No. 24-9176

In The

Supreme Court of the United States

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES EX REL. Riley ORTEGA,

Respondent

ON PETITION FOR CERTIORARI FROM THE

UNITED STATES COURT OF APPEALS

FOR THE SEVENTEENTH CIRCUIT

BRIEF FOR RESPONDENT

Team 3317

Attorneys for Respondent

QUESTIONS PRESENTED

1. Whether courts are to read federal preemption into state product liability laws in the absence of any evident intent of Congress to occupy the field.

2. Whether fraud perpetrated collectively on the FDA and CMS is actionable under the False Claims Act.

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The United States Court of Appeals for The Seventeenth Circuit issued its opinion on April 1, 2024. It is unreported but appears on pages 2—24 of the record. The United States District Court for the Southern District of Transylvania issued its opinion on October 15, 2023. It is also unreported but appears on pages 25–42 of the record.

STATUTORY PROVISIONS

The False Claims Act, codified in 31 U.S.C. § 3729, *et seq*, is relevant to deciding the issues before this court, as is Transylvania Statute § 630.545(a-c). These provisions are reproduced in Appendix A.

INTRODUCTION

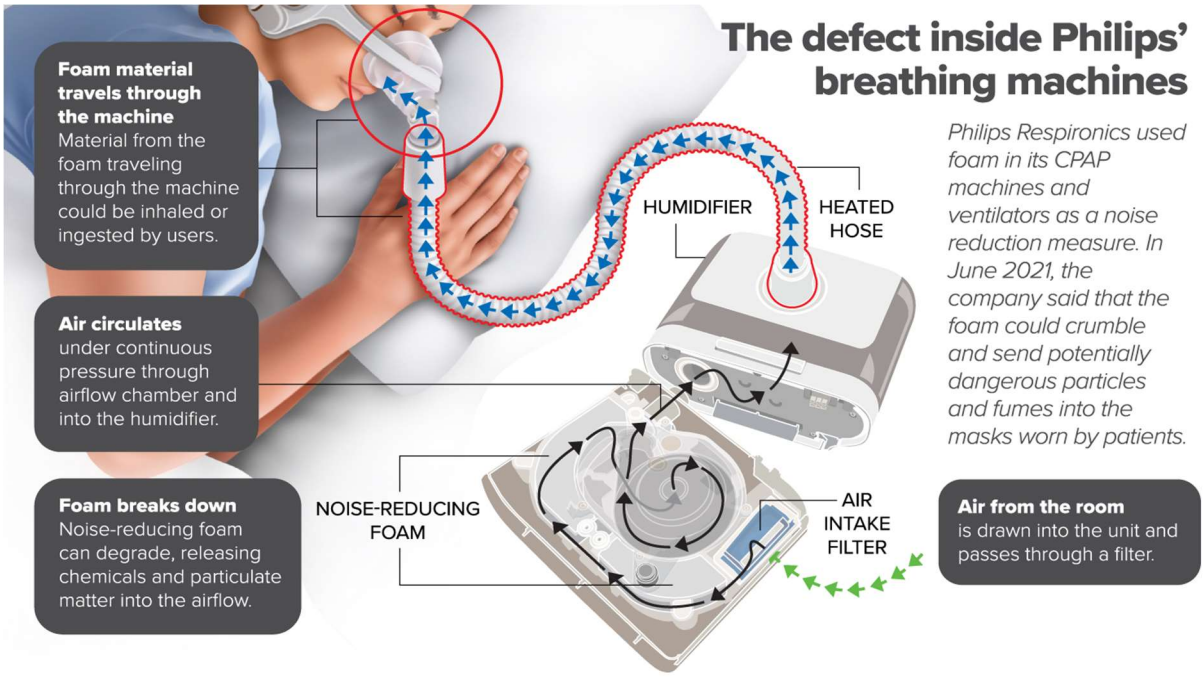
In response to Mednology's petition for Certiorari, Respondent Ms. Ortega asks this Court to uphold the rulings of the Seventeenth Circuit Court in remanding her state law claims and her federal claims under the FDA to be argued before the trial court.

STATEMENT OF THE CASE

The injured party in this case, U.S. Army Veteran Ms. Riley Ortega, has Post-Traumatic Stress Disorder (PTSD) stemming from her combat service with symptoms of insomnia and sleep apnea. R. at 2. Ms. Ortega was prescribed the Sleepternity CPAP by her doctor—a medical device approved by the FDA in its original configuration in December 2022. R. at 4. The bill for Ms. Ortega's CPAP was submitted to CMS for payment and was paid due to the device having been recently approved by the FDA. R. at 4. Unfortunately for Ms. Ortega and for CMS, the actual device she was given has undergone a dangerous and unreported modification.

Following FDA approval, but before fulfilling Ms. Ortega's order, Mednology replaced the silicone-based foam (used for noise reduction) with one made from polyester-based polyurethane (PE-PUR)—a substance known to pose serious health risks if inhaled. *Id.* PE-PUR frays into volatile organic compounds (VOCs) which may then be inhaled or swallowed. *Id.* This is especially likely if released into a breathing tube, such as those found on a CPAP machine, into the airway of an unsuspecting patient. *Id.* Far from novel, this modification had been made to a nearly identical

device by rival medical device manufacturer "Philips Respironics" (Philips), and was subject to a nationwide recall beginning in June of 2021.[1]



[2]

Despite the prolific and public notoriety of this failed configuration, Mednology's desire to cut costs at the expense of patient safety led to them knowingly replicating and perpetuating the same harm onto Ms. Ortega and many others. R. at 4. These models all experienced the fraying of invisible PE-PUR remnants that were subsequently inhaled or swallowed by patients, with Phillips acknowledging that "*the foam it had chosen could crumble in heat and humidity and send potentially 'toxic and carcinogenic' material into the noses, mouths, throats and lungs of users*." *Id.*

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[1] *Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, https://www.fda.gov/medical-devices/respiratory-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines (updated Apr. 10, 2024).

