No. 24-9176

IN THE

Supreme Court of the United States

NOVEMBER TERM 2024

MEDNOLOGY, INC.,
Petitioner,

— versus —

UNITED STATES EX REL. Riley ORTEGA,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Fifteenth Circuit

BRIEF FOR RESPONDENT

TEAM 3307

Attorneys for Respondent

QUESTIONS PRESENTED

I. Does federal law under the FDCA preempt Transylvania state law under 21 Trans. Comp. Stat. § 630.546(a-c) when a plaintiff's claims are primarily based in state tort law and only use FDA requirements as a comparable state element of the tort claims?

II. May a relator rely on a fraud-on-the-FDA theory to state a claim under the False Claims Act's *qui tam* provision when a medical device manufacturer shirked FDA regulations thereby causing a governmental agency in CMS to pay for the device's coverage?

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

UNITED STATES SUPREME COURT CASES:

UNITED STATES CIRCUIT COURT OF APPEALS CASES:

UNITED STATES DISTRICT COURT CASES:

CONSTITUTIONAL AND STATUTORY PROVISIONS:

ADMINISTRATIVE MATERIALS:

LEGISLATIVE MATERIALS:

RESTATEMENTS OF LAW:

OTHER AUTHORITIES:

OPINIONS BELOW

The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2–24 of the record. The district court DENIED the Defendant's motion to dismiss the Plaintiff's state tort claims and GRANTED the Defendant's motion to dismiss the Plaintiff's claim under the False Claims Act. The opinion of the United States Court of Appeals for the Seventeenth Circuit is also unreported but appears on pages 25–42 of the record. The district court AFFIRMED the district court's judgment on the dismissal of Plaintiff's state tort claims, and REVERSED the district court's judgment on the dismissal of Plaintiff's False Claims Act claim.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2. This case also involves two statutory provisions, 21 U.S.C. § 360k(a) and 21 U.S.C. § 377(a) which govern the federal preemption of the Federal Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"). This case also involves the False Claims Act under 31 U.S.C. § 3729.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves the Fifteenth Circuits finding that certain claims made by the plaintiff were preempted in part, but not wholly preempted by federal law. It

also involves the Fifteenth Circuits determination that the plaintiff successfully pled sufficient facts to bring a *qui tam* claim under the False Claims Act.

The Plaintiff Riley Ortega. Riley Ortega is a veteran who served as an artillery officer for the United States Army. R. at 3. Ortega suffers from PTSD due to trauma from her service. R. at 3. Her PTSD contributes to recurring and overwhelming symptoms of sleep apnea and insomnia. R. at 3. Seeking medical attention for her symptoms, Ortega visited her somnologist to discuss options to alleviate her pervasive respiratory symptoms. R. at 3. Ortega's somnologist prescribed a "state-of-the-art" CPAP machine, Sleepternity. R. at 3.

Mednology's Sleepternity Device. Sleepternity was manufactured by Mednology. R. at 4. Ortega intended to use this device to treat her sleep apnea and insomnia. R. at 3. The Sleepternity device was originally approved by the FDA as a Class III medical device on December 30, 2022. R. at 3–4. A major feature of the device is headphones which emit a vibration that was supposed to help users fall asleep. R. at 3.

Sleepternity's FDA Approval. Shortly after its FDA approval, the Centers for Medicare and Medicaid Services ("CMS") began providing coverage to individuals prescribed Sleepternity. R. at 4. After providing coverage, CMS would compensate for the costs of using the machine. R. at 4. CMS only provided coverage because the FDA had approved this version of the Sleepternity. R. at 4. The FDA approved model of Sleepternity was based in part on the device using a silicon-based sound dampening foam in its headphones. R. at 5.

Sleepternity's Noncompliance with FDA Approval. With the effect of avoiding FDA approval, Mednology modified the Sleepternity machine to no longer include a silicon-based sound dampening foam, but a PE-PUR based foam. R. at 4. PE-PUR foams are noticeably cheaper to manufacture than silicone-based foams. R. at 5. Mednology did not give notice in any way to consumers or the FDA that it changed a critically important component of its device. R. at 4. The FDA's own research has established that PE-PUR foams constitute a significant health risk to consumers. R. at 4. PE-PUR foams can break down in isocyanates, an allergen resulting from the breakdown of polyurethane. R. at 5–6. Mednology, despite altering the design of its device, also did not change its warning label to reflect the health risks of isocyanates and adequately warn consumers. R. at 5.

Dangers of PE-PUR Foams. PE-PUR foams will break down into volatile organic compounds ("VOCs") when subject to vibrations. R. at 4. These VOCs are particulates which are not visible, and can be breathed in by CPAP users resulting in severe health risks. R. at 4. In 2021, over a year prior to the approval of the Sleepternity, another major medical manufacturer recalled its CPAP machine which utilized PE-PUR foams. R. at 4. This company, Philips Respironics, attempted to address its recall by replacing the PE-PUR foams with the safer, silicon-based foams – the same foam material that in part caused the Sleepternity to be approved by the FDA. R. at 4.

Ortega's Injury and Suffering. Ortega suffers an allergy to the isocyanates which are a byproduct of the Sleepternity's PE-PUR foam. R. at 5. After using the

Sleepternity device, Ortega suffered severe asthma attacks. R. at 4. Ortega was later rushed to the emergency room, where she was hospitalized and required stabilization by hospital staff. R. at 4–5. The hospital physician who stabilized Ortega recommended that she no longer use the Sleepternity device. R. at 5. Her primary care physician later concluded that Ortega's asthma attacks were an unknown side effect of using Sleepternity. R. at 5. Ortega's physician, knowing of her allergy to isocyanates, would have made a more immediate and conclusive diagnosis of Sleepternity's effect the presence of isocyanates been noted on the device's label. R. at 5. Priot to her hospitalization, Ortega was unaware that Mednology had changed the Sleepternity device. R. at 4. Ortega now suffers chronic lung inflammation, further exacerbating her unresolved, and now untreated, sleep apnea. R. at 5. Ortega's acute asthma attacks ended when she stopped using the Sleepternity device's mask and headphones. R. at 5.

Ortega Learns of Mednology's Actions. Ortega's brother worked as an assembly manager for Mednology. R. at 5. After her hospitalization, Ortega learned from her brother that Mednology used the silicon-based foams to achieve FDA approval, and then switched to PE-PUR foams as a cost saving measure. R. at 5. Ortega subsequently researched PE-PUR foams substituted by Mednology, learning it breaks down into her allergen, isocyanates, which inflamed her lungs and caused her asthma attacks. R. at 5–6. Mednology has since voluntarily recalled its device following Ortega's injuries. R. at 29.

II. NATURE OF THE PROCEEDINGS

The District Court. On June 21, 2023, Riley Ortega brought two claims against Mednology in federal district court for violations of state tort claims and the False Claims Act. R. at 6.

Ortega alleges state tort violations of a manufacturer's duty of care under Trans. Compl. Stat. § 545. R. at 6. Responding to the state tort claims, Mednology invoked a manufacturer's immunity provision of state law under Trans. Compl. Stat. § 546(a). R. at 9. Section 546 features three major exceptions to immunity. R. at 7–8. The district court found that it only need to consider the exceptions in Trans. Compl. Stat. § 546(b–c): misrepresentation, and failure-to-warn. R. at 24, n.7. Mednology moved to dismiss Ortega's state tort claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on the theory that these state exceptions to immunity are preempted by federal law. R. at 9. The district court held that the misrepresentation exception under Section 546(b) was not preempted by the FDCA because the exception sounded in traditional tort law. R. at 15–16. The district court found that the failure-to-warn exception under Section 546(c) was also not preempted by the FDCA for the same reason. R. at 18.

Ortega also brought a *qui tam* action on behalf of the government asserting that Mednology violated the False Claims Act. R. at 6. Ortega alleges that Mednology's fraudulent actions in adulterating the Sleepternity device contrary to its FDA approval caused a government organization in CMS to erroneously pay for its coverage. R. at 19. Mednology moved to dismiss Ortega's claim under Federal

Rule of Civil Procedure 12(b)(6) for failure to state a claim, arguing that Ortega may not use a "fraud-on-the-FDA" theory to plead under the False Claims Act. R. at 9. The district court initially granted Mednology's motion to dismiss Ortega's False Claims Act action. R. at 24.

