No. 24-9176

IN THE

Supreme Court of the United States

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES EX REL. RILEY ORTEGA,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE SEVENTEENTH CIRCUIT

BRIEF FOR RESPONDENT

Team 3324
Counsel of Record

QUESTIONS PRESENTED

1. Is Transylvania's immunity defense scheme preempted by federal law when Transylvania is regulating within the realm of traditional state interests and the immunity defense scheme is consistent with the FDCA's purpose of protecting public health and safety?
2. Can Mr. Ortega rely on the fraud-on-the-FDA theory to bring a False Claims Act action against Petitioner, where Petitioner's failure to disclose it fraudulently secured FDA approval of Sleepternity caused the Government through the Centers for Medicare and Medicaid Services to pay fraudulent reimbursement claims?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

U.S. Supreme Court Cases

U.S. Court of Appeals Cases

Other Court Cases

Secondary Sources

Constitutional and Statutory Provisions

OPINIONS BELOW

This matter arises from an opinion issued by the United States Court of Appeals for the Seventeenth Circuit on April 1, 2024, docketed as Case No. 24-1000. *See* R. at 25. An earlier opinion, related to this instant matter, was decided by the United States District Court for the Southern District of Transylvania on October 15, 2023, docketed as Case No. 24-cv-12121. *See* R. at 2.

CONSTITUTIONAL PROVISIONS & STATUTES INVOLVED

The central constitutional provision is the Supremacy Clause, U.S. Const. art. VI, cl. 2. The central statutory provisions are the False Claims Act, specifically 31 U.S.C. §§ 3729-3730(b), and the State of Transylvania's products liability statute, 21 Trans. Comp. Stat. §§ 630.545-.546 (2024). Each of these provisions are set forth in relevant part in Appendix A.

STATEMENT OF THE CASE

Riley Was Prescribed Sleepternity to Treat her PTSD Symptoms

Riley Ortega, Respondent, is a United States Army veteran who has post-traumatic stress disorder (PTSD) due to her military experience. R. at 3. Because of her PTSD, Riley suffers from insomnia and sleep apnea symptoms. R. at 3. Riley's somnologist prescribed her Sleepternity, a sleep-inducing medical device manufactured by Mednology, Inc., Petitioner, to help alleviate her unfortunate symptoms. R. at 3.

The prospect of Sleepternity—a state-of-the-art continuous positive airway pressure (CPAP) machine—was initially promising for Riley. R. at 3. Sleepternity contained numerous unique features that made "the medical device revolutionary in

that it can also help users to effectively reduce insomnia." R. at 3. Given the revolutionary nature of Sleepternity, the Food and Drug Administration (FDA) approved the CPAP machine for marketing as a Class III medical device on December 30, 2022. R. at 3-4. Since Sleepternity received FDA approval, the Centers for Medicare and Medicaid Services (CMS) began providing coverage to those prescribed Sleepternity. R. at 4.

Petitioner Cut Sleepternity's Manufacturing Costs at the Expense of Riley's Health

After using Sleepternity, Riley experienced severe asthma attacks that required her to go to the emergency room. R. at 4. The emergency room and primary care physicians believed that her asthma attacks may be a side of effect of Sleepternity and, consequently, that Riley should stop using Sleepternity. R. at 4-5. Riley followed her doctors' recommendations, and although her asthma symptoms subsided, her previous asthma attacks caused chronic inflammation in her lungs. R. at 5. Unfortunately, Riley's sleep apnea symptoms returned and continue to this very day. R. at 5.

Riley assumed Sleepternity was just one of the many sleep apnea treatments unsuitable for treating her symptoms. R. at 5. However, that was not the case. Riley's brother, Jim, works for Petitioner. R. at 5. Jim told Riley that Petitioner *only* used silicone-based sound abatement foam in its Sleepternity device to secure FDA approval. R. at 4. After receiving FDA approval, Petitioner instantly replaced the silicone-based foam with polyester-based polyurethane (PE-PUR) foam to save manufacturing costs. R. at 5. Petitioner made this replacement without notifying

any outside individuals or entities, including the FDA, CMS, or Sleepternity users. R. at 4.

PE-PUR foams can present *significant health risks*. R. at 4. According to the FDA, PE-PUR foam breaks down over time, and when it does, users can breathe in or swallow volatile organic compounds (VOCs). R. at 4. Due to the potential significant health risks associated with breathing in VOCs, one medical device company, Philips Respironics, recalled its CPAP machines containing PE-PUR and replaced the foam with a safer alternative—silicone-based foam. R. at 4.

The revelation that Petitioner's Sleepternity device contains PE-PUR foam suddenly made Riley's symptoms make sense. R. at 5-6. Riley is allergic to isocyanate, a VOC found in degraded PE-PUR foam. R. at 5. Although Riley's doctors knew she was allergic to isocyanate, they never considered her allergy to be the root cause of her asthma attacks because Sleepternity's warning label did not disclose the presence of isocyanates in the device. R. at 5.

Petitioner Suddenly Recalled Sleepternity Following Riley's Lawsuit

On June 1, 2023, following the discovery of PE-PUR foam in Sleepternity, Riley brought a products liability action against Petitioner and reported Petitioner's fraudulent conduct to the FDA. R. at 6. Riley alleged Petitioner violated Transylvania's product liability statute, 21 Trans. Comp. Stat. §§ 630.545-.546, by breaching (1) its duty of care and good faith, (2) its duty to disclose its modifications to the FDA, and (3) its duty to warn about the dangers associated with PE-PUR foam. R. at 6. Further, Riley relied on the fraud-on-the-FDA theory to bring a qui

tam action under the False Claims Act (FCA), 31 U.S.C. §§ 3729-30. R. at 6. The United States declined to intervene in Riley's FCA action. R. at 6.

Shortly after receiving a copy of Riley's complaint, Petitioner voluntarily recalled Sleepternity from the market. R. at 7. Consequently, the FDA stopped investigating Petitioner's conduct to "focus on investigating other allegedly defective products in the marketplace that have not been recalled." R. at 7.

