No. 24-9176

Supreme Court of the United States

NOVEMBER TERM, 2024

MEDNOLOGY, INC.,
PETITIONER

V.

UNITED STATES EX REL. RILEY ORTEGA,
RESPONDENT

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTEENTH CIRCUIT

BRIEF FOR THE RESPONDENT

Team #3312
Counsel for Respondent

QUESTIONS PRESENTED

I. Whether federal law preempts a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer misrepresenting or withholding information to obtain Food and Drug Administration ("FDA") approval or failing to comply with any FDA requirements.

II. Whether a relator may bring a False Claims Act ("FCA") claim, on behalf of the government, against a medical device manufacturer that engaged in fraudulent conduct to obtain FDA approval.

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The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2–24 of the record where the district court DENIED the Defendant's motion to dismiss Plaintiff's state law claims and GRANTED the Defendant's motion to dismiss Plaintiff'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 circuit court AFFIRMED the district court's denial of Defendant's motion to dismiss the state law claims and REVERSED the district court's granting of Defendant's motion to dismiss the FCA claim.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case falls within Article VI of the Constitution of the United States, the United States Code, and the state law of Transylvania. The involved provisions of the United States Code, specifically the Food, Drug and Cosmetics Act and the False Claims Act, include 21 U.S.C. § 337, 21 U.S.C. § 360, 31 U.S.C. § 3729, and 31 U.S.C. § 3730. The relevant Transylvania state law includes 21 Trans. Comp. Stat. § 630.544 – 630.546.

STATEMENT OF THE CASE

1. STATEMENT OF FACTS

Riley's Medical Conditions. When Respondent, Riley Ortega, ("Riley") retired from her service as an artillery officer in the United States Army, memories of the traumatic events she endured disrupted her life as a civilian. R. at 3. Diagnosed with Post-Traumatic Stress Disorder ("PTSD"), Riley suffered, in

addition to lasting distress, insomnia and sleep-apnea symptoms which unsettled her day-to-day functioning. R. at 3. Seeking reprieve from her sleepless nights, Riley sought advice from a somnologist who prescribed a sleep-inducing medical device known as Sleepternity. R. at 3.

Sleepternity Class III Device. Sleepternity is a continuous positive airway pressure ("CPAP") machine intended to assist users relax and fall asleep. R. at 3. Sleepternity included several distinct features to their device, including an automatic pressure adjustment system, a heated humidifier, and an accompanying smart phone app. R. at 3. Additionally, the device came with noise-cancelling headphones that attached to the mask. R. at 3. Sleepternity installed these features to benefit users like Riley, who suffered both sleep-apnea and insomnia. R. at 3. The FDA granted Sleepternity approval as a Class III medical device; subject to the FDA's most stringent pre-market approval standard. R. at 3.

Modifications Post-FDA-Approval. At some point after obtaining FDA approval for the marketing of Sleepternity, Mednology made the undisclosed, unapproved decision to substitute the silicone-based foam with a polyester-based polyurethane (PE-PUR) foam. R. at 4. Mednology forwent the silicone-based foam, which had been used in the device at the time of the FDA approval, in an alleged attempt to cut manufacturing costs. R. at 4. The significant health risks of PE-PUR were not unknown; in June 2021, a Philips Respironics device had to be recalled due to the use of PE-PUR foam. R. at 4. The FDA found that PE-PUR

foams had the potential to break down over time, and consequently posed a danger to consumers as it could be swallowed or inhaled by device users. R. at 4.

Riley's Continual Suffering. It wasn't until after a serious asthma attack and visit to the emergency room that Riley became aware of the presence of PE-PUR in Sleepternity. R. at 4. Riley and her physician did not think to consider her isocyanate allergy, a potential byproduct of the broken-down PE-PUR particles, to be the cause of her asthma attacks because the warning label on Sleepternity contained no information about the dangers of PE-PUR foam and the possible presence of isocyanates. R. at 5. Riley continued to face lasting health concerns after she terminated her use of the device, including chronically inflamed lungs and the return of her sleep apnea symptoms. R. at 5. The revelation of the substitution did not even come from the corporation itself, but rather from her brother, Jim, who happened to be an assembly manager at Mednology. R. at 5. Jim deemed the substitution of PE-PUR foams to have such significance that he informed Riley about the modification. R. at 5. Coincidentally, Mednology voluntarily recalled Sleepternity shortly after Riley served a summons and copy of her complaint to Mednology. R. at 7. More conveniently for Mednology, the FDA suspended their investigation into the fraudulent activity after the voluntary recall. R. at 7.

2. PROCEDURAL HISTORY

Southern District of Transylvania. On June 21, 2023, Riley Ortega filed a products liability action against Mednology, asserting that Mednology fraudulently produced its CPAP machine, Sleepternity and violated Transylvania's product liability statute. R. at 6. Riley claimed that Mednology breach its duty of care and

good faith, duty to disclose, and duty to warn under the state's tort law. R. at 6. Further, she brought a False Claims Act claim, in reliance on the fraud-on-the-FDA theory. R. at 6. Mednology responded by filing a motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, arguing that the exceptions within subsection (b) and subsection (c) of Transylvania's immunity statute were preempted by the federal Food, Drug and Cosmetic Act ("FDCA"). R. at 2, 9. Mednology further argued that the False Claims Act claim should be dismissed because the fraud-on-the-FDA theory cannot be the basis of the claim. R. at 9. On October 15, 2023, the United States District Court for the Southern District of Transylvania held that Petitioner's motion to dismiss be granted in part and denied in part. R. at 2. The court denied Petitioner's motion to dismiss Riley's state law claims; the court granted Petitioner's motion to dismiss Riley's FCA claim. R. at 24.

