No. 24-9176

IN THE

Supreme Court of the United States

NOVEMBER TERM 2024

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES OF AMERICA, EX REL.
RILEY ORTEGA

Respondent.

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

BRIEF FOR PETITIONER

TEAM 3306
Attorneys for Petitioner

QUESTIONS PRESENTED

1. Whether the Fifteenth Circuit Court of Appeals properly held that federal law does preempt a state-law statutory exception that is based on an allegation of the manufacturer fraudulently obtaining FDA approval or allegedly failing to comply with FDA requirements, without actual FDA findings of violation or fraud?

2. Did the Fifteenth Circuit Court of Appeals incorrectly analyze False Claims Act jurisprudence to determine whether a fraud-on-the-FDA framework is a proper legal strategy against a medical device manufacturer in a *qui tam* action?

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STATEMENT OF THE CASE

I. STATEMENT OF THE FACTS

This case is about whether federal agencies actually retain the powers granted to them by Congress, or if they can be usurped by individuals through the judicial system.

Mednology, Inc. (Mednology). Mednology is a medical device manufacturer focused on innovative solutions to help patients improve their sleep. R. at 4. They manufacture the Sleepternity, a state-of-the-art continuous positive airway pressure (CPAP) machine that has unique features that increases patient comfortability and allows for customization to help address joint issues of insomnia and sleep apnea. R. at 3. Sleepternity was approved for marketing as a Class III medical device by the FDA in December 2022. R. at 4. The Centers for Medicare and Medicaid Services (CMS) began reimbursement for the costs of patient use of Sleepternity shortly thereafter. *Id.* After Riley Ortega filed this initial lawsuit, Mednology issued a voluntary recall for Sleepternity CPAP devices that include PE-PUR sound abatement foams. R. at 7. After completion of the recall procedures, Mednology was no longer subject to FDA scrutiny for this matter.

Riley Ortega. Riley Ortega is a citizen of the State of Wohio who has symptoms of sleep apnea, insomnia, and lung inflammation, exacerbated by post-traumatic stress disorder and asthma. R. at 3-4. To help ease her symptoms, she consulted her physician, who prescribed the Sleepternity. R. at 3. Riley Ortega is allergic to isocyanate, a substance that is produced when PE-PUR breaks down. R. at 5-6. Her physician believes that exposure to isocyanate likely contributed to her chronic lung inflammation. *Id.* Riley Ortega brought a products liability action against Mednology, as well as a *qui tam* False Claims Act action.

The FDA. The U.S. Food and Drug Administration (FDA) is the federal agency with a mandate that includes approval of medical devices, as well as enforcing regulations affiliated

with these devices. R. at 3-5. The FDA advises the U.S. Department of Justice on False Claims Act investigations and has their own enforcement mechanisms at their disposal. These enforcement mechanisms include forced recalls and required testing and documentation. *Id*. The FDA previously approved and conducted enforcement relating to the Philips Respironics recall, as well as the recall for Mednology's Sleepternity CPAP device. *Id.* The FDA chose not to intervene further in Mednology's case, upon completion of Mednology's voluntary recall.

Philips Respironics Recall. Philips Respironics (Philips) is a medical device manufacturer that produces ventilators, BiPAP, and CPAP devices. These devices contained polyester-based polyurethane (PE-PUR) foams to be used for sound abatement. R. at 4. Philips conducted a voluntary recall of certain CPAP machines that contained PE-PUR foams, because the FDA determined that PE-PUR foams can break down over time, into volatile organic compounds (VOCs). *Id.*

II. PROCEDURAL HISTORY

Riley's claim. Riley Ortega ("Riley") brought a products liability suit against Mednology for alleged fraudulent production of Sleepternity and conduct to the FDA, on June 21, 2023. R. at 6. Riley asserts that Mednology breached its duty of care and good faith violation of Transylvania's product liability statute. *Id.* Under the statute, Riley asserts that Mednology breached 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 presence of PE-PUR foams in the Sleepternity device. *Id.* Riley also relies on a "fraud-on-the-FDA" theory to bring a False Claims Act ("FCA") (31 U.S.C. §§ 3729–3733 (2024)) action under the Act's qui tam provision (31 U.S.C. § 3730(b)) against Mednology. *Id.* The United States declined to intervene in her FCA action against Mednology. *Id.*

United States District Court for the Southern District of Transylvania. At the district court, Mednology filed a motion to dismiss arguing that subsections (b) and (c) of the Transylvania immunity statute were preempted by the FDCA and that in regards to the FCA claim, fraud-on-the-FDA was not a viable basis for the claim. R. at 9. The district court hear arguments on this motion on September 12, 2023. *Id.* The district court ultimately held that no subsection in the immunity statute was preempted by the FDCA, denied Mednology's motion to dismiss the state law claim, but granted Mednology's motion to dismiss Riley's False Claims Act action, because an FCA claim cannot be based on Mednology's alleged fraudulent conduct to the FDA. R. at 24

