No. 24-9176

IN THE

Supreme Court of the United States

MEDNOLOGY INC.,

Petitioner,

Versus

Riley ORTEGA,

Respondent.

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

BRIEF FOR PETITIONER

TEAM 3316
Attorneys for Petitioner

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Questions Presented

1. Whether the FDCA preempts Transylvania's manufacturer's immunity statute when the exceptions are based on Mednology fraudulently obtaining FDA approval or failing to comply with the FDA requirements by replacing the silicone-based foam in its Sleepternity device with polyester-based polyurethane foam.
2. Whether it is improper for a relator such as Ms. Ortega to rely on the fraud-on-the-FDA theory when bringing suit under the False Claims Act, where the FDA and CMS have taken no action against Mednology.

Opinions Below

The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2-24 of the record, wherein the District Court denied Mednology's motion to dismiss Ms. Ortega's state law claims but did dismiss her False Claims Act claim. The opinion of the United States Circuit Court of Appeals for the Seventeenth Circuit is also unreported but is found on pages 25-42 of the record, wherein the court affirmed in part and reversed in part the District Court's judgment. Specifically, they affirmed the denial of Mednology's motion regarding Ms. Ortega's state law claims and reversed the granting of their motion to dismiss her claims under the False Claims Act.

Constitutional and Statutory Provisions Involved

This case involves three provisions of the United States Code 21 U.S.C. § 360k(a), 21 U.S.C. § 337(a), and 31 U.S.C.A § 3729. This case also involves Art. VI cl. 2 of the United States Constitution and Transylvania's state statute 21 Trans. Comp. Stat. § 630 (2024). The full text of the Transylvania statute may be found on pages 7 and 8 of the Record.

Statement of the Case

Statement of Facts

This case involves a products liability action brought under Transylvania's product liability statute against Petitioner, Mednology, by Respondent, Ms. Riley Ortega. R. at 2. Mednology's motion to dismiss the claims brought by Ms. Ortega was unjustifiably dismissed. Mednology appeals the United States Circuit Court of Appeals for the Seventeenth Circuit's decision to deny Mednology's motions to dismiss Ms. Ortega's state law claims and Ms. Ortega's False Claims Act claim. R. at 43.

Mednology. Mednology designed a continuous positive airway pressure (CPAP) machine called Sleepternity with several unique features, making it especially effective for those users suffering from insomnia. R. at 3. These features included an automatic pressure adjustment system to increase therapy comfort, a heated humidifier that helps to decrease dryness and irritation, and a mobile device app that allows users to customize their Sleepternity experience by changing the machine settings. *Id.* Sleepternity also includes noise cancelling headphones that emit gentle pulses that advance to the wearer's brain to help lull them to sleep. *Id.*

On December 30, 2022, the FDA classified Sleepternity as a Class III medical device and approved Sleepternity for marketing. R. at 4. Soon after this approval, the Centers for Medicare and Medicaid Services (CMS) provided coverage for the cost of Sleepternity to users who were prescribed the device. *Id.*

PE-PUR Foam Modification. After receiving the FDA's approval, Mednology modified Sleepternity by replacing the silicone-based foam in the sound

dampening foam with polyester-based polyurethane (PE-PUR) foam. *Id.* PE-PUR foams can sometimes lead to health risks. *Id.* Such as in the CPAP machine from Philips Respironics, where the PE-PUR foams used in the machine, broke down over time and volatile organic compounds could be breathed in or swallowed by users of the Philips Respironics CPAP machines. *Id.* This breathing in or swallowing of the VOCS could lead to health risks, so Philips Respironics recalled their machines. *Id.*

Riley Ortega. Ms. Ortega, a retired artillery officer of the United States Army is a citizen of the State of Wohio. R. at 3. Ms. Ortega has been diagnosed with post-traumatic stress disorder (PTSD) because of her time in the military. *Id.* Ms. Ortega's PTSD results in her having insomnia and sleep apnea. *Id.* To relieve some of her symptoms, Ms. Ortega was prescribed Sleepternity. *Id.*

However, Ms. Ortega experienced asthma attacks and was transported to the emergency room of a nearby hospital. R. at 4-5. The emergency room physician recommended that Ms. Ortega stop her use of Sleepternity, which was echoed by her primary care physician, when they determined that her symptoms were caused by Sleepternity. *Id.* Ms. Ortega is allergic to isocyanate, a VOC that is found in polyurethane, however, Sleepternity's warning label did not display information about isocyanates. R. at 5.