[2] *Philips kept warnings about dangerous CPAP machines secret while profits soared*, Pittsburgh Post-Interactive, https://newsinteractive.post-gazette.com/philips-respironics-cpap-defect-recall/ (last visited Aug. 23, 2024)(diagram depicts the Phillips Dreamstation; a nearly identical C-PAP device to the Sleepternity device at issue in the case at bar).

(emphasis added). The recall regarding Phillips' Dreamstation CPAP machines eventually expanded to twenty other CPAP and BiPAP machines, as well as other specific models of their Trilogy Evo ventilators. *Id.* The PE-PUR foams breakdown resulted in a variety of adverse health events, resulting in reports of as many as 2,000 cases of cancer, 600 liver and kidney illnesses and 17,000 respiratory ailments." *Id.*

As a result of the fraying of PE-PUR in her Sleepternity device, Ms. Ortega inhaled VOCs to which she was allergic, resulting in asthmatic reactions and a return of her sleep apnea. R. at 4-6. Unaware that Mednology's covert acts had exposed her to these VOCs, Ms. Ortega continued to utilize the Sleepternity CPAP machine. *Id.* The invisible VOCs invaded her body for an unascertained period, resulting first in an asthmatic reaction for which she sought emergency medical care. R. at 4. She immediately discontinued use at the prompting of her primary care physician, but it was too late, and the damage done; Ms. Ortega's ingestion of VOCs—including isocyanates, to which she has a documented allergy—has left her with not just an asthmatic reaction, but with relapsing sleep apnea that is now unresponsive to pharmaceutical treatment. R. at 5. This allergic reaction would not have happened if she had been using the Sleepternity device approved by the FDA. Neither Ms. Ortega nor CMS knew that this dangerous modification had occurred when they consented to accept and pay for the device, respectively.

Fortunately for Ms. Ortega, her brother was a Mednology employee who knew that the company had engaged in the fraudulent swapping of components prior to her injury. R. at 5. In June of 2023, Ms. Ortega filed a complaint against Mednology in

the United States District Court for the Southern District of Transylvania, pleading a fraud-on-the-FDA claim arising under the False Claims Act (FCA) and a negligence claim under Transylvania's product liability statute. R. at 6. She alleged in her complaint that Mednology breached their duty of care, duty of good faith, and duty to warn consumers of the health risks associated with PE-PUR foams. *Id.* As pled in her complaint, Mednology submitted false claims to CMS by shipping an unapproved and dangerous configuration of the Sleepternity device to patients. *Id.* Mednology, on notice of Ms. Ortega's claims, subsequently recalled Sleepternity pursuant to 21 C.F.R. § 7.40(b), in an apparent effort to limit liability once their fraud was exposed. R. at 7. *Id.* The FDA, aware of the filed litigation and subsequent recall, declined to continue their investigation into the fraud, focusing their limited resources instead on other dangerous devices not yet recalled. *Id.*

Finding no substantive defense to their fraud in the facts of the case, Mednology's counsel scrambled to defend these acts through procedural arguments. R. at 9. Despite the apparent contradictions inherent, they claimed immunity under 21 Trans. Comp. Stat. § 630.546(a), but also federal preemption of sections (b) and (c), asserting that the Food, Drug, and Cosmetic Act (FDCA) somehow was intended to preempt a state law's exceptions to immunity, but not the immunity itself. *Id.* Lastly, in a gambit to fully escape culpability for their actions, Mednology sought to avoid having to defend against Ms. Ortega's FCA claim under the assertion that a fraud-on-the-FDA theory cannot support such a claim. Armed with this bevy of

procedural defenses, Mednology sought a 12(b)(6) dismissal in federal district court before discovery could expose additional details of the fraud at issue.

SUMMARY OF THE ARGUMENT

Ms. Ortega's claims have earned the right to be presented to the factfinders at trial. Her state law claims are not preempted by either the FDCA or the MDA, as Congress passed these statutes to aid rather than to stymie private citizens' efforts to be safe from predatory medical companies. Mednology's efforts to benefit from one section of a state statute while claiming preemption of the remaining sections is both cynical and unsustainable. Far from aligned with the intent of Congress, this assertion of preemption is expressly contrary to the intention of the legislature in passing both the FDCA and by amendment the MDA—acts that at their inception and at their core exist to protect the American public from unfit or predatory actions of companies like Mednology that flout the law in search of profit.

Similarly, her claim under the FCA was astutely recognized by the Seventeenth Circuit as a viable claim using the fraud-on-the-FDA theory. This approach simply follows this Court's guidance in *Escobar* by recognizing that billing CMS for a product that deviates from the FDA-approved configuration constitutes fraud on the federal government. Ms. Ortega, in exposing the fraudulent claims made to CMS, pleads a claim aligned with the purpose and intent of the FCA. As both claims assert plausible causes of action that survive the *Twombly-Iqbal* standard for surviving dismissal, they have earned their right to be remanded to the trial court for discovery and an eventual judgment by the trial court.

ARGUMENT

I. PREEMPTING TRANSYLVANIA'S IMMUNITY EXCEPTIONS SHIELDS CORPORATIONS THAT OBTAIN FDA APPROVAL BASED ON FRAUDULENT BEHAVIOR.

Mednology attempts here to have it both ways, shielding itself under a state statute's available immunity provision while simultaneously claiming that the same statute's exceptions are preempted. Their argument defies both this Court's precedent as well as the intent of Congress by not allowing plaintiffs recovery for injuries sustained by medical devices. Moreover, preemption of state law claims against medical device manufacturers defies established tort principles of statutory construction, as applicable case law and statutory schemes were not designed to give such defendants blanket immunity for harmful devices that can critically injure plaintiffs. The acts of Mednology in this case gave Ms. Ortega standing under state law to bring claims that are properly pled and to which preemption should not apply.