Fifteenth Circuit Court of Appeals. In a 2-1 decision, Fifteenth Circuit Court of Appeals ultimately held that subsections (b) and (c) of Transylvania's immunity statute were preempted by the FDCA, overruling the district court. R. at 29, 31. However, the court of appeals denied Mednology's motion to dismiss, affirming the district court, but on different grounds. R. at 25. The court of appeals denied Mednology's motion to dismiss because it determined that Riley had pled sufficient facts–by merely alleging that Mednology had a duty to warn about the presence of PE-PUR foam to overcome the presumption of compliance housed in Transylvania's immunity statute. R. at 35. Finally, the court of appeals denied Mednology's motion to dismiss the FCA claim on the basis that Riley had alleged sufficient facts to prove her FCA claim, reversing the district court's decision.

SUMMARY OF ARGUMENT

At its core, this case fully revolves on federalism. Claims that seek to privately enforce duties owed to the FDA, as Riley seeks to do in this case, are impliedly preempted, regardless of how the claim is labeled. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). However, the 8th Circuit has articulated the "narrow gap" in which a state law claim can survive both explicit and implied preemption. *See Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. 2010). In order to fit into this gap "[t]he plaintiff must be suing for conduct that violates the FDCA (or else [the] claim is expressly preempted by [the FDCA] but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)" *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (emphasis omitted) (citing *In re Medtronic*, 623 F.3d at 1204). Riley's state law claim does not fit through this gap. When the relationship between the FDA and the manufacturer is so inherently federal in nature, the presumption against preemption cannot apply. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). The FDCA preempts the immunity exception found in section (b) of Transylvania's immunity statute because Riley is asking the court to decide if Mednology committed fraud against the FDA, when Congress has clearly reserved that power for the FDA. The *Buckman court* was highly concerned with the federalism implications of state law claims that impede on the FDA's investigatory and police power granted to it by Congress. *See Buckman*, 531 U.S. at 348–49 (explaining the many ways the FDA has been granted police power by Congress and the enforcement mechanisms at its disposal) Absent a finding from the FDA that had Mednology disclosed the change to PE-PUR foam the FDA would have not approved Sleepternity or that Mednology had access to different information than Phillips Respironics indicating that the foam was more dangerous than current studies are saying, Riley has not sufficiently pleaded that Mednology had a duty to warn consumers of any

the presence of and any potential risks associated with PE-PUR foam. The Court should affirm that *Garcia* applies to situations where, as in this case, a plaintiff seeks to neutralize a defendant's immunity from product liability by relying on failure to warn immunity exceptions that are based on allegations of violations of FDA requirements, and not actual finding of any violations by the FDA. *See generally* Lofton v. McNeil consumer & Specialty Pharms., 672 F.3d 372, 380 (5th Cir. 2012) (reasoning that "the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." and adopting Garcia's approach rather than Desiano's approach). Transylvania's products liability immunity exceptions (21 Trans. Comp. Stat. § 630.546(b)–(c)) are preempted by the Food, Drug, and Cosmetics Act and Riley has not pleaded sufficient facts to overcome Transylvania's presumption of compliance for medical device makers under 21 Trans. Comp. Stat. § 630.546(a). The Court should affirm the court of appeals holding that Transylvania's immunity exceptions are preempted and reverse the court of appeals denial of Mednology's motion to dismiss Riley's state law claims.

False Claims Act attaches liability to anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false of fraudulent claim." 31 U.S.C. § 3729(a)(1)(A); 31 U.S.C. § 3729(a)(1)(B). Individuals were given the authority to bring suit against a party knowingly defrauding the government—on behalf of the government—to ensure that the federal government could recoup any funds misappropriated from the public. *See* 31 U.S.C. § 3730(b)(1). Riley Ortega is attempting to fundamentally shift False Claims Act jurisprudence by implying that Mednology, Inc. defrauded the United States

government through misrepresentation during the approval process for the Sleepternity medical device using a fraud-on-the-FDA theory.

Riley alleges that Mednology intentionally misrepresented materials found in the CPAP device in pre-market approval procedures and communications with the U.S. Food and Drug Administration (FDA) and further alleges that this misrepresentation has caused false or fraudulent claims to be submitted to the Centers for Medicare and Medicaid Services (CMS) for payment. R. at 6. Riley claims that without this alleged misrepresentation, CMS would not have approved payment for use of the Sleepternity. R. at 6.