Procedural History

After receiving Riley's complaint, Petitioner filed a Fed. R. Civ. P 12(b)(6) motion to dismiss. R. at 9. In its motion to dismiss, Petitioner asserts that (1) federal law preempts the provisions of Transylvania's product liability statute that Riley relies on, and (2) its allegedly fraudulent conduct cannot serve as a valid basis for an FCA claim. R. at 2, 9.

The United States District Court for the Southern District of Transylvania denied Petitioner's motion to dismiss Riley's state products liability claims. R. at 2. However, the Southern District of Transylvania granted Petitioner's motion concerning Riley's FCA claims. R. at 2-3. Riley and Petitioner appealed to the United States Court of Appeals for the Seventeenth Circuit. R. at 25. The Seventeenth Circuit affirmed the denial of Petitioner's motion to dismiss Riley's state products liability claims. However, the Seventeenth Circuit reversed the district court's decision to grant Petitioner's motion to dismiss Riley's FCA claim. R. at 25. This Court granted certiorari on August 1, 2024. R. at 43.

SUMMARY OF THE ARGUMENT

Petitioner deceived the FDA—it used silicone-based foam in Sleepternity solely to secure FDA approval and instantly upon receiving such approval, replaced the foam with a material linked to significant health risks. R. at 4-5. Even worse, Petitioner failed to disclose this fact to anyone of importance—namely, the FDA, CMS, or Sleepternity users. R. at 4. Petitioner's failure to disclose this critical fact harmed individuals like Riley and also caused the government, through CMS, to pay fraudulent reimbursement claims. Consequently, Riley brought state products liability and FCA claims against Petitioner. To avoid liability, Petitioner claims that (1) the FDCA preempts Transylvania's products liability statute and (2) the fraud-on-the-FDA theory Riley relied on is not a valid basis of liability under the FCA.

Subsections (b) and (c) of Transylvania's products liability statute are not preempted by federal law because Riley is suing for conduct that violates a federal requirement (avoiding express preemption)–namely, violations of disclosure and warning requirements–but the violation of the federal requirement is not the sole basis of her claim (avoiding implied preemption)–rather, the violation of the federal requirements helps her overcome the immunity defense, not impose liability.

Transylvania is legislating in a field traditionally occupied by the States and the presumption against preemption applies to preserve the constitutional safeguards of state sovereignty. Transylvania did not have to provide medical device manufacturers with an immunity defense at all, and defining the confines of such immunity by providing limitations on the defense is well within Transylvania's

police powers. Preempting subsections (b) and (c) would improperly intrude on state sovereignty by dismantling Transylvania's immunity defense scheme—especially when subsections (b) and (c) are interwoven into the purpose and design of subsection (a).

Even if subsection (b) and (c) are preempted, Petitioner does not satisfy the requirements to receive immunity under subsection (a). When Sleepternity received premarket approval from the FDA, Petitioner provided that Sleepternity would utilize silicone-based foam. After obtaining FDA approval, however, Petitioner switched to PE-PUR foam. By switching the foam base, Petitioner clearly was not in compliance with the premarket approval received from the FDA.

With respect to Riley's FCA claim, this Court should first find that the fraud-on-the-FDA theory is a valid basis of liability under the FCA. Any conclusion to the contrary would allow Petitioner to escape liability under the FCA despite falsely and fraudulently certifying to CMS that it had complied with all the FDA's approval requirements. To avoid this result, this Court should rely on Supreme Court and Ninth Circuit caselaw to formally recognize the fraud-on-the-FDA theory.

This Court should further find that Riley successfully stated a claim for relief under the FCA using the fraud-on-the-FDA theory. CMS required Sleepternity to comply with all FDA approval requirements—material requirements Petitioner had actual knowledge of or, at the very least, deliberately ignored or recklessly disregarded. Despite knowing this, Petitioner discretely modified Sleepternity after receiving FDA approval by adding an unsafe material the FDA has previously

expressed concern over without notifying the FDA, CMS, or users of its device. Thus, Petitioner *knowingly* failed to disclose its violation of the *material* FDA approval requirements, *causing* CMS to pay *fraudulent* claims.

Therefore, this Court should affirm the Seventeenth Circuit's denial of Petitioner's motion to dismiss Riley's state products liability and FCA claims.

ARGUMENT

Petitioner fraudulently secured FDA approval for Sleepternity—namely, Petitioner used silicone-based foam solely to secure approval, and after receiving such approval, *discretely* replaced it with PE-PUR foam, a material linked to significant health risks. R. at 4. Given the secretive nature of Petitioner's actions, Riley was unaware of the presence of PE-PUR in Sleepternity, causing her to be transported to the emergency room with an allergic reaction after using Sleepternity. R. at 4. Riley only seeks to hold Petitioner liable for violating Transylvania's products liability statute and the FCA. R. at 6. To avoid being held liable for its fraudulent actions, Petitioner has sought out every potential loophole—specifically, Petitioner argued that (1) the FDCA preempts Transylvania's products liability statute and (2) the fraud-on-the-FDA theory Riley relied on for her FCA claim is not a valid theory of liability. However, Petitioner's arguments constitute a misguided attempt to escape liability.

The appropriate standard of review for the preemption and FCA issues is de novo. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375 (5th Cir. 2012); *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir.

2017). When reviewing a motion to dismiss, this Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of Riley. *Crescent Plaza Hotel Owner, L.P. v. Zurich Am. Ins. Co.*, 20 F.4th 303, 307 (7th Cir. 2021). Thus, to survive Petitioner's motion to dismiss, Riley must 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 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). Consequently, this Court can only dismiss Riley's complaint if "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)).

Riley has sufficiently met the pleading standards needed to survive a motion to dismiss, as all of her claims are plausible on their face. The FDCA does not preempt Transylvania's products liability statute because Riley's products liability claim is rooted in traditional tort law, and the immunity defense scheme, which provides limitations on when such immunity applies, does not conflict with the FDCA's purposes or federal scheme. Further, the fraud-on-the-FDA theory is a valid theory of liability under the FCA; consequently, Riley sufficiently alleged that Petitioner violated the FCA when it failed to disclose its fraudulent conduct to the FDA and CMS. Therefore, this Court should affirm the Seventeenth Circuit's denial of Petitioner's motion to dismiss Riley's state products liability and FCA claims.

