No. 24-9176

IN THE SUPREME COURT OF THE UNITED STATES

NOVEMBER 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 THE PETITIONER

Team #3313
Counsel for Petitioner

QUESTIONS PRESENTED

I. Whether federal law preempts state laws when claims arising under such laws require state courts to make decisions reserved to the executive branch of the federal government?

II. Whether a relator may use the fraud-on-the-FDA theory as a basis for liability under the False Claims Act when there is no indication from the FDA that it was defrauded?

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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. The opinion of the United States Court of Appeals for the Seventeenth District is also unreported but appears on pages 25-42 of the record.

CONSTITUTIONAL PROVISION

The following provision of the United States Constitution is relevant to this case:
The Supremacy Clause provides that the federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

STATUTORY PROVISIONS

The following provisions of the State of Transylvania are relevant to this case: 21 Trans. Comp. Stat. § 630.546(a), § 630.546(b), and § 630.546(c).

The following provisions of the United States Code are relevant to this case: 21 U.S.C. § 360k(a), 21 U.S.C. § 337(a), and 31 U.S.C § 3729(a)(1)(A), (B).

STATEMENT OF THE CASE

1. Statement of Facts

This case involves the federal preemption of the State of Transylvania's immunity exceptions for drug or medical device manufacturers. R. at 8. These immunity exceptions would allow the State of Transylvania to make decisions Congress reserved for the Food and Drug Administration (FDA). R. at 9. Additionally, this case pertains to the ability of a plaintiff to rely on a theory of fraud-on-the-FDA to bring a claim under the False Claims Act (FCA). R. at 6.

Riley's Condition. Riley Ortega is a citizen of Wohio, recently retired from military service as an artillery officer for the United States Army. R. at 3. Riley was diagnosed with post-

traumatic stress disorder (PTSD), which caused symptoms of insomnia and sleep apnea. R. at 3. Her somnologist prescribed Sleepternity, a continuous positive airway pressure (CPAP) machine to help alleviate her symptoms. R. at 3.

The Sleepternity Machine. Sleepternity, manufactured by Mednology, is a revolutionary machine that can be used to address both sleep apnea and insomnia. R. at 3. Sleepternity functions as a traditional CPAP machine while also providing additional features including an automatic pressure adjustment system to increase therapy comfort, a heated humidifier to reduce irritation and dryness, and an app to allow users to customize settings. R. at 3. Additionally, the mask comes with noise canceling headphones which release gentle electrical pulses to the user's brain, promoting relaxation and assisting the user to fall asleep. R. at 3.

The FDA approved Sleepternity for marketing as a Class III medical device on December 30, 2022. R. at 3-4. Because the device was approved for marketing by the FDA, the Centers for Medicare and Medicaid Services (CMS) began to provide coverage for the cost of using the device for individuals prescribed Sleepternity. R. at 4.

After receiving approval from the FDA, Mednology changed the sound dampening foam in the Sleepternity machine from silicone-based foam to polyester-based polyurethan (PE-PUR) foam. R. at 4. Riley believes that the PE-PUR foam degraded, causing her ongoing insomnia and sleep apnea. R. at 4-5.

Riley filed a claim against Mednology. R. at 6. Shortly after Riley filed her claim, Mednology voluntarily recalled the Sleepternity device from the market. R. at 7. The FDA did not pursue an investigation of Mednology's conduct. R. at 7.

Transylvania's Immunity Statute. Transylvania's state laws provide for common law tort liability, including product liability. R. at 7. However, the legislature also sought to shield

drug and medical device manufacturers from liability in cases where the FDA had approved the product. R. at 8. This was accomplished through an immunity provision which provides:

> 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). However, the legislature also enacted two exceptions to the immunity granted by subsection (a). R. at 8. Subsection (b) provides:

> 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.

Id. § 630.546(b). Additionally, subsection (c) provides: "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." *Id.* § 630.546(c).

The False Claims Act (FCA). Riley also seeks to hold Mednology liable through the FCA. R. at 1. The overall purpose of the FCA is to protect the government from paying fraudulent claims. R. at 22. The FCA does so by holding parties liable who submit false or fraudulent claims. R. at 22. Additionally, the FCA includes a *qui tam* provision, allowing an individual to bring a civil action for an FCA violation on behalf of themselves and the United

States Government. R. at 19. If the government elects not to intervene, the individual who initiated the FCA claim shall have the right to conduct the action. R. at 20.

1. Procedural History

District Court of Transylvania. Riley sued Mednology in district court alleging Mednology breached its duty of care and good faith in violation of Transylvania's products liability statute. R. at 6. Specifically, Riley alleged that Mednology failed to disclose to the FDA the modifications it made to the materials used in the sound abatement foams in Sleepternity and failed to warn about the dangers and risks associated with the presence of PE-PUR foams. R. at 6. Additionally, she used a "fraud-on-the-FDA" theory to bring an FCA action under the *qui tam* provision. R. at 6. She asserted that the FDA would not have approved Sleepternity had they known of Mednology's use of PE-PUR foams rather than silicone-based materials. R. at 6.

Mednology filed a motion to dismiss for failure to state a claim. R. at 9. First, Mednology contended that the immunity exception subsections were preempted by the Food, Drug, and Cosmetic Act (FDCA). R. at 9. Second, regarding the FCA claim, Mednology stated that the fraud-on-the-FDA theory was not a viable basis for bringing this claim. R. at 24. The court ultimately held that the two subsections of Transylvania's immunity statute were not preempted by federal law and denied the motion to dismiss on those grounds. R. at 24. However, the court granted the motion to dismiss the FCA claim, finding that the action could not be based on Mednology's fraudulent conduct. R. at 24.

Seventeenth Circuit. Both parties cross appealed the district court's decision granting in part and denying in part Mednology's motion to dismiss. R. at 25. Riley alleged that the district court erred in finding that she could not rest her FCA claim on Mednology's alleged fraudulent conduct towards the FDA. R. at 25. Conversely, Mednology argued that the district court erred in

finding that federal law did not preempt the immunity exceptions provided in subsections (b) and (c) of Transylvania's immunity statute. R. at 25.

The circuit court affirmed, although on different grounds, the district court's denial of Mednology's motion to dismiss. R. at 25. The circuit court held that while federal law preempts the two immunity exceptions, Mednology could not seek protection from the immunity statute if Sleepternity was not in compliance with the FDA's approval when it was marketed and sold. R. at 26. Therefore, the circuit court affirmed the district court's denial of the motion to dismiss Riley's state law action. R. at 26. In addition, the circuit court reversed the district court's granting of Mednology's motion to dismiss Riley's FCA claim. R. at 26. It reasoned that the district court erred by not analyzing whether the Supreme Court's precedent in *Universal Health Services v. United States ex rel. Escobar* applied to this case. R. at 26-27. It noted that had the court applied *Escobar*, it would have found that a plaintiff may rely on the implied false certification theory if the basis for the claim was the fraudulent obtention of FDA approval. R. at 26-27.

