No. 24-9176

In the Supreme Court of the United States

MEDNOLOGY, INC.,
Petitioner,
v.
UNITED STATES EX REL. Riley ORTEGA,
Respondent.

On Appeal from the United States District Court
for the Southern District of Transylvania

BRIEF FOR RESPONDENT

3322
Attorneys for Respondent

QUESTIONS PRESENTED

I. Whether federal law preempts a statutory exception to a manufacturer's immunity under Transylvania state law when the exception is based on the manufacturer fraudulently obtaining U.S. Food & Drug Administration (hereinafter "FDA") approval or failing to comply with any FDA requirements.

II. Whether Riley Ortega brought a valid False Claims Act *qui tam* civil suit using the fraud-on-the-FDA theory against Mednology.

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STATEMENT OF THE CASE

I. Factual Background

Plaintiff, Riley Ortega (hereinafter "Ortega"), recently retired as an artillery officer for the United States Army. Ortega was diagnosed with post-traumatic stress disorder (hereinafter "PTSD") due to traumatic experiences in the Army. Her PTSD symptoms contribute towards her insomnia and sleep apnea. Ortega's physician prescribed a medical device called Sleepternity, which is manufactured by Mednology, Inc. (hereinafter "Mednology"), to address her insomnia and sleep apnea.

Sleepternity is a continuous positive airway pressure (hereinafter "CPAP") machine that automatically adjusts pressures to increase therapy comfort, has a heated humidifier mask attachment to reduce dryness and irritation, and a smartphone app to allow for greater customization of Sleepternity device settings. In addition to the CPAP features to control sleep apnea, Sleepternity offers a sleep inducing feature through noise-canceling headphones attached to the CPAP mask that emit gentle pulses to the user's brain to aid users to relax and fall asleep.

Sleepternity obtained approval for marketing from the FDA as a Class III medical device on December 30, 2022. The Centers for Medicare and Medicaid Services (hereinafter "CMS") began to provide coverage for the costs of the device since the device was approved by the FDA.

Without permission and following FDA approval, Mednology modified the materials of the Sleepternity device to utilize polyester-based polyurethane (hereinafter "PE-PUR") foam for sound-dampening instead of the approved silicone-based foam. Polyurethane is cheaper than silicone, but can present significant health

risks if the foam breaks down. When the foam breaks down, volatile organic compounds (hereinafter "VOC") are released and can be breathed in and swallowed by CPAP users. Isocyanate is the VOC that is formed by the breakdown of polyurethane.

Ortega began experiencing asthma attacks and visited the emergency room at a nearby hospital. The emergency room physician recommended that she stop using Sleepternity, and her primary care physician agreed. Ortega and her physician knew she was allergic to isocyanate but did not consider the allergy because Sleepternity's warning label did not contain information about the presence of isocyanates in the medical device. Ortega's asthma symptoms subsided after discontinuing her use of Sleepternity but her sleep apnea symptoms returned.

Ortega's brother, Jim, works as an assembly manager at Mednology. Jim hypothesized that Ortega's asthma symptoms were due to the PE-PUR foams in Sleepternity and notified her that Mednology swapped foams after obtaining FDA approval to save on manufacturing costs.

II. Procedural Background

On June 21, 2023, Ortega brought a product liability action against Mednology following a report to the FDA alleging fraudulent misconduct from Mednology. Ortega alleged Mednology breached the duties of care and good faith, the duty to disclose modifications, and the duty to warn about the dangers and risk, per the Transylvania state product liability statute. Ortega also brought a False Claims Act ("FCA") *qui tam* suit against Mednology, alleging that Mednology fraudulently obtained FDA

approval for the Sleepternity CPAP device by utilizing silicone-based foams during the application process and failing to disclose material modification to the PE-PUR foams post-approval. Ortega contends that, but for the utilization of the silicone-based foam and the lack of material modification disclosure, the FDA would not have approved the device for sale, and CMS would not have established and begun payments for the device. (R. at 6).

The United States District Court for the Southern District of Transylvania denied in part and granted in part Mednology's motion to dismiss Ortega's state law claims. The district court held Ortega's state law claims are not preempted, so the motion is denied. However, the district court granted the motion to dismiss regarding Ortega's claim under the False Claims Act because "her False Claims Act action cannot be based entirely on Mednology's conduct of fraudulently obtaining FDA approval for its medical device." (R. at 3).

On appeal, the United States Court of Appeals for the Seventeenth Circuit affirmed the district court's decision to deny Mednology's motion to dismiss Ortega's state law claims, but gave different reasoning than the district court. Unlike the district court, the circuit court held the claims were preempted by federal law. But, the motion was still denied because Mednology was not compliant with federal requirements. The circuit court also reversed the district court's granting of Mednology's motion to dismiss Ortega's FCA claim and remanded for further proceedings consistent with the opinion. (R. at 25).

The decision entered by the Seventeenth Circuit was petitioned for certiorari, which the Supreme Court of the United States granted. (R. at 43).