Seventeenth Circuit. Following the district court's decision, Riley appealed to the United States Court of Appeals for the Seventeenth Circuit. R. at 25. The circuit court affirmed the district court's denial of the motion to dismiss Riley's state law claims. R. at 25. The circuit court further reversed the district court's granting of the motion to dismiss the FCA claim. R. at 25. Ultimately, the circuit court remanded the case for further proceedings consistent with its opinion. R. at 25.

Writ of Certiorari. Following the decision of the Seventeenth Circuit, Mednology petitioned for a writ of certiorari. R. at 43. On August 1, 2024, the Supreme Court granted writ. R. at 43.

Motion to Dismiss. To survive a 12(b)(6) motion to dismiss, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face", meaning that from the pleading, the court can reasonably infer that the defendant is liable. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). A plaintiff must provide "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Twombly*, 550 U.S. at 555. With this standard in mind, the Court must take the factual allegations as true for purposes of Rule 12(b)(6) and review the merits of the argument.

SUMMARY OF ARGUMENT

This Court should AFFIRM the holding of the Seventeenth Circuit Court of Appeals, in which the court denied Petitioner's motion to dismiss. The first issue should be affirmed, though on different grounds; the second issue should be affirmed in its entirety.

I.

This Court should AFFIRM the Seventeenth Circuit's denial of Petitioner's motion to dismiss, but on different grounds. Transylvania's immunity statute is neither expressly nor impliedly preempted by the Federal Food Drug and Cosmetics Act ("FDCA"). The Seventeenth Circuit failed to apply the presumption against preemption when evaluating whether federal law preempted the Transylvania immunity statute. Instead, the presumption against preemption must be applied because the immunity statute falls within the purview of state authority to police matters of health and safety.

Section 337 of the FDCA provides that all proceedings on matters of regulatory enforcement must be by and in the name of the United States. Section 360k of the FDCA prohibits states from enacting medical device requirements different from those provided in the federal code. Neither section, however, limits the state's authority to police products liability claims brought under state tort law. Transylvania's immunity statute is not expressly preempted by section 337 or 360k of the FDCA because it defines and limits the bounds in which Transylvania citizens may bring matters of common law liability against medical device companies with FDA approval. Furthermore, it does not differ from or extend upon the requirements already established by the FDA. Next, Transylvania's immunity statute is not impliedly preempted by section 337 or 360k, because the exceptions do not allow citizens to bring claims against medical device companies based solely on fraud against the FDA, nor do they require a finding of fraud by a state court to apply.

Moreover, the statute provides an avenue for recourse when the FDA otherwise abandons an investigation into withdrawing approval when the defendant voluntarily recalls their harmful product from the market. Under a sweeping application of federal preemption, these injured parties would never obtain federal findings sufficient to bring their claims against deceitful medical device manufacturers.

Accordingly, this court should find no infringement on government policing authority by the Transylvania immunity statute. The statute exists to limit the

circumstances under which a private citizen may bring a products liability claim. The exceptions provide judicial recourse in the rare event that a party is injured by non-compliant devices with prior FDA approval. The statute and its exceptions are entirely rooted in state tort law and pose no risk of impeding the federal authority to police fraud against its agencies.

II.

This Court should AFFIRM the Seventeenth Circuit Court of Appeals decision regarding Respondent's False Claims Act claim and hold that a relator may rely on the fraud-on-the FDA theory in the context of implied false certification to bring an FCA claim under the Act's *qui tam* provision.

Under the False Claims Act, a claimant must prove that a false statement or fraudulent course of conduct made with the scienter was material, causing the government to pay out money or forfeit moneys due. The fraud-on-the FDA theory, stemming from the theory of fraudulent inducement, is a viable theory of FCA liability when a company's violation of FDA regulations materially induces the FDA to approve a product or medical device, which in turn causes payments made by the Centers for Medicare and Medicaid (CMS) in relation to those products. In the context of the implied false certification theory, fraud-on-the FDA liability can occur when a company's misleading representations impliedly certify that it has complied with material requirements and indicate that it is entitled to reimbursement or money forfeited from the government, regardless of who submits the claims for such payment.

Here, Respondent's [usage of/reliance on] these theories proves valid because Petitioner made false representations which fraudulently induced the FDA to grant pre-marketing approval for its medical device, Sleepternity. As follows, by filing a claim for reimbursement to CMS, Petitioner implicitly certified that it had complied with all the requirements for obtaining the FDA's approval. Ultimately, it was Sleepternity's fraudulent FDA approval that induced CMS to submit payment claims and cause financial loss to the government.

Furthermore, Respondent has satisfied all elements of a fraud-on-the FDA claim, as continued FDA approval is not a requisite for causation or materiality. In the context of the implied certification theory, Respondent can prove that Petitioner's fraudulent misrepresentations were material and caused payment from the government. And, as is required at the pleading stage, materiality and causation are both matters of proof rather than a legal ground to dismiss a complaint.

Accordingly, this Court should AFFIRM the Seventeenth Circuit Court of Appeal's decision to deny Petitioner's motion to dismiss and hold that fraud-on-the FDA is a viable theory of liability under the False Claims Act.