SUMMARY OF ARGUMENT

This Court should REVERSE the holding of the Seventeenth Circuit Court of Appeals. The court was correct in deciding that subsections (b) and (c) of Transylvania's immunity statute are preempted by the FDCA. However, the court erred in holding that Mednology's motion to dismiss should still be denied because the compliance portion of subsection (a) is preempted as well. Additionally, this Court should reverse the decision that Riley can base her implied false certification theory on a fraud-on-the-FDA claim.

I.

The FDCA preempts Transylvania's immunity exceptions and the compliance section of its immunity statute. Accordingly, this Court should rule in favor of Mednology's motion for dismissal of Riley's state law claims. The court was correct in holding that Transylvania's immunity exceptions are preempted by the FDCA. The FDCA preempts state laws which attempt to police fraud against the FDA, even when fraud-on-the-FDA is part of a larger tort claim. When examining issues of federal preemption, courts may choose to apply a presumption against preemption where issues of historic primacy of states' police powers are implicated. Such a presumption does not extend to state laws which ask state courts to make determinations reserved to the FDA. There is no significant difference between state law actions for fraud-on-the-FDA and state law tort actions requiring a finding of fraud-on-the-FDA as an element of a tort claim.

Additionally, the FDCA preempts the compliance portion of the Transylvania immunity statute. This preemption stems from the concept that courts should avoid inter-branch meddling and allow the FDA to police fraud claims, rather than inappropriately usurping executive authority. Finally, preemption of both the immunity exceptions and the compliance section of the statute promote agency efficiency and innovation that would otherwise be hindered by frivolous litigation and paperwork.

II.

A relator may bring an FCA action under an implied false certification theory. However, if the relator wishes to predicate the implied false certification theory on a finding of fraud-on-the-FDA, the finding of fraud must be made by the FDA itself, not by the court system. Here, Riley is asking the state court to make a finding that Mednology committed fraud-on-the-FDA to

use as the basis of her implied false certification theory. This is improper. Because the FDA never made a finding of fraud by Mednology, Riley is foreclosed from using fraud-on-the-FDA to support an implied false certification theory to bring her FCA claim.

The Seventeenth Circuit erred by holding that Riley's claim presented a matter of proof issue and thus deciding the claim did not need to be dismissed. Riley's claim does not present a matter of proof issue as it was well documented that the FDA was aware of Mednology's actions and still made the deliberate decision not to make a finding of fraud on the agency. The Seventeenth Circuit then prematurely applied *Escobar* on the assumption that fraud-on-the-FDA could serve as a basis for an FCA claim.

Furthermore, the Court incorrectly applied *Escobar* in finding Mednology's switching to PE-PUR foam to be material to the FDA's approval of and CMS's payment for Sleepternity. Riley offers no facts to support a causal link between Mednology's actions and the agencies' decisions. Therefore, the implied false certification theory is unsupported, and the claim should be dismissed.

STANDARD OF REVIEW

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).

ARGUMENT

I. THE DISTRICT COURT AND APPELLATE COURT ERRED BY DENYING THE MOTION TO DISMISS BECAUSE THE EXCEPTIONS AND COMPLIANCE SECTION OF THE TRANSLYVANIA IMMUNITY STATUTE ARE PREEMPTED BY THE FDCA.

To determine if a state statutory scheme is preempted by federal law, courts first decide whether a presumption against preemption should be applied. The court bases this decision on the legislative intent of the statutes and relevant judicial precedent, such as *Buckman* and *Medtronic* in the present case. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 34 (2001); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Then, utilizing the presumption determination, public policy considerations, and, here, the analyses established in the cases of *Garcia* and *Desiano,* the court considers the facts of the case to reach a conclusion on preemption. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

To begin, the Constitution's Supremacy Clause provides: the federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution *or Laws of any State to the Contrary notwithstanding*." U.S. Const. art. VI, cl. 2 (emphasis added). The Supremacy Clause serves as the basis for the principle of preemption, wherein state laws may be superseded by federal laws. *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).

Preemption may be express or implied ". . . and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Gade*, 505 U.S. at 98 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Express preemption occurs when a federal law explicitly specifies that no state laws may govern

the same domain. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001). Preemption will also apply where an actual conflict arises between a federal and a state law. *See, e.g., Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 232-36 (1947); *De Canas v. Bica*, 424 U.S. 351, 359-60 (1976). Even where no conflict occurs and state law is not expressly preempted, federal law may still impliedly preempt state law where courts determine that it was Congress's intent to occupy the entire regulatory field. *See Arizona v. United States*, 567 U.S. 387, 399 (2012); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

In analyzing cases of implied preemption, "the purpose of Congress is the ultimate touchstone." *See, e.g., Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992); *Gade*, 505 U.S. at 96; *Malone v. White Motor Corp.*, 435 U.S. 497 (1978). Because of this, the scope of a preemption statute must rest primarily on "a fair understanding of congressional purpose." *Cipollone*, 505 U.S. at 530, n. 27 (opinion of STEVENS, J.). In analyzing preemption, the purpose of the statutory scheme is key, "as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic*, 518 U.S. 470 at 485-86.

A. No Presumption Against Preemption Should be Applied When Analyzing Whether the FDCA Preempts Transylvania's Immunity Statute.

Courts may adopt a presumption against preemption by federal legislation in fields the states traditionally occupied. *Id.* at 485. This includes matters that fall within the States' police power, such as public health and safety regulations. *Id.* This presumption stems from the idea that Congress does not cavalierly preempt state law causes of action. *Id.*

Here, the federal statutory scheme in question is the FDCA, which authorizes the FDA to oversee and regulate the production, sale, and distribution of food, drugs, medical devices, and cosmetics. 21 U.S.C. § 301. The FDCA contains an express preemption provision which provides that states may not establish requirements that are "different from, or in addition to, any requirement applicable under [the FDCA] . . . ." 21 U.S.C. § 360k(a). Additionally, Section 337(a) of the FDCA provides that "all . . . proceedings for the enforcement . . . of this Act shall be by and in the name of the United States." 21 U.S.C. § 337(a). This Court interpreted Section 337(a) to impliedly preempt state laws that allow private litigants to recover under fraud-on-the-FDA claims. *Buckman,* 531 U.S. 341 at 352.