Yet, upon review of the plain text of the False Claims Act, a false claim requires a demand for some sort of tangible payment. *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *11 (S.D.N.Y. Dec. 8, 2021), *aff'd*, No. 22-107, 2022 WL 7785044 (2d Cir. Oct. 14, 2022). Yet, in fraud-on-the-FDA claims, the medical device manufacturer seeking approval by the FDA does not make a request for tangible payment. Rather, they make a request for approval by the agency—a request divorced from payment altogether, because FDA approval does not entitle a manufacturer to a payment. *See id*; *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). Additionally, fraud-on-the-FDA claims undermine the FDA's ability to use discretion in enforcement. The purpose of the False Claims Act is to "[p]rotect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8-9 (1st Cir. 2016). The FDA has tools to ensure compliance, including recalls and additional research requirements. Yet, expansion of the False Claims Act scope undermines the ability of the FDA to exercise this discretion and these enforcement mechanisms.

ARGUMENT AND AUTHORITIES

STANDARD OF REVIEW. This appeal raises two legal questions. The Supreme Court of the United States reviews questions of law de novo. *Pierce v. Underwood*, 487 U.S. 552, 558 (1988) . And any questions of fact are fact are reviewed for clear error. *Monasky v. Taglieri*, 140 S. Ct. 719, 730 (2020). The issue of whether federal law preempts subsections (b) and (c) of Transylvania's immunity statute is a question of law and therefore is reviewed de novo. See *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed de novo."). The dismissal of any claim under the False Claims Act is also reviewed de novo. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017).

I. MEDNOLOGY IS IMMUNE UNDER TRANSYLVANIA'S PRODUCT LIABILITY IMMUNITY STATUTE (21 TRANS. COMP. STAT. § 630.546(A)) BECAUSE THE FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. §§ 301–399I) PREEMPTS TRANSYLVANIA'S IMMUNITY EXCEPTIONS.

The Supremacy Clause of the Constitution provides the basis for federal preemption doctrine. *See Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018); *see also Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). The Supremacy Clause states the federal law is "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. This Court has explained that preemption "'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" meaning preemption can be explicit or implied. *Gade, 505 U.S. at 98 (quoting Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

The FDCA has long provided for premarket approval of new drugs. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). However, before 1976, the introduction of new medical devices was left to the power of the states. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). Congress

enacted the Medical Device Amendments to the FDCA, in 1976, which "swept back some state obligations and imposed a regime of detailed federal oversight." *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2013) (citing *Riegel,* 552 U.S. 312 at 316).

Three Supreme Court cases address preemption under the Medical Device Amendments of the FDCA, Medtronic, *Buckman*, and *Riegel*. *Medtronic* and *Riegel* involved express preemption, and *Buckman* involved implied preemption. In *Medtronic*, "five Justices concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323-24 (citing *Medtronic*, 518 U.S. at 512 (opinion of O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ.); *id*. at 503-05 (opinion of Breyer, J.)). However, the federal laws and regulations at issue in *Medtronic* did not impose device-specific requirements. *Medtronic*, 518 U.S. at 492-94, 500-01. The Court in *Riege*l held that the FDCA preempted common-law claims challenging the safety and effectiveness of a medical device that had received premarket approval from the FDA. Unlike *Medtronic* and *Riegel*, this case turns on whether Transylvania's immunity statute is impliedly preempted, and thus *Buckman* should guide the Court's analysis.

The FDCA provides that states may not establish requirements that are "different from, or in addition to, any requirement applicable under [the FDCA] to the device." 21 U.S.C. § 360k(a). Further, this Court has read Section 337(a) of the FDCA to be "clear evidence that Congress intended the [FDCA] be enforced *exclusively* by the Federal Government."–impliedly preempting state law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001); *see* 21 U.S. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [21 U.S.C. §§ 301 et seq.] shall be by and in the name of the United States.") (emphasis added. This means the authority to bring a claim solely based on

noncompliance with the FDCA lies with "the Federal Government rather than private litigants," therefore impliedly preempting state law claims of the same basis. *Buckman*, 531 U.S. at 349 n.4.

Claims that seek to privately enforce duties owed to the FDA, as Riley seeks to do in this case, are impliedly preempted, regardless of how the claim is labeled. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017). However, the 8th Circuit has articulated the "narrow gap" in which a state law claim can survive both explicit and implied preemption. *See Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. 2010). In order to fit into this gap "[t]he plaintiff must be suing for conduct that violates the FDCA (or else [the] claim is expressly preempted by [the FDCA] but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)" *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (emphasis omitted) (citing *In re Medtronic*, 623 F.3d at 1204). Riley's state law claim does not fit through this gap.

A. The Court of Appeals correctly applied the presumption against preemption to Riley's state tort claims against Mednology.

The Court of Appeals was correct to not apply the presumption against preemption. Transylvania's product liability immunity statute shields medical device manufacturers from product liability and if the FDA has approved the drug or medical device in question stating:

> If the… medical device was approved for efficacy and safety by the United States Food and Drug Administration, and the… medical device was in compliance with the [FDA]'s approval at the time the… medical device left the control of the manufacturer or distributor. Such…device is presumed to have been in compliance with the [FDA]'s approval, and the party challenging a manufacturer's or distributor's immunity under this statute bears the burden of rebutting this presumption.

