No. 24-9176

In The

Supreme Court of the United States

October Term 2024

Mednology, Inc.
Petitioner

v.

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 3305

Attorneys for Respondent

QUESTIONS PRESENTED

1. Does federal law preempt a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer fraudulently obtaining FDA approval or failing to comply with any FDA requirements?
2. May a relator rely on the fraud-on-the-FDA theory to bring a False Claims Act claim against a medical device manufacturer under the Act's *qui tam* provision?

TABLE OF CONTENTS

TABLE OF CONTENTS (CONT'D)

TABLE OF CONTENTS (CONT'D)

TABLE OF AUTHORITIES

Page(s)

UNITED STATES SUPREME COURT CASES:

UNITED STATES CIRCUIT COURT OF APPEALS CASES:

TABLE OF AUTHORITIES (CONT'D)

UNITED STATES DISTRICT COURT CASES:

CONSTITUTIONAL AND STATUTORY PROVISIONS:

RULES PROVISIONS:

TABLE OF AUTHORITIES (CONT'D)

OTHER AUTHORITIES:

OPINIONS BELOW

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 Mednology's motion to dismiss Ortega's state law claims and GRANTED Mednology's motion to dismiss Ortega's False Claims Act claim. The opinion of the United States Court of Appeals for the Seventeenth Circuit is also unreported but appears on pages 25-42 of the record where the appellate court AFFIRMED the district court's denial of Mednology's motion to dismiss Ortega's state law claims and REVERSED the district court's granting of Mednology's motion to dismiss Ortega's FCA claim.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves five statutory provisions of Transylvania law: the Transylvania product liability statute, 21 Trans. Comp. Stat. § 630.545; that statute's statement of purpose, 21 Trans. Comp. Stat. § 630.544; an immunity-granting provision under that statute, 21 Trans. Comp. Stat. § 630.546(a); and two separate exceptions to the immunity granted under subsection(a), 21 Trans. Comp. Stat. § 630.546(b) and (c). This case also involves two provisions of the United States Code: the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301–399i, and the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733. Finally, this case implicates Art. VI, Cl. 2 of the United States Constitution.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves attempts by a medical device manufacturer to evade liability under both state and federal law for a dangerous and deceptively marketed product.

Mednology's Sleepternity. On June 20, 2021, Philips Respironics recalled its CPAP machines that contain polyester-based polyurethane (PE-PUR) foams to replace this material with silicone-based foams as a safer alternative, due to the health risks posed by inhaling the volatile organic compounds (VOCs) that are a byproduct of the PE-PUR foams. R. at 6. On December 30, 2022, Sleepternity, a CPAP device manufactured by Mednology, was approved for marketing as a Class III medical device by the Food and Drug Administration (FDA). R. at 3-4. Shortly afterwards, the Center for Medicare and Medicaid Services (CMS) began to provide coverage for Sleepternity due to its recent FDA approval. R. at 4. Sometime after approval, Mednology modified Sleepternity by replacing the FDA approved silicone-based foams with PE-PUR foams, without informing the FDA or the public of this change. R. at 4. Sleepternity's warning label did not contain any information about the presence of VOCs such as isocyanate in the device. R. at 5.

Ortega. Riley Ortega (Ortega) recently retired from the US Army as an artillery officer. R. at 3. Due to her time spent in the army, Ortega was diagnosed with Post-Traumatic Stress Disorder (PTSD), which disrupts her day-to-day functioning. R. at 4. This disruption contributes to her insomnia and sleep apnea

symptoms. R. at 4. Ortega visited her somnologist seeking relief for her sleep apnea and insomnia and was prescribed Sleepternity to treat both. R. at 4. After beginning Sleepternity to treat her symptoms, Ortega began experiencing asthma attacks and was taken to the emergency room. R. at 4. The ER physician and her doctor counselled Ortega to discontinue use of Sleepternity, believing her asthma attacks to be an unknown side effect of the device. R. at 5. Ortega and her PCP were both aware that she was allergic to isocyanate, a byproduct of degraded polyurethane. R. at 5. They did not consider the allergy to be a cause of her asthma attacks, however, because the warning label does not mention the presence of isocyanates in the device. R. at 5–6.

At this point, Ortega discontinued her use of Sleepternity and was relieved of her asthma symptoms. R. at 5. However, she continued to suffer chronic lung inflammation due to the asthma attacks and a return of her sleep apnea symptoms that do not respond to medications. R. at 5. Ortega's brother, a Mednology assembly manager, suspected that the switch to PE-PUR foam may have contributed to her asthma attacks and informed her of the switch. R. at 5–6. He informed Ortega that Mednology initially designed Sleepternity with the silicone-based foams in order to secure FDA approval, and later made the switch to PE-PUR foams before distributing Sleepternity in order to save on manufacturing costs. R. at 5. Based on this information and further research, Ortega realized that the PE-PUR foam likely contributed to the asthma attacks that led to her lung inflammation as PE-PUR contains isocyanates, a byproduct of polyurethane. R. at 5–6. Ortega reported Mednology's alleged fraudulent conduct to the FDA and filed suit against Mednology.

R. at 6. Shortly after the service of the complaint, Mednology voluntarily recalled Sleepternity from the market. R. at 7. In response, the FDA decided to stop investigating Mednology's alleged fraudulent conduct to focus on other devices still on the market. R. at 7.

II. NATURE OF PROCEEDINGS

On June 21, 2023, Ortega brought a state products liability action and an FCA *qui* tam action against Mednology. R. at 6. The United States declined to intervene in the FCA action. R. at 6. Mednology filed motions to dismiss Ortega's state-law claims and claims under the FCA. R. at 9. On September 12, 2023, the district court heard arguments on Mednology's motion to dismiss. R. at 9. The district court issued an order granting in part and denying in part Mednology's motion to dismiss. R. at 24. Ortega appealed to the district court's order dismissing her FCA claim to the Seventeenth Circuit. R. at 25. Mednology then cross-appealed the district court's order allowing Ortega's state law claim to proceed. R. at 5. The Seventeenth Circuit issued an order affirming, on different grounds, the district court's denial of Mednology's motion to dismiss Ortega's state law claims. R. at 25. This order also reversed the district court's grant of Mednology's motion to dismiss Ortega's FCA claim and remanded for further proceedings. R. at 25.

SUMMARY OF THE ARGUMENT

This Court should affirm, albeit on different grounds, the order of the Seventeenth Circuit Court of Appeals affirming the district court's denial of Mednology's motion to dismiss Ortega's state law claims brought under

Transylvania's product liability statute. This Court should further affirm the Seventeenth Circuit's reversal of the district court's order granting Mednology's motion to dismiss Ortega's claim under the *qui tam* provision of the FCA.

I.

The Seventeenth Circuit Court of Appeals properly held that Mednology's motion to dismiss for failure to state a claim should be denied. The decision of the Seventeenth Circuit correctly held that Ortega has pleaded sufficient facts that give rise to the claim that Mednology has not complied with the FDA requirements. However, the Seventeenth Circuit was incorrect to state that immunity exceptions (b) and (c) under Transylvania's product liability statute are preempted by federal law, specifically, the FDCA and Medical Device Amendment (MDA).

Under immunity exception (b), Mednology is not immune as it misrepresented its sound abatement materials to the FDA and did not inform the FDA of the switch to PE-PUR from silicone-based foam after receiving FDA approval for the silicone. Ortega's claim is not only based on Transylvania's state product liability statute, but also parallels the federal requirements regarding FDA approval. The Supreme Court properly held, that state law claims that parallel federal requirements, but do not impose additional or different requirements, are not expressly preempted. The Supreme Court has also held claims preempted over the concern that they interfered with the FDA's exclusive authority to police fraud against itself. Here, that is not the case. Ortega's claim aligns with federal law, doesn't police FDA regulations, and therefore should not be preempted.

Ortega can bring her claims under an exception to immunity provided in Transylvania's statute, § 630.546(b), which states that immunity does not apply if the manufacturer intentionally misrepresents or withholds information required by the FDA, and if accurate information had been provided, FDA approval would not have been granted or would have been withdrawn. Ortega's claim is based on Mednology's misrepresentation of its product to both consumers and the FDA, aligning with federal law rather than adding any new obligations

Per subsection (c), the immunity granted under subsection (a) does not apply if Mednology fails to warn about the medical device's dangers or risks as required by the FDA and codified in various federal statutes. The FDA regulates the safety and effectiveness of medical devices through its premarket approval (PMA) process. The safety of medical devices is further regulated through strict federal laws governing labeling requirements, including the need to list the materials contained in the device on the label. Once PMA is obtained, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. Ortega's claim parallels those federal requirements, and because this court has previously held that parallel state law claims are not preempted, the court should similarly find Ortega's claims not preempted and allow them to proceed.

A plaintiff's claims are plausible if they allow the court to reasonably infer liability. Ortega has alleged facts showing Mednology's intentional misrepresentation to the FDA and failure to warn about PE-PUR foam, which satisfies this standard.

Further, while manufacturers are generally presumed to comply with FDA requirements under 21 Trans. Comp. Stat. § 630.546(a), Ortega has rebutted this presumption by pleading facts demonstrating that Mednology intentionally misled the FDA, bringing her claims under the exception outlined in § 630.546(b).

