NO. 24-9176

IN THE

Supreme Court of the United States

NOVEMBER TERM 2024

MEDNOLOGY, INC.,

Petitioner,

— versus —

UNITED STATES EX REL. Riley ORTEGA,

Respondent.

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

BRIEF FOR PETITIONER

TEAM 3314
Attorneys for Petitioner

QUESTIONS PRESENTED

I. Whether federal law preempts Transylvania's product liability immunity exception where the state law overwhelmingly conflicts with the operation of federal law and the relator relies solely on a theory of fraudulent conduct towards the FDA, thus prohibiting Riley from bringing such a claim against Mednology.

II. Whether Riley's failure to adequately plead a material and causal link between Mednology's conduct, FDA approval, and the Centers for Medicare and Medicaid Services' payment decisions necessitates dismissal at the pleading stage of her False Claims Act, on the grounds that her reliance on a fraud-on-the-FDA theory is legally insufficient.

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United States Supreme Court Cases:

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United States Circuit Court of Appeals Cases:

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Lofton v. McNeil Consumer & Specialty Pharms.,
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United States ex rel. Campie v. Gilead Scis.,
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United States ex rel. Cimino v. Int'l Bus. Machines Corp,
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United States ex rel. Foreman v. *AECOM,*
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United States ex rel. Hendow v. Univ. of Phoenix,
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United States ex rel. Main v. Oakland City Univ.,
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United States ex rel. Nargol v. DePuy Orthopaedics, Inc.,
865 F.3d 29 (1st Cir.

United States ex rel. Petratos v. Genentech Inc.,
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United States ex rel. Rostholder v. Omnicare, Inc.,
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United States ex rel. Wilkins v. United Health Group, Inc.,
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United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,
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United States v. Luce,
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United States District Court Cases

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The unreported opinion of the United States District Court for the Southern District of Transylvania, *In Re United States Ex rel. Riley Ortega, United States Ex rel. Riley Ortega v. Mednology, Inc.*, Case No. 24-cv-12121 (Oct. 12, 2023), is contained in the Record of Appeal at pages 1-24. The district court DENIED and GRANTED in part the Petitioner's motion to dismiss. The unreported Opinion of the United States Court of Appeals for the Seventeenth Circuit, *In re United States Ex rel. Riley Ortega, United States Ex rel. Riley Ortega v. Mednology, Inc.*, Case No. 24-100 (Apr. 1, 2001), is contained in the Record of Appeal at pages 25-42. The appellate court AFFIRMED and REVERSED the district court's decision in part.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the following provisions of the United States Code: 21 U.S.C. §§ 301–399i; 31 U.S.C. §§ 3729–3733, and 42 U.S.C. § 1395y(a)(1)(A). Also relevant to this case are the following Statutes under the State of Transylvania: 21 Trans. Comp. Stat. § 630.545 and § 630.546 (a-c). Additionally, this case involves Art. VI cl. 2 under the United States Constitution.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case concerns Mednology, Inc.'s (Petitioner) motion to dismiss Riley Ortega's (Respondent) state claims under the State of Transylvania's product liability statute and The Federal False Claims Act (FCA). R. at 3. Mednology manufactures medical devices, and Riley is a recently retired military officer. R. at 3.

The FDA approves Sleepternity. In 2022, Mednology manufactured a continued positive airway pressure (CPAP) machine called Sleepternity to help users who suffer from sleep apnea and insomnia. R. at 3. Sleepternity offers a range of unique features that traditional CPAP machines do not, including a smartphone app, an automatic pressure adjustment system, a heated mask humidifier, and noise-canceling headphones attached to the mask. R. at. 3. In addition to helping users reduce sleep apnea, these revolutionary features aid in reducing insomnia. R. at 3. Sleepternity was granted FDA approval on December 30, 2022, for marketing as a Class III medical device. R. at 3-4. Thereafter, the Centers for Medicare and Medicaid Services (CMS) authorized coverage for the costs of using Sleepternity. R. at 4.

Mednology Modifies Sleepternity. Approval for Sleepternity was granted when the device utilized a silicone-based sound-dampening foam to reduce user noise and vibration. R. at 4. However, to reduce manufacturing costs before packaging and distributing the device, Mednology modified Sleepternity. Mednology replaced the device's silicone-based foam with a more cost-effective polyester-based polyurethane (PE-PUR) foam, without disclosing this modification to the FDA. R. at 4. PE-PUR foam may deteriorate over time and once broken down, may release invisible volatile organic compounds (VOCs) that CPAP users may ingest or inhale. R. at 4. In recent years, a medical device manufacturer, Phillip Respironics (Phillips), recalled CPAP machines containing PE-PUR foam and replaced the polyurethane-based foam with silicone-based foam.

Mednology's Voluntary Recall in Response to Riley's Device Use. To address sleep apnea and insomnia related to post-traumatic stress disorder, Riley's somnologist prescribed her Sleepternity R. at 3. Riley is allergic to isocyanate, a VOC resulting from degraded polyurethane. R. at 5. Riley was aware of this allergy the entire time she used Sleepternity. R. at 5. Soon after using Sleepternity, Riley began experiencing asthma attacks, resulting in hospitalization, at which point her primary care physician advised discontinuing the use of the device. R. at 4. Sleepternity's warning label did not contain information about the presence of isocyanates. R. at 5. Riley did not consider that her isocyanate allergy caused her asthma attacks but still concluded that Sleepternity was incompatible with treating her condition. R. at 5. It was only after her brother, Jim, an assembly manager at Mednology, informed her that Sleepternity now contained PE-PUR foam that Riley considered that the device may have triggered her asthma attacks. R. at 5.

After further research, Riley determined that the breakdown of Sleepternity's PE-PUR foam into certain forms of isocyanate likely caused her asthma attacks. R. at 5. Riley's asthma symptoms subsided when she discontinued her use of Sleepternity to treat her sleep apnea. R. at 5. Yet, her symptoms have returned despite her use of myriad medications. R. at 5. Even so, Riley continues to use the Sleepternity headband to treat her insomnia. R. at 5.

In response to Riley's concerns, Mednology proactively initiated a voluntary recall of Sleepternity from the market. R. at 7. The FDA, recognizing Mednology's immediate action, declined to continue investigating the company's conduct. R. at 7.

Instead, the FDA has focused on other alleged defective products that have not been recalled and may pose a more immediate threat to public health. R. at 7.

II. NATURE OF PROCEEDINGS

The District Court. Riley brought a product liability claim against Mednology alleging fraudulent conduct to the FDA for its production of Sleepternity. R. at 6. Riley filed a complaint in the Southern District of Transylvania. R. at 2. In response, Mednology moved to dismiss Riley's state law claims alongside her claim under the *qui tam* provision of the FCA. R. at 6. The United States federal government declined to intervene in Riley's FCA action. R. at 2. The court denied the motion to dismiss Riley's state law claims, holding that federal law does not preempt any provisions that would neutralize Mednology's immunity under the State of Transylvania's immunity statute. R. at 2. However, the court granted the motion to dismiss Riley's claims under the FCA because she did not provide a viable basis for bringing the claim. R. at 19.

The Seventeenth Circuit Court of Appeals. The circuit court affirmed the district court's denial of Mednology's motion to dismiss Riley's state law claims, although on different grounds than the district court. R. at 25. The court held that the FDCA preempts both immunity exceptions of Transylvania's immunity statute. However, because Riley alleged sufficient facts to rebut the compliance issues, the motion should still be denied. R. at 26. Additionally, the court reversed the district court's granting of Mednology's motion to dismiss Riley's FCA claim, finding that she

alleged sufficient facts to plausibly satisfy the materiality element of her FCA claim. R. at 38.

