No. 24-9176

IN THE

SUPREME COURT OF THE UNITED STATES

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 OF PETITIONER

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I. Questions Presented

1. Does federal law preempt a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer fraudulently obtaining FDA approval or failing to comply with any FDA requirements?

2. May a relator rely on the fraud-on-the-FDA theory to bring a False Claims Act claim against a medical device manufacturer under the Act's *qui tam* provision?

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IV. STATEMENT OF THE ISSUES

Issue 1: Federal law will not preempt state law unless explicitly or implicitly stated by Congress. The Medical Device Amendments (MDA) added to the Federal Food, Drug, and Cosmetic Act (FDCA) provide an express preemption clause when state law conflicts with federal requirements. Does Transylvania's statutory exception regarding immunity conflict with federal law, triggering the MDA preemption clause in this case?

Issue 2: Federal agencies such as the FDA have long been deferred to regarding enforcements and approvals. The Federal Government has declined to take action regarding accusations of

Mednology's misrepresentation in this case. Is a private relator entitled to take *qui tam* action and bring a False Claims Act claim via fraud-on-the-FDA theory against Mednology to hold them accountable?

V. STATEMENT OF THE CASE

Riley Ortega (Ortega) filed suit in the Southern District of Transylvania against the medical device manufacturer Mednology. R. at 2. Ortega's claims include breaching the duty of care and duty to disclose modifications to the FDA pursuant to Transylvania's State products liability statute (21 Trans. Comp. Stat. § 630.545 (2024)) and violating the False Claims Act (31 U.S.C. §§ 3729–3733 (2024)) using fraud-on-the-FDA theory under the qui tam provision. (31 U.S.C. § 3730(b)). R. at 6.

Ortega is a retired US Army veteran who suffers from post-traumatic stress disorder and sleep apnea resulting from her service. R. at 3. Ortega's somnologist prescribed her the Sleepternity continuous positive airway pressure (CPAP) machine to treat Ortega's sleep apnea. R. at 3. Sleepternity is an FDA-approved Class III CPAP machine manufactured by Mednology, Inc. (Mednology). R. at 3. It is undisputed that after receiving FDA approval, Mednology replaced the silicone sound abatement foam in the Sleepternity device with a polyester-based polyurethane (PE-PUR) sound abatement foam to reduce production costs. R. at 4.

After using the Sleepternity CPAP machine, Ortega began experiencing asthma attacks. *Id*. Ortega was informed by her brother, who works as an assembly manager at Mednology, that the Sleepternity device had been modified with the PE-PER foam. R. at. 5. Ortega and her primary care physician concluded that the PE-PUR foam in the Sleepternity was the cause of her asthma attacks. *Id*. Ortega discontinued the use of the CPAP device and continues to have

chronic inflammation of her lungs from the frequent asthma attacks. *Id*. Ortega filed a suit against Mednology on June 21, 2023. R. at 6. Once Mednology was served with Ortega's complaint, Mednology promptly and voluntarily recalled Sleepternity from the market pursuant to 21 C.F.R. § 7.40(b). R. at 7. The FDA did not continue an investigation into Mednology for fraudulent conduct. *Id*.

The District Court dismissed Ortega's False Claims Act claim, citing the ruling in *D'Agostino*. R. at 21. In *D'Agostino*, the First Circuit ruled that the plaintiff could not assert an FCA claim because the FDA failed to withdraw approval of the medical device in dispute. *Id*. With facts similar to this case, the District Court concluded that Ortega's action could not rely fully on the allegations that Mednology fraudulently obtained FDA approval for its medical device Sleepternity. *Id*. The District Court denied Mednology's motion to dismiss Ortega's state law claims. R. at 24. The District Court determined that Ortega's state law claims were not preempted by federal law. *Id*.