21 Trans. Comp. Stat. § 630.546(a). States have historically "exercised their police powers to protect the health and safety of their citizens." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). However, when the relationship between the FDA and the manufacturer is so inherently federal

in nature, the presumption against preemption cannot apply. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

In *Buckman v. Plaintiffs' Legal Committee*, the Court explained that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" 531 U.S. 341, 347 (2001) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The Court in *Buckman* clarified 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." *Id* at 348.In *Buckman*, the Court held that the plaintiffs' claim was preempted by the FDCA because the claim was based on the assertion that the defendant made fraudulent representations to the FDA and concluded that the presumption against finding federal preemption of state-law claim did not apply. *Id.* at 343–44, 347–48. The Court explained that to apply the presumption against preemption would disrupt the "delicate balance of statutory objectives" that "amply empowers the FDA to punish and deter fraud against [the FDA]." *Id.* The federal relationship between the FDA and medical device manufacturer seen in *Buckman*, can also be seen in this case.

As the Court of Appeals noted "[j]ust as *Buckman* involved the FDA regulating a corporation that manufactured orthopedic bone screws, the entity being regulated in this case by the FDA is Mednology." R. at 27; *see also Buckman*, 531 U.S. 341, 343. Like in *Buckman*, the FDA regulates how Mednology obtains approval for marketing medical devices it manufactures. *See Id.* at 343–44. Because the Court in *Buckman* concluded that the presumption against preemption did not apply to its case, The Court should affirm the Court of Appeals and hold that the presumption does not apply in this case.

B. The Food, Drug, and Cosmetic Act preempts the immunity exception provided in 21 Trans. Comp. Stat. §630.546(b) because Riley is asking the Court to determine if Mednology committed fraud against the FDA. This raises federalism concerns by allowing the courts to interfere with the FDA's Congress granted power to police fraud.

The FDCA preempts the immunity exception found in section (b) of Transylvania's immunity statute because Riley is asking the court to decide if Mednology committed fraud against the FDA, when Congress has clearly reserved that power for the FDA. Congress has given the FDA substantial authority to investigate potential violations of the FDCA and a range of mechanisms for enforcing the Act including, but not limited to civil penalties. 21 U.S.C. §§ 332-34, 372. While private citizens may request that the FDA take action on potential violations. 21 C.F.R. §§ 10.25(a), 10.30. Private enforcement is explicitly prohibited. 21 U.S.C. § 337(a).

Instead of bringing a state-law fraud-on-the-FDA claim, like the plaintiffs in *Buckman*, Riley is using an allegation of fraudulent representation from Mednology to the FDA to neutralize Mednology's immunity under Transylvania's product liability Statute. *See Buckman*, 531 U.S. at 346–47; R at 28; *See generally* 21Trans. Comp. Stat. § 630.545. The Court of Appeals was correct to address the distinction between a Second Circuit case–*Desiano*– and a Sixth Circuit case–*Garcia*–and ultimately use *Garcia* to guide its analysis. R. at 28. As noted by the Court of Appeals, both cases examine whether the same immunity exception of a Michigan statute[1], which is extremely similar to that of Transylvania, was preempted by the FDCA. *Id.; see generally Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). While *Desiano* and *Garcia* both address the issue of

[1] *See* Mich. Comp. Laws § 600.2946(5)

preemption under the FDCA, *Garcia properly* applies the precedent set in *Buckman*, is more factually on point and should be used to guide the Courts' preemption analysis.

In *Garcia*, the plaintiff had been using a FDA approved medication that ultimately caused liver failure and required the plaintiff to undergo a liver transplant. *Garcia*, 385 F.3d 961, 963. The plaintiff sued the drug manufacturer for making and selling an unsafe product under Michigan's product liability statute and then, like in our case, the defendant voluntarily withdrew the drug from the market. *Id.* The defendant filed a motion to dismiss based on Michigan's product liability statute's immunity provisions, like Mednology. *Id.* As the Court of Appeals noted, the Michigan products liability statute and its immunity provisions are strikingly similar to this case. R. at 28. The key factual difference in *Desiano*, is that the FDA had previously requested that the drug maker withdraw the drug in question from the market. *Desiano*, 467 F.3d 85, 88 (citing *Desiano v. Warner-Lambert Co.*, 326 F.3d 339,344 (2d Cir. 2003). In *Garcia*, and in this case, the drug or device was withdrawn voluntarily. *Garcia*, 385 F.3d 961, 964. Finally, while both cases address the *Buckman* decision, only *Garcia* properly applies the precedent set by this court by also addressing the policy concerns raised in *Buckman* about interfering with the FDA's responsibility to police fraud. *Id.* at 966.

