No. 24-9176

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER 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 PETITIONER

TEAM 3323

Attorneys for Petitioner

QUESTIONS PRESENTED

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

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

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OPINIONS BELOW

The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 1-24 of the record where the district court DENIED the

Defendant's motion to dismiss Plaintiff's state law claims but GRANTED the Defendant's motion to dismiss Plaintiff's FCA claim. The opinion of the United States Court of Appeals for the Seventh Circuit is also unreported but appears on pages 25-42 of the record where the circuit court AFFIRMED the district court's judgment and REVERSED the district court's judgment on the FCA claim.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves two provisions of the United States Code 21 U.S.C. § 301 et seq. (Federal Food, Drug, and Cosmetic Act – FDCA) and 31 U.S.C. §§ 3729-3733 (False Claims Act – FCA). This case also involves United States Constitution Article 1 Section 8 that lists the specific "enumerated powers" of the U.S. Congress, which includes regulating commerce among the states and Art. VI, Clause 2 (Supremacy Clause) and 21 Trans. Comp. Stat. § 630.545 and § 630.546 (Transylvania Product Liability Statute).

STATEMENT OF THE CASE

I. Statement of Facts

This case concerns a circuit court's unlawful affirmation of state law tort claims and an FCA (False Claims Act) claim. The court found that the FCA claim satisfies the materiality element and that, despite the preemption of state law claims by federal law, Riley alleged sufficient facts to plausibly rebut the presumption that Mednology was in compliance with the FDA. The Court of Appeals denied Petitioner Mednology's motion to dismiss Respondent Riley Ortega's state law claims and reversed the district court's decision to grant Mednology's motion to dismiss Riley's FCA claim.

The ruling is based on faulty interpretation of the rules that govern the approval and regulations of medical equipment under the FDA.

Sleepternity. Mednology, Inc., a leading manufacturer of medical devices, developed Sleepternity, a state -of-the-art continuous positive airway pressure (CPAP) machine, designed to help patients reduce sleep apnea and insomnia. Sleepternity offers advanced features, including automatic pressure adjustment, a heated humidifier, and noise-canceling sleep headphones. Sleepternity recently received FDA approval for marketing as a Class III medical device on December 30, 2022, after a thorough review of its safety and effectiveness. However, its existence was short-lived when its manufacturer voluntarily recalled it from the market pursuant to 21 C.F.R.7.0 (b).

After obtaining FDA approval, Mednology made a production decision to replace a small component to abate sound, the silicone-based sound-dampening foam originally used in the Sleepternity device with a polyester-based polyurethane (PE-PUR) foam. This change was implemented to streamline production and to reduce costs. The substitution was consistent with industry standards and did not require additional FDA approval. Alternatively, if the FDA required the submission of further information, it would still fall within the FDA's framework and governance.

Crossed Paths. Riley Ortega, a Sleepternity user and former military officer with a medical history relevant for post-traumatic stress disorder (PTSD), insomnia, sleep apnea, asthma, and an allergy to isocyanates—a type of volatile organic compound (VOC)—began experiencing asthma-like symptoms after using the device. Initially unaware of a substitution in the foam material, Ortega believed her symptoms were unrelated to the device. However, after discussing her condition with her brother, who is employed by Mednology, she learned about the change in foam material. Ortega subsequently connected her health issues to the presence of PE-PUR

foam, which had been associated with potential risks in a recall involving a different manufacturer.

Upon learning of Ortega's concerns, Mednology voluntarily recalled the Sleepternity devices containing PE-PUR foam and worked closely with the FDA to ensure compliance with all safety protocols.

II. Nature of Proceedings

This case stems from legal actions initiated by Riley Ortega against Mednology, Inc., the manufacturer of the Sleepternity CPAP device, on June 21, 2023, approximately six months after the device's FDA approval. Ortega filed a product liability lawsuit in the United States District Court for the Southern District of Transylvania, alleging that Mednology breached its duty of care and duty to warn, and engaged in fraudulent conduct by failing to disclose to the FDA that it had replaced the originally approved silicone-based sound-dampening foam with polyester-based polyurethane (PE-PUR) foam in its Sleepternity devices. Ortega contended this omission violated the False Claims Act (FCA) and caused state law claims under Transylvania's product liability statute.

The District Court. Ortega's lawsuit included both federal and state law claims. Specifically, Ortega asserted that Mednology's fraudulent omission during the FDA approval process led to the government unknowingly reimbursing claims related to the Sleepternity device under Medicare and Medicaid, which constituted a violation of the FCA. Additionally, Ortega argued that under Transylvania state law, Mednology breached its duty of care by failing to warn consumers about the potential risks associated with the PE-PUR foam.

Mednology responded by filing a motion to dismiss the same state law claims pursuant to Federal Rule of Civil Procedure 12 (b)(6) for failure to state a claim arguing that Ortega's FCA

claim did not meet the required elements of fraud, particularly the materiality standard. Mednology also contended that federal law, specifically the Food, Drug, and Cosmetic Act (FDCA), preempted Ortega's state law claims because the FDA had already approved the device, and it was therefore governed by federal laws.

The district court granted Mednology's motion to dismiss the FCA claim, finding that Ortega had failed to establish that the alleged fraudulent conduct was material to the FDA's decision to approve the Sleepternity device, and thus, to the government's payment decisions. However, the court denied Mednology's motion to dismiss the state law claims, holding that these claims were not preempted by federal law. The court reasoned that the state law claims were based on traditional common law duties of care, which did not conflict with the FDA's regulatory authority.

United States Court of Appeals for the Seventeenth Circuit. Following the district court's ruling, both parties appealed. Mednology appealed the denial of its motion to dismiss the state law claims, arguing that the district court erred in not applying federal preemption under the FDCA. Ortega cross-appealed the dismissal of her FCA claim, contending that the district court misapplied the materiality standard, and that the fraudulent omission was indeed central to the FDA's approval and the government's subsequent payments.

The appellate court reviewed the district court's decisions de novo. After considering the arguments from both parties, the appellate court reversed the district court's dismissal of the FCA claim, finding that Ortega had sufficiently alleged that the fraudulent omission could have influenced the FDA's approval and thus the government's payment decisions. The court affirmed the district court's decision to deny the motion to dismiss the state law claims, agreeing that

federal preemption did not apply because the state law claims were based on duties that existed independently of the FDCA.