The Fifteenth Circuit Court of Appeals. Both Mednology and Ortega appealed the district court's ruling. R. at 25. Mednology appealed the finding that Section 546 was not preempted by the FDCA. R. at 25. Ortega appealed the finding that she failed to state a claim pursuant to the False Claims Act. R. at 25.

The Court of Appeals affirmed a finding that Section 546 was not preempted on different grounds than the district court. R. at 25. The court considered Section 546(a) and found that a plaintiff's ability to allege noncompliance with the FDA was not preempted. R. at 35. The court noted that the relevant difference was in the preservation of some sort of remedy for injured plaintiffs. R. at 34–35. However, the court found that Section 546(b) and Section 546(c) were both preempted. R. at 38.

The Court of Appeals reversed a finding that Ortega failed to state a claim to support an action under the False Claims Act. R. at 37–38. The court held that pleading a False Claims Act claim is a matter of proof rather than a legal basis for dismissal. R. at 37. The court ruled that Ortega had alleged sufficient facts to sustain her claim. R. at 38.

SUMMARY OF THE ARGUMENT

This Court should affirm the Fifteenth Circuit Court of Appeals ruling that Trans. Compl. Stat. § 546(a) is not preempted under the FDCA because it preserves an individuals' right to a state tort cause of action. This Court should also reverse the appellate court's decision that sections 546(b–c) are preempted by the FDCA because such claims sound in traditional tort law and are not an attempt at federal enforcement. Finally, this Court should affirm its decision that sustaining a False Claims Act cause of action is a matter of proof and that Ortega has successfully alleged sufficient plausible facts to meet the pleading standard.

I.

The exception to state tort immunity under Trans. Compl. Stat. § 546(a) regarding a presumption of FDA compliance is not preempted by the FDCA. Section 546(a) exactly parallels FDA requirements in order to sustain a state tort claim. The parallel nature of the exception causes the statute to avoid express preemption. Additionally, the because the claim only uses FDA regulations as a proxy for measuring traditional state tort liability, it establishes that it is a traditional state tort claim pursuant to Section 545. Because the claim is a traditional state tort claim, it also avoids implied preemption and does not seek to enforce or restrain violations of the FDCA.

II.

In the alternative, if this Court finds that the exceptions do not sound in traditional tort law, the immunity provision of Section 546(a) would necessarily be

preempted by federal law. Mednology's immunity relies on a determination that the Sleepternity device was FDA compliant. Mednology indisputably modified its device to avoid FDA regulation. This device by the FDA's own guidance is a device different from the FDA-approved device. If this Court requires a factual finding of compliance by the FDA, then the state court cannot endorse a presumption of immunity for a new device without a factual finding by the FDA.

III.

The misrepresentation exception to state tort immunity under Section 546(b) is also not preempted by the FDCA. While there is a court split regarding when a misrepresentation or "fraud-on-the-FDA" claim is preempted, the facts of this case constitute a narrow application that has never been considered by the circuit courts. The fact that a device has indisputably been adulterated speaks to the characterization of Ortega's claim as sounding in traditional tort law and a manufacturer's particularly injurious conduct. Holding that these narrow circumstances sound in traditional tort law preserves the intention of the FDCA in protecting individual consumers, and prevents manufacturers from using their fraudulent conduct as a shield to tort liability under the broad view of preemption.

IV.

The failure-to-warn exception to state tort immunity under Section 546(c) is not preempted by the FDCA. Section 546(c) indicates that its parameters only parallel federal requirements, but that it is clearly a traditional state tort claim. Failure-to-warn claims in particular have long been recognized as a traditional tort

claim. It is not impliedly preempted because it sounds in traditional tort law and this statute does not require any aspect of fraud, a distinction that otherwise would have made it subject to a court split. Additionally, the FDCA and Congress in passing it have long indicated that it would want to preserve the rights of individuals to seek a failure-to-warn claim, and that this enhances the FDA's regulatory regime. Finally, the court of appeals incorrectly decided that a state failure-to-warn claim's intersection with an immunity statute made any appreciable difference to a state tort analysis.

V.

Ortega has pled sufficient facts to overcome a motion to dismiss her False Claims Act claim. This Court has already held that liability can attach to fraud-on-the-FDA claims submitted under the False Claims Act. Ortega has made a claim plausible on its face that Mednology knew it was violating a material requirement, and that this requirement was material to the government's payment decision.

Ortega has also pled sufficient facts to survive a 12(b)(6) motion dismiss her fraud-on-the-FDA claim based on fraudulent misrepresentation. This Court should follow the Ninth Circuit's standard, which is more appropriate for this claim, faithful to the purpose of the FCA, and better suited to address fraud claims. Ortega has pled sufficient facts to establish that if the FDA had known of the changed foam material in Sleepternity devices, it would not have approved it and, therefore, CMS would not have paid for it.

ARGUMENT AND AUTHORITIES

Standard of Review. This appeal raises two questions of law. The Supreme Court reviews questions of law *de novo*. *See Highmark Inc. v. Allcare Health Mgmt. Sys.*, 572 U.S. 559, 563 (2014). Federal preemption of applicable state law is a question of law reviewed *de novo*. *See Smiley v. Citibank (s.D.), N.A*, 517 U.S. 735, 744 (1996). Dismissal for failure to state a claim under the False Claims Act is a question of law reviewed *de novo*. *See United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 568 (9th Cir. 2016).

I. SECTION 546(a)'S COMPLIANCE PROVISION IS NOT PREEMPTED BY THE FDCA BECAUSE IT IS NOT EXPRESSLY PREEMPTED BY 21 U.S.C. § 360K(A) OR IMPLICITLY PREEMPTED BY 21 U.S.C. § 337(A).

Case law regarding preemption under the FDCA has identified two clear avenues that establish preemption, neither of which are established by Mednology here. First, there may be "express preemption" under 21 U.S.C. § 360k(a). Second, there may be "implied preemption" under 21 U.S.C. § 337(a).

A. Trans. Compl. Stat. § 546(a) is Not Expressly Preempted Because it Does Not State Requirements "Different From or in Addition to" FDA Regulation and Instead Parallels Federal Requirements

According to 21 U.S.C. § 360k(a), states may not create legislation which is "different from or in addition to" FDCA requirements. This Court has routinely interpreted this phrase to mean that state tort requirements which are "parallel" to

federal requirements can avoid express preemption. 21 U.S.C. § 360k states in relevant part that no state may make requirements "different from, or in addition to, any requirement applicable under [the FDCA]". *See* 21 U.S.C. § 360k(a).

1. The Plain Language of Trans. Compl. Stat. § 546(a) Indicates That it Does Not State Requirements "Different From or In Addition to" FDA Regulations.

"Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (emphasis added). Here, Section 546(a) does not make any statement that is "different from, or in addition to" any requirements under the FDCA and instead parallels those requirements. *See* 21 U.S.C. § 360k(a).

Section 546(a) states that a manufacturer may not find immunity under state law if two things are true: first, "if the drug or medical device was approved for efficacy and safety by the United States Food and Drug Administration" and second, "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". Trans. Compl. Stat. § 546(a). For the purpose of express preemption, this language indicates that the state has adopted a tort liability standard that only parallels the requirements as defined by the FDA.

Consequently, Section § 546(a) is a state tort action which does not state any requirement that is "different from, or in addition to" federal requirements, but states requirements that are exactly the same as substantive FDCA requirements.

2. This Court Has Routinely Held That State Requirements Which "Parallel" Federal Requirements May Avoid Express Preemption.

This Court has consistently recognized that state actions which only "parallel" FDCA requirements are not preempted by federal law under 21 U.S.C. § 360k(a). *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) ("§ 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.") (citing *Lohr*, 518 U.S., at 495).

The Fifth Circuit in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) interpreted *Riegel* to provide a repeatable framework for considering preemption problems under 21 U.S.C. § 360k(a). The *Hughes* court held in relevant part:

> First, we ask if the FDA has established requirements applicable to the particular device at issue. Second, we ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is "different from or in addition to" the federal requirement.

Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011) (citing *Riegel*, 552 U.S., at 322) (internal citations omitted).

The language of Section 546(a) describes a statute that would *not* be preempted by federal law under *Riegel*. First, the FDA has established explicit requirements "applicable to the device at issue". *See, e.g.*, 21 C.F.R. § 814.39(a) (noting that "[c]hanges in the performance or design specifications, circuits, *components*, ingredients, principle of operation, or physical layout of the device" must be reported by a PMA supplement) (emphasis added). This regulation applies to the device at issue because Mednology's undisputed modification of the Sleepternity device is the primary example of its FDA non-compliance.