On appeal, the Seventeenth Circuit Court of Appeals affirmed the denial of Mednology's motion to dismiss the state law claims on separate grounds and reversed and remanded the dismissal of Ortega's FCA claim. R. at 25. The Seventeenth Circuit held that (1) Federal law preempts the immunity exceptions in Transylvania's statute, but Ortega alleged sufficient facts to plausibly rebut the presumption that Sleepternity complied with FDA approval, and (2) Ortega's FCA claim based on the fraud-on-the-FDA theory could proceed, as the materiality issue presented a matter of proof rather than a legal ground for dismissal. R. at 26.

The U.S. Supreme Court granted certiorari to address two questions. First (1), does federal law preempt a statutory exception to a manufacturer's state-recognized immunity when

the exception is based on fraudulently obtaining FDA approval or failing to comply with FDA requirements? Second (2), may a relator rely on the fraud-on-the-FDA theory to bring an FCA claim against a medical device manufacturer under the Act's *qui tam* provision? R. at 43.

VI. SUMMARY OF THE ARGUMENT

This Court should reverse and remand the Seventeenth Circuit's ruling that Respondent has stated a claim under Transylvania's immunity statute. Ortega does not state a claim for which relief can be granted because the FDA has not found that Mednology committed fraud or failed to comply with the FDA. State claims requiring a court to determine whether a manufacturer has fraudulently obtained FDA approval are invalid because the "plaintiff asks a state court to find bribery or fraud on the FDA." *Garcia v. Wyeth-Ayerst Lab'ys,* 385 F.3d 961, 966 (6th Cir. 2004). Allowing states to determine violations against the FDA disregards the purpose of the MDA. The MDA asserts federal preemption for regulating medical devices unless the state claim parallels a federal claim. To parallel a federal claim, a federal agency needs to determine a defendant acted fraudulently against the FDA.

The FDA has not found fraud in this case; therefore, the immunity exception under 21 Trans. Comp. Stat. is preempted by the MDA preemption clause. As in *Buckman,* we ask this court to again find that "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

In light of the arguments presented, it is clear that relators should not be permitted to use fraud-on-the-FDA theories in qui tam False Claims Act (FCA) actions. The reversal of the

district court's granting of Mednology's motion to dismiss Riley's FCA claim was based on the materiality element delineated in Escobar, however we emphasize that several other requirements are not met for Riley to prevail on her FCA claim. First, such theories extend the FCA and its qui tam provision beyond their intended scope, transforming a statute designed to combat direct financial fraud against the government into a broad regulatory enforcement mechanism. *Buckman*, 531 U.S. at 349 n.6. Second, fraud-on-the-FDA theories fail to meet the rigorous materiality standard established by the Supreme Court in Escobar, as they rely on attenuated chains of causation and speculative reasoning about agency decision-making. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 8 (1st Cir. 2016). Finally, these qui tam actions are unnecessary and potentially counterproductive given the comprehensive framework of existing mechanisms for addressing fraud in FDA approvals, including the FDA's own enforcement tools and the option for government-led FCA actions. *Buckma*n, 531 U.S. at 353.

Allowing such theories would risk interfering with established regulatory processes, undermining agency expertise, and potentially leading to less effective and consistent outcomes in protecting public health. Therefore, we respectfully request that the Court rule in favor of Mednology on this issue, affirming that fraud-on-the-FDA theories cannot serve as a valid basis for *qui tam* FCA actions. Such a ruling would preserve the integrity of both the FCA and the FDA approval process, ensuring that these important mechanisms continue to serve their intended purposes effectively.

VII. ARGUMENT

A. Transylvania's Statutory Exception Regarding Immunity Conflicts With Federal Law Thereby Triggering The MDA Preemption Clause.