This Court addressed preemption of state tort laws by the FDCA in *Medtronic, Inc. v. Lohr,* and again in *Buckman Co. v. Plaintiff's Legal Comm.* In *Medtronic*, the Court applied a presumption against preemption. 518 U.S. at 486. However, the Court decided no presumption against preemption applied in *Buckman.* 531 U.S. at 346. While both cases contemplated the scope of federal preemption, *Buckman* is far more analogous to the present case and therefore no presumption against preemption applies here, just as none applied in *Buckman*.

In *Medtronic*, the plaintiff sued Medtronic, a medical device manufacturer, after his wife's pacemaker failed. 518 U.S. at 487. The plaintiff relied on Florida common law to recover damages from Medtronic. *Id.* Medtronic argued that the Medical Device Amendments of 1976 (MDA), a federal statutory scheme regulating medical devices, preempted state common law actions for negligence or failure to warn. *Id.* Medtronic argued that by passing the MDA, Congress meant to preclude any state right of action for relief from injuries resulting from a defective medical device. *Id.* Although Medtronic asserted that the express preemption provision under 21 U.S.C. § 360k(a)(1) preempted the plaintiffs' claims, the Court agreed with the

plaintiffs that state laws relying on common law liability were not preempted. *Id.* at 495. There, the Court concluded that a presumption against preemption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485.

On the other hand, the Court in *Buckman* held that no presumption against preemption applied because of differences in the challenged law to that at issue in *Medtronic*. *Buckman,* 531 U.S. at 343. Accordingly, it decided that the state law was preempted by the FDCA. *Id.* In *Buckman*, the plaintiffs were injured by orthopedic bone screws manufactured by the defendants. *Id.* The plaintiffs claimed that the manufacturer made fraudulent representations to the FDA during the process of obtaining approval to market the screws. *Id.* The plaintiffs' claim rested on the proposition that the fraudulent representations were a "but for" cause in their injuries, asserting that if not for the fraudulent representations, the FDA would not have approved the devices for marketing, and the plaintiffs therefore would not have been injured. *Id.*

To support its holding, the Court reasoned that "[p]olicing fraud against federal agencies is hardly "a field which the States have traditionally occupied," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Id.* Further, the Court surmised that ". . . the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. Cf. *Boyle* v. *United Technologies Corp.,* 487 U.S. 500, 504-05, 101 L. Ed. 2d 442, 108 S. Ct. 2510 (1988) (allowing pre-emption of state law by federal common law where the interests at stake are "uniquely federal" in nature)." *Id.* Because of the inherent federal nature of the relationship and in contrast to situations which implicate "federalism concerns and the historic primacy of state regulation of matters of health and safety,"

no presumption against preemption applied in *Buckman*. *Buckman*, 531 U.S. at 346-48. In other words, the state laws sought to regulate federal interests, not those in which the states have any substantial or historic power or interest, so it would have been improper to impose a presumption against preemption.

Here, unlike *Medtronic*, Mednology is not contending that a common-law cause of action is a "requirement" which alters incentives and imposes duties "different from, or in addition to," the generic federal standards that the FDA imposed. *Medtronic*, 518 U.S. at 486. Additionally, the statute at issue here does not deal with common law remedies for those injured by a medical device like the statute challenged in *Medtronic*. Rather, the issue here implicates questions of who can enforce compliance with the FDCA, just as the statute in *Buckman* did. Furthermore, the entirety of Transylvania's statute is based on and governed by the relationship between the FDA and the entities it regulates. *See* 21 Trans. Comp. Stat. § 630.546(a). The very premise of the regulation is to minimize liability for manufacturers who have obtained FDA approval for their device. The operative piece of the statute is the relationship between the FDA and the manufacturer, which is inherently federal.

The Transylvania immunity exception requires a finding of fraud-on-the-FDA. While there may have been no legislative intent for the FDCA to preempt common law causes of action for injuries by medical devices, the same does not hold true for common law causes of action resting on findings of fraud-on-the-FDA. There is absolutely no indication that Congress intended for states to involve themselves in the relationship between a federal agency and the subjects of its regulation.

Furthermore, Congress intended for the FDCA to be enforced solely by the FDA, not the states. The FDA has a plethora of investigation and enforcement mechanisms at its disposal to

address fraud against the Agency. This Court has reasoned that because Congress so amply empowered the Agency, there is no space for states to address the same concerns. *Buckman*, 531 U.S. at 349. For all these reasons, this Court should follow *Buckman* rather than *Medtronic* and affirm no presumption against preemption.

B. This Court Should Apply the *Garcia* Analysis Rather Than the *Desiano* Analysis to Determine That the Transylvania Immunity Statute is Preempted.

When deciding if subsection (b) and (c) are preempted by the FDCA, this Court should defer to the analysis used by the Sixth Circuit in *Garcia v. Wyeth-Ayerst Labs.* rather than the Second Circuit's analysis in *Desiano v. Warner-Lambert & Co.* This is because the *Garcia* court accurately relied on *Buckman* in deciding that no presumption against preemption applied.

In *Garcia*, the court asked whether a Michigan statute nearly identical to the one at issue here was preempted by the FDCA. *Garcia*, 385 F.3d at 964. In that case, the plaintiff was prescribed a drug for pain management which eventually caused her to suffer liver failure, requiring a liver transplant. *Id.* at 963. The plaintiff sued the drug's manufacturer for making and selling an unsafe drug. *Id.* The Michigan statute immunized manufacturers from liability in suits claiming that their products were unreasonably dangerous or defective "if the drug was approved for safety and efficacy by [the FDA], and the drug and labeling were in compliance with [the FDA's] approval at the time the drug left the control of the manufacturer or seller." Mich. Comp. Laws § 600.2946(5). The immunity was subject to exception if "the manufacturer intentionally withheld or misrepresented material information concerning the drug that it is required to be submitted under the Food and Drug Cosmetics Act and the drug would not have been approved, or the FDA would have withdrawn approval if the information was accurately submitted to the FDA . . . " Mich. Comp. Laws § 600.2946(5)(a).

The *Garcia* court reasoned that although the Michigan legislature provided an immunity exception for claims relying in part on fraud-on-the-FDA, as opposed to a specific cause of action for fraud-on-the-FDA, the difference was immaterial in light of *Buckman*. *Garcia*, 385 F.3d at 965-6. The court held that *Buckman* indicates any state tort remedies which require state courts to find fraud-on-the-FDA are preempted by the FDCA. *Id.*

However, the *Garcia* court clarified that while *Buckman* prohibits a plaintiff from invoking the exceptions based on state court findings of fraud-on-the-FDA, the same concerns do not arise when the FDA itself determines that a manufacturer committed fraud. *Id.* at 966. Allowing claims to rely on state court findings of fraud-on-the-FDA would implicate the same concerns of inter-branch-meddling noted by the *Buckman* Court. *Id. Cf. Buckman*, 531 U.S. at 351 ("Fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court."). Accordingly, *Garcia* held "the exemptions are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA)." *Id.* at 966.