II.

The Seventeenth Circuit properly held that Ortega has pleaded a viable claim under the FCA. The appellate court's decision correctly reversed the earlier, improper ruling of the district court that the so-called "fraud-on-the-FDA" theory may not serve as a basis for bringing a claim under the FCA's *qui tam* provision. Although both courts below were correct to note that a circuit split has emerged regarding whether an allegation of implied false certification of a requirement for FDA approval may engender liability under the FCA, the appellate court applied the most appropriate precedent, including guidance from this Court, and ultimately came to the proper conclusion that Ortega's allegations give rise to FCA liability.

Ortega has pleaded facts, with the level of specificity required at this stage, to demonstrate that Mednology engaged in a calculated ruse designed to induce government payment for a product that would not have made it to market but for the untruthfulness of its manufacturer. Ortega's allegations reveal that Mednology was aware that Sleepternity would likely not have received PMA had the company disclosed its intention to manufacture the product with PE-PUR foams known to the FDA to pose precisely the health risks experienced by Ortega. Because approval from the FDA is the key to CMS providing payment for a medical device such as

Sleepternity, and because Ortega has credibly pleaded that Mednology knowingly misrepresented to the FDA the composition of its product with the intention of inducing government reimbursement for that product, Ortega has sufficiently pleaded causation, materiality, and scienter as required by an FCA claim.

The district court's concern that allowing an allegation of "fraud-on-the-FDA" to serve as a basis for an FCA claim would threaten the independent judgment of the FDA is misplaced, as the appellate court noted. The facts of this case, wherein a manufacturer made material misrepresentations to the FDA to procure payment for its product, fall within the scope of fraudulent conduct that the FCA was designed to penalize. Allowing FDA approval, even when fraudulently obtained, to serve as a shield for FCA liability would subvert the Act's purpose and allow manufacturers to engage in fraud to evade liability for fraud.

This Court should AFFIRM the Seventeenth Circuit's denial of Mednology's motion to dismiss Ortega's state law claims and should further AFFIRM that court's reversal of the district court's order granting Mednology's motion to dismiss Ortega's FCA claim.

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). Additionally, when a claim is dismissed under Federal Rule of Civil Procedure 12(b)(6), the appellate court reviews the lower court's determination de

novo. *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1116 (9th Cir. 2020).

I. THE COURT SHOULD UPHOLD THE DECISION OF THE SEVENTEENTH CIRCUIT BECAUSE FEDERAL LAW DOES NOT PREEMPT TRANSYLVANIA'S STATUTE ALLOWING FOR MANUFACTURER LIABILITY.

Transylvania's product liability statute parallels federal requirements enumerated in the MDA. 21 U.S.C. § 331. Ortega's claims are not preempted by federal law because they parallel federal requirements. *E.g., Wyeth v. Levine,* 555 U.S. 555, 581 (2009); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc., v. Lohr.*, 518 U.S. 470, 478 (1996).

Transylvania's Product Liability Statute. In Transylvania, a plaintiff can withstand a defendant's motion to dismiss if the plaintiff pleads sufficient facts to state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 570, 570 (2007). A claim is plausible when a plaintiff asserts factual content that allows the court to draw reasonable inferences that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 678, 687 (2009).

Transylvania's statute intended to shield drugmakers or medical device manufacturers from product liability suits but does not insulate Mednology from liability for negligence. R. at 8. On the facts pleaded, this negligence led to Ortega's injuries and Mednology cannot take advantage of this state-law immunity. R. at 4-5.

The statute provides that a manufacturer or distributor is not liable for negligence if the FDA approved a drug or medical device, and the drug or medical

device was compliant with the FDA at the time it left its control. 21 Trans. Comp. Stat. § 630.546(a). Here, Sleepternity was not FDA-compliant when released to the market, as it was preapproved with silicone-based foams, not the distributed PE-PUR foams. R. at 4.

Mednology is not immune from liability under state law, however, because two critical exceptions to the immunity granted under subsection (a) apply to Ortega's claims. 21 Trans. Comp. Stat. §§ 630.546(b), 630.546(c). Under subsection (b), the immunity protection does not apply if a manufacturer like Mednology intentionally withholds from or misrepresents to the FDA information required to be provided by law and FDA approval would not have otherwise been granted or would have been withdrawn. *Id.* § 630.546(b). Lastly, per subsection (c), the immunity granted under subsection (a) does not apply if the defendant fails to warn about the device's risks as required by the FDA. *Id.* § 630.546(c).

Ortega's claims survive a motion to dismiss because federal law does not expressly or impliedly preempt the exceptions provided under state law. *See* 21 U.S.C. §§ 360k(a), 337(a). The FDCA does not preempt subsections (b) and (c) because the MDA expressly bars only state law claims that impose requirements different from, or in addition to, federal requirements. *Id.* § 360k(a). The MDA amended the FDCA to give the FDA authority to regulate and ensure reasonable safety and effectiveness of medical devices. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

Risk-Based Classification. The MDA created a three-class risk-based classification system for medical devices. 21 U.S.C. § 360c. A device is assigned to Class III for the most rigorous review, if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C)(ii). Mednology's Sleepternity is a Class III medical device. R. at 3-4.

Under the MDA, the FDA subjects new Class III medical devices to a process of federal review for safety and effectiveness called "premarket approval." *See* 21 U.S.C. § 360e; *Riegel,* 552 U.S. at 317-20. PMA is a rigorous process, and the FDA spends an average of 1,200 hours reviewing each application. *Lohr*, 518 U.S. at 477. A manufacturer must submit what is typically a multivolume application; It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 C.F.R. § 814.20 (2024). The FDA grants PMA only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." *Id.* § 360e(d). The agency must "weig[h] any

probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* § 360c(a)(2).

Premarket Approval Process. The PMA process ensures safety and effectiveness of medical devices. *Id.* § 360e; *See* 21 C.F.R. § 814.20 (2024). The FDA also evaluates the medical device's safety and effectiveness under the label's conditions of use. 21 U.S.C. § 352; *See* 21 C.F.R. §§ 801.4-801.15. After completing its review for PMA, the FDA may grant or deny PMA. 21 U.S.C. § 360e(d). The agency is also free to impose device-specific restrictions by regulation. *Id.* § 360j(e)(1); *Riegel,* 552 U.S. at 318-319. Sleepternity received PMA based on its application in which the device contained silicone-based foams. R. at 4. Because Sleepternity received PMA, CMS provided insurance coverage for the device. R. at 4.

Once a device has received PMA, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i). If the applicant wishes to make a change, it must submit, and the FDA must approve, an application for supplemental PMA, to be evaluated under largely the same criteria as an initial application. 21 C.F.R. § 814.39 (2024); *Riegel*, 552 U.S. at 319. After receiving PMA, Mednology replaced the silicone-based foams with PE-PUR material without seeking FDA approval for the change. R. at 4.

Ortega's Claims. Ortega's claims are not expressly preempted because she is not solely making a claim based on fraud-on-the-FDA, but rather her claims parallel federal law while seeking to enforce Transylvania's state laws. R. at 6. Implied

preemption, on the other hand, is not explicitly stated in the statute but is inferred from the statutory scheme; although 21 U.S.C. § 337(a) of the FDCA states that all actions to enforce FDA requirements must be brought by and in the name of the United States. 21 U.S.C. § 337(a). The Supreme Court has interpreted this provision to mean that private litigants cannot bring claims that essentially attempt to enforce FDA regulations against manufacturers, such as "fraud-on-the-FDA" claims. *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 349-50 (2001). Fraud-on-the-FDA refers to situations in which a manufacturer deliberately provides false or misleading information to the FDA to gain approval for a drug or medical device. *Id.*

A. **Mednology is not immune from liability under section 21 Trans. Comp. Stat. § 630.546(b) because it intentionally withheld from the FDA that the PE-PUR foams replaced silicone-based materials in Sleepternity, and, as Ortega is seeking to enforce state law without imposing any additional requirements beyond the FDA mandates, federal law does not preempt her claim.**

Ortega can bring her claims under the immunity exception in subsection (b), which states that the immunity granted under subsection (a), does not apply if the manufacturer intentionally misrepresents or withholds information required to be provided by law to the FDA; and the product would not have been approved, or the FDA approval would have been withdrawn if accurate information had been provided. 21 Trans. Comp. Stat. § 630.546(b). Ortega can bring her claims because they parallel federal law, along with seeking to enforce state law. *See Desiano v. Warner-Lambert.,* 467 F.3d 85, 94 (2d Cir. 2006); *Buckman,* 531 U.S. at 346-47; *Lohr*, 518 U.S. at 501.