This Court reviews the Seventeenth Circuit's dismissal of Mednology's state law claims *de novo*. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed *de novo*."). *Id*. State claims are preempted when Congress has expressly or impliedly delegated authority to an agency. Congress delegated the regulation of medical devices to the Food and Drug Administration (FDA) through the express preemption clause in the Medical Device Amendments of 1976 (MDA). (21 U.S.C.S. § 301). The express preemption provision in the MDA applies to state statutes that add requirements "different from, or in addition to" federal provisions under the Food, Drug, and Cosmetic Act (FDCA). *Id*. State causes of action place additional requirements on medical devices because state litigation inevitably will result in different rulings among the states. However, the MDA does not apply broad preemption and allows for recovery when state claims are "parallel" to federal claims. Courts have clarified that "parallel" claims exist when the federal government has determined that there is fraud or failure to comply with the FDCA. Federal law preempts a statutory exception to a manufacturer's state-recognized immunity unless the federal government determines that a manufacturer fraudulently obtained FDA approval or failed to comply with any FDA requirements.

1. Congress Expressly Delegated The Power to Regulate Medical Devices Through The Enactment of The Food, Drug, And Cosmetic Act And The Medical Device Amendments.

The United States Supreme Court ruled in *Buckman* that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law." *Buckman,* 531

U.S. at 348. The conflict arises because Congress has provided the FDA the power to investigate, punish, and deter fraud against the Agency. By delegating police powers to the FDA, Congress has expressly prevented states from determining what they consider fraudulent activity against the FDA. Allowing state law claims solely based on noncompliance with the FDCA are preempted because the authority to bring such claims rests with "the Federal Government rather than private litigants." *Id.* at 349. *See Rice* v. *Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947) (Policing fraud against federal agencies is hardly "a field which the States have traditionally occupied."). *Id*. See *Lohr* v. *Medtronic Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) (holding that "preemption under the MDA cannot be defeated by a common lawsuit alleging a violation of the statutory standards"). *Id*.

Congress further clarifies the intention to ensure that the regulation of medical devices stays with the federal government through the enactment of the MDA. The MDA's preemption clause states:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act. (21 U.S.C. § 301).

The MDA classifies medical devices into three categories. *Id.* In this case, the device is a state-of-the-art Class III CPAP machine called Sleepternity. Since Sleepternity is different than other

CPAP machines, the FDA would have gone through a pre-market approval process (PMA) for Class III devices rather than the § 510(k) process, which approves medical devices that are substantially similar to other approved devices. *Buckman Extended: Federal Preemption of State Fraud-on-the-FDA Statutes*, 69 Food Drug L.J. 113, 119. Since Class III devices approved through the PMA process are challenged for their safety and not their similarity to other devices, they are "expressly preempted by the FDCA." *Id*. This includes the Transylvania immunity exception for manufacturer's non-compliance with the FDCA or fraudulently obtaining FDA approval because the FDA is the only party equipped to evaluate and determine compliance or fraud against itself.

Further, the Supreme Court recognized that "Congress could have applied the pre-emption clause to the entire FDCA...instead wrote a pre-emption clause that applies only to medical devices." *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 327 (2008). The enactment of the MDA is where the regulation of medical devices and drugs by the FDA splits. The lower court did not recognize this distinction in their analysis of *Marsh*. The Sixth Circuit in *Marsh* determined that preemption applied to a claim against a drug manufacturer under the Michigan products liability statute. *Marsh*, 693 F. 3d at 552. The lower court was not persuaded by the ruling of the Sixth Circuit because Marsh's claim was for "procedural non-compliance" with the FDA and not that the drug was adulterated. *Id*. at 553. The lower Court argues that Mednology's actions were "analogous to a drug being adulterated." (R. at 34). However, the Seventeenth Circuit missed that Marsh had a higher threshold needed to argue preemption because the controversy was about a drug and not a medical device.

The Seventeenth Circuit erred in its decision to apply preemption to part and not all of the Transylvania statute. Recognizing the statutory exception allows the Court to determine

Mednology's compliance with the FDCA. It is not a court's place to determine whether Mednology committed fraud against or failed to comply with the FDA. Doing so allows states to overstep the "inherently federal relationship" between medical device regulation and the FDA. *Marsh,* 693 F. 3d at 553.