The case was remanded to the district court for further proceedings consistent with the appellate court's findings, including a full trial on both the FCA and state law claims.

SUMMARY OF THE ARGUMENT

This Court should reverse the holding of the United States Court of Appeals for the Seventeenth Circuit. The court of appeals improperly held that Riley's allegations satisfy the materiality element of her FCA claim. The district court also incorrectly held that the state law claims were not preempted.

I.

The Court of Appeals erred in denying Mednology, Inc.'s motion to dismiss Riley Ortega's state law claims. These claims, which are predicated on state product liability law, are preempted by federal law under the Food, Drug, and Cosmetic Act (FDCA). This summary will outline why federal preemption applies and why the district court's decision should be reversed.

Federal Preemption Should Apply. The FDCA, as interpreted by the U.S. Supreme Court, preempts state laws that impose requirements on medical devices that differ from or add to federal requirements. Riley's state law claims effectively challenge Mednology's compliance with FDA regulations by asserting that the use of PE-PUR foam in the Sleepternity device, even after FDA approval, violates state product liability laws. These claims impose obligations that go beyond those required by the FDA, thus triggering federal preemption. Class III devices that are approved through the FDA's rigorous pre-market approval process ("PMA") automatically satisfy the "federal requirements" prong of the preemption analysis. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-323 (2008); *Bass v. Stryker Corp.,* 669 F.3d 501, 507 (5th Cir. 2012).

Mednology's Compliance with FDA Regulations. Mednology acted within the bounds of federal law by substituting the silicone-based foam with PE-PUR foam in the Sleepternity device. The FDA approved the device based on Mednology's submissions, which were in full compliance with federal regulations. The substitution of materials did not alter the safety profile of the device in a manner that would have required re-submission for FDA approval, nor did it breach any specific federal requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). Therefore, Ortega's claims based on state law should be barred as they conflict with the federal regulatory framework.

Impact of Preemption on State Law Immunity Exceptions. Transylvania's immunity statute includes exceptions that remove a manufacturer's immunity if there is evidence of fraud or failure to comply with FDA requirements. However, these exceptions are themselves preempted by federal law, as they seek to impose state-level penalties and obligations on manufacturers that differ from those mandated by federal regulations. *Riegel v. Medtronic* at 321. The Supreme Court has consistently held that the FDCA's preemption provisions are designed to ensure uniformity in the regulation of medical devices, and allowing state law exceptions to circumvent this framework would undermine the federal regulatory scheme. Additionally, the Supreme Court has held that state law claims are preempted when the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it because those claims are considered state-law fraud-on-the-FDA and they are in conflict with the FDA's authority and responsibility to police fraud, regulate, and enforce drug and device regulations. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965 (6th Cir. 2004), *Marsh v. Genentech, Inc.*, 693 F.3d 546 ,548 (6th Cir. 2012).

The Role of the FDA as the Sole Enforcer of Its Regulations. The Supreme Court has emphasized that the FDA is the sole enforcer of the FDCA. Claims based on fraud or misrepresentation to the FDA are preempted because they infringe upon the federal agency's exclusive authority to police its own regulations. Ortega's state law claims, which are fundamentally based on alleged misrepresentation and non-compliance with FDA regulations, are therefore preempted and should have been dismissed.

The state law claims brought by Ortega are preempted by federal law, as they impose additional requirements on Mednology that conflict with the comprehensive regulatory framework established by the FDCA.

In 1976, Congress enacted the Medical Device Amendments to the Food Drug and Cosmetics Act that empowered the FDA to regulate and penalize manufacturer's disclosures in the approval process. This has been interpreted by the court system as evidence that Congress intended for the FDA to have exclusive federal enforcement.

However, the Court of Appeals and the district Court's ruling against Mednology by allowing preemption and invading FDA's powers establishes a flawed system that bypasses democratic oversight. Their ruling failed to recognize Congress's intentions and properly interpret the law, leading to confusion and ambiguity by setting unclear parameters to balance the power between federal and state governments.

In conclusion, the United States Court of Appeals for the Seventeenth Circuit's denial of Mednology's motion to dismiss was erroneous. This court should reverse the lower court's decision and dismiss Ortega's state law claims in their entirety.

II.

Requiring plausible or conclusive allegations to prove the element of materiality in the False Claims Act contradicts the authority of the FDA. The appeals court unquestionably erred in adopting the Ninth Circuit's test, which unreasonably requires alleged facts to be sufficient to change the issue of materiality from a legal ground for dismissal to a matter of proof, satisfying the materiality element under the FCA claim. This is a grave mistake as it's suggested the element of materiality only recently changed when public interest associated with the allegations intensified. By exercising congressional authority, the FDA provides regulatory oversight in patient safety and compliance standards, which in turn encourages public confidence. In the past, courts placed significant weight on whether a device manufacturer would be held liable for noncompliance based on the FDA's response. For example, if the FDA would cease payments for claims, then the Court would commonly hold the company in noncompliance, acknowledging the discretion the FDA administers with possible civil penalties. Now, the materiality bar has shifted from concrete, particular evidence to plausible assertions of noncompliance, putting further pressure on device companies in line for liability as they exercise internal authority with their own contracted providers.

While the FDA does have the authority to impose civil penalties on device manufacturers that make modifications to their devices after FDA approval, they do allow for changes to be made to a device without FDA notification if the alteration does not impact the device's safety or effectiveness §814.39(b). Currently, there is a debate about recent court decisions, suggesting that the FDA needs to apply stricter criteria in determining what constitutes insignificant changes, as the standard for public safety has been perceived to weaken. Nevertheless, the associated cost of obtaining additional FDA approval is exceedingly high. This financial burden may result in delays in bringing the devices to the market, potentially leading to loss of lives.

Therefore, finding the right balance between circumventing a second FDA approval and overcoming the challenges involved in filing FCA is a complex issue to address.

Based on the above, adopting the plausibility condition to establish a causal connection to materiality would make it difficult for Ortega to prove that Mednology violated the FCA. These cases, however, discussed below strongly suggest that lower courts modified the sufficiency of the materiality element in response to the egregious conduct of providers not employed by Mednology. It's possible that there was a public demand for providers to adhere to the ethical standards trusted by their patients, which was seriously compromised. It would be unfair to burden Mednology with meeting state licensing requirements that were neglected by the providers. Therefore, despite the newer standard of materiality adopted by this Court, Ortega's claims are unable to meet it, and the appeals court erred in denying Mednology's motion to dismiss.