After discontinuing her use of Sleepternity, Ms. Ortega's asthma attacks have stopped, however, her lungs have been left chronically inflamed and she still experiences sleep apnea. *Id.* Ms. Ortega believed that Sleepternity was not the right

device for her, but Ms. Ortega's brother, Jim, an assembly manager at Mednology, believed that Ms. Ortega's symptoms were contributed to by the PE-PUR foams. *Id.* Explaining that Mednology replaced the foam to cut down on the costs of manufacturing before sending the device to the distributors. *Id.* After conducting her own research, Ms. Ortega concluded that her asthma attacks were most likely caused by isocyanate in Sleepternity. R. at 5-6.

Nature of Proceedings

District Court. Riley Ortega brought suit against Mednology in United States District Court for the Southern District of Transylvania, suing under both a state law products liability statute and the False Claims Act. R. at 2. The District Court granted Mednology's motion to dismiss Ms. Ortega's False Claims Act claims because she failed to establish the required causation element. R. at 24. However, the District Court denied Mednology's motion to dismiss Ms. Ortega's state law claims, holding that the Transylvania statute's two exception clauses were not preempted by the Food Drug and Cosmetics Act (FDCA). *Id.*

Seventeenth Circuit Court of Appeals. Both parties appealed the District Court's decision; Mednology appealed the denial of its motion to dismiss Ms. Ortega's state law claims, and Ms. Ortega appealed the dismissal of her False Claims Act claims. R. at 25. The Court of Appeals affirmed the denial of Mednology's motion to dismiss the state law claims and reversed the dismissal of Ms. Ortega's False Claims Act claims, remanding the case back to the District Court. *Id.* The Court of Appeals held specifically that Ms. Ortega had met all of the

required elements of the False Claims Act and that the materiality of her allegations was a factual determination. R. at 38. They also held that, while two key sections of the Transylvania statute were preempted, a third provision allowed Ms. Ortega's case to escape dismissal. *Id.*

Summary of Argument

The Court of Appeals was correct in determining that presumption against preemption does not apply to Mednology's claim that federal law preempts Transylvania's immunity statute exceptions. Federal agencies are the sole regulators of policing possible fraud committed against themselves. Therefore, by Ms. Ortega claiming that Mednology's FDA approval was only gained by them committing fraud-on-the-FDA, presumption against preemption may not apply, as it is an inherently federally based claim.

Subsection (b) of Transylvania's immunity statute is preempted by the FDCA because Ms. Ortega's claims of fraud do not rely on any federal findings of fraud. Ms. Ortega's claims are only based on her own determination that Mednology committed fraud. In fact, the FDA halted its investigation into Mednology's alleged fraudulent conduct once Mednology had voluntarily recalled Sleepternity from the market.

Subsection (c) of Transylvania's immunity statute is also preempted. Subsection (c) may only apply when a defendant fails to comply with a requirement of the FDA. Once again, this exception is based on fraud committed against the FDA and interferes with the FDA being able to regulate itself.

Federal law preempts the compliance section of the immunity statute. Although the Court of Appeals determined that Ms. Ortega's claims, where she stated that Sleepternity was not in compliance with the FDA's regulations, were

plausible. This determination is inconsequential because non-compliance with these regulations is an inherently federal claim that should only be regulated by the FDA.

The United States Circuit Court of Appeals for the Seventeenth Circuit also improperly held that Mednology's motion to dismiss Ms. Ortega's False Claims Act claims should be denied. Ms. Ortega failed to sufficiently establish multiple elements of a claim under the False Claims Act, regardless of whether she brought suit under a fraud-on-the-FDA theory or an implied false certification theory. There is no factual dispute regarding the FDA's actual knowledge of Mednology's conduct, and therefore materiality must be properly addressed at this stage.