A. MS. ORTEGA'S CLAIMS SURVIVE PREEMPTION BECAUSE CONGRESS DID NOT INTEND TO BAN STATE LAW CLAIMS.

A finding of preemption of Transylvania's immunity provisions is against the legislature's intent, the touchstone in every federal preemption analysis. The Supremacy Clause of the United States Constitution is the backdrop of every federal preemption analysis as federal law is "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, the Supremacy Clause "invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 712

(1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824)). Preemption further exists in two distinct categories; "expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

In the medical device context, the FDCA provides 21 U.S.C. § 360k(a), an express preemption provision that provides that states may not establish requirements that are "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

Additionally, this Court has interpreted 21 U.S.C. § 337(a) of the FDCA to impliedly preempt state law, stating that this provision is "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Section 337(a) of the FDCA provides that "all . . . proceedings for the enforcement . . . of this Act shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, the *Buckman* Court stated that "the Federal Government rather than private litigants are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co.*, 531 U.S. at 349 n.4.

Sister circuit courts remain split on whether state law claims and manufacturer immunity exceptions are preempted under the FDCA. Two cornerstones guide federal preemption questions. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Second, "all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,'" require that the analysis begin "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id*. (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). It is with this guidance in mind that it can be understood that Congress did not intend to ban state law claims against medical device manufacturers, particularly claims that may be based on fraudulent behavior by such defendants.

The legislative histories of the MDA and the FDCA clarify that Congress had no intention to abandon all state common law tort remedies. Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. Ill. U.L.J. 453, 485 (2010). Under the MDA there is no explicit cause of action against manufacturers and no suggestion that it creates an implied right of action. *Lohr*, 518 U.S. at 487. Petitioner asserts that § 360k provides for broad immunity to a plethora of state law claims, but this runs afoul of the goal of the MDA, as it was created for the purpose of greater regulation of medical devices after a series of medical device failures. *Id.*

In *Silkwood*, this Court looked to evaluate the preclusion of state tort remedies under the Atomic Energy Act of 1954. *Id*. at 487 n.167. The *Silkwood* Court reasoned,

> [t]here is no indication that Congress even seriously considered precluding use of such remedies when it enacted the Atomic Energy Act of 1954 or when it amended it in 1959 . . . [t]his silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct . . . [i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.

Id. at 251.

Silkwood parallels the case at bar because *Silkwood* was based on traditional state tort law principles, just as Ms. Ortega's claims are here. *Id.* The lack of alternative remedies for plaintiffs injured by illegal fraudulent conduct cannot stand.

Justices Stevens and Ginsburg's additional opinions in *Riegel* further emphasize the importance of legislative intent to preemption analysis. Both agree that the "overriding purpose of the legislation was to provide additional protection to consumers, not to withdraw existing protections." *Riegel*, 552 U.S. at 331 (Justice Stevens, concurring). Justice Ginsburg goes even further, stating that broad readings "of § 360k(a) saves the manufacturer from any need to urge" to defenses based on regulatory compliance because "regardless of the strength of a plaintiff's case, suits will be barred *ab initio*." *Id*. at 345 (Justice Ginsburg, dissenting).

Barring state law claims based on federal preemption of state law immunity provisions would counter the aims of the FDCA and its subsequent amendment, the MDA. This Court should find that Transylvania's immunity exceptions are not

preempted by federal law because the purpose of Congress was not to restrict plaintiffs from recovering from injuries sustained by dangerous medical devices.

B. THE SECOND CIRCUIT'S APPROACH IN *DESIANO* IS PROPER BECAUSE MS. ORTEGA'S STATE LAW CLAIMS ARE NOT PRINCIPALLY ROOTED IN VIOLATIONS OF FEDERAL LAW.

The *Buckman* Court considered plaintiffs' claims that a medical device manufacturer made fraudulent misrepresentations to the FDA to secure premarket approval. *Buckman Co.* 531 U.S. at 343. Plaintiffs further stated that without these fraudulent misrepresentations, the manufacturers would not have obtained approval. *Id*. The Court starts its analysis by stating "[p]olicing fraud against federal agencies is hardly a field with the States have traditionally occupied." *Id.* at 347. Because of this long held belief and implicating federalism concerns, no presumption against preemption was obtained. *Id*. at 348. The Court further held fraud-on-the-FDA claims were conflicted with and are therefore impliedly preempted by federal law. *Id*. As the Second Circuit described, "policing fraud on the FDA through a tort action could interfere with how the FDA might wish to police that kind of fraud itself. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 93 (2d Cir. 2006). The *Buckman* Court accordingly found the plaintiffs' fraud-on-the-FDA claims impliedly preempted by federal law. *Buckman Co.,* 531 U.S. at 343.

The Second Circuit reads the *Buckman* decision narrowly, allowing for a state's manufacturer immunity provisions to survive preemption. In *Desiano*, the central question on appeal was whether the FDCA preempts a Michigan manufacturer's immunity exception. *Desiano,* 467 F.3d at 87. The facts of the case revolve around a

group of Michigan residents who alleged injuries caused by a drug marketed and sold by the appellees. *Id*. at 88. The Michigan residents brought numerous common law claims after discovering the drug produced adverse liver-related effects. *Id.* Subsequent to the claims, the manufacturer simultaneously took the drug off the market. *Id*. The central question on appeal and the facts are on point for resolving the issue of federal preemption, particularly so because Michigan's statute and Transylvania's are strikingly similar.

In deciding that the FDCA did not preempt Michigan's immunity provision, the Second Circuit's analysis begins with the presumption against preemption. The *Desiano* court found the presumption to apply because following this Court's reasoning, "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Lohr*, 518 U.S. at 485. While the *Buckman* Court prevented the application of the presumption due to State interference in federal agency concerns, the *Desiano* case cannot reasonably be characterized as such. The legislative scheme's object was to regulate and restrict when victims could continue to recover under preexisting state product liability law. *Desiano*, 467 F.3d at 94. This desire falls within the preview of the state of Michigan's interest to "regulat[e] matters of health and safety," which is an area where the presumption against preemption applies. *Id*.

