No. 23-1738

In the Supreme Court of the United States

MEDNOLOGY, INC., *Petitioner*

-v-

UNITED STATES EX EL. RILEY ORTEGA, *Respondent*

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

BRIEF IN SUPPORT OF RESPONDENT

Team 3319
Counsel for Respondent,
Riley Ortega

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

SECONDARY SOURCES

CONSTITUTIONAL PROVISIONS

QUESTIONS PRESENTED

I. Does the Food Drug and Cosmetics Act preempt state products liability actions when the elements of those actions focus upon the relationship between the consumer and the manufacturer, rather than between the manufacturer and the FDA?

II. May a relator rely on the fraud-on-the-FDA theory to bring a False Claims Act's *qui tam* provision when a manufacturer conceals safety risks or misrepresents compliance during the FDA approval process, causing the government to pay for unsafe medical devices?

OPINION BELOW

The opinion of the United States Southern District Court of Transylvania is unreported but appears on pages 2-24 of the record where the District Court DENIED the Respondent's motion to dismiss. The opinion of the United States Court of Appeals for the Seventeenth Circuit is also unreported and appears on pages 25-42 of the record where the circuit court AFFIRMED District Court's denial of Petitioner's motion to dismiss but REVERSED and REMANDED the lower court's decision on granting Petitioner's motion to dismiss Respondent's False Claims Act claim.

CONSTITUTIONAL PROVISIONS AND RULES

This case involves the application of the Food and Drug Cosmetics Act *See* App. A. and the False Claims Act. *See*. App. B.

INTRODUCTION

I. STANDARD OF REVIEW

Generally, this Court reviews questions of law *de novo* and questions of fact for clear error. *Monasky v. Taglieri*, 140 S. Ct. 719, 730 (2020). Thus, "questions of law regarding preemption are reviewed *de novo*." *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012). Finally, issues of dismissal regarding claims brought under the False Claims Act are reviewed *de novo*. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017).

II. SUMMARY OF ARGUMENT

This case is about ensuring that the relationship between manufacturers and customers has legal recourse. Regardless of the Food and Drug Administration's ("FDA") federally granted powers, customers who have standing deserve the legal ability to file claims. State legislatures that pass laws to protect this right infringe no harm upon federal agencies – especially when the agency, for whatever reason, refuses to act. This Court will determine whether manufacturers of medical devices may be held liable for submitting product designs one way, then building them differently to cause foreseeable injuries.

The Seventeenth Circuit's preemption analysis must be reversed because both an express preemption analysis and an implied preemption analysis concludes that the FDCA does not preempt the Transylvania products liability statute provision that provides an exception to state-granted immunity for manufacturers. First, the very meaning of "device" is an issue in the case at bar. The Seventeenth Circuit's reasoning presumes that there was a "device" within the meaning of the FDCA to apply to this

case. 21 U.S.C. §321(h) Raw materials, however, are not "devices." *Id.*; *see Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219 (6th Cir. 1995). However, even if there is a device, the state claims do not add duties that are "different from, or in addition to" duties provided under the FDCA. 21 U.S.C. §360(k)(a).

The jurisprudence in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) does not squarely apply to this case for two reasons: the facts do not line up, and the causes of action differ too greatly. While the facts in *Buckman* concerned devices, the facts in the present case concern raw materials. The causes of action are notably different as well: the Transylvania statute provisions in question do not involve "fraud-on-the-FDA" claims in an element for a cause of action. Instead, any fraudulent behavior that a manufacturer may have performed towards the FDA merely provides evidence that can overcome state-recognized immunity. In other words, the primary focus of the causes of action that Ms. Ortega pleads concerns the relationship between Mednology and herself – not Mednology and the FDA.

Even if this Court finds that there is implied preemption, it should still affirm the lower court's denial of Petitioner's motion to dismiss because to hold otherwise would ensure the existence of a legal loophole for manufacturers to avoid liability. The facts before this Court would provide an easy blueprint for future manufacturers to broadcast misrepresentations to the FDA and avoid any and all liability, so long as they pull their products before the FDA completes an investigation.

Because the Transylvania immunity provisions do not use misrepresentation to the FDA as an element of a cause of action, they survive the presumption over

preemption. The analysis set forth in *Desiano v. Warner-Lambert & Co.*, 547 F.3d 85, (2d Cir. 2006) correctly interprets the scope of *Buckman* to specifically apply to "fraud-on-the-FDA claims," which is not at issue in a preemption question.

Finally, concerns with infringing upon the reserved police powers of the States require this Court to rule narrowly to the facts before it and hold that state immunity exceptions may exist in state codes without risk of federal preemption. *Desiano, Metronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996), and *Buckman* emphasize the importance of state police power, and denying Mednology's motion to dismiss would rule consistently with both cases.

Among the tension between federal preemption and state police powers, this Court must carefully scrutinize whether Ms. Ortega demonstrated enough issues of material fact to deny Mednology's motion to dismiss. The District Court correctly identified which cases are more on point here and held that the presumption against preemption preserves Ms. Ortega's causes of action. Although the Seventeenth Circuit incorrectly reversed the District Court's finding, it nonetheless correctly held that Mednology's motion to dismiss must be denied, and this Court should do the same.

Furthermore, the FCA imposes liability on medical manufacturers that knowingly submit false claims to the government for payment, particularly when claims implicate federal healthcare programs such as Medicare and Medicaid. 31 U.S.C.A. §§ 3729-30 (West). For a successful FCA claim, a relator must prove: (1) a false statement or fraudulent course of conduct; (2) knowledge of the fraud (scienter);

(3) materiality; and (4) that the fraud caused the government to pay money. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999); *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 899 (9th Cir. 2017). The materiality and causation requirements are the central issues in Ms. Ortega's case.

The FCA's broad reach keeps companies accountable for fraud that may not be facially evident in government claims but nonetheless affects government payments *Campie*, 862 F.3d at 899. To meet the materiality requirement, the fraudulent conduct must have the potential to influence the government's decision to pay claims. *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182 (2016). Mednology's blatant omission of its substitution of an FDA-approved silicone-based foam with a cheaper, hazardous PE-PUR foam for its Sleepternity CPAP machine is not a mere minor violation, but rather a fundamental modification that jeopardizes public safety.

Mednology's omission was material to both FDA approval and the government's decision to reimburse claims for the device. The FDA's previous recall of devices containing the same hazardous foam demonstrates that this omission would have significantly influenced the government's decision R. at 4. Mednology's fraudulent conduct meets the materiality standard established in *United States ex rel. Krahling v. Merck & Co.* 44 F. Supp. 3d 581 (E.D. Pa. 2014), where fraudulent misrepresentations about a medical device's safety were regarded as material to governmental payments. The undisclosed substitution of the foam meets the materiality requirement because it fundamentally altered the safety standards of the CPAP machine, which were essential for CMS reimbursement.

Moreover, under the FCA's *qui tam* provision, a relator satisfies the causation requirement upon demonstrating that false claims submitted by a healthcare provider or manufacturer caused the government to make payments it otherwise would not have made. *United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021). Additionally, in *Campie*, the Ninth Circuit held that fraudulent statements made to the FDA that led to government payment met the causation requirement, even if the FDA did not recall the device or revoke its approval. 862 F.3d at 899. This established causality standard applies to Ms. Ortega's case, where Mednology's fraudulent omission and concealment of the foam substitution directly influenced the FDA's approval and subsequent CMS payments. The causal link remains unbroken because the fraud was crucial to the government's decision to pay for Sleepternity devices. *Id.; see also In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II)* 332 F. Supp. 3d 927 (D.N.J. 2017).