Ms. Ortega made vague allegations against Mednology but failed to identify any specific allegations that Mednology's conduct was material to either FDA approval or government payment being issued. Mednology's conduct was not material to any governmental payment decision and is therefore irrelevant to the False Claims Act. Ms. Ortega faced a steep burden in establishing the materiality of Mednology's alleged misconduct, and she has failed to meet it.

Ms. Ortega also failed to establish causation, another essential element of claims arising out of the False Claims Act. By failing to plausibly plead that Mednology's alleged omissions are causally related to either the FDA's approval or the government's payment, Ms. Ortega has not satisfied this requirement. Ms. Ortega has made no indication of the causal link between Mednology's actions and the false claim she alleges, failing to plead whether the FDA would have acted differently with full knowledge of Mednology's alleged omission. It would be

improper for the Court to allow this action to continue, as enabling a lay jury to make these determinations regarding actions the FDA might have – but did not – take would interfere with the FDA's own authority and decision-making power.

Argument

I. The FDCA impliedly preempts state law claims that attempt to regulate fraud-on-the FDA claims.

The District Court was correct in their explanation of the doctrine of federal preemption. Federal preemption is rooted in the Supremacy Clause of the United States Constitution, specifically from the statement "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. Therefore, Congress is given the power to "pre-empt, i.e., invalidate, a state law through federal legislation." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015).

The District Court was also correct in describing the main types of preemption, either express or implied preemption. Express preemption occurs when "a federal statute expressly states the intent to preempt state law." *McAllister v. G&S Investors*, 358 F.Supp.2d 146, 150 (E.D.N.Y. 2005). Implied preemption occurs when "a statute's scope indicates an intent to wholly occupy a field or where there is an actual conflict between the federal and state laws." *Id.* 21 U.S.C. § 360k(a) makes clear that any state statutes regarding "a device intended for human use" invokes express preemption. 21 U.S.C. § 360k(a) (2024). 21 U.S.C. § 337(a) of the FDCA is referred to as the "'implied preemption' provision." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1325 (11th Cir. 2017). The Supreme Court demonstrated in *Buckman* that 21 U.S.C. § 337(a) impliedly preempts state law claims when such claims are for fraud-on-the-FDA because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency,

and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

a. Presumption against preemption does not apply to Ms. Ortega's claims that Mednology fraudulently represented Sleepternity to the FDA.

We urge this Court to follow the Court of Appeals's determination that presumption against preemption does not apply to this case. The Court of Appeals correctly applied the case of *Buckman* where it was determined that presumption against preemption did not apply. *Id.* Presumption against preemption occurs when "the 'historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.'" *Corbett v. Pharmacare U.S., Inc.*, 567 F.Supp.3d 1172, 1188 (S.D. Cal. 2021) (quoting *United States v. Locke*, 529 U.S. 89, 107 (2000)). In *Buckman*, the Court stated that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347. Therefore, federal agencies are the sole regulators of possible fraud committed against them. Accordingly, there is no "presumption against finding federal pre-emption of a state-law cause of action." *Id.* at 347. Like in *Buckman*, where the defendant manufacturer was being regulated by the FDA and the plaintiff claimed that the defendant "made fraudulent representations to the Food and Drug Administration," here, Mednology is also being regulated by the FDA and Ms. Ortega is claiming "that Mednology

fraudulently obtained FDA approval for its Sleepternity device." *Id.* at 343; R. at 6.[1] We, therefore, urge this Court to apply *Buckman* and find that presumption against preemption does not apply to this situation.