Second, because Transylvania law only reiterates the FDA's requirements exactly, it cannot state requirements "different from or in addition to" federal requirements. Thus, express preemption is not applicable to Trans. Compl. Stat. § 546(a) under any conception of preemption across circuits.

B. Section 546(a) is Not Subject to Implied Preemption Because a Claim For Non-Compliance "Sounds in Traditional Tort Law" Regarding Products Liability Claims.

The court of appeals correctly reasoned that a plaintiff should be able to overcome the presumption of compliance that is provided in the final clause of Section 546(a). *See* Trans. Compl. Stat. § 546(a) ("[T]he party challenging a manufacturer's or distributor's immunity under this statute bears the burden of

rebutting [the presumption of FDA compliance]"). Implied preemption is governed by 21 U.S.C. § 337(a), which states in relevant part:

> Except as provided in subsection (b), all such proceedings for the *enforcement, or to restrain violations*, of this Act [21 USCS §§ 301 et seq.] shall be by and in the name of the United States.

21 U.S.C. § 337(a) (emphasis added).

This Court should find that Section 546(a) exemplifies a state tort claim and is not subject to implied preemption. A constrained interpretation of 337(a) would be consistent with the plain language of FDA regulations, the intention of the legislature in preserving tort actions against manufacturers, and prevent a slew of issues that current case law regarding 337(a) preemption has not yet contemplated.

1. Section 546(a) is Not Trying to "Restrain Violations" or Seek "Enforcement" of the FDCA, but Instead Enforcing a Traditional State Tort Claim for Products Liability.

First, Transylvania state is not attempting to seek "enforcement" or "restrain violations" of the FDA under Section 546(a). *See* 21 U.S.C. § 337(a). Instead, Section 546(a) merely establishes the requirements for a state tort claim of products liability, and these state tort claims *happen* to parallel FDA requirements.

Case law across all circuits is unanimous on this point. A claim for strict liability, negligence, or other traditional state tort violations is not subject to implied preemption. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) ("Our sister circuits have uniformly held that, in cases dealing with violations of the

MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action. . ."). Ortega's claim under Trans. Compl. Stat. § 546(a) merely associates the standard for state tort liability with the FDCA's compliance requirements. Thus, because the claim for compliance is outside the pre-market approval process each circuit would find that this claim "sounds in traditional tort law" and is not preempted.

2. Preventing a State From Enforcing Tort Claims that Follow the FDA's Expressly Enumerated Regulations Insulate Manufacturers from All Justified Tort Liability.

Second, it would be a prohibitively expansive interpretation of 21 U.S.C. § 337(a) for the court to hold that *all* state actions require the FDA to give its position before allowing state tort claims to proceed. The Second Circuit in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006) contemplated the consequences of an expansive reading of federal preemption, stating, "preemption of traditional common law claims where fraud is not even a required element . . . would result in preemption of a scope that would go far beyond anything that has been applied in the past." *Desiano*, 467 F.3d, at 96.

In addition, the expansive interpretation is a misconstruction of Congress's legislative intent in passing the FDCA, which did not include the goal of nullifying all state tort actions against manufacturers. *See Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[B]ecause 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.").

II. IN THE ALTERNATIVE, THE EXPANSIVE VIEW OF FEDERAL PREEMPTION FROM THE SIXTH CIRCUIT WOULD HOLD THAT SECTION 546(A)'S PRESUMPTION OF IMMUNITY WOULD NECESSARILY BE PREEMPTED BY FEDERAL LAW.

In the alternative, if this Court decides that only the FDA has the authority to make a determination necessary to sustain a state tort claim, then Section 546(a)'s immunity provision must also be preempted by federal law, as it relies on a state's presumption of federal compliance. Consequently, Mednology cannot rely on Section 546(a)'s immunity provision to avoid liability under Transylvania state tort law as it would be impliedly preempted.

A. Under the Sixth Circuit's Broad View, Section 546(a)'s Immunity Provision Requires States to Act On a Presumption of FDCA Compliance That Only the FDA May Enforce

The plain language of Section 546(a)'s immunity provision requires the state government to endorse a presumption that a particular device was FDA approved. Section 546(a)'s immunity provision states, "[s]uch drug or medical device is *presumed to have been in compliance* with the United States Food and Drug Administration's approval". Trans. Compl. Stat. § 546(a) (emphasis added).

On the facts of this case, the phrase "such drug or medical" device refers to an adulterated device that was not FDA approved under the plain language of the FDCA. It is undisputed that Mednology has modified the Sleepternity device,

thereby shirking FDA compliance and effectively resulting in a *different device* than what was originally FDA approved. In support of this distinction, the FDA defines a "device" by the following standard:

> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . ."

21 U.S.C. § 321(h)(1) (emphasis added).

Because the definition of a device is dependent on the components that make up the device, as defined by 21 U.S.C. § 321(h), a device which is modified must necessarily be a different device. The conclusion on these facts is that the Sleepternity device which uses a PE-PUR foam rather than a silicon-based foam is a device different from the one which was originally FDA approved.

If this Court upholds the view of the Sixth Circuit, then it must also hold that the state has no authority to endorse a presumption of immunity for a device that is *not* FDA approved. This is especially true when the device is adulterated, and by the FDA's own definitions, a different device. Instead, only the FDA could hold that an adulterated medical device is still approved. By the Sixth Circuit's broad standard, Mednology is not entitled to state law immunity based on a presumption which can only be definitively made by the FDA.

B. States Ability to Grant Complete Immunity to Manufacturers Conflicts With the FDA's Federal Regulatory Power, Especially When the Manufacturer Adulterates its Product.

This Court has repeatedly voiced concerns about state law conflicting with the FDA's ability to effectively regulate. *See, e.g.*, *Buckman*, 531 U.S., at 348 (noting the importance of achieving "a somewhat delicate balance of statutory objectives" through federal preemption). A provision of state law *presuming* immunity for manufacturers blatantly disrupts these concerns and hampers the FDA's regulatory power. To combat this disparity in regulatory ability, even the broad view of the Sixth Circuit would find that a presumption of immunity for a new device is not within the authority of a state proceeding. *See Garcia*, 385 F.3d 961, 966 (noting that "a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*").

III. SECTION 546(B)'S MISREPRESENTATION PROVISION SHOULD NOT BE PREEMPTED AS IT DOES NOT STATE REQUIREMENTS "DIFFERENT FROM OR IN ADDITION TO" FEDERAL LAW AND SOUNDS IN TRADITIONAL TORT LAW

The misrepresentation provision of Trans. Compl. Stat. § 546(b) is not expressly preempted by federal law because it does not state requirements "different from or in addition to" FDA regulations, and the claim sounds in traditional tort law. *See, e.g.*, 21 C.F.R. 814.39; 21 C.F.R. 814.80. Additionally, the Second Circuit's decision in *Desiano* is instructive in the particular factual

circumstances that has not yet been addressed by this Court or the lower courts. Section 546(b) provides:

> The immunity granted under subsection (a) does not apply if the defendant, at any time before the event that allegedly caused the injury, intentionally withholds from or misrepresents to the [FDA] information concerning the drug or the medical device that is required to be submitted under the [FDCA] and *the drug or medical device would not have been approved, or the [FDA] would have withdrawn approval for the drug or medical device if the information were accurately submitted*.

Trans. Compl. Stat. § 546(b) (2024) (emphasis added).

This Court should clarify the limits of implied preemption under the FDCA and hold that a plaintiff may avoid implied preemption if the plaintiff's claims sound in traditional tort law regardless of state immunity provisions. Such a ruling would reflect a correct reading of 21 U.S.C. § 337(a), Congress' intentions in passing the statute, and prevent the unintended result of allowing a manufacturer to escape tort liability through a technicality that rests on a broad application of preemption.

A. Section 546(b) is Not Expressly Preempted by the FDCA Because it Parallels FDA Requirements in the PMA Approval Process and it Does Not Relate to the Device's "Safety and Effectiveness".

Express preemption is avoided because Mednology has violated FDA regulations under 21 C.F.R. 814.39 and 21 C.F.R. 814.80. Case law considering fraud-on-the-FDA claims establishes that express preemption can be avoided by invoking these regulations. In addition, prior case law has identified that a misrepresentation claim does not violate express preemption because the claim does not relate to the "safety or effectiveness" of the device. *See* 21 U.S.C. § 360k(a)(ii).