SUMMARY OF THE ARGUMENT

This Court should reverse the Holding of the Seventeenth Circuit Court of Appeals. The appellate court erred when it affirmed the denial of Mednology's motion to dismiss despite conceding that federal law preempts subsection (b) and (c) of Transylvania's product liability statute. Additionally, the court improperly held that a relator may rely on the fraud-on-the-FDA theory to bring a False Claims Act where that relator has failed to allege essential elements of the claim. Moreover, the motion to dismiss should be granted because Riley has not pled sufficient facts to survive a Rule 12(b)(6) motion to dismiss.

I.

The appellate court improperly affirmed the denial of Mednology's motion to dismiss despite finding that subsection (b) and (c) of Transylvania's product liability statute are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA). As the appellate court recognizes, the state law is impliedly preempted by federal law. However, subsection (a) of the statute is also preempted by federal law and elicits the same preemption concerns as subsection (b) and (c). Thus, the motion to dismiss should be granted.

First, the relationship between the FDA and Mednology is inherently federal. Particularly, the federal regulatory framework governing the FDA's oversight of Mednology precludes state courts from intervening in matters concerning fraud-on-

the-FDA claims. These issues are typically within the exclusive purview of their respective federal agencies. Thus, the presumption against preemption doctrine cannot be applied to Mednology.

Additionally, subsections (b) and (c) are impliedly preempted because Riley's claims are based on alleged fraudulent conduct towards the FDA rather than an independent finding of fraud by the agency itself. This type of policing would undermine the uniformity and authority of the federal regulatory scheme. Although Riley asserts that she is using these claims to neutralize Mednology's immunity, her claims are solely based on a theory of fraud-on-the-FDA, which are impliedly preempted. Further, subsection (a) is also impliedly preempted because Riley has not pled sufficient facts to rebut noncompliance on Mednology's part, nor has the FDA found a compliance violation. Thus, each section of the immunity clause is preempted by federal law.

Moreover, there are significant policy concerns regarding the disruption of the FDA's regulatory authority if the state courts were given the authority to intervene in matters traditionally governed by federal agencies. This type of inter-branch meddling should not be encouraged as it could potentially erode the FDA's authority and expertise, increase litigation in state courts, and create uncertainty in the FDA's ability to serve its purpose as a regulating entity and safeguard public health. Finally, notwithstanding these issues, Riley fails to state a plausible claim and has not pled sufficient facts to survive a Rule 12(b)(6) motion to dismiss. Therefore, this Court

should reverse the appellate court's decision and grant Mednology's motion to dismiss Riley's state law claim.

II.

The United States District Court for the Southern District of Transylvania properly granted Mednology's motion to dismiss Riley's FCA claim, finding that she failed to sufficiently allege that Mednology's alleged misconduct caused CMS to make payments it otherwise would not have. To survive Mednology's Rule 12(b)(6) motion to dismiss, Riley must sufficiently plead all four elements of her FCA claim, but she has failed to do so concerning the elements of materiality and causation. Riley's inability to meet the pleading standards outlined in *Twombly* and *Iqbal* necessitates dismissing her claim.

Under the FCA, materiality and causation are related but distinct elements, each requiring separate analysis under their respective standards. Riley and the appellate court improperly conflate these elements and assume that establishing materiality automatically satisfies causation. This misstep led to an incomplete assessment of causation, which is essential to establishing materiality.

A proper causation analysis reveals that Riley has not demonstrated a causal link between Mednology's conduct and CMS payments for two key reasons. First, Riley's allegations overstate CMS's reliance on FDA approval, as CMS payment is not predicated solely on the agency's approval. Second, the FDA has not withdrawn Sleepternity's premarket approval. When a regulatory agency with substantial

enforcement authority chooses not to respond to allegations of fraud, it strongly suggests that FDA approval was not fraudulently obtained.

Similarly, a proper materiality analysis reveals that Riley has not alleged that CMS denied or revoked payments in response to Mednology's voluntary recall. When the government continues paying claims despite knowledge of alleged violations of payment conditions, this serves as compelling evidence that the requirement in question was not material. The appellate court's reliance on *Campie* adopts a watered-down materiality standard that directly contradicts this Court's precedent in *Escobar*. The court erroneously concluded that because the FDA *could* have denied Sleepterinty's approval, CMS *could* have withheld payments—an approach that falls short of the requirement to plead more than speculative inferences to establish materiality. The court further erred in treating materiality as a matter of proof rather than a legal question to be resolved at the pleading stage. This approach allowed Riley to shirk her obligation to plead materiality with particularity under Rule 9(b).

Finally, the FCA is an inappropriate vehicle for addressing Mednology's alleged misconduct. Using the FCA in this context undermines the FDA's regulatory role and transforms the statute into a tool for second-guessing agency decisions. Furthermore, it risks flooding the courts with unsubstantiated FCA claims better suited for the FDA's enforcement authority.

STANDARD OF REVIEW

This appeal raises two questions of law. On appeal, questions of law are reviewed *de novo*. *In re Irving Tanning Co.*, 496 B.R. 644 (B.A.P. 1st Cir. 2013).

Federal preemption issues and claims asserted under the FCA are reviewed *de novo*. *See Bower v. Egyptair Airlines Co.*, 731 F.3d 85, 92 (1st Cir. 2013); *see also United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017). Furthermore, whether a claim should be dismissed under Rule 12(b)(6) for failure to state a claim is a legal question that warrants *de novo* review. *Calogero v. Shows, Cali & Walsh, L.L.P.*, 970 F.3d 576, 580 (5th Cir. 2020).

ARGUMENT

I. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (FDCA) IMPLIEDLY PREEMPTS THE IMMUNITY EXCEPTIONS TO TRANSYLVANIA'S PRODUCT LIABILITY STATUTE BECAUSE THE STATUTE CONFLICTS WITH THE FEDERAL REGULATORY FRAMEWORK

Transylvania's product liability statute conflicts with and is, therefore, impliedly preempted by federal law because of the federal regulatory nature of the relationship between the FDA and Mednology. The appellate court correctly held that the FDCA preempts the immunity exception provided within subsections (b) and (c) of Transylvania's product liability statute. Although the appellate court affirmed the denial of Mednology's motion to dismiss, the decision was based on grounds different from those of the district court. There are three primary issues concerning preemption before this Court: (1) the inapplicability of presumption against preemption in this case, (2) the conflict between the operation of state and federal law, preempting subsection (b) and (c), and (3) federal preemption of subsection (a), the noncompliance portion of the immunity exception.

A. The Appellate Court Properly Recognized the FDA's Relationship with Mednology as Inherently Federal, Thus Deciding That the Presumption Against Preemption to Transylvania's Immunity Statute Does Not Apply.

The Supreme Court has refused to find federal preemption of state law when there is either an absence of a clear statutory provision or a direct conflict between federal and state law. *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504 (1988). This is because "states are independent sovereigns in our federal system." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). In fact, "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).

The Court has also clarified that federal law preempts state law when the interests involved are so "uniquely federal." *Boyle v. United Technologies Corp.*, 487 U.S. at 504. Combined with establishing a conflict between "federal policy or interest and the [operation] of state law," *Id.* at 507 (quoting *U.S. v. Kimbell Foods, Inc.,* 440 U.S. 715 at 728 (1979)), establishing an area of "uniquely federal" interest is sufficient to preempt state law. *Id.* at 507. Applying this framework to federal agencies, the Court in *Buckman* explained that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship from, is governed by, and terminated according to federal law." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347 (2001).