In contrast, the *Desiano* court examined the same Michigan statute at issue in *Garcia* but held that the immunity exceptions were not impliedly preempted by the FDCA. *Desiano*, 467 F.3d at 98. There, the plaintiffs took a medication for diabetes manufactured by the defendant and subsequently suffered injuries to their livers. *Id.* at 88. The plaintiffs asserted various common law claims against the drug manufacturer. *Id.* Applying the logic of *Buckman*, the manufacturer moved to dismiss the claims, asserting that the fraud exception to Michigan's immunity statute was preempted by the FDCA. *Id.* at 89. The *Desiano* court held that no presumption against preemption applied. *Id. a*t 98. Further, it noted that because fraud-on-the-

FDA was one element of a larger tort law claim, rather than the entire basis of the claim, the statute was not preempted. *Id.* at 93.

The Seventeenth Circuit properly concluded that the reasoning used in the Sixth Circuit's *Garcia* decision, not that used in the Second Circuit's *Desiano* decision, applies to this case. To decide that the Michigan immunity statute was not preempted, *Desiano* assumes there is a significant difference between state law claims for fraud-on-the-FDA and state law claims that require proof of fraud-on-the-FDA as an element of the overall claim. *Desiano* ignores the purpose of preemption as applied in the *Buckman* decision, which is to guard the ability of the FDA to consistently police fraud against itself. The *Garcia* standard comports more closely with the legislative intent behind the FDCA, which is to empower the FDA to deter and punish fraud against the Agency while balancing other competing objectives. Allowing states to police fraud against the FDA, even when it is just one element of a claim, would disrupt this balance and undermine federal objectives.

Other courts have grappled with the circuit split on this issue and arrived at the same conclusion as the Seventeenth Circuit. In *Lofton v. McNeil*, the Fifth Circuit considered the validity of the two courts' competing analyses, ultimately finding the *Garcia* analysis more compelling. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012). The court highlighted that by requiring a plaintiff to "establish" a violation of FDA requirements "the plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury." *Id.* at 380. Accordingly, the court found *Garcia* to be more applicable and faithful to *Buckman* than *Desiano* and, applying the *Garcia* analysis, held that imposing state liability on a drug manufacturer for defrauding the FDA intruded on the competency of the FDA and its relationship with the entities it regulates. *Id.* Like the *Lofton* court, this Court should opt

to follow the *Garcia* analysis instead of the *Desiano* analysis, as it is more faithful to *Buckman* and preserves the legislative intent behind the FDCA.

1. The FDCA preempts the immunity exceptions provided in subsection (b) and subsection (c) of the statute.

Applying the *Garcia* analysis to the present case, subsection (b) and (c) of Transylvania's immunity statute are preempted by the FDCA. The analysis indicates that the exceptions are invalid when a state tort claim relies on state court findings of fraud-on-the-FDA, but not when the claim relies on findings made by the FDA itself. Furthermore, even if this Court chooses to apply a *Desiano* analysis, both subsections are still preempted by the FDCA.

Here, subsection (b) of Transylvania's immunity statute is preempted because Riley is asking the state court to find fraud-on-the-FDA. Nowhere in her complaint does Riley allege that the FDA officially found Mednology fraudulently obtained pre-marketing approval for its medical device. Additionally, there is no indication that the FDA determined that Mednology engaged in any fraudulent conduct. In fact, the FDA terminated its investigation of Mednology's conduct after the company voluntarily recalled Sleepternity from the market; this suggests that there were no facts related to fraud worthy of deeper investigation. Therefore, Riley is asking the district court to find fraud on the FDA and this reliance on judicial fact-finding causes the immunity exceptions to be impliedly preempted under *Garcia.*

In addition to preemption of subsection (b), the FDCA preempts the immunity exception provided in subsection (c). Although subsection (c) is concerned with failure to warn, the issue here is not whether federal law preempts state failure to warn claims, as the district court erred in finding. Rather, as noted by the Seventeenth Circuit, the issue is whether federal law preempts a provision neutralizing manufacturers immunity from state product liability claims. Accordingly, the same *Garcia* analysis applied to subsection (b) is also applicable to subsection (c).

This analysis indicates that subsection (c) would be preempted unless a plaintiff relies on the FDA's independent finding that Mednology violated requirements to warn about the dangers or risks of the medical device. *Garcia*, 385 F.3d at 966. Here, Riley's subsection (c) claim does not rely on FDA findings of Mednology's failure to warn. Rather, Riley's claim turns on state court findings of wrongdoing based on FDA requirements, just as her subsection (b) claim does. Therefore, under *Garcia*, subsection (c) is also preempted.

While this Court should apply the *Garcia* analysis because it most closely comports legislative intent and judicial precedent, an analysis under *Desiano* still indicates that subsections (b) and (c) of the immunity statute are preempted.

In applying a *Desiano* analysis to this case, it is essential to note the ways in which the Michigan statute differs from the Transylvania statute. While the Michigan statute allowed defendants to raise FDA approval as a defense against an immunity exception, the Transylvania statute clearly states that the party challenging the manufacturer's immunity bears the burden of rebutting the presumption of immunity. *See* 21 Trans. Comp. Stat. § 630.546(a). Thus, it is not a defense that the manufacturer may possibly raise, but instead an element of the claim that the proponent *must* prove. In relevant part, the statute provides: "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).

The *Desiano* decision rested heavily on the assertion that, because FDA approval would not be raised in every case, the Michigan statute did not implicate the concern of state courts retreading federal ground in each fraud-on-the-FDA action. Additionally, it reasoned that because the issue would be raised infrequently, companies would not feel compelled to submit

significantly more documentation to the FDA to avoid liability under state laws. However, here, the issue will arise constantly. Thus, the FDA will be burdened with additional documentation from every applicant, slowing the approval process. The facts the *Desiano* court utilized to reach its conclusion differ so substantially from the present facts that even if this Court applies a *Desiano* analysis, a holding of preemption is still required.

2. The FDCA preempts the compliance section of the statute.

While the Seventeenth Circuit correctly noted that subsections (b) and (c) of the immunity statute are preempted by the FDCA, it erred in deciding that the compliance section of the statute was not preempted and that therefore Riley could allege facts to rebut the statutory presumption of compliance. The Transylvania immunity statute only protects defendants who meet the condition that "the drug or medical device was in compliance with the United States Food and Drug Administration's approval at the time the drug or medical device left the control of the manufacturer or distributor." 21 Trans. Comp. Stat. § 630.546(a). Medical products are presumed to be in compliance with FDA approval standards and "the party challenging a manufacturer's or distributor's immunity . . . bears the burden of rebutting this presumption." *Id.* Accordingly, Riley pled facts to rebut the presumption that Mednology was in compliance with the FDA's approval of Sleepternity. However, the circuit court erroneously dismissed the notion that the compliance section of the statute is preempted by federal law.