ARGUMENT AND AUTHORITIES

Standard of Review. The standard of review for this appeal is *de novo*. This case involves questions of federal preemption under the Supremacy Clause of the U.S. Constitution, as well as the application of the Food, Drug, and Cosmetic Act (FDCA) to state law claims. The determination of whether federal law preempts state law is a question of law, which the Supreme Court reviews de novo.

Additionally, the district court's decision to dismiss claims under Rule 12(b)(6) of the Federal Rules of Civil Procedure is also reviewed de novo. This standard requires the court to determine whether the complaint, viewed in the light most favorable to the non-moving party, contains sufficient factual matter to state a claim that is plausible on its face.

In this context, the court must examine whether Riley Ortega's state law claims impose requirements that conflict with, or add to, federal requirements established by the FDA, thereby invoking federal preemption. The Court must also determine whether the district court properly assessed the materiality of the alleged omissions and whether those omissions could support a claim under the False Claims Act.

These legal questions require a fresh, independent analysis, unbound by the district court's and circuit courts' conclusions.

I. The Appellate Court Erred in Failing to Apply Federal Preemption, Contrary to the Supreme Court's Established Precedents.

The appellate court erred in failing to apply the doctrine of federal preemption to bar state law claims against Mednology, Inc., which is regulated under the Federal Food, Drug, and Cosmetic Act (FDCA).The Supreme Court has held consistently that state law claims against medical device manufacturers who obtain federal premarket approval (PMA) are preempted by Section 360k(a) of the MDA when liability is premised on violations of state law requirements that are "in addition to or different from" federal requirements regulating devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In this case, the appellate court ruled that Mednology was not in compliance with the FDA based on Ortega's allegations, without recognizing that this was not a parallel claim. Ortega's state law claims involved requirements beyond those established by the FDA. Federal preemption requires an understanding of preemption doctrine, Congressional intent, the FDA's classification of medical devices, premarket approval, and the specific status of Mednology's device (Sleepternity).

A. Preemption

The Supremacy Clause is the source of preemption doctrine, which invalidates state laws that are contrary to federal statutes. Preemption is the application of the Supremacy Clause:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof, and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.
>
> U.S. Const. art. VI, cl. 2.

Preemption can be categorized as either express or implied. Express preemption happens when a legislature explicitly prohibits regulation in a specific area. Implied preemption can occur in two ways: through conflict preemption or field preemption. Conflict preemption arises when state laws conflict with federal laws. See *Kennedy Tank & Mfg. Co. V. Emmert Indus. Corp*, 67 N.E.3d 1025, 1028 (Ind. 2017). Field preemption occurs when state laws encroach on a field already regulated by a federal entity.

B. Express Preemption Under FDCA

The FDCA contains an express preemption clause under 21 U.S.C. § 360k(a), which prohibits states from establishing requirements for medical devices that differ from or add to those set by the FDA. In *Riegel v. Medtronic, Inc.*, the Supreme Court confirmed that state law claims imposing additional requirements on medical devices are preempted by federal law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). In this case, Riley Ortega's state law

claims against Mednology, Inc. seeks to impose liability based on state requirements for the disclosure of modifications and risks associated with medical devices—requirements that are not mandated by federal law. As such, these claims are expressly preempted by 21 U.S.C. § 360k(a), and the appellate court's failure to apply this preemption was erroneous. The court ruled in *Williams v. Bayer, that* any claim based on statements approved by the FDA would require a determination that the product "did not conform to the descriptions approved by the FDA. Such claims are preempted." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 603 (Mo. Ct. App.2017). Similarly, any claim that Mednology did not conform to the descriptions approved by the FDA under the stringent Class III requirements should also be preempted.

The MDA established a new regime whereby the FDA has almost exclusive authority to regulate medical devices. The MDA expressly preempts state law claims that impose requirements different from or in addition to federal requirements for Class III medical devices approved through the PMA process. The claims for failure to warn, defective design, negligence, recklessness, and breach of implied warranties impose additional requirements and are therefore preempted. *Delaney v. Stryker Orthopaedics*, Civil Action No. 08-03210 (DMC), 1,10 (D.N.J. 2009). Similarly, to *Delaney* where the plaintiff failed to state a claim when was unable to specify any deviation from the FDA and the claim was dismissed, in here, Ortega is unable to specify the deviation Sleepternity had from the FDA-approved manufacturing process and it her state law claims should be dismissed as well. *Id.* at 18.

The court in *Lofton v. McNeil* ruled that "authorizing tort liability for failure to comply with FDA disclosure requirements would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Lofton v. McNeil Consumer $Specialty Pharms.*, 672 F.3d, 372, 376 (5th Cir. 2012). Similarly, here, Mednology's non-compliance with

the FDA is an extraneous pull on the scheme set by Congress. Thus, the Court of Appeals erred in its ruling when it considered that state law claims were not preempted and therefore, authorized tort liability for failure to comply with the FDA.

1. Classification of Medical Equipment under the FDCA

The Medical Device Amendments to the Federal Food, Drug and Cosmetics Act, 21 U.S.C.S. § 360c et seq., establishes three levels for medical devices depending on the risks the device presents. The levels are classified as follows: Class I devices pose the least risk and are subject to only general federal control such as labeling requirements. 21 U.S.C.S. § 360c(a)(1)(A). Class II devices are potentially more harmful and, therefore, manufacturers of Class II devices must comply with federal performance regulations known as special controls. 21 U.S.C.S. § 360c(a)(1)(B). Nevertheless, Class I and Class II medical devices may be marketed without receiving premarket approval from the FDA. 21 U.S.C.S. § 360(a)(1)(A)-(B).

Devices that either present a potential unreasonable risk of illness or injury, or which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, are designated as Class III. 21 U.S.C.S. § 360c(a)(1)(C)(ii). Class III devices are subject to the Food and Drug Administration's rigorous premarket approval (PMA) process. 21 U.S.C.S. § 360e. Products approved via the PMA process, 21 U.S.C.S. § 360k(a) expressly preempts state law claims that are different from, or in addition to, the federal requirements because the medical devices have undergone a rigorous federal safety review.