The *Buckman court* was highly concerned with the federalism implications of state law claims that impede on the FDA's investigatory and police power granted to it by Congress. *See Buckman*, 531 U.S. at 348–49 (explaining the many ways the FDA has been granted police power by Congress and the enforcement mechanisms at its disposal). The flexibility of the FDA's enforcement is "a crucial component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman,* 531 U.S. at 349. For example, the FDA simultaneously maintains the exhaustive Pre-market Approval and § 510(k)

processes[2] "in order to ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time." *Id.* at 349–50. *Buckman* held that Congress intended that the Medical Device Amendments of the FDCA be enforced exclusively by the Federal Government. *Id.* at 352. With these policy concerns in mind, the Court should follow the Court of Appeals and use *Garcia* to guide its analysis and affirm the Court of Appeals decision that subsection (b) is preempted by the FDCA.

1. *The Food, Drug, and Cosmetic Act preempts the immunity exception provided in 21 Trans. Comp. Stat. §630.546(c) because Riley is relying on an allegation of fraud on the FDA, not an actual finding of fraud by the FDA to neutralize Mednology's immunity.*

Unlike subsection (b), subsection (c) does not concern whether a drug or medical device manufacturer committed fraud toward the FDA, instead, if it applies, it neutralizes a medical device manufacturer's immunity from products liability suits if the manufacturer "fails to warn about the dangers or risks of the drug or medical device as required by the FDA." *See* 21 Trans. Comp. Stat. § 630.546(b)– (c).

The district court improperly characterized the scope of the FDCA's preemption of state law. The FDCA preempts any state law that attempts to undermine the federal regulatory scheme of the FDA as correctly noted by the court of appeals. R. at 31. (adopting the Sixth Circuit's analysis in *Garcia*, instead of the Second Circuit's analysis in *Desiano*). While the district court

[2] For more information on the FDA's Pre-Market Aproval Process and § 510(k) exceptions, *see* *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma#overview*

evaluated the circuit split regarding if the FDCA preempts failure to warn claims[3], as the court of appeals aptly noted, this is not a failure to warn case. R. at 30. Instead, this case is about whether the FDCA preempts a failure to warn provision that *neutralizes* a medical device manufacturer's statutory immunity from a products liability lawsuit. *See* 21 Trans. Comp. Stat. § 630.546(a), (c).

The court of appeals correctly rejected the district court's application of *Desiano* because it incorrectly focused on if Mednology's alleged violations of the FDA's requirement of warning about risks or dangers involved with Sleepternity were the sole basis for Riley's state law claims. R. at 30. Conversely, the court of appeals properly focused on the federalism concerned with state courts interfering with the FDA's police power over its regulated entities, like Mednology. R. at 31. The Court should affirm that *Garcia* applies to situations where, as in this case, a plaintiff seeks to neutralize a defendant's immunity from product liability by relying on failure to warn immunity exceptions that are based on allegations of violations of FDA requirements, and not actual finding of any violations by the FDA. *See generally* Lofton v. McNeil consumer & Specialty Pharms., 672 F.3d 372, 380 (5th Cir. 2012) (reasoning that "the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." and adopting Garcia's approach rather than Desiano's approach). By allowing a defendant's immunity to be neutralized only when the FDA has found there to be a violation of the FDCA, the policy concerns raised in *Buckman*, are taken

[3] The Eleventh and Eighth Circuits have held that failure to warn claims are preempted by the FDCA. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017) (concluding that the plaintiff's failure to report theory for his negligence claim was impliedly preempted by federal law); *Bryant v. Medtronic, Inc. (In re Medtronic, Inc*.), 623 F.3d 1200 (8th Cir. 2010) (holding that federal law preempted the plaintiff's failure to warn and related claims). Conversely, the Fifth and Ninth Circuits have held that failure to warn claims are not impliedly preempted by the FDCA. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013); *See also Grace M. Zogaib, Note, Preemption After Buckman: State Tort Failure to Warn Claims Based on Lack of Disclosure to FDA, 21 Ave Maria L. Rev. 236, 242–61 (2023)* (reviewing the circuit split over the preemption of state law failure to warn tort claims and explaining how the split should be resolved).

into consideration and resolved, while still allowing plaintiffs to utilize immunity neutralizing provisions in state products liability statutes. *See generally Buckman*, 531 U.S. 341 (2001).

Therefore, subsection (c) and other failure to warn immunity exceptions should be preempted so long as it impedes in the federal regulatory system created by Congress. *See Garcia*, 385 F.3d at 966 ("[E]xemptions are invalid as applied in some settings (e.g., when a plaintiff asks a state court to find bribery or fraud on the FDA)"). Unless a plaintiff relies on an independent finding that the defendant has violated requirements to warn about the dangers or risks of the drug or medical device by the FDA, unlike in this case. See *Garcia*, 385 F.3d at 966 (concluding that claims based on federal findings of bribery or fraud on the FDA are valid). The Court should affirm the court of appeals decision and hold that "[i]n this case, federal law preempts subsection (c) because Riley's reliance on the subsection is not based on the FDA's finding of Mednology's failure to warn." R. at 31.