Finally, as a matter of public policy, the fraud-on-the-FDA theory aligns with the FCA's targets of promoting transparency and accountability, especially in a healthcare system with over $4.5 trillion in annual expenditures. Fred D. Ledley et al., 323 J. Am. Med. Ass'n 834, 837 (2020). To further bolster public policy in favor of Ms. Ortega's claim, the DOJ has recently endorsed the fraud-on-the-FDA theory, stating that fraud involving FDA approval can viably form the basis for FCA claims, particularly when concealed safety threats lead to government expenses. *U.S. ex rel. Crocano v. Trividia Health Inc.*, 615 F. Supp. 3d 1296 (S.D. Fla. 2022). The DOJ's

position highlights the government's commitment to holding companies accountable for fraudulent conduct. By allowing Ms. Ortega's fraud-on-the-FDA FCA claim to proceed, this Court would signal that public safety takes precedence over corporate profit, further supporting whistleblowers acting as safeguards of regulatory integrity. Therefore, Ms. Ortega's fraud-on-the-FDA theory is viable under the FCA's *qui tam* provision.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

Wohio citizen Riley Ortega, as a result of her service in the United States Army, developed Post-Traumatic Stress Disorder ("PTSD"). R. at 3. One manifestation of her PTSD is chronic insomnia. R. at 3. To resolve this symptom, her doctor prescribed, and her U.S.-funded healthcare insurance covered payment for, a device manufactured by Mednology known as Sleepternity. R. at 3-4. Sleepternity is a type of continuous positive airway pressure ("CPAP") machine. R. at 3. Sleepternity helps users fall asleep by emitting specific frequencies of soundwaves that the user hears through the headset portion of the Sleepternity device. R. at 3.

When Mednology submitted its design of Sleepternity to the FDA, the makeup of the headset portion was of a silicone-based foam. R. at 4. Shortly after receiving FDA approval, but before mass distribution, Mednology modified the makeup of the headset from silicone to polyester-based polyurethane ("PE-PUR") foam, without informing the FDA. R. at 4. Unlike the silicone-based foam, the PE-PUR foam may emit volatile organic compounds ("VOCs"), small enough in size for users to inhale and cause health problems, such as asthma attacks. R. at 4.

After she began using her Sleepernity device, Riley developed asthma attacks, and promptly sought treatment in an emergency room. R. at 4. After discussing her health and medications, the on-call physician recommended that Riley stop using her Sleepternity device. R. at 4-5. While her asthma attacks subsided, Riley's lungs were chronically inflamed as a result of the asthma attacks, and the insomnia she experienced before using Sleepternity returned. R. at 5.

After Riley's brother, an assembly worker employed at Mednology, informed her of the switch from silicone to PE-PUR foam, Riley conducted her own research. R. at 5. She concluded that the polyester in her device broke down, forming types of isocyanate, a compound that Riley is allergic to. R. at 5. Breathing in the isocyanate, a VOC emitted from the PE-PUR in the Sleepternity device, likely led to her asthma attacks and inflamed lungs, forcing her to choose between her ability to breathe and her ability to sleep. R. at 5-6.

II. PROCEDURAL HISTORY

In June 2023, Ms. Ortega initiated a product liability lawsuit against Mednology asserting that the company fraudulently secured FDA approval for its Sleepternity CPAP medical device when it substituted the approved silicone material for PE-PUR foam. R. at 2. Ms. Ortega asserts that that Mednology violated its duties under Transylvania's product liability statute when it failed to disclose the material change to the FDA and by neglecting to warn consumers of the new material's associated risks. *Id.* Additionally, Ms. Ortega brings a claim under the FCA's *qui tam* provision, relying on a fraud-on-the-FDA theory. R. at 2-3. Although the United States government declined to intervene in the lawsuit against Mednology, Ms. Ortega asserts that the FDA would not have approved the CPAP device had it been aware of the material change to the machine. R. at 6.

Upon Ms. Ortega's service of the complaint, Mednology recalled the CPAP machine, which halted FDA investigations into the company's fraudulent conduct. R. at 7. In response to the complaint, Mednology filed a motion to dismiss, claiming

immunity under Transylvania's statutory protection for FDA-approved medical devices. R. at 9. On October 15, 2023, the Southern District Court of Transylvania addressed Mednology's motion to dismiss Ms. Ortega's claims. R. at 24. Mednology sought dismissal on two grounds: federal preemption of Transylvania state law under the FDCA and the applicability of the fraud-on-the-FDA theory under the FCA. *Id,*. United States District Judge Burns DENIED Mednology's motion to dismiss Ms. Ortega's state law claims, holding that federal law did not preempt the state's product liability statute and the misrepresentation statute applied. *Id.* Judge Burns also DISMISSED Ms. Ortega's FCA fraud-on-the-FDA claim. *Id.* Both parties appealed. R. at 25.

On April 1, 2024, the United States Court of Appeals for the Seventeenth Circuit issued a decision, AFFIRMING in part and REVERSING in part the district court's ruling. *Id.* The Appellate Court ruled in favor of Ms. Ortega on the FCA claim but ruled partially in favor of Mednology by finding that state law immunity statutory exceptions were preempted by federal law. R. at 42. Following the appellate decision, Mednology petitioned the Supreme Court of the United States for review on August 1, 2024. R. at 43.

ARGUMENT

I. THE FDCA DOES NOT PREEMPT TRANSYLVANIA'S PRODUCTS LIABILITY IMMUNITY PROVISIONS.

The Seventeenth Circuit improperly analyzed the preemption issue and improperly reversed the District Court's analysis. The lower court should have first examined express preemption before considering possible implied preemption. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) does not wipe out express preemption analysis.

A. A PROPER PREEMPTION EXAMINATION WOULD FIRST FIND THAT THERE IS NO EXPRESS PREEMPTION AT ISSUE, BECAUSE 1) THERE IS NO "DEVICE" AT ISSUE WITHIN THE MEANING OF THE FDCA, AND 2) EVEN IF THERE IS A "DEVICE," THE STATE CLAIMS DO NOT ADD DUTIES THAT ARE "DIFFERENT FROM, OR IN ADDITION TO" DUTIES PROVIDED UNDER THE FDCA.

Federal law "shall be the supreme law of land," and "Judges in every State shall be bound" first and foremost to federal law, any conflicting State law "notwithstanding." U.S. Const. art. VI, cl. 2. "The underlying rationale" is that the Supremacy Clause only invalidates state laws "'that interfere with, or are contrary to'" federal ones. *Chicago and N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)). At the same time, "in the interest of avoiding unintended encroachment" of state police powers, courts "will be reluctant to find pre-emption." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). Even where preemption occurs, "state law is preempted to the extent that it actually conflicts" with applicable federal law. *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Com'n*, 461 U.S. 190, 204 (1983). Correct application of the Supremacy Clause "requires

determination of, and balancing of, state and local action against federal policy." *DeKalb County, Ga. v. Henry C. Beck Co.*, 382 F.2d 992, 996 (5th Cir. 1967).

The express preemption provision of the Food Drug and Cosmetic Act (FDCA) provides that no State may impose requirements upon manufacturers that are 1) "different from, or in addition to" FDCA requirements, and 2) relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. §360(k)(a). This Court has held that Section 337(a) of the FDCA means that Congress intended the FDCA "to be enforced exclusively by the federal government," preempting state law. *Buckman*, 531 U.S. at 352. However, as the Eleventh Circuit found, plaintiffs bringing state law claims may survive preemption issues if they bring claims about the defendant's violation of a federal requirement, but are not brought solely because of the violation – thereby surviving both express and implied preemption. *Mink v. Smith Nephew Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017).