I. Riley's products liability claim must proceed because she has overcome Petitioner's immunity defense whether subsections (b) and (c) are preempted or not.

Petitioner asserts that Riley's products liability claim cannot proceed because subsections (b) and (c) are preempted by the FDCA–meaning, Petitioner is immune from liability. While Petitioner would like this court to focus solely on whether subsections (b) and (c), standing alone, are preempted, the question before this court is whether Riley has overcome Petitioner's immunity defense, such that her products liability claim may move forward. In analyzing that question, this court must examine Transylvania's immunity defense scheme as a whole under 21 Trans. Comp. Stat. § 630.546(a)-(c).

Petitioner's motion to dismiss fails and the Seventeenth Circuit's denial of Petitioner's motion to dismiss should be affirmed. First, Riley's products liability claim is rooted in traditional tort law–an area Transylvania has great latitude in regulating under its general police powers–and the immunity defense scheme, which provides limitations on when such immunity applies, does not conflict with the FDCA's purposes or federal scheme. Thus, subsections (b) and (c) are not preempted by federal law. Second, even if subsections (b) and (c) are preempted, subsection (a) still provides a limitation on Petitioner's immunity which allows Riley to overcome the immunity defense. Riley's products liability claim must proceed as Petitioner was not in compliance with FDA approval and cannot benefit from immunity.

A. Subsections (b) and (c) are not preempted by federal law.

Preemption derives from Article 6, Clause 2 of the Constitution which provides that 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.

As the Supreme Court has held, the categories of preemption–express preemption, implied field preemption, and implied conflict preemption–are not "rigidly distinct" or "analytically airtight." *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 104 n.2 (1992); *Gonzalez v. Ideal Tile Importing Co., Inc.*, 853 A.2d 298, 305-06 (N.J. Super. Ct. App. Div. 2004); *R.F. v. Abbott Labs.*, 162 N.J. 596, 618 (2000); *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990). The ultimate inquiry in a preemption analysis is to determine Congress's purpose: did Congress intend to take over all regulatory authority or share the regulatory authority with the States? *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Further, if Congress intended to share the regulatory authority with the States, then (1) is state regulation consistent with the structure and purpose of the statute as a whole or does state regulation stand as an obstacle and (2) does state regulation make compliance with both federal and state regulations a "physical impossibility?" *See Gade*, 505 U.S. at 98 ("The court's 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 make it through, 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). Riley's claim survives preemption because Riley is suing for conduct that violates a federal requirement (avoiding express preemption)–namely, violations of disclosure and warning requirements–but the violation of the federal requirement is not the sole basis of her claim (avoiding implied preemption)–rather, the violation of the federal requirement helps her overcome the immunity defense.

1. Transylvania is legislating in a field traditionally occupied by the States and the presumption against preemption applies to preserve the constitutional safeguards of state sovereignty.

The United States Constitution establishes a system of dual sovereignty which accords States incredibly broad regulatory power under their general police powers. State sovereignty is a bedrock principle of federalism, and intrusion upon state sovereignty through preemption "is not to be lightly presumed." *Turner v. First Union Nat'l Bank*, 162 N.J. 75, 88 (1999); *see also Kincer v. State*, 527 P.3d 837, 840 (Wash. Ct. App. 2023) (emphasizing that "our Supreme Court adheres to a rigorous analysis of the preemption issue because of its continuing desire to uphold state sovereignty to the maximum extent, tempered only by the mandate of the supremacy clause of the United States Constitution"). Thus, the preemption analysis begins with the presumption that "Congress did not intend to displace state law." *See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Cipollone v. Liggett Grp.*, 505 U.S. 504, 518 (1992) (holding federal statutes must be construed

"in light of the presumption against the preemption of state police power regulations").

When Congress legislates in a field traditionally occupied by the States, the presumption against preemption is at its strongest. *See Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) (holding the preemption analysis starts with the "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress"). This assumption reinforces constitutional safeguards and affirms that the "federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *see also Gade*, 505 U.S. at 116-17 (Souter, J., dissenting) (emphasizing that preemption may not be inferred and the presumption controls "if the statute's terms can be read sensibly not to have a preemptive effect").

Regulating matters relating to public safety and public health are deeply rooted in States' historic general police powers. *See Berman v. Parker*, 348 U.S. 26, 32 (1954) (recognizing public safety and public health as "some of the more conspicuous examples of the traditional application of the police power"); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (emphasizing matters of health and safety are "primarily, and historically, . . . matters of local concern"). States hold great latitude in regulating matters of health and safety under their police

powers; to find otherwise would disrupt the delicate balance of federalism and the historic role of state regulation. *See Medtronic*, 518 U.S. at 475.

The interest here is rooted in the traditional ability to protect the health and safety of their citizens, which "common law tort claims have been described as a critical component of." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2d Cir. 2006). Transylvania's products liability immunity defense scheme strikes a delicate balance between relieving manufacturers from burdensome litigation while also ensuring manufacturers still prioritize the health and safety of its consumers. *See Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757, 771 (D. Md. 2012) (holding that "because the immunity provision is a reflection of the state legislature's desire to rein in state-based tort liability, the provision falls into a sphere in which the presumption against preemption applies"). Preempting subsections (b) and (c) would improperly intrude on state sovereignty by dismantling the immunity defense scheme Transylvania enacted under its general police powers—especially when subsections (b) and (c) are interwoven into the purpose and design of subsection (a). Transylvania did not have to provide medical device manufacturers with an immunity defense at all, and defining the confines of such immunity by providing limitations on the defense is well within Transylvania's police powers.

Under 21 Trans. Comp. Stat. § 630.546(a), a medical device in question is not defective or unreasonably dangerous–thereby insulating the medical device manufacturer from liability for products liability claims–if the medical device was

approved by the FDA and that medical device was in compliance with FDA approval. However, an injured individual may overcome this immunity defense by rebutting the presumption that the medical device was in compliance with FDA approval. The plain language and structure of the statute indicates that subsections (b) and (c) are two means of rebutting the presumption of compliance under subsection (a). In other words, subsections (b) and (c) are limitations or conditions on the immunity defense in the same way compliance serves as a condition to receiving immunity under subsection (a).