State law claims based on common law duties between manufacturers and consumers are not always preempted. *See Desiano*, 467 F.3d at 94; *Buckman* 531 U.S. at 346–47; *Lohr*, 518 U.S. at 501; *Riegel*, 552 U.S. at 323. These claims do not simply allege fraud against the FDA but instead rely on the state's established products liability statute. *See Desiano*, 467 F.3d at 94; *Lohr*, 518 U.S. at 501. Furthermore, when state statutes align with federal requirements, these claims are not preempted by federal law because they parallel federal law and do not create any additional obligations. *See Lohr*, 518 U.S. at 501; *Riegel,* 552 U.S. at 323. For example, in *Desiano*, the patient's health insurers brought a class action claim against the drug manufacturer based on a statutory exception to Michigan's immunity law, which allowed liability if the drug manufacturer committed fraud-on-the-FDA during the approval process. 467 F.3d at 89. The Second Circuit held that these claims were not preempted because they did not challenge the FDA's authority or seek to impose additional requirements beyond the requirements already established by federal law. *Id.* at 94. Instead, the Second Circuit relied on Michigan's state law principles of consumer protection which exist alongside federal regulations when ruling that the patient's claim could go forward. *Id.*

In *Lohr*, the patient's husband sued the device manufacturer for state damages when his wife's pacemaker failed. 518 U.S. at 474. The manufacturer argued that the MDA preempted state law. *Id.* at 484. The Court held that his claims were not preempted, ruling that Congress did not intend to preempt most state common law duties, and those federal requirements reflected concerns regarding device regulation

generally, not concerns regarding a specific medical device which violates a state-law statute. *Id.* at 477. Furthermore, § 360k of the MDA does not preempt state-law claims based on violations of common-law duties when those duties are equivalent to, or substantially identical to, requirements imposed under federal law. *Id.* at 478. The Court reasoned that the MDA does not preempt the patient's state law claims because these claims parallel the federal requirements, and thus do not create any additional obligations. *Id.* at 495.

In contrast, in *Buckman*, the patients' claims, centered on allegations that the manufacturer had committed fraud against the FDA by making misrepresentations during the approval process of the device, were based solely on fraud against the FDA. 531 U.S. at 352. The patients did not argue that the manufacturer violated any state law requirements, but rather made claims that were entirely premised on federal regulatory fraud, which is exclusively within the scope of the FDA. *Id.* at 350. Therefore, unlike cases which involved state law claims, *Buckman* did not include a state law component. *Id.* at 347-48. This Court held that such claims were preempted by federal law because they interfered with the FDA's exclusive authority to police fraud against itself. *Id.* at 333-44. The Court reasoned that allowing state-law claims based solely on fraud-on-the-FDA would disrupt the balance of the FDA's regulatory regime, where the federal government has the sole responsibility to ensure compliance with its regulations. *Id.* at 347. In *Riegel*, the patient was severely injured when a catheter ruptured in his coronary artery during surgery. 552 U.S. at 315. The patient sued the manufacturer, challenging the safety and effectiveness of the

catheter. *Id.* at 315-16. The Court held that the MDA expressly preempted the patient's claims under §360k(a), because New York's tort duties requirements were different from, or in addition to the federal requirements. *Id.* at 330; *See Desiano*, 467 F.3d at 94 (reasoning that the patient's state law claims were not preempted by federal law because they did not impose additional requirements). The patient's state tort law claims would have imposed requirements that differed from or went beyond what the FDA had approved, thereby disrupting the federal regulatory scheme. *Riegel*, 552 U.S. at 322–23.

Ortega can bring her claims under the immunity exception in 21 Trans. Comp. Stat. § 630.546(b) because, although they involve FDCA violations, they are primarily based on Transylvania state law duties, such as Mednology's alleged misrepresentation of sound abatement materials to consumers. Like the state law tort claims made in *Desiano* and *Lohr,* while Ortega's claim does have an element based on the fraud of the FDCA, it is not the sole element of her claim. R. at 6. Similarly to how the court ruled that Michigan statute providing immunity in *Desiano* was not the state's attempt to police fraud against the FDA, the same can be said for subsection (b) of Transylvania's immunity statute. 21 Trans. Comp. Stat. § 630.546(b). While an element of the claim relates to the fraud against the FDA, the claim is based on holding Mednology accountable for misrepresenting its sound abatement materials to its consumers in violation of Transylvania's product liability statute. This state claim differs from *Buckman*, where the patients' claims were solely based on the fraudulent acts committed against the FDA, without having a state

statute counterpart to base its claim off, or parallel requirements to. 531 U.S. at 347-48. While it could be argued that Ortega is making a claim that alleges fraud against the FDA, importantly, Ortega is also making a claim to neutralize Mednology's immunity from Transylvania's product liability statute.

Furthermore, since the requirements of subsection (b) of Transylvania's product liability statute aligns with federal requirements, Ortega's claim is not preempted as it does not create any additional obligations. R. at 9. Like in *Lohr*, where the patients' claims, such as defective design, manufacturing, and failure to warn, were based on duties that mirrored those imposed by federal law, these claims were not preempted. R. at 9. Similarly, both the FDCA and Ortega's Transylvania statute claim require that accurate and complete information be submitted to the FDA for the approval of drugs and medical devices. R. at 7; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–392 (Suppl. 5 1934). The FDCA requires that manufacturers provide accurate representations to the FDA as part of the approval process, and failure to do so can lead to regulatory sanctions. 21 U.S.C. § 331. Transylvania's statute mirrors this requirement by stating that immunity does not apply if the manufacturer intentionally withholds or misrepresents information that the FDA requires. 21 Trans. Comp. Stat. § 630.544(b). It further specifies that this exception applies if the FDA would not have approved the product, or would have withdrawn its approval, had it received accurate information. *Id.* While, in *Riegel*, where the patient's state law claims had imposed requirements different from, or in addition to those already imposed by the FDA, the present case between Ortega and

Mednology does not have that problem. R. at 8. Ortega's claims regarding Mednology's misrepresentation to the FDA parallels requirements imposed by the FDA. R. at 15. Her claim does not impose any additional or different requirements beyond those already mandated by the FDA. R. at 9. Thus, the Court should affirm, on different grounds, that Mednology's motion to dismiss should be denied because Ortega's state claims are not preempted by federal law. R. at 9.

B. **Mednology is also not immune from liability under 21 Trans. Comp. Stat. § 630.546(c) because it failed to warn about the dangers or risks associated with the presence of PE-PUR foams in Sleepternity, and, as Ortega is seeking to enforce state law without imposing additional or different requirements to those mandated by the FDA, federal law does not preempt her claim.**

Ortega can also bring her claims under the immunity exception provided in subsection (c), which states that the immunity granted under subsection (a), does not apply if the manufacturer fails to warn about the dangers or risks of the drug or medical device as required by the FDA, because her claim parallels federal requirements, without imposing additional or different requirements. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013); *Bryant v. Medtronic Inc., (In re Medtronic, Inc.)*, 623 F.3d 1200, 1205 (8th Cir. 2010). This provision escapes preemption under this Court's guidance in *Levine*, in which it emphasized that state law claims are not preempted if they enforce federal requirements without imposing additional burdens. *Levine,* 555 U.S. at 581.

In *Levine*, the patient sued the manufacturer after she lost her arm from gangrene from receiving the drug intravenously, claiming that the manufacturer's

device label did not adequately warn about the risk of gangrene. *Id.* at 559. This Court held that FDA approval does not preempt state-law failure-to-warn claims. *Id.* at 581. The Court reasoned that these state claims appropriately parallel federal law, and that strengthening current drug warnings after FDA approval further protects consumers. *Id.*

The Fifth Circuit Court held that state-law claims are not preempted by federal law if they parallel federal requirements. *Hughes,* 631 F.3d at 776. In *Hughes*, the patient sued the manufacturer for injuries sustained after she was burned by a medical device designed for the treatment of menorrhagia, or excess uterine bleeding, alleging inadequate warning. *Id.* at 765. The court ruled that the patient's failure-to-warn claims were not expressly or impliedly preempted because the claims did not impose additional or different requirements to federal regulations but instead, were parallel to MDA requirements under section 360i. *Id.* at 773. Similarly, in *Stengel,* the Ninth Circuit Court found that a state-law failure-to-warn claim was not preempted because the claim paralleled a federal-law duty imposed by the MDA in section 360i(a). 704 F.3d at 1233.

In *Bryant*, the district court granted the manufacturer's motion to dismiss the patients' product liability claims for design defect, manufacturing defect, failure-to-warn, and breach of warranty, on the ground that the claims were preempted by section 360k of the MDA. 623 F.3d at 1205. The crucial question on appeal was whether those claims were parallel claims that avoided preemption because they would not impose state requirements different from or in addition to the federal PMA

requirements. *Id.* The appellate court ruled that the failure-to-warn and related claims were preempted by 21 U.S.C. § 360k because the FDA's PMA included specific language for Class III device labels and warnings and the patients did not allege that the corporation modified or failed to include FDA-approved warnings. *Id.* Rather, patients alleged that, by reason of state law, the corporation was required to give additional warnings, precisely the type of state requirement that was different from or in addition to the federal requirement and therefore preempted. *Id.*

Similarly, in *Riegel*, the patient was injured following a catheter rupture during surgery. 552 U.S. at 320. The patient sued the manufacturer, challenging the catheter's safety, and alleging that the FDA-approved labeling for the catheter violated a state-law requirement for additional warnings. *Id.* The Court held that the MDA expressly preempted the patient's claims under section 360k(a) because New York's tort duty requirements were different from, or in addition to the federal requirements. *Id* at 329. In *Riegel*, this Court established a two-prong test for determining if a state-law tort claim is preempted by section 360k(a) of the MDA. *Id.* at 322. First, the Court must determine that the FDA has established requirements applicable to the device at issue. *Id.* Second, the Court must ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is "different from or in addition to" the federal requirement." *Id.* Although the Court found that the patient's claim was preempted, it reasoned that this was due to the additional requirements imposed by state law, unequivocally holding that parallel state claims survive a manufacturer's preemption defense under

the MDA because states may impose an additional "damages remedy for claims premised on violation of FDA regulations." *Id.* at 330.