III. The Regulatory Scheme

A. Preemption

The Sleepternity device is a Class III Medical Device, meaning that the device is considered to be life supporting, life sustaining, or important in preventing impairment of human health. 21 U.S.C. § 360c(a)(1)(C)(ii). Class III medical devices go through a pre-market approval (PMA) process to determine the safety and effectiveness of the device. *Id.* During the PMA process, the FDA inspects the facilities where the device is manufactured to ensure good manufacturing processes. "The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's safety and effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 316, 318 (2008) (internal quotation removed).

After the device received approval, the FDA continues to monitor the device through a post-market safety process. The manufacturer is forbidden "to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319.

If the manufacturer wishes to make modifications that could impact the safety or effectiveness of the device after receiving approval, a PMA supplement may be required. 21 C.F.R. § 814.39(f). There are four types of PMA supplements: panel track

supplement, 180-day supplement, real-time supplement, and special PMA supplement. For a change in material, a 180-day supplement is required. "The term '180-day supplement' means a supplement to an approved premarket application or premarket report under section 360e of this title that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling." 21 U.S.C. § 379i(4)(C).

B. FCA Claim

The FCA is a federal statute which imposes liability on persons or entities who defraud government programs. The statute allows private individuals, known as relators, to file *qui tam* suits on behalf of the U.S. government, who may then choose to intervene or allow the suit to continue privately. In the healthcare industry, FCA claims generally pertain to fraudulent statements or conduct which lead to claims for reimbursement through the Center for Medicare and Medicaid Services ("CMS").

31 U.S.C. 3729(a)(1)(A) and (B) establish liability for anyone who knowingly, through conduct or statement, submits, or causes someone else to submit, a false claim to the government for payment. The scienter element of a false claim is clarified through the definition of "knowing":

(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

31 U.S.C. 3729(b). In other words, a person or entity must know of or be intentionally or recklessly ignorant to the falsity of the information they provide to the government. Courts have reiterated the lack of need for specific intent to defraud the government, provided there is evidence of either knowledge of the falsity or reckless disregard for the truth, as defined in the statute. See *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016) (hereafter, "*Escobar*").

Ortega is entitled to file a *qui tam* civil suit against Mednology through the relator provision in 31 U.S.C. 3730(b), provided she is able to bring forth a material claim of fraud. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." U.S.C. 3729(b)(4).

SUMMARY OF THE ARGUMENT

This Court should deny Mednology's motion to dismiss Ortega's state law claims because they are not preempted by federal law and Mednology was noncompliant with its federal requirements as a Class III medical device with premarketing approval. The State of Transylvania passed several statutes to safeguard the health and safety of its residents. The first is a product liability claim under tort common law, which provides manufacturers and distributors owe a duty of care and good faith, a duty to warn, and a duty to make disclosures to the appropriate agencies or government officials. (*See* Appendix A). The statute aimed to also shield drugmakers and medical device manufacturers from product liability suits

as long as it had FDA approval and was in compliance with federal requirements. The statute provides that a medical device manufacturer is not liable to a person injured by a medical device if the FDA approved the device for marketing and the device and its labeling complied with the FDA's approval. (*See* Appendix B). There are two immunities provided that could remove a manufacturer's liability: (1) subsection (b), if the manufacturer intentionally withheld information from or misrepresented information to the FDA during the approval process and it would not have been approved had the FDA known; and (2) subsection (c), the manufacturer fails to warn about the dangers or risks of the device as required by the FDA. (*See* Appendix C).

Mednology filed a motion to dismiss Ortega's state law claims, arguing the Food and Drug Cosmetic Act (hereinafter "FDCA"), as amended by the Medical Device Amendments (hereinafter "MDA") preempts the Transylvania state laws Ortega relies on to bring her state law claims. This Court should deny Mednology's motion to dismiss.

The Supremacy Clause of the United States Constitution states that the Constitution is the "supreme Law of the Land" and should take precedence over any conflicting state laws. (U.S. Const., Art. VI, sec. 2). The presumption against preemption exists when Congress legislates an area that is traditionally reserved for the states. State police power gives states the authority to protect the health, safety, and general welfare of its citizens. U.S. Const., Amend. X. The presumption against preemption should apply in this case because it is not clear that Congress intended

to completely remove the state's ability to create laws in this field. This Court recognizes two types of preemption: express and implied preemption. To determine whether a claim can escape preemption:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

Riley v. Cordis Corp., 625 F.Supp.2d 769, 777 (D. Minn. 2009). Because Ortega's claims escape both express and implied preemption, we respectfully request this Court to affirm the decision of the lower court denying Mednology's motion to dismiss Ortega's claims.

Riley Ortega's False Claims Act (FCA) complaint against Mednology alleges that the company fraudulently obtained FDA approval for its Sleepternity CPAP device by misrepresenting the use of PE-PUR foam during manufacturing. Mednology is accused of using a silicone-based foam during the FDA approval process but then switching to a PE-PUR foam, which was known to be hazardous, after obtaining approval.