The District Court incorrectly determined that presumption against preemption applies, after applying *Medtronic* to this case. In *Medtronic*, presumption against preemption applied because the petitioner made a strict liability claim against the manufacturers. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 494 (1996). The Court reasoned that Congress, in enacting the premarket approval process, only intended "to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." *Id.* There has been no "statutory scheme" or "legislative history" that the premarket approval process was "intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Id.* The petitioner in *Medtronic* brought a strict products liability claim, alleging "a breach of Medtronic's 'duty to use reasonable care in design, manufacture, assembly, and sale of the subject pacemaker[.]'" *Id.* at 481. The strict liability claim was an inherently state-law claim, allowing for the Court to apply the presumption against preemption. *Id.* at 494. However, here, Ms. Ortega makes an inherently federal claim when she bases her claim on the fraudulent

[1] "R. at #" refers to a citation to a specific page of the Record.

conduct of Mednology toward the FDA, by breaching "its duty to disclose to the FDA the modifications it made to the sound abatement foams in Sleepternity and its duty to warn about the dangers and risks associated with the presence of PE-PUR foams in the Sleepternity device." R. at 6. Therefore, presumption against preemption cannot apply to our case.

1. The FDCA preempts the immunity exception under subsection (b) because it relies on federal findings of fraud against the FDA.

We urge this Court to agree with the Court of Appeals's decision that subsection (b) of Transylvania's immunity statute is preempted by the FDCA. The Court of Appeals correctly applied *Garcia v. Wyeth-Ayerst Labs.* here over the District Court's decision to apply *Desiano v. Warner-Lambert & Co.*. R. at 28-29. While the District Court did not err in its application of *Desiano* when determining that subsection (b) of the immunity statute is preempted, *Desiano* determined that presumption against preemption applied in that case, therefore not aligning well with our case, unlike the Sixth Circuit decision in *Garcia*.

In *Garcia*, the court had to determine if an exception to a state drug products liability statute was preempted when the "FDA itself" had determined that fraud had "been committed on the agency during the regulatory-approval process." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). The Court determined that a State may "incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process." *Id.* From their analysis, the *Garcia* court held that the

immunity exception with respect to the petitioner's claim was preempted because it alleged fraud on the FDA but did not include any federal findings of fraud. *Id.* at 967. As already determined in *Buckman*, a state's own findings of fraud on the FDA "prohibits a plaintiff from invoking the exceptions on the basis of state court findings of fraud on the FDA." *Id.* at 966. This determination prevents "inter-branch-meddling" and instead "place[s] responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *Id.* at 967. *See also Henderson v. Merck & Co.*, No. 04-cv-05987-LDD, 2005 U.S. Dist. LEXIS 45106 (E.D. Pa. Oct. 11, 2005).

Ms. Ortega supports her state law claims by alleging fraudulent conduct by Mednology against the FDA. R. at 6. Ms. Ortega does not provide an actual showing that fraud was found by either the FDA or the state; Ms. Ortega only provides her belief that Mednology replaced the silicone-based foams in Sleepternity with PE-PUR foams after obtaining approval from the FDA. R. at 6, 29. The FDA had originally begun to investigate this claim of fraud but halted their investigation after the voluntary recall of Sleepternity from the market by Mednology. R. at 7. The FDA, acting within its discretion, determined that an investigation into supposed fraudulent conduct was no longer necessary, and it was best to focus their resources on investigating those alleged fraudulent products still on the market. *Id.* Accordingly, we urge this Court to determine that subsection (b) of the Transylvania immunity statute is preempted by the FDCA.

2. The FDCA preempts the immunity exception under subsection (c) because Ms. Ortega's claims are solely based on Mednology violating the FDA's requirements.

We urge this Court to agree with the Court of Appeals's decision to apply *Garcia* to this case to determine that the immunity exception of subsection (c) is preempted by the FDCA. The District Court contends that because Ms. Ortega is bringing a failure to warn claim against Mednology, their immunity is neutralized because of the exception provided in subsection (c) of Transylvania's immunity statute, stating "'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.'" R. at 8, 18. The District Court equates Ms. Ortega's claims under subsection (c) to the claims brought by the plaintiff in *Desiano*. R. at 17. The exception in subsection (c) of Transylvania's immunity statute, along with the exception to the Michigan immunity statute in *Desiano* "apply when a defendant violates a federal requirement." R. at 18. As determined in *Mink*, to defeat preemption, "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink v. Smith & Nephew*, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017). The District Court believes that Ms. Ortega's claims, similarly to the claims brought by the plaintiff in *Desiano*, are not solely based on Mednology's failure to warn about the dangers and risks associated with Sleepternity and is instead bringing her claims under Transylvania's product liability statute. R. at 18. Therefore, the District Court determined that subsection (c) is not preempted, and Ms. Ortega may use this exception to neutralize