The Third Circuit outlined a proper preemption examination in 2018; while the substance of the examination does not squarely apply, the process of its analysis remains on point with how the Seventeenth Circuit should have examined preemption. In *Shucker v. Smith & Nephew, PLC*, 85 F.3d. 760, 769 (3d Cir. 2018), the plaintiff brought causes of action against the defendants based on common law negligence actions and violations of federal law after experiencing pain as a result of hip replacement complications. After noting the two-step framework provided in 21 U.S.C. §360(k)(a), the court considered two questions: 1) "'whether the Federal

Government has established requirements applicable" to the specific "device" at issue," *Id.* (quoting *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 321) and if so, 2) "whether the [plaintiffs'] claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting 21 U.S.C. §360(k)(a)). Answering both questions in the affirmative would yield an express preemption, and answering only the first question in the affirmative would yield an implied preemption. *Id.*

To answer the first question, the court had to hold what "device" meant in this context, since the hip replacements were composed of different parts, classified under both Class II and Class III components. *Id.* at 772. The Third Circuit gave three reasons in support with both the defendants' and the FDA's assertion that "analysis at the component level is the only way to harmonize various provisions of the statute." *Id.* First, the definition of device in the FDCA includes "any component, part, or accessory" of the system. 21 U.S.C. §321(h). Regulations adjacent to this provision support this plain reading, detailing that the definition of device may include "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. §820.3(c).

Second, the FDCA as a whole "supports a component-level analysis" because it anticipates that physicians may prescribe FDA approved devices for off-label use. *Shuker*, 85 F.3d. at 772. Third, the court found the FDA's amicus brief convincing when they argued that because the definition of "device" includes "'component[s],

part[s], [and] accessor[ies]' . . . the relevant device for preemption purposes must be evaluated at the component level." *Id*. at 773 (quoting FDA Amicus Br. 7).

Working through both prongs, the Third Circuit answered each question in the affirmative. *Id*. at 774. In relevant part, the court found that 1) the particular component of the hip replacement at issue received Class III approval from the FDA, and 2) "the heart" of the plaintiff's claims "challenged the safety and effectiveness" of the device. *Id*. Thus, the plaintiff's claims were expressly preempted by the FDCA.

The one crucial difference between *Shuker* and this case is the defendants in *Shuker* did not hide the ball from the FDA. Unlike the defendants in *Shuker*, Petitioner here submitted a design for FDA approval, and then modified a particular component of the device without notifying the FDA afterwards. R. at 4. Because this modified component is at the crux of the factual analyses, it is impossible for this Court to answer the first prong in the affirmative. It cannot be said that "the Federal Government has established requirements applicable" to the PE-PUR foam, when that particular foam does not exist in the design that Mednology submitted to the FDA. *Shucker* at 769 (quoting *Medtronic*, 552 U.S. at 321).

Furthermore, the second prong must be answered in the negative because the heart of Ms. Ortega's claims does not establish requirements relating "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the *device*." 21 U.S.C. §360(k)(a) (emphasis added). Rather, her claims relate to the safety and effectiveness of a specific raw material with which Mednology chose to modify its device – the PE-PUR foam. The Sixth Circuit, in step with the

Second Circuit, held that when the FDA has merely classified a raw material, but imposed no regulations on said material, preemption issues do not arise. *See Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219 (6th Cir. 1995).

The *Jacobs* Court was persuaded by the Second Circuit, in *Lamontagne v. E.I. du Pont de Numerours & Co.*, 41 F.3d 846 (2d Cir. 1994) holding that relevant federal regulations limit preemption to "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. §808.1(d). Simply put: if the material at issue concerns raw material, and not a "device" within the meaning of 21 U.S.C. §321(h), then implied preemption does not apply. In the case before this Court, Mednology has failed to show any evidence on the record that the FDA has specifically regulated this PE-PUR material – therefore, viewing the facts in light most favorable to the nonmovant, 21 U.S.C. §360(k)(a) does not apply. Ms. Ortega's claims may proceed pursuant to 21 Trans. Comp. Stat. § 630.545 (2024).

B. THEN, A PROPER IMPLIED PREEMPTION EXAMINATION WOULD RESULT IN NO IMPLIED PREEMPTION, BECAUSE *BUCKMAN* DOES NOT SQUARELY APPLY TO THIS CASE.

The Seventeenth Circuit incorrectly concluded that *Buckman*'s analysis squarely applies, but such a holding misunderstands the relationship between the factual issues and legal issues in the case here. First, *Buckman* does not concern the situation where a raw material is at issue rather than a device. Second, the cause of action Ms. Ortega filed does not relate to the federal relationship between Mednology and the FDA.

1. First, the facts in Buckman *concern regulated devices, whereas here, the facts at issue concern raw materials.*

The facts underlying the *Buckman* Court do not fit into the case before this Court. In *Buckman*, the defendant sought approval from the FDA for its bone screw device as a Class III medical device. *Buckman* 351 U.S. at 346. After the FDA rejected the application twice, the defendant successfully obtaining approval by "'split[ting] the . . . device into its component parts," renaming them, and then rephrasing how they would be used in the subsequent application. *Id*. Plaintiffs, who had implants involving these devices, brought suit alleging that "the devices were improperly given market clearance and were subsequently used" to their detriment. *Id*. at 347. The *Buckman* Court went on to discuss the powers granted to the FDA in how they may regulate devices seeking its approval. *See Id*. at 348.

However, the facts before this Court differ too greatly for the same analysis to apply. The Sleepternity device as a whole presents no issues – in fact, Ms. Ortega took control of her chronic insomnia as a direct result of using the device, and her "sleep apnea symptoms returned" only after she was instructed by the ER physician to stop using it. R. at 5. Nor does the general design of the Sleepternity device submitted to the FDA present an issue before this Court. Rather, the causes of action rest alone on one simple but crucial fact – the presence of PE-PUR foam. Because the basis of the causes of action concern a raw material, not a device, the holding in *Jacobs* more squarely applies, and the presumption over preemption preserves Ms. Ortega's claims. *Jacobs*, 67 F.3d 1219.

2. Second, the pleaded cause of action does not concern the nature of the federal relationship between Petitioner and the FDA. Rather, the federal relationship only concerns immunity exception provisions.

While the Seventeenth Circuit ultimately correctly affirmed the District Court's denial of Petitioner's motion to dismiss, they improperly held that preemption applied. Specifically, the lower court incorrectly relied on the federal relationship as a basis for preemption. R. at 27. The Seventeenth Circuit incorrectly applied *Buckman*, in that it only examined how the FDA regulates Mednology generally. R. at 27-28. *Buckman* does not stand for the proposition that the only inquiry is the general relationship between the federal agency and the defendant – *Buckman* specifically addressed implied preemption for "state-law fraud-on-the-FDA claims." 531 U.S. at 348.

It is clear that the *Buckman* Court was primarily concerned with preserving FDA enforcement powers under the FDCA, and distinguished the FDA regulating manufacturers from States enforcing legal action against manufacturers. *See id.* at 344-345 (describing FDA procedure for Class III approval), 349-350 ("This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives . . . 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.") The FDA's regulatory powers are not infringed by Ms. Ortega's claims; rather, the relationship

between the manufacturer and the FDA represents a procedural burden that Ms. Ortega must overcome in order to proceed with her claims on the merits.