First, under 21 C.F.R. § 814.39(a), "[c]hanges in the performance or design specifications, circuits, *components*, ingredients, principle of operation, or physical layout of the device" must be reported by a PMA supplement. 21 C.F.R. § 814.39(a) (emphasis added). This regulation speaks to Mednology's misrepresentation to the FDA because it did not adhere to its representations that it would maintain the Sleepternity as originally approved through the PMA process. This regulation has been used to avoid express preemption. *See, e.g.*, *In re Medtronic, Inc.*, 465 F. Supp. 2d 886, 895 (D. Minn. 2006) (finding that a plaintiff's "misrepresentation by omission" claim avoids express preemption by relying in part on a violation of 21 C.F.R. § 814.39).

Second, under 21 C.F.R. 814.80, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is

inconsistent with any conditions to approval specified in the PMA approval order for the device". This provision of FDA regulations speaks directly to the aspect of Mednology's breached duty of care through its misrepresentation to the FDA. Mednology has represented its device in one capacity to achieve FDA approval and later modified its device in violation of this regulation to the harm of state consumers. Case law has also recognized this regulation as a precedent for avoiding express preemption for fraud-on-the-FDA claims. *See, e.g.*, *Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 886 (N.D. Ill. 2018) (finding that modifying a device was a breach of PMA approval that supported an un-preempted fraud-on-the-FDA claim). Similarly, the fact that Mednology has modified a component in its Sleepternity device in violation of 21 C.F.R. 814.80 speaks to its misrepresented to the FDA what it was manufacturing. This misrepresentation again had the consequence of breaching Mednology's duty of care to state consumers and causing Ortega harm.

Based on the plain language of these regulations, a state tort claim that is premised on some aspect of fraud-on-the-FDA or misrepresentation is not expressly preempted by federal law.

B. This Court Should Adopt an Exception to Implied Preemption When the Claim "Sounds in Traditional Tort Law", as this Approach Accurately Reflects the Concerns Animating Implied Preemption.

The Second Circuit in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006) is instructive in deciding whether a state tort claim is implicitly preempted by the FDCA. The court should adopt this "sounds in traditional tort law" exception to questions of implied preemption under the FDCA, as this approach does not conflict with this Court's precedence in *Buckman* and *Lohr* on FDCA preemption claims, better reflects the legislative intentions of Congress in passing the FDCA, and prevents manufacturers from taking improper advantage of preemption as a shield for its fraudulent behavior.

1. The "Sounds in Traditional Tort Law" Framework Best Captures the Legislative Intent of the FDCA and the Protection of Individual Rights to Tort Claims.

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). First, the framework provided in *Desiano* better captures this intention and the purpose of the FDCA. It was not Congress' intention in passing the FDCA's preemption provisions to allow manufacturers complete immunity to state tort claims, let alone immunity for a manufacturer defrauds the FDA and consumers.

Congress has made its intentions in passing the FDCA clear. "[T]he objective of the legislation is to establish a mechanism in which the public is afforded reasonable assurance that medical devices are safe and effective. . .". Rep. No. 853, 94th Cong., 2d Sess., 15–16 (1976). The facts of this case make clear that the FDA cannot assure the public of the safety of its devices if manufacturers are allowed to use blatantly fraudulent practices as a shield from liability.

This Court has reiterated this sentiment that preemption ought not be so expansive in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, stating, "it is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Lohr*, 518 U.S. 470, 487 (1996) (internal citations omitted). Finally, this Court has often pointed to the principle that traditional common law claims face a presumption against preemption. "[I]n all pre-emption cases . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act. . .'" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Lohr*, 518 U.S., at 485)

To allow a manufacturer to escape liability for blatantly fraudulent action awaiting a procedural FDA decision "would result in preemption of a scope that no one is contemplating, let alone advocating." *Desiano*, 467 F.3d, at 97. In addition, the Second Circuit took the correct approach in protecting traditional state tort claims that coincides with the intention of the FDCA *not* to completely usurp state tort law.

2. The Plain Language and Purpose of Section 546(b) Indicates that it Sounds in Traditional State Tort Law, and is Only Partially Reliant of FDCA Regulations.

Under the *Desiano* framework and even this Court's precedent in *Buckman*, it is clear that the claims against Mednology here are based in traditional state tort claims of fraud and misrepresentation to consumers. As a result, this Court should rule that these particular fraud-on-the-FDA claims sound in traditional state products liability law, and only peripherally rely on FDA regulations in order to state a claim. In addition, the court of appeals erred in finding that a state immunity provision provided any discernible difference to a state tort analysis. Thus, implied preemption is not applicable to Section 546(b).

Section 546(b) only becomes relevant after consideration of the traditional state products liability protections enumerated in Trans. Compl. Stat. § 545. In this way, the misrepresentation provision of Section 546(b) is only a modification of the traditional state products liability claim in Section 545. This Court in *Buckman* noted the difference in such claims by comparing the claims in that case with the claims in *Lohr*. "[I]t is clear that the *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." *Buckman*, 531 U.S. at 352 (citing *Lohr*, 518 U.S. at 481). Here, the interpretation is the same. Respondent's claim in this case is predicated on the "duty of care and good faith" to

protect consumers from injuries which is only *evidenced* by its FDA violations. *See* Trans. Compl. Stat. § 545.

The fact that the device in this case is adulterated is another important distinction which speaks to the "traditional state tort" nature of this claim. The Seventh Circuit's considerations in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) are instructive on this point. "[T]he federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law". *Bausch*, 630 F.3d, at 557. In this way, the facts of this case indicating the Mednology changed the Sleepternity device speak to the idea that this action is more than a "fraud-on-the-FDA" claim previously contemplated. Instead, it is an enhanced products liability claim, where the duty of care has been breached by the manufacturer's blatant avoidance of federal compliance.

As an added testament to the state tort nature of these claims, the legislature also stated that it is "the goal of the legislature to encourage consumers who believe their injury resulted from a *manufacturer and/or distributor's failure to exercise care, precaution, or good faith in manufacturing* and/or distributing the product to bring a valid claim." Trans. Compl. Stat. § 544 (emphasis added). Lower court interpretations coincide with this emphasizing such state tort purposes, finding that the purpose of the original cause of action should be controlling over *exceptions* invoked by a different statute. *See, e.g.*, *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) ("The statute creates no cause of action. In fact, [the

defendant] has pled the statute as an affirmative defense."); *In re Medtronic, Inc.*, 465 F. Supp. 2d, at 899 (distinguishing between "fraud-on-the FDA" claims without any basis as opposed to a claim where fraud constitutes support for a tort).

The circumstances of this case are the same here with respect to the above-mentioned cases. Mednology here seeks to invoke Section 546(b) as an affirmative defense to Ortega's *traditional state tort* claims under Trans. Compl. Stat. § 545. By recognizing this framework, this Court will prevent allowing manufacturers to use federal regulations as a shield for their own fraudulent actions to the injury of consumers, particularly when the facts surrounding fraud are clear.

C. This Court Should Limit the Sixth Circuit's Decision in *Garcia* to Hold That Implied Preemption Can Be Avoided if a Plaintiff Pleads Evidence of Fraud-on-the-FDA by Clear and Convincing Evidence.

The court of appeals relied entirely on the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) in order to find that implied preemption applied to Section 546(b). This decision reflects an ongoing split between the lower courts regarding the limits of federal preemption. *Cf. Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006) (finding that preemption does not apply to entirely protect manufacturers from state tort claims). However, the facts of this case are distinguishable from *Garcia* as the Sixth Circuit has never dealt with a case in which a manufacturer fraudulently adulterated or changed its

product. Consequently, this case introduces novel issues that the *Garcia* court did not contemplate and this Court has the opportunity to correctly address.

1. The Facts of This Case Constitute a Narrow Factual Exception to the Broad Approach That the Sixth Circuit Took in *Garcia* Which Has Not Yet Been Directly Addressed by the Sixth Circuit.

The Garcia decision hinged on the fact that the "[p]laintiff had submitted no evidence supporting its claims of bribery or misrepresentations to the FDA". *Garcia*, 385 F.3d, at 968 n.1. It is undisputed in this case that Mednology fraudulently modified its device after achieving FDA approval. To endorse the *Garcia* court's ruling on these facts would be to allow manufacturers to first find FDA approval and then use federal preemption as a shield for its own fraudulent actions.