Mednology's liability under Transylvania's statute, so she can assert her state products liability claim against Mednology. *Id.*

The Court of Appeals agreed the District Court was correct in applying *Desiano* here because of the issue being "whether federal law preempts a failure to warn provision that neutralizes a drug or medical device manufacturer's statutory immunity from product liability lawsuits." R. at 30. We implore this Court to concur with the Court of Appeals that the District Court improperly applied *Desiano*. *Id.* This is due to the District Court focusing on the wrong issue of whether federal law preempts Ms. Ortega's state law claim instead of the issue of "whether federal law preempts the immunity exception provided under subsection (c)." R. at 30-31. The Court of Appeals was correct in following the Fifth Circuit's lead of applying *Garcia* in the case of *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) where a main concern of the court was a state statute invading the "FDA's investigatory process" when a defendant was accused of violating a requirement of the FDA. R. at 31. We respectfully request this Court to do the same and by applying *Garcia* find that subsection (c) of the Transylvania immunity statute is preempted by the FDCA.

3. The compliance section of Transylvania's Immunity Statute is preempted by the FDCA because regulation of a medical device is a duty specifically for the federal agency.

We implore this Court to determine that federal law preempts the compliance part of Transylvania's immunity statute and that the Court of Appeals erred when determining that Mednology's motion to dismiss Ms. Ortega's state law claims

should be denied by finding that Ms. Ortega pled sufficient facts to plausibly rebut the presumption of compliance. The Court of Appeals determined that Ms. Ortega, in her complaint, cited "'sufficient factual matter'" that would allow "'the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" R. at 33 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). However, this determination is inconsequential, as federal law, specifically the FDCA, preempts the compliance section of Transylvania's immunity statute.

For this reason, we urge this Court to follow the belief of Justice Ruzich in his dissenting opinion. We agree with Justice Ruzich that the Sixth Circuit's Opinion in *Marsh v. Genetech, Inc.*, 693 F.3d 546 (6th Cir. 2012) applies to this case. R. at 41-42. In *Marsh*, the plaintiff alleged that the defendant "failed to comply with the FDA's post marketing reporting requirements." *Marsh v. Genetech, Inc.*, 693 F.3d 546, 552 (6th Cir. 2012). Therefore, the defendant was not protected by Michigan's Immunity Statute. *Id.* at 549. However, the court explained that a "failure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency under the state Act." *Id.* at 553. The court in *Marsh* continued to explain that a report on non-compliance against the FDA is a wrong "perpetrated upon the agency, and thus implicates the 'inherently federal' relationship described in *Buckman*." *Id.* at 553 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)). Therefore, the court in *Marsh* determined that the FDA non-compliance section of the Michigan Immunity Statute was preempted. *Id.* at 355.

Here, Ms. Ortega is arguing that Sleepternity was not in compliance with the FDA requirements and therefore Mednology cannot have immunity under Transylvania's immunity statute. R. at 33-34. However, even if this Court could determine that Ms. Ortega's claims are plausible, it could not make a difference because the claims are based on Mednology's failure to follow FDA regulations, a claim that is inherently federal and therefore preempted by the FDCA. Permitting the compliance section of the immunity statute to stand would infringe upon the FDCA and create "inter-branch meddling." R. at 42. To quote Justice Ruzich, "it is the FDA's expertise, not the court, that is best suited for determining whether Sleepternity was in compliance with the FDA's approval by the time it left Mednology's control." R. at 42.

II. Ms. Ortega cannot rely on her fraud-on-the-FDA allegations to assert her False Claims Act claim, nor has she properly pleaded any claim upon which relief can be granted.

Mednology urges this Court to reverse the Court of Appeals's decision and affirm the District Court's decision that Ms. Ortega's claim under the False Claims Act should be dismissed for failure to state a claim.

a. The Court of Appeals erred in denying Mednology's motion to dismiss on the basis that materiality is an issue of proof.