Transylvania's immunity statute likewise was devised precisely for this reason because the "goal of the legislature to encourage manufacturers and distributors of various products to prioritize the health and safety of its consumers" and "to

encourage consumers who believe their injury resulted from a manufacturer and/or distributor's failure to exercise care, precaution, or good faith . . . to bring a valid claim against the manufacturer and/or distributor." 21 Trans. Comp. Stat. § 630.546(a). Ms. Ortega brought valid claims asserting that if Mednology had not substituted the PE-PUR sound abatement foams for the approved silicone-based components, she would not have suffered injuries due to breathing in VOCs. R. at 6.

The decision in *Buckman* can further be distinguished because, unlike in the case at bar and *Desiano,* the plaintiffs in *Buckman* were not just claiming fraud-on-the-FDA. Ms. Ortega is bringing state law claims that sound in traditional state tort law, just as in *Desiano*. R. at 4. As the Second Circuit describes, *Buckman* suggested that "the source and vintage of the duty the drug maker is accused of breaching in fraud-on-the-FDA claims is different from the source and vintage of the duty that obtains in traditional tort claims." *Buckman,* 531 U.S. at 352. The *Buckman* court similarly found that in *Silkwood v. Kerr-McGeeCorp*, plaintiff's "claim was not based on any sort of fraud-on-the-agency theory but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Id.*

With this rationale, the *Desiano* court found that since all the claims advanced by the plaintiffs were premised on traditional duties between a product manufacturer and Michigan consumers, concluding that the claims were preempted would be holding that Congress—without any explicit intent to do so—have modified traditional state law duties between pharmaceutical companies and their consumers.

Desiano, 467 F.3d at 95. The *Desiano* court saw this as an unreasonable inference outside of the purview of the courts, in keeping with Supreme Court precedent. *Id.* This Court can recognize its own guidance in these matters and find that a preemption ruling for Mednology is equally unfounded. Ms. Ortega brings independent state tort law claims that invoke traditional duties owed by medical device manufacturers to their consumers.

Another key difference that the Second Circuit finds between common law actions and fraud-on-the-FDA claims is that FDA fraud cases suggest that proof of fraud against the FDA is alone sufficient to impose liability. *Id*. "In *Buckman*, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements." *Id*. *Buckman* distinguishes *Medtronic*, stating that common-law negligence action against the manufacturer of an allegedly defective product:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Id.

As in *Medtronic* and *Desiano*, Ms. Ortega's state law action parallels federal safety requirements but does not sound principally in a manufacturer's failure to comply with federal requirements. Ms. Ortega presents state law causes of action rooted in Transylvania's product liability statute. R. at 6. The *Desiano* court found that the

"pre-existing common law claims survive under M.C.L. § 600.2946(5) because there is also evidence of fraud in FDA disclosures." *Desiano* at 95. However, the claims in *Buckman* are based only on the culpable act of defrauding the FDA. *Buckman*, supra. Given *Buckman's* explanation of *Medtronic*, *Buckman* cannot be read as precluding common law liability based on other wrongs, even when those claims rely upon evidence of fraud against the FDA. *Id*.

Here, Ms. Ortega's claims following the rationale laid out in *Desiano* are proper because the narrow reading of *Buckman* allows plaintiffs to bring causes of action rooted in traditional state law permitting adequate recourse against manufacturers. Even if the immunity exception would be preempted, Plaintiff's would have to rely on the FDA's independent findings that Defendant has violated FDA requirements—a requirement that would make these early-stage pleading nearly impossible without the aid of subsequent discovery. Such a standard has no basis in this Court's precedent and would be antithetical to the intentions of Congress in passing both the FDCA and the MDA.

C. MS. ORTEGA HAS PLED SUFFICIENT FACTS TO REBUT THE PRESUMPTION THAT SLEEPTERNITY COMPLIED WITH THE REQUIREMENTS FOR FDA APPROVAL.

Ms. Ortega has met the demanding pleading standard to avoid dismissal. To withstand a motion to dismiss under Fed. R. Civ. P. (Rule) 12(b)(6), a plaintiff "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible whenever the plaintiff asserts "factual content that allows the court to draw the reasonable

inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556). Conversely, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citing Twombly, 550 U.S. at 555).

When reviewing a defendant's motion to dismiss, the Court must accept all well-pled facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Crescent Plaza Hotel Owner, L.P. v. Zurich Am. Ins. Co*., 20 F.4th 303, 307 (7th Cir. 2021). Moreover, dismissal of plaintiff's complaint is permitted only when "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) (citing *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957)).

This "standard effectively eliminates speculative claims that would otherwise lead to expensive discovery and protracted litigation," but is often misapplied and "sweeps legitimate complaints out of court." Daniel W. Whitney, *Guide To Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 Food Drug L.J. 113, 123 (2010). Plaintiffs in medical device litigation face higher pleading standards than the aforementioned jurisprudence, as these plaintiffs must also state parallel claims at the initial pleading stage of the lawsuit. Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. Ill. U.L.J. 453, 476 (2010).

Even so, Ms. Ortega meets this high bar. Ms. Ortega asserted that the FDA would not have approved Sleepternity if the medical device contained PE-PUR sound

abatement foams rather than silicone-based foams. R. at 6. She cites a recent incident where the FDA found that PE-PUR foams contained in CPAP machines presented health hazards when broken down. *Id*. Using this reference, Respondent demonstrates that Sleepternity would not have obtained pre-marketing approval from the FDA.

The dissent in the Court of Appeals draws attention to the Sixth Circuit case *Marsh v. Genentech*, which relies on its own precedent in *Garcia v. Wyeth-Ayerst Laboratories*. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 549 (6th Cir. 2012). Genentech designed, manufactured, and sold medication which the FDA approved. *Id*. Marsh began to use this medication and subsequently suffered from viral meningitis and a collapsed lung which she attributes to her use of said medication. *Id*. at 548. Genentech moved to dismiss on the grounds that the immunity provision under the state act held drug manufacturers not liable if its label the FDA approved its label and were compliant with the FDA's approval at the time that the drug left the manufacturer's control. *Id*. at 549. Marsh countered that Genentech was not entitled to immunity due to their failure to submit updated safety information after the drug went to market or otherwise comply with FDA regulations upon which ongoing approval was conditioned. *Id*.