Providing a limitation or condition on a defense, when conduct negates the basis for proving that defense, is not uncommon. For example, the regulatory compliance defense in traditional products liability law allows a manufacturer to use compliance with federal regulations as a defense against a plaintiff's assertions that a product was defective or the manufacturer acted negligently. However, the compliance must be trustworthy in order to hold any weight. *See* Restatement (Third) of Torts: Prod. Liab. § 4 cmt. e (Am. L. Inst. 1998) (stating that "when the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product, compliance with regulation is entitled to little or no weight"). This same exact principle is reflected in Transylvania's immunity defense scheme: if compliance with the requirements imposed by the FDA to obtain approval are the basis for providing medical device

manufacturers immunity, then the basis for providing immunity is no longer applicable and a medical device manufacturer cannot obtain immunity when the medical device manufacturer: (1) fraudulently obtains FDA approval and (2) violates requirements necessary for approval.

Transylvania's immunity defense scheme is consistent with traditional tort law principles, and the presumption against preemption must apply; preempting subsections (b) and (c) improperly intrudes on state sovereignty.

a. *Transylvania is regulating within the realm of traditional state interests, not in a purely federal realm, leaving the Buckman reasoning inapplicable and unpersuasive.*

The presumption against preemption does not apply where "the interests at stake are 'uniquely federal' in nature." *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (reasoning that regulating a company's relationship with a federal agency is not an area States have traditionally occupied). On the other hand, a claim based on traditional common law tort duties, and not based solely on a violation of federal requirements, undermines the concerns raised in *Buckman* that lead the court to find the presumption against preemption does not apply.

Subsections (b) and (c) do not rely on federal agency regulation to create liability, but rather to create a limited defense. *See Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 888 (D.N.J. 2010). Because a finding on violations of FDCA requirements would not be a finding of liability, and instead would just allow a plaintiff to move forward on a common law claim, the state is not interfering with FDA enforcement authority. Riley's products liability claim, which is based on preexisting state law tort principles, neither attempts to usurp the FDA's authority,

nor seeks to enforce FDCA violations how claims based solely on a violation of federal requirements do.

Just because subsections (b) and (c) implicate FDCA requirements, Riley's claim does not automatically become "uniquely federal in nature" and an improper regulation of a medical device manufacturer's relationship with a federal agency. *See Desiano*, 467 F.3d at 96 (holding "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect"). Rather, the Transylvania legislature is merely displaying deference to the trustworthiness of the FDA process to establish a medical device is not defective or unreasonably dangerous–thereby providing medical device manufacturers with immunity. *See Yocham*, 736 F. Supp. 2d at 888 (holding a similar statute, almost identical to Transylvania's, "merely defers to federal agency regulation to create a limited defense"). This in no way improperly regulates the relationship between Petitioner and the FDA.

The approach taken in *Garcia*, which only allow products liability claims to proceed if there is a federal finding, is counterintuitive due to the distinction the *Buckman* court itself made as to which claims are entitled to the presumption against preemption. Making findings of fraud under subsection (b) and determining whether a company failed to warn of dangers and risks under subsection (c) in no way conflicts with the federal scheme or with the FDA's authority because these findings have no effect on the relationship between the medical device

manufacturer and the FDA. See *id.* at 889 (holding that "having state courts interpret what information is required by FDA regulations does not interfere with the federal scheme" because there is not an "actual effect on interactions between drug companies and the FDA caused by the state statute"). Not only does allowing state courts to make these findings not implicate concerns warranting preemption, but requiring federal findings fails to safeguard against situations such as here– where the FDA would likely make federal findings in the injured individuals favor, but the claim may not proceed due to administrative failures. Here, the FDA stopped their investigation after Petitioner voluntarily recalled the device in order to focus on other allegedly defective products that had not been recalled yet. Requiring federal findings in order for a claim to proceed puts too much of a burden on the FDA and will result in many injured individuals with strong cases to be locked out of the courtroom. In fact, this approach would harm the very purpose of the FDCA by allowing medical device manufacturers to escape liability after voluntarily recalling a device that has harmed the health and safety of individuals.

2. Congress intended to share regulatory authority with the States, rather than take over all regulatory authority.

There is no indication that Congress intended to preempt state tort claims when enacting the FDCA. *See Wimbush v, Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (quoting *Desiano*, 467 F.3d at 94-95) (holding "the case law supports the conclusion that Congress did not intend to preempt state tort law claims when it passed the FDCA"). Even though there is an express preemption provision for medical devices, there is no indication Congress intended that provision to preempt state tort claims.

See Medtronic, 518 U.S. at 489 (holding that "when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions"). After examining the legislative history, the Supreme Court in *Medtronic* concluded that nothing demonstrated Congress intended "a sweeping preemption of traditional common-law remedies." *Id.* at 491. If that was Congress' intent, congressional silence while aware of ongoing products liability litigations indicates "at least some common-law claims against medical device manufacturers may be maintained after the enactment of the MDA." *Id.*

There is a general unwillingness to leave injured individuals without any remedy, especially in the products liability sphere. *See Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 451 (2005) (emphasizing the concern that individuals would be left with no remedy if state tort suits were preempted). Because the FDCA does not provide a private right of action, individuals injured by medical devices would have no means of judicial recourse. Common law claims, however, "perform an important remedial role in compensating accident victims"—especially when no compensatory scheme exists under the Federal Act. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

Preempting state common law claims would "contravene common sense" because the FDCA does not provide a private right of action and preemption of state common law claims would leave injured individuals with no judicial recourse. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (emphasizing that "it is

difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct"). Removing all means of judicial recourse would actually harm the FDCA's purpose of protecting public health; it is illogical to say that Congress declining to provide a private right of action and eliminating the availability of common law claims furthers the purpose of protecting public health. *See Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 659 (S.D. Tex. 2010) (holding 21 USCS § 360(k) does not prohibit States from providing damages remedy for claims premised on FDA violations). The absence of an alternative compensatory scheme–such as the National Vaccine Injury Compensation Program created by Congress to provide injured individuals compensation after preempting tort liability for vaccine manufacturers–further indicates Congress did not intend to preempt state common-law claims. Thus, it is clear Congress intended to share regulatory authority with the States.

a. *The immunity defense scheme is consistent with the FDCA's purpose of protecting public health and safety, and do not stand as an obstacle to the FDA's achievement of that goal.*

The immunity defense scheme does not stand as an obstacle to the FDCA's goal of protecting public health, but rather advances that goal by providing circumstances in which injured individuals may hold medical device manufacturers liable–adding an extra incentive for medical device manufacturers to produce safe and effective products. While immunity is important to encourage innovation, placing the burden of regulatory or scientific failures and malfeasance on the backs of individuals is clearly not the intent of Congress or Transylvania.