2. The Sleepternity Device

Mednology has developed Sleepternity, an innovative CPAP (Continuous Positive Airway Pressure) device designed to effectively manage sleep apnea—a prevalent sleep disorder

impacting 20% of the U.S. population. According to the National Council on Aging, approximately 39 million U.S. adults suffer from obstructive sleep apnea (OSA), and around 33 million use CPAP machines, including notable figures like President Joe Biden.

Untreated sleep apnea can result in impaired cognitive function, cardiovascular issues, and stroke, significantly deteriorating quality of life and increasing the burden of care. Effective treatment with a CPAP machine like Sleepternity not only improves quality of life but also helps regulate blood pressure, offering substantial health benefits.

3. Premarket Approval

Medical devices are regulated by the Food and Drug Administration pursuant to the Food, Drug, and Cosmetics Act and the Medical Device Amendments of 1976 (MDA) 21 U.S.C. 360c *et seq.* The FDA approves Class III devices for the market through two different processes: the Section 510(k) process or the PMA process. The PMA process entails extensive and stringent evaluation that is entirely different from the 510(k)-pre-market notification process.

The FDA does not conduct an independent evaluation of a medical device's safety and effectiveness approved under section 510(k). Instead, this process permits a device manufacturer to leverage the comprehensive review and approval of an existing device by showing that the new device is "substantially equivalent" to a predicate device. The predicate device may be marketed while awaiting a full premarket approval process.

Since no specific federal requirements are imposed on Class III medical devices approved under Section 510(k), state law claims against such devices are not preempted under the MDA. However, as the PMA process is the most rigorous review process, applicable to only a small percentage of Class III medical devices, the MDA's preemption applies to state law claims

that are different from, or in addition to, the federal requirements, as such medical devices undergo specific federal safety review.

Sleepternity was designated as a Class III medical device, pursuant to the MDA, which means its design, manufacturing process, and labeling underwent the rigorous scrutiny of the FDA's premarket approval process. *See* 21 U.S.C. 360e.

C. Implied Preemption under FDCA applies when Manufacturers fail to disclose information and are therefore non-compliant.

Beyond express preemption, implied preemption also applies to Ortega's claims. In *Buckman Co. v. Plaintiffs' Legal Comm.*, the Supreme Court held that state law claims alleging fraud on the FDA are impliedly preempted because they interfere with the FDA's regulatory authority. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Ortega's claims that Mednology failed to disclose modifications to the FDA fall within the scope of *Buckman*'s implied preemption. The district court's application of a presumption against preemption contradicts *Buckman*'s clear ruling that federal law occupies the field of FDA-related fraud claims, and state law cannot impose additional duties on entities regulated by the FDA.

Non-compliance with the FDA claims are considered a violation of federal law that triggers the police and regulatory powers of the FDA and are therefore preempted. *Marsh* at 548. Furthermore, the court ruled that it is irrelevant when or how the non-compliance occurred, because both are controlled by the FDA. *Id.* In here, the appellate court erred in its ruling that Mednology had no state law immunity because it was not in compliance because the non-compliance with the FDA preempts state law claims.

D. Precedent Supporting Preemption

The Sixth Circuit's ruling in *Garcia v. Wyeth-Ayerst Labs.* further supports the application of preemption in this case. There, the court held that state-law claims imposing additional requirements on a drug manufacturer were preempted by federal law. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), Similarly, in *McMullen v. Medtronic, Inc.*, the court emphasized that the FDCA preempts state-law claims that challenge the FDA's regulatory authority. *McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005). Additionally, the Sixth Circuit held in *Marsh* that in a case of non-compliance premised on violation of federal law, it implicated "the relationship between a federal agency and the entity it regulates," it is therefore preempted because it required to usurp a role held by the FDA. *Marsh v. Genentech, Inc. at 555.* These cases reinforce the principle that federal law preempts state efforts to regulate medical devices in ways that differ from federal standards, directly applicable to the claims against Mednology.

The appellate court's failure to apply federal preemption to Ortega's state law claims contravenes established Supreme Court precedent. The FDCA's express and implied preemption provisions, as interpreted in *Riegel* and *Buckman*, clearly preempt Ortega's claims. Therefore, the appellate court's decision should be reversed, as it is inconsistent with federal law and the Supreme Court's precedents.

II. Even if Federal Preemption Were Not Dispositive, The State Law Claims Should Be Dismissed Because They Imposed Requirements Inconsistent with the FDA's Regulatory Scheme

Even if federal preemption does not outright bar Ortega's state law claims, they should still be dismissed because they impose requirements that are fundamentally inconsistent with the

FDA's comprehensive regulatory scheme. The FDA has established a detailed framework for the regulation of medical devices, including standards for design, manufacturing, labeling, and post-market surveillance. Allowing state law claims to proceed would undermine this federal framework by imposing inconsistent obligations on manufacturers.

In *Marsh,* the court acknowledged FDCA's autonomy when it articulated that the "FDCA sets forth a "comprehensive scheme" of disclosure requirements as part of the approval process." Additionally, the FDCA vests the FDA with power to penalize fraud. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012).

The ruling in *Marsh* clearly identified the delicate balance between state and federal government and interpreted the provisions of the FDCA as evidence that Congress intended for enforcement to be exclusively federal. Like *Marsh,* here, FDA has the power to assess the adequacy of Mednology's disclosures, and behaviors during and after the approval process. Therefore, any misconduct or lack of compliance should be governed by the FDA, as it is the regulatory agency that by law approved the product. On a minor scale, ruling otherwise undermines the regular functioning of commerce by potentially creating a dual system where manufacturers must adhere to two separate systems for approval and compliance (state and federal systems). On a larger scale, this could disrupt the delicate balance between state and federal laws and affect our overall democratic system.

A. Conflict with the FDA's Risk-Benefit Determination

The FDA's regulatory scheme for medical devices is based on a careful balancing of risks and benefits. In *Geier v. American Honda Motor Co.*, the Supreme Court held that state law claims are preempted when they conflict with the objectives of federal regulations. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 874-75 (2000). Ortega's state law claims demand

disclosure of modifications and risks that the FDA, through its regulatory process, has determined do not warrant such disclosures. This directly conflicts with the FDA's authority to set uniform standards for what constitutes adequate warnings and disclosures for medical devices.