The court held that federal law preempts a plaintiff's ability to assert that the defendant's drug did not comply with the FDA's approval, thereby enabling the defendant to remain protected. *Id*. at 552. "Put another way, the statutory language suggests that immunity requires substantive compliance with FDA approval, but the

plaintiff only alleged procedural non-compliance. *Id*. Here, Ms. Ortega alleges that Mednology violated substantive compliance with FDA regulations by replacing the sound abatement foams with a known dangerous component. R. at 6.

Often victims of harmful products "may not be able to determine without discovery and further investigation" the necessary elements of their claim. *Bausch v. Stryker*, 630 F.3d 546, 560 (7th Cir. 2010). Allowing dismissal at the initial stages would cause claims like Ms. Ortega's to fail without proper discovery. Therefore, the Seventeenth Circuit Court of Appeals correctly found that Ms. Ortega pleaded sufficient facts to rebut the presumption because she pled parallel violations that do not infringe on the FDA's jurisdiction, and she pled with enough specificity to make her claims are plausible on their face.

D. Public Policy Favors Holding Manufacturers Liable for Fraudulent Acts that Inflict Real Harm on the Populace.

Imposing liability on manufacturers who fraudulently represent their products to the public and governmental agencies was the precise evil Congress intended to combat with the FDCA, the MDA and the FCA. These acts were passed for the good of both consumers and the overall public interest in avoiding fraud and harmful goods entering the market. Such sound in traditional tort principles in providing avenues for recovery for those injured and the encouragement of responsible behavior on behalf of the manufacturers. Grace M. Zogaib, *Preemption After Buckman: State Law Failure to Warn Claims based on Lack of Disclosure to the FDA*, 21 Ave Maria L. Rev. 236, 250 (2023).

Under the FDCA and MDA, no private right of action is explicitly stated or implied for medical devices that have earned FDA approval. *Lohr*, 518 U.S. at 487. Therefore, in the medical device context, litigants are often left without remedy where implied preemption bars state law claims. Further, with the looming threat of litigation, medical device manufacturers must be more diligent in adhering to FDA regulations and creating products that are not defective. Former Chief Counsel for the FDA articulated this point by stating:

> FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. . . Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices.

Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food Drug L.J. 7, 11 (1997).

However, claims that imposition of such liability will inhibit innovation and cause "desirable products to be withdrawn from the marketplace" are overblown. A. Mitchell Polinsky and Steven Shavell, *The Uneasy Case for Product Liability*, 123 Harv. L. Rev. 1437, 1488 (2010). The imposition actually "incentivizes companies to actively monitor their products [and] reinforces a norm of attentiveness to safety." *Id*. at 991 (quoting John C.P. Goldberg & Benjamin C. Zipursky, *The Easy Case for Product Liability Law: A Response to Professors Polinsky and Shavell,* 123 HARV. L. REV. 1919, 1941 (2010)). In the interests of the greater public good, the FDCA should not preempt Transylvania's state law immunity provisions.

II. FRAUD ON THE FDA IS A VIABLE ACTION UNDER THE FALSE CLAIMS ACT, AS IT EMBODIES THE TRUE PURPOSE AND INTENT OF THE ACT AS PASSED AND AMENDED BY CONGRESS.

Respondent's case exemplifies the Congressional purpose behind the False Claims Act, as it consists of an American citizen harmed by fraud perpetrated against the United States government. Respondent Ms. Ortega's claims plead a legitimate cause of action under the FCA, as they allege an act of fraud against the federal government in the form of billing CMS for an unapproved medical device configuration not approved by the FDA. R. at 6. This unreported and unapproved alternate configuration replaced a benign component with one made from PE-PUR—a material known to break down into "volatile organic compounds" (VOCs) that are then likely to be inhaled or swallowed by users. R. at 3. These acts, perpetrated with knowledge and intent to defraud the federal government, are sufficient to support Respondent's claims under the FCA.

A. THE NINTH CIRCUIT'S PRECEDENT FROM *CAMPIE* IS THE PROPER GUIDANCE, AS IT BETTER FOLLOWS THIS COURT'S PRECEDENT FROM *ESCOBAR* AND THE INTENT BEHIND THE FCA.

The Seventeenth Circuit faced a circuit split in analyzing Mednology's efforts to have Ms. Ortega's FCA claim dismissed. The First Circuit in *D'Agostino v. ev3, Inc.* and the Ninth Circuit in *United States ex rel. Campie v. Gilead Scis.* cited this Court's reasoning in *Escobar*, but came to notably different analyses regarding the viability of the fraud-on-the-FDA theory. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016); *see also United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 907 (9th Cir. 2017). *Campie* gives superior guidance to our case, but a closer look at *D'Agostino*

shows that even the First Circuit did not dismiss such theories outright. *Id.* The *Campie* court's guidance is also better aligned with the Congressional intent that guided both the Act itself and the analysis that guided this Court's prior interpretations.