As a testament to the narrow circumstance that *Garcia* was decided in, the court noted the concern that manufacturer might "use bribery or fraud as a means of obtaining FDA approval, then rely on that approval as a shield from products liability". *Garcia*, 385 F.3d, at 967. However, the facts of this case demonstrate that Mednology *is* attempting to use its fraud as a "shield" to escape products liability. The fact that the *Garcia* court recognized this effect as a concern provides the basis for this Court to constrain the Sixth Circuit's approach and limit this unintended consequence.

Subsequent courts in the Sixth Circuit have expanded upon *Garcia*'s reasoning, revealing additional distinctions which would cause preemption not to

apply on the current facts. For example, the Sixth Circuit's decision *Marsh v. Genentech, Inc.*, 693 F.3d 546 (6th Cir. 2012) describes the circuit's reasoning in comparison to Supreme Court precedent. "[Such claims] interfere with the federal regulatory scheme for the approval of drugs and medical devices and because they implicate the "inherently federal" issue of "the relationship between a federal agency and the entity it regulates.". *See Marsh*, 693 F.3d, at 550 (quoting *Buckman*, 531 U.S. at 347–350).

The facts of this case are substantially distinguishable from these concerns. Here, Mednology's fraud and modification of the Sleepternity device is an attempt to completely shirk this federal relationship that the Sixth Circuit bases its practice on. When a manufacturer attempts to dilute this federal relationship to such an extreme degree, a state attempting to enforce products liability actions against it is in no sense attempting to step into federal territory. State products liability actions in the face of fraud merely protect a state's citizens when a manufacturer has abandoned the federal relationship by its conduct.

As a result, the facts of this case are substantially different from the practice that the Sixth Circuit endorsed. This Court should instead rule that a plaintiff may nonetheless avoid preemption when a manufacturer indisputably adulterates its device by clear and convincing evidence. These circumstances reflect the fact that exceptions to an immunity provision are not conceptually any different than a *prima facie* statement of tort liability under Section 545.

D. To Recognize a Narrow Exception to the Approach in *Garcia* Still Coincides with the Concerns That Animated This Court's Interpretation of Preemption in *Buckman* and *Lohr*.

Adopting a pleading standard for fraud-on-the-FDA claims resolves the issues that animated this Court's decision in *Buckman*. This Court in *Buckman* voiced concern that allowing fraud-on-the-FDA claims would "cause applicants to fear that their disclosures to the FDA, while deemed appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351. However, the facts of this case instead represent the complete *abandonment* of these concerns on behalf the applicant/manufacturers who fraudulently alter their devices after achieving FDA approval.

Allowing states to preserve state tort claims in such extreme circumstances *enhances* the FDA's ability to police the most blatant fraud against the agency. *See* Hannah Rogers, Note, T*he 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 ("[F]raud-on-the-FDA claims do not necessarily conflict with federal law, but rather complement it to a degree that only boosts the efficiency of the FDA as a whole in regulating and policing fraud.").

This Court should provide a narrow rule: when a manufacturer has indisputably and fraudulently adulterated its FDA-approved medical device, a plaintiff does not violate implied preemption because the unique nature of a claim for an adulterated device sounds in traditional tort law. Such a ruling preserves the

delicate balance of the FDA's regulatory regime and still maintains the goal of the legislature in preserving the health and safety of consumers.

IV. SECTION 546(c)'S FAILURE-TO-WARN PROVISION IS NOT PREEMPTED BY THE FDCA BECAUSE IT EXPRESSLY PARALLELS FDA REQUIREMENTS AND IS UNIVERSALLY RECOGNIZED AS "SOUNDING THE TRADITIONAL TORT LAW"

Section 546(c)'s failure-to-warn provision is not subject to federal preemption because it does not state any requirement "different from or in addition to" federal law. In addition, failure-to-warn is commonly recognized as a state tort claim and thus Section 546(c) "sounds in traditional tort law" and is not attempting to enforce or prohibit any action under the FDCA. This Court should rule that a claim for failure-to-warn is not one which is subject to preemption under the FDCA.

A. Section 546(c) is not Expressly Preempted Because it Parallels Federal Requirements Surrounding Adulterated Use and Warnings for Misbranded Products.

Section 546(c) represents a state tort cause of action which parallels federal labelling requirements of adulterated products not limited to 21 U.S.C. § 352(f) and 21 C.F.R. 801.15(c). Further, this Court has previously held that failure-to-warn claims can serve as a basis for avoiding express preemption. Such a reasoning has been further endorsed across the circuits. As a result, Ortega's failure-to-warn claim is not subject to express preemption because it does not state a requirement "different from or in addition to" federal law. *See* 21 U.S.C. § 360k(a).

21 C.F.R. 801.15(c) states: "[a]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling for a device shall appear thereon in one or more of the following formats . . .". *See* 21 C.F.R. 801.15(c). In addition, "[u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health. . .", there is a violation of labelling requirements. *See* 21 U.S.C. § 352(f). Mednology has violated this provision of the FDCA by providing *no* labeling provision or warning that gave notice of the presence of isocyanates due to the PE-PUR foams that it was using. As a result, Mednology has "failed to warn of the dangers" in using the modified Sleepternity device. *See* Trans. Compl. Stat. § 546(c). Mednology's failure to "warn of dangers" is therefore not expressly preempted because its failure-to-warn is predicated on the parallel federal requirements enumerated in 21 U.S.C. § 352(f).

Case law is particularly controlling here as well. This Court has offered the most controlling disposition on failure-to-warn claims: "[a]lthough we recognize that some state-law claims might well frustrate the achievement of congressional objectives, [this failure-to-warn claim] is not such a case". *Wyeth*, 555 U.S., at 581. In addition, the *Wyeth* court considered that the FDA always considered failure-to-warn claims as a traditional state tort claim, holding "[the FDA] cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims". *Id.* at 577–578.

Across the board, it is not express preemption that has created a debate surrounding failure-to-warn claims. Instead, a court split has generally formed on whether these claims are implicitly preempted by 21 U.S.C. § 337(a). *See* Grace M. Zogaib, Note, *Preemption After Buckman: State Law Failure to Warn Claims Based On Lack of Disclosure to the FDA*, 21 AVE MARIA L. REV. 236, 242–248 (discussing the court split surrounding implied preemption as opposed to express preemption). As a result, Ortega's failure-to-warn claim is not expressly preempted.

B. Section 546(c) is not Impliedly Preempted Because Failure-to-Warn Claims Historically "Sound in Traditional Tort Law" and the Legislative History Supports a Claim for Failure-to-Warn.

Failure-to-warn claims as stated by Section 546(c) have long been recognized by tort regimes as a traditional claim. This Court has the opportunity to clarify that a failure-to-warn claim "sounds in traditional tort" law, especially when a manufacturer deliberately adulterates its product without warning consumers. This role for failure-to-warn claims supports the regulatory regime and benefits the purpose of the FDCA. As a result, a failure-to-warn claim does not seek to "enforce" or "restrain violations" of the FDCA and is not preempted. *See* 21 U.S.C. § 337(a).

A number of courts have coincided with the idea that a failure-to-warn claim is one which traditionally sounds in tort law. *See, e.g.*, *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427 at *2 (N.D. Ill. 2013) (noting plaintiffs' claims can be "capable of existing independent of these regulations as failure of the duty to warn"); *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 840 (W.D. Ky. 2014)

("Plaintiffs are alleging a recognized state tort claim based on the underlying state-law duty to warn about the dangers or risks of a product.").

The claims in these cases are *distinct* from the "fraud-on-the-FDA" claims contemplated in *Buckman*. *See Hughes*, 631 F.3d, at ("[Plaintiff's claim does not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*.") Unlike *Buckman*, and comparable to *Hughes*, Section 546(c) includes no contemplation of fraud. The statute in Section 546(c) therefore does not seek to "enforce" or "restrain violations" of any FDA regulation by finding fraud. It merely holds that if a manufacturer does not meet warning criteria that *parallels* federal law then it is liable for products liability under Section 545. *See* Trans. Compl. Stat. § 546(c).

Additionally, a state claim for failure-to-warn has long been recognized by tort regimes prior to the passage of the FDCA. *See* Restat. (2d) of Torts, § 388 (describing a failure-to-warn claim premised on manufacturer negligence). Congress itself intended to preserve failure-to-warn claims themselves and even treat such state claims as an extension of the FDA's regulatory ability. "[I]t is worthwhile at least to note that when Congress passed the FDCA, it apparently intended to leave room for the independent operation of state tort law." Leslie C. Kendrick, Article, *FDA's Regulation of Prescription Drug Labeling: A Role for Implied Preemption*, 62 FOOD DRUG L.J. 227, 238 (citing H.R. 6110, 73d Cong., § 25 (1933); S. 1944; 73d Cong., § 24 (1933) for the premise that Congress *declined* to include a federal enforcement mechanism in favor of uplifting state tort law).