In *Petix v. Kabi Pharmacia Ophthalmics*, the court ruled that even if a plaintiff can show that a defendant did not comply with the FDA requirements in the marketing and withdrawing of its product from the market, the express preemption of state law claims leaves states with no authority to police manufacturers' compliance with federal procedures. *Petix v. Kabi Pharmacia Ophthalmics*, 884 F. Supp. 92, 99 (W.D.N.Y. 1995). In this case, the express preemption of Ortega's state law claims leaves Transylvania state law with no authority to police Mednology's compliance with federal procedures.

Furthermore, the court has held that for a device that received pre-market approval by the FDA, like Mednology, and "it was later withdrawn from the market, even if the FDA had mandated the withdrawal, [did] not change the fact that the MDA preempted state law requirements concerning its safety, effectiveness, and otherwise." *Kemp v. Pfizer, Inc*., 835 F. Supp. 1015, 1023 (E.D. Mich. 1993).

In this case, MDA also preempts state law requirements concerning the risks, safety, and effectiveness that Mednology's medical device, Sleepternity had, even though it was recalled and discontinued from the market.

In *Mutual Pharmaceutical Co. v. Bartlett*, the Supreme Court further emphasized that state laws that impose conflicting duties on manufacturers—such as the duty to label a product in a way that diverges from FDA requirements—are preempted. *Mutual Pharmaceutical Co. v. Bartlett,* 570 U.S. 472, 480 (2013). Allowing Ortega's state law claims to proceed would force

Mednology, Inc. to choose between complying with state-imposed requirements and following the FDA's federally mandated guidelines, which is precisely the kind of conflict that federal law seeks to prevent.

B. Undermining the FDA's Exclusive Authority

The FDA's authority in regulating medical devices is designed to ensure consistency across all states, preventing a patchwork of state laws from disrupting the uniform application of federal standards. In *PLIVA, Inc. v. Mensing*, the Supreme Court held that when it is impossible for a manufacturer to comply with both federal and state requirements, the state law is preempted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). Ortega's claims, which seek to impose additional obligations on Mednology beyond those required by the FDA, would create such a conflict. This would undermine the FDA's exclusive authority to regulate medical devices and create inconsistencies that could lead to varying standards across states, defeating the purpose of the FDA's nationwide regulatory scheme.

C. FDA's Regulatory Scheme as a Federal Uniform Standard

The FDA's regulatory scheme serves as a uniform standard for the evaluation and approval of medical devices, including post-market requirements. Allowing state law claims like Ortega's to impose additional requirements would result in conflicting obligations that undermine the FDA's role as the sole arbiter of device safety and efficacy. This is inconsistent with the Supreme Court's rulings in cases like *Riegel v. Medtronic, Inc.*, where the Court emphasized the need for uniform federal regulation in the medical device industry. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008). Permitting state law claims that impose additional or different requirements would disrupt the uniform regulatory framework established by the FDA, leading

to potentially conflicting obligations for manufacturers and a dilution of the federal standards intended to protect public health.

In sum, even if federal preemption does not completely bar Ortega's state law claims, they should still be dismissed because they impose requirements that are inconsistent with the FDA's regulatory scheme. The FDA's framework is designed to be the exclusive standard for the regulation of medical devices, and any state law claims that conflict with this framework is impermissible. The district court should have dismissed these claims to preserve the uniformity and effectiveness of the FDA's regulatory authority.

III. The Court Improperly Allowed State Law Immunity Exceptions to Circumvent Federal Regulatory Authority

The district court erred by allowing state law immunity exceptions to circumvent the federal regulatory authority of the FDA. The FDA's comprehensive regulatory scheme for medical devices is intended to be the final authority on the safety, effectiveness, and labeling of these products. By permitting state law immunity exceptions, the court undermined the federal framework established by Congress, leading to inconsistent and conflicting obligations for manufacturers.

A. Federal Regulatory Authority Preempts State Immunity Exceptions

The Supreme Court has consistently held that federal law preempts state laws that conflict with federal regulatory objectives, particularly in areas where the federal government has established a comprehensive regulatory scheme. In *Cipollone v. Liggett Group, Inc.*, the Supreme Court emphasized that federal preemption extends to state laws that impose additional or different obligations that conflict with federal regulations. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). State law immunity exceptions, such as those that allow for additional

claims or defenses, conflict with the FDA's authority by permitting legal actions that federal law precludes. This creates a direct conflict between state and federal law, warranting preemption.

In the context of medical devices, the FDA's authority is paramount, and any state law that allows exceptions to immunity or liability standards established by federal law must be preempted to maintain the uniformity and effectiveness of the federal regulatory scheme. The district court's failure to recognize this undermines the FDA's exclusive role in determining the safety and labeling of medical devices, as well as the scope of liability for manufacturers.

B. Conflict with the FDA's Determination of Safety and Effectiveness

State law immunity exceptions that allow claims not recognized under federal law directly conflict with the FDA's determination of the safety and effectiveness of medical devices. In *Wyeth v. Levine*, the Supreme Court held that state law claims are preempted when they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Wyeth v. Levine*, 555 U.S. 555, 563 (2009). Allowing state law immunity exceptions to create additional avenues for liability imposes burdens on manufacturers that are inconsistent with the FDA's determinations and regulatory decisions.

For example, if the FDA has approved a medical device with specific warnings and labels, a state law immunity exception that allows for claims based on the absence of additional warnings effectively second-guesses the FDA's judgment. This undermines the FDA's role as the sole arbiter of what constitutes adequate safety measures for medical devices and creates conflicting obligations for manufacturers.

Additionally, the court in *Kemp* correctly interpreted Congress's intent to promote and encourage the development of medical devices. Even if these devices have the potential to be harmful, they are created in good faith to advance health. The MDA supports this goal by

allowing and encouraging manufacturers to develop new medical devices without the risk of tort litigation.

The court reasoned that "if manufacturers knew that their umbrellas would be snatched from them whenever it began to rain, then they would have no incentive to take the risk and venture outside." *Kemp v. Pfizer, Inc*., 835 F. Supp. 1015, 1023 (E.D. Mich. 1993).

Consistent with the reasoning in *Kemp*, Mednology entered the field to address a health condition affecting over 30 million individuals (approximately the population of Texas). We face a significant need to address the consequences of sleep apnea, and, as in *Kemp*, Mednology sought to tackle this serious health concern through innovative measures. The risks and effectiveness of these measures should not be subject to state laws but should instead be regulated by the federal agency designated for this purpose, as established by the Constitution, and implemented through federal processes created by Congress under the FDCA.