In fact, the *Buckman* Court noted that it did not conduct a 21 U.S.C. §360(k)(a) analysis on the basis that implied preemption was already found. *Id.* at n.2 ("In light of this conclusion, *we express no view* on whether these claims are subject to express pre-emption under 21 U.S.C. §360(k)." (emphasis added). The *Buckman* Court's finding of implied preemption neither erases the significance of express preemption outright, nor aggrandizes federal relationships to always preempt every cause of action against a manufacturer that secured FDA approval. Erroneously expanding the scope of *Buckman*, the Seventeenth Circuit did not even attempt to conduct an express preemption analysis, despite the presence of a genuine issue of material fact – specifically, whether the meaning of "device" applies to the raw material portion of the headset. 21 U.S.C. §321(h). The test that the Seventeenth Circuit *should* have applied, the same 2-prong test in *Shuker*, would have resulted in an outcome consistent with *Jacobs* and *Lamontagne*.

C. EVEN IF THERE MIGHT BE IMPLIED PREEMPTION, MS. ORTEGA MUST BE ALLOWED TO PURSUE HER CAUSE OF ACTION, BECAUSE THE FDA FORWENT ITS OPPORTUNITY TO PROCEED AGAINST PETITIONER WHEN IT WITHDREW ITS INVESTIGATION.

The Seventeenth Circuit's policy concern fails to equitably resolve the preemption issue, and in fact, introduces a legal loophole that would undermine both the FDA's concerns of ensuring honest applications for medical devices and States' concerns of preserving the welfare of its citizens. After Ms. Ortega filed her claims,

Petitioner, removed their Sleepternity device from the market. R. at 7. As a result, the FDA withdrew its investigation on possible fraud, since it would have otherwise continued to deploy finite resources to enforce a possibly negligently made device that no longer existed on the market. R. at 7.

The issue with the Seventeenth Circuit's opinion is that it fails to account for this crucial fact. Specifically, the Seventeenth Circuit observed a concern "about state courts interfering with the FDA's discretion to police the conduct of regulated entities," and adopted the holding in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 1994) as binding on that principle. R. at 31. Upon applying the ruling in *Garcia*, the lower court found that subsection (c) of the Transylvania's immunity provision "directly invade[d] the FDA's investigatory processes whenever the issue of whether a defendant has violated the FDA's warning requirements." R. at 31. However, this holding protects a nonexistent investigatory process. Of its own volition, the FDA ceased investigating Mednology and will not publish a determination. In other words, there is no risk in the case at bar of statutorily conflicting judgments against Mednology: the only party proceeding against them is the one harmed, Ms. Ortega. The Seventeenth Circuit also relied on *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), where the Fifth Circuit expressed a "concern about the need 'to preserve the agency's discretion to police the conduct of regulated entities.'" R. at 31. However, this concern does not apply, because the FDA likely would have continued its investigation had Mednology not pulled Sleepternity from the market.

If this Court affirms the Seventeenth Circuit's holding, it would solidify a legal loophole for manufacturers like Mednology to avoid liability. Future manufacturers could lie to the FDA about their medical devices, receive FDA approval based on those misrepresentations, and profit until a harmed consumer wishes to file claims against them. At which point, the manufacturer will voluntarily remove its device from the market in the hopes that the FDA will not investigate. And, the FDA likely will not: it is but one agency, approved for limited funding, and must make its best judgments as to how most effectively use such funding. Without any investigation, courts following the Seventeenth Circuit's reasoning would find that until there *is* a determination by the FDA, plaintiffs may not proceed to recover in a suit concerning the pulled device – shielding manufacturers from liability entirely.

Harmed consumers should not be robbed of their day in court simply because the FDA made a reasonable financial decision to cease investigating medical devices not on the market. While the Seventeenth Circuit's policy concern is sympathetic, in this case it would lead to nothing less of an unacceptable conclusion. Because there is no risk of contradicting statutory judgments here, and because the purpose of the FDCA, as well as state law claims, would be undermined by the presence of a foreseeable loophole from liability, this Court must reverse the Seventeenth Circuit to find that subsections (b) and (c) of the Transylvania's immunity provision are not preempted by the FDCA.

Airing against preemption, in fact, might assist the FDA in carrying out its obligations put forth in the FDCA. One of the largest barriers to efficient regulation,

the time of approval can slow down the regulatory process and produce inefficient market entries with lengthy approval processes. *See* Van Norman, Gail A., Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices (2016), JACC: Basic to Translational Science, Vol. 1, Iss. 4, 277, 287 ("moving new devices from concept to market takes an average of 3 to 7 years."). The FDA, one agency limited in manpower and funding, cannot reasonably monitor the vast totality of all approved devices with an idealistic watchful eye.

However, faster-moving entities such as state legislatures, can provide enforcement mechanisms that may assist the FDA in other regulatory ways, such as pursuing investigations on devices that may or may not be negligently designed or warned. Rather than wiping out this entire mechanism, allowing provisions similar to the case at bar to remain functional carries out the purpose of the FDCA while simultaneously preserving the abilities of consumers to proceed in causes of action that complement its goals. *See* David A. Kessler & David C. Vladeck, A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 Geo. L.J. 461 (2008).

D. TURNING TO THE STATE LAW IN QUESTION, SUBSECTIONS (B) AND (C) OF THE TRANSYLVANIA IMMUNITY PROVISION SURVIVE THE PRESUMPTION OVER PREEMPTION, BECAUSE THE FEDERAL RELATIONSHIP ONLY CONCERNS THE IMMUNITY EXCEPTIONS, RATHER THAN THE CAUSES OF ACTION.

The Seventeenth Circuit misapplied *Buckman* when analyzing the preemption issue, and incorrectly held that *Garcia* controlled, rather than *Desiano v. Warner-Lambert & Co.*, 547 F.3d 85, (2d Cir. 2006). The Seventeenth Circuit correctly distinguished *Buckman* from the present case by noting that Ms. Ortega brings up Mednology's conduct "to neutralize [its] immunity," but erroneously expanded the reach of *Buckman's* policy concerns to hold that *Garcia* controls the present case. R. at 28. This portion of the Seventeenth Circuit's opinion must be reversed.

Desiano's analysis correctly interprets the scope of *Buckman* to specifically apply to "fraud-on-the-FDA" claims, not to preemption analyses. The state law claim in *Desiano*, much like the state law claim here, included an immunity provision, providing:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

M.C.L. § 2946(5). Likewise, the language in the Transylvania immunity provision provides materially the same language. *See* 21 Trans. Comp. Stat. § 630.546(a). Even the District Court noted the "substantial similarity" between the two immunity provisions, which played a major factor in the District Court's

reasoning to find that *Desiano* controlled. R. at 15. The *Desiano* Court noted "three differences" that distinguished its case from *Buckman*: 1) the presumption against preemption, 2) traditional common law liability, and 3) immunity as an affirmative defense. *Desiano*, 467 F.3d at 93.

The first difference, presumption over preemption, existed because the statute "cannot reasonably be characterized as a state's attempt to police fraud against the FDA" since the legislative intent was "to regulate and restrict when victims could continue to recover." *Id*. at 94. Similarly, here, Ms. Ortega's cause of action cannot be characterized as policing fraud against the FDA, because, much like the Michigan legislature's intent, the Transylvania legislature's intent is "to encourage consumers who believe their injury resulted from a manufacturer and/or distributor's failure to exercise care, precaution, or good faith in manufacturing and/or distributing the product to bring a valid claim." 21 Trans. Comp. Stat. § 630.544. Both legislative bodies enacted statutes that fall "squarely within [their] prerogative" to protect the welfare of their citizens – such prerogatives do not encroach on federal agency regulation. *Desiano*, 467 F.3d 85 at 94.