2. *The Court should reverse the District Court's and Court of Appeals decision and grant Mednology's motion to dismiss because Riley has not alleged sufficient facts to plausibly rebut the presumption that Sleepternity complied with the requirements for FDA approval when it left Mednology's control.*

The court of appeals was incorrect to accept that because Phillips CPAP machines had been recalled voluntarily because of potential risks with PE-PUR sound-abatement foam inside the machine, Sleepternity's use of PE-PUR sound-abatement foam required a mandatory disclosure to the FDA. Riley has not pleaded sufficient facts to overcome the presumption of compliance granted to Mednology's Sleepternity product and therefore the court should grant Mednology's motion to dismiss. Dismissal of a plaintiff's complaint is permitted when "it is

clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) (citing *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957)). To withstand a motion to dismiss, a plaintiff is required to plead "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when "the plaintiff pleads 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). However, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555).

Under Transylvania's immunity statute, medical device manufacturers like Mednology will not receive immunity from any claims asserted under Transylvania's product liability statute if they fail to comply with the requirements for obtaining the FDA's approval. 21 Trans. Comp. Stat. § 630.546(a). However, medical devices are "presumed to have been in compliance with the [FDA]'s approval". *Id.* The party challenging a manufacturer's immunity under Transylvania's Product Liability Statute bears the burden of rebutting the presumption that the device manufacturer's product was in compliance with the FDA's approval when the device left the manufacturer's control. *Id.*

Mednology manufactures Sleepternity. *See generally* R. at 4. Sleepternity is a state-of-the-art continuous positive airway pressure (CPAP) machine that has several features unique to Sleepternity. R. at 3. These additional features are unique to Sleepternity making it revolutionary in that it can also help users to effectively reduce insomnia. *Id.* Sleepternity was approved by the FDA as a Class III medical device in December of 2022. R. at 3–4. Like Mednology, Phillips Respironic manufactures many CPAP machines. R. at 4. In June 2021, Philips initiated a

voluntary recall notification for certain CPAP sleep therapy devices address potential health risks related to the PE-PUR sound abatement foam in their devices. *See* Phillips Respironics*, Explained: The voluntary Philips Respironics sleep and respiratory care devices recall* (2021). Philips became aware of the potential issues with using PE-PUR foam and its potential significance in early 2021. *Id.* Philips took actions that led to the voluntary recall in June 2021. *Id.* The recall decision was made "after careful consideration of a reasonable worst-case scenario, rather than deferring the recall decision to conduct more definitive testing." *Id*. Phillips has continued extensive testing and research regarding PE-PUR foam in its devices and based on their research to date, "third-party experts concluded that use of the sleep therapy devices is not expected to result in appreciable harm to health in patients," though research is still ongoing. *Id.*

The entire basis for Riley's claim is that because Sleepternity's product contains the same foam as the Phillips products, Mednology had a duty to warn its customers about the presence of the foam, even though the research that has been conducted to date has shown that that the presence of the foam in the device doesn't presently create a risk of harm to patients. This is not enough to reasonably imply that Mednology had a duty to warn consumers about its use of PE-PUR foam. A voluntary recall from another CPAP manufacturer is not enough to rebut the presumption of compliance. The FDA did not mandate a recall; Phillips elected to initiate the recall and is working with the FDA–in good faith– to ensure that adequate research on the effects of PE-PUR found abatement foam in CPAP machines is done. *Id*. At present, Riley has provided no facts that reasonably imply that the FDA would not have approved Sleepternity had it known that PE-PUR foam was in the machine. What Riley has pleaded is that PE-PUR is contained within the Sleepternity machine, like the Phillips machines. R. at 4. Had the Phillips machines

been recalled by the FDA, and not been voluntary, providing the Phillips recall would likely have been enough to rebut the presumption of compliance. This is not the case at hand.

Further, even if the fact the Phillips voluntarily recalled its CPAP machines is enough, Riley has not even pleaded that the use PE-PUR foam in Sleepternity's machine is at all similar to the foam in Phillips Respironics' products. There is no evidence that the foam is housed in a similar location to that in the Phillips products or used in the same quantities as the Phillips products. All that Riley has alleged, at this point, is that the Phillips Respironics' products were voluntarily recalled because they contained PE-PUR foam. Riley has not alleged anything more than a conclusory statement about the connection between another medical device company's voluntary recall and an allegation that Mednology had a duty to warn consumers. *See generally Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555) (holding that mere recitations of the elements of a cause of action supported by conclusory statements do not satisfy pleading requirements).

Absent a finding from the FDA that had Mednology disclosed the change to PE-PUR foam the FDA would have not approved Sleepternity or that Mednology had access to different information than Phillips Respironics indicating that the foam was more dangerous than current studies are saying, Riley has not sufficiently pleaded that Mednology had a duty to warn consumers of any the presence of and any potential risks associated with PE-PUR foam. The Court should reverse the court of appeals decision and grant Mednology's motion to dismiss Riley's state law claims because Riley has failed to plead sufficient facts against Sleepternity's presumption of compliance under 21 Trans. Comp. Stat. § 630.546(a) to satisfy her burden of proof and therefore maintaining Mednology's immunity.