In the Sixth Circuit case of *Marsh v. Genentech, Inc.*, the court examined the previously mentioned Michigan immunity statute and held that the compliance portion of the statute was preempted by federal law. 693 F.3d 546, 555 (6th Cir. 2012). Like Riley, the plaintiffs there argued that the immunity exceptions did not apply because of the defendant's "alleged non-compliance with the terms of the FDA's approval of" the drug it distributed by failing to submit

updated safety information to the FDA. *Id.* at 552-53. The court there concluded the assertion of non-compliance was premised on a violation of federal law, thereby implicating the relationship between the FDA and the entity it regulated. *Id.* at 555. Accordingly, the plaintiffs were asking the court to assume a policing role usually held by the FDA itself. *Id.* It further noted concerns raised in *Buckman* and *Garcia* related to inter-branch meddling between the court and an executive agency, before holding that the compliance section was preempted. *Id.* at 553, 555. Justice Moore emphasized that having the court determine compliance would "both usurp the agency's role and go beyond the court's institutional expertise." *Id.* at 544.

The facts of this case closely resemble those in *Marsh* and implicate similar policy concerns. As noted in *Marsh*, it is critical that this Court preserve the separation of powers doctrine and avoid interfering with the FDA's role of policing fraud consistent with its own internal objectives. Furthermore, the FDA is the only entity with the judgement, resources, and knowledge to decide complex compliance issues like Riley's Sleepternity claim. The FDCA was created to grant the FDA the authority that allows the agency to function properly; therefore, this Court should follow Sixth Circuit guidance and decide that the compliance portion of this statute is preempted along with subsections (b) and (c).

C. Allowing State Law Claims for Fraud-on-the-FDA to Stand Will Negatively Impact the FDA, Companies, and Consumers.

Allowing state laws such as Transylvania's immunity exceptions to stand will bury the FDA in frivolous paperwork and documentation, slowing down the FDA approval process and preventing much needed drugs and medical devices from reaching the market. Companies will bear the burden of submitting far more documentation than the FDA itself has deemed necessary for public safety out of fear they will be held liable in state court under unforeseen avenues of

liability. This will impose exorbitant costs on companies, diverting funds and resources from the actual development and deployment of life saving medical technologies.

The FDA is balancing a whole host of objectives when making regulatory and compliance decisions. An essential component of this decision-making is seeking to protect consumers while not interfering with healthcare professionals' knowledge and discretion in using drugs and medical devices for off-label uses. *Buckman* considered the practical reality for manufacturers attempting to comply with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes. 531 U.S. 350. The Court reasoned that allowing states to maintain their own tort regimes for fraud-on-the-FDA would dramatically increase the burdens faced by applicants to levels not contemplated by Congress when enacting the FDCA. *Id.* Allowing for that might discourage would-be applicants from seeking approval of their devices with beneficial off-label use for fear that such use might expose the manufacturer to unpredictable civil liability. *Id.* In other words, state-law fraud-on-the-FDA claims could cause the Agency's reporting requirements to deter off-label use despite the FDCA expressly disclaiming any intent to directly regulate the practice of medicine and even though off-label use is generally accepted. *See* 21 U.S.C. § 396 (1994 ed., Supp. IV); *Buckman*, 531 U.S. at 350-51.

Finally, one of the driving purposes of the FDCA is to give the FDA discretion to police fraud on the Agency; allowing states to maintain their own tort regimes for fraud-on-the-FDA would dramatically increase the burdens faced by applicants to levels not contemplated by Congress. *Id.* at 350. These laws must be preempted to protect companies from undue burdens, allow consumers to access necessary medical treatments, and preserve the legislative intent behind the FDCA in empowering the FDA with the discretion to police fraud and govern medical device regulation.

II. RILEY CANNOT RELY ON THE FRAUD-ON-THE-FDA THEORY TO BRING A CLAIM UNDER THE FCA WHEN THE FDA ITSELF HAS NOT FOUND FRAUD.

The FCA makes liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false statement or record material to a false or fraudulent claim." 31 U.S.C § 3729(a)(1)(A), (B). For a relator under the act's *qui tam* provision to bring a claim under the FCA, they must establish the following: (1) a false statement or fraudulent course of conduct; (2) made with scienter; (3) that was material, causing (4) the government to pay out money or forfeit money. *United States ex rel. Campie v. Gilded Sciences, Inc*., 862 F.3d 890, 899 (9th Cir. 2017) (quoting *United States ex rel. Hendow v. University of Phoenix,* 461 F.3d 1166, 1174 (9th Cir. 2006)). In addition, merely alleging regulatory violations is insufficient to trigger liability under the FCA. *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). Rather, the plaintiff must show that but for the false statements or claim, the government would not have paid or forfeited money for the product's use. *Id.*

Riley seeks to assert here, that the fraud-on-the-FDA theory can be used to establish liability by arguing that Mednology's conduct that led to fraudulent FDA approval caused the claim they submitted to CMS to be fraudulent under the FCA. Riley relies on the implied false certification theory as an avenue for liability. This theory states that in submitting claims to the government for payment, the individual or corporation impliedly certifies compliance with all requirements. *Universal Health Serv. Inc., v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). While this Court has held that the implied false certification theory can be used to establish liability under the FCA, circuit courts are split on whether the fraudulent FDA approval can serve as a basis for an implied false certification theory claim.

This Court should adopt the First Circuit's analysis in *D'Agostino v. ev3*, and find that because Riley cannot show the fraudulent conduct by Mednology caused the government to pay for Sleepternity use, she cannot rely on this theory to establish liability. *See* 845 F.3d 1 (1st Cir. 2016). However, even if this court sides with the Ninth Circuit's approach, Riley's claim still fails because as a matter of proof, she cannot show a causal link between the fraudulent conduct and the subsequent government payment.

A. Before Analyzing Riley's Claim Under *Escobar*, Riley Must Show That Fraud-on-the-FDA Can be the Basis for an Implied False Certification Theory.

Under the FCA, a claim includes requests for Government payment and reimbursement requests made to the receipts of federal funds under federal benefit programs. 31 U.S.C. § 3729(a). The implied false certification theory states that when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. *Escobar*, 579 U.S. at 180. If that claim fails to disclose the defendant's violation of a material statutory, regulatory or contractual requirement, the defendant has made a misrepresentation that renders the claim "false or fraudulent" under the FCA. *Id.* While Congress did not define "false or fraudulent" in the FCA, it is a "well settled term that absent other indication, Congress intends to incorporate the well-settled meaning of the common-law term it uses." *Escobar*, 579 U.S. at 177 (quoting *Sekhar v. United States*, 133 S.Ct. 2720, 2724 (2013)).