Ortega's claim parallels federal requirements because she alleges that Mednology failed to adhere to the FDA's mandate to warn about the dangers associated with PE-PUR foams. R. at 6. Federal regulation of medical devices is a complex topic enumerated in multiple federal statutes, but essentially requires manufacturers to warn of the risks associated with their medical device. *See* 21 C.F.R. §§ 801.4-801.15, 814.20 (2024). The FDA regulates safety and effectiveness of medical devices through its PMA process. 21 U.S.C. § 360e; *See* 21 C.F.R. § 814.20 (2024). The safety of medical devices is further regulated through strict federal laws governing labeling, including the need to list the materials contained in the device. 21 U.S.C. § 352; *See* 21 C.F.R. §§ 801.4-801.15. Once PMA is obtained, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness. 21 U.S.C. § 360j(e)(1).

Similar to *Levine* and *Hughes*, where patients sued manufacturers for failure to warn and their claims were not blocked by federal law because they were based on negligence that paralleled federal regulations, Ortega's claims follow the same approach. *Levine*, 555 U.S. at 581; *Hughes*, 631 F.3d at 771. Ortega's claim aligns with the rulings in *Hughes* and *Stengel*, where similar state-law claims were not preempted because they did not impose additional requirements but rather enforced existing federal duties. *Hughes,* at 776; *Stengel,* 704 at 1224. Like *Hughes* and

Stengel, Ortega's claim does not allege anything different from, or in addition to federal requirements, and instead, aligns with the federal requirements to provide adequate warnings. R. at 9. Ortega's claims are based on Mednology's negligent failure to comply with the FDA's requirement to warn of the risks via labeling and ensured through PMA. R. at 9. Mednology failed to adequately warn by misrepresenting the material in their CPAP device when it received PMA with silicone-based foams but distributing Sleepternity with PE-PUR foams. R. at 6.

Ortega's case is unlike *Bryant,* because her claim simply parallels federal requirements to warn about the dangers associated with the presence of PE-PUR foams in Sleepternity. R. at 9. In *Bryant*, the patients alleged that, by reason of state law, the corporation was required to give additional warnings, precisely the type of state requirement that was different from or in addition to the federal requirement and therefore preempted. *Bryant*, 623 F.3d at 1205. Ortega is alleging only that Mednology failed to include FDA mandated warnings, and therefore her claim should not be preempted. R. at 9. Ortega's claim is also distinguished from *Riegel*, where the patient alleged labeling requirements additional to federal requirements, for a catheter under New York tort law, and therefore, their claims were expressly preempted. 552 U.S. at 320. If this Court would apply the two-prong test for determining express preemption developed in *Riegel*, it will find that Ortega's claims are not expressly preempted. *Id.* at 322. Here, prong one is satisfied because the FDA regulates the safety and effectiveness of medical devices through PMA and device labeling requirements, which encompasses the need to warn. 21 U.S.C. §§ 352, 360e;

See 21 C.F.R. §§ 801.4-801.15, 814.20 (2024). Prong two requires the court to ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is different from or in addition to the federal requirement. 552 U.S. at 322. Ortega is alleging only that Mednology failed to adhere to the FDA's mandate to warn about the dangers associated with PE-PUR foams. R. at 9. She alleges no additional requirements like the patients in *Bryant* and *Riegel* attempted. R. at 9.

In *Desiano*, the patient's health insurers brought a class action claim against the drug manufacturer based on a statutory exception to Michigan's immunity law, which allowed liability if the drug manufacturer committed fraud-on-the-FDA during the approval process. 467 F.3d at 89. The Second Circuit held that these claims were not preempted because they did not challenge the FDA's authority or seek to impose additional requirements beyond the requirements already established by federal law. *Id.* at 94. Instead, the Second Circuit relied on Michigan's state law principles of consumer protection, which exist alongside federal regulations, in ruling that the patient's claim could go forward. *Id.*

Further, the Second Circuit Court held that the cause of action under Michigan's drugmaker immunity statute is not preempted by the FDA. *Id.* at 94. The Circuit Court reasoned that Michigan's product liability law "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Id.* In contrast, in *Buckman*, the plaintiffs' claims were based solely on alleged fraud against the FDA. *Buckman,* 531 U.S. at 352. The Supreme Court held that state-law fraud-on-the-FDA

claims were impliedly preempted because they conflicted with the FDA's authority. *Id.*

In the present case, Ortega's claim under 21 Trans. Comp. Stat. § 630.546(c) is based on Mednology's failure to warn about the dangers associated with the PE-PUR foams in Sleepternity, which parallels the federal requirement to report adverse events and ensure device safety. R. at 6. Further, like *Desiano*, Transylvania's immunity statute does not necessarily reflect Transylvania's attempt to police fraud against the FDA. *See* 21 Trans. Comp. Stat. § 630.546(a). Rather, Transylvania's legislature sought to minimize the liability drugmakers or medical device manufacturers could otherwise face from product liability lawsuits. R. at 9. In *Buckman*, the court was concerned that the state law was an attempt to police the FDA, but here, Ortega's claim incorporates elements of fraud-on-the-FDA, without mere repetition of federal statute. R. at 9. Therefore, this Court should follow the reasoning of *Desiano*, not *Buckman*. R. at 9.

C. Mednology's motion to dismiss should be denied because Ortega has presented sufficient facts alleging Sleepternity was negligent by not complying with the requirements for FDA approval when Mednology distributed the device into the market.

A plaintiff will survive a motion to dismiss as long as their complaint contains, on its face, sufficient evidence of factual matter, accepted as true, to state a claim to relief that is plausible. *Twombly*, 550 U.S. 570, at 570. A claim is factually plausible whenever a plaintiff asserts factual content that allows the court to draw reasonable

inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. 678 at 687. Ortega has met this standard. R. at 9.

The manufacturer is presumed to comply with the FDA and to show these state law claims are not preempted, the plaintiff must rebut that presumption. 21 Trans. Comp. Stat. § 630.546(a). For example, in *Marsh*, the Michigan state law provides immunity from liability for manufacturers except where intentional misrepresentation on behalf of the manufacturer to the FDA or where bribery was involved. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 549 (6th Cir. 2012). The patient alleged that the manufacturer failed to submit updated safety information, thus, rendering the drug noncompliant with FDA approval. *Id.* at 550. The court reaffirmed the manufacturer's immunity and held that the claim was preempted, reasoning that the patient's alleged procedural noncompliance was premised on a violation of federal law. *Id.* at 553. Furthermore, being compliant with FDA's regulations does not necessarily provide blanket immunity for corporations from state law claims. *Id.* at 555.

Furthermore, it would be anomalous for the compliance provision of a state's immunity statute to be preempted, as such a ruling would leave patients without any alternative means to hold manufacturers liable for being negligent under the state's product liability laws. *Levine*, 555 U.S. at 573-74; *Lohr,* 518 U.S. at 495; *Hughes,* 631 F.3d at 771. For example, in *Lohr,* this Court ruled that when Congress enacted the FDCA, it did not intend to shield drug or medical device manufacturers from product liability. 518 U.S. at 477. This Court reasoned that its goal was to ensure the safety

of health-related products and medical devices. *Id.* at 485. In *Levine*, the patient sued the drug manufacturer after she lost her arm from gangrene after receiving the drug intravenously, claiming that the manufacturer did not adequately warn about the risk of gangrene on the drug's label. 555 U.S. at 558. This Court held that FDA approval does not preempt state-law failure-to-warn claims. *Id.* at 573. This Court reasoned that these state claims appropriately parallel federal law, and that strengthening current drug warnings after FDA approval further protects consumers. *Id.* at 573-74.

In *Hughes*, the patient sued claiming that the manufacturer did not properly warn about the device's dangers. 631 F.3d at 764. The court held that the state claim made by the patient was not preempted by federal law. *Id.* at 765. The court reasoned that the patient's claims mirrored federal law and is based on the manufacturer's negligence which also violates state law. *Id.* at 766.

While this Court should hold that subsections (b) and (c) are not preempted by the FDCA, the immunity statute under 21 Trans. Comp. Stat. § 630.546(a) will also not protect Mednology since Ortega has pleaded sufficient facts to rebut the presumption that Sleepternity complied with FDA requirements. R. at 9. Ortega's case differs from *Marsh*, where the patient's alleged procedural noncompliance was premised on a violation of federal law. 693 F.3d at 550. Even though, under Michigan law, fraud-on-the-FDA is an exception to a grant of immunity to the manufacturer rather than a standalone cause of action, it nonetheless ultimately "requir[es] proof of fraud committed against the FDA" to succeed. *Id.* at 553. In the present case,

Ortega asserted both that Mednology intentionally misrepresented its sound abatement materials to the FDA, along with failure to warn about the dangers of PE-PUR foams. R. at 4. Therefore, if Ortega fails to meet her burden of proof on the fraud-against-the-FDA claim, she can still prevail by proving failure to warn and showing that the device's label did not list PE-PUR as a material. R. at 34.