In conclusion, Transylvania's products liability immunity exceptions (21 Trans. Comp. Stat. § 630.546(b)–(c)) are preempted by the Food, Drug, and Cosmetics Act and Riley has not pleaded sufficient facts to overcome Transylvania's presumption of compliance for medical device makers under 21 Trans. Comp. Stat. § 630.546(a). The Court should affirm the court of appeals holding that Transylvania's immunity exceptions are preempted and reverse the court of appeals denial of Mednology's motion to dismiss.

II. FIFTEENTH CIRCUIT ERRONEOUSLY HELD THAT A RELATOR MAY RELY ON A FRAUD-ON-THE-FDA THEORY IN AN ACTION UNDER THE FALSE CLAIMS ACT.

C. Statutory Plain Language Requires Some Demand of Tangible Payment.

The False Claims Act attaches liability to anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false of fraudulent claim." 31 U.S.C. § 3729(a)(1)(A); 31 U.S.C. § 3729(a)(1)(B). The statute defines a claim as "any request or demand, whether under contract or otherwise, for money or property." 31 U.S.C. § 3729(b)(2). As such, the plain language reading of the statute requires a defendant to make a "request of some sort of tangible payment from the government." *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *11 (S.D.N.Y. Dec. 8, 2021), *aff'd*, No. 22-107, 2022 WL 7785044 (2d Cir. Oct. 14, 2022). Yet, in fraud-on-the-FDA claims, the medical device manufacturer seeking approval by the FDA does not make a request for tangible payment. Rather, they make a request for approval by the agency—a request divorced from payment altogether, because FDA approval does not entitle a manufacturer to a payment. *See id*; *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). Without such a tangible payment, the

Court should find that the fraud-on-the-FDA theory does not meet the plain meaning of the statute.

D. Fraud-on-the-FDA Arguments Rely on Stretching the Causal Chain.

When a device manufacturer or other defendant's alleged fraudulent behavior induces a government actor to enter into a contract with said defendant, the claims submitted in adherence to that contract qualify as a false claim. *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412, 417 (D.C. Cir. 2021). However, alleged fraudulent behavior levied against a defendant under a fraud-on-the-FDA theory stretches the causal chain too far, rendering causation incomplete. The U.S. District Court for the Southern District of New York did not apply the fraudulent inducement theory to cases where parties do not enter into a contract. *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *10 (S.D.N.Y. Dec. 8, 2021), *aff'd*, No. 22-107, 2022 WL 7785044 (2d Cir. Oct. 14, 2022). Mednology did not enter into a contract with CMS when it sought FDA approval for the Sleepternity and, as such, the Court should find that this causal chain stretches too far for an adequate claim.

Further, the District Court of Transylvania also finds that a causal link between Mednology's alleged misrepresentation to the FDA and the payments made to CMS should be required for a successful claim. R. at 20-21. The District Court found that the "[d]efendant's conduct must 'cause the government to make a payment or to forfeit money owed.'" R. at 20 (citing *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016)). Again, the remove from Mednology's request for FDA approval and the CMS payments shows the stretch in the causal chain that should render Riley's claim too tenuous to survive. In fact, the District Court found that Riley failed to establish causation element of her claim. R. at 21. In fact, her complaint did

not show that the FDA demanded a recall of Sleepternity devices or withdrew approval of the device upon her report of Mednology's allegedly fraudulent conduct, let alone CMS's withdrawal of coverage for the device. *Id*. Regardless of the extent of the causal chain, the District Court found that Riley did not prove causation at all. R. at 23.

E. Fraud-on-the-FDA Arguments Circumvent FDA Enforcement Mechanisms.

Riley contends that the FDA would never have allowed Mednology to market Sleepternity CPAP devices to consumers, had the FDA known that the devices included PE-PUR foam rather than silicone-based foam. R. at 19. However, Riley does not support this assertion with any particularity. Rather, the District Court highlighted the Philips Respironics voluntary recall of CPAP devices that included PE-PUR foam for sound abatement, initially announced in June 2021. R. at 4. Since the initial voluntary recall, the FDA has worked with Philips Respironics to determine mitigation plans and observed the company's internal PE-PUR testing and analysis to evaluate the risks posed to users of the CPAP devices. *FDA Activiites Related to Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, 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 (last updated Apr. 2024).

Despite the voluntary recall, the FDA also released guidance for patients that discussed the logistics of whether to cease use of the Philips CPAP machines with PE-PUR. The FDA advised that, "[f]or some patients, stopping use of the recalled device may involve greater risk than continuing its use" and suggested that patients discuss the best options for them with their physician. *Recommendations for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-

machines-and-cpap-machines/recommendations-recalled-philips-ventilators-bipap-machines-and-cpap-machines#should (last updated Apr. 2024). So, despite the risks, the FDA is certainly not mandating patients cease use of the devices and sees potential value in their use.