C. Undermining Uniformity in the Regulation of Medical Devices

The FDA's regulatory scheme is designed to provide uniformity in the regulation of medical devices across all states. State law immunity exceptions disrupt this uniformity by creating inconsistent standards that vary from one jurisdiction to another. In *Riegel v. Medtronic, Inc.*, the Supreme Court emphasized that the purpose of the FDA's premarket approval process is to ensure that medical devices meet consistent safety and effectiveness standards nationwide. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). Allowing state law immunity exceptions would result in a patchwork of regulations that conflicts with the FDA's goal of uniform national standards for medical devices.

The district court's decision to permit state law immunity exceptions circumvents the FDA's authority, leading to inconsistent regulatory standards that jeopardize the uniformity of medical

device regulation. This not only undermines the FDA's role but also exposes manufacturers to varying levels of liability depending on the state in which they operate, which is precisely what the federal regulatory scheme seeks to avoid.

The district court improperly allowed state law immunity exceptions to circumvent federal regulatory authority, thereby undermining the FDA's comprehensive regulatory framework. The FDA's determinations regarding the safety, effectiveness, and labeling of medical devices are intended to be uniform and nationwide. Allowing state law immunity exceptions to override these determinations conflicts with established Supreme Court precedents and the objectives of the FDA's regulatory scheme. The court's decision should be reversed to uphold the primacy of federal regulatory authority in this area.

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

Under the FCA, the relator is unable to rely on the fraud -on the FDA theory against a medical device manufacturer when the alleged material evidence can insufficiently be linked to causation from the actions of Mednology.

Under the fraud-on-the- FDA theory, False Claims Act may impose liability on any person who knowingly submits or conspires to submit a "false or fraudulent claim for payment" to the government or makes "a false record or statement material to" such a claim. 31 U.S.C. § 3729(1)(A)–(C). Thus, to bring this claim under the FCA, a plaintiff must allege: "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing, (4) the government to pay out money or forfeit moneys due." United *States ex rel. Campie v. Gilead Scis., Inc*., 862 F.3d 890, 899 (Ninth Cir. 2017). It is authorized to impose civil penalties on any person who "knowingly presents, or causes to be presented, a false or

fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A); *see* S. Rep. No. 99-345, at 2 (1986). To advance this policy, the FCA authorizes private citizens to initiate qui tam actions as "relators" on behalf of the government. See 31 U.S.C. § 3730(b). The details of the case are kept private initially to give the government a chance to decide whether to take on the case or let the whistleblower pursue it on the government's behalf. *See id*. at § 3730(b)(2).

Past court decisions disagree on whether the type of facts alleged are necessary enough to support materiality, and thereby conditions that may be "false or fraudulent" under FCA. *Compare D'Agostino v. ev3, Inc., 845 F.3d 1 (First Cir. 2016)* (holding 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) with *United States ex rel. Campie v. Gilead Scis.,* 862 F.3d 890 (Ninth 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). While all federal fraud complaints must be detailed and specific in their allegations, this Court has adopted a perspective of accepting conclusionary allegations to support material evidence, or inconsistent claims of materiality when the "Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," or "Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position*". Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 195 (2016).

A. When state law claims of Fraud on the FDA are preempted by the FDA's authority, Congressional authority is protected to secure FDA regulation and the safety of medical devices.

Congress was clear in siding with FDA in authorizing an express pre-emption provision in the MDA. which allows FDA to preempt state law. Medical Device Amendments (MDA), 21 U.S.C.S. § 360e(b)(1)(A). Moreover, if the relator argues that an alternative method should be applied contrary to the established pre-emption provision, that argument is bound to fails because a clear preemption rule nor an exception bar the normal rules for managing conflict between laws. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). And if there is any doubt in Congress' intention, the only agency that has authority to answer is the FDA authority given to it by Congress. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019). These cases suggest that adding reluctance to the supreme decision maker, the FDA, was never the intent of Congress, stamping the FDA to override state law as it pertains to FDA regulation.

B. Mednology's conduct of fraudulently completing a requirement for receiving payment is absent because the FDA allows for minor modification of device post approval.

The FDA holds an open policy to interpreting the significance of device modification, where insignificant changes do not require a new 510(k) application. *Kapps v. Biosense Webster, Inc*., 813 F. Supp. 2d 1128, *quoting* C.F.R. § 807.81(a)(3)(i). Determining whether changes are insignificant depend on whether modifications to a device raise new issues of safety and effectiveness. *Gross v. Gynecare*, (Super. Ct. App. Div. Mar. 29, 2016). Lastly, that claim exclusively resides within the FDA's jurisdiction. *Catheter Connections, Inc. v. Ivera Med. Corp* (D. Utah July 17, 2014). Once again, these cases suggests that the FDA determines which types of modifications are considered insignificant-- not fraudulent-- based in its interpretation of the extent of device modifications. *Id.* Moreover, liability isn't automatically imposed, even when a clearly established payment requirement is violated without disclosure. *Kapps v. Biosense*

Webster, Inc., 813 F. Supp. 2d 1128, 1138. Thus, strongly weighed liability in combination with insignificant device modifications is insufficient to demonstrating requirement for receiving payment.

The FDA is unlikely to consider changes to Sleepternity significant, consequently inadequate to receiving payment. Whether changes to a device are impactful depends on if the device is made to be less safe or less effective. *Gross v. Gynecare,* (Super. Ct. App. Div. Mar. 29, 2016). In *Gross*, Ethicon demonstrated by published material and proven clinical trials health dangers the vaginal mesh-imposed post 510(k) clearance. The jury found *Gynecore* liable for failing to warn and fraudulent misrepresentation claims. By contrast, Mednology does not assert that any evidence that a change to PE-PUR results in harmful risks, nor had published any materials to assert otherwise. It is only after Ortega served Mednology with her complaint that Mednology made the responsible decision to voluntarily recall Sleepternity from the market. Mednology was believed to have become aware of potential public health risks only the complaint was served. This leaves no doubt that Mednology made device modifications while considering the potential health risks to the public. Due to the changes made by Mednology to reduce manufacturing costs, unaware of known bodily injury or risk, and without any evidence demonstrating its awareness of such changes prior to Philips' recall, it would be costlier to make modifications only to recall them later. Considering the actions Mednology took to mitigate potential risks, it's clear that building public confidence outweighed more expensive decisions to recall it's products. Thus, it's unlikely Ortega will be able to show Mednology violated an absolute requirement to notify the FDA to make changes post FDA approval.