Moreover, it would be inconsistent to find the compliance part of Transylvania's immunity statute to be preempted by federal law because Ortega would have no other options for holding Mednology liable under Transylvania's product liability statute. *See Levine*, 555 U.S. at 581; *Lohr*, 518 U.S. at 485; *Hughes*, 631 F.3d at 767. As this Court ruled in *Lohr,* Congress did not intend to shield medical device manufacturers completely from liability, rather, Congress intended to ensure the safety of medical devices. 518 U.S. at 476-77. Like *Levine* and *Hughes*, where patients sued manufacturers for failure to warn and their claims were not blocked by federal law because they were based on negligence that paralleled federal regulations, Ortega's claims follow the same approach. *Levine*, 555 U.S. at 581; *Hughes*, 631 F.3d at 767. Ortega's claims are also based on Mednology's negligence and failure to comply with the FDA's requirements. R. at 9. Ortega alleges sufficient facts to give rise to a claim of negligence under state law that does not seek to enforce requirements in addition to or different from FDA requirements. R. at 9.

Therefore, Ortega requests that this Court affirm, on different grounds, the order of the Seventeenth Circuit Court affirming the district court's denial of

Mednology's motion to dismiss Ortega's state law claims brought under Transylvania's product liability statute.

II. ORTEGA MAY RELY ON THE FRAUD-ON-THE-FDA THEORY TO BRING A CLAIM AGAINST MEDNOLOGY UNDER THE *QUI TAM* PROVISION OF THE FALSE CLAIMS ACT.

This Court should uphold the Seventeenth Circuit's reversal of the district court's granting of Mednology's motion to dismiss Ortega's FCA claim. The fraudulent acts of which Mednology stands accused invite liability under the theory of implied false certification, and this Court has previously supplied guidance regarding the evidence that must be offered to support each element of an FCA claim brought by a relator under this theory. *See generally Universal Health Servs. v. United States ex. rel. Escobar*, 579 U.S. 176 (2016). Ortega has pleaded facts more than sufficient to plausibly state a claim upon which relief may be granted. *See Twombly*, 550 U.S. at 570; *Iqbal*, 556 U.S. at 678. A plaintiff's claim must survive a motion to dismiss if the plaintiff pleaded sufficient facts, as opposed to empty allegations, that permit the court to reasonably infer the defendant's liability. *See Iqbal*, 556 U.S. at 678; *United States v. Molina Healthcare of Ill., Inc.*, 17 F.4th 733, 740-41 (7th Cir. 2021) (explaining that detailed allegations will suffice for an FCA claim to survive a 12(b)(6) motion). Regarding each of the elements of causation, materiality, and scienter, Ortega has pleaded factual allegations beyond what is required for her claim to survive Mednology's motion to dismiss and for the court to proceed with fact-finding. Foreclosing Ortega's opportunity to prove her claims would frustrate the FCA's purpose of facilitating recovery when the government has been induced by fraud to

expend payment. *See United States v. Walgreen Co.*, 591 F. Supp. 3d 297, 307 (E.D. Tenn. 2022) (articulating protection of government interests through restitution as FCA's primary purpose).

Dismissing Ortega's claim at this stage would also shield Mednology from liability in a manner irreconcilable with the guidance established by this Court in *Escobar*. *See* 579 U.S. at 180-81; *United States ex rel. Campie v. Gilead Sciences*, 862 F.3d 890, 905 (9th Cir. 2017) (holding that allowing FDA approval to preclude FCA liability is inconsistent with *Escobar*). The lower courts' applications of the *Escobar* standards are instructive on this point. While Mednology insists that the First Circuit's decision in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016) absolves it of liability for its misrepresentations to the FDA, the circumstances of this case are distinguishable from those that informed *D'Agostino*. Rather, the Ninth Circuit's application of *Escobar* serves as the appropriate template for resolving the matter before this Court, as *Campie* involved a fact pattern analogous to this one. *See Campie*, 862 F.3d at 895-97; *see also* R. at 36. That case, which the Seventeenth Circuit agreed was instructive for adjudicating the question of Mednology's liability under the FCA, holds that FDA approval cannot be unilaterally used to shield a defendant from liability, particularly when it is alleged that the approval itself was fraudulently procured. *See Campie*, 862 F.3d at 905; *see also* 1 Joel M. Androphy & Carla Lassabe, *Federal False Claims Act and Qui Tam Litigation* § 5.06A (1st ed. 2024) (explaining rationale behind allowing fraud-on-the-FDA claims to proceed despite ongoing FDA approval).

Finally, despite concerns raised by the district court, granting Ortega the opportunity to prove the facts she has credibly alleged poses no threat to the independent regulatory decisions of the FDA. If Mednology is able to disprove her claims, it will be absolved of liability; if Ortega is not so much as given the chance to produce the evidence that will substantiate her claims, FDA approval will be permitted to serve as a total bar to imposing liability on defendant manufacturers who defraud the United States but remove their product from market before disciplinary action is taken. *See Campie*, 862 F.3d at 905. Further, the district court's reliance on *D'Agostino* in granting Mednology's motion to dismiss ignored critical differences between that case and this one, and the Seventeenth Circuit made clear that it did not share the district court's reservations regarding allowing Ortega's claims to proceed. R. at 36-37. Ortega thus requests that this Court affirm the Seventeenth Circuit's reversal of the district court's granting of Mednology's motion to dismiss her action under the FCA.

A. The Court should apply the Ninth Circuit's interpretation of *Escobar*, as the facts underlying *Campie* are analogous to this case and Ortega has pleaded sufficient facts to satisfy each element of an FCA claim.

As the Seventeenth Circuit agreed, the FCA violations Mednology stands accused of are best characterized as implied false certification. R. at 36. This Court has unanimously blessed this theory as a legitimate basis of liability under the FCA, and has provided clear guidance regarding when it may be invoked and what a relator seeking to establish liability must demonstrate. *See generally*, *Escobar*, 579 U.S. 176. *Escobar*, then, as the appellate court agreed, is the proper place to begin an analysis

of a motion to dismiss an FCA claim brought on a theory of implied false certification. R. at 36. As *Escobar* emphasizes, this theory of liability, like any other under the FCA, requires a demonstration that the fraudulent misrepresentations in question were 1) made with scienter and 2) material to the government's decision to produce payment, which element also requires a direct causal link between the alleged fraud and the payment. *See Escobar*, 579 U.S. at 183; *Campie*, 862 F.3d at 902. Ortega has pleaded with sufficient particularity each required component of an FCA claim.

1. *Campie* provides the most suitable guidance for evaluating the sufficiency of a pleading alleging implied false certification under the FCA, as the noncompliance with FDA requirements of the defendant in that case is substantially similar to that of Mednology, and the court correctly relied on *Escobar* to reach its conclusions.

The Ninth Circuit's decision in *Campie* provides an apt model for resolution of the question before this Court, as that decision drew heavily on *Escobar* and the facts are substantially analogous to the present case. In *Campie*, defendant pharmaceutical manufacturer Gilead was alleged to have violated the FCA by procuring FDA approval for its products without disclosing that it was sourcing some of its ingredients from facilities that did not meet FDA standards, in violation of representations made, in the course of the approval process, that materials would be sourced from specified facilities where conditions met these standards. *See* 862 F.3d at 896. The court denied Gilead's motion to dismiss, holding that the relators had produced sufficient factual allegations to support each element of their claim, and that questions of fact existed about whether the FDA and CMS had actual knowledge of the noncompliance. *Id.* at 906-07. The court held that the FDA's continual approval

of the Gilead products in question did not serve as a means for dismissing the claim at this early stage of litigation, citing those outstanding questions of fact pertaining to the government's knowledge of Gilead's exploits. *Id.* Unlike *D'Agostino*, the *Campie* opinion derives its central premises from *Escobar*'s explanation of what a relator must allege for an implied false certification claim to survive a motion to dismiss and cites that decision extensively. *See id.* at 902-03; *see also* R. at 36 n. 9 (noting *Escobar* mentioned only once in *D'Agostino*).

Like Gilead, Mednology is accused of procuring from CMS fraudulent reimbursements for a product after altering the manufacturing process without disclosure following FDA approval. R. at 4. In applying for PMA, Mednology represented to the FDA that its product would be produced using a silicone-based sound dampening foam, but replaced that component with a cheaper and more dangerous PE-PUR foam prior to delivery to the market, without informing the FDA. R. at 4. As is the case for all pharmaceutical and medical products, reimbursement by CMS is contingent upon first obtaining FDA approval. *See Campie*, 862 F.3d at 897. But as the *Campie* court clarified, failure of the FDA to withdraw approval, and thus a lack of certainty about whether CMS would have halted its reimbursements, should not serve as a basis for dismissal of FCA claims at this stage. *See id.* at 906-07. *Campie* thus represents a considered application of this Court's precedent and a comprehensive factual analogue to the case at bar, and should be followed for the purposes of evaluating Ortega's FCA claim.