This Court has analyzed whether the implied false certification theory of liability can be used to bring an FCA claim. *See Escobar*, 579 U.S. at 176. The Court ultimately held that while the implied false certification theory can trigger FCA liability, it can only do so in limited circumstances. *Id.* at 180. Specifically, this Court articulated two conditions that must be met for a plaintiff to bring a valid FCA claim under this theory. *Id.* First, the claim must not merely request payment but make specific representations regarding the goods or services provided. *Id.*

Second, the defendant must disclose non-compliance with material statutory, regulatory, or contractual requirements. *Id.* If the defendant fails to do so, the misrepresentation is considered a misleading half-truth. *Id.*

However, before even analyzing whether Riley's claim fits into the limited circumstances that allows for FCA liability under this theory, this Court must determine whether fraudulent FDA approval can serve as the underlying basis for the implied false certification FCA claim. Specifically, Riley must show that Mednology's fraudulent obtention of FDA approval caused the government to pay for Mednology's claim.

B. Circuit Courts Are Split on Whether Fraud-on-the-FDA Can Serve as a Valid Basis for Bringing an FCA Claim.

Lower courts differ on whether under this theory, approval from the FDA, even if fraudulent, can establish the causation element of an FCA claim. Specifically, to bring a claim under the FCA, this Court has held that the alleged misrepresentation must be material to the government's payment decision. *See Escobar*, 579 U.S. at 191. Lower courts emphasized that the false or fraudulent conduct must not only be material to the government's decision but must cause the government to pay for the product's use. *Campie*, 862 F.3d at 899. Material in this context is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Put another way, the relator must show that the misrepresentation induced, or caused, not only the FDA's approval, but the subsequent payment by CMS.

In *D'Agostino*, a relator brought an FCA action against a corporation that developed, manufactured, and marketed medical devices. *D'Agostino*, 845 F.3d at 3. The claim was specifically brought against a product called Onyx, a liquid used to treat malformed brain vessels. *Id.* The plaintiff alleged that the defendant fraudulently obtained FDA approval for Onyx

by promoting to the FDA that the product would be used in a narrow manner, that there would be a rigorous training program for any physician using it, and that the manufacturer omitted critical safety information. *Id.* at 7. The First Circuit ultimately held that the plaintiff's allegation was insufficient to establish a causal link between the misrepresentations made to the FDA and the payments made by CMS. *Id.* at 7. The Court reasoned that the plaintiff's claim only showed that the fraudulent representations "could have" caused the FDA to approve the product. *Id.* The court dismissed the claim because the FDA never made an independent finding of fraud. *Id.*

The Ninth Circuit once again addressed the issue of causation in *Campie*. There, two drug company employees filed a *qui tam* suit against their former employer, Gilead, alleging that the HIV drugs manufactured by Gilead were not eligible to receive payment or reimbursement. *Campie*, 862 F.3d at 895. The relators alleged that Gilead concealed violations of FDA regulations pertaining to the sourcing of a compound found within the drug. *Id.* Specifically, the claim alleged that the FDA required the company to source one of the ingredients from registered facilities. *Id.* at 896. However, Gilead manufactured the ingredient at an unregistered facility. *Id.* The court noted that in this case, it was not a finding of fraud-on-the-FDA that allowed for claim to proceed, but rather that CMS itself was defrauded. *Id.* at 903. Nonetheless, The Ninth Circuit held that fraud-on-the-FDA can serve as a basis for liability if the plaintiff could plausibly prove that the agency was defrauded. *Campie*, 862 F.3d at 907. Therefore, the court held that claim presented a matter of proof issue rather than legal grounds to dismiss. *Id.* at 907.

1. This Court should side with the First Circuit's analysis in *D'Agostino* because it most accurately reinforces the requirements set forth in the FCA and the overall goals of the Act.

Riley's claim is highly analogous to the situation in *D'Agostino*. The allegations asserted by Riley fail to show a causal link between Mednology's conduct and the government's decision to pay for the use of Sleepternity. First, Riley points to nothing in her allegation to show the FDA would not have approved the product for marketing had it known that the materials used in Sleepternity were PE-PUR based. In fact, Riley reported the material switch to the FDA and yet it still discontinued its investigation into Mednology. R. at 7. Similarly, the decision to recall Sleepternity was based entirely on Mednology's own discretion; the recall was not required or dictated by the FDA. R. at 7.

In short, Riley's claim poses the same argument that the First Circuit found insufficient in *D'Agostino*. Riley's allegation poses no more certainty that Mednology's conduct caused the FDA's approval—and the subsequent payments by CMS—then the "could have" allegation set forth in *D'Agostino*. Riley asserts that the FDA's decision to approve the product was based solely on its belief that Sleepternity would use silicone-based materials. However, it is apparent that the FDA's decision was just as likely predicated on the fact that the product was ground-breaking in many other aspects including smartphone capability and a built-in heated humidifier.

In addition, an incident involving another company, Phillips, casts serious doubt on the assertion that Mednology's misrepresentation caused the FDA to approve the product. Phillips received FDA approval for its C-PAP machine, despite disclosing to the FDA that the machine contained PE-PUR materials. R. at 6. While Phillips voluntarily recalled the machine, the FDA's approval indicates that even if Mednology had represented to the FDA that Sleepternity used PE-

PUR materials, it would have still approved Sleepternity for marketing. R. at 6. This fact alone severs the causal link that Riley urges this Court to find.

The standard set forth by the First Circuit in *D'Agostino* involves crucial reasoning that this Court should adopt. The reasoning correctly balances the need for compliance with FDA requirements against the need to allow important technology to enter the marketplace despite insubstantial violations. By analyzing these claims under this lens, the *D'Agostino* court correctly articulated that allowing claims such as the one relevant here runs the risk of eliminating the value of FDA approval. *See D'Agostino*, 845 F.3d at 8 (explaining that if Court found that the FDA had been defrauded, despite the FDA not withdrawing approval for the product, would turn the FCA into a tool where a jury could retroactively eliminate the value of FDA approval).

It is crucial that the FCA is utilized in the way that the statute was intended to when it was first enacted. The FCA's long-standing purpose has been to deter "massive" frauds, not insubstantial compliance issues. *See United States v. Bornstein*, 423 U.S. 303, 309 (1976) (stating that the FCA was originally aimed principally at stopping the massive frauds perpetuated by large contractors during the civil war). Riley is essentially asking that the courts, rather than the FDA themselves find that fraud was committed, despite the FDA being in the best position to make that determination. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017).

