No. 24-9176

IN THE

Supreme Court of the United States

OCTOBER TERM 2024

Mednology, Inc.

Petitioner,

— versus —

United States ex rel. Riley Ortega

Respondent.

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

BRIEF FOR RESPONDENT

TEAM 3310
Attorneys for Petitioner

QUESTIONS PRESENTED

I. In *Buckman*, this Court held that the FDCA preempts standalone tort claims because the plaintiff was trying to police fraud on the FDA, which would interfere with the FDA's ability to balance its statutory and regulatory objectives. Transylvania's tort immunity statute contains exceptions for defrauding the FDA and failing to warn the FDA. The exceptions are not attempts to police fraud and do not impede the FDA's ability to pursue its objectives. Does *Buckman* demand that the FDCA preempt the statute?

II. The False Claims Act requires a relator to plead that a false statement made with scienter was material in causing government payment. Ortega relied on the fraud-on-the-FDA theory to plead that Mednology knowingly made false statements to the FDA, resulting in Medicare coverage for Sleepternity. Has Ortega pleaded sufficient facts to establish the Act's materiality and causation elements?

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INTRODUCTION

This case addresses a critical issue at the intersection of consumer protection and medical device regulation: the ability of injured consumers to seek redress against medical device manufacturers who fraudulently introduce dangerous products to the market. Several states have enacted tort immunity statutes to encourage the production of life-saving medical devices, but those statutes also include exceptions. These exceptions are triggered when manufacturers either defraud the FDA during the device approval process or fail to warn the agency about the dangers of a product.

In *Buckman Co. v. Plaintiffs' Legal Committee*, this Court held that the Food, Drug, and Cosmetic Act (FDCA) preempts tort claims based solely on a manufacturer's fraud against the FDA. Since then, some manufacturers have misinterpreted *Buckman*, arguing that it preempts fraud-on-the-FDA exceptions in state immunity statutes. Two circuit courts have adopted this overly broad interpretation, barring plaintiffs from recovery unless the FDA itself issues a finding of fraud. This outcome neither aligns with this Court's holding in *Buckman* nor proves practical given the FDA's resource constraints and extensive responsibilities.

This case involves Respondent Riley Ortega, who suffered injuries from a CPAP machine manufactured by Petitioner Mednology Inc. Ortega sued in the Southern District of Transylvania, where Mednology claimed immunity under the state's tort immunity statute. This statute includes exceptions for FDA fraud and failure to warn, which Mednology argued were preempted. The district court rejected

Mednology's motion to dismiss, finding that the FDCA did not preempt exception. On appeal, the Seventeenth Circuit affirmed the denial of Mednology's motion to dismiss because Mednology did not qualify for immunity under Transylvania's statute, but it concluded that the FDCA preempted both exceptions.

Furthermore, Ortega brought a *qui tam* action under the False Claims Act (FCA), alleging that Mednology's fraud led to improper Medicare and Medicaid payments for Sleepternity. The district court dismissed this claim, but the Seventeenth Circuit reversed, holding that Ortega pled sufficient facts to proceed on the "fraud-on-the-FDA" theory.

This Court should affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss. But this Court should do so by explicitly holding that the Mednology does not qualify for immunity and the FDCA does not preempt either of the statute's exceptions. Additionally, we ask the Court to affirm the reversal of Mednology's motion to dismiss the FCA claim.

These rulings are crucial to preserve injured plaintiffs' right to seek recovery when harmed by fraudulently marketed medical devices. To decide otherwise would incentivize manufacturers to neglect the responsibilities they owe to the FDA, potentially flooding the market with dangerous products and leaving injured consumers without recourse. This Court has the opportunity to clarify the law, uphold consumer protections, and ensure that medical device manufacturers remain accountable for their actions.

OPINIONS BELOW

The opinion and order of the United States District Court for the Southern District of Transylvania is unreported and set out in the record. (R. 2–24). The opinion and order of the United States Court of Appeals for the Seventeenth Circuit is also unreported and set out in the record. (R. 25–42).

STATUTORY PROVISIONS

The following provisions of the Food, Drug, and Cosmetic Act are relevant to this case: 21 U.S.C. §§ 337(a); 360e(c), 360e(d)(5)(A)(i), (f); 360k(a); 393(b).