C. Mednology's absence of modification disclosure to the FDA is unlikely to trigger liability when the evidence is regarded as speculative.

Mednology is likely to avoid liability as the primary evidence is based on the opinion not of the plaintiff. According to *Kapps*, the expert testimony was regarded as "overly speculative" and connected to "existing data only by *ipse dixit* of the expert." *Id* at 1146. (quoting *" Gen. Elec. Co. v. Joiner*, 522 U.S. 136). The expert testimony was inadequate in establishing any causal connection between the exterior glue smear on the device and the device failure. *Id* at 1153. Similar to the events in Mednology, Ortega relied on the opinion of an assembly manager who claims the replacement with PE-PUR foams played a contributing factor the asthma attacks she suffered from. Taken from the experience or day to day responsibilities of an assembly worker, it is uncommon for one to be privy to financial executive decisions, more than likely executed by the board of directors. With lacking evidence, based primarily on the statement of this assembly worker, liability fails automatic initiation.

D. The material element is not satisfied and insufficient to meet the possibility of causation required for connecting possible misrepresentations to the FDA.

Ortega is unable to prove fraud on behalf of Mednology when she fails to indicate specific instances. Furthermore, relators have a higher obligation to prove within their allegations of fraud. Under Rule 9(b), "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed.R.Civ.Proc. 9(b). Conclusory allegations are insufficient, and the facts constituting the fraud must be alleged with specificity. *Moore v. Kayport Package Exp., Inc.,* 885 F.2d 531, 540 (Ninth Cir. 1989). Here, the relator merely alleges fraud absent specific details pertinent to the act of fraud.

Ortega's assertions are conclusory and fail to point out specific fraudulent statements or actions by Mednology. Seen in *Wool,* the plaintiff failed to specify detailed conduct that led to the allegation of inflating the market price of securities. *Id* at 541. Here the complaint did not

disclose key details of which plaintiff made purchases through the stockbroker, or the securities that were allegedly purchased. *Id*. Such allegations were deemed conclusory resulting in the claims being dismissed. As compared to Mednology, Ortega based her claims on unsubstantiated testimony from an assembly worker, assumingly not central to making boardroom decisions. The testimony failed to account for detailed time and dates, nor persons linked to the decision to replace with PE-PUR. Moreover, omitting particular information from the exaggerated claims clarifying why Philips Respironics recalled certain CPAP machines is requisite to establishing particularity, which was not attached. For example, Ortega did not disclose key information that would take her claim form hearsay to hard evidence, which requires a timeline from when the defendant may have learned of the health risks, meeting to address steps moving forward, executive personnel whom influenced the decision, or even evidence of a memo that agrees to the terms that the decision to modify Sleepternity was far more than a financial one. Therefore, with insufficient particularity to satisfy causation of misrepresentation, the material element was not met.

E. Government's decision to withdraw payment upon discovering alleged fraud is not influential because the evidence is immaterial.

Under the False Claims Act defendants can be held liable for failing to comply with regulatory conditions at the time it submits a claim for payment. 31 U.S.C.S. § 3729. Those claims may hold the defendant liable under two conditions: First, the claim may not simply a request for payment, but it also includes detailed assertions about products and services rendered. Additionally, the defendant's failure to disclose noncompliance with regulatory requirements must" make[] those representations misleading half-truths". *United States ex rel. Campie v.*

Gilead Scis., 862 F.3d 890, 901. The cases below will illustrate the Court's interpretation of the facts presented that measure up to violations of the FCA.

A former interpretation of materiality would be met if the FDA withdraws approval post compliance violation. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 10. For example, a relator accused the defendant of off label use to treat a blood clot in the brain as well as performing surgery absent adequate training. Ultimately, the FDA "cautiously" approved the drug contingent upon adherence to the doctor's training requirements. *Id* at 4. And with the demanding standard of materiality imposed, the relator argues that the fraudulent representation to the FDA panel, played small role in influencing FDA approval. However, since the FDA made no changes to its payment processing, going so far as processing reimbursement, the Court interpreted the FDA's inaction as insufficient materiality. Here to establish materiality, the causal link between the relator's fraudulent FDA representations and claims for reimbursements would need to be substantiated by clear FDA disapproval .*Id* at 7 As the foremost authority in FCA, if the FDA were to act in opposition to the device manufacturer's noncompliance, then it would provide that a one or more events directly lead to another, further proving liability. *Id*. It's highly likely that the Court would find in favor of the relator had the FDA insisted on ceasing with payment reimbursement, further demonstrating how the Courts should address comparable cases. *Id* Thus, the Court held that materiality failed to be satisfied. *Id.*

Ortega's is unlikely to demonstrate materiality when causation is insufficient. In this case, the original complaint brought by Ortega includes weak allegations: the Philips recall and her recent asthma attack were caused by modification of Sleepternity. Fortunately, the First circuit adhered to the high standard of materiality that is commanded by looking to the actions of the FDA after learning of the approved device's recent change. Like in *D'Agostino*, the FDA

took no action ill against Mednology. Post recall of Sleepternity, the FDA held its own internal investigation into Mednology's alleged fraudulent conduct, but it failed to penalize the device manufacturer. Here we saw an alignment of Mednology with its authoritative agency, the FDA. Furthermore, the lack of communication we saw in *D'gostino* with the FDA is not mirrored in our case. In order for the FDA to cease an investigation it would require clear communication with its agents in meeting safe product goals. In *D'gostino* the FDA did not provide full approval of its device, whereas I had with Sleepternity. Because the FDA's approval was absent contingencies or "caution" it is assumed it had the full support of the FDA to prerogatively make changes as it was confident in the health benefits the devices posed to the public. With this high level of support, it's quite possible to believe the FDA did not impose such conditions as there was minimal concern that significant modifications would transpire absent FDA notification. As a matter of fact, the FDA confidence in the safety of Mednology's device was restored when the investigation was closed without severe civil penalties imposed. As a result, it's presumed that under this investigation, it found that any potential risks were averted, holding the Mednology is in fact working to protect the public by ensuring products meet tough regulatory standards. Here, Mednology's conduct failed to cause the FDA to make a payment or forfeit monies owed for each modified Sleepternity device. The First Circuit did not err in holding that Ortega failed to establish causation element of her FCA claim.