States' concurrent role in regulating public health and safety is crucial. The immunity exceptions also are consistent with the FDCA's purpose of protecting public health and do not stand as an obstacle because state common law claims encourage injured individuals to provide information which "helps federal regulators identify where to target their regulatory efforts, thereby ensuring that potential hazards do not escape federal regulatory scrutiny." Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 Colum. L. Rev. 1, 32 (2011). As the former chief counsel to the FDA explained:

> FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection . . .

See Riegel v. Medtronic, Inc., 552 U.S. 312, 337-38 (2008) (Ginsburg, J., dissenting). In fact, the way FDA regulation and state tort claims operate together to achieve their shared goal is exemplified here: once Riley served her complaint, Petitioner voluntarily recalled Sleepternity. Allowing a state claim got a defective product out of the market, prevented others from getting harmed by the product, saved the FDA's time and resources investigating to get a defective product out of the market, and allowed the FDA to focus on getting other potentially defective devices out of the market.

B. Even if subsections (b) and (c) are preempted, Petitioner does not satisfy the requirements to receive immunity under subsection (a).

Even if subsections (b) and (c) are preempted, Petitioner is clearly not in compliance with FDA approval. Transylvania did not intend to provide medical device manufacturers with absolute immunity; the presumption that a manufacturer was in compliance with FDA approval is rebuttable and overcomes the immunity defense. *See* 21 Trans. Comp. Stat. § 630.546(a).

When Sleepternity received premarket approval from the FDA, Petitioner provided that Sleepternity would utilize silicone-based foam. After obtaining FDA approval for a CPAP machine using silicone-based foam, Petitioner then switched to a polyester-based polyurethane (PE-PUR) foam. By switching the foam base, Petitioner clearly was not in compliance with the premarket approval received from the FDA–the FDA provided approval for the use of silicone-based foam, not polyester-based polyurethane foam.

The Medical Device Amendments to the FDCA clearly establish that making such a switch would render Sleepternity not in compliance with FDA approval. "Once a device has received premarket approval, the manufacturer must obtain FDA approval before making any changes in the device's design specifications, manufacturing processes, labeling, or any other attribute that would affect its safety or effectiveness." *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 834 (S.D. Ind. 2009); *see also Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6) (2024)). In other words, making this change would negate the first FDA approval, and require Petitioner to get a new approval. Without getting approval for replacing

the sound abatement foam, Petitioner was not in compliance with FDA approval. In essence, Sleepternity was an adulterated product.

Most importantly, Petitioner clearly knows that Sleepternity is not in compliance with FDA approval. CPAP machines, manufactured by Phillips, containing PE-PUR sound abatement foam had recently been recalled due to the significant health risks PE-PUR foam presented. To remedy the issue, Phillips sought to find a safer alternative to replace the PE-PUR foam and began testing the safety of silicone-based foams. If the FDA recalled CPAP machines using PE-PUR foam which were then replaced with silicone-based foam, Petitioner knew, or should have known, that switching to PE-PUR foam after FDA approval for silicone-based foam would not be in compliance with FDA approval.

II. Riley, relying on the fraud-on-the-FDA theory, stated a plausible claim under the FCA by demonstrating that Petitioner fraudulently secured Sleepternity's FDA approval, causing CMS to pay fraudulent claims.

This Court should affirm the Seventeenth Circuit's denial of Petitioner's motion to dismiss Riley's FCA claim. Under the False Claims Act (FCA), 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 or fraudulent claim" is "liable to the United States Government . . ." 31 U.S.C. § 3729(a)(1)(A), (B) (2024). A 'claim' "includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 182 (2016);

see § 3729(b)(2)(A). Riley brought an action for Petitioner's violation of the FCA on behalf of herself and the United States Government, which is allowed under the FCA's qui tam provision. *See* 31 U.S.C. § 3730 (2024).

All claims under the FCA, regardless of the specific theory plead, require a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Campie*, 862 F.3d at 899. These elements are all interrelated and often not analyzed in isolation. Riley stated a plausible claim for relief under the FCA by pleading sufficient facts demonstrating each required element. Using the fraud-on-the-FDA theory, Riley successfully established that the United States Government, through CMS, would have refused to provide payments and reimbursements for Sleepternity if it knew that Petitioner fraudulently obtained FDA approval for the CPAP machine. Accordingly, this Court should affirm the judgment of the Seventeenth Circuit and allow Riley's case to proceed past the motion to dismiss stage.

A. The fraud-on-the-FDA theory is a valid, cognizable theory of liability under the FCA.

Through the fraud-on-the-FDA theory, those who fraudulently obtain FDA approval are liable under the FCA because the fraudulent approval causes the government—here, CMS—to pay unnecessary, fraudulent claims. *See generally id.* at 899-908. This Court has not seen an FCA claim brought under the fraud-on-the-FDA theory and, consequently, has yet to formally recognize this theory of liability. A circuit split exists between the First and Ninth Circuits; the Ninth Circuit

recognizes this theory of liability, whereas the First Circuit does not. *See id.* at 907; *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016). This Court should follow the lead of the Ninth Circuit because that court applied the guidance provided by the Supreme Court in *Escobar* to recognize the fraud-on-the-FDA theory.

The Supreme Court did not formally discuss the fraud-on-the-FDA theory in *Escobar*. However, the Supreme Court did emphasize that when "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Escobar*, 579 U.S. at 187. The Ninth Circuit in *Campie* used the Supreme Court's guidance to formally recognize the fraud-on-the-FDA theory as a valid form of liability under the FCA. 862 F.3d at 907. The First Circuit, however, seemingly ignored *Escobar*, except for mentioning it once in a string citation to explain how a relator can use factual or statistical evidence to strengthen the inference of fraud. *D'Agostino*, 845 F.3d at 10-11.