Ortega argues that her FCA claim is valid and Mednology's motion to dismiss for failure to state a claim is invalid. She bases this assertion on an argument that her claim, based on both the fraud-on-the-FDA and implied false certification theory, meets all elements of a valid FCA claim. Ortega contends that Mednology's use of PE-PUR foam, which was not approved by the FDA, constitutes a false statement or

misrepresentation. Ortega argues that Mednology either had actual knowledge of the misrepresentation or acted with reckless disregard for the truth. She points to the timing of the recall of Philips Respironics CPAP machines using PE-PUR foam as evidence that Mednology should have been aware of the hazard.

Ortega asserts that the FDA approval was material to CMS's decision to pay for the Sleepternity devices; by urging the Court to side with the Ninth Circuit's decision in *Campie* and the Seventeenth Circuit's decision in this matter's appeal, she contends that she has successfully provided enough evidence to shift the issue of materiality to a matter of proof rather than a legal grounds to dismiss her claim. Finally, Ortega argues that Mednology's fraudulent conduct directly caused CMS to pay for the Sleepternity devices. She argues that the FDA's approval was a prerequisite for CMS payments and that Mednology's misrepresentation led to the approval, citing several judicial precedents and a statement of interest from the Department of Justice ("DOJ") supporting the use of the fraud-on-the-FDA theory's use in FCA claims. Ortega supports these arguments with a reasonable analysis of the FCA's purpose and its use to promote the integrity of the FDA process. In conclusion, Ortega's complaint presents a plausible case that Mednology's fraudulent conduct violated the FCA. The Court should deny Mednology's motion to dismiss and allow the case to proceed to discovery and trial.

STANDARD OF REVIEW

The determination of whether federal law preempts subsections (b) and (c) of Transylvania's immunity statute is reviewed *de novo*. See *Lofton v. McNeil*

Consumer & Specialty Pharms., 672 F.3d 372, 375 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed *de novo*."). The matter of the FCA claim shall also be reviewed *de novo*. See *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017).

ARGUMENT

I. Mednology's Motion to Dismiss State Law Claims

1. Federal law does not preempt a state-recognized statutory exception to Mednology's immunity because the presumption against preemption applies and Ortega's claims are not expressly or impliedly preempted.

The state of Transylanvania's immunity exceptions are not preempted because the state is exercising its police powers and the exceptions are parallel to and do not conflict with the FDCA. The Supremacy Clause of the United States Constitution invalidates any state laws that "interfere with, or are contrary to" federal law due to the doctrine of federal preemption. *Gibbons v. Ogden*, 22 U.S. 1, 211 (1844). This Court recognizes two types of preemption: express preemption and implied preemption. To determine whether a claim can escape preemption –

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

Riley, 625 F.Supp.2d at 777.

The presumption against preemption exists when Congress legislates an area that is traditionally reserved for the states. "States traditionally have had great

latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (internal quotations removed). "The State of Transylvania's legislature recognizes the importance of safeguarding the health and safety of its residents" and codified various common law tort claims to facilitate protection. (R. at 7). *See* Appendix A-C. Transylvania's legislature took the product liability statute further by introducing a provision specific to drugs and medical devices. *See* Appendix B. The "legislature intended to shield drug makers or medical device manufacturers from product liability as long as the FDA had approved the drug or medical device in question." (R. at 7).

The FDCA contains an express preemption provision that ousts state power. Under the provision, 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). This Court has held in both *Riegel* and *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996) that § 360k(a) only applies to Class III medical devices that have received PMA pursuant to 21 U.S.C. § 360e. In *Buckman*, this Court interpreted 21 U.S.C. § 337(a) as providing Congress's intent that the Act only be enforced by the Federal Government, impliedly preempting state law and barring suits from private litigants "for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 352 (2001). Ortega's claims fall within the narrow exception between *Riegel* and *Buckman*, and thus should not be preempted.

1.1 The presumption against preemption should apply in this case.

Due to the ambiguity of the FDCA leading to ongoing confusion amongst courts, the presumption against preemption should apply. When Congress legislates an area traditionally reserved for the states, the court should assume that area regulated by state law is not superseded by federal law unless Congress has asserted a clear purpose to do so – creating a presumption against preemption. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947). *See, e.g., Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) ("consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law."). The MDA was enacted in 1990 to protect consumers by ensuring medical devices are safe and effective for their intended use. But throughout history, "[s]tates have exercised their police powers to protect the health and safety of their citizens." *Lohr*, 518 U.S. at 475.

"[T]he MDA's preemption provision is highly ambiguous. That provision makes clear that federal requirements may preempt state requirements, but it says next to nothing about just when, where, or how they may do so." *Lohr*, 518 U.S. at 505 (Breyer, J., concurring in part and concurring in the judgment). Its ambiguity is further supported by ongoing district court and circuit court splits with determining whether federal law preempts parallel state-tort common law claims against Class III medical device manufacturers. This Court's decision in *Buckman* was intended to "resolve a split among the Courts of Appeals on this question" in 2001, but lower courts still struggled. *Buckman*, at 347. This Court decided *Riegel* in 2008 to further

answer this question, but the splits continue. The Fifth[1] and Seventh[2] Circuits maintain that it is possible for state tort common law claims that are parallel to federal law to survive express[3] and implied preemption. The Sixth[4] and Eighth[5] Circuits both adopted expansive views of *Buckman* to impliedly preempt traditional state tort law claims.