As a result, this Court should decline to adopt preemption in failure-to-warn cases, because such claims have commonly been recognized as traditional tort claims which *support* the regulatory regime both in Congress and by the courts.

C. The Court of Appeals Erroneously Held that Section 546(c)'s Intersection With the State Immunity Provision Made Any Appreciable Difference to the State Tort Analysis

The court of appeals found that Section 546(c) was preempted because it modified the *immunity* provision of state law. The court of appeals erred because the presence of an immunity statute creates no intelligible difference in the "traditional state tort" analysis, and its conclusion not reflected in the authorities that were relied on.

First, the facts of this case are distinguishable from those relied on by the court in citing *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012). *Lofton* dealt with a case where "the statute at issue conditions recovery on 'establishing' what amounts to fraud on the agency". *Lofton*, 672 F.3d, at 380. As discussed above, and unlike the statute in *Lofton*, Section 546(c) is not premised on Mednology *lying* to the FDA, but that its insufficient labelling for its adulterated product caused harm. Further drawing this distinction, the statute in *Lofton* expressly required misrepresentation to the FDA in order to state a claim for failure-to-warn *Id.* at 381. The same conclusion cannot be drawn on the plain language of Section 546(c) which merely requires failure-to-warn within FDA requirements *without* any mention of fraudulent conduct.

Second, this case is distinguishable from what the court of appeals relied on when it cited *Garcia* from the Sixth Circuit. The court of appeals relied on the importance of the FDA's ability "to preserve the agency's discretion to police the conduct of regulated entities". *See Garcia*, 385 F.3d, at 965 (citing *Buckman*, 531 U.S., at 350). However, a failure-to-warn claim under Section 546(c) does not threaten agency discretion to police conduct when a manufacturer adulterates its device without warning and instead only enhances the ability of the regulatory regime in identifying bad actors. *See* Rogers, *supra* page 29. Further, *Garcia* hinged on a discussion of whether "given a choice between immunity absent a finding of bribery or fraud by the [FDA] and no immunity, the Michigan Legislature would prefer the former option." *Id.* at 967. Thus, just like in *Lofton*, the *Garicia* decision is inapplicable to this statute, as Section 546(c) makes no requirement for fraud.

The court of appeals erred because it mischaracterized the applicability of these cases to Transylvania state law under Section 546(c). The approach does not hinge on the presence of immunity. The baseline for considering these claims absent a statutory fraud requirement across all circuits is whether the claim "sounds in traditional tort law".

V. THIS COURT SHOULD FOLLOW THE NINTH CIRCUIT AND FIND THAT ORTEGA COULD PLEAD A "FRAUD-ON-THE-FDA" THEORY TO SUPPORT A *QUI TAM* ACTION UNDER THE FALSE CLAIMS ACT.

The False Claims Act (FCA) was enacted during the Civil War with the purpose of policing and punishing frauds against the U.S. Government. *Universal*

Health Servs. v. United States ex rel. Escobar, 579 U.S. 176, 181 (2016) [hereinafter *Escobar*]. Since its original enactment, Congress has amended the Act multiple times and had continuously affirmed its commitment to punishing those who directly submit false claims or indirectly induce others to do so. See 31 U.S.C. § 3729(a). Claims include "direct payment requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs," like Medicare and Medicaid. *Escobar* at 182. *See also* § 31 U.S.C. 3729(b)(2)(A). For a claim to be actionable under the FCA, the defendant must have "knowingly violated a [statutory, regulatory, or contractual] requirement that the defendant knows to be material to the Government's payment decision." *Id.* *See also Escobar* at 181. A defendant knowingly violates a requirement when they have "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." § 31 U.S.C. 3729(b)(1)(A). A requirement is deemed "material" when it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 31 U.S.C. 3729(b)(4).

The claim at issue in this case is the request for payment from the Centers for Medicaid and Medicare Services (CMS) for the Sleepternity device. Mednology committed fraud-on-the-FDA both when securing pre-market approval and each time it submitted a request for payment for the Sleepternity device. Suing *qui tam*, Ortega is suing Mednology on behalf of the Government for Mednology's violation of the FDCA, for implied false certification of their device at the time of payment

requests made to CMS and for fraudulent representation during the pre-market approval process for Class III devices.

Ortega's claims need only to plead sufficient for the claim to be plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). Ortega has pled sufficient facts to meet all pleading standards and therefore should survive a motion to dismiss.

D. Ortega's Suit is Allowed Under an "Implied False Certification Theory".

Ortega's case relies on implied false certification theory, which is a basis for liability for fraud-on-the-FDA FCA claims. Implied false certification occurs when an entity requests payment from the government and in that request misrepresents the item for which payment is requested. See *Escobar* at 177. This Court held in *Escobar* that "[t]he implied false certification theory can be a basis for FCA liability when a defendant makes specific representations about the goods or services provided, but fails to disclose noncompliance with a material statutory, regulatory, or contractual requirements which make those representations misleading. . ." *Id.* Mednology made implied false certifications when it requested payment from CMS for the Sleepternity device.

This Court also held in *Escobar* that requirements need not be express conditions for payment by the government for a misrepresentation to be actionable. "What matters is not the label the government attaches to the requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision." *Escobar* at 178 (interpreting the

intersection of implied false certification theory and its requirements under the FCA).

1. Ortega Has Pled Sufficient Facts to Plausibly Demonstrate that Mednology Made Specific Representations About Sleepternity and Failed to Disclose Noncompliance with Material Regulatory Requirements.

Ortega's claim under the implied false certification theory is viable because she has pled sufficient facts to demonstrate that Mednology's misrepresentations satisfy the two conditions created in *Escobar*. To succeed, (1) the claim must make "specific representations about the goods or services provided" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar* at 190. Ortega sufficiently pled facts to plausibly demonstrate that specific representations were made and those representations were misleading.

Mednology made specific representations about Sleepternity to CMS through omitting important information in its labeling and implying in payment requests the device's specifications remained unchanged since FDA approval. Mednology's representations were made through omission. "Omissions render[ing] those representations misleading" are appropriate for attaching liability. *Id.* at 181. The specific representation was made through omission of "critical qualifying information," i.e. that the foam was no longer made of silicone, but of PE-PUR. By

not indicating the modification, Mednology represented Sleepternity as a device made with the approved specification, which was false. In so doing, Mednology misrepresented to CMS that the product they reimbursed was the same presumably safe product which had gone through a Class III approval process.

Mednology made specific representations about Sleepternity to the government when it requested payment from CMS: that the represented device was the device approved by the FDA. Since Mednology submitted claims for payment to CMS, it is plausible that they used CMS's industry-standard identification codes. In *Escobar*, this Court held that submitting CMS codes for mental health care when the practitioners were improperly identified by that code qualified as a specific representation. *Escobar* at 188–89. Without discovery, Ortega cannot confirm that Sleepternity made analogous representations to those in Escobar. However, since CMS has a standard system of operations for reimbursements, it is plausible that the code Mednology used to submit the payment request is similar to the circumstance in *Escobar*. If Mednology submitted its requests for payment under an unsuitable code, it is has made specific representations to the government.

2. Ortega Has Pled Sufficient Facts to Demonstrate the Plausibility that Mednology's Implied False Certification of the Device was Material to CMS's Decision to Pay for the Device.

Ortega has plead sufficient facts to plausibly satisfy the knowledge and materiality requirements of her FDA claim. *See Ashcroft*, 556 U.S., at 678. This

Court has plainly stated that compliance need not be an express condition of payment, but the plaintiff must show the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 579 U.S., at 178. Ortega has pled sufficient facts to show CMS would not have paid for Sleepternity without Mednology's false certification that the device, as it was produced, was FDA-approved.

Mednology's use of PE-PUR foam instead of the approved silicone was in noncompliance with material regulatory requirements, specifically in failing to issue a PMA supplement, or a 510(k) if the change following the approval of the Sleepternity device required the approval of an entirely new device happened after the approval. See 21 C.F.R. § 814.39 (requiring a PMA supplement) and 21 § C.F.R. 807.94 (requiring a summary and certification). In following the FDA's non-binding guidance, Mednology may have been required to go through the 510(k) process after the change, but at minimum were required to file a PMA supplement.