STANDARD OF REVIEW

The standard of review of a decision to dismiss a claim under FED. R. CIV. P. 12(b)(6) concerns a question of law and "is subject to de novo review." *Kelson v. City of Springfield*, 767 F.2d 651, 653 (9th Cir. 1985). As such, the decision of the Seventeenth Circuit regarding whether federal law preempts a statutory exception

to a manufacturer's state-recognized immunity is also reviewed de novo. *Id.* Whether Riley can rely on the fraud-on-the-FDA theory to bring a False Claims Act claim under the act's *qui tam* provision is reviewed de novo. *Pierce v. Underwood*, 487 U.S. 552, 558 (1988) (stating that questions of law are reviewed de novo).

ARGUMENT

I. THE MEDICAL DEVICE AMENDMENT OF THE FOOD, DRUG, AND COSMETIC ACT DOES NOT PREEMPT THE EXCEPTIONS TO TRANSYLVANIA'S IMMUNITY STATUTE.

The Supremacy Clause of the United States Constitution has been well-established to invalidate state laws that "interfere with, or are contrary to" federal laws, stating that "the laws of the United States . . . . shall be the supreme Law of the Land." U.S. Const. art. VI, § 2. From this clause, Congress derives its power to preempt state law both expressly and impliedly. *See Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018); *see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). In express preemption, Congress may outwardly state, by explicit language, their intention to supersede any state law. *Gade,* 505 U.S. 88 at 108. In the absence of such explicit language, federal law may still preempt state law if Congress intended for the federal government alone to occupy a regulatory field. *Id.* This intent may be inferred by evaluating the structure and purpose of the state law. *Id.* When analyzing if a state law is impliedly preempted by federal law, the court must assume that "a state law is valid and should be reluctant to resort to the Supremacy Clause." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 at 966 (quoting *Garcia v. Wyeth-Ayerst Labs.*, 265 F.Supp.2d 825 at 831).

The FDCA contains two express preemption provisions. Section 337 reserves all proceedings that enforce or restrain FDA regulations to be "by and in the name of the United States." 21 U.S.C. § 337(a). Section 360k prohibits any state from imposing a requirement in regards to a medical device "which is different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a).

First, the statute abides by the express preemption provision under section 337 of the FDCA. Under section 337, the FDA provides that all proceedings "for the enforcement, or to restrain violations, of [FDA regulations] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Though the federal government maintains exclusive policing power over FDA regulatory requirements, section 337 does not invalidate proceedings of state tort law in matters of health and safety. *Id.* Thus, Transylvania's immunity statute survives express preemption with respect to section 337.

The same principle applies to section 360k. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 471 (1996). Respondent recognizes the importance of upholding the FDA's discretion to police its regulatory schemes. The FDCA provision, however, does not prohibit State legislatures from providing traditional remedies for violations of state common law statutes when those statutes are parallel to federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008); *Medtronic*, 518 U.S. 470 at 491 (1996). In both structure and purpose, the Transylvania immunity statute reinforces, rather than undermines, section 360k and survives express preemption.

A. Presumption Against Preemption Applies.

The Seventeenth Circuit incorrectly held that the presumption against preemption does not apply to the case at bar. Presumption against preemption alludes to the traditional analysis that when addressing cases of preemption, "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947). Later Supreme Court decisions established the applicability of the presumption against preemption to cases involving state tort actions. *Medtronic*, 518 U.S. 470 at 485 (1996).

Presumption against preemption applies to common law statutes. In *Medtronic*, a defect in a pacemaker injured the plaintiff, resulting in a complete heart block and emergency surgery. *Id*. at 474. Medtronic filed a motion for summary judgment, alleging that Florida's state products-liability claims were preempted by section 360k of the FDCA. *Id.* at There, this Court held that preemption under section 360k is limited only to situations in which the state requirement differs from or extends upon the device's federal requirements. Common law claims, not specific to a particular device, are not preempted. *Medtronic* correctly emphasizes that presumption against preemption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485.

In *Buckman*, this Court declined to apply the presumption against preemption to the petitioner's state-law-fraud-on-the-FDA claims because they

conflicted with the "somewhat delicate balance of statutory objectives." *Buckman Co. V. Plaintiffs' Legal Committee*, 531 U.S. 341, 347 (2001). This Court reasoned that allowing litigants to bring fraud-on-the-FDA claims under state law infringed upon a field of regulation that the federal government exclusively occupied. *Id.* at 348. However, this Court's holding applies narrowly, pertaining *only* to "fraud-on-the-FDA" claims created by state law. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006). Accordingly, lawsuits primarily based on "traditional and preexisting tort sources," and only incidentally on evidence of misrepresentation, are not prohibited through preemption.

The circumstances at hand are distinct from *Buckman*, as Riley is attempting to neutralize the Transylvania immunity statute rather than bring a claim for federal non-compliance through state courts. *See Id.* at 93. The statute in question more closely resembles the statute evaluated by this Court in *Medtronic,* because they neither added nor differed from the FDCA medical device requirements. *See Medtronic*, 518 U.S. at 471. Here, the Transylvania immunity statute mirrors the intent of the FDCA by limiting liability for medical device manufacturers from product liability suits, provided they obtain FDA approval. *See* 21 Trans. Comp. Stat. § 630.545 (2024); 21 U.S.C. § 360k(a). The state legislature's statement of purpose includes the goal, "to encourage manufacturers and distributors of various products to prioritize the health and safety of its consumers . . . . [and] to encourage consumers . . . . to bring a valid claim against the manufacturer and/or distributor." *Id*. at § 630.544-45 (2024).