The plaintiffs in *Buckman* asserted the PMA contained fraudulent misrepresentations to the FDA (hereinafter "fraud-on-the-FDA claim) and alleged that if factual information was submitted, the FDA would not have approved the device and the plaintiffs would not have been injured. *Buckman,* 531 U.S. at 343. This Court concluded the presumption against preemption did not apply because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 357. The court reasoned that it cannot allow fraud-on-the-FDA claims under state tort law because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against [it]" and uses its authority to achieve a "somewhat delicate balance of statutory objectives." *Id.* at 348. The

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[1] *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) (the state-law "failure to warn claim is neither expressly nor impliedly preempted by the MDA").

[2] *See Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) *cert. denied* (the patient's claims were not expressly preempted and were not impliedly preempted due to the device being adulterated).

[3] The court in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) discusses the possibility of escaping express preemption, but does not agree with the implied preemption analysis of *Hughes.* But, *Stengel* is flagged for severe negative treatment, which is why the Ninth Circuit is not listed with the other four Circuit Courts that weigh in on this issue.

[4] *See Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) *reh'g denied and cert. denied.* (negligence per se claims, fraud-on-the-FDA claims, and failure to warn claims were preempted).

[5] *See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, Bryant, et al., v. Medtronic, Inc., et al.,* 623 F.3d 1200 (8th Circuit 2010) (the MDA preempted failure to warn claims, defective design claims, manufacturing defect claims, and breach of express warranty claims). The separate opinion draws attention to a "'back door for plaintiffs' left open by *Riegel*[,]" where "departure from such FDA-approved specifications could conceivably escape preemption." *Id*. at 1211 (Melloy, J., concurring in part and dissenting in part).

presumption should apply for Ortega because her claims are based on traditional state tort law, not fraud-on-the-FDA.

Instead of relying on the *Buckman* analysis for presumption on preemption, this Court should rely on *Desiano*, where the court distinguished *Buckman* because the claims depended on traditional state common law tort sources, not fraud-on-the-FDA claims. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2nd Cir. 2006). The United States District Court for the Southern District of Transylvania agreed with Ortega that *Desiano* is on point for the determination of whether to apply the presumption against preemption to this case. (R. at 13). The cause of action in *Desiano* "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." *Desiano*, 467 F.3d at 94. Transylvania, like Michigan in *Desiano*, intended to "shield drugmakers or medical device manufacturers from product liability suits[.]" (R. at 8). *See* 21 Trans. Comp. Stat. § 630.546(a). *See also Desiano* 467 F.3d at 94n.5 ("the main impetus driving the legislation was a desire to limit the liability of drug makers under state tort law[,]" . . . not "preventing or punishing fraud against the FDA").

Although Mednology will argue that the presumption against preemption should not apply and *Garcia* should apply, it is not applicable because the court in *Garcia* relies on *Buckman*, but that is not the correct case to use because Ortega is not attempting to police fraud on the FDA. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). Fraud-on-the-FDA and product liability are two distinct legal theories to hold manufacturers accountable for their actions and they should not be

conflated. The presumption against preemption should be applied here, as it "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Lohr*, 518 U.S. at 485.

1.2 Ortega's claims are not expressly preempted under § 360k(a).

Ortega's claims are not expressly preempted under § 360k(a) because Mednology failed to seek supplemental PMA approval to change the materials used in the Sleepternity device, in direct violation of their obligations as a PMA Class III medical device manufacturer. The FDCA contains an express preemption provision that prevents states from establishing requirements "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). "[Section] 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,* 552 U.S. at 330. (internal quotations removed).

In *Wolicki-Gables*, the court held the injured party failed to allege a parallel claim and demonstrate the defect in the pump "most probably" caused her injuries, and thus her claims were expressly preempted by the MDA. *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1302 (11th Cir. 2011). The catheter in a Class III, implantable pain medication pump malfunctioned and the injured party sued under state law. Unlike the injured party in *Wolicki-Gables*, Ortega did not rely on the "magic words '[manufacturer] violated FDA regulations' in order to avoid preemption." *Id.* at 1301. Ortega listed the parallel claims in her initial pleadings and

alleged Mednology violated their PMA by replacing the approved silicone foam with an unapproved PE-PUR foam. Ortega presented facts to allege how Mednology's failure to follow the FDA's requirements caused her injury – and her claims regarding Mednology's material substitution could be corroborated by the testimony of an assembly manager at Mednology.

The court in *Bausch* held the claim was not expressly preempted as long as the injured party could prove the allegations of harm, relying on *Riegel* and *Lohr* to make a determination regarding parallel claims. *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) *cert. denied*. Previous Supreme Court decisions make certain boundaries clear –

> Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they *comply* with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law.

Id. at 550. Mednology cannot seek immunity under the subsections because Sleepternity was not compliant with the Class III approval when it was marketed and sold to consumers such as Ortega. But, historically, plaintiffs have struggled in many cases to meet the evidentiary burden required to establish their claim to overcome preemption.