The First Circuit rejected the fraud-on-the-FDA theory outside the narrow cases where the FDA rescinds its approval. *Id.* at 8. In *D'Agostino*, Appellant brought an FCA claim against a medical device company, alleging that the company made false submissions and statements to secure FDA approval of Onyx, a medical device CMS reimburses for. *Id.* at 7. Since CMS will only reimburse for FDA-approved medical devices, Appellant, relying on the fraud-on-the-FDA theory,

claimed the medical device company caused physicians to submit false reimbursement claims by fraudulently securing FDA approval. *Id.*

The First Circuit, primarily concerned with allowing claims under the FCA to hinder the FDA's regulatory authority, rejected the fraud-on-the-FDA theory, stating that Appellant failed to establish a causal link—the fraudulent representations *could have* caused the FDA to approve Onyx. *Id.* at 7, 9. However, the FDA *could have* also approved Onyx, notwithstanding the fraudulent representations. *Id.* Consequently, the First Circuit suggested that the only way to prove a causal link is for the FDA to withdraw its approval of Onyx. *See id.* at 8 ("The FDA's failure actually to withdraw its approval of Onyx in the face of [Appellant's] allegations precludes [Appellant] from resting his claims on a contention that the FDA's approval was fraudulently obtained."). The Southern District of Transylvania took this same position earlier in this case. R. at 20-24.

The First Circuit's narrow view allows defendants to escape liability under the FCA solely because the FDA—an understaffed and overworked government organization—failed to withdraw its approval. If the FDA's failure to withdraw approval automatically allowed defendants to escape liability under the FCA, then every defendant that knew about a likely FCA suit against them would voluntarily recall their products, like Petitioner did here. R. at 7. Although the FDA can continue to investigate and potentially withdraw approval of a defendant's device despite a voluntary recall, the FDA's decision to halt investigations should not automatically free a defendant of all liability under the FCA. Here, for example, the

FDA only stopped investigating Petitioner's fraudulent conduct "to focus on investigating other allegedly defective products in the marketplace *that have not been recalled*." R. at 7 (emphasis added). The FDA simply ended investigations because Petitioner voluntarily recalled Sleepternity, not because the FDA determined Petitioner's actions were or were not fraudulent. R. at 7.

Instead of adopting the First Circuit's strict view, this Court should recognize, as the Ninth Circuit did in *Campie*, that "[m]ere FDA approval cannot preclude False Claims Act liability, especially where . . . the alleged false claims procured curtails approvals in the first instance." *Campie*, 862 F.3d at 905. Although the Ninth Circuit expressed some concern about the plaintiffs' ability to prove materiality and causation since the device in question was FDA-approved at all times, the court still found that the plaintiffs pleaded sufficient factual allegations to survive a motion to dismiss and state a claim under the FCA. *Id.* at 903, 907. Thus, in the Ninth Circuit, the fraud-on-the-FDA theory is a viable form of liability under the FCA. *Id.* at 907.

This Court should draw its reasoning from *Campie*—a case where the court followed the Supreme Court's guidance—and other Ninth Circuit caselaw to formally recognize the fraud-on-the-FDA theory under the FCA. *Id.* The First Circuit's concerns about wading into the FDA's regulatory regime are misplaced; "just as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government's fisc." *Id.* at 905. Further, although both the First and Ninth Circuits expressed concerns

about the ability of plaintiffs to prove materiality and causation, this Court should allow the specific facts of each case to speak for themselves instead of instituting a categorical ban on fraud-on-the-FDA theory claims. Therefore, this Court should let Riley's claims proceed to the next step of stating a claim under the FCA—analyzing Petitioner's fraudulent conduct.

B. Petitioner fraudulently represented that Sleepternity was FDA approved when Petitioner failed to disclose it secretly modified Sleepternity by adding a material known to present significant health risks.

Petitioner made a false statement or engaged in a fraudulent course of conduct within the meaning of the FCA by failing to inform the FDA and CMS that it *only* used silicone-based foam to secure FDA approval and subsequently discretely replaced such foam with unsafe PE-PUR foam. R. at 4. Although Congress refrained from defining "false" or "fraudulent" in the FCA, courts have long accepted that false or fraudulent claims encompass express falsehoods, misrepresentations by omission, and half-truths. *See Escobar*, 579 U.S. at 188 ("[H]alf-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations.").

Given the expansive definition of the term fraudulent, numerous different theories have developed to allow litigants to bring actions for false and fraudulent claims under the FCA; here, the theory of importance is the implied false certification theory. *See id.* at 181 ("[I]n certain circumstances, the implied false certification theory can be a basis for liability" under the FCA.); *Campie*, 862 F.3d at 901 ("Claims under an implied false certification theory can also be viable under

the False Claims Act."). According to the implied false certification theory, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, . . . the defendant has made a misrepresentation that renders the claim "false or fraudulent" under §3729(a)(1)(A)." *Escobar*, 579 U.S. at 180.

The Supreme Court has formally recognized the implied false certification theory as a basis of liability under the FCA. *Id.* at 181. In *Escobar*, parents sued their daughter's healthcare provider under the FCA after unlicensed staff treated their daughter in violation of state Medicaid regulations. *Id.* at 185. The healthcare provider submitted numerous reimbursement claims in which Medicaid paid; however, Medicaid was unaware that the healthcare provider "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations." *Id.* at 184-85. Consequently, the Supreme Court concluded that by "using payment and other codes that conveyed this information without disclosing [its] many violations of basic staff and licensing requirements for mental health facilities, [the healthcare provider's] claims constituted misrepresentations." *Id.* at 190.

Although the Supreme Court explicitly recognized the implied false certification theory as a basis for liability, the Court also required the following two conditions to be satisfied, both of which are present here:

> First, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Id. Petitioner easily satisfies the first condition. In *Campie*, the plaintiff argued, and the Ninth Circuit accepted at the motion to dismiss stage, that "by submitting claims for payment or reimbursement for [three medications], [the defendant] represented that it provided medications approved by the FDA that were manufactured at approved facilities and were not adulterated or misbranded." *Campie*, 862 F.3d at 902. Thus, this Court should find, as the Ninth Circuit did in *Campie*, that by submitting claims for payment or reimbursement for Sleepternity, Petitioner made specific representations about Sleepternity—namely, that the Sleepternity machine CMS reimbursed for was FDA-approved. Consequently, Petitioner's fraudulent conduct satisfies the first condition under the implied false certification theory.