The relationship between Mednology and the FDA is like that in *Buckman*. In *Buckman*, the FDA regulated a corporation that manufactured medical equipment,

such that they regulated how the corporation would obtain approval for marketing their equipment. *See Id.* at 343-44. The Court reasoned that this relationship was "uniquely federal" because a corporation is governed by federal law. *Id.* at 347. In the same way, Mednology is regulated by the FDA, thus making their relationship and interests "uniquely federal." *See Id.* It is a common truth that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347. *See also Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 93 (2d Cir. 2006) (accepting this statement by the *Buckman* Court as "undoubtedly true").

The Supreme Court in *Buckman* overrides the presumption because of the conflict between federal law and competing state regulations. *See Buckman,* 531 U.S. at 351. Despite the Supreme Court's ruling, the district court uses *Desanio* to guide its analysis of this issue. *See Desanio*, 467 F. 3d at 85. In *Desanio*, the court differentiates their plaintiff's cause of action from the one in *Buckam*, stating that within their case, the cause of action "cannot reasonably be characterized as states attempt to police fraud against the FDA." *Desanio*, 467 F. 3d at 85. Though this may be true in *Desanio*, it is not applicable in this case. Here, the avenue through which Riley can successfully assert her state law claims of fraud-on-the-FDA directly deprives the FDA of their inherent right to investigate fraud through their procedures, thus policing fraud against the federal agency. Therefore, the presumption against preemption in this case does not apply.

B. Subsection (b) and (c) of Transylvania's Immunity Statute are Impliedly Preempted because Riley's Claim is Based on a State Court Finding of Fraud on the FDA and is Based Solely on Violations of FDA Requirements.

The Constitution's Supremacy Clause provides the foundation for the doctrine of federal preemptions, where it iterates that federal law is "the supreme law of the land." *See* U.S. Const. art. VI, cl. 2. This indicates that federal law will prevail when federal and state law conflict. *New Jersey Thoroughbred Horsemen's Association v. National Collegiate Athletic Association*, 584 U.S. 453, 471 (2018). Even so, the Court has noted that in "analyzing implied preemption, a court must begin with the assumption that a state law is valid and should be reluctant to resort to the Supremacy Clause." *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965 (6th Cir. 2004).

There are two types of federal preemption: (1) express or (2) implied. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). In the absence of explicit pre-emptive language (express preemption), an implied preemption may surface where the (1) "federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)), or (2) where "state law stands as an obstacle to the accomplishments and execution of the full purposes and objectives of Congress." *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

The Supreme Court has clarified that their ultimate task in any preemption case is to "determine whether state regulation is consistent with the structure and purpose of the statute as a whole"; to do this, they look at the law and its object and

policy. *Id.* Under express preemption, state law is only preempted if its requirements do not absolutely parallel the federal requirements, such that they do not add or differ from any federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). However, a state law that interferes with federal law, such as a law that conflicts with the FDA's authority, is impliedly preempted. *Buckman*, 531 U.S. at 347. Taken together, "*Riegel* and *Buckman* create a narrow gap" through which a state claim must fit if it is to escape preemption." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). For a state claim to survive preemption, "the plaintiff must be suing for conduct that *violates* the FDCA; but must not be suing *because* the conduct violates the FDCA." *Id.* Looking towards congressional intent, the Court in *Buckman* states that "the FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions" of federal law. *Buckman*, 531 U.S. at 349 n.4. Specifically, within the context of the FDA, the agency is "empowered to investigate suspected fraud and citizens may report wrongdoings and petition the agency to take action." *Id.*

1. Riley's state law claims fall under the purview of the FDA, thus conflicting with the FDA's administrative and regulatory roles.

The appellate court correctly used the Sixth Circuit's decision in *Garcia* to guide their analysis. The circumstances of the present action are more comparable to that case because the *Garcia* court does not apply the presumption against preemption doctrine and deals with an immunity exception like that of Transylvania's. *See Garcia* 385 F.3d at 967. Like the defendant in *Garcia*, Riley's product liability claim is based

on the theory that Mednology fraudulently represented its product to the FDA. As the Court in *Buckman* explains, "State-law-fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objective." *Buckman*, 531 U.S. at 350. Given this, the Sixth Circuit in *Garcia* laid out the context in which immunity exceptions apply. *Garcia,* 385 F. 3d. at 966. The immunity exception is invalid when the plaintiff asks a state court to find bribery or fraud on the FDA, but valid where the claims are based on a finding of fraud by the federal agency itself. Id.

Under this framework, subsection (b) and (c) of Transylvania's immunity statute should be preempted because Riley's claims are not based on the FDA's finding of fraud. Subsection (b) of the immunity statute 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.

21 Trans. Comp. Stat. §630.546(b). There is also an additional exception under subsection (c), which 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). These exceptions do not apply to Mednology because Riley provides no evidence that the FDA has made a finding of fraud on behalf of Mednology at any stage. The FDA ceased its investigation after

Mednology voluntarily recalled Sleepternity from the market. Allowing a state court to re-open an investigation and suggest their own finding of fraud would undermine the FDA's authority and strip them of their exclusive right to regulate entities as they see fit. Transylvania's state law encourages state courts to second-guess the FDA's approval and oversight of medical devices. As the Fifth Circuit in *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) reasoned when they adopted *Garcia*'s approach, "the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." *Id.* at 380. Indeed, the FDA's pre-market approval review process "involves a time-consuming inquiry into the risks and efficacy of each device." *Buckman,* 531 U.S. at 348. Any disruption of this process severely undermines the uniformity the FDA aims to establish through its regulations and set protocols. The fact that there is no evidence suggesting that the FDA has made a finding that Mednology engaged in fraud is a critical component in analyzing federal preemption and should not be ignored.

2. Riley's assertion of state law claims to neutralize Mednology's immunity is not relevant to the issue of federal preemption.

Subsections (b) and (c) of Transylvania's immunity statute were created with the intent to "shield drugmakers or medical device manufacturers from product liability suits as long as the FDA approved the drug or medical device in question." R. at 8. As previously mentioned, Riley asserts common law claims under Transylvania's product liability statute; however, she does so based on fraudulent

representation to the FDA to neutralize Mednology's immunity rather than bring a state-law fraud-on-the-FDA claim. R. at 6. This means Riley is suing because Mednology violated a federal requirement, and this violation strips Mednology of its immunity. The appellate court notes the distinction between Riley's assertion and those made in the *Buckman* case. R. at 28.

However, there is a split among the circuit courts regarding this issue, which is rooted in the decision to apply the presumption against preemption doctrine to Michigan's immunity statute, like Transylvania's immunity statute. The Second Circuit in *Desanio* applies the doctrine, whereas the Sixth Circuit in *Garcia* does not. *See Desanio,* 467 F. 3d at 98; *see Garcia*, 385 F. 3d at 967. Furthermore, the court in *Desanio* utilizes a deficient approach to this issue, opting to conclude that federal preemption of state law claims used to neutralize a drugmaker's immunity "would result in a preemption of a scope that goes far beyond anything that has been applied in the past." *Desanio,* 467 F. 3d at 96. Further, the court reasons that the practical concerns "if deemed controlling, would prove too much." *Id.* at 97. However, where the court in *Desanio* fails to recognize the crucial risks of state law fraud-on-the-FDA claims, the court in *Garcia* captures the importance of these seemingly essential issues.

Thus, it is unsurprising that the appellate court was inclined to follow the Sixth Circuit's framework in *Garcia* to support their analysis because (1) as established, the presumption against preemption does not apply in this case, and (2) the policy concerns in *Garcia* accurately reflect the concerns that arise in this case.