The majority in *Bausch* agreed with the separate opinion in *In re Medtronic, Inc.*, where "Judge Melloy argued that the plaintiffs could not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents." *Id.* at 554. The separate opinion in *In re*

Medtronic, Inc. draws attention to the need to "take into account the practical difficulties inherent in situations, like this, where the 'crucial information . . . tend[s] systematically to be in the sole possession of defendants." *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation, Bryant, et al., v. Medtronic, Inc., et al.,* 623 F.3d 1200, 1211-1212 (8th Circuit 2010) (Melloy, J., concurring in part and dissenting in part) (citing *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 598 (8th Cir. 2009)). *See Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 598 (8th Cir. 2009) ("[i]f plaintiffs cannot state a claim without pleading facts which tend systematically to be in the sole possession of defendants[,]" the information imbalance will lead to the suffering of "crucial rights secured" because the "remedial scheme of the statute will fail[.]").

The Seventeenth Circuit Court held subsection (b) of the Transylvania immunity exceptions (appendix D) was preempted under *Garcia* because "[Ortega] is seeking to prove Mednology's fraudulent conduct solely through judicial fact-finding." (R. at 29). The Seventeenth Circuit Court draws attention to the fact that Ortega has not alleged the FDA officially found Mednology fraudulently obtained PMA for Sleepternity. The Circuit Court failed to acknowledge that the FDA stopped investigating Sleepternity after Mednology voluntarily recalled the device to instead "focus on investigating other allegedly defective products in the marketplace that have not been recalled." (*Id.* at 7). While Ortega does not have reports from the FDA specifically about Sleepternity, Ortega does have access to public records regarding a massive recall of Philips Respironics, Inc. (hereinafter "Philips") CPAP, bilevel

positive airway pressure machines (hereinafter "BiPAP"), and ventilator devices because of health risks associated with the breakdown of PE-PUR foam. The FDA released several reports publicly regarding polyurethanes that showed the degraded foam was not biocompatible and posed a significant health risk to humans utilizing devices made from that material. FDA Guidance 2020 and ISO 10993-1:2018. Mednology received its PMA to use silicone foam, not PE-PUR, on December 30, 2022.[6] (R. at 4). The Philips recalls, national media headlines, and lawsuits relating to the recalls began before Mednology received its PMA from the FDA. Despite Philips injury reports and FDA investigation reports being public, Mednology chose to change its foam material to PE-PUR. Mednology is an expert in the field of medical device manufacturing and knew or should have known their device would be susceptible to the same issues caused by PE-PUR.[7] The FDA implemented a replacement program for Philips to replace all devices impacted by the recalls with silicone-based foam, like the foam Mednology originally planned to use.[8] Allowing a judicial discovery process in such instances where a specific violation was alleged and is linked directly to a

[6] The FDA is supposed to conduct inspections every two years, but reports show the FDA estimated inspections for high risk devices every three years. U.S. Gen. Accounting Office, GAO-08-428T, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections* (2008). Ortega filed suit on June 21, 2023, within six months of Mednology receiving notice the FDA granted their PMA. Due to the quick turnaround, this would have been well before the FDA was slated to inspect Mednology's facilities again, which also contributes to the lack of official information available to Ortega regarding her claims and Sleepternity's noncompliance.

[7] *See, e.g., Rosa v. Taser Intern., Inc.* 684 F.3d 941 (9th Cir. 2012) ("[W]ith regard to the duty to warn, a manufacturer is held to the knowledge and skill of an expert in the field; it is obliged to keep abreast of any scientific discoveries and is presumed to know the results of all such advances.").

[8] *See Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, (April 10, 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#:~:text=Following%20the%20initial%20recall%20in,2021%20on%20the%20new%20foam.

health issue would uphold Ortega's rights and remove limitless immunity from noncompliant companies.[9]

1.3 Ortega's claims are not impliedly preempted under § 337(a).

Ortega's claims are not impliedly preempted under § 337(a) because she is trying to enforce a traditional state law tort, not privately enforce a duty owed to the FDA. Even if the claims are not expressly preempted by § 360k(a), they may still be impliedly preempted under § 337(a). Sometimes called the "no-private-right-of-action" clause, § 337(a) governs implied preemption by requiring "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Express and implied preemption, "operating in tandem, have created what some federal courts have described as a 'narrow gap' for pleadings." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017). "[A] plaintiff may proceed on her claim so long as she claims the "breach of a well-recognized duty owed to her under state law" and so "long as she can show that she was harmed by a violation of applicable federal law." *Id.* at 1327 (citing *Bausch*, 630 F.3d at 558).

For example, in *Mink*, the court held that the negligence claim was not impliedly preempted under the MDA because the duty of manufacture to use due care predated the MDA and the manufacturer owed the duty to the consumer, rather than

[9] This Court in *Lohr* rejected the manufacturer's argument that the plain language of § 360k(a) preempts any and all state common law claims. Rejecting the idea of complete immunity, this court reasoned that the MDA was not intended to "have the perverse effect of granting complete immunity from [tort] liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use." *Lohr*, 518 U.S. at 487.

the FDA – making it fall into the category of a traditional state tort law. In *Mink*, the patient brought several state law actions against the manufacturer of a hip replacement system after he required surgery to remove the system due to heavy metal toxicity. "Section 337(a) can prohibit only actions to enforce FDA requirements by private parties," so claims under traditional state tort law that predated the federal law and did not implicate a duty owed to the FDA are not impliedly preempted. *See* Appendix E.