The second difference distinguishes *Desiano* and this matter from *Buckman*; unlike the "fraud-on-the-FDA" claims brought in *Buckman*, *Desiano* and this case involve claims "sound in traditional state tort law." *Id*. Notably, the *Desiano* Court applied the *Buckman* Court's analysis when distinguishing between duties manufacturers have in "fraud-on-the-FDA" claims versus duties in "traditional tort claims." *Id*. In other words, the difference between the two kinds of claims is that

while the former focuses on the relationship between the manufacturer and the agency, the latter focuses on the relationship between the manufacturer and the consumer – not "newly-concocted dut[ies] between a manufacturer and a federal agency." *Id.* at 95.

The third difference, immunity provisions, involves the fact that in the Michigan and Transylvania statutes, "proof of fraud against the FDA is not even an *element* of a products liability claim." *Id.* at 96. The *Desiano* Court noted that FDA approval of the device in question became material to the state claim "*only* if a defendant company chooses to assert an affirmative defense." *Id.* Similarly, here, subsections (b) and (c) of the Transylvania immunity statute, respectively, provide that "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" and "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(b)-(c).

The *Desiano* Court held that because these provisions do not require "the plaintiff to prove fraud as an element of his or her claim," they do not encroach on the relationship between manufacturers and the FDA. *Desiano*, 67 F.3d 85 at 96. Furthermore, "until and unless" Congress explicitly states an intent to invalidate such immunity exceptions, the *Desiano* Court "decline[d] to read general statutes like the FDCA and the MDA as having that effect." *Id.* To narrowly read these state laws

in a way that provides recourse for state plaintiffs remains consistent with federal jurisprudence.

The Seventeenth Circuit, however, relied on the false notion that "*Garcia* correctly applied the Supreme Court's precedent in *Buckman* by accounting for the policy concerns the Court in *Buckman* raised about state courts interfering with the FDA's responsibility to police fraud." R. at 28. The lower court's reasoning lied in the notion that such immunity exception provisions are invalid whenever "a plaintiff requests a state court to find defendant's fraudulent conduct toward the FDA." R. at 29. However, this is a clear misinterpretation of the Transylvania statute. Similarly to how *Desiano* framed this issue, a plaintiff bringing her claims under 21 Trans. Comp. Stat. § 630.545 does not request the tribunal to find fraudulent conduct any more than manufacturers might ask the same pursuant to a defense. The underlying nature of Ms. Ortega's claims concerns the relationship between herself and Petitioner Mednology – any mention of the FDA by Ms. Ortega only applies as to the question of defenses Mednology may bring to escape liability. Defenses are not elements of causes of action, and Ms. Ortega's claims under Transylvania law pass constitutional muster.

E. THIS COURT SHOULD ALSO AFFIRM BOTH LOWER COURTS' DENIALS OF THE MOTION TO DISMISS OUT OF ANOTHER PARAMOUNT CONCERN: CONSTITUTIONALLY PROTECTED STATE POLICE POWER.

The Tenth Amendment of the Constitution provides that powers not granted to the federal government "are reserved to the States." U.S. Const. amend. X. This

one sentence explicitly provides the foundation of federalism that the Constitution contemplates. Both federal and State governments must harmonize in their jurisdictional bounds, lest one usurps power at the expense of the other. To affirm the Seventeenth Circuit's preemption analysis would not only validate the misinterpretation of *Buckman*, but also unnecessarily strip too much of state police power. This Court can narrowly rule on the preemption issue consistently with the binding Medical Device Amendments jurisprudence while also preserving what is rightfully reserved to the States: the ability to protect the health and safety of its citizens. The Constitution, *Desiano*, *Medtronic*, and *Buckman* all enforce this great policy consideration.

The *Desiano* Court notably began its opinion with: "It has long fallen within the province of states to safeguard the health and safety of their citizens." *Desiano*, 467 F.3d at 86. This opinion, delivered five years after *Buckman*, reads as a response to the most famous sentence in that opinion: "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230). As Circuit Courts responded to *Buckman* by using this sentence as a controlling mechanism for preemption analysis (*see Garcia*, 385 F.3d 961 (6th Cir. 1994)), *Desiano* framed its opinion with the value of States' rights in order to place this famous sentence from *Buckman* in its proper context. The *Desiano* Court intentionally distinguished the facts before it from the facts in *Buckman*, by identifying the source of the laws brought forth in both cases. *See Desiano,* 467 F.3d at 94. While the plaintiffs in the latter case

brought laws that originate from "fraud-on-the-FDA" claims, the plaintiffs in the former case brought suit with state laws based "in traditional state tort law." *Id.* If the policy behind preemption is to articulate which causes of action belong to the federal government and which ones belong to the States, then claims rooted in common law liability, which have "formed the bedrock of state regulation," certainly are reserved by the Tenth Amendment. *Id.* at 86.

Similarly, this Court in *Medtronic* observed that "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens." *Metronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The *Medtronic* Court, in the facts before it, weighed this police power against the "significant role" that the FDA has "in the protection of our health and our people." *Id.* The Court began its preemption analysis by acknowledging that "States are independent sovereigns in our federal system," and then noting that Congress's purpose remains the "ultimate touchstone" with every preemption case. *Id.* at 485. The manufacturer's argument that 21 U.S.C. §360(k)(a) preempted the plaintiff's common law claims fell short of persuading the *Medtronic* Court, because the Court doubted that Congress clearly and expressly intended to "preclud[e] state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Id.* at 487. The manufacturer's interpretation of the Medical Device Amendments would "bar[r] most, if not all, relief for persons injured by defective medical devices." *Id.*

Notably, Justice Stevens pointed out that if that *had* been Congress's purpose, Congress could have more clearly achieved that result by using the broader term

"remedy" rather than "requirement" as it did in the preemption provision. *Id.* Because the manufacturer's interpretation would strip States of "any role in protecting consumers from the dangers" in medical devices, a role encompassed within a fundamental power to ensure the welfare of its citizens, the *Medtronic* Court required express Congressional intent of such an interpretation and ruled in favor of the consumer. *Id.* at 489.

Even the *Buckman* Court gave credence to this foundational principle. While declaring that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" the holding in *Buckman* stands for the proposition that there is a distinguishable difference between a state fraud-on-the-FDA claim and a state claim rooted in traditional tort law. *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230); *Id.* at 352-53. The *Buckman* Court rejected the consumer's claims that *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) and *Medtronic* applied to their matter, because both of those cases involved claims "based on traditional state tort law principles," and "not solely from the violation of FDCA requirements." *Id.* at 352, 353.

The *Buckman* Court would similarly find that the present case is distinguished on the same grounds – the claims Ms. Ortega brings against Mednology do not arise solely from FDCA violations, but rather from the relationship between Mednology and herself. *See* 21 Trans. Comp. Stat. § 630.545. The only significance of the relationship between the Petitioner and the FDA is to surpass Transylvania's

immunity provision, which cannot reasonably be read as an element to her cause of action. *See* 21 Trans. Comp. Stat. § 630.546(a)-(c).

Desiano, *Medtronic*, and *Buckman* emphasize the importance of state police power, and denying Petitioner's motion to dismiss is the only way to consistently rule with these three cases. In fact, several of the Seventeenth's sister circuits have held that the FDCA cannot preempt state causes of action that rest on a manufacturer's violation of the FDCA, so long as those provisions do not expressly conflict with 21 U.S.C. §360(k)(a). *See* Hannah Rodgers, The Presumption Against Implied Preemption: How State Law Fraud-on-the-FDA Claims Complement, Rather than Conflict with, Federal Law, 45 Fla. St. U. L. Rev. 861, 874-75 (2018). The Seventeenth Circuit's improper interpretation of how *Buckman* applies must be reversed, as its sweeping expansion undermines the very principle that *Buckman* stands for.