2. In alleging that Mednology misrepresented the composition of its product to the FDA in order to secure the approval necessary for CMS to provide reimbursement, Ortega has pleaded sufficient facts to satisfy the causation requirement of an FCA claim.

Ortega's pleadings chronicle a direct causal link between Mednology's actions and CMS reimbursements for a noncompliant product that is sufficient to satisfy the causation element of her FCA claim. As alluded to in *Escobar* and by both courts below, a finding of a causal connection between a defendant's misrepresentations of a requirement for payment and the government's decision to provide payment is a necessary component of the materiality element. *See Escobar*, 579 U.S. at 194-95; R. at 39 (emphasizing importance of causation in satisfying materiality).

A decision by CMS to provide payment for a given product is dependent upon the FDA first deciding to approve that product. *See Campie*, 862 F.3d at 905 ("FDA approval is 'the *sine qua non*' of federal funding" in cases involving government reimbursements for pharmaceutical products"); Androphy & Lassabe, *supra*, § 5.06A ("CMS often reimburses claims for approved drugs and devices somewhat automatically"). Reimbursement by CMS is statutorily conditioned on FDA approval, with the agency's payment programs using FDA approval as an indicator of a product's "safety and effectiveness." *See Campie*, 862 F.3d at 905; *see also Medicare Carriers Manual* 7, CMS (May 25, 2001), https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1704b3.pdf (specifying that Class III Medical Devices such as Mednology's Sleepternity require PMA in order for CMS to furnish payment). Therefore, because CMS funding is conditioned on FDA approval, it stands to reason that a showing of fraudulent activity that caused the FDA to

approve a product may establish a causal nexus between the fraudulent activity and the government's decision to issue payment. *See Campie*, 862 F.3d at 903-04. Precedent makes clear, however, that neither withdrawal of FDA approval nor a decision by CMS to halt reimbursements are necessary for a claim to survive a pretrial motion to dismiss. *See Escobar*, 579 U.S. at 195; *Campie*, 862 F.3d at 905-07; *Molina*, 17 F.4th at 744. In *Escobar*, the defendant was a mental health treatment facility that sought and received Medicaid reimbursement for services offered, despite misrepresentations by staff members to Medicaid about compliance with the program's licensing requirements. 579 U.S. at 183-84. The plaintiffs brought suit under the FCA on a theory of implied false certification after their daughter died of an adverse reaction to a medication prescribed by a member of the facility's staff that had purportedly diagnosed the child with bipolar disorder, having falsely presented herself to the patient and to Medicaid as possessing the clinical authority to do so. *Id.* at 183. This Court allowed the suit to proceed, holding that the plaintiffs had pleaded sufficient facts to establish a causal connection between the staff's intentional falsification of Medicaid requirements and the reimbursement of claims that would not have been paid but for perceived compliance with these requirements. *Id.* at 196. In allowing the case to proceed despite Medicaid's continued payments to the defendant, this Court noted that the plaintiffs' allegations, if proven, "may well" have constituted an FCA violation, as the misrepresented licensing and treatment requirements were so critical to Medicaid standards that the program likely never would have provided reimbursement had it been aware of the transgressions. *See id.*

Similarly, and more directly comparable to the circumstances of this case, *Campie* defendant Gilead was alleged to have sourced drug ingredients from facilities that it did not disclose to the FDA, and which did not meet FDA standards. 862 F.3d at 896. A case brought by relators on a theory of implied false certification was permitted to proceed despite Gilead's argument that the government's continual payments for its products, and the fact that the FDA never withdrew its approval, evinced a lack of causal connection between the alleged fraud and the government's payments. *Id.* at 906-07. Instead, the court held that the lack of government action could not serve as the basis for dismissing the claim, as genuine questions of fact existed as to whether the FDA was aware of the violations of its requirements. *Id.* The relators were permitted the opportunity to demonstrate that actual knowledge of the violations would have caused the withdrawal of approval and, in turn, the loss of federal payments for the drugs. *Id.*; see also *Barnett v. Centoni*, 31 F.3d 813, 816 (9th Cir. 1994) (holding that a complaint may only be dismissed if it is beyond doubt that the plaintiff cannot prove facts that would entitle him to relief).

In the present case, Mednology's decision to modify its product surreptitiously after receiving FDA approval is sufficient to establish the requisite causal link between the alleged fraudulent behavior and CMS's payment decision. Ortega has pleaded facts to support the allegation that the FDA would not have approved, and thus that CMS would not have issued payment for, Mednology's product had the defendant disclosed its use of unsafe PE-PUR foams rather than the approved silicone foams. R. at 4-5. These facts include the acknowledgement of a Mednology assembly

manager that the silicone foams had been used specifically to procure marketing approval, and that another manufacturer had recently recalled its PE-PUR-containing CPAP machines and entered a Recall Remediation Plan with the FDA. *See* R. at 5; *see also Foam Testing Summary for Recalled Phillips Ventilators, BiPap Machines, and CPAP Machines*, FDA (Apr. 2024), https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/foam-testing-summary-recalled-philips-ventilators-bipap-machines-and-cpap-machines#inspection. The FDA, of course, did not withdraw its approval of Mednology's product, and CMS did not have to make the decision to halt reimbursements, because Mednology withdrew Sleepternity from the market. R. at 6-7. But like the claims of the relators in *Escobar* and *Campie*, Ortega's claim is not defeated at this stage by a lack of governmental action. *See Escobar*, 579 U.S. at 195; *Campie*, 862 F.3d at 905-07. Just as claims against the *Escobar* defendant were permitted to proceed on the basis that the pleadings indicated the presence of a causal connection that could be proved, and as the claims against Gilead in *Campie* survived a motion to dismiss despite a lack of affirmative government action proving direct causation, this Court should permit Ortega to establish the alleged causal nexus by a preponderance of evidence. *See id.*

3. **In alleging that Mednology knew that its product would not be approved or paid for if it disclosed its use of PE-PUR foams, and that removal of Sleepternity from the market precluded the need for the FDA to take action, Ortega has pleaded sufficient facts to satisfy the materiality requirement of an FCA claim.**

In addition to having established causation, Ortega's pleadings are sufficient to satisfy the materiality standard. As with the sub-element of causation, *Escobar* and *Campie* are instructive for ascertaining the required showing of a relator pleading a material connection between a defendant's false certification and a decision by CMS to produce payment. *See* R. at 36-37 (discussion by the Seventeenth Circuit of why these cases are instructive for resolving the case at bar). *Escobar* provides the most comprehensive statement of the demands of the materiality requirement as it applies to an implied false certification FCA claim. 579 U.S. at 192-93. While cautioning that other factual circumstances may also demonstrate materiality, this Court explained that "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular ... requirement" is a very strong indicator that materiality has been satisfied. *Id.* at 194-95.

In *Campie*, the court found the relator to have pleaded sufficient facts to establish a material relationship between defendant Gilead's misrepresented use of nonconforming drug ingredients and the government's decision to provide payment for the finished drug products. *See* 862 F.3d at 905-06. The court disagreed with Gilead's contention that continued FDA approval and CMS payment following the relators' revelations foreclosed a finding of materiality, writing instead that fact-

finding must proceed to determine the government's level of knowledge at the relevant times and, crucially, that Gilead's decision to stop using the nonconforming ingredients affected the weight accorded to continued FDA approval when assessing materiality. *Id.* ("[T]he government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance"); *see also* Androphy & Lassabe, *supra*, § 5.06A (noting that "most courts look beyond the fact that CMS paid claims for a drug or device with fraudulently-obtained FDA approval when analyzing fraud-on-the-FDA claims").

The factual circumstances underlying *Campie* are comparable to those of the present case for aiding an analysis of the materiality of Mednology's misrepresentations. As demonstrated by *Campie*, any decision by the FDA to maintain approval cannot alone serve as a basis for dismissal, as a relator who has pleaded sufficient facts to allege materiality should be granted the opportunity to substantiate those claims, and it is the role of the fact-finder to assess the actual knowledge held by the government at the relevant times. 862 F.3d at 906-07. Ortega has credibly alleged that Mednology's violation of FDA requirements- namely, the substitution for a safe and commonly used material of a dangerous alternative that is the source of a recall of a similar product- would have resulted in a denial or withdrawal of FDA approval if presented truthfully, and thus that CMS would not have provided coverage for the product. *See* R. at 4-6. Just as Gilead's decision to remove its nonconforming drugs from the market changed the relevance of FDA approval to the materiality analysis, Mednology's withdrawal of Sleepternity from

the market likewise obviated the need for the FDA to reevaluate its approval status. *Campie*, 862 F.3d at 906; *see* R. at 7. Precedent counsels that Ortega should be granted the opportunity to prove that the FDA would have withdrawn its approval, and thus that CMS would have halted its payments, had the adulterated Sleepternity remained on the market. *See Campie*, 862 F.3d at 906-07.