Mednology will likely argue Ortega's claims fail due to field, obstacle, and/or conflict preemption, but it will not be successful because it is possible to comply with both the state and federal law. Ortega was not alleging a state law fraud-on-the-FDA claim like the plaintiffs in *Buckman*; instead, she is alleging fraudulent representation to limit Mednology's immunity. The Seventeenth Circuit Court relied on *Buckman* when incorrectly determining the Transylvania state law was impliedly preempted by the FDCA. Unlike the Sleepternity device that received PMA, the device in *Buckman* received § 501(k) approval because it was already on the market when the MDA was enacted. *Buckman*, 531 U.S. at 341. In *Buckman*, the court concluded that the plaintiff's cause of action for fraud-on-the-FDA was impliedly preempted under the FDCA because it conflicts with the FDA's responsibility to police fraud. *Id.* at 342. However, this Court stated that traditional state tort law causes of action are generally not impliedly preempted if they predate the federal enactments and do not implicate a duty owed to the FDA. *Id.* at 353.

When not in conflict, the federal and state laws can actually complement each other. State law often provides the only remedy for injured parties. *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 448 (2005). State-law actions often produce additional information about the risk of products, which would assist the FDA and prompt manufacturers to address the problem. *Bates,* 544 U.S. at 451. For example, Mednology voluntarily recalled Sleepternity following Ortega's lawsuit, but before the FDA completed an investigation.

II. Riley Ortega's False Claims Act Complaint

Per case law, a valid False Claims Act complaint consists of (a) a false statement or misrepresentation, (b) made with scienter, (c) that was material and (d) caused the government to pay out money or forfeit moneys due. See *U.S. ex rel Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. Ct. 2017), citing *Escobar* (2016). The matter of a falsity is not in question, as Mednology conceded, through voluntary recall of the Sleepternity CPAP devices, that the use of PE-PUR foam rather than silicone-based was a misrepresentation of the device as approved by the FDA. The following arguments show that Ortega's assertions meet all other elements of a valid FCA claim, and therefore the Court should deny Mednology's motion for dismissal of the claim.

In order to survive a motion to dismiss, a plaintiff's complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" R. at 33, citing *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) (emphasis added).

1. Ortega's claim is valid as to the scienter requirement, whether the Court decides it is met under "actual knowledge" or "reckless disregard for the truth".

Ortega asserts that Mednology acted with actual knowledge of the misrepresentation of their product to the FDA in order to obtain market approval for the product. She argues that the company chose an industry-approved silicone-based foam to incorporate into their Sleepternity device during the FDA application process, but manufactured the product using the hazardous PE-PUR foam after obtaining market approval. This conduct suggests that the silicone-based foam was used for the application process with the sole intent of obtaining market approval, though this is up for Court determination.

However, if the Court declines the assertion that Mednology acted with actual knowledge, the evidence brought by Ortega can still show that Mednology conducted itself with reckless disregard for the truth. Sleepternity was approved for market dispersal by the FDA on December 30, 2022. Philips Respironics ("Philips") recalled CPAP machines using the PE-PUR foam due to safety concerns in June 2021, a recall which the FDA endorsed upon further investigation. See *Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, (April 10, 2024). Per the timing of this recall, Mednology had the opportunity to learn of the hazardous effects of the PE-PUR foam. Federal Courts have long held that it is the duty of manufacturers to maintain health standards and to update those standards

in keeping with new findings of hazards. See *Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008) (holding that industry leaders remain knowledgeable regarding current and evolving safety concerns) and *In re DePuy Orthopaedics, Inc.*, 888 F.3d 753 (5th Cir. 2018) (holding that the manufacturer failed to meet industry standards relating to safety updates; that manufacturers have a duty to maintain evolving knowledge pertaining to evolution of safety standards and recall news). If the Court rejects that Mednology had no actual knowledge of the falsity of it's material modifications, Ortega will counter with the assertion that it was the company's duty to know of the hazard PE-PUR foam was now known to cause, and that should establish evidence of scienter under the "reckless disregard for the truth."

2. Ortega asserts the implied false certification theory to support her Fraud-on-the-FDA theory, both of which establish materiality sufficient to be determined a matter of proof rather than a legal ground to dismiss the relator's complaint.

The Fifth and Ninth Circuit Courts are split on whether the fraud-on-the-FDA theory constitutes a valid basis for bringing an FCA claim. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (explaining that the relator's allegation fell "short of pleading a causal link between the representations made to the FDA and the payments made by CMS"); *see also United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 907 (9th Cir. 2017) (holding that the relators have alleged, as part of their reliance on the implied false certification theory, sufficient facts to state a claim for relief under the FCA that is plausible on its face). Mednology will urge that the Court should side with *D'Agostino*, while Ortega will urge the opposite. In it's appellate decision on this matter, the Seventeenth Circuit sided with the Ninth Circuit, stating

that Ortega's fraud-on-the-FDA theory is supported by an implied false certification theory, which reasonably inferred the fraudulent activity so as to shift the issue of materiality from a legal grounds to dismiss to a matter of proof which validates the FCA claim.