This Court has also previously noted that requiring judges, rather than the FDA itself, to decide what caused the government's payment would lead to significant constraints on the FDA's responsibility to police fraud in general. *See Buckman*, 531 U.S. at 350. For these reasons, this Court should side with the First Circuit and hold that Riley cannot rest her claim on a fraud-on-the-FDA basis because the FDA did not itself find it was defrauded.

2. The Seventeenth Circuit erred in holding that this matter presented a matter of proof issue rather than legal grounds to dismiss and incorrectly applied *Escobar*.

The Seventeenth Circuit had all the facts necessary to grant the motion to dismiss and hold that Riley's claim failed to show that she was entitled to relief. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the pleaded factual content allows the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In addition, claims alleging fraud are held to a heightened pleading standard. *See* FED. R. CIV. P. 9(b). In alleging fraud, a party must state with particularity the circumstances constituting fraud or mistake. *Id.*

The Seventeenth Circuit implied that Riley's claim met the standards mentioned above, even though Riley's claim lacks particularity regarding her entitlement to relief as well as Mednology's fraudulent conduct. In addition, the Seventeenth Circuit prematurely applied *Escobar* without first addressing whether fraud-on-the-FDA can be used as a basis to establish the implied false certification theory to bring an FCA claim.

a. <u>The facts of this matter do not establish a matter of proof issue and should have been analyzed under the legal grounds to dismiss standard.</u>

The Seventeenth Circuit erred in finding that Riley's claim presented a matter of proof issue rather than legal grounds to dismiss. The court held *Campie* to be analogous and decided Riley could plausibly plead facts to establish a causal relationship between the fraudulent approval of Sleepternity and the decision by CMS to provide payment for the product's use. R. at 36. Therefore, the court held that there were no grounds for dismissal. R. at 37.

However, one factor easily distinguishes *Campie* from Riley's claim. In *Campie*, there was a factual dispute over whether the government knew about the violation that would have made the FDA approval fraudulent. 862 F.3d at 906-07. Because it may have been possible to show that the government regularly pays this particular type of claim despite its knowledge of violations, the claim presented a matter of proof issue. *Id.* at 907.

Here, Riley informed the FDA of Mednology's alleged violations. R. at 7. In addition, the FDA began, but ultimately terminated, an investigation into Mednology's conduct. R. at 7. This shows that the FDA knew of the suspected violations and still decided not to pursue any kind of punitive action. Therefore, the Seventeenth Circuit clearly erred in holding that Riley's claim presented a matter of proof issue.

b. The Seventeenth Circuit incorrectly applied *Escobar*.

The Seventeenth Circuit expressly stated that its decision to side with the Ninth Circuit's analysis in *Campie* was partly due to the court's application of *Escobar*. R. at 37. However, this application was premature. In *Escobar*, this Court held that the same theory that Riley seeks to use here, the implied false certification theory, can be used to establish liability in certain circumstances. 579 U.S. at 180. Although *Escobar* appears to be instructive for this claim, the allegation there was not based on the fraud-on-the-FDA theory. *Id.* Rather, the case involved a claim alleging that the Massachusetts Medicaid program itself was defrauded. *Id.* at 184. Likewise, the state Medicaid program there independently found that it had been defrauded. *Id.* While *Escobar* is instructive in analyzing the implied false certification theory, it is not instructive for determining whether the overarching theory of liability can be based on fraudulent FDA approval.

In articulating its decision, the Seventeenth Circuit sought to have non-FDA entities find that the FDA was defrauded even after the FDA made clear it did not believe that to be the case. If the FDA believed that Mednology had fraudulently obtained its approval, it is reasonable to think that one of two actions would have been taken: either (1) the FDA would have disapproved the product following its receipt of Riley's report, or (2) CMS would have requested reimbursement for paying claims based on the product's fraudulent approval. However, neither of these actions occurred and therefore the implied false certification theory is precluded here. Ignoring this fact, the Seventeenth Circuit prematurely applied *Escobar* to reach its incorrect decision.

C. Even if This Court Finds That Fraud-On-The-FDA Can Serve as The Basis for an Implied False Certification Theory, Riley's Claim Fails to Establish That Mednology's Violation Was Material Under *Escobar*.

The term "material" is defined having a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). This Court emphasized in *Escobar* that this materiality standard is demanding. *Escobar*, 597 U.S. at 194. This is because the FCA is not meant to serve as an "all-purpose antifraud statute." *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008). The purpose of the FCA is not to punish "garden-variety breaches of contract or regulatory violations." *Id.* Nor is it a means of imposing damages or other penalties for "insignificant regulatory or contractual requirements." *Escobar*, 579 U.S. at 196. Similarly, a violation is not material solely because the government would be entitled to refuse payment if it were aware of the violation. *Id.* at 195.

Proof of a requirement being material can include evidence that the defendant knows that the government refuses to pay claims based on noncompliance with certain requirements. *Id.* However, if the government pays a particular claim in full despite its actual knowledge that

certain requirements were violated, this is a strong sign that the requirements are not material. *Id.* Likewise, if the government does not withdraw approval, despite knowing of these violations, this is compelling evidence that the violations are not material. *Id.*

This Court analyzed what constitutes a material violation in *Escobar.* There, parents brought suit following their daughter's death while being treated at a mental health clinic in Massachusetts. *Id.* at 183. In violation of various Massachusetts state regulations, the clinic allowed unlicensed and unsupervised medical workers to care for the plaintiffs' daughter. *Id.* The daughter was diagnosed with bipolar disorder and was then prescribed medication that caused her to experience an adverse reaction which led to her death. *Id.* This Court held that the defendants could be held liable under the implied false certification theory because they made specific representations in their claim but omitted their violation of state licensing requirements. *Id.* at 186-87. This Court noted that the claim did more than merely demand payment; it omitted material information that caused the misrepresentations regarding compliance with state licensing requirements to be misleading half-truths. *Id.* at 188.