3. FDA is Aware of Mednology's Use of PE-PUR and Opted Not to Intervene.

The FDA was made aware of the Mednology's use of PE-PUR—at the very latest—when Riley filed the complaint in this case. Mednology conducted a voluntary recall of Sleepternity pursuant to 21 C.F.R. § 7.40(b), and the FDA subsequently decided not to continue with an investigation of Mednology's alleged misrepresentation and chose not to intervene. R. at 7. This discretion is important, because it allows the FDA to focus their resources on mitigation of the greatest risks and protects device manufacturers, in particular, when they make a judgment call that could cut either way, in terms of FDA transparency.

Device manufacturers are not always required to file a new premarket notification with the FDA for materials changes. *See Deciding When to Submit a 510(k) for a Change to an Existing Device*, FDA, https://www.fda.gov/media/99812/download (last updated Oct. 25, 2017). The FDA has non-binding guidance that it provides the device manufacturers and the general public to help companies determine the best option when they make a materials change. The decision-making flowchart for when a manufacturer makes a materials change includes opportunities for manufacturers to complete documentation, rather than an entirely new pre-market approval or 510(k) application. *Id*.

The mind can conjure reasonable examples of when the FDA may desire to exercise enforcement discretion. For instance, if a device manufacturer is making a good faith attempt to adhere to FDA requirements and conducts a voluntary recall, the FDA may determine that this is enough of an action to keep the public safe. Another example may be when the FDA's preferred

method of repair is also not a viable option. For instance, in late 2021, the FDA also received word that a silicone-based foam used in a device marketed outside of the United States that was similar to the recalled Philips CPAP device also failed a safety test for the release of volatile organic compounds (VOCs). *Recommendations for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, FDA, https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/recommendations-recalled-philips-ventilators-bipap-machines-and-cpap-machines#should (last updated Apr. 2024). Penalizing Mednology for using PE-PUR foam rather than the originally planned silicone-based foam through a False Claims Act inquiry may not have been the highest priority for the FDA.

4. *Allowing This Theory to Prevail Would Allow for a Jury's Decision to Supersede Agency Discretion*.

The purpose of the False Claims Act is to "[p]rotect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8-9 (1st Cir. 2016). Riley is asking the Court to make assumptions about the FDA's desires, despite a wide berth of discretion afforded to the agency. By allowing a relator to use a fraud-on-the-FDA theory to win the day, the Court would choose to allow "a jury of six people [to] effectively require that a project largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id*. Allowing an individual to intervene in this manner takes the discretion out of the hands of the experts and into the hands of the judiciary.

While the judiciary may have broad expertise and an ability to understand the legal factors at play, mixing the spheres of influence may be unnecessary when adequate systems are in place. Despite a statement of interest by the U.S. Department of Justice urging the court to

acknowledge a fraud-on-the-FDA theory, the U.S. District Court for the Southern District of Florida found that alleged misrepresentation by a medical device company need not be addressed through expansion of False Claims Act jurisprudence, because enforcement mechanisms exist to address issues with misrepresentation to the FDA. United States' Statement of Interest as to Def.'s Mot. to Dismiss at 5, United States ex rel. Crocano v. Trividia Health Inc., No. 22-CV-60160-RAR, 2022 WL 612632 (S.D. Fla. Jun. 3, 2022); Order Granting Motion to Dismiss at 14-15, United States ex rel. Crocano v. Trividia Health Inc., 22-V-60160-RAR (S.D. Fla. July 18, 2022). The Court should validate the separation of enforcement mechanisms, allowing the FDA to maintain their ability to use agency discretion as they deem appropriate.

II. FIFTEENTH CIRCUIT SHOULD APPLY ALL *ESCOBAR* FACTORS TO DETERMINE WHETHER A FRAUD-ON-THE-FDA CLAIM SHOULD SURVIVE.

The U.S. Supreme Court identified essential elements of liability under the False Claims Act in *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 188-93 (2016). These essential 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* (emphasis added). The U.S. District Court for the Southern District of Transylvania found the *Escobar* factors compelling and thus sided with Riley, as the Ninth Circuit applied the *Escobar* factors in *Campie.* R. at 36. Yet, the Ninth Circuit in *Campie* only applies the materiality factor. In order to adequately apply the *Escobar* factors in False Claims Act analysis, the Court should apply all of the factors. Most importantly, the Court should determine whether falsity and causation exist. As previously discussed, the logical leap that it takes to say that FDA approval induces claim for payment by CMS is not reasonable. As such,

the Court should find that the fraud-on-the-FDA theory of False Claims Act jurisprudence should not survive *Escobar* analysis.

CONCLUSION

In conclusion