2. State Claims That Rely on a Manufacturer's Fraudulent or Non-Compliant Actions With The FDA Are Preempted by Federal Law.

State claims that rely on a manufacturer's fraudulent or non-compliant actions with the MDA are preempted because state actions add to federal requirements and impact the federal-state relationship. If circuits apply inconsistent understandings of the MDA, they would essentially "be imposing requirements that are different from, or in addition to, those imposed by federal law." *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995). Further, tasking a court to evaluate the compliance with or fraud against the FDA regarding Class III medical devices would conflict with the FDA's "judgment and objectives" and overburden the FDA's ability to regulate in the "shadow of 50 States' tort regimes." *Buckman,* 531 U.S. at 350. *See also Reeves*, 44 F. 3d at 307 (Allowing juries to second-guess the FDA's enforcement contradicts the uniformity of compliance intended by the MDA.)

The dissent by Justice Ruzich in the Seventeenth Circuit ruling correctly identifies the concerns for inter-branch meddling that occurs when allowing state claims asserting fraud on the FDA to stand. (R. at 42). Ortega argues that the immunity exception in Transylvania's products liability statute is triggered by Ortega's assertion that Mednology fraudulently obtained FDA approval for its Sleepternity device. (21 Trans. Comp. Stat. § 630.546(a)-(c)). However, "Congress intended that the MDA be enforced exclusively by the Federal

Government." *Buckman*, 531 U.S. at 352. Therefore, Ortega cannot bring a private action against Mednology for fraud against the FDA unless the FDA itself finds fraud. See *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) ("We find nothing to indicate that preemption is conditional upon satisfactory compliance with the federal standard.") *Id*.

3. The Federal Government Needs to Determine That a Manufacturer Acted Fraudulently For a State Parallel Claim to Defeat Preemption.

The United States Supreme Court clarified that the MDA does not preempt all state claims and allows for remedies in claims that "parallel, rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. Establishing a parallel state claim requires a federal finding of fraud. *See also Marsh*, at 551 *(*requires proof of fraud found by the Agency for a state claim to succeed) *Id. See also Fragomeli v. Novartis Pharms. Corp. (In re Aredia & Zometa Prods. Liab. Litig.)*, 352 F. App'x 994 (6th Cir. 2009) (Sixth Circuit preempts state claims "unless some federal agency has already found the requisite fraud on the FDA"). *Id.*

For Riley to state a parallel claim under Transylania's statute, she would have to present evidence that the FDA had a finding of fraud against Mednology, which she has not. Accepting the respondents' arguments that Mednology committed fraud on the FDA would conflict with the United States Supreme Court's ruling in *Buckman*. The Court in *Buckman* refused to allow "any violation of the FDCA" to automatically support a state-law claim. *Buckman*, 531 U.S. at 353. *See Lofton*, 672 F. 3d at 373. ("Therefore, it was preempted by the Food, Drug and Cosmetic Act unless the FDA itself found fraud."). *Id*.

Ortega relies on the exception in the Transylvania product liability statute that states:

> "The immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the drug or medical device as required by the FDA." (21 Trans. Comp. Stat.§ 630.546(c)).

This exception requires a finding that Mednology failed to warn of dangers as required by the FDA. For the reasons above, a court is not permitted to determine if a manufacturer did not comply with the FDA.

B. Relator Riley Ortega May Not Rely On The Fraud-on-the-FDA Theory to Bring a False Claims Act Claim Against Mednology Under the Act's Qui Tam Provision.