Ortega asserts that Mednology fraudulently obtained FDA approval through implied false certification by asserting compliance with the approval despite utilizing a materials modification without proper disclosure. Further, Ortega contends that but for that misrepresentation to the FDA, CMS would not have approved Sleepternity for reimbursement, thereby making any claims for payment false claims. These assertions are a combination of the fraud-on-the-FDA and implied false certification theories, which–as previously stated–the Ninth Circuit in *Campie* and the Seventeenth Circuit in its appeal held to be a valid materiality argument. In *Campie*, the Court held that the FDA's approval was a prerequisite for any government payment and that the alleged fraud went directly to the essential purpose of the FDA approval process. When analyzing the facts of *Campie* using the *Escobar* standard for materiality, the Court found that the assertions put forth by the relator were material and should be analyzed further, thus reversing dismissal under failure to state a claim.

Ortega's assertion that Mednology's alleged fraudulent conduct was made in an effort to obtain FDA market approval parallels these facts. She alleges that CMS's payment for Sleepternity devices was conditioned upon FDA approval, which was conditioned upon certification of true statements from Mednology. By applying the

device using a safe material, Mednology all but ensured that Sleepternity would not be denied approval based on use of the hazardous PE-PUR foam it actually used in post-approval manufacturing. Further, failure to disclose the materials modification to the FDA ensured that no investigation potential recall would occur prior to at least a number of CMS payments. On February 16th, 2024, the U.S. District Court for the Central District of California denied Medtronic's motion for summary judgment, holding that failure to disclose a non-approved use of a medical device could constitute a false claim. *United States ex rel. The Dan Abrams Company LLC v. Medtronic Inc.*, No. 2:15-cv-01212-JAK-AS (C.D. Cal. Feb. 16, 2024).

While this case does not address an undisclosed use for Sleepternity, the FDA requires that materials modifications not considered during the PMA process be disclosed by manufacturers, often using a PMA supplement. 21 U.S.C. § 379i(4)(C) (for a change in material, a 180-day supplement is required). Mednology failed to disclose its materials modification to the FDA, constituting fraud by omission and noncompliance with FDA standards. Therefore, Ortega's assertion that the alleged fraud constituted implied false certification is reasonable, and it connects Mednology's fraud on the FDA to the CMS's reliance on the FDA's determinations regarding the device's safety for market.

3. Mednology's conduct established a causal link between the fraudulent conduct and CMS payments for the Sleepternity device, despite the FDA's cessation of investigation into the noncompliance.

Ortega asserts that Mednology had either the knowledge or the opportunity to learn of the safety hazards caused by PE-PUR foam in similar medical devices to their

Sleepternity CPAP. It is the manufacturer's duty to maintain standards of safety and to adjust them in response to recalls showing hazards to the public. Failure to do so likely constitutes reckless disregard for the truth, also a valid scienter determination for an FCA claim. Whether Mednology had actual knowledge of the hazard or not, its certification of truth was a requirement for its FDA application for market approval. Since the scienter element is satisfied, and the argument for materiality is established, causal links must now be connected between the alleged fraud and the false claims with CMS. The Courts in *Escobar* and *Campie* recognized that materiality and causation are often interwoven when addressing fraud-on-the-FDA allegations. In *Campie*, the Court held that if the alleged fraud is material to FDA approval, it follows that the fraud is in turn material to payment decisions by CMS.

In 2021, the First Circuit Court held that a proximate cause standard should be applied to FCA claims because the standard requires a direct causal link between the alleged fraud and false claims and detailed that specific false claims must be linked to the alleged fraud. Further, the Court affirmed that materiality links to causation, stating that the alleged fraud's material effect on the FDA's approval supports the argument that the misrepresentation or misconduct constitutes proximate cause for the subsequent false claims. In order to dismiss Mednology's motion to dismiss, Ortega need only show a plausible connection between the alleged fraud and false claims. Assuming the Court accepts the materiality argument above, Ortega need only to show that specific false claims were made for payment by CMS, which she is able to do by producing her own medical records. Upon order and

purchase of any medical device, medical providers are required to keep a record of the claims submitted for payment by CMS, which include Ortega's own Sleepternity CPAP in this case. Therefore, the causation element for a valid FCA claim may be satisfied by Ortega, and the Court should deny Mednology's motion for dismissal.

Mednology will argue that the FDA's cessation of investigation into the alleged fraud precludes an establishment of a causal link between the application misrepresentation and failure to disclose the materials modification and the CMS claims for payment. However, Ortega asserts that the FDA's closed investigation is not an automatic preclusion of causation. Ortega contends that there are many plausible reasons for the FDA to drop its investigation, among them and most likely of which is to save agency resources. Her argument that the issue of causation should be argued as a matter of proof, similarly to materiality, rather than dismissed. Courts have consistently held that government knowledge of noncompliance or alleged fraud does not preclude causation, even if they choose to continue payment or to not act. See *U.S. v. Allergan, Inc.* 46 F.4th 991 (9th Cir. 2022) and *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017). *Campie* further held that government knowledge of noncompliance or alleged fraud does not automatically preclude causation. Applying this precedent to these facts, Mednology's argument that there is automatically no causal link between the alleged fraud on the FDA and CMS's payments cannot be supported.