The following provisions of the False Claims Act are relevant to this case: 31 U.S.C. §§ 3729(a)(1)(A), (B), 3729(b)(1); 3730(b), (c), (d); 3731(d).

The following provisions of the Social Security Act are relevant to this case: 42 U.S.C. §§ 1395x(n); 1395y(a)(1)(A).

The following provisions of the Code of Federal Regulations are relevant to this case: 21 C.F.R. §§ 814.82(a), 814.47(a), 816.46(a); 42 C.F.R. §§ 424.5(a)(5).

RULE PROVISIONS

The following provision of the Centers for Medicare and Medicaid Services, Medicare National Determinations Manual is relevant to this case: Medicare Benefit Policy Manual, ch. 14, § 10; ch. 15 § 110.1(C).

STATEMENT OF THE CASE

STATEMENT OF FACTS

Riley Ortega suffers from insomnia and sleep apnea symptoms, which are made worse by the post-traumatic stress disorder she developed after serving in the military. (R. 3). To combat these issues, Ortega's somnologist prescribed her a new medical device called "Sleepternity" to help her fall asleep. (R. 3). Sleepternity is a "state-of-the-art" CPAP machine designed to make its users more comfortable. (R. 3). Unlike traditional CPAP machines, Sleepternity has headphones to aid users in relaxing and falling asleep. (R. 3). Mednology, Inc. manufactured Sleepternity, and posited that its special features, coupled with those of a traditional CPAP machine, allow Sleepternity to combat both sleep apnea and insomnia symptoms. (R. 3–4).

The FDA approved Sleepternity as a Class III medical device on December 30, 2022. (R. 3–4). As a result, the Centers for Medicare and Medicaid Services began providing coverage for individuals prescribed Sleepternity. (R. 3–4). Mednology received approval to market the device using silicone-based, sound-dampening foam. (R. 3–4) However, Mednology allegedly violated its requirement to manufacture the device as approved by replacing the silicone-based foam with polyurethane-based foam, which breaks down over time. (R. 4, 8). When polyurethane-based foam breaks down, it can form volatile organic compounds that CPAP users can breathe in or swallow, causing significant health risks. (R. 4). These health risks led Philips Respironics (another medical device manufacturer) to recall their CPAP machines containing polyurethane-based foams to replace them with safer, silicone-based foam.

(R. 4). The Philips recall happened in June 2021, around eighteen months before Mednology allegedly replaced the silicone-based foam in their CPAP machines with polyurethane foam. (R. 4).

Ortega suffered a severe asthma attack while using Sleepternity and was rushed to the emergency room. (R. 4). Two doctors recommended that she stop using Sleepternity, concluding that the device caused her asthma attack. (R. 5). Unknown to the doctors, the polyurethane foam in the CPAP machine could break down into isocyanate, a volatile organic compound that Ortega is allergic to. (R. 5). Ortega's primary physician was aware of her allergy, but could not expect that Sleepternity would expose her to the compound because the warning label "did not contain any information about the presence of isocyanates in the device." (R. 5). Ortega's asthma attack chronically inflamed her lungs, causing her persistent sleep apnea symptoms. (R. 5).

Ortega's brother, who works at Mednology as an assembly manager, believed that Mednology replacing the silicone-based foam with the polyurethane foam is what caused her asthma attacks. (R. 5). He later told her that Mednology "initially utilized silicone-based foams to secure marketing approval from the FDA and that it replaced such foams with [polyurethane] foams to save manufacturing costs." (R. 5). Ortega then sued Mednology alleging fraud (R. 7). Mednology issued a recall of its CPAP machines shortly after being served process. (R. 7). The FDA began to investigate Mednology, but because Mednology recalled its device, the FDA ceased its investigation to focus on companies whose devices remained on the market. (R. 7).

PROCEDURAL BACKGROUND

Ortega brought a products liability suit against Mednology, alleging a number of state law tort claims. (R. 6). She also brought a FCA claim under the Act's *qui tam* provision, alleging that Mednology defrauded the FDA. (R. 6). She argued that, because Philips recalled its CPAP machine due to the health risks associated with the use of polyurethane foam, the FDA would not have granted Mednology premarket approval if it had disclosed