The United States Court Appeals for the Seventeenth Circuit reviews dismissal of any claims under the False Claims Act *de novo*. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017). As the United States declined to intervene, Riley Ortega alternatively brought a False Claims Act claim against Mednology under the Act's *qui tam* provision for private relators, turning to the fraud-on-the-FDA theory as a way to hold them accountable for their misrepresentation. R. at 6. The issue at hand is whether the False Claims Act (FCA) allows relators to bring claims based on fraud-on-the-FDA theories, and whether it would be appropriate for a relator to do so under the Act's *qui tam* provision. Furthermore, private relator Riley Ortega does not meet the materiality and causation standard required for False Claims Act liability, particularly in the context of *qui tam* actions. Finally, this *qui tam* action based on the fraud-on-the-FDA theory is not necessary or appropriate given the existence of other mechanisms for addressing fraud in FDA approvals.

1. Fraud-on-the-FDA Theories Extend the False Claims Act and Qui Tam Provision Beyond Their Intended Scope.

The FCA and *qui tam* provision have traditionally been utilized only to the extent that they are truly necessary—that is, to the extent that there has been a veritable, material defrauding of the government and no other means of holding the manufacturer accountable. *Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*, 529 U.S. 765, 775 (2000); *United States v. Bornstein*, 423 U.S. 303, 324 n.11 (1976); *D'Agostino v. ev3, Inc.*, 845 F.3d 1 n.9. It has specifically been a whistleblower provision in cases of serious defrauding of the government (in direct connection with financial losses and its ability to recover those losses), not a broad statute meant to enforce all regulatory violations and compliance issues. *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266 (9th Cir. 1996); *See also United States ex rel. Steury v. Cardinal Health, Inc.,* 625 F.3d 262, 268 (5th Cir. 2010). It therefore follows that the main issue is whether the False Claims Act and its *qui tam* provision should be narrowly interpreted to apply only to cases of material, direct fraud against the government resulting in financial loss, or broadly construed to encompass regulatory violations and compliance issues, potentially overstepping into the domain of regulatory agencies and risking abusive litigation.

The FCA's *qui tam* provision, 31 U.S.C. § 3730(b), allows private individuals to bring suits on behalf of the government against those who have defrauded the government. However, statutory interpretation should also consider the statute's text, legislative history, and purpose. *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000). The Supreme Court has routinely held that the FCA's primary purpose is to indemnify the government against losses caused by misrepresentation. *Bornstein*, 423 U.S. at 309.

Qui tam provisions have roots in English common law, designed to incentivize private individuals to uncover fraud against the government. *Ex rel. Stevens*, 529 U.S. at 774. The FCA, including its *qui tam* provision, was enacted in 1863 to combat fraud by government contractors during the Civil War. *Id.* at 768. Historically, *qui tam* actions focused on direct financial fraud against the government, not regulatory compliance issues; in fact, FDCA 21 U.S.C. § 337(a) "…leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman*, 531 U.S. at 349 n.4.

Furthermore, the text of § 3730(b) allows a person to bring a civil action "for the person and for the United States Government" against anyone who violates § 3729. The legislative history of the 1986 amendments to the FCA indicates Congress intended to enhance the government's ability to recover losses from fraud, but nothing in the text or legislative history suggests Congress intended the *qui tam* provision to be used as a tool for policing regulatory compliance with agencies like the FDA. *Ex rel. Stevens*, 529 U.S. at 795. Thus, Fraud-on-the-FDA theories shift the focus from direct financial fraud against the government to alleged misrepresentations made during the regulatory approval process. Fraud-on-the-FDA theories undermine the FCA's fundamental purpose by shifting focus away from direct financial fraud against the government and failing to establish the requisite causal link for FCA liability. These theories extend the FCA beyond its intended scope as a tool for combating false claims for payment, potentially transforming it into a general anti-fraud statute or a means of enforcing regulatory compliance. Such an expansion is inconsistent with the text, history, and judicial interpretations of the FCA. These theories create an attenuated chain of causation between the

alleged fraud and any financial loss to the government, unlike traditional *qui tam* actions where the connection is direct.