4. Public policy and recently published government intent suggest the Court should find in favor of the Fraud-on-the-FDA theory with which Ortega asserts her FCA claim.

4.1. Integrity of the FDA Approval Process

The FDA approval process is integral to society's health and wellbeing, and, as such, it is crucial that Courts allow relators to file claims alleging fraud within applications. Fraudulently obtained market approval risks the public's safety by allowing manufacturers to misrepresent the true nature of their biologic or device. Without access to a False Claims Act *qui tam* suit on a theory of fraud-on-the-FDA, private persons are left without a valid civil claim against such hazardous conduct. Allowing FCA claims based on this theory may deter manufacturers from submitting false information to the FDA, which would allow the FDA to accurately assess device safety, thereby ensuring that CMS is less likely to even see reimburse claims for an unsafe devices.

4.2. 2022 DOJ Statement of Interest

The FCA's purpose is to establish liability for fraudulent statements and conduct; denying FCA claims based on a fraud-on-the-FDA theory is counterintuitive to this purpose. It is the Courts' mission to uphold statutory intent. The Circuit Court split regarding the fraud-on-the-FDA theory is likely due to various courts' different interpretations of intent. However, the Southern District of Florida released a decision in which the Department of Justice ("DOJ") intervened with a statement of purpose in 2022. *U.S. ex rel Crocano v. Trividia Health*, 615 F.Supp.3d 1296 (S. D. Fla. 2022). Though the Court did not rule in the relator's favor and dismissed the case

on other grounds, the Court considered the DOJ's statement of interest involving use of the fraud-on-the-FDA theory. See Yolanda Y. Campbell, U.S. Dept. Justice Civil Div., United States' Statement of Interest as to Defendant's Motion to Dismiss, *U.S. ex rel Crocano v. Trividia Health*, 615 F.Supp.3d 1296 (S. D. Fla. 2022). The DOJ stated the following:

> [I]t is possible to articulate a viable FCA claim based on materially false or fraudulent statements made to the FDA regarding drugs or medical devices for which the government provides payment or reimbursement. [...] [F]ederal healthcare programs rely on the FDA's decision as to whether the drug or device is sufficiently safe and effective to be sold [...] [T]he FDA relies on information provided by the manufacturer, and therefore the manufacturer's compliance with its *reporting obligations*. [...] When a manufacturer perpetrates a fraud on the FDA by hiding material information concerning the safety or efficacy of a device – either during or after the approval process or to avoid a recall –and federal healthcare programs then pay for that device, that fraud may be "integral to a causal chain leading to payment" and can be actionable under the FCA. *Univ. of Phoenix*, 461 F.3d at 1174 (quoting *Oakland City Univ.*, 426 F.3d at 916)."

In essence, the DOJ establishes here that, barring factual insufficiency in a claim, there are valid materiality and causation arguments to be made within an FCA claim asserting the fraud-on-the-FDA theory. If a relator can make a reasonable showing that the alleged fraud was material to the FDA approval, then it can be inferred that a causal link connects that alleged fraud to CMS payments.

CONCLUSION

This Court should uphold the decision of the district court, denying Mednology's motion to dismiss Ortega's state law claims on the basis that the claims are not federally preempted. But, if this Court holds the immunity exceptions are

preempted, this Court should affirm the circuit court, which would still result in denying Mednology's motion – but for a different reason – because Mednology was not compliant with federal requirements and thus was not eligible for immunity under state law.

Additionally, this Court should affirm the Ninth Circuit Court's holding that the materiality of Ortega's FCA claim is sufficient to create a matter of proof to be determined by judicial analysis. Further, holdings in Campie and Escobar reiterate that Ortega's assertions relating Mednology's fraudulent conduct–utilizing silicone-based foam for the FDA application process but manufacturing with the PE-PUR foam without disclosure of this modification–show a causal link through materiality of the fraudulent conduct which, even with government conduct suggesting otherwise, can serve as a basis for a valid FCA claim.

APPENDIX

Appendix A: Transylvania Product Liability State Statute (General)

The State of Transylvania's product liability statute provides the following:

> 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.

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

Appendix B: Transylvania Product Liability State Statute (Drug or Medical Device Manufacturer Specific)

The pertinent section states:

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

21 Trans. Comp. Stat. § 630.546(a).

Appendix C:Transylvania Product Liability State Statute (Specific) Immunity Exceptions

The legislature enacted two critical exceptions to the immunity granted under 21 Trans. Comp. Stat. § 630.546(a). The exception under subsection (b) provides:

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

Id. § 630.546(b).

The exception under subsection (c) provides:

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

Id. § 630.546(c).

Appendix D: 21 U.S.C. § 360k(a)

Section 360k(a) applies to Class III medical devices and says:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Appendix E: 21 U.S.C. § 337(a)

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. § 337(a).