In another case applying *Escobar's* clarification of the materiality requirement to an implied false certification claim, the Seventh Circuit found sufficient support for materiality in the relator's pleadings for the claim to survive the defendant's motion to dismiss. *Molina*, 17 F.4th at 742-44. In that case, defendant Molina, a managed care company that provides care in partnership with Medicare and Medicaid, was alleged to have defrauded CMS by impliedly certifying that its beneficiaries were receiving expensive skilled nursing facility (SNF) services. *Id.* at 743. In reality, Molina had ceased offering these services, but continued to submit to CMS enrollment forms for new enrollees in the most expensive tier group, despite membership in that tier no longer conferring the benefit of the services. *See id.* The court denied Molina's motion to dismiss the relator's claim, despite the fact that the government twice renewed its contract with Molina after the relator's allegations came to light, holding that the degree of actual knowledge held by the government was a matter for discovery, and that Molina, an industry expert, very likely knew that the lack of costly SNF services being provided would affect the government's decision to provide payment for such an expensive service tier. *See id.* at 736, 743-44 ("Sophisticated players in the healthcare market know that services come at a cost ...

and payors expect to receive value for their money"). Such knowledge strongly supports the clarification from *Escobar* that materiality may be shown by demonstrating that the government attaches significance to the misrepresented requirement. *Id.* at 743 (citing *Escobar*, 579 U.S. at 193).

Mednology, possessing industry-specific expertise as did Molina, was aware that the FDA would not approve its product, and thus that CMS would not provide coverage for it, if it disclosed its use of PE-PUR foams. *See* R. at 5. This allegation is supported by the FDA's awareness of the dangers associated with these materials, the agency having recently entered a Recall Remediation Plan with another manufacturer that had been forced to recall its PE-PUR-containing products. *See* R. at 4. Ortega alleges, based on information provided by a Mednology employee, that the company knew that the FDA would not approve Sleepternity if the agency was aware that the product contained PE-PUR foams, and thus resorted to deception. *See* R. at 5. In *Molina*, a credible allegation that the defendant knew of the significance to the government's payment decisions of the lack of SNF services in the benefits it was paying for was held to satisfy the materiality element. 17 F.4th at 743-44. So, too, should Ortega's credible pleading that Mednology knew of the significance for FDA approval, and CMS coverage, of disclosing the presence of PE-PUR foams in its product serve as a showing of materiality sufficient to defeat Mednology's motion to dismiss.

4. In alleging that Mednology was aware of an ongoing recall of a PE-PUR foam-containing product, Ortega has pleaded sufficient facts to satisfy the scienter requirement of an FCA claim.

Finally, Ortega's pleadings elucidate a pattern of behavior sufficient to establish that Mednology acted with the requisite knowledge when engaging in the misrepresentations that procured FDA approval and CMS reimbursement. The FCA attaches liability to those who "knowingly" cause the government to make a fraudulent payment, a standard which does not require specific intent to defraud and encompasses defendants who have actual knowledge of their falsehoods as well as those who act with reckless disregard, deliberate ignorance, or gross negligence. 31 U.S.C. § 3729(b); *United States v. Krizek*, 111 F.3d 934, 941-42 (D.C. Cir. 1997). Still, scienter, like materiality, is a demanding element to prove. *Escobar*, 579 U.S. at 192. In *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), this Court elucidated the scienter requirement, reaffirming that the requisite mental state may be proven by a showing that a defendant knew, or had every reason to know as a result of the circumstances, of the fraudulent nature of the claim at the time it was made. 749-50. In that case, defendant pharmacy companies Safeway and SuperValu were held to have acted with sufficient knowledge to incur FCA liability when they sought reimbursement from the government at a rate substantially higher than what they were charging most customers, with this Court emphasizing that scienter had been demonstrated because the pharmacies had previously received notice as to which prices they could and could not permissibly charge. *See id.* at 753-54. Similarly, in *Molina*, the relator's claim survived a motion to dismiss on the reasoning that

defendant Molina, a managed care company that regularly contracted with Medicare and Medicaid, was aware that it was charging those programs at the same high rate despite having removed the most expensive services from the suite that was being offered to beneficiaries. *See* 17 F.4th at 744-45.

Ortega's pleadings make undeniably clear that Mednology's decision to substitute the silicone-based foams in Sleepternity with PE-PUR foams was an intentional one designed to save the company money. R. at 5. Further, and despite a specific intent to defraud not being necessary to demonstrate scienter, Ortega has credibly alleged that the substitution was undertaken in order to procure FDA approval, as the company possessed knowledge of an ongoing recall of PE-PUR containing CPAP machines, and thus understood that its own product would fail to receive approval if its intent to use PE-PUR foams was disclosed. *See* R. at 4-5. Just as a previous communication delineating which prices could be permissibly submitted to CMS for reimbursement constituted evidence of scienter in *Schutte*, Mednology's awareness, based on an ongoing recall, that its use of PE-PUR foams would prevent its product from receiving FDA approval and CMS coverage is evidence of its culpable mental state. *See Schutte*, 598 U.S. at 753-54; R. at 4-5. Ortega has thus pleaded with sufficient particularity facts to satisfy the scienter requirement and should be granted the opportunity to proffer further evidence that will substantiate these claims.

B. Allowing Mednology to escape liability because the FDA terminated its investigation following the recall of Sleepternity would run counter to the precedent established by *Escobar* and frustrate the purpose of the FCA.

In *Escobar*, this Court declared that implied false certification may serve as a basis for liability under the FCA. 579 U.S. at 181. Though some courts have declined to allow such claims to proceed when they involve allegations of fraud-on-the-FDA, such an arbitrary line is improper because it transforms FDA approval into a tool with unintended power to undermine fraud investigations; allows manufacturers to evade liability for fraudulent conduct; and weakens *Escobar*'s embrace of implied false certification as a legitimate basis for FCA liability. *See Campie*, 862 F.3d at 906. This Court should affirm the holding of the Seventeenth Circuit and decline to endorse the First Circuit's narrow view of FCA liability.

1. Following *D'Agostino* in this case would lead to a misapplication of *Escobar* because significant factual differences distinguish this case and *D'Agostino*, including the strength of the material connection pleaded and the action taken by the FDA in response to the relators' allegations.

The First Circuit in *D'Agostino* declined in a case somewhat like this one to allow allegations of fraudulent misrepresentations to the FDA to serve as the basis for an implied false certification claim under the FCA. 845 F.3d at 9-10. That case, however, involved distinct factual circumstances, and to apply its logic to these facts would result in a perversion of *Escobar*'s embrace of implied false certification as a legitimate ground for FCA liability. *See Escobar*, 579 U.S. at 190.

In *D'Agostino*, a relator sued under the FCA based on allegations that medical device manufacturers ev3 and MTI had never intended to honor certain physician-

training requirements that they had certified to the FDA, in the process of securing approval for a device called Onyx, would be enforced. 845 F.3d at 4-5. In his pleadings, the relator argued that the companies' misrepresentations "could have" influenced the FDA's approval decision, and thus CMS's payment decision. *Id.* at 7. In addition to holding that such a feeble claim was insufficient to satisfy the element of materiality, the court granted the manufacturers' motion to dismiss on the grounds that the six years of FDA inaction that followed the relator's allegations was strong evidence that the alleged misrepresentations had not been a true cause of the FDA's approval of Onyx. *See id.* at 7, 14.

Among the factual differences between *D'Agostino* and the case at bar are 1) the more direct causal connection between the defendant's behavior and the rendering of payment by CMS that Ortega alleges, and 2) the actions taken by both the FDA and the defendant following Ortega's allegations of wrongdoing. Whereas the relator in *D'Agostino* alleged that the actions of ev3 and MTI "could have" induced FDA approval, a pleading that the First Circuit correctly designated as insufficient to demonstrate materiality, Ortega's more specific allegations, including evidence that Mednology was aware that its use of PE-PUR foams would doom its chances of receiving approval, are sufficient to withstand a motion to dismiss. *See D'Agostino*, 845 F.3d at 7; R. at 5. The more crucial distinction to be made between the two fact patterns, though, is that in the case of *D'Agostino*, the FDA failed to act once the relator's allegations became known, and Onyx always remained on the market. *D'Agostino*, 845 F.3d at 8. In the present case, the FDA initiated an investigation into

the circumstances of Sleepternity's approval once Ortega came forth with her allegations, and Mednology speedily removed its nonconforming product from the market. R. at 7. To equate a lack of FDA action on a product that is no longer being sold with a lack of action on a product still on the market would subvert *Escobar*'s premise that omissions of noncompliance with material requirements for payment- in this case, FDA approval- may serve as a basis for liability under the FCA. *Campie*, 862 F.3d at 905-06 (citing *Escobar*, 579 U.S. at 186-87). To apply *D'Agostino* to the facts of the present case would lead to a result at odds with *Escobar*'s core holding sanctioning liability via implied false certification even where the government continues to provide payment and would do so by relying on a decision that mentioned *Escobar* only once. *See D'Agostino*, 845 F.3d at 10; R. at 36 n. 9.

2. The FCA's purpose of preventing the government from paying fraudulent claims would be frustrated by dismissing Ortega's claims at this stage, as Mednology would be permitted to use the FDA approval it fraudulently procured to shield itself from liability for inducing reimbursements based on that approval.