1. Petitioner represented that it followed the FDA approval requirements; however, Petitioner's failure to disclose its violations made those representations misleading half-truths.

Petitioner also satisfies the second condition under the implied false certification theory: Petitioner's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements ma[de] those representations misleading half-truths." *Escobar*, 579 U.S. at 190. To satisfy this condition, Riley must only show that (1) FDA approval was material to CMS's payment decision and

(2) Petitioner's failure to disclose its noncompliance with this material requirement made those representations misleading half-truths. *Id.*

a. *FDA Approval Was Material to CMS's Decision to Reimburse for the Use of Sleepternity.*

To be liable under the FCA, a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the Government's payment decision." *Id.* at 192 (emphasis added). Petitioner could be liable for failing to disclose its noncompliance with material requirements even if such requirements were not expressly designated as conditions of payment. *Id.* at 181. Although "the Government's decision to expressly identify a provision as a condition of payment is relevant," it is not automatically dispositive. *Id.* at 194. Here, CMS's decision to reimburse individuals for the cost of using Sleepternity was based on Sleepternity receiving FDA approval; in other words, CMS's condition of payment was requiring Sleepternity to satisfy all FDA approval requirements. *See* R. at 4 (emphasis added) (CMS "began to provide coverage to individuals who were prescribed Sleepternity for the costs of using the device, *since the device was approved for marketing by the FDA*."); *United States ex rel. Stenson v. Radiology Ltd., LLC*, 2024 U.S. App. LEXIS 10136, at *6 (9th Cir. 2024) ("CMS requires medical suppliers to obtain FDA approval before introducing their devices into the stream of commerce.").

Thus, Riley must only plead sufficient facts showing that Petitioner's failure to disclose that the Sleepternity machines CMS reimbursed for were not the same Sleepternity machines that were FDA-approved was material to CMS's payment

decision. The FCA defines "material" as "having 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). The Supreme Court has said the "materiality standard is demanding," so an act cannot be material "where noncompliance is minor or insubstantial." *Escobar*, 579 U.S. at 194. Beyond these statements, the Supreme Court has yet to establish a formal test for materiality. However, the Court has laid out some ways to prove that Petitioner's conduct was material to CMS's payment decision:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, 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. Or, if 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, that is strong evidence that the requirements are not material.

Id. at 194-95. Since CMS solely reimbursed for Sleepternity because "the device was approved for marketing by the FDA," R. at 4, Petitioner would be hard-pressed in saying that the FDA approval requirement was immaterial to CMS's payment decision. This case presents a prime example of a situation where the Government—here, CMS—"refuses to pay claims in the mine run of cases based on noncompliance with" the FDA approval requirements. *Escobar*, 579 U.S. at 195. Consequently, a violation of FDA requirements—namely, replacing an approved material with an unsafe, unapproved material after FDA approval and without telling the FDA—would clearly be material to CMS's payment decision.

This Court need not find Riley's arguments wholly convincing; it must only find that, accepting all allegations in the complaint as true, Riley could plausibly satisfy the materiality element at this stage of litigation. *Twombly*, 550 U.S. at 570. In *Campie*, the defendant argued that its violations of FDA requirements were not material to the government's payment decision since the government continued paying for such claims despite knowing of the defendant's violations. 862 F.3d at 906-07. After noting that there was a factual dispute over what the government knew and when, the Court concluded that the issue of materiality constituted a matter of proof, not a legal ground to dismiss the complaint. *Id.* at 907. Thus, since Riley's allegations are plausible, this Court should find, as the Ninth Circuit did in *Campie*, that the issue of materiality constitutes a matter of proof rather than a legal ground to dismiss Riley's complaint.

b. *Petitioner's failure to disclose its violation of the material FDA approval requirements caused CMS to pay fraudulent claims.*

Since Riley established that FDA approval was material to CMS's reimbursement decision, or at the very least, demonstrated that the issue of materiality constitutes a matter of proof, Riley must next show that Petitioner's failure to disclose its noncompliance with the FDA approval requirement made those representations misleading half-truths. *Escobar*, 579 U.S. at 190. Each time CMS received a reimbursement claim, Petitioner represented that Sleepternity was FDA-approved. However, the Sleepternity machine CMS actually reimbursed for was not FDA approved as Petitioner replaced the approved silicone-based foam with

the unapproved, potentially harmful PE-PUR foam—a crucial fact Petitioner failed to disclose to CMS. R. at 4.

Implicit within the materiality requirement is the issue of causation—the misleading half-truth must *cause* the government to pay. *Escobar*, 579 U.S. at 190. Thus, Riley must establish a causal link showing that CMS would have withdrawn its payment if it knew that Petitioner replaced the FDA-approved silicone-based foam in its Sleepternity machines with PE-PUR foam—a material that can present significant health risks—after obtaining approval. *Id.* at 194-195; R. at 4. Here, Riley can easily show a causal relationship, given the FDA's statements expressing concern over using PE-PUR foam in CPAP machines.

According to the FDA, PE-PUR foam can break down, and if it does, "volatile organic compounds (VOCs) that are not visible could be breathed in or swallowed by CPAP users." R. at 4. Since breathing in VOCs can be harmful, another medical device company, Philips Respironics, recalled its CPAP devices containing PE-PUR foam and replaced the foam with silicone-based foams as a *safer alternative*. R. at 4. Given Philips Respironics recall and the FDA's negative statements about PE-PUR foam, it is plausible—even probable—that the FDA would not have approved Sleepternity if it knew about Petitioner's use of PE-PUR foam. In other words, it is unlikely that CMS would have continued to reimburse for Sleepternity if it knew that the machine it was reimbursing for contained PE-PUR foam, a material that (1) the FDA previously expressed concern over, (2) can have significant health risks, and (3) has resulted in at least one medical device company recalling its CPAP

machines. R. at 4. Even if CMS did not require FDA approval, it is unlikely that CMS would reimburse for Sleepternity containing PE-PUR foam, knowing the adverse history surrounding PE-PUR foam.