The critical concern is that interfering with the FDA leaves room to dismantle the system. The Third Circuit in *Farina v. Nokia Inc.*, 625 F.3d 97, 126 (3rd Cir. 2010) explains that because agencies "have a unique understanding of the statutes they administer [, they possess] an attendant ability to make informed determinations about how state requirements may pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* Moreover, the court in *Garcia* points out that preemption exceptions are more helpful than harmful, seeing as that it "will not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval"; instead, it will "merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *See Garcia*, 385 F. 3d at 967.

Here, Riley's claims against Mednology, even if they are being used to remove Mednology's immunity, are still based on the company's alleged fraudulent conduct toward the FDA. This Court has made clear in *Buckman* that such claims are preempted by federal law because of an agency's authoritative role over its administration. *See Buckman,* 531 U.S. at 348. Hence, Riley is suing solely based on fraudulent conduct toward the FDA, such that the court in *Garcia* is on point for resolving this issue and adequately supports the conclusion that Riley's claims are still preempted by federal law.

C. Federal Law Preempts Subsection (a) of Transylvania's Product Liability Statute.

The appellate court denied Mednology's motion to dismiss based on their erroneous belief that Riley alleged sufficient facts to plausibly rebut the statutory

presumption that Sleepternity complied with FDA requirements. This decision was wholly incorrect. Not only does Riley plead insufficient facts to rebut noncompliance, but it is essentially irrelevant to the fact that Mednology is immune to this state law claim. Moreover, the policy concerns that arise from denying this motion are significant and a true example of why this type of inter-branch meddling would wreak havoc on the system.

The Sixth Circuit analyzed a noncompliance issue similar to that disputed in this case. *See Marsh v. Genetech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012). In *Marsh*, the court reviewed the compliance part of Michigan's immunity statute, which is quite similar to Transylvania's immunity statute. *Compare Id.* at 550 with 21 Trans. Comp. Stat §630.546(a). The court in *Marsh* held that the defendant was entitled to immunity under the immunity statute because the plaintiff's claims were essentially a fraud-on-the-FDA claim. *Id.* at 555. Oddly enough, the majority in the appellate court disregards this case as a solution for resolving the issue of whether federal law preempts Riley's ability to assert Mednology's non-compliance with FDA approval; they reason that Riley's assertion of non-compliance is based on more substantive grounds than the plaintiff's assertion in *Marsh*. R. at 34. However, as Justice Ruzich emphasized in his dissent, this perspective overlooks the Sixth Circuit's view that the "same preemption concerns would still be triggered" should this motion to dismiss be denied. R. at 41. Riley's claim is still based on a theory of fraud-on-the-FDA, which, according to established precedent in *Buckman* and *Garcia*, is preempted unless

there is an independent finding of fraud by the FDA. *See Buckman,* 531 U.S. at 350; s*ee also Garcia,* at 385 F. 3d. at 967.

The district court and the appellate court failed to consider the repercussions that denying Mednology's motion to dismiss could have on the FDA's authority to regulate within their jurisdiction. This decision would only encourage the inter-branch meddling that *Buckman* and *Garcia* warn against. *Id.* If state courts are given the authority to override federal regulatory law, it could open the floodgates to all types of litigation that state courts have no business dealing with and could lead to a general lack of trust in the FDA's ability to regulate entities and protect public health. Because the FDA is the ultimate expert in their regulatory process, it is not within a state court's realm to determine whether Sleepternity complied with the FDA's approval by the time it left Mednology's control. Since the FDA has not made any conclusions suggesting Mednology's non-compliance, subsection (a) of Transylvania's immunity statute is preempted by federal law. Therefore, Mednology's motion to dismiss should be granted.

D. Riley Fails to Plead Enough Factual Material to Survive a Motion to Dismiss Under Rule 12(b)(6).

The Court should grant Mednology's motion to dismiss because Riley has not pled sufficient factual material under Federal Rules of Civil Procedure 12(b)(6). A Rule 12(b)(6) dismissal "can be based on a lack of cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Campie*, 862 F.3d. at 898 (quoting *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990)). The Supreme Court outlined pleading standards requiring a complaint to include

sufficient factual content that, if accepted as true, states a claim for relief that is plausible on its face. *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009). While a complaint need not contain "detailed factual allegations" to withstand a Rule 12(b)(6) motion to dismiss, it must offer "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Likewise, mere "naked assertions" of wrongdoing are generally insufficient to state a claim for relief. *Id*. at 557.

A plausible claim asks for more than the "sheer possibility that a defendant has acted unlawfully." *Iqbal* 556 U.S. at 678. Therefore, pleading facts that are "merely consistent with" a defendant's liability "stops short of the line between possibility and plausibility of 'entitlement to relief.' *Id.* (quoting *Twombly*, 550 U.S. at 557). Instead, a plaintiff's allegations "must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555.

The appellate court incorrectly determined that Riley "alleged sufficient facts to plausibly rebut the presumption" that Mednology complied with FDA requirements when Sleepternity was distributed and sold to the market. R. at 32. Under Rule 12 (b)(6), a complaint must be dismissed if it does not state a claim on which relief can be granted. Riley has not met this standard. Riley asserts that Mednology breached its duty to disclose to the FDA the modifications it made to Sleepternity, which consisted of changing the silicone-based sound abatement foam in the CPAP machines to PE-PUR. R. at 6. She contends that the FDA would not have

approved this modification had they known it was made. R. at 6. However, Riley bases these allegations on Philips Respironics' decision to voluntarily recall their medical device, which contained PE-PUR. R. at 6. Riley's allegations do not plausibly rebut Mednology's noncompliance because the evidence presented does not indicate that the FDA would not have recalled Sleepternity based on a previous incident from a different medical device company. Additionally, Phillips voluntarily recalled their CPAP machine, such that the FDA did not give any clear indication that any future machine containing PE-PUR would not be approved. R. at 4. Thus, Riley's claims offer nothing more than factual conclusions based on speculation, and she does not plead sufficient facts to meet the standard required to survive a Rule 12(b)(6) motion to dismiss.

II. RILEY MAY NOT RELY ON THE FRAUD-ON-THE-FDA THEORY TO BRING A FALSE CLAIMS ACT (FCA) CLAIM AGAINST MEDNOLOGY.

The district court correctly dismissed Riley's FCA claim. Under Rule 12(b)(6), Riley fails to state a plausible FCA claim. To prevail on an FCA claim under 31 U.S.C. § 3729 et seq., a relator must demonstrate (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due. *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006). In short, the moving party must sufficiently prove: (1) falsity, (2) knowledge, (3) materiality, and (4) causation. *Id.* Riley's claim that Mednology's actions caused CMS to make payments it otherwise would not have is based on assumptions and inferences rather than on the objective

standard outlined *supra*. The elements of causation and materiality, which Riley fails to establish, are particularly relevant to this Court's *de novo* review.

A. Assuming That Falsity and Knowledge Are Adequately Pleaded, Riley's FCA Claim Nonetheless Fails as a Matter of Law Because She Insufficiently Pleads Materiality and Causation.

Mednology does not concede that Riley has adequately pleaded falsity and knowledge. However, even if the Court assumes *arguendo* that these elements are satisfied, Riley still fails to set forth facts upon which the Court can grant relief for an FCA claim. Riley has not adequately pleaded the elements of materiality and causation, which are fundamental to her claim. Therefore, Mednology need not and does not address at length Riley's assertions regarding falsity and knowledge. Absent sufficient allegations of materiality and causation, Riley's claim must be dismissed.