The FCA's purpose of penalizing those who engage in fraudulent misrepresentations to cause the government to make payments is sabotaged by an approach to such claims that insulates from accountability any manufacturer that achieves FDA approval for its product, regardless of the circumstances of that approval. *See Campie*, 862 F.3d at 906. As explained by the Ninth Circuit, continued FDA approval may provide at most a presumption against materiality but cannot serve on its own as a total bar to liability under the FCA. *See id.* As acknowledged by defendant Gilead in that case, myriad factors may influence the FDA's decision to

withdraw, or not, its approval of any given product, including a manufacturer's decision to remove its product from market, effectively ending any FDA scrutiny. *See id.* More importantly, while FDA approval of a product may be the linchpin of government payments, the prevention of fraud on the government's dime is not a responsibility of that agency. *See id.* at 905. That objective falls squarely within the purpose of the FCA, which this Court has held may confer liability on a defendant that has misleadingly omitted a material violation of an implicit requirement to induce payment by CMS. *See Escobar*, 579 U.S. at 186-87. Were FDA approval alone to be permitted to defeat a claim of fraud, savvy manufacturers would always be able to escape liability by engaging in duplicity to procure such approval, and the government without recourse to recoup payments induced by falsehoods. *See Campie*, 862 F.3d at 905. CMS rightly looks to FDA approval as the quintessential indicator of safety and efficacy when deciding whether to proffer payment for a product; it does not follow that CMS would expect a fraudulent inducement of that approval, and thus the expending of its own funds on a nonconforming product, to be beyond investigation and penalty. *See id.*

The matter now before the Court presents an opportunity to endorse the intuitive concept that FDA approval cannot single-handedly defeat an action alleging fraudulent misrepresentation where each element of an FCA claim is adequately pleaded. Mednology is credibly alleged to have made a calculation regarding its chances of FDA approval, and by extension CMS coverage, and to have chosen to feign compliance with FDA standards while in reality manufacturing a nonconforming

device. *See* R. at 5. The purpose of the FCA is to penalize fraudulent inducements of government spending regardless of the manner in which they occur, and it is the prerogative of the government to seek damages flowing from such fraud. *See Walgreen*, 591 F. Supp. 3d at 307-08; Androphy & Lassabe, *supra*, § 2.01 ("No matter who is perpetrating the fraud, the FCA remains the Government's most effective weapon to recover billions of dollars pilfered every year from the coffers of the Federal treasury"). Here, though it was Ortega who was directly harmed by Mednology's misrepresentations, the government, too, has suffered an injury in the form of its payments for a product engineered to subvert the FDA approval process. R. at 5. While the persistent inflammation Ortega suffers rightfully gives rise to product liability claims under Transylvania statute, the government's expenditures on Sleepternity are the kind of fraudulent claims that the FCA was designed to address.

C. Granting Ortega the opportunity to prove her allegations against Mednology does not threaten the ability of the FDA to make independent decisions pertaining to product availability, as the *Escobar s*tandards are favorable to defendants such as Mednology and Mednology voluntarily withdrew Sleepternity from the market.

In response to concerns raised by the *Escobar* defendant that allowing the claim in that case to proceed would open the floodgates of claims not originally contemplated by the enactors of the FCA, this Court replied that these concerns were unfounded for two reasons: 1) the scope of liability entertained by the FCA was intentionally designed to be broad, and 2) the demanding requirements of each element of an FCA claim serve as a check on frivolous or unfounded claims. *See id.* at 191-192. The First and Seventh Circuits, respectively, applied *Escobar*'s clarification

of these rigorous requirements in *Campie* and *Molina*; the former noted that the relators faced an "uphill battle" in proving materiality based on the continued FDA approval of defendant Gilead's products, while the latter similarly noted that the relators would need to overcome a presumption of immateriality due to the government's continual contracting with defendant Molina. *See Campie*, 862 F.3d at 905; *Molina*, 17 F.4th at 743-44. The demands of the scienter requirement are similarly exacting. *Escobar*, 579 U.S. at 192.

As was true of the defendants in *Escobar*, *Campie*, and *Molina*, Mednology is not without recourse if Ortega's claim is allowed to proceed. The defendant may still produce any number of pieces of evidence to rebut the factual assertions alleged by Ortega. Just as Gilead enjoyed an advantageous position in *Campie* due to continuing FDA approval, and Molina was similarly well-situated due to continuing government payments, Mednology remains favorably positioned because the FDA never rescinded its approval for Sleepternity. *See Campie*, 862 F.3d at 905; *Molina*, 17 F.4th at 743-44; R. at 39-40. In stark contrast, if Ortega's claims are dismissed at this early stage, the government will be wholly without remedy for payments made because of fraudulent activity.

Further, the solution that the question before the Court invites should present the FDA with no cause for concern that its approval decisions will become subject to judicial overpolicing. In *D'Agostino*, six years elapsed between the relator's first allegations of fraudulent inducement in the approval of Onyx and the disposition of the case. 845 F.3d at 8. During that period, the FDA took no disciplinary action

against the manufacturers and demanded neither recall nor relabeling of Onyx. *Id.* The First Circuit was therefore motivated by a fear that allowing the relator's claims to proceed may force off the shelves a product on which the FDA had theretofore seen no reason to take adverse action, and thus to the judiciary impinging on the considerable latitude the agency enjoys in making product safety decisions. *See id.* at 9-10.

The case now before the Court presents no such need for concern. In contrast to the FDA's inaction regarding Onyx, the agency launched an investigation into Sleepternity shortly after Ortega came forward with her claims. *See* R. at 7. Either because it feared this investigation would lead to the revocation of Sleepternity's approval, or to relieve itself of scrutiny from the agency, Mednology initiated a voluntary recall of its product shortly thereafter. R. at 7. Thus, unlike *D'Agostino*, which had implications for a product still on the market, a decision by this Court to allow Ortega's FCA claims to proceed poses no threat to an independent decision of the FDA.

For the foregoing reasons, Ortega respectfully requests that this Court affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss her action under the FCA.

CONCLUSION

Ortega respectfully requests that this Court affirm both the Seventeenth Circuit's denial of Mednology's motion to dismiss her state law claims and that court's reversal of the district court's granting of Mednology's motion to dismiss her FCA claim.

Respectfully submitted,

/s/ 3305

Attorneys for Respondent

APPENDIX A

Statutory Provisions

Transylvania Product Liability Statute

Manufacturers and distributors of a product owe a duty of care and good faith to their consumers throughout the manufacturing and distribution of such product, including the duty to warn of any dangers or risks associated with the product, the duty to comply with all the state and federal laws and regulations governing the manufacturing and distribution of the product, and the duty to make disclosures to appropriate agencies or government officials about any modifications made to the product. Any resulting injury or death that would not have occurred but for the breach of any of the aforementioned duties shall serve as adequate basis for liability under this statute. 21 Trans. Comp. Stat. § 630.545.

Transylvania Product Liability Statute Statement of Purpose

It is the goal of the legislature to encourage manufacturers and distributors of various products to prioritize the health and safety of its consumers when manufacturing or distributing such products. It is also the goal of the legislature to encourage consumers who believe their injury resulted from a manufacturer and/or distributor's failure to exercise care, precaution, or good faith in manufacturing and/or distributing the product to bring a valid claim against the manufacturer and/or distributor. 21 Trans. Comp. Stat. § 630.544.

Transylvania Product Liability Statute Immunity-Granting Provision

In a product liability action against a manufacturer or distributor, a product that is a drug or a medical device is not defective or unreasonably dangerous, and the manufacturer or distributor is not liable, if the drug or medical device was approved for efficacy and safety by the United States Food and Drug Administration, and 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. Such drug or medical device is presumed to have been in compliance with the United States Food and Drug Administration's approval, and the party challenging a manufacturer's or distributor's immunity under this statute bears the burden of rebutting this presumption. 21 Trans. Comp. Stat. § 630.546(a).

Transylvania Product Liability Immunity Exception (b)

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).

Transylvania Product Liability Immunity Exception (c)

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).

Food, Drug, and Cosmetic Act

Express Preemption Provision:

§360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), 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 relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Implied Preemption Provision:

§337a. Extraterritorial jurisdiction

There is extraterritorial jurisdiction over any violation of this chapter relating to any article regulated under this chapter if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

False Claims Act

§3729: False claims

(a) Liability for Certain Acts.

(1) In General. Subject to paragraph (2), any person who-

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 1), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages. If the court finds that-

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and
(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions. For purposes of this section-

(1) the terms "knowing" and "knowingly"-
(A) mean that a person, with respect to information-
(i) has actual knowledge of the information;
(ii) acts in deliberate ignorance of the truth or falsity of the information; or
(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"-
(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that-
(i) is presented to an officer, employee, or agent of the United States; or
(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government-
(I) provides or has provided any portion of the money or property requested or demanded; or
(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal

employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

Medical Device Amendments of 1976

Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

21 U.S.C. § 360(c)

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 515, to premarket Post, p. 552. approval to provide reasonable assurance of its safety and effectiveness. If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

APPENDIX B

Constitutional Provisions

Supremacy Clause

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be 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. Art VI, Cl. 2.

APPENDIX C

Rules Provisions

Fed. R. Civ. P. 12(b)(6): Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

(b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(1)ck of subject-matter jurisdiction;

(2) lack of personal jurisdiction;

(3) improper venue;

(4) insufficient process;

(5) insufficient service of process;

(6) failure to state a claim upon which relief can be granted; and

(7) failure to join a party under Rule 19.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.