Consequently, Petitioner's misleading half-truth—its failure to disclose that the device CMS is reimbursing for is not FDA approved and contains an unsafe, potentially harmful material—caused CMS to pay fraudulent claims. Although Riley established a causal link, this Court need not make such a determination. Instead, this Court should find that the issue of causation, like the materiality requirement, constitutes a matter of proof at this stage of litigation. *Campie*, 862 F.3d at 907. Here, Riley alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations," sufficiently pleading materiality and causation at this stage of litigation. *Id.*

Therefore, Petitioner's conduct satisfies the second condition of the implied false certification theory—Petitioner's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190. Since Riley satisfied each element under the implied false certification theory—falsity, materiality, and causation—or established that certain elements constitute matters of proof, this Court should deny Petitioner's motion to dismiss and allow Riley to proceed forward under the implied false certification theory.

2. Petitioner consciously violated the FDA approval requirement despite knowing the requirement was material to CMS's payment decision.

Since Riley sufficiently pleaded falsity, including materiality and causation, at the motion to dismiss stage, the only remaining element is establishing scienter. *See Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1118 (9th Cir. 2020) ("[F]alsity is a necessary, but not sufficient, requirement for FCA liability—after alleging a false statement, a plaintiff must still establish scienter."). The FCA assumes a certain mental state—a defendant must "knowingly violate[] a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 579 U.S. at 181. The 'knowingly' requirement does not require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). Instead, under the FCA's scienter requirement, the term "knowingly" describes a person that has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). "Innocent mistakes, mere negligent misrepresentations and differences in interpretations are not false certifications under the Act." *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 44 F.4th 838, 851-852 (9th Cir. 2022) (citing *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996)).

Petitioner can have "'actual knowledge' that a condition is material without the Government expressly calling it a condition of payment." *Escobar*, 579 U.S. at 191. For example, if "the Government failed to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds

contracts if the guns do not shoot, the defendant has 'actual knowledge.'" *Id.* Here, even if CMS failed to expressly state that FDA approval was material to its payment decision, Petitioner had actual knowledge of the materiality of the FDA requirement given that Petitioner knew the sole reason CMS reimbursed for Sleepternity was because the CPAP machine received FDA approval. R. at 4. Therefore, Petitioner had actual knowledge that CMS's payment decisions hinged on Sleepternity satisfying all of the FDA's approval requirements.

Even if Petitioner did not have actual knowledge of the FDA approval requirements, this Court should find that Petitioner deliberately ignored or recklessly disregarded such requirements. A defendant acts with deliberate ignorance when they "are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." *United States ex rel. Schutte v. SuperValue Inc.*, 598 U.S. 739, 751 (2023). The reckless disregard standard is similar and covers "defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.*

The deliberate ignorance and reckless disregard standards cover "the ostrich type situation[s] where an individual has buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1174 (9th Cir. 2016) (internal quotation marks omitted). Building off the previous example where the Government rescinds contracts if the guns do not shoot, "because a

reasonable person would realize the imperative of a functioning firearm, a defendant's failure to appreciate the materiality of that condition would amount to "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information" even if the Government did not spell this out." *Escobar*, 579 U.S. at 191. Here, a reasonable person would realize the materiality of the FDA approval requirement. Since CMS only reimbursed for Sleepternity because it received FDA approval, a reasonable person would realize that CMS would refuse payment if Sleepternity violated any of the FDA's requirements to obtain or maintain approval. Thus, this Court should find that Riley plausibly pleaded the scienter element by demonstrating that Petitioner knowingly violated a material requirement.

Overall, Petitioner's fraudulent conduct satisfies each of the four requisite elements of an FCA claim—falsity, materiality, causation, and scienter—based on the fraud-on-the-FDA theory. *See Campie*, 862 F.3d at 899. Riley plausibly pleaded the first three elements through the implied certification theory at this stage of litigation: (1) The FDA approval requirement was *material* to CMS's payment decision, and (2) Petitioner's choice to *falsely* certify its compliance with this requirement (3) *caused* CMS to pay fraudulent claims. Further, Petitioner's conduct also satisfies the scienter requirement—Petitioner *knowingly* failed to disclose its violation of the material FDA approval requirement. Therefore, since Riley's factual allegations are plausible on their face, this Court should affirm the Seventeenth Circuit's denial of Petitioner's motion to dismiss and allow Riley's FCA claim to proceed forward on its merits. *See Barnett v. Centoni*, 31 F.3d 813, 816 (9th Cir.

1994) ("A complaint may not be dismissed unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief.").

CONCLUSION

For these reasons, this Court should affirm the judgment of the Seventeenth Circuit Court of Appeals.

Team 3324
Counsel of Record

APPENDIX A

Constitutional Provisions

The Supremacy Clause, U.S. Const. art. VI, cl. 2, provides in pertinent part:

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

Statutory Provisions

31 U.S.C. § 3729 provides in pertinent part:

> (a) Liability for Certain Acts.—
> (1) In general.—Subject to paragraph (2), any person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .
> (b) Definitions.—For purposes of this section—
> (1) the terms "knowing" and "knowingly"—
> (A) mean that a person, with respect to information—
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information; and
> (B) require no proof of specific intent to defraud;
> (2) the term "claim"—
> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to

advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3730(b) provides in pertinent part:

(b) Actions by Private Persons.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting. . . .

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action. . . .

21 Trans. Comp. Stat. § 630.545 (2024) provides in pertinent part:

Manufacturers and distributors of a product owe a duty of care and good faith to their consumers throughout the manufacturing and distribution of such product, including the duty to warn of any dangers or risks associated with the product, the duty to comply with all the state and federal laws and regulations

governing the manufacturing and distribution of the product, and the duty to make disclosures to appropriate agencies or government officials about any modifications made to the product. Any resulting injury or death that would not have occurred but for the breach of any of the aforementioned duties shall serve as adequate basis for liability under this statute.

21 Trans. Comp. Stat. § 630.546 provides in pertinent part:

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