II. A RELATOR MAY RELY ON THE FRAUD-IN-THE-FDA THEORY TO BRING A FALSE CLAIMS ACT CLAIM AGAINST A MEDICAL DEVICE MANUFACTURER UNDER THE ACT'S *QUI TAM* PROVISION.

Under the False Claims Act ("FCA"), liability arises when a medical manufacturer knowingly submits or causes false claims to be submitted for government payment, particularly under Centers for Medicare and Medicaid Services ("CMS"). 31 U.S.C.A. §§ 3729-30 (West 2009). An FCA action requires proof of four elements: "(1) there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that *caused* the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')." *Harrison v. Westinghouse Savannah River Co.*,

176 F.3d 776, 788 (4th Cir. 1999); *see United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 899 (9th Cir. 2017) (quoting *United States v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006)). In the case before this Court, the materiality and causation requirements are the only elements in dispute.

When a medical device manufacturer engages in fraudulent behavior or misrepresentation regarding FDA approval for a device that later becomes the subject of government payments, the fraud-on-the-FDA theory provides a strong basis for an FCA claim. *See* Kelly Carty Zimmerer, *Health Fraud from Fda Approval to CMS Payments: Why Fraud-on-the-FDA Should Be A Viable Form of Liability Under the False Claims Act*, 62 U. Louisville L. Rev. 713 (2024). Here, permitting Ms. Ortega's fraud on the FDA claim not only holds Mednology accountable, but it also serves the broader public interest by "discouraging fraud against government, and [the] whistleblower provision is intended to encourage those with knowledge of fraud to come forward. *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948 (5th Cir. 1994). Because "provisions in no way act to penalize FCA defendant", allowing a relator to present a fraud on the FDA claim under the FCA's *qui tam* provision ensures that the FCA fulfills its role in protecting public health. *United States v. NEC Corp.*, 11 F.3d 136 (11th Cir. 1993); 31 U.S.C.A. § 3730(b)(5)(c) (West). This maintains the integrity of drug and medical device approvals while safeguarding taxpayer dollars from fraudulent activities and unsafe products. *See id.*

A. MEDNOLOGY'S OMISSION OF PE-PUR FOAM RISKS WAS MATERIAL TO BOTH FDA APPROVAL AND GOVERNMENT PAYMENT PROCESSES

Courts have construed the FCA broadly, "intending to reach all types of fraud without qualification that might result in financial loss to the government." *Campie*, 862 F.3d at 899 (quoting *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166 (9th Cir. 2006)). Under this construction of the FCA, a claim for government payment does not have to be overtly or facially false to trigger liability. If claims involve noncompliance or fraudulent actions—even if a claim for payment appears to be legitimate—the FCA holds entities accountable for deceptive practices that may not be immediately evident. *Id.*

In *Escobar*, this Court held that for a false claim to be material, the misrepresentation must have a "natural tendency to influence or be capable of influencing" the government's decision to pay. *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182 (2016). The materiality standard set forth by this Court ensures that liability is not imposed for minor or insignificant regulatory violations, but instead emphasizes whether the non-compliance would have affected the government's payment decision. *Id.* Misrepresentations must be of such gravity to influence government payments rather than being ancillary or tangential to the government's interests. *See id.*

Here, Mednology's omission is not a minor violation of noncompliance, it is a substantial omission with overwhelming implications. This is especially critical given that Sleepternity is a Class III medical device, which demands even more strict safety requirements due to the device's potential to pose significant health risks, the highest risk of all three classes. *See* R. at 4; *see also Classify Your Medical Device*, U.S. Food

and Drug Administration (Feb. 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

By replacing the FDA-approved silicone with a hazardous PE-PUR foam that is proven to degrade into volatile organic compounds, Mednology altered the fundamental nature of the device to cut costs, which significantly increased the risk to patients. R. at 4. This manufacturing shift in safety, had it been disclosed to the FDA, would have critically affected FDA approval and CMS's decision to provide reimbursement for the Sleepternity device. Mednology's actions go right to the heart of materiality analysis: the undisclosed foam substitution is material because it directly affects the core regulatory and safety standards for Class III medical devices that are prerequisites for CMS payment.

This Court made it abundantly clear in *Escobar* that materiality cannot be established by the mere possibility that the government would have withheld payment if it had known of the regulatory noncompliance. *See Escobar (Universal Health)* at 196. Instead, this Court expressed that the government's actual behavior in analogous situations is more indicative of materiality. *Id.* Here, the government's prior actions, specifically recalling Philips Respironics CPAP devices containing the exact same PE-PUR foam, provide strong evidence that Mednology's substitution would have been material to the government's decision to make claim payments. *See* R. at 4.

Given that the FDA had recalled devices containing the volatile compound, Mednology's fraudulent omission starkly contradicts the government's established

concern with the safety of PE-PUR-based materials. *Id.* The historical pattern of rejecting and recalling devices that use the toxic materials signals Mednology's noncompliance would have significantly influenced CMS payment decisions. *Id.* As a result, Mednology's fraudulent conduct readily satisfies the materiality standard under the FCA.

In *U.S. ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581 (E.D. Pa. 2014), the federal court builds upon the materiality standard set forth in *Escobar*. In *Krahling*, medical device company, Merck, fraudulently misrepresented the efficacy of a vaccine by falsifying data, which led the government to make payments on vaccine claims. *Id*. at 587. Further, the *Krahling* case broadened the interpretation of materiality by emphasizing that omissions related to a medical device's core safety and efficacy can be material, even if not expressly tied to specific government payment decisions. *Id.* at 595. Ultimately, *Krahling* held that when misrepresentations fundamentally alter the nature of the medical device, the misrepresentations are material because that conduct directly influenced the governmental evaluation of a medical device's fitness for continued distribution and government claim payments. *Id.*

Applying *Krahling* to Ms. Ortega's case, the undisclosed change was a fundamental alteration against established FDA standards for sleep apnea CPAP machines. Similar to *Krahling*, the undisclosed replacement of the approved foam with PE-PUR mirrors Merck's fraudulent vaccine testing that led to false certification and government payment. Both Merck and Mednology cut costs while putting the

public at serious risk, indicating that the government's decision to reimburse these products would have been different had the fraud been disclosed to the FDA.

Just as the *Krahling* Court recognized that misrepresentation could influence the government's broader decision to pay for and distribute the vaccine, Mednology's omission affected core safety standards, which would have similarly shaped the government's decision to continue paying for CMS claims for the Sleepternity device. Under *Krahling*, Mednology's misrepresentation has a ripple effect, and the omissions are thus material. Ms. Ortega's case surpasses the materiality test under both the narrower interpretation from *Escobar* and the broader interpretation established in *Krahling*. Therefore, Ms. Ortega's claim clearly passes muster for establishing materiality under the FCA.

B. Causation Is Satisfied When Fraudulent Conduct Affects Initial FDA Approval, Even If the FDA Does Not Withdraw the Device

Under the FCA's *qui tam* provision, a relator's complaint against a healthcare provider sufficiently satisfies the causation requirement when it asserts that the healthcare provider's submission of false claims to the government for payment caused the government to pay significant sums that it would not have paid with full knowledge of the situation. *United States v. Molina Healthcare of Illinois, Inc.,* 17 F.4th 732 (7th Cir. 2021).