The False Claims Act was signed into law by President Abraham Lincoln in 1863, originally intending to hold contractors liable for providing the Union with fraudulent claims for payment during the Civil War. § 21:19. False Claims Act—History and background, 3 White Collar Crime § 21:19 (3d ed.). The Act allowed for direct actions brought by the federal government as well as qui tam actions to be brought by private citizens on the U.S. government's behalf. *Id.* Qui tam actions date back to the Roman Empire and entered American law through the common law traditions of the English Courts. James B. Helmer, Jr. & Robert Clark Neff, Jr., *War Stories: A History of the Qui Tam Provisions of the False Claims Act, the 1986 Amendments to the False Claims Act, and Their Application in the United States Ex Rel. Gravitt v. General Electric Co. Litigation*, 18 Ohio N.U. L. Rev. 35, 37 (1991). These actions allowed private citizens to be compensated for bringing such actions by sharing in the damages awarded. *Id.*

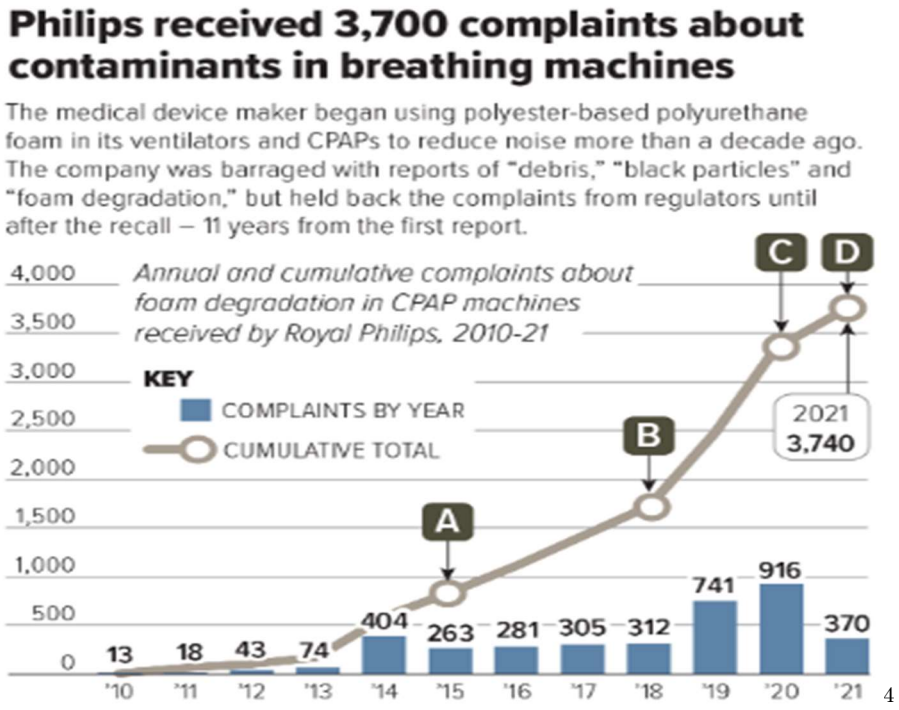
As the act evolved by Congressional amendments over time, the FCA grew into a potent tool of consumer protection as well, able to hold fraudsters accountable for both their dishonest submission of bills to the government and for the harm they may visit on consumers as a result of the same guilty acts. Helmer & Neff, *supra.* Access to this cause of action was expanded over time by court doctrine, as it did in *Escobar*,

wherein this Court validated the false certification theory as an alternative method to proving fraudulent billing of the federal goverment. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186 (2016). The *Escobar* court found that such fraudulent acts "can, at least in some circumstances, provide a basis for liability" under the FCA. *Id.*

The *Escobar* Court dealt with a case wherein a mental health clinic caused the death of a teen through reckless and inappropriate administration of medications, leading to her parents filing a qui tam action under the FCA. *Id.* at 176. As relators under the FCA, they alleged that the clinic violated the Act under the "'implied false certification' theory," wherein the submission of treatment bills for reimbursement by Medicaid "implicitly certifies compliance with regulations" and renders such submissions "fraudulent." *Id.* at 176-7. This Court in *Escobar* explained that "the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions." *Id.* at 187. They further held that when a medical care or device provider "omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Id.* at 187. These claims would be pled validly under the FCA as long as the fraudulent act was "material to the Government's payment decision." *Id.* at 192.

Following this Court's guidance from *Escobar*, the *Campie* court identified that under this theory, FCA liability attaches when the defendant "represented that it provided [goods or services] approved by the FDA that were manufactured at

approved facilities and were not adulterated or misbranded." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir. 2017). That court recognized as well that the misrepresentation made by the defendant under the FCA must be one "wherein the falsity is knowingly perpetrated and the underlying fraud is material to the government's decision to pay." *Id.* at 902. This is closely analogous to the case at bar, wherein the relator alleges that Mednology knowingly replaced the approved silicone-based foam with one made from PE-PUR—a component responsible for a comparable device's loss of FDA approval just two years prior.[3]



[4]

[3] *Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines,* FDA, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/foam-testingsummary-recalled-philips-ventilators-bipap-machines-and-cpapmachines#:~:text=Following%20the%20initial%20recall%20in,2021%20on%20the%20new%20foam (last updated Apr. 10, 2024).

[4] Note 2, *supra* (timeline showing the escalation of complaints relation to PE-PUR foams in Phillips' Dreamstation CPAP. This timeline shows that by 2021, two years before Mednernity began substituting PE-PUR into their CPAP machines, the adverse health risks of that compound was well-known and inescapable to any responsible medical device manufacturer).

In the First Circuit, the court in *D'Agostino* cited *Escobar* while analyzing an allegation that a medical device manufacturer violated the FCA in relation to two FDA-approved products. *D'Agostino* at 10. D'Agostino, the relator, sought to press a claim under the FCA alleging that ev3 had allowed the device to be used by professionals with insufficient training. *Id.* at 4–5. The device's conditional approval by the FDA had been contingent upon the medical professionals utilizing the device having received specialized training, but D'Agostino alleged that as an indirect result of the manufacturer's sales quotas and marketing approach, that training never occurred. *Id.*

The *D'Agostino* court ultimately ruled that "[t]he FDA's failure actually to withdraw its approval [of the product] in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained." *Id.* at 8. Notably, the First Circuit never stated that *all* fraud-on-the-FDA claims must fail but that the relator must also demonstrate that the FDA would not have approved the substituted configuration. *Id.* at 9. As Ms. Ortega's claim succeeds in doing so by showing that the FDA revoked approval for an identical device modification, her case succeeds where D'Agostino's failed.