Petitioner may argue that the presumption against preemption would interfere with the FDA's authority and policing power over medical devices. However, state regulation of health and safety matters is nonetheless clearly implicated. States are the primary governmental entity responsible protecting "the lives, limbs, health, comfort, and quiet of all persons." *Medtronic*, 518 U.S. at 485. As such, they employ their policing power to enact laws that ensure the prosperity and general wellbeing of the people. The State of Transylvania's product liability statute protects both federal authority over agency regulation and state primacy in matters related to individual health and safety. The immunity provision under subsection (a) of the Transylvania statute demonstrates absolute regard for federal regulatory authority by granting full immunity to medical device manufacturers who legally and legitimately obtained FDA approval. 21 Trans. Comp. Stat. § 630.546(a). Riley does not argue that the federal government maintains exclusive authority to "punish and deter fraud against the Administration." *Buckman,* 531 U.S. 341 at 348 (2001). However, federal proceedings for fraud provide no alternative recovery method for private individuals with state-law tort claims. *Id.* at 355 (Stevens, J., concurring) ("declining to infer that a federal statutory scheme that affords no alternative means of seeking redress pre-empted traditional state-law remedies"). Thus, the duty to create pathways for individual redress under traditional state-law claims falls firmly upon the state itself. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 253 (1984) (the federal government's exclusive authority

to set safety standards did not foreclose the use of state tort remedies). Resulting statutes that carry out this duty demand the presumption against preemption.

B. *Desiano* is the Applicable Standard When Determining If Federal Law Preempts A State Law Immunity Exception.

The Seventeenth Circuit erred when adopting the Sixth Circuit's analysis in *Garcia* to deny the presumption against preemption. Exceptions to state immunity statutes do not constitute attempts by states to police agency regulations. *Desiano*, 467 F.3d at 92. The court in *Garcia* relied on an imprecise understanding of this court's ruling in to preempt Michigan's immunity exceptions by confusing them with fraud-on-the-FDA claims. *Id.* at 93. In doing so, the Sixth Circuit concluded that federal law impliedly preempted both exceptions. *Id.* at 88. However, these exceptions merely provided a method for citizens to bring common law tort claims against medical device manufacturers with FDA approval. *Id.* at 96. The court in *Garcia* mistakenly conflated these exceptions with state-law-fraud-on-the-FDA claims. *Id.* at 92.

Instead, *Desiano* is the proper case law to adopt. In *Desiano*, a Michigan immunity statute sought to minimize instances in which citizens could continue to recover from medical device manufacturers under state product liability law. *Desiano*, 467 F.3d at 88. Similarly here, the immunity statute and its exceptions are not an attempt to police fraud against the FDA. Rather, the immunity statute, which establishes that medical device manufacturers are generally immune from product liability lawsuits, seeks to minimize liability. 21 Trans. Comp. Stat. § 630.546(a). The exceptions to Transylvania's immunity statute are narrowly

tailored and applicable only to a limited set of facts, including those at hand. 21 Trans. Comp. Stat. § 630.546(b)(c).

Here, like the court in *Garcia*, the Seventeenth Circuit erroneously characterized the immunity exceptions under subsections (b) and (c) state-law-fraud-on-the-FDA claims. Subsection (b) neutralizes the Transylvania immunity statute by allowing injured citizens to bring product liability claims against a medical device company that "intentionally [withheld] . . . . information" inconsistent with its FDA approval. 21 Trans. Comp. Stat. § 630.546(b). A claim brought under this exception, like Riley's, does not constitute an attempt to police fraud against a federal agency, nor does it require a finding of fraud by the state court. *See Desiano*, 467 F.3d at 93. Rather, this exception permits the court to proceed with Riley's common law claim through an evidentiary showing that Petitioner withheld information from the FDA. The Seventeenth Circuit correctly concluded that Riley presented sufficient evidence to proceed on a state-law tort claim because the undisclosed information regarding Petitioner's device posed a substantial risk to consumer health and would have invalidated their prior approval. R. at 33. Subsection (c) of Transylvania's immunity statute neutralizes a drug or medical device manufacturer's immunity from product liability suits when the manufacturer "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); *see Wyeth v. Levine*, 555 U.S. 555, 563 (2009) (holding that state tort law product liability claims for failure to warn are not preempted by federal law).

C. *Garcia*'s Independent Finding Requirement Unreasonably Eliminates Avenues Of Recourse For State Product Liability Claims And Curtails States' Policing Powers Concerning The Health And Safety Of Their Citizens.

The Seventeenth Circuit erroneously relied on *Garcia* in asserting that misrepresentation and failure to warn exceptions "would be preempted unless a plaintiff relies on the FDA's independent finding that the defendant has violated [the FDA's] requirements." R. at 31. This requirement is too narrow. When Mednology replaced the silicone-based foam with polyester-based polyurethane, they failed to disclose their modification to the FDA despite its probable impact on their prior approval. R. At 4. Likewise, there is no doubt that Mednology failed to warn both the FDA and consumers about the potential presence of isocyanates in Sleepternity. The health risks of PE-PUR foams were not unknown. *See* R. at 4, n. 1 (recounting the June 2021 incident in which Philips Respironics had to recall CPAP machines that contained PE-PUR foams). Riley was entirely unaware of the presence of PE-PUR foams until after experiencing severe asthma attacks, which required emergency transportation to a nearby hospital. R. At 4. Again, her doctors did not even consider Riley's isocyanate allergy to be responsible for her symptoms, as Mednology failed to provide any information about this presence on Sleepternity's warning label. R. At 5. Even after terminating the use of Sleepternity, Riley faced lasting health issues, including chronically inflamed lungs and the return of her sleep apnea symptoms. R. At 5. It took for her brother Jim, rather than the corporation itself, to finally inform Riley about the substitution of foams which ultimately resulted in her health issues. R. At 5.