Moreover, in *Campie*, the Ninth Circuit held that causation under the FCA was fully satisfied when a false statement made to the FDA in approval is an integral part of a chain of events that leads to governmental payment of claims. 862 F.3d 890, 899 (9th Cir. 2017). Even if the fraudulent statement is not directly included in the reimbursement claim itself, nevertheless, liability still attaches if the fraud plays a role in securing FDA approval, which CMS then relies upon to pay claims for devices. *Id.* Additionally, the Ninth Circuit further rejected the notion that continued FDA approval fully severs the causal chain and held on the contrary: FCA liability extends to *any* payments that are grounded in fraud regardless of the decisions made by the FDA, even after the fraud has been uncovered. *Id.* Thus, under *Campie*, FCA causation hinges on whether fraudulent conduct was integral to obtaining government payment, not the FDA's subsequent actions. *Id.*

In *Campie*, pharmaceutical company, Gilead Sciences, obtained approval from the FDA for HIV drugs based on false representations about the manufacturing process. *Campie* at 899. More specifically, the pharmaceutical company concealed the use of an unapproved manufacturing facility, submitting falsified data to the FDA. *Id.* Even though the Medicare and Medicaid continued to reimburse the claims for the drugs after misrepresentations were discovered, the Ninth Circuit determined that the fraudulent conduct was indeed integral to the government's decision to pay for the HIV drugs given that approval from the FDA was a condition of its payment. *Id.*

The Court ultimately held that the chain of causation remained intact because the initial fraud—falsely obtained FDA-approval—befouled all subsequent claims for payment. *Id.* This decision emphasized that fraudulent representations form the foundation for a medical device's perceived safety and marketability, which therefore cause the government to pay for the claims. *See id*.

Here, Mednology's fraudulent conduct regarding the PE-PUR foam closely parallels Gilead's actions in *Campie*. Mednology's fraudulent concealment of substituting the safe, FDA-approved silicone-based foam with the unapproved toxic PE-PUR foam was an essential element of FDA approval for Sleepternity. Like Gilead, Mednology's fraudulent conduct was rooted in the approval process, which directly influenced subsequent CMS reimbursements.

The approval was critical to allowing Sleepternity to be distributed and reimbursed, just as FDA approval was for Gilead's HIV medication. In both cases, fraudulent misrepresentation of unapproved manufacturing components affected the safety and long-term efficacy of the products. Further, both cases illustrate that had the FDA been aware of the fraud, it likely would not have approved the products given the products' reputation of consumer risk and harm. Because the Ninth Circuit held that such misrepresentation and reliance create a causal chain between fraudulent FDA approval and subsequent government payments, Ms. Ortega sufficiently established the causal chain necessary for her FCA claim.

Moreover, the causation standard outlined in *Campie* is further bolstered by the *Plavix* decision, emphasizing that under the FCA, the relator must show that

fraudulent conduct proximately caused the government to fulfill payments it otherwise would not have completed. *In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927 (D.N.J. 2017). In *Plavix*, the medical device company failed to disclose that the blood-thinning drug, Plavix, was as effective as aspirin, but marketed it as superior, which led to the drug's inclusion on Medicaid formularies and automatic reimbursement by the government. *Id.* The Court set forth a causation standard, emphasizing materiality and requiring that the fraud be material to the government's decision to reimburse the claims. *Id.*

The standard that the Court in *Plavix* applies further clarifies that if the government had been aware of the truth, it likely would have refused payment. *Id.* This decision further reinforces the direct link between fraudulent statements made to the FDA and government payment decisions, given that FDA approval plays a major role in the government's determination to either approve or reimburse claims. *See id.*

Here, the *Plavix* standard can be applied similarly. Just as the fraudulent misrepresentation of Plavix's effectiveness led the government to reimburse an expensive, non-superior drug, Mednology's failure to disclose the PE-PUR foam in the Sleepternity device influenced the government's decision to pay claims. Both cases hinge on the fact that fraudulent omissions misled the government into reimbursing the products under false pretenses. FDA approval was a key factor in the government's payments, and the misrepresentations undermined that very approval.

Together, *Campie* and *Plavix* establish that causation under the FCA can be met if the fraudulent conduct is integral and material to government payment decisions. Even if the FDA did not formally withdraw its approval of the device, FCA liability still attaches. Therefore, the causality requirement is met in Ms. Ortega's claim given that the fraud was integral to the continued payment of claims related to an extremely defective CPAP medical product.

Moreover, Petitioner misinterprets *D'Agostino* in its causal analysis. *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). Under the First Circuit's rule set forth in *D'Agostino*, to establish causation, the plaintiff must show that the fraudulent conduct directly caused government payments that otherwise would not have been paid. *Id.* The plaintiff must also show that the fraud is material to the government's reimbursement approval and the fraud must "actually induce" the government to make the payment. *Id.* at 7. In *D'Agostino*, medical device company MTI made false representations during the approval process for a drug overstating training provided to doctors which concealed safety issues related to the device. *Id.* The relator argued that the fraudulent approval led to government payments. *Id* at 8. Yet, the Court rejected the claim because the FDA never withdrew approval, indicating there was no direct causal link between the fraud and payments. *Id.*

However, Ms. Ortega's case is distinguishable from *D'Agostino* because here, the fraud occurred after the CPAP machine was approved and on the market. The fraudulent act involved an undisclosed, post-approval modification that directly affected the safety of the marketed product. Mednology's conduct caused real harm

to Ms. Ortega and other consumers in addition to causing the government to continue paying claims because the manufacturer fraudulently substituted a key component without disclosure to the FDA. In *D'Agostino* however, the fraudulent conduct occurred before the product entered the market, which led to the claim about government payments being speculative. *See id*.

Here, the key difference was the premarket conduct in *D'Agostino* and post-approval fraudulent conduct in addition to keeping a defective product on the market. In *D'Agostino*, the FDA did not take corrective action; however, in Ms. Ortega's case, the FDA was unaware of the fraudulent substitution, which is why it did not withdraw the product from the market. Yet, had the FDA known about the substitution of the harmful material, it would have acted to recall or withdraw the product, thereby preventing more government reimbursements. The risks of the foam were well established, and the FDA had already warned against the use of such material in similar Philips devices. R. at 4. However, the FDA cannot act against a risk they are unaware of due to manufacturer concealment. Therefore, the *D'Agostino* causation interpretation does not apply because Ms. Ortega's causal link was not speculative and indirect. Instead, the causal link was the direct continuous misconduct that affected users and caused government payment.

C. APPLYING FRAUD-ON THE-FDA THEORY TO THE FALSE CLAIMS ACT *QUI TAM* PROVISION EMPOWERS WHISTLEBLOWERS AND SAFEGUARDS REGULATORY INTEGRITY.

The fraud-on-the-FDA theory aligns with the fundamental public policy goals of both the FCA and the FDA by encouraging accountability and transparency. The immense scale of the healthcare industry—with government healthcare expenditure of approximately $4.5 trillion dollars in 2022—requires various durable mechanisms to combat the issue of fraud within the healthcare industry. *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323 J. Am. Med. Ass'n 834, 837 (2020). By holding large corporations accountable under the FCA in a time where the FDA is under-funded and understaffed, fraud-on-the-FDA claims reinforce regulatory integrity and ease ever-increasing healthcare costs. *See O'Neill v. Novartis Consumer Health, Inc.*, 55 Cal. Rptr. 3d 551 (Ct. App. 2007).