Allowing such a shift would effectively turn *qui tam* relators into private regulators, a role not envisioned by the FCA's text or legislative history. This expansion of *qui tam* actions could interfere with the FDA's regulatory discretion and enforcement priorities, potentially undermining the agency's effectiveness. Additionally, there is potential for abusive litigation and a corresponding chilling effect on medical device innovation. Based on the historical context, statutory text, and legislative intent, the *qui tam* provision of the FCA should not be interpreted to allow claims based on fraud-on-the-FDA theories. Such an interpretation would exceed the intended scope of *qui tam* actions and potentially interfere with established regulatory processes.

2. Ortega's Fraud-on-the-FDA Theory Claim Does Not Meet the Materiality Standard Required for False Claims Act Liability.

In the present case, Riley Ortega brings a *qui tam* action against Mednology, alleging that the company fraudulently obtained FDA approval for its Sleepternity device by misrepresenting the materials used in its construction. Ortega contends that this alleged fraud led to government payments through Medicare and Medicaid that would not have occurred had the true facts been known. Consequently, the issue at hand is whether Ortega is entitled to a fraud-on-the-FDA theory claim, given whether Mednology's fraudulent conduct satisfied the materiality element of liability under the FCA.

The FCA defines "material" 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). In *Universal Health Services v. United States ex rel. Escobar*, the Supreme Court held that a) the materiality

standard for FCA claims is "demanding" and "rigorous," b) a misrepresentation is not material merely because the government designates compliance with a particular requirement as a condition of payment, c) materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation, and d) 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. *Ex rel. Escobar,* 579 U.S. 176. Lower courts have further refined the materiality standard, holding that a) materiality is not established where the government continues to approve and pay for medications after learning of alleged regulatory infractions, and b) mere regulatory non-compliance does not equate to materiality under the FCA. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017); *United States ex rel. Nargol v. DePuy Orthopaedics, Inc*., 865 F.3d 29 (1st Cir. 2017).

Fraud-on-the-FDA theories involve alleged misrepresentations made during the FDA approval process, not directly in claims for payment. Moreover, the False Claims Act is not "an all-purpose anti fraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations:

> A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.
> *Ex rel. Escobar*, 579 U.S. 176 at 194.

Fraud-on-the-FDA theories essentially treat FDA regulatory compliance as a condition of payment, which Escobar explicitly rejected as sufficient for materiality. These theories blur the line between regulatory infractions and false claims, a distinction that courts have consistently maintained. To establish materiality, a relator would need to prove that the FDA would not have approved the device if it had known the truth, and that CMS would not have paid for the device without FDA approval. This requires speculative reasoning about agency decision-making, which courts are generally reluctant to engage in. The materiality of alleged misrepresentations to the FDA involves complex scientific and regulatory considerations, and Courts have generally deferred to agency expertise in such matters, making it difficult for a relator to establish materiality independently.

Fraud-on-the-FDA theories are unlikely to meet the demanding materiality standard established by Escobar and subsequent cases. The attenuated connection between alleged misrepresentations to the FDA and government payment decisions, coupled with the government's continued payment in many such cases, strongly suggests that these theories fail to establish materiality under the FCA. Therefore, relators should not be permitted to bring qui tam actions based on fraud-on-the-FDA theories, as they cannot satisfy this crucial element of FCA liability.

3. *Qui Tam* Actions Based On Fraud-on-the-FDA Theories Are Not Necessary or Appropriate Given The Existence of Other Mechanisms For Addressing Fraud in FDA Approvals.

The proliferation of *qui tam* actions based on fraud-on-the-FDA theories raises a critical question: Are such actions necessary or appropriate given the existing mechanisms for addressing fraud in FDA approvals? This issue implicates fundamental principles of agency

discretion, regulatory expertise, and the proper balance between administrative and judicial enforcement of federal laws. It also touches on the broader question of whether expanding the use of *qui tam* actions in this context could potentially undermine the established regulatory framework and lead to less effective and consistent outcomes in addressing fraud in FDA approvals.