Given that Mednology voluntarily recalled its medical device from the market, the FDA consequently terminated its investigation of the alleged fraudulent conduct. Requiring that plaintiffs provide independent findings on behalf of the FDA permits medical device companies to evade consequences for resulting injury, hindering the historic tradition of states' policing powers concerning the protection of the health and safety of its citizens.

For the aforementioned reasons, this Court should conclude that the presumption against preemption applies to the Transylvania immunity statute. In doing so, this Court should agree that federal law does not preempt the exceptions in subsections (b) and (c) because they do not qualify as state-fraud-on-the-FDA claims. To hold otherwise is counterintuitive to the principles of federalism and jeopardizes the importance of state authority over matters of health and safety.

II. RESPONDENT MAY RELY ON THE FRAUD-ON-THE FDA THEORY IN THE CONTEXT OF THE IMPLIED FALSE CERTIFICATION THEORY TO BRING A FALSE CLAIMS ACT CLAIM AGAINST PETITIONER UNDER THE ACT'S *QUI TAM* PROVISION.

Riley's reliance on the fraud-on-the-FDA theory in bringing a False Claims Act claim is valid under the Act's *qui tam* provision. The False Claims Act is a federal statute that allows the government to recover damages and penalties from actors who have defrauded government programs. 31 U.S.C. § 3729(b)(2)(A). The Act finds liable "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(A), (B).

Bringing an action under the FCA is advantageous both to the government and to the affected individuals who initiate the claim. Under the Act's *qui tam* provision, private individuals acting as relators or whistleblowers may bring a civil action for an FCA violation on behalf of the United States government. *Id.* § 3730(b)(1). In such action, the government has the right to intervene and assume primary responsibility for prosecuting the action. *Id.* § 3730(c)(1).

However, if the government chooses not to intervene, the individual who initiated the FCA action will still "have the right to conduct the action." *Id.* § 3730(c)(3). *Qui tam* actions benefit the government and incentivize its use of the FCA because the private plaintiffs do much of the critical preliminary work, decreasing the burden on government agents. Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong RX*, 12 J. HEALTH CARE L. & POL'Y 119, 139 (2009). Congress has also incentivized individuals to engage in *qui tam* actions by allowing relators to share a percentage of the government's recovery, in "an amount which the court decides is reasonable for collecting the civil penalty and damages." 31 U.S.C. § 3730(d)(1)-(2). Thus, despite the government's decision not to intervene, Riley may still bring an FCA claim against Petitioner, and if successful, can share in monetary damages for her contributions to the prosecution of the action.

Riley relies on the fraud-on-the-FDA theory in the context of the implied false certification theory to bring a FCA claim against Petitioner. R. at 6, 36. The purpose of the FCA is to hold actors such as medical device companies accountable

for false and misleading statements that cause financial loss to the United States government. 31 U.S.C. § 3729(a)(1)(A)-(B). Because federal healthcare programs usually require FDA approval to grant reimbursement for medical devices, the fraud-on-the-FDA theory aims to hold liable medical device companies who fraudulently obtain FDA approval and cause trusting healthcare companies to submit reimbursement claims to the government for payment. *United States ex rel. D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (2016); *United States ex rel. Campie v. Gilead Sciences*, 862 F.3d 890, 99 (9th Cir. 2017).

This Court has affirmed FCA liability in the context of the implied false certification theory. *Universal Health Services v. United States ex rel. Escobar*. 579 U.S. 176, 181 (2016). The implied certification theory creates liability under the FCA when a claimant "makes specific representations about the goods or services provided . . . . and . . . . the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id*. at 190. Under the theory of implied certification, it follows that an actor that fraudulently obtained FDA approval and then submitted or caused another to submit a reimbursement claim has impliedly communicated that it has satisfied all requirements for financial assistance and is entitled to that payment. *See id*. at 18. Utilizing aspects of implied false certification and other FCA-related theories, the fraud-on-the-FDA theory is a viable and productive form of liability under the FCA because it holds accountable

actors who, from a fraudulent starting point, set off a chain of causation steeped in dishonesty that inextricably leads to the government's financial loss. *Id.* at 715.

Here, Riley's reliance on the above theories of FCA liability prove valid because: (1) the fraud-on-the-FDA theory is a viable theory of liability under the FCA; (2) Riley satisfies the requisite elements of a fraud-on-the-FDA claim in the context of implied false certifications; (3) the fraud-on-the-FDA theory satisfies the FCA's heightened pleading standards; and (4) overall, this interpretation coincides with the purpose of the FCA. As such, this Court should AFFIRM the Seventeenth Circuit's holding.

A. The Seventeenth Circuit Correctly Concluded that Fraud-on-the-FDA is a Viable Form of Liability Under the FCA.

To successfully bring a claim under the FCA, a relator must demonstrate: (1) a false statement or fraudulent course of conduct; (2) made with the scienter; (3) that was material, causing; (4) the government to pay out money or forfeit moneys due. *See e.g.*, *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999); *Campie*, 862 F.3d 890, 899; *United States v. Univ. of Phx.*, 461 F.3d 116, 1174 (9th Cir. 2006). As noted by the Seventeenth Circuit, there is a circuit court split between the First and the Ninth Circuit over the viability of fraud-on-FDA as a form of FCA liability regarding its ability to satisfy the requisite elements. R. at 36.