The Third Circuit in *United States ex rel. Petratos v. Genentech Inc.* also applied this Court's analysis from *Escobar*. In *Petratos*, the defendants produced a multi-billion-dollar cancer drug. 855 F.3d at 485. The plaintiff alleged that the defendant suppressed data that would have showed that the drug posed significant health risks. *Id.* The Circuit court analyzed whether the misrepresentation about compliance was material to the government's payment decision. *Id.* at 488. The court ultimately held that the plaintiff's claim did not establish materiality because there were no factual allegations showing that "CMS would not have reimbursed these claims had these deficiencies been cured." *Id.* at 490. The Court in *Petratos* further noted that the fact that the plaintiff had disclosed information to the FDA regarding the misrepresentation and that

in response, the FDA did not change its position on approval, was evidence that weighed heavily in showing no material violation. *Id.*

Applying this Court's precedent in *Escobar* to this matter, Riley's allegation fails to show that the violation in this case meets this demanding materiality standard. First, Riley's claim fails to point to any other instance in which the government has withheld payment upon realizing that a manufacturer was using PE-PUR materials. Further, Riley sent a report to the FDA outlining these misrepresentations. R. at 6. However, even after being notified of these alleged violations, the FDA discontinued its investigation into Mednology. R. at 7. This fact is analogous to the situation in *Petratos*, where the plaintiff reported the violation, and the FDA did not change its position on the product's approval. Additionally, while the Sleepternity product was recalled, the decision to do so was made completely within Mednology's own discretion. R. at 7. The FDA did not require the recall to take place, once again showing that even after the violations were reported, its stance on the product's approval had not changed.

Furthermore, another company, Phillips, used PE-PUR sound abatement foams. R. at 6. However, that product was still approved for marketing and, like Mednology, was not recalled by the FDA, but rather was recalled completely under their own discretion. R. at 6. Even if the FDA required a ban on PE-PUR materials, their response to both companies' use of the materials shows the violation is not material as they have not changed their position in light of the use of those materials. Overall, Riley's claim does not show that Mednology's use of PE-PUR materials in Sleepternity violated any material statutory, regulatory, or contractual requirement.

D. Even if This Court Finds the Materiality Element is Satisfied, Riley's Claim Still Fails as She is Unable to Establish the Causation Element Required to Bring This Claim.

This Court has explained that not only must the statutory, regulatory, or contractual violation be material, but the resulting misrepresentation must induce government's payment decision. *See Escobar*, 579 U.S. at 192. Therefore, here Riley must show that Mednology's misrepresentation about the sound abatement foam induced CMS' decision to pay for Sleepternity's coverage.

1. This court's decision in *Escobar* requires a causal link between the defendant's conduct and the product's approval.

This Court did not address the issue of causation in *Escobar* explicitly. *See Escobar*, 579 U.S. at 192-93 (discussing the materiality aspect of the plaintiff's claim). However, the language of this Court's decision in that matter indicates that a causal relationship between the material misrepresentation and the government's payment decision must be present. *Id.* Likewise, for FCA claims, circuit courts have adopted the requirement that the material misrepresentation causes the government's subsequent payment decision. *See Campie*, 862 F.3d at 899.

In his dissent to the Seventeenth Circuit's decision, Justice Ruzich correctly points out that the language of *Escobar* implicitly requires a causal link between fraudulent FDA approval and the government's decision to pay. *See Escobar*, 579 U.S. at 194-95. Although the *Escobar* court sought to analyze the materiality standard, it also highlighted the need for a causal link to be established. *Id.* at 192 (explaining that this claim also requires the misrepresentation to be material to the government's decision). In analyzing the materiality standard, the Court notes that materiality can be proven through evidence that the defendant "knows the government consistently refused to pay claims in the mine run of cases based on noncompliance with material requirements." *Id.* at 194-95. Put another way, materiality can be established if the

defendant *knows* that noncompliance with material requirements will cause the government not to pay the claim.

Additionally, when this Court addressed situations where materiality was likely not established, it explained:

> If the government pays a particular claim in full, despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 195. This Court is emphasizing that the non-compliance with a material requirement must *cause* the government's payment decision, a material violation alone is insufficient. The careful analysis in *Escobar* supports this view.

Riley fails to establish this causal link as there is no indication that the material violation, Mednology's switch to PE-PUR materials, caused CMS to pay for the claim. This is further evidenced by the fact that despite having knowledge of the violation, CMS has not requested reimbursement for the payments made to claims covering Sleepternity's use.

2. Allowing Riley to recover without establishing causation damages the purpose of the FCA and the decision-making capability of both the FDA and CMS.

Many courts, this one included, have warned of the potential issues of allowing unfounded claims under the FCA. For example, the First Circuit warned that not requiring a causal link to be established runs the risk of allowing juries to "retroactively eliminate the value of FDA approval." *D'Agostino*, 845 F.3d at 8. The First Circuit court there further warned that without a requirement to establish causation, state court claims could force the FDA withdraw products from the market despite the Agency itself seeing no reason to do so. *Id.* Additionally, this Court has explained that the FCA is not meant to serve as an all-purpose anti-fraud statute. *See*

Escobar, 579 U.S. at 179 (explaining that the materiality standard was adopted to ensure everyday regulatory violations were not punished under the statute).

To decide that Riley's allegation meets the burden of bringing a claim under the FCA is to ignore all the concerns that this Court and others have articulated in their previous decisions. Furthermore, if this Court were to find a causal link between Mednology's conduct and the FDA's approval, this decision would significantly impede the FDA's autonomy to decide which products are fit for approval. After all, the FDA knows its own requirements better than any other third party and CMS plays a crucial role in determining which products are worth covering. *See Petratos*, 855 F.3d at 489 (explaining that the CMS and FDA are best positioned to make high-level policy decisions, including market approvals).

The FCA is not designed to allow courts to question the decision-making of the FDA and CMS. These two agencies, the FDA and CMS, must carefully balance considerations regarding the approval and payment for products. For example, one of the most significant responsibilities is balancing a product's risks against its benefits. The FDA is comprised of medical and scientific experts, who are placed in the best position possible to make these difficult decisions. To allow courts to retroactively second-guess those decisions would disrupt this delicate balance and harm companies and consumers alike. Requiring a causal link to be established protects the FDA's autonomy from encroachment.

It would be inappropriate for this Court to second-guess federal agency decisions simply because Riley alleges misrepresentation could have played a part in approving the marketing of and payment for Sleepternity. The FDA and CMS are best suited to make these complex decisions. Therefore, this Court should not interject and find a causal link where the FDA and CMS have not indicated they were defrauded.

CONCLUSION

The immunity exceptions as well as the compliance section of the Transylvania's Immunity Statute are preempted by the FDCA. Additionally, Riley cannot base her implied false certification claim on a fraud-on-the-FDA theory. Therefore, her FCA action is precluded. For the aforementioned reasons, Petitioner respectfully requests that this Court reverse the decision of the Court of Appeals for the Seventeenth Circuit and remand the case for further proceedings.

Respectfully Submitted,

s/ Team 3313

Attorney for Petitioner

PROOF OF SERVICE

We certify that a copy of Petitioner's brief was served upon Respondents through the counsel record by certified U.S. mail return receipt requested, on this, the 9th day of September, 2024.

s/ Team 3313

Attorney for Petitioner