B. Materiality and Causation Are Separate Elements Under the FCA and Should Not Be Conflated.

An FCA claim that conflates the elements of materiality and causation undermines the integrity of FCA litigation. The appellate court egregiously suggests that causation need not be established because materiality is met, which is directly at odds with the statute's pleading requirements. *See United States ex rel. Cimino v. Int'l Bus. Machines Corp*, 3 F.4th 212, 419 (D.C. Cir. 2021) (holding that materiality does not suffice in lieu of causation under the FCA). In other words, the court's approach endorses a finding that materiality suffices to establish a causal link between Mednology's alleged fraud and CMS payment decisions. *Id.* Under the FCA, materiality and causation are related, but they are distinct elements that must be pleaded under different standards. *See United States ex rel. Petratos v. Genentech*

Inc., 855 F.3d 481, 491 (3d Cir. 2017) (holding that materiality and causation are separate elements).

Materiality focuses on whether a misrepresentation has a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). To establish materiality, a relator must show that a defendant's misrepresentation of compliance with a "statutory, regulatory, or contractual requirement" influenced the government's decision to reimburse a claim. *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 194 (2016) [hereinafter *Escobar*]. Whether compliance with a requirement is a condition of payment, or that the government may choose to decline payment if it knew of the noncompliance, is relevant to establishing materiality, but is not dispositive. *Id.* Instead, a material misrepresentation must be "so central" to the claims that the government "would not have paid [the] claims if it [was aware] of [the] violation." *Id.* at 196. In short, the standard is "demanding." *Id.* at 194.

Causation is established when a relator sufficiently shows that a defendant's conduct "cause[d] the government to make a payment or to forfeit money owed." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016). This involves pleading a clear link between the fraud and the government's payment. *Id.* Under the FCA, fraudulent conduct must be a substantial factor in bringing about government payment, not merely a but-for cause. *United States v. Luce*, 873 F.3d 999, 1009-14 (7th Cir. 2017). Simply put, causation refers to whether a misrepresentation triggered payment, whereas materiality refers to whether it mattered to, or influenced

payment. *Cimino*, 3 F.4th at 419 ("[A] statement could be material—that is, capable of influencing the government's decision to enter a contract—without causing the government to do so."). Thus, using causation to establish materiality allows a relator to bypass *Escobar*'s more demanding analysis, which focuses on the significance of the fraud in the government's payment process. *See Escobar*, 579 U.S. at 193 (applying tort and contract law principles of fraud).

In the instant case, the appellate court "[collapses] the materiality analysis into a causation inquiry." *Petratos*, 855 F.3d at 491. Riley argues that materiality is met because if the FDA had not approved Sleepternity, CMS would not have reimbursed claims. R. at 23. Implicit in this argument is the assumption that Mednology's conduct actually caused FDA approval. R. at 23. However, materiality requires showing that Mednology's misrepresentation was central to the *government's* payment decision, not just that it influenced an intermediary party like the FDA. *Escobar*, 579 U.S. at 193 ("[M]ateriality look[s] to the effect on the likely or actual behavior of the *recipient* of the alleged misrepresentation." (citations omitted)). To establish materiality, Riley must show that, independent of FDA approval, Mednology's conduct directly influenced CMS reimbursement decisions. *Id.* The FDA's approval of Sleepternity is relevant only to the extent that it shows claims with implied false certifications *arrived at or reached* CMS. In other words, the FDA's approval is no more than a link in the causal chain and is properly analyzed under causation–not materiality. Riley's assumption that FDA approval alone establishes

materiality conflates the two elements, which results in a failure to properly analyze causation, which is necessary to properly plead her claim.

Riley's focus on but-for causation to establish materiality further blurs the distinction between the two elements. Riley contends that materiality is established because Mednology's alleged fraud was the but-for cause of submitted claims. R. at 36. However, the but-for causation theory Riley relies on is insufficient by itself to meet the FCA's "restrictive standard" for causation. *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995). If the but-for causation theory is by itself insufficient to meet the causation element, it therefore follows that it also is "insufficient to demonstrate materiality." *Petratos*, 855 F.3d at 491. Under the FCA, fraud must be both the but-for (actual) and proximate (legal) cause of government harm. *Luce*, 873 F.3d at 1009-14 (applying *Escobar* and finding that Congress intended the FCA to incorporate common law concepts of fraud). To establish proximate cause, it must be shown that fraud is an integral part of the causal chain leading to payment. *Ruckh v. Salus Rehab, LLC*, 963 F.3d 1089, 1107 (11th Cir. 2020). More specifically, proximate cause requires a "sufficient nexus between the defendant's conduct and the submission of a false claim." *Id.* Therefore, to plead causation, Riley must 1) plausibly allege facts establishing but-for causation and 2) establish the fraud was a substantial factor in causing CMS payment. *See Cimino*, 3 F.4th at 420-21 (holding that a relator must plead actual, but-for cause, as well as proximate cause).

Moreover, conflating materiality and causation causes Riley to overlook the nuanced relationship between the elements. R. at 39. Materiality is most clearly established when it is also evident that causation has been. R. at 39. Even the court's concurring opinion acknowledges that to meet materiality under *Escobar*, a causal link must be made between Mednology's alleged fraud-on-the-FDA and the government's decision to reimburse for Sleepternity:

> [A] defendant's fraudulent violation of a particular requirement must cause the government to withdraw its payment. Put another way, the government's decision to withdraw payment for the defendant's product must be based on the defendant's violation of a particular requirement that serves as a condition for payment. Therefore, establishing causation between a defendant's conduct of fraudulently completing a requirement for receiving payment and a government's decision to withdraw payment upon discovering such fraud is necessary for satisfying the materiality requirement clarified in *Escobar*.

R. at 39. Thus, while distinct, the elements are interconnected. R. at 39. Conflating them overlooks their separate standards and the need to meet both independently. *Petratos v. Genentech Inc.*, 855 F.3d at 491.

Ultimately, in conflating the elements, the court assumes causation has been met without subjecting Riley's claim to a causation analysis. The court's approach dilutes the stringent pleading requirements of materiality established in *Escobar* and allows Riley's claim to survive without properly demonstrating that Mednology's alleged fraud was material to, or even caused, CMS payments. Therefore, this Court should require Riley to establish both materiality and causation under their respective standards.

C. CMS Payment Decisions Are Partly Conditioned on FDA Approval, But Approval Alone Does Not Guarantee Payment.

Riley's argument under the implied false certification theory of liability rests on the assumption that Mednology's failure to disclose its foam modification to the FDA automatically renders claims for reimbursement fraudulent. R. at 36. However, under this theory, liability arises only for failure to disclose noncompliance with a *material* condition for payment. *Escobar*, 579 U.S. at 190. As delineated in *Escobar*, whether a provision is expressly or impliedly labeled a condition of payment is relevant to, but not dispositive of, materiality. *Id.* at 191. Riley's claim fails under the theory because it wrongly assumes that FDA approval, or lack thereof, is axiomatic of CMS payment decisions. *Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012) (acknowledging that FDA approval alone does not entitle a device to coverage). In reality, FDA approval is not wholly determinative of CMS payment decisions. *Id.*

CMS coverage decisions do rely on FDA approval as a measure of a device's safety and efficacy, but CMS also considers other factors such as cost-effectiveness and overall healthcare policy. *See Petratos*, 855 F.3d at 487 (denying a *qui tam* relator's FCA claim and holding that CMS reimbursement determinations are made involving the FDA, CMS, and individual physicians). Accordingly, FDA approval is a "necessary, but not sufficient" condition for determining coverage. *See Int'l Rehabilitative Scis., Inc. v. Sebelius,* 688 F.3d 994, 1002 (9th Cir. 2012). As aptly noted by the Fourth Circuit, FDA approval may inform CMS coverage decisions "as to whether a device is "reasonable and necessary, [but] it cannot tie the Secretary's hands." *Almy*, 679 F.3d at 308.