The Ninth Circuit in *Campie* applied this Court's clarifications set forth in *Escobar*, focusing on materiality and giving little weight to causation. *Campie*, 862 F.3d at 909. In contrast, the First Circuit in *D'Agostino* failed to properly incorporate this Court's precedent, and instead relied heavily on what it found to be

an insufficient causal link between misleading statements and reimbursement from the CMS. *D'Agostino*, 845 F.3d 1, 3, 10. Because the Ninth Circuit correctly applied *Escobar*'s framework, this Court should adopt the Ninth Circuit's reasoning and AFFIRM the Seventeenth Circuit's ruling that fraud-on-the-FDA is a viable form of liability under the FCA. R. at 38.

1. The Ninth Circuit correctly applied the standards that this Court set forth in *Escobar*.

The Ninth Circuit properly upheld fraud-on-the-FDA as a form of liability under the FCA. *Campie*, 862 F.3d at 909. There, two relators brought a fraud-on-the-FDA based FCA claim in the context of the implied false certification theory against a biopharmaceutical company. *Id.* at 895. They alleged that the company deceived the FDA with false and misleading submissions. *Id.* The relators explained that the company sourced ingredients for three HIV-related drugs from an unapproved facility but reported to the FDA that they used only approved facilities. *Id*. at 895-96. Additionally, they alleged that the company concealed and falsified data concerning contaminated batches of said ingredients. *Id.* The relators therefore argued that because the company made false and fraudulent claims to receive FDA approval, any claims presented to the government for payment were tainted by the company's misrepresentations. *Id.*

Ultimately, the Ninth Circuit held for the relators, emphasizing materiality as the pinnacle of an FCA claim's success and properly centering its holding around this Court's clarifications of materiality set in *Escobar*. *Campie*, 862 F.3d at 895–96. The court rejected the company's argument that, because the FDA failed to

withdraw approval upon discovery of the company's fraud, the fraud was not material in obtaining FDA approval. *Id*. at 906. The court further reasoned that the relators had alleged, as part of their reliance on the implied certification theory, sufficient facts to state a claim for relief under the FCA that is plausible on its face. *Id.* (citing FED. R. CIV. P. 8(a); *Ashcroft*, 556 U.S. at 678 (2009)). As such, the Ninth Circuit concluded that the issue of materiality led to a matter of proof, rather than a legal ground to dismiss a complaint. *Campie*, 862 F.3d at 907.

This interpretation of fraud-on-the-FDA gives the FCA and FDA the space they need as separate federal authorities to do their respective jobs, yet still work symbiotically. *See id.* at 905. As the Ninth Circuit noted, and as is consistent with *Escobar*, "[m]ere FDA approval cannot preclude False Claims Act liability, especially where . . . . the alleged false claims procured certain approvals in the first instance." *Id*. at 905. As the Ninth Circuit highlighted, the FDA's continued approval of a fraudulently approved drug has little significance, as the FDA and FCA are two entirely different legal entities with different purposes: "just as it is not the purpose of the FCA to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government." *Id*. Holding that the FDA's approval is of the utmost importance would put the FCA and FDA in an adversarial position, creating a "shield" through which companies can hide from liability for fraud. *Id.* at 906.

The Ninth Circuit's interpretation also adequately acknowledges that the FDA's decision to continue or withdraw approval of a medical device is dependent

on a variety of reasons unrelated to "the concern that the government paid out billions of dollars for nonconforming and adulterated drugs." *Id.* For example, the government may find the fraud temporally moot due to a fraudulent company's corrective conduct, such as the company in *Campie*'s discontinued use of the unapproved facility in manufacturing its drug. *Id.* The Ninth Circuit explained that "the 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." *Id.* Because the Ninth Circuit properly applies this Court's precedent and accounts for these considerations, this Court should find its analysis persuasive in evaluating Riley's claims.

2. The First Circuit incorrectly rejected the fraud-on-the-FDA theory by ignoring Supreme Court precedent.

The First Circuit rejected the fraud-on-the FDA theory as a viable form of liability under the FCA. *D'Agostino*, 845 F.3d at 10. There, a relator brought a *qui tam* action accusing a medical device company of liability under the FCA based on the theory of fraud-on-the-FDA. *Id.* at 5. The relator claimed that the medical device company made false submissions to the FDA, promising that Onyx, the medical device in question, had a "narrow scope of indication" and that the physicians using Onyx would undergo a rigorous training program and receive extensive assistance. *Id.* at 4. The relator alleged that the company's commitment to these important, high standards quickly fell through, and that trainings became inadequate and often non-existent, and off-label marketing became encouraged. *Id.* He argued that because FDA approval is a precondition to CMS reimbursement for

use of a medical device, and that the company made fraudulent representations to the FDA for approval, then the company's fraudulent representations induced the government to make payments via CMS. *Id.* at 7.