The Court of Appeals relied on *Campie* in determining that materiality should not be addressed at this stage of the case at hand. R at 37. However, *Campie* presents a very different set of facts from those at issue now. Gilead, a drug company, informed the FDA that they would source the active ingredient for their new product from approved manufacturers, but later sourced the ingredient from

unapproved factories in China. *United States ex rel. Campie v. Gilead Sci., Inc.*, 862 F.3d 890, 896 (9th Cir. 2017). Gilead argued that the FDA was aware of the alleged violation, citing correspondence from as early as 2010 and as late as 2014. *Id.* at 906. The Ninth Circuit in *Campie* determined that materiality was a matter of proof because "the parties dispute exactly what the government knew and when, calling into question its "actual knowledge." *Id.* at 906-7.

Unlike in *Campie*, neither Mednology nor Ms. Ortega dispute whether or when the FDA became aware of Mednology's alleged violations. R. at 4, 7. Neither party alleged that the FDA knew of Mednology's departure from its original approval until this action commenced. *Id.* Therefore, there is no issue of proof in this case.

Additionally, the Court of Appeals designated Ms. Ortegas claim as an implied false certification theory rather than a fraud-on-the-FDA theory in order to rely on *Campie*, but this should not change their core analysis of the issue at hand. R. at 36. Regardless of Ms. Ortega's precise theory under the False Claims Act, the elements of proof remain the same and the District Court's dismissal should have been upheld. *Campie*, 862 F.3d at 901. "Although Escobar clarifies the conditions upon which an implied false certification claim can be made, the four essential elements… remain the same." *Id.* at 901. Regardless, Ms. Ortega did bring this suit under the fraud-on-the-FDA theory and has subsequently failed to properly allege the required elements. R. at 6, 9. Therefore, it is improper for her to bring suit

under this theory, and Mednology urges this Court to reverse the Court of Appeals's decision and dismiss the case for failure to state a claim.

b. Ms. Ortega failed to adequately plead all of the factors required by the False Claims Act.

Four elements must be established in order to incur liability under the False Claims Act. *Campie*, 862 F.3d at at 902. These elements are "(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." *Id.* (citing *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 200-202 (1st Cir. 2016).). At issue on this appeal are the third and fourth elements of materiality and causation. Ms. Ortega has failed to plausibly allege either of these elements under the pleading standards enumerated in *Twombly* and *Ashcroft*, and therefore her claim must be dismissed. To state a plausible claim, the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and Ms. Ortega's allegations fall into this latter category. *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).).

1. Riley Ortega failed to meet the "demanding" materiality standard required by the FCA, and therefore her claim must be dismissed.

"The materiality standard is demanding," and it cannot be satisfied by the vague allegations Ms. Ortega has raised against Mednology. *Escobar*, 842 F.3d at 2003. Ms. Ortega has failed to plausibly allege that Mednology's modification to its

foam was material to the CMS's payment. As the Supreme Court made clear in *Escobar*, "a misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* Therefore, Ms. Ortega cannot merely rely on the allegation that Mednology's conduct violated FDA regulations for her claim that this departure from the regulation is material; she must demonstrate a more concrete relation between the defendant's conduct and the government's decision to issue payment. *D'Agostino v. ev3*, 845 F.3d 1, 7 (1st Cir. 2016); *see also United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017); *In re Plavix Marketing, Sales Practice and Products Liability Litigation No. II*, 332 F.Supp 927, 958 (D.N.J 2017).

Despite this, she does not identify any case in which the FDA or CMS rescinded approval or payment for a product which used PE-PUR foams. R. at 5-6. In fact, she draws the court's attention to the Philips Respironics recall in 2021. R. at 4. Philips Respironics issued a voluntary recall of their devices which also contained PE-PUR foams, and the FDA declined to take further action, encouraging users to continue their use of these products until an alternative treatment was identified. *Foam Testing Summary for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines* (Nov. 12, 2021) https://public4.pagefreezer.com/browse/FDA/19-09-2023T12:39/https:/www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-

health-risks; *Urgent: Medical Device Recall* (last visited Sept. 7, 2024) https://public4.pagefreezer.com/content/FDA/19-09-2023T12:39/https:/www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf.