On the other hand, materiality may be satisfied when the relator exceeds the possibility of assertion, however, contend that the government is cognizant of the violations, thereby refusing payment. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 907 (Ninth Cir. 2017). *In Campie,* the proof for materiality diminished from clear evidence to mere assertions. Relators allege that Gilead made false statements regarding test results, altered inventory codes, including

mislabeling tracking information. *Id.* We find that these allegations conform precisely with the partial truths rule, thereby deemed actionable misrepresentations to the FCA. *Id* at 904. In light of this, the government continued to pay the claim in full after learning of the FDA violations, nor did it withdraw drug approval. Common belief holds that if the FDA does not act, then FDA does not consider the violation to be material, which is necessary for satisfying the FCA. *Id*. With the Court stretching the margins to the definitions of materiality, it further inserts itself into the domain of the FDA. *Id.* Here the Court held materiality to be satisfied despite the FDA not suspending payment after learning of noncompliance. *Id*.

In contrast to the Ninth Circuits holding, Mednology was not seen to purposefully harming the lives of the public. In *Campie*, we observe outright negligence by individuals held to a high standard of ethics. As physicians, principles of honesty and respect is imbued in the reputation to ensure a balance of trust with their patients. Regrettably, physicians were the individuals acting without integrity in complying with to operate on their patients, knowing full well they did not meet the standards to qualify to operate, which dismantles the trust in the quality of care the public deserves. Immediately, a cry of public interest demands reform, that additionally serves as a message to other bad actors involved where they too may be subject to penalties. However, the facts are not similar to our case as Sleepternity was not manufactured for a doctor to install using invasive operation. The extent of doctor facilitation was its mere prescription because the patient is responsible for slipping it over their face before sleep. Dangers side effects that may arise from an invasive brain operation as compared to wearing a CPAP are not comparable. It's clear here the Ninth circuit imposed an unprecedent decision to decrease the support needed to meet the element of materiality because of an additional factor of the physician's egregious involvement which threatens fracture the public trust within the

healthcare system. Yet still we do not see that in our case as it does not demand critical patient care—self monitored. The patient carries the choice of putting on their Sleepternity device and removing it as they so wish, nor is it a life saving measure. Ortega had and made the choice of choosing to wear the device and when to stop wearing it. At no time was she required to have surgery to install or remove; at no time did she require post-surgical care; and there are no accounts of her having a hospital stay due to her use. Thus, the Ninth Circuit imposing an incredibly harsh penalty leaves no room for manufacturers to efficiently work within the domains of FDA authority when circumstantial evidence of plausibility is used to satisfy material evidence. A more prudent strategy to include a public interest condition that must be met in order to broaden the scope of material evidence would prove advantageous. As a result, the Ninth Circuit erred in accepting factual disputes as support for material evidence, as opposed to aligning itself with FDA payment response.

Finally, the Courts settle the interpretation of materiality by distinguishing a condition of payment with clear violations of state licensing requirements. The plain language of the False Claims Act underscores the importance of obligatory conditions by establishing it as a duty for a "licensor-licensee relationship." 31 U.S.C.S. § 3729(b)(3). In *Universal,* the defendant was obligated to maintain strict staff licenses for supervisory positions, however, unbeknownst to the state Medicaid program, unlicensed and unsupervised staff claims were billed. In doing so, *Escobar*, made false misrepresentations triggering liability. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 185. It was shown that the primary goal in highlighting violation of the state regulation was to point out the significance of a "clearly imposed condition of payment", further providing a causal connection to satisfying the element of materiality. *Id* at 186. Even though the substance of what is considered material evidence may be open to

interpretation, this case demonstrates that provable violations against state statutes prove to be a contributing factor. *Id*. The Supreme Court held regulation compliance as a material condition of payment. *Id.*

Mednology was not bound by state licensing requirements to be subject to state violations of regulation. Unlike in *Universal,* Mednology operated under the umbrella of federal regulation, not state for production of Sleepternity. Nor was it required to employ certain kinds of staff to supervise its administration over patients. In our case, the physicians carried the responsibility of prescribing the Sleepternity device to its patients under their care, not Mednology's care. Moreover, removing patient care responsibility should reduce the manufacturers liability in these matters, but in light of the recent decision by *Campie*, the evidence needed to rise to materiality backs device manufactures in a corner. Again, we see, individuals in a position of power over stretching their authority as they administer drugs absent the necessary state license. We can disregard this in our case as there are no purported claims that Mednology's physicians were ever unlicensed. *Esobar* suggests that Mednology could possibly be liable for not fulfilling requirements, which by no way within its statutory duty to duty to abide by. With the Ninth Circuit finding that, it in some way forces device companies to scrutinize the day-to-day operations of its providers, potentially violating business practices of its partners would be on the rise. As a result, the material element should not be met as Mednology did not violate any state regulation required for the FDA to make payments

CONCLUSION

For the foregoing reasons, Mednology, Inc. respectfully requests that this Court reverse the district court's decision denying Mednology's motion to dismiss Riley Ortega's state law claims. The appeals court erred in holding that the exceptions to the immunity statute under

Transylvania law were not preempted by the Federal Food, Drug, and Cosmetic Act (FDCA). The FDCA preempts state law claims that conflict with federal regulatory authority, and the district court failed to appropriately apply the principles of federal preemption as established by the Supreme Court.

Furthermore, in consideration of the preceding points, if this Court were to adopt the plausibility condition to establish a causal connection to materiality, Ortega's ability to demonstrate that Mednology violated the FCA would be greatly diminished. As the cases discussed below strongly, suggest that lower courts altered the sufficiency of the materiality element in response to the egregious conduct of providers not employed by Mednology. It is possible that there was a public outcry for providers to adhere to the ethical standards relied upon by their patients, resulting in an irreparable fracture. The imposition of the responsibility of meeting state licensing requirements that were neglected by the providers onto Mednology is fundamentally unfair. Consequently, despite the newer standard of materiality adopted by this Court, Ortega's claims are unable to satisfy it, and the appeals court erred in dismissing Mednology's motion to dismiss.

This Court should REVERSE the Seventeenth Circuit Court of Appeals judgment in all respects.

Respectfully Submitted,

ATTORNEYS FOR PETITIONER