In addition to FDA approval—which, we remind the Court, has not been withdrawn—CMS requires all reimbursed medical devices be "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). To determine coverage, Medicare contractors determine whether a service falls under the reasonable and necessary category through assessing whether the service is (1) safe and effective, (2) not experimental or investigational, and (3) appropriate. *Medicare Program Integrity Manual*, Ch. 13 § 13.5.4 (2019). The Third Circuit has noted that CMS's "reasonable and necessary determination does not end with FDA approval," but that it incorporates physician recommendations and determinations. *Petratos*, 855 F.3d at 487-88. Claims must be ""reasonable and necessary for [the] *individual patient*" based on accepted standards of medical practice and the medical circumstances of the individual case." *Id.* at 488. (quoting Medicare Benefit Policy Manual, ch. 15 § 40.4.3). The Third Circuit further explained that physicians play a significant role in determining patient device use. *Id.* Under Medicare Parts A and B, Medicare payment is often conditioned on physician certification as to the necessity of device use and continued need for use. *Id.* In the Philips litigation, the recall FAQ page notes that:

> [F]or some patients, stopping use of the recalled or repaired device may involve greater risk than continuing its use. If you and your health care provider decide that the benefits of using the device outweigh the risks, you may decide to continue to use your recalled device.

U.S. Food & Drug Administration, *FDA Activities Related to Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/fda-activities-related-recalled-philips-ventilators-bipap-machines-and-cpap-machines

(Apr. 2024.) Thus, for many patients suffering from sleep apnea, the extreme risks of leaving their condition untreated outweigh the possible drawbacks of using a voluntarily recalled CPAP machine. *Id.* In the instant case, Riley's physician recommends she stop using Sleepternity. R. at 5. However, Riley's claims imply fraud affecting a broader patient population, where individual circumstances may vary significantly. Consequently, since CMS payment decisions are not strictly dictated by FDA approval, CMS could continue reimbursing Sleepternity for patients who, after physician consultation, choose to continue using the device. *Almy*, 679 F.3d at 308. Alternatively, CMS could impose supplemental conditions for coverage rather than discontinue payments altogether. Simply put, CMS could plausibly continue coverage for patients who demonstrate a continued need for Sleepternity.

In sum, the appellate court's acceptance of Riley's claim reflects a misunderstanding that FDA approval decisions automatically dictate whether CMS will pay. *Id.* The court's confusion allows Riley's claim to proceed based on a mere showing that the FDA approval process *may* have been compromised. This Court should instead require Riley to demonstrate that, irrespective of the additional payment considerations outlined *supra*, at 32-33, Mednology's misrepresentation directly influenced CMS payments, which is a significantly higher threshold requiring a specific linkage between the alleged fraud and the claims. *Escobar,* 579 U.S. at 194.

D. Riley Has Not Alleged the FDA Has Withdrawn Approval, Indicating a Break in Causation Between Mednology's Conduct and CMS Payments.

Riley's claim relating to CMS payment for the use of Sleepternity is predicated on what is known as a fraud-in-the-inducement theory of liability, under which Riley argues the FDA was induced into granting approval it would not have otherwise had it known of Sleepternity's use of PE-PUR foam. R. at 22. A relator basing an FCA claim on the theory of fraudulent inducement must plead "not only that the omitted information was material but also that the government was induced by, or relied on, the fraudulent statement or omission." *D'Agostino*, 845 F.3d at 7–8 (distinguishing between elements of materiality and causation in a fraudulent inducement claim).

D'Agostino made clear that to plead causation, it is insufficient to allege that a defendant's misrepresentation made to the FDA "could have influenced the FDA… and the payments made by CMS." *Id.* at 7. Rather, "the defendant's conduct must cause the government to make a payment or to forfeit money owed." *Id.* at 8. Thus, if the FDA would have approved of Sleepternity regardless of Mednology's misrepresentation, then the link between the alleged fraud and CMS payments that purportedly depend on FDA approval is severed. *Id.*

In the instant case, Riley does not allege that the FDA withdrew or suspended its approval of Sleepternity. R. at 21. Instead, the agency terminated its investigation after Mednology promptly issued a voluntary recall. R. at 29. The FDA's decision to continue its approval after learning of Riley's claims, therefore, suggests the misrepresentation did not influence FDA approval. *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir. 2017) (finding that evidence of agency inaction is particularly compelling when an agency, like the FDA, is "armed

with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position."). As the First Circuit has pointed out, the FDA's decision not to withdraw device approval after receiving allegations of fraud precludes any argument that approval was fraudulently obtained. *D'Agostino*, 845 F.3d at 8. Ergo, the FDA's decision not to withdraw or suspend its approval weighs heavily against a finding of causation. *See Nargol*, 865 F.3d at 34 (holding that the relator failed to state an FCA claim due to a break in causation between the misstatements and any claim payments as the FDA did not withdraw or suspend its approval after the relators' allegations).

At most, Riley's allegations establish a timeline that Mednology switched from a silicone-based foam to PE-PUR foam after the FDA had approved Sleepternity, which is not enough to show causation. *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) ("The FCA "requires a causal rather than a temporal connection between fraud and payment."). Therefore, only an official action from the FDA confirming that its approval was fraudulently procured would fill this gap in Riley's claims. *D'Agostino*, 845 F.3d at 9. Riley will likely retort that the FDA's inaction is perhaps attributable to factors unrelated to Mednology's misrepresentation. *Campie*, 862 F.3d at 906. However, the FCA is intended to protect the government from fraud in conjunction with the FDA's "[judgment] about whether to rescind regulatory rulings," rather than to "second-guess" its decisions. *D'Agostino*, 845 F.3d at 8-9. As such, inferring other explanations for the FDA's inaction undermines the agency's judgment. *Id.* Thus, this Court should find that short of

action from the FDA that elucidates its position, it remains only a possibility that Mednology's conduct influenced the FDA and CMS. It therefore bears repeating that this falls short of the pleading expectations outlined in Twombly and Iqbal, which requires more than possibility. *Iqbal*, 556 U.S. at 678.

3. FDA approval of PE-PUR foam remains plausible.

Moreover, FDA approval of PE-PUR foam is both possible and plausible. The FDA's premarket approval process is "rigorous." *Riegel*, 552 U.S. at 317-18. During this process, the FDA weighs any "probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). Consequently, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* It is plausible that, despite the FDA's awareness of the risks associated with PE-PUR foam, the agency would approve of Sleepternity if no comparable alternatives offered the same revolutionary benefits and if patients with sleep apnea were better off using Sleepternity despite its potential risks. *Id.*

4. Recall does not invalidate a device's premarket approval.

Finally, Mednology's voluntary recall does not support a finding that FDA requirements were violated during Sleepternity's premarket approval process. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 497 (W.D. Pa. 2012). The premarket approval process and the withdrawal of a premarket approval are "governed by a completely separate statutory and regulatory regime." *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1155 (D. Minn. 2009). Accordingly, recalling

a medical device, which allows a manufacturer to act to prevent the problem from occurring again, does not necessarily invalidate a device's premarket approval. *Id.*