B. The False Certification Theory from Escobar Allows Ms. Ortega to Demonstrate that CMS Would Not Have Paid for the Device if it Knew of the Fraud Perpetrated by Petitioner

The FCA was intended to allow a cause of action against companies that have defrauded the federal government, and the false certification theory is a valid method under the Act. Implied certification theory cases—like all FCA cases—rely upon a

showing that the federal government was defrauded into paying for services other than what was represented. *Escobar*, supra. As this Court identified in *Escobar*, implied certification claims are viable if they are made with the following two elements: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 190. The theory, therefore, treats as implied that when Mednology submitted for Medicaid reimbursement for the Sleepternity machine, it knew that CMS replied upon FDA approval. Re. at 4. The FDA approval was for the configuration containing the silicone-based foam rather than the unapproved configuration containing PE-PUR foam. *Id.* By knowingly submitting these bills for a product other than what was approved, Mednology defrauded CMS, an agency of the federal government. This set of facts is like if a contractor pharmaceutical company obtained approval for a medication, and then replaced it with a placebo. The only difference here is that not only did the product not treat the condition for which it was prescribed, it in fact exacerbated those conditions and visited new harms upon Ms. Ortega and other unfortunate victims.

The Sixth Circuit dealt with a similar case in *U.S. ex rel. Gilligan v. Medtronic, Inc.*, in which a medical device manufacturer submitted one version of their medical device to the FDA for approval, and then following that approval, substituted a key component with one that posed a danger to consumers. 403 F.3d 386, 388 (6th Cir.

2005). While the Sixth Circuit ultimately dismissed that claim, it was not because the plaintiff failed to raise sufficient facts to support a fraud-on-the-FDA qui tam action, but because it was filed after a public release of sufficient facts for the government to pursue the claim on their own, in violation of the FCA's public disclosure bar. *Id.* at 391. Because Ms. Ortega's claim was filed before Mednology recalled the Sleepternity device, no such bar exists to keep the claim from moving forward. R. at 7.

As cited by the Third Circuit in *Greenfield*, "the [FCA] is intended to reach all fraudulent attempts to cause the Government to pay ou[t] sums of money or to deliver property or services,' and '[a] false claim for reimbursement under Medicare, Medicaid, or similar program . . . may be false even though the services are provided.'" *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96 (3d Cir. 2018). As such, the FCA was intended to address facts such as ours, where a company seeks payment from CMS for goods and services in a configuration other than what the FDA actually approved.

Replacement of the approved formulation with one posing a known health risk constitutes a valid FCA complaint. As noted by the District Court of Transylvania, the government's payment for the device "was based on the FDA approving the medical device for marketing and distribution, it can reasonably be inferred that Mednology falsely certified to the payor that it had complied with all the requirements for obtaining the FDA's approval." R. at 36. This undeniably relegates the question of whether CMS would have approved the device with the PE-PER

components as an "issue of materiality to present a matter of proof rather than a legal ground to dismiss the relators' complaint." *Id.* The district court was correct in finding that whether a jury finds this misrepresentation is sufficient to issue a favorable judgment on Ms. Ortega's claim is undeniably a question of fact—not of law. As such, this must be presented to a proper factfinder for judgment at trial.

C. THE FACTS ALLEGED ARE SUFFICIENT TO SUPPORT A FRAUD-ON-THE-FDA THEORY, AS THE FDA'S HISTORY DEMONSTRATES WILLINGNESS TO WITHDRAW APPROVAL FOR SIMILAR RECONFIGURATIONS.

The allegations in the case at bar are sufficient to demonstrate that the FDA would normally withdraw approval in similar cases. CMS will generally not pay for a medical device unless that device has passed the requisite approval process required for FDA approval. 42 C.F.R. § 419.66(b)(1). The FDA approval process is dependent upon the classification given to the device being submitted, with Class III devices being required to pass through the FDA's Premarket Approval process.[5] As described by this Court in *Riegel*, "a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness," and in cases where it "presents a potential unreasonable risk of illness or injury." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). This process includes a rigorous process, and includes "a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation.'" *Id.* at 318.

[5] *Premarket Approval (PMA)*, FDA, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma#when (last visited Aug. 23, 2024).

The process, as described by the FDA, states:

> A Premarket Approval (PMA) application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of the Class III device. There are administrative elements of a PMA application, but good science and scientific writing is a key to the approval of PMA application. If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it could impact FDA's review and approval. PMA applications that are incomplete, inaccurate, inconsistent, omit critical information, and poorly organized have resulted in delays in approval or denial of those applications. Manufacturers should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well-organized format.
>
> *Id.*

This rigorous process includes an analysis of the physical properties of the proposed device as assessed during clinical and non-clinical studies, including assessments of "stress, wear, shelf life . . . . adverse reactions and complications, device failures and replacements" and "should include all applicable elements described in the device-specific guidance documents." *Id.* Such data collection would require disclosure of the presence of volatile organic compounds and those known to break down into toxic fragments, such as PE-PUR. The FDA then requires notification of alterations in approved devices after it has received Premarket Approval, referred to as a "premarket notification."[6] 21 CFR 807.81(a)(3) requires such notification "when a legally marketed device subject to 510(k) requirements is

[6] *Is a new 510(k) required for a modification to the device?*, FDA, https://www.fda.gov/medical-devices/premarket-notification-510k/new-510k-required-modification-device#:~:text=Major%20modifications%20to%20the%20device,of%20manufacture%2C%20or%20intended%20use (last visited Aug. 23, 2024).

significantly changed or modified in design, components, method of manufacture, or intended use. *Significant changes or modifications are those that could significantly affect the safety or effectiveness of the device*, or major changes or modifications in the intended use of the device." *Id.* (citing 21 C.F.R. § 807.81)(emphasis added).

As noted by this Court in *Riegel*, "[o]nce a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, *supra*, at 319. A change that replaces a safe component with one known by the FDA to cause significant health risks would meet the FDA's directive for such a disclosure. It strains credulity to think that changing a configuration to ape the now-infamous Phillips Dreamstation would be a danger lost on the FDA.