Of relevance is the fact that the FDA advisory panel–the group that, in tandem with the FDA, reviews submissions and recommends or denies FDA approval–made it clear to the company that the representations it made about training requirements were "critically important" to the safe use of Onyx. *Id.* The panel explained it was with "cautious approval" that it recommended FDA approval of Onyx, and that it would advise rescission if the company did not carefully monitor Onyx cases with the care the company purported it would. *Id.*

Regardless, the First Circuit held in favor of the company, rejecting the fraud-on-the-FDA theory wholly because the relator's complaint failed to establish a causal link. *Id.* at 3, 10. The court's reasoning, however, relied disproportionately on the causation element of an FCA claim. Specifically, unlike the Ninth Circuit, it found that because the FDA had not withdrawn approval of Onyx even after the relator's allegations, the failure to withdraw precluded any claim of causation. *Id.* at 8. Thus, to the First Circuit, the chain of causation formed between the fraudulent misrepresentations made to the FDA and the payment of claims for reimbursement by the government was too tenuous to assert liability under the fraud-on-the-FDA theory. *Id.* at 10. This approach, however, ignores this Court's ruling in *Escobar*, overlooking the importance of materiality and placing improper weight on causation.

B. Riley Satisfies the Requisite Elements for an FCA Claim.

Congress' purpose of enacting the FCA "was broadly to protect the funds and property of the government from fraudulent claims regardless of the particular form, or function, of the government instrumentality upon which such claims were made." *Rainwater v. United States*, 356 U.S. 590, 592 (1958). Further, the FCA "intended to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943). Consequently, this Court has cautioned that the act should not be given a narrow reading. *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968). This Court should apply, as it historically has, a broad lens in evaluating Riley's FCA claims.

Regarding the materiality element, to succeed on a false certification theory the fraudulent actor's conduct must be material to the payor's decision to grant payment. *Campie*, 862 F.3d at 899; *Escobar*, 579 U.S. at 190. Conduct is material if it "has a natural tendency to influence, or be capable of influencing, the payment or recipient of money or property." 31 U.S.C. § 3729(b)(4). This Court clarified this definition, analyzing causation as an implicit sub-component of proving the materiality element, and suggesting that the two factors are necessarily intertwined. *See Escobar*, 579 U.S. at 194–95. As Justice Ruzich similarly recognized in his concurrence to the Seventeenth Circuit's decision, "These explanations of the materiality element indicate that a defendant's fraudulent violation of a particular requirement must cause the government to withdraw payment." R. at 39 (citing *Escobar*, 579 U.S. at 194–95).

Additionally, this Court in *Escobar* also expanded the definition of materiality, explaining that a relator cannot depend solely on CMS's requirement for FDA approval for reimbursement. *Escobar*, 579 U.S at 194–95. While a violation of the government's condition of payment is relevant to the materiality of fraudulent conduct, it is not automatically dispositive, and a relator must show something more. *Id*. For example, "proof of materiality can include, but is not necessarily limited to, 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 statutory, regulatory, or contractual requirement." *Id*. Thus, although the materiality standard is demanding, a fraud-on-the-FDA claim can certainly survive the pleading stage and is a legally viable form of liability under the FCA. *Id*.

Here, Riley has alleged sufficient facts of materiality and causation to survive Petitioner's motion to dismiss. To start, CMS's reimbursement for Sleepternity was conditioned on the FDA's approval of the medical device, and CMS would have never provided payment if it had known of Petitioner's violative and fraudulent conduct. R. at 37. Just as safety and efficacy are material to the FDA's approval of a product, safety and efficacy are material to a healthcare provider's decision to use a product and to CMS's eventual decision for repayment of said product. *See* Kelly Carter Zimmerer, *Health Fraud from FDA Approval to CMS Payments: Why Fraud-on-the-FDA Should Be a Viable Form of Liability Under the False Claims Act*, 62 U. Louisville L. Rev. 713, 730 (2024). In other words, what is material to the FDA is

material to the subsequent entities involved with the product. *See id.* Therefore, a company's implied certification that its product is ready for public usage is "capable of influencing" a healthcare providers' decision to submit a claim for reimbursement.

Further, although continued FDA approval does not preclude a finding of materiality or causation, Petitioner voluntarily recalled Sleepternity from the market shortly after Riley served a summons and complaint. R. at 7. As the Ninth Circuit noted, the FDA's decision to remain uninvolved can stem from myriad reasons, and here, "the FDA decided not to continue investigating [Petitioner's] alleged fraudulent conduct to focus on investigating other allegedly defective products in the marketplace that have not been recalled." *Campie*, 862 F.3d at 906; R. at 7. Thus is the beauty of the FCA's *qui tam* provision: the FDA can focus its limited time and resources on actively defective or misrepresented products, and still trust that punitive and preventative actions are being taken in response to deceitful conduct against the government.

Finally, as this Court identified in *Escobar*, Riley can prove materiality through evidence of the government's refusal to pay fraud-based claims "in the mine run of cases." *Escobar*, 579 U.S. at 194–95. Specifically, the FDA recalled a device using the same type of PE-PUR foam deceptively used in Sleepternity. *FDA Activities Related to Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA.GOV, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/fda-activities-related-recalled-

philips-ventilators-bipap-machines-and-cpap-machines. On June 30, 2021, the FDA initiated a Class I recall of certain Philips Respironics ("Philips") ventilators due to potentially severe health risks associated with the PE-PUR foam's tendency to break down. *Id.* While the FDA recommended speaking to healthcare providers about risks before immediately stopping use of the device, it terminated the production and sale of new devices using the PE-PUR foam until Philips took the appropriate steps towards remediation and met all requirements related to a Class I recall. *Id.*

Here, Riley asserts that because the FDA recalled Philips' CPAP devices due to the health risks associated with PE-PUR abatement foams, it would not have approved Sleepternity if its use of the material had not been misrepresented. R. at 6. The FDA's treatment of PE-PUR foam in the past is strong evidence of how the agency would handle Sleepternity had Petitioner not immediately pulled the device from the market prior to the FDA's ability to recall. Just as the presence of the foam in Philips was deemed material or integral enough to influence the 2021 recall of the device, here, the concealed PE-PUR foam in Sleepternity holds the same influence over the casual chain leading to payment from CMS. *United States ex rel. Main v. Oakland City*, 426 F.3d 914, 916 (7th Cir. 2005) (reasoning that a misrepresentation that is integral to a causal chain leading to payment meets causation "[despite] how the federal bureaucracy has apportioned the statements among layers of paperwork.")