The FDA may recall a Class III medical device when "there is a reasonable probability that [the] device intended for human use would cause serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1). When a device's premarket approval is suspended or completely withdrawn, the FDA is required to provide manufacturers with "due notice and opportunity for informal hearing," which suggests that FDA action is first required to initiate the process of suspending or withdrawing approval. 21 U.S.C. § 360e(e). The FDA itself recognizes the distinction between recall and revocation of premarket approval. *In re Medtronic*, 592 F. Supp. 2d at 1155 ("There cannot be an "again" for a recalled device if the recall invalidated the device's PMA."). Thus, Riley's argument falls short of overcoming the hurdle of the FDA's inaction. *Id.* The FDA's incontrovertible authority to revoke approval and the clear decision not to do so rebuffs Riley's assertion that the agency would have made a different approval decision if fully informed. *Id.*

E. A Weakened Materiality Standard Directly Contradicts This Court's Rigorous Requirements Under Escobar.

Like causation, materiality is evaluated in part based on the government's response to noncompliance with a relevant provision. *Escobar*, 579 U.S. at 194. The government's knowledge of a violation may be highly relevant, or probative, to determining materiality. *Id.* Evidence that the 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" serves as "strong evidence that

the requirements are not material." *Id.* at 195. Applying the *Escobar* standard, the First Circuit rejected a relator's argument that a misrepresentation made to the FDA is material when that misrepresentation "could have" influenced FDA approval. *D'Agostino*, 845 F.3d at 7. The court held that FCA pleadings must show that a misrepresentation is "material to the government's payment decision itself" and determined that when the government continues to pay for a device after learning of a relator's claims, such evidence "casts serious doubt on the materiality of the fraudulent representations" alleged. *Id*. Similarly, the Third Circuit has held that a relator's failure to plead examples of CMS consistently denying payment due to underlying misrepresentations "militates against a finding of materiality." *Petratos*, 855 F.3d at 490.

Under *Escobar*, relators "face an uphill battle in alleging materiality sufficient to maintain their claims." *Campie*, 862 F.3d at 905. Yet despite this acknowledgment, the *Campie* decision misapplies and grossly undermines *Escobar*'s high bar for materiality. In *Campie*, the Ninth Circuit determined that FDA inaction does not preclude a relator from basing an FCA claim on the theory of fraud-on-the-FDA, even when the government continues to pay for services after learning of FDA violations. *Id.* In contrast to other Circuits, the court found the relator sufficiently pled materiality. *Id.*

The appellate court's adoption of *Campie* is problematic because the Ninth Circuit's decision was based on flawed reasoning:

> "[T]he showing that the Ninth Circuit held was sufficient to defeat a motion to dismiss - "*more than the mere possibility* that the government

> would be *entitled* to refuse payment if it were aware of the violations" - squarely conflicts with *Escobar*'s materiality standard. Rather than looking to probabilities and legal entitlement, *Escobar* "look[ed] to the *effect* on the [government's] *likely or actual* behavior," a far higher standard than the court of appeals' language suggests.

Brief for Chamber of Commerce et al. as Amici Curiae in Support of Petitioner at 8, Gilead Scis., Inc., v. United States ex rel. Campie, 862. F.3d 890 (9th Cir. 2017) (No. 17-936), 2018 WL 739739, at * 8 (citations omitted) [hereinafter *Brief for Chamber of Commerce*]. In applying *Campie*, the appellate court departs from the stricter approach set by the First and Third Circuits, which have held that FDA inaction creates a significant hurdle for a relator to overcome. *See D'Agostino*, 845 F.3d at 7; *see also Petratos*, 855 F.3d at 490.

In the instant case, Riley fails to provide non-conclusory allegations explaining why Mednology's violation would materially impact CMS payment decisions. The record suggests she has not alleged instances of FDA revoking premarket approval or CMS refusing to pay claims in analogous cases, such as the Philips litigation. In fact, the record suggests she has not alleged *whatsoever* that CMS has declined or revoked payments, let alone exercised discretion independent of FDA approval. If CMS is still paying claims, it suggests that any potential FDA violation have little to no effect on the agency. And again, the FDA's continued approval suggests the immateriality of Mednology's misrepresentation. Without an official action from CMS declining payment, the gap in Riley's claims remains unfilled. *See D'Agostino*, 845 F.3d at 9 (holding only an official action from the FDA can confirm whether approval was fraudulently obtained).

Despite this, the appellate court suggests that it is enough that the FDA *could* have denied approval based on Mednology's misrepresentation, which in turn *could* have led CMS to deny payments. The Court should find that this reasoning is speculative and relies on conjecture about the potential impact of Mednology's misrepresentation on CMS payment decisions. Riley's deficient claims only imply the possibility that CMS *could* have refused payment, which this Court has specifically instructed does not establish materiality. *Escobar*, 579 U.S. at 194. Her failure to meet *Escobar*'s high bar for materiality also indicates a failure to plead with plausibility under the less demanding standards of *Twombly* and *Iqbal*, which make clear that mere possibilities are insufficient to withstand a motion to dismiss. *Iqbal*, 556 U.S. at 678. To satisfy both pleading standards, Riley's allegations must demonstrate how CMS *did* or *likely* would have withheld or declined payment because of Mednology's misrepresentation, which she fails to do. *Id.*; *Escobar*, 579 U.S. at 193.

In a post-*Campie* decision, the First Circuit reaffirmed its decision in *D'Agostino*, emphasizing the importance of FDA inaction as evidence of immateriality. *Nargol*, 865 F.3d at 35. In *Nargol*, the court found that the relator's failure to allege "that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations" was "very strong evidence that those requirements are not material." *Id.* The court further noted that:

> The example of a valid claim given in *Campie* would be valid under *D'Agostino* too, since it rests not on lying to the FDA but rather on palming off one product as another. Additionally, the record in Campie lacked what we have here: a situation in which the FDA was not alleged

> to have ever withdrawn its approval, even long after it acquired full knowledge of Relators' claims. Otherwise, *Campie* offers no rebuttal at all to *D'Agostino's* observation that six jurors should not be able to overrule the FDA. And it offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything. Instead, it decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solutions can be envisioned, even in theory.

Id. at 36. Thus, in applying *Campie*, the appellate court has lowered the bar for relators bringing FCA claims under a theory of fraud-on-the-FDA. *Id.*

Campie partly justifies its decision by suggesting that there may be "many reasons" for FDA inaction or CMS payments, which Riley is likely to rely on. *Campie*, 862 F.3d at 906. However, applying this rationale at the pleading stage is problematic if courts are required to discern the countless potential reasons behind continued FDA approval or CMS payment. *Brief for Chamber of Commerce* at 9. It is also illogical to accept that any possible reason "would suffice to defeat a motion to dismiss" when *Escobar* is silent on the other reasons CMS could continue to pay but directs courts to assess "outwardly and readily determinable" facts. *Brief for the United States as Amicus Curiae, Gilead Scis., Inc., v. United States ex rel. Campie,* 862 F.3d 890 (9th Circuit. 2017) (No. 17-936), 2018 WL 6305459, at *22. Furthermore, the pleading standards of *Tombly* and *Iqbal* require Riley to "plausibly plead facts to support such possible alternative explanations." *United States ex rel. Foreman* v. *AECOM*, 19 F.4th 85, 115 (2nd Cir. 2021). To sustain her FCA claim, Riley would need to explain why continued CMS payment is not indicative of immateriality because of other reasons—a requirement she is unlikely to meet. *Id.* at 116.

Therefore, under this Court's standards, materiality cannot be met where the FDA may have other reasons for not withdrawing approval. *See Escobar*, 579 U.S. at 178 (holding that a misrepresentation is not material simply because the government would have the option to decline payment).