Moreover, in the Department of Justice's (DOJ) recent statement of interest in 2022, the DOJ offered a robust defense of the fraud-on-the-FDA theory under the FCA. *U.S. ex rel. Crocano v. Trividia Health Inc.*, ECF No. 127, No. 22-CV-60160-RAR; *See United States ex rel. Crocano v. Trividia Health Inc.*, 615 F. Supp. 3d 1296 (S.D. Fla. 2022). The DOJ disagreed with the defendant in *Crocano* and argued that when "a manufacturer perpetrates a fraud on the FDA by hiding material information concerning the safety or efficacy of a device—either during or after the approval process or to avoid a recall—and federal healthcare programs then pay for

that device, that fraud may be 'integral to a causal chain leading to payment' and can be actionable under the FCA." *Id*. The DOJ ultimately proposed that when a defendant "mask[s] problems" through false statements that would lead to the FDA to recall a product, "subsequent claims relating to the affected devices could be rendered 'false or fraudulent,' because the government would not have paid the claims for those affected devices but for the defendant's conduct." *Id*.

By making the statement, the DOJ indicated a clear governmental interest in holding companies accountable for concealing material safety information regarding medical devices. The fact that the DOJ weighed in on the issue of fraud-on-the-FDA demonstrates that fraudulent conduct affecting FDA-regulated products must be taken seriously and that the FCA is an appropriate avenue to pursue such claims. The DOJ's perspective gives significant persuasive authority to claims like Ms. Ortega's, signaling to courts that fraud-on-the-FDA theories are not only valid under the FCA, but crucial for upholding the integrity of both governmental healthcare expenditures and public safety.

Finally, the purpose of the False Claims Act is to discourage fraud against the government, and the purpose of *qui tam* provisions of the Act is to encourage those with knowledge of fraud to come forward. *See Neal v. Honeywell, Inc.*, 826 F. Supp. 266 (N.D. Ill. 1993), aff'd, 33 F.3d 860 (7th Cir. 1994). Ms. Ortega's case fits squarely within this statutory framework and legislative intent while advancing a broader societal goal of encouraging transparency. Mednology's undisclosed foam substitution of a safe silicone in the Sleepternity machine with a cheaper, health-hazardous PE-

PUR alternative was not only a risk to the public, but also led to fraudulent claims eventually paid by CMS. This conduct unfairly places the financial burden directly on taxpayers. Mednology's fraudulent action, aimed at achieving a minimal cost-saving advantage, is entirely at odds with public policy and general welfare.

By allowing Ms. Ortega's case to proceed, this Court has the opportunity to send a clear message: medical device companies cannot prioritize profit over human life. *Qui tam* relators are essential in exposing fraudulent conduct. Relators effectively lift the veil on illegal practices that would otherwise remain unchecked, which would compromise regulatory integrity and public safety. Therefore, as a matter of public policy in the interest of public health and taxpayer funds, Ms. Ortega's fraud-on-the-FDA theory should be recognized as a valid claim under the FCA's *qui tam* provision.

CONCLUSION

Ultimately, the Seventeenth Circuit's preemption analysis fails because it relies on presumptions that involve genuine issues of material fact. The meaning of "device" in 21 U.S.C. §321(h) does not cover raw materials, and since Ms. Ortega's pleaded claims focus on the PE-PUR foams present in the device, rather than the device itself, the holding in *Jacobs* covers the present case more accurately than the holding in *Buckman*. *See Jacobs*, 67 F.3d 1219. While the Third Circuit in *Shuker* found that raw materials may be within the meaning of "device," the FDA limits this to components that are "intended to be included" – and unlike in *Shuker*, it is not clear whether the raw material "intended to be included" here is the silicone foam or the PE-PUR foam. 21 C.F.R. §820.3(c); *see Shuker*, 85 F.3d at 775.

Additionally, the lower court incorrectly delved into the preemption analysis by completely neglecting a proper examination of both express and implied preemptions. R. at 27-28. Had it done so, it would have followed the two-step framework for preemption examinations, outlined in *Shuker*, and ruled consistently with the Sixth and Second Circuit holdings found in *Jacobs* and *Lamontagne*. *See Shuker*, 85 F.3d. 760, 769 (3d Cir. 2018); *see Jacobs*, 67 F.3d 1219 (6th Cir. 1995); *see Lamontagne*, 41 F.3d 846 (2d Cir. 1994).

The lower court erroneously found that *Buckman* squarely applies, when both the facts and the pleadings differ too greatly from this case for such a holding. First, *Buckman*'s holding involves an uncontested application of the meaning of "device," which does not parallel Ms. Ortega's cause of action. 351 U.S. at 346. Second,

Buckman concerned state law fraud-on-the-FDA claims, rather than state product liability actions. *Id*. at 348. The relationship between Mednology and the FDA only applies as evidentiary to the immunity provisions set forth in 21 Trans. Comp. Stat. § 630.546(b)-(c), rather than an element of any cause of action, and *Buckman* does not speak to such provisions.

The lower court, inconsistent with FDCA policy, found that because the FDA did not provide a finding of Mednology's conduct, Ms. Ortega cannot proceed with her causes of action. However, this ruling opens a gap in the legal process that would allow manufacturers in the future to escape liability, and strip harmed consumers of legal recourse. This Court should close this gap introduced by the lower court and protect both the interests of the FDA and the States by allowing Ms. Ortega to proceed with her claims, since the FDA withdrew its investigation.

The District Court properly followed the Second Circuit's holding in *Desiano*, which noted "three differences" that distinguished its case from *Buckman*: 1) the presumption against preemption, 2) traditional common law liability, and 3) immunity as an affirmative defense. *Desiano*, 467 F.3d at 93. Like the Michigan Legislature in Desiano, the Transylvania Legislature is within its prerogative to protect the welfare of its citizens and do not harm federal regulation. *Id.* at 94.

A similar policy concern, reserving state police powers, requires this Court to reverse the lower court's finding of implied preemption. In fact, this Court in *Buckman* distinguished the facts before it from claims that were "based on traditional state tort law principles," and "not solely from the violation of FDCA requirements."

Buckman at 352, 353. Similarly, this Court in *Medtronic* ruled that "[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens." *Metronic,* 518 U.S. at 475. The only ruling consistent with *Buckman* and *Medtronic* would reverse the lower court in finding implied preemption, but affirming its denial of Mednology's motion to dismiss.

Further, the Circuit Courts' decisions support Ms. Ortega's fraud-on-the-FDA theory under the FCA's *qui tam* provision because Mednology's fraudulent conduct was both material and caused CMS to make payments it would not have otherwise made. *See. United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732 (7th Cir. 2021); *see also United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 899 (9th Cir. 2017).

For the reasons discussed herein, Respondent Riley Ortega requests that this Court reverse the Seventeenth Circuit Court of Appeals' holding that the FDCA preempts Transylvania's products liability statute and reverse its holding that Respondent cannot proceed under the False Claims Act. Respondent also requests that this Court affirm the lower court's denial of Petitioner's motion to dismiss.

Dated this 9th day of September 2024.

Respectfully submitted,
/s/ Team 3319
Attorneys for Respondent, Riley Ortega

APPENDIX A

21 U.S.C.A. § 321h – Definitions; generally

(h)(1) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

(2) The term "counterfeit device" means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such

device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.

21 U.S.C.A. § 360(k)(a) – State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

APPENDIX B

31 U.S.C.A. § 3729 – False Claims

(a) Liability for certain acts.–

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

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

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

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

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

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

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

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or

property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

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

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

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation, the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

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

(b) Definitions.--For purposes of this section--

(1) the terms "knowing" and "knowingly" --

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

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

(2) the term "claim"--

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

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

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

(c) Exemption from disclosure.--Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

31 U.S.C.A. § 3730(d) – Civil Actions for False Claims

(d) Award to qui tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting2 Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive

an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.