The weight of evidence shows that FDA approval for the altered configuration would have been denied if Mednology had properly filed the 510(k) notification. Mednology's Sleepternity device was granted FDA approval as a Class III device based upon a formulation with the silicone-based foam. R. at 3-4. When Mednology then replaced that component with a PE-PUR foam, they were effectively selling an unapproved medical device that replicated the failed and deadly design flaw of the recalled Phillips Dreamstation, which was already widely taken off the market two years prior. R. at 4. There have been no intervening changes in the FDA's position on Phillips' device, save that on April 9, 2024, the FDA issued a consent decree that specified a limitation on any future production of the machines containing PE-PUR

foam and specified additional parameters Phillips must follow in terms of refunding affected patients for past purchases. Note 1, *supra*.

To accept Mednology's assertion that the FDA may have still approved the modified configuration asks this Court to blind itself to FDA standards and precedent. The Phillips Dreamstation recall is still occupying the FDA today, as the thousands of injured parties are receiving updated guidance as recently as April of 2024. *Id.* Mednology has offered no evidence to suggest that the FDA would allow ongoing premarket approval for a device nearly identical to one subject to a mandatory recall. Ms. Ortega has plausibly alleged that Sleepternity would have been forcibly recalled if Mednology had not done so voluntarily. Therefore, Ms. Ortega pled a plausible and viable theory by which the FCA has been properly invoked, her claim reaches this Court's standards to survive summary judgment, and the Seventeenth Circuit's ruling accordingly should be upheld.

D. MS. ORTEGA'S CLAIM UNDER THE FCA ARE WELL-PLED AND SUFFICIENT TO WARRANT REMAND TO THE TRIAL COURT.

As established by this Court in *Ashcroft*, any well-pled allegations that go beyond recitation of conclusory statements and naked recitation of the elements of a claim are to be treated as true, and that such factual allegations then survive dismissal is they state a plausible claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 663-64 (2009). Far surpassing plausibility, Ms. Ortega has related a textbook case of implied certification theory by way of fraud-on-the-FDA that can and should support her case proceeding before a jury. This Court in *Escobar* did not permit simply any claim of fraud to move forward under the FCA, but where both a material misrepresentation

to the FDA has occurred, and that misrepresentation caused the CMS to pay for something other than what was approved, the claim can and must be allowed its proper day in court. See *Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016).

Petitioner is alleged to have substituted a benign component of their approved device with a deleterious and volatile compound known to pose a direct risk to patients. R. at 6. Prior CPAP devices using the same harmful material in the same manner were recalled following nearly ten years of documented injury to patients. R. at 4. The alleged conduct goes far beyond plausibility, and it will be proven through discovery that Mednology acted with scienter and disregard for the safety of patients. The conduct alleged defrauded the federal government by submitting for payment to CMS for a device that not only was not the approved configuration, but was in fact a replica of a failed and recalled Phillips; device that is known to have resulted in thousands of injuries. R. at 4 This is why the learned judges of the Seventeenth Circuit rightly reversed the trial court's dismissal of Respondent Ms. Ortega's FCA claim. R. at 38. Respondent submits to this Court that the legislative intent of the FCA, the facts of the case, and this Court's own precedent cannot lead to a different finding.

CONCLUSION

Ms. Ortega's claims survive this Court's scrutiny and deserve their day in court. Mednology's claims of selective preemption lack support in the law, and this case must be allowed to proceed into discovery to uncover the full extent of their

culpability. Justice Ginsburg in *Riegel* noted that "[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis" as they "did not regard FDA regulation and state tort law claims as mutually exclusive." *Riegel* 552 U.S. at 334-44 (Justice Ginsburg, dissenting) (citing *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005). The misconduct alleged here victimized both an American combat veteran and the federal government itself, and the argument for preemption is not supported by the purpose of either the FDCA or the MDA.

Ms. Ortega's federal complaint properly alleges a claim of fraud against the federal government, as Mednology intentionally deceived CMS to reimbursement for an unapproved configuration of the Sleepternity device. As recognized by the Seventeenth Circuit, Ms. Ortega has shown that the alleged fraud on the FDA claims "are sufficient to transform the issue of materiality from a legal ground for dismissal to a matter of proof, since Ms. Ortega could plausibly satisfy the materiality element of her FCA claim under these allegations." R. at 37. The Seventeenth Circuit was correct to overturn the district court's grant of dismissal and to remand the case back for discovery, wherein the material facts may be presented to the finders of fact. Failing to do so would embolden other opportunistic companies to exploit Medicare funds and the safety of our American combat veterans for easy profit.

Respectfully submitted,

/s/ 3317

Attorneys for Respondent

APPENDIX A

Statutory Provisions

False Claims Act 31 U.S.C. § 3729(a)(1), (b). 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.

(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.

31 U.S.C. § 3730(b), (e)(2)(A). Civil Actions for False Claims

(b) Actions by private persons.

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

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure.1 The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

21 Trans. Comp. Stat. § 630.545 (2024).

Manufacturers and distributors of a product owe a duty of care and good faith to their consumers throughout the manufacturing and distribution of such product, including the duty to warn of any dangers or risks associated with the product, the

duty to comply with all the state and federal laws and regulations governing the manufacturing and distribution of the product, and the duty to make disclosures to appropriate agencies or government officials about any modifications made to the product. Any resulting injury or death that would not have occurred but for the breach of any of the aforementioned duties shall serve as adequate basis for liability under this statute.

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

(b) The immunity granted under subsection (a) does not apply if the defendant, at any time before the event that allegedly caused the injury, intentionally withholds from or misrepresents to the United States Food and Drug Administration information concerning the drug or the medical device that is required to be submitted under the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301–399i)

and the drug or medical device would not have been approved, or the United States Food and Drug Administration would have withdrawn approval for the drug or medical device if the information were accurately submitted.

(c) The immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the drug or medical device as required by the FDA.