Finally, as noted by the trial court, "even if this Court were to adopt the standards set forth by the Ninth Circuit in *Campie*, Riley cannot rely on Mednology's alleged fraudulent conduct as a viable basis for bringing her FCA claim against Mednology, since the causation element has not been met." R. 24. And perhaps more significantly, the appellate briefing in *Campie* was completed before this Court's decision in *Escobar*. *Brief for the United States as Amicus Curiae at 1, Gilead Scis., Inc., v. United States ex rel. Campie*, 862 F.3d 890 (9th Circuit. 2017) (No. 17-936), 2018 WL 6305459, at *22. In light of this, the arguments considered by the Third Circuit were "less developed than they would [have been] in a case pleaded and litigated after that decision." *Id.* As a result, *Campie* should be deemed an inappropriate precedent for addressing the materiality issue presented in this case. This Court should reject the appellate court's diluted standard and instead find that under *Escobar*, sufficient allegations of CMS actions remain crucial to determining materiality, and Mednology's misrepresentation must be material to CMS payment decisions.

F. The Treatment of Materiality as a Matter of Proof Allows Riley to Bypass the Heightened Pleading Requirements for Fraud, Thereby Violating Rule 9(b).

The *Campie* decision further dilutes the materiality standard, conflicting with *Escobar*'s requirement that relators plead materiality with sufficient plausibility and particularity. *Escobar*, 579 U.S. at 230 n.6. This Court has made clear that FCA claims must comply with the heightened standards of Rules 8 and 9(b), which requires relators to plead facts to support their allegations of materiality. *Id.* In treating materiality as a matter of proof, the appellate court shifts the burden from the court to the factfinder, contrary to *Escobar*'s instruction that "materiality is [not] too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss." *Id.* Therefore, materiality should be treated as legal grounds for dismissal, not a matter of proof. *Id.*

Allowing materiality to be assessed later in the proceedings by a factfinder, effectively absolves Riley of her duty to plead with particularity, as Rule 9(b) demands more than inferences and conclusions. *U.S. ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d, 1217 (11th Cir. 2012) (holding that under Rule 9(b), a relator must identify the "who, what, when, where, and how" of the fraudulent conduct). Rule 9(b) requires that Riley "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To comply with the heightened pleading standard required for fraud claims, she must clearly demonstrate *how* Mednology's misrepresentation was material to CMS's payment decisions. *Id.* At most, all she suggests is that fraudulent claims must have been or likely were submitted. *See Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (holding that allegations of improper practices alone are insufficient

Furthermore, the appellate court's flawed finding of materiality, stemming from its conflation of materiality with causation, fails under Rule 9(b). The court's failure to evaluate materiality independent of causation means the court relied on unsupported inferences about how Mednology's misrepresentation affected CMS-decision making. The focus on FDA approval as a proxy for materiality reveals a lack of particularity explaining how the misrepresentation impacted CMS payment decisions. To fill this gap, the court improperly presumed that if the FDA would not have granted approval, it would have led to CMS withdrawing payment. This flawed approach underscores the deficiencies in Riley's pleadings, which presumably lack the required particularity for establishing materiality under Rule 9(b).

While Riley may argue that information about past CMS payment decisions in analogous cases is not readily accessible, this does not obviate Riley's duty to meet the pleading standard. *See United States ex rel. Atkins v. McInteer,* 470 F.3d 1350, 1360 (11th Cir. 2006). Relators are held to the same standard as the government in FCA cases, and the inaccessibility of certain facts does not justify lowering the bar. *Id.* ("[We] cannot furnish a *qui tam* relator with an easier burden than the government would bear if it intervened and assumed the prosecution of the case."). Rule 9(b) requires clear allegations of fraud at the outset precisely to prevent the advancement of claims that turn on "facts learned through the costly process of discovery." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 380 (4th Cir. 2008). Without adhering to Rule 9(b)'s standards, treating materiality as a matter of proof will expose Mednology to the costly burden of

defending against an immaterial claim and potentially opens the door to similarly immaterial FCA suits.

Ultimately, the Court should focus on what Riley alleges at the pleading stage and require those allegations to be made with sufficient plausibility and particularity. As they stand, Riley's materiality allegations "struggle to meet even the more forgiving pleading standard of Rule 12(b)(6), much less the heightened Rule 9(b) standard." *United States ex rel. Bid Solve, Inc. v. CWS Mktg. Grp., Inc.*, 567 F. Supp. 3d 59, 69 (D.D.C. 2021). Therefore, the dismissal of Riley's FCA claim for failure to sufficiently plead materiality is justified under both Rule 12(b)(6) and Rule 9(b).

G. The False Claims Act is an Inappropriate Tool for Addressing Mednology's Alleged Misconduct Because It Undermines the FDA's Authority as the Ultimate Regulatory Body.

The Court should refrain from extending the FCA's reach into regulatory enforcement because the FDA's regulatory authority is best suited for ensuring Mednology's full compliance with agency standards. The FCA is not an "all-purpose antifraud statute" designed to address all misconduct related to government spending programs, especially when other enforcement mechanisms, like those overseen by the FDA, are already equipped to handle such issues. *Escobar*, 579 U.S. at 194; *United States ex rel. Crocano v. Trivida Health Inc.*, 615 F. Supp. 3d 1296, 1301 (S.D. Fla. 2022) (declining to extend the FCA on the basis that the FDA's power could be exercised to ensure compliance). The FCA's purpose is to alert the federal government to potential fraudulent claims related to its spending programs. *Id.* at 1310. Its purpose is not to "second-guess agencies' judgments about whether to rescind

regulatory rulings." *D'Agostino*, 845 F.3d at 8. Using the FCA in this manner could lead to excessive litigation better suited for FDA enforcement.

Courts have cautioned against using the FCA to encroach on the FDA's regulatory role. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 307 (3rd Cir. 2011) ("...the [FCA] was not designed for use as a blunt instrument to enforce compliance with all...regulations..."); *see also United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (holding that allowing FCA liability could "short-circuit the very remedial process the Government has established to address non-compliance" when an agency can enforce its own regulations). Even this Court held that the FDCA, which grants the FDA its authority, preempts state law claims alleging fraud-on-the-FDA during the 510(k)-clearance process. *Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies is hardly "a field which the States have traditionally occupied" (quoting *Rice*, 331 U.S. at 230). The First Circuit has since extended this principle to the FCA context. *D'Agostino*, 845 F.3d at 7-9.

As this Court notes, the FDA is empowered with myriad enforcement options that "allow it to make a measured response to suspected fraud." *Buckman*, 531 U.S. at 349. These options include investigating suspected fraud, 21 U.S.C. §372, seeking injunctive relief, 21 U.S.C. § 332, seizing devices, 21 U.S.C. § 334(a)(2)(D); pursuing criminal prosecutions, 21 U.S.C. § 333(a); and imposing civil penalties, 21 U.S.C. § 333(f)(1)(A). *Id*. Accordingly, the FDA is the proper vehicle for pursuing fraud-on-the FDA claims. Mednology seeks not to diver the Court from its duty to uphold justice

but to allow the FDA to administer justice as it sees fit. To allow otherwise "would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA sees no reason to do so." *D'Agostino*, 845 F.3d at 8.

CONCLUSION

This Court should REVERSE the appellate court's decision to deny Mednology's motion to dismiss where the operation of federal law conflicts with Riley's state law claims and impliedly preempts the immunity exception provided within the state law. Further, this Court should AFFIRM the district court's judgment and determine that Riley may not rely on the theory of fraud-on-the-FDA to bring an FCA claim against Mednology where she fails to sufficiently plead the elements of materiality and causation.

Respectfully Submitted,

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ATTORNEYS FOR PETITIONER