The Food, Drug, and Cosmetic Act (FDCA) provides the FDA with various enforcement tools, including the power to withdraw approval of medical devices (21 U.S.C. § 360e(e)), authority to seek injunctions (21 U.S.C. § 332), and criminal prosecution for fraud (21 U.S.C. § 333(a)(2)). The FDA also has the authority to refer cases to the Department of Justice for civil and criminal prosecution (21 U.S.C. § 337). As previously stated, in *Buckman* the Supreme Court ruled that the Federal Government, not private relators, can act against manufacturers for non-compliance—the FCA and its *qui tam* provision is reserved only for true defrauding of the government that meets the materiality standard. *Buckman*, 531 U.S. 341 (2001). That being said, Courts have generally taken the preferable action of deferring to agency discretion in regulatory enforcement matters. *Heckler v. Chaney*, 470 U.S. 821, 831-2 (1985).

The FDA should still have the discretion to enforce in this case, recognizing that agencies are best positioned to allocate their limited resources and set enforcement priorities. *Qui tam* actions based on fraud-on-the-FDA theories could undermine this principle by allowing private litigants to second-guess agency enforcement decisions. The FDA has a comprehensive set of tools to address fraud in the approval process, including the power to withdraw approval, seek injunctions, and pursue criminal charges. These tools allow the FDA to respond flexibly and proportionately to different types and degrees of fraud or misrepresentation. Moreover, the FDA's scientific and regulatory expertise makes it better equipped than courts to evaluate the

significance of alleged misrepresentations in the complex approval process. The FDA can refer cases to the DOJ for civil or criminal prosecution when it deems necessary; this mechanism allows for serious cases of fraud to be addressed through the judicial system while maintaining the FDA's primary role in overseeing the approval process. Additionally, DOJ prosecutions benefit from the combined expertise of FDA regulators and federal prosecutors, likely leading to more effective outcomes than *qui tam* actions.

In general, it is preferable that FCA actions are taken by the government as it can bring FCA actions directly if it believes fraud in FDA approvals has led to false claims. This approach allows the government to pursue FCA cases strategically, focusing on instances where there is a clear link between fraud in approvals and false claims for payment. Government-led FCA actions are less likely to interfere with FDA regulatory processes than *qui tam* actions brought by private relators, and allowing *qui tam* actions based on fraud-on-the-FDA theories could interfere with the government's ability to balance competing regulatory priorities. *Qui tam* actions might conflict with ongoing FDA investigations or enforcement actions, potentially hampering the agency's efforts. For example, multiple *qui tam* actions could lead to inconsistent outcomes and create uncertainty for regulated entities, unlike the more coordinated approach possible through existing mechanisms.

The existing mechanisms for addressing fraud in FDA approvals, including FDA enforcement tools, DOJ referrals, and government-led FCA actions, provide a comprehensive and well-established framework for dealing with such issues. These mechanisms respect agency expertise, maintain regulatory flexibility, and allow for coordinated enforcement efforts. In contrast, *qui tam* actions based on fraud-on-the-FDA theories risk interfering with these established processes, potentially leading to less effective and less consistent outcomes.

Therefore, such *qui tam* actions are not only unnecessary but could be counterproductive to the overall goal of ensuring the integrity of the FDA approval process and protecting public health.

VIII. Conclusion

We respectfully ask this Court to reverse and remand the lower Courts ruling in favor of Mednology, ordering the dismissal of all Ortegas claims made under the Transylvania product liability statute including the exception provisions. Allowing courts to operate as factfinders in state claims regarding PMA approved Class III medical devices would violate the Federal- State relationship.

Additionally, we ask this Court to reverse and remand the lower Courts ruling, in favor of Mednology, dismissing Ortega's assertion that a relator may use fraud-on-the-FDA theories in *qui tam* False Claims Act (FCA) actions. This would affirm that fraud-on-the-FDA theories cannot serve as a valid basis for *qui tam* FCA actions.