The 510(k) process demonstrates that Mednology knew or should have known they were violating a material requirement. Scienter under the FCA "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." § 3729(b)(1)(A). See also *Escobar* at 182. The 510(k) process required of Mednology would have provided the knowledge needed to understand the risks of switching the foams and the regulatory requirements to make the change. Therefore, unless Mednology failed to complete the process altogether, which would

also be a regulatory violation, Mednology either knew the risks and ignored it, or knew the process and failed to comply.

It is plausible that Mednology knew they were violating a material requirement because when changing the foam material, they should have consulted the FDA's guidance on when changes require additional documentation or certification. In the FDA's flow chart, if there is a change in a material type for an approved Class III device, the company must then consider if the changed material with directly or indirectly contact bodily tissues or fluids. Since the foam on the Sleepternity headphones comes into contact with human skin, Mednology would have needed to conduct a risk assessment about the biocompatibility of the foam.

As part of this risk assessment process, Mednology would have conducted research to determine if the PE-PUR foam posed risks. A simple Google search would have been sufficient to illuminate the risks associated with switching. As the switch occurred after FDA approval in December 2022, the FDA had already released its assessment on PE-PUR foams in CPAP machines *and* Philips Respironics had already recalled their CPAP for this reason. FDA, Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines, Foam Testing Summary for Recalled Phillips Ventilators, BiPap Machines, and CPAP Machines (Upd. Apr. 9, 2024), https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/foam-testing-summary-recalled-philips-ventilators-bipap-machines-and-cpap-machines, (heinafter Foam Testing Summary). Mednology *knew or should have known* that since the FDA had

identified the precise risks associated with the material change Mednology proposed and a similar device had already been recalled for use of the PE-PUR foam, that this was a material requirement.

No matter what Mednology's risk assessment would have found, they would have either been required to document the change or submit a new 510(k). Since the risk assessment should have yielded concerns about safety due to the breakdown of VOCs entering a user's respiratory system, submitting 510k was required. *See* FDA, Premarket Notification 510(k) Premarket Submissions: Selecting and Preparing the Correct Submission (Sep. 9, 2024), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#who. By neither documenting the change nor submitting a new 510k, they violated a material regulatory requirement (documentation) or a statutory requirement by not submitting the 510(k) and certification. See FDA, Premarket Notification Class III Certification and Summary, Premarket Submissions: Selecting and Preparing the Correct Submission (Sep. 7, 2024), https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary.

Finally, as part of that submission, Mednology would have certified they "conducted a reasonable search of all information known or otherwise available about the types and causes of safety and/or effectiveness problems that had been reported for" and "were aware of all of the types of problems to which [Sleepternity] is susceptible to." *Id*. Any "reasonable" search would have found the Philips recall

and FDA research elucidating what the Sleepternity device was, at minimum, susceptible to if using PE-PUR foam. Mednology knew or should have known that there were risks which required filing a 510(k).

Even if Mednology concluded filing a new 510(k) upon changing the foam material was unnecessary, the process was fresh in their mind. They knew they had to certify the silicone and should have known that through the 510(k) process they would not be able to similarly certify the PE-PUR foam in good faith. Alternatively, if Mednology concluded they did not need to go through a new 510(k) process due to the change in foam, under §814.39, they were still required to "submit a PMA supplement for review and approval *before* making a change affecting the safety or effectiveness of the device." See 21 C.F.R. § 814.39(a). Because the material was in contact with human tissue, the change in foam would affect "safety or effectiveness of the device" and this should have been known to Mednology because of the Philips recall. Even if Mednology incorrectly concluded that the new foam would not affect the "safety or effectiveness of the device," they were still required to report the change to the FDA. See 21 C.F.R. § 814.39(b). No matter the standard, Mednology knew or should have known they violated a material regulatory requirement by not informing the FDA of the change.

Since this is an allegation of fraud relating to a matter of the mind, the pleading requirements for scienter are subject to 9(b) of the Federal Rules of Civil Procedure. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other

conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b). Legal scholars disagree about whether particularity is a substitute for the plausibility requirement of *Twombly/Iqbal* or plaintiffs must plead both particularity and plausibly. *See generally*, Benjamin Spencer, *Pleading Conditions of the Mind Under Rule 9(b): Requiring the Damage Wrought by Iqbal*, 41 CARDOZO L. REV. 3. (2020) (discussing whether the plausibility standard in *Iqbal* applies to Rule 9(b)). In this case, the distinction is immaterial because Ortega has satisfied both standards.

Ortega has pleaded sufficient facts to satisfy both standards. Because Mednology has required processes to follow, it is plausible that they knew or should have known about the risks related to switching the foams and the requirements for doing so. Ortega has also pleaded with particularity in identifying the points in the process where they knew or should have known. Without discovery no plaintiff could provide more insight into a "matter of the mind" without resorting to speculation.

The district court rightfully notes concern about a tribunal being another more than second-guessing a reading of the "FDA's mind," but is premature is voicing it. R. at 22-23. The evidence to demonstrate that Mednology's scienter would most likely need to come through a discovery request for internal documents and research – something Ortega would not and could never access prior to discovery. Legislative history demonstrates that keeping the *qui tam* option for pursuing FDA claims has long been important to Congress. *See United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1154 (3rd

Cir. 1991) (noting the immediate amendments forwarded to the FCA when courts narrowed the act's *qui tam* scope) (citing 1986 U.S. Code Cong. & Admin. News 5288-89).

Therefore, dismissing this claim before discovery when Ortega has given no indication that she could not prove these claims in a trial goes against the purpose of the statute. Furthermore, as the dissent noted Ortega should be given the opportunity to plead those facts because it is not beyond a reasonable doubt that she could. R. at 40.

Ortega sufficiently demonstrated it is plausible that the FDA's approval of the Sleepternity device was material to the CMS's payment for use of it. Section 3729(b)(4) of the FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of property." 31 U.S.C. 3729(b)(4). CMS, and other government agencies, regularly rely on the approval of the FDA, who, in turn, relies on the information provided to them by the companies seeking approval. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 905 (9th Cir. 2017). Ortega has demonstrated it is plausible that the CMS would not have paid for the Sleepternity device without Mednology's false certification "that it had complied with all the requirements for obtaining the FDA's approval." R. at 36

This Court determined in *Escobar*, that materiality is demanding and though some facts may be dispositive, the list is not exclusive. See *Escobar* at 191–93. "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the

mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual agreement." *Escobar* at 194–95. This Court provided several examples provided by this Court in determining proof of materiality. *Id*. (Stating that express conditions of payment and the Government consistently refusing to pay claims based on noncompliance with a particular requirement). However, none of those fact patterns are analogous to Ortega's claim.

There is a circuit split on proving materiality and the standard of proof. This Court should follow the Ninth Circuit's interpretation. According to the Ninth Circuit,

> A claim under the False Claims Act requires a *showing* of "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, *causing*, (4) the government to pay out money or forfeit moneys due."

Campie, 862 F.3d at 899 (citing *United States ex rel. Hendow*, 461 F.3d at 1174) (emphasis added).

The Ninth Circuit has held that like the other elements, "causality," requires a "showing" (i.e. is a matter of proof). *Campie*, 862 F.3d, at 907. To survive the motion to dismiss, Ortega must make a claim plausible on its face that Mednology's fraudulent conduct was material and caused the government to pay the CMS claim.

Ortega has met this pleading standard under the Ninth Circuit's requirement because the facts show that it is plausible the implied certification of the Sleepternity device as FDA-approved caused CMS to pay for it use.

> When a manufacturer perpetuates 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.

United States ex rel. Hendow, 461 F.3d at 1174 (quoting *Oakland City Univ.*, 426 F.3d at 916).

This is particularly important because payments by CMS are conditioned on FDA approval because CMS looks to FDA-approval "as a determination of the 'safety and effectiveness' of the drugs at issue." *Campie*, 862 F.3d at 905. *See* e.g. 48 C.F.R. § 46.408(a)(1) (FDA is responsible for quality assurance for "drugs, biologics, and other medical supplies" for all government agencies).

