie*, 862 F.3d 890, 905 (9th Cir. 2017).

C. If This Court Adopts the Fraud-on-the-FDA Theory, it Will Give Juries the Power to Overturn FDA Decisions.

If the Court does agree with the Ninth and Seventeenth Circuits' rationale that the materiality and causation elements are a matter of proof and not legal grounds for dismissal, the Court should still dismiss her claims as a matter of public policy. Allowing Respondent to base her FCA claim on the fraud-on-the-FDA theory poses several public policy considerations that weigh in favor of its dismissal. In relying on a fraud-on-the-FDA theory, Respondent is asking this court to step in the shoes of the FDA and decide whether it was correct in giving approval for Sleepternity.

The First Circuit addressed several concerns with allowing the fraud-on-the-FDA theory to be a basis for FCA claims in *D'Agostino*. *See D'Agostino,* 845 F.3d at 8-9. First, Respondent is attempting to transform the FCA into a mechanism "with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id.* Put another way, the First Circuit explained that the purpose of the FCA is "to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." *Id.* The Fifth Circuit found its sister circuit's "cautions…forceful" a year later,

quoting the same concerns verbatim. *United States ex rel. Harman v. Trinity Indus.,* 872 F.3d 645, 661-62 (5th Cir. 2017). Other courts across the country have followed its lead.[1]

Additionally, the First Circuit expressed doubts with the "practical problems of proof" that courts would be faced with in fraud-on-the-FDA FCA claims like Respondent's. *D'Agostino,* 845 F.3d at 9. The court raised questions such as:

> "How would a relator prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind? Whose? What if former officials no longer in government were of one view, and current officials another? These and similar questions all support our position that the absence of some official agency action confirming its position and judgment in accordance with the law renders [relator]'s fraud-on-the-FDA theory futile."

Id. See also United States v. Bristol-Myers Squibb Co. (In re Plavix Mktg., Sales Practice & Prods Liab. Litig.), 332 F. Supp. 3d 927, 959 (D.N.J. 2017). Respondent is asking the Court to answer these same questions. Whether or not the FDA would have rescinded its approval of Sleepternity had the FDA known that PE-PUR foams would be used rather than silicone-based foams is not a legal question that courts should answer. That is the role of the FDA. If this Court decides to adopt Respondent's fraud-on-the-FDA theory, the Court "would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014).

[1] *See United States ex rel. Bennet v. Bayer Corp.*, No. 2:17-cv-04188, 2022 U.S. Dist. Lexis 59793 (D.N.J. March 31, 2022); *United States ex rel. Krahling v. Merck & Co.*, No. 2:10-cv-04374, 2023 U.S. Dist. Lexis 135853 (E.D. Pa. July 27, 2023); *United States v. Bristol-Myers Squibb Co. (In re Plavix Mktg., Sales Practice & Prods Liab. Litig.),* 332 F. Supp. 3d 927, 959 (D.N.J. 2017); *State ex rel. Harman v. Trinity Indus.*, No. M2022-00167-COA-R3-CV, 2023 Tenn. App. LEXIS 247, at *59 (Ct. App. June 13, 2023)

CONCLUSION

Federal law preempts subsection (b) and (c) of Transylvania immunity statute without a federal finding of fraudulent conduct or failure to warn under FDA requirements and without such finding subsection (a) preempts Ortega's state law claims against Mednology. Further, Ortega's FCA fraud-on-the-FDA claim fails to state an FCA claim because such a theory fails to satisfy both the material and causation elements required under the FCA. Furthermore, such theory transfers regulatory power from the FDA to a trial jury. This Court should REVERSE the Seventeenth Circuit Court of Appeals' judgment in all respects.

Respectfully submitted,

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ATTORNEYS FOR PETITIONER