Therefore, given this Court's broad interpretation of the FCA and its emphasis on the interconnectedness of causation and materiality, this Court should find that that Petitioner's misrepresentations about the materials used in its Sleepternity device aided in causing reimbursement, and ultimately, that Riley's reliance on the fraud-on-the-FDA theory is substantiated.

C. Fraud-on-the-FDA Can Survive the FCA's Heightened Pleading Standards as Required by Federal Rules of Civil Procedure 8(a) and 9(b).

Claims under the FCA involve allegations of fraud and are thus governed by both Federal Rules of Civil Procedure 8(a) and 9(b). In general, to comply with Rule 8(a), a complaint must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). FCA claims must also satisfy the heightened pleading standards outlined in Rule 9(b), which requires that the claims be pled with particularity. FED. R. CIV. P. 9(b). The elements of "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* Even with these heightened pleading standards, claims alleging FCA violations under fraud-on-the-FDA theory, can survive 12(b)(6) motions. Notably, "while not all fraud-on-the-FDA claims will survive the pleading stage, the theory of liability itself should not bar the claim if the claimant pleads facts with particularity that make it plausible the elements of the FCA can be met." Kelly Carter Zimmerer, *Health Fraud from FDA Approval to CMS Payments: Why Fraud-on-the-FDA Should Be a Viable Form of Liability Under the False Claims Act*, 62 U. Louisville L. Rev. 713, 741 (2024).

Here, Riley is not required to show at the pleading stage that Petitioner's conduct was material to and/or caused the government's payment for reimbursement claims. Instead, Riley need only plead each element in the complaint with particularity. There is no requirement under Rule 8(a) or 9(b) that requires Riley to prove Petitioner's fraudulent conduct led to a particular result. As Justice Ruzich stated in his concurrence to the Seventeenth Circuit's holding, "Because Riley has not indicated that she would be unable to prove causation between [Petitioner's] fraudulent conduct and CMS's payment decision, I would grant her the opportunity to provide such proof." R. at 40; *see*, *e.g.*, *Barnett v. Centoni*, 31 F.3d 813, 816 (9th Cir. 1994).

Ultimately, Riley's reliance on the fraud-on-the-FDA theory as a form of FCA liability is substantiated. In applying this Court's broadened interpretation of the FCA, Petitioner's conduct satisfies the requisite elements of a fraud-on-the-FDA claim in the context of implied false certification theory. Further, the fraud-on-the-FDA theory is able to survive the FCA's heightened pleading standards and, overall, this interpretation coincides with the purpose of the FCA. As such, this Court should AFFIRM the Seventeenth Circuit's holding.

CONCLUSION

The Seventeenth Circuit did not apply the presumption against preemption, and consequently erred in holding that the exceptions in subsection (b) and subsection (c) of Transylvania's immunity statute were preempted. This Court must AFFIRM the Seventeenth Circuit's denial of Petitioner's motion to dismiss,

but for the reason that the exceptions are neither expressly nor impliedly preempted by the FDCA. Holding as such would enable injured victims to recover against non-compliant medical device manufacturers without the unreasonable burden of federal findings of fraud.

Further, the Seventeenth Circuit correctly held that fraud-on-the-FDA is a viable theory of liability under the FCA. Its analysis properly applied this Court's precedent, and it correctly acknowledged that a claim brought under this theory can survive the FCA's strict pleading standards. Its holding coincides with the FCA's intent of working in tandem with the FDA and its purpose of comprehensively defending the government from fraudulent conduct.

For the foregoing reasons, Respondent respectfully requests that this Court AFFIRM the decision of the Seventeenth Circuit.

Respectfully Submitted,

Team No. 3312

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APPENDIX A

CONSTITUTIONAL PROVISIONS

U.S. CONST. art. VI § 2

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.

APPENDIX B

STATUTORY PROVISIONS

21 U.S.C. § 337. Proceedings in the name of the United States

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

21 U.S.C. § 360k. State and local requirements respecting devices

(a) 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 for human use any requirement—
(1) Which is different from, or in addition to, any requirement applicable under this chapter to the device, and

31 U.S.C. § 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;
. . . .

(b) **Definitions.**– For purposes of this section–
(2) the term "claim"–
(A) means any requirement 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 . . . .
. . . .

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

. . . . .

31 U.S.C. § 3730. Civil actions for false claims

(c) **Actions by private persons.**–

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasoning for consenting.

. . . .

(c) **Rights of the parties to qui tam actions.**–

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

. . . .

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. . . .

. . . .

(d) **Award to qui tam plaintiff.**–

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds for the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. . . .

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. . . .

. . . .

21 Trans. Comp. Stat. § 630.544. 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. § 630.545.

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,t he duty to comply with all 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. § 630.546.

(a) 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.

(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.

(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.