There is a clear plausible causal chain from Mednology's fraud to CMS's payment. Mednology violated material regulatory and statutory requirements during and after the FDA approval process. Mednology knew or should have known that changing the foam was not making a harmless substitution. In making the substitution anyway, without notice, Mednology was no longer manufacturing or marketing the same Sleepternity device that had been approved by the FDA. So, every time Mednology submitted a claim to CMS for payment, it was falsely certifying the device was the device approved by the FDA, when they knew or should have known that it was not. Furthermore, hrough omission, Mednology

implied that Sleepternity was not like the Philips device that had been recalled and was no longer receiving payments from CMS. Mednology also implied that Sleepternity was certified not to be susceptible to the same issues with the foam because they had satisfied the regulatory certification requirements.

The First Circuit applies a different standard in one important respect: proving causation is a requirement to survive a 12(b)(6) motion to dismiss. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (stating that a plaintiff must plead "actual" causation). The First Circuit believed that without actually proving causality at the pleading stage, allegations in future cases would resort to what "could have" happened, rather than what did happen. *Id.* This is not an appropriate standard for Ortega's case, nor for this Court to adopt generally. First, a claim could not survive the pleading standard by merely alleging what "could have happened" it is already settled law that a plaintiff must plead plausibility, not possibility under Rule 8. FED. R. CIV. P. 8; *Ashcroft*, 556 U.S., at 678. Second, causality in this type of case is "matter of the mind." FED. R. CIV. P. 9(b). To prove a causal link in most claims at this stage would require evidence of knowledge and intent behind the CMS's decision. Under 9b, the Federal Rules of Civil Procedure state that for matters of the mind in cases of fraud, the facts need to pleaded with "particularity," but alleged "generally." *See* FED. R. CIV. P. 9(b). Even if the plausibility standard applies to Rule 9b, the combined standard is still well below an evidentiary standard of "preponderance of the evidence." See generally Spencer, supra page 44.

The court should not create a standard of proof for causality higher than already exists.

Should this Court find that a causal link must be established, then it will weaken *qui tam* lawsuits, which fundamentally undermines the purpose of the FCA. The First Circuit held that because CMS continued to approve and pay for a device after learning it was noncompliant, the plaintiff could not establish a causal link necessary to state a claim. *D'Agostino*, 845 F.3d at 10. Ortega's claim can be distinguished from that in *D'Agostino* because Ortega filed the claim which led to the FDA investigation which resulted in the voluntary recall of the Sleepternity device. It is plausible that since the device has been recalled, CMS is no longer making payments. However, without Mednology's admission or the opportunity for Ortega to do discovery, Ortega can do no more to prove the causality.

Nor will holding that materiality and causality is a matter of proof will lead to consequences outlined by the First Circuit or the District Court. The District Court echoed concerns that allowing a lesser standard than proof of the causal link would simply lead to "second-guessing" the FDA's approvals. R. at 22. This is unwarranted. Uncovering fraud which led to the FDA's approval of a device is not second-guessing the FDA's decision. There may be some fact patterns, like that the FDA declines to rescind approval or continues to pay for the years for the device or has conducted their own research and determined the fraudulent behavior doesn't warrant a recall of the device. See e.g. *D'Agostino v. ev3, Inc.*, 845 F.3d at 8; see also *Escobar* at 195. However, not every case will have these facts present, nor will every

qui tam plaintiff be able to obtain the facts without discovery. By limiting causality to a pleading standard, the court is not prevented from dismissing the suit after discovery nor is a defendant prevented from submitting proof that the plaintiff cannot make a plausible claim. This Court should not adopt the First Circuit's standard and limit a relator ability to make a claim.

Concerns about providing sufficient evidence are equally unconvincing. They argue that no relator of these claims could provide sufficient proof in the trial that wouldn't amount to second-guessing the FDA. They present a limited number of potential sources of this evidence and prematurely conclude that none would be satisfactory at any stage of the trial. R. at 22. For this Court to allow this would undermine the heart of the adjudicatory process. It is the daily task of trial courts to ask juries to judge state of mind elements, competing experts to testify, and for juries to render verdicts based on competing expert testimony. Furthermore, if an expert was being "asked to read someone's mind," the court could prevent this with evidentiary hearings or sustained objections during trial. To allow this standard to become the law of the land would render the FCA ineffective and create unnecessary hurdles for relators the government relies on to prosecute fraud.

E. The District Court Erroneously Dismissed Ortega's FCA Claim of Fraud-on-the-FDA Because Ortega Has Met the Pleading Standard to Overcome a 12(b)(6) Motion to Dismiss.

Ortega has pleaded sufficient facts to demonstrate it is plausible that Mednology's use of silicone foam at the time of its FDA approval induced the FDA to

approve the device. To survive dismissal, Ortega must plead sufficient facts to plausibly satisfy the causation element of the materiality requirement of her FDA claim. *See Ashcroft*, 556 U.S., at 678. Therefore, Ortega must demonstrate it is plausible that the FDA would not have approved the Sleepternity device if Mednology had used the PE-PUR foam at the time of the FDA approval. From the facts alleged, Ortega has met the plausibility standard showing that if Mednology used the PE-PUR foam rather than the silicone in the device submitted to the FDA for approval, it is plausible that the device would not have been approved.

Pre-market approval for Class III devices takes a significant amount of time and is an extremely rigorous process. *Riegel*, 552 U.S., at 317–18. Sleepternity was very likely under review by the FDA while the FDA was simultaneously investigating a similar device make by competitor Philips Respironics for concerns with the same PE-PUR foam at issue in this case. At minimum, the FDA had already required Philips to recall their CPAP machine in June 2021, more than a year prior to the FDA's approval of Sleepternity in December 2022. R. at 4. According to the FDA's own report, the machine was recalled because the PE-PUR foam was believed to cause respiratory issues. See Foam Testing Summary. The FDA's website indicates that testing for Philips remains ongoing which means that this was a known issue at the time the FDA approved Sleepternity. *Id.* The FDA has still not allowed Philips to re-release the device with the PE-PUR foam since the recall. *Id.* If FDA would not allow Philips to sell devices with PE-PUR at the time of the approval and has not changed course since, it is plausible that the FDA

would not have approved the device had it known Mednology used PE-PUR foam instead of the silicone in the model approved. With the known facts, is not just possible, but plausible that Sleepternity would not have been approved but-for using the silicone for the approval and then switching to PE-PUR in production.

Mednology's misrepresentation of the foam that would be used in the device when marketed broadly was a material misrepresentation which caused the FDA to issue approval. Under the Ninth Circuit's standard, Ortega would need to state a claim plausible on its face that Mednology's use of silicone foam for approval was material misrepresentation which caused the FDA to approve the device. *Ashcroft*, 556 U.S., at 678. This Court has already provided examples of what is dispositive to prove or disprove causality where misrepresentation to the FDA is at issue. See *Escobar* at 194–95. The examples provided do not apply in this case nor have the fact presented been previously held dispositive. *See Id.* With the lack of guiding precedent, Ortega's fraudulent misrepresentation claims should be evaluated as a matter of proof rather than grounds for dismissal.

As discussed above, the matter of proof standard for causality proposed by the Ninth Circuit is also more appropriate here. To require more from Ortega would require her to *speculate*, just like the First Circuit and District Court voiced concerns over. Ortega does not have the opportunity to provide admissible evidence or prove the causal link between the misrepresentation to the FDA without discovery. Allowing cases like this to proceed into discovery allows the plaintiff the

opportunity to obtain the information necessary make that claim in trial while side-stepping concerns expressed by the District Court and the First Circuit.

CONCLUSION

This Court should hold that the state law provisions of Trans. Compl. Stat. § 546(a–c) are *not* preempted under the FDCA. Each provision avoids express and implied preemption because they sound in traditional tort law. Allowing state tort claims to proceed under each of these claims speaks to the legislative intent and principles that have governed preemption doctrine under the FDCA. Further, a decision preserving individual's tort rights is necessary on the current facts, where a manufacturer attempts to use federal preemption as a shield for its fraudulent behavior. Alternatively, if this Court holds that state law relies on a substantive FDA ruling, then it must also determine that Section 546(a)'s immunity provision is preempted by the same reasoning.

This Court should also hold that a relator may rely on a fraud-on-the-FDA theory to state a claim under the False Claims Act's *qui tam* provision when a medical device manufacturer shirked FDA regulations thereby causing a governmental agency in CMS to pay for the device's coverage. The court should follow the Ninth Circuit and hold that the materiality and causality elements of fraud-on-the-FDA FCA claims is a matter of proof, not legal grounds for dismissal. This Court should affirm the Court of Appeals's decision to uphold Ortega's FCA claim based on implied false certification theory claim and overturn the district

court's decision to dismiss Ortega's FCA claim based on fraudulent misrepresentation.