As stated in *Escobar*, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." 842 F.3d at 2003; *see also Kelly*, 846 F.3d at 334. The Philips recall fits this description, as does the case at hand. After Mednology issued its voluntary recall, much like Philips, the FDA declined to investigate or take further action. R. at 4. Therefore, Ms. Ortega has failed to plausibly allege that Mednology's use of PE-PUR foams had any material impact on the FDA's approval or CMS's coverage.

Similarly, in *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed.Appx. 237, 242 (5th Cir. 2020), the Fifth Circuit relied on this same language from *Escobar* and held that the government's continued payments to a nursing facility after learning of alleged non-compliance with nurse licensing requirements "substantially increase the burden on Plaintiff-Appellant in establishing materiality." Based on this analysis, the FDA's treatment of Philips and Mednology after each company's voluntary recalls increases the already steep burden Ms. Ortega faces in establishing materiality, and she has failed to plead any plausible facts that would indicate that the use of PE-PUR foams was material to the FDA and CMS's approval of the product and subsequent payment.

2. Further, Ms. Ortega failed to establish a causal link between Mednology's alleged fraud and the government's payment.

Ms. Ortega also must establish that Mednology's conduct caused the government to issue payment. [E]ven if the alleged fraudulent representations were material as defined by the FCA, the elements of… fraudulent inducement claims include not just materiality but also causation; the defendant's conduct must cause the government to make a payment." *D'Agnostino*, 845 F.3d at 8-9. The District Court properly evaluated this requirement and found that Ms. Ortega had not properly plead this allegation, and the FDA has not mandated a recall of Sleepternity, much like D'Agnostino wherein the FDA never withdrew approval of the drug at issue. *Id.* at 10. In fact, Ms. Ortega's complaint proved the opposite; once the FDA became aware of Mednology's alleged misconduct in the form of Ms. Ortega's lawsuit, they declined to take any action. The False Claims Act required that plaintiffs establish that the defendant's actions "procured" approval and payment, and this has not been alleged by Ms. Ortega's complaint. R. at 7, 9. This is similar to *United States ex rel. Petratos v. Genentech*, 855 F.3d 481, 490 (3rd Cir. 2017), wherein the plaintiff acknowledged that the FDA "would not 'have acted differently'" regardless of the defendant's reported behavior. Further, in *Petratos*, the Court "do[es] not think it appropriate for a private citizen to enforce [FDA] regulations through the False Claims Act." *Id.*

We respectfully urge the Court to follow the reasoning of *D'Agnostino* and *Petratos*. Straying from this decision would set the precedent that the False Claims

Act can be used to "retroactively eliminate the value of FDA approval" and "second-guess agencies' judgments." *D'Agnostino*, 845 F.3d at 8-9. Were Ms. Ortega's lawsuit to proceed to trial without properly pleading the critical elements of materiality or causation, it would render the FDA and CMS's decision-making powers effectively meaningless at the hands of a jury. One accusation of wrongdoing should not substitute for the regulatory power of these agencies and the experts who make these judgments. Additionally, allowing a jury the power to determine what facts are at issue or are sufficient for the FDA's decision-making would interfere with the FDA's entire regulatory process. *Id.* Juries may be more or less lenient than the FDA, and this would deter some applicants for approval and encourage others to submit extraneous information, creating a backlog in their approval process and potentially slowing critical products hitting the market. *Id.* For these reasons, we implore the Court to dismiss Ms. Ortega's False Claims Act claims for failure to state a claim upon which relief can be granted.

Conclusion

The exceptions to Transylvania's immunity statute are preempted by the FDCA because of its reliance on a federal finding of fraud against the FDA. The compliance section of the immunity statue is also preempted by the FDCA and therefore, whether Ms. Ortega's claims of Mednology's failure to comply with the FDA requirements are found to be plausible is inconsequential. Additionally, Ms. Ortega must satisfy all four elements under the False Claims Act in order to bring such a claim against Mednology, and she failed to establish both materiality and

causation. This Court should reverse the Court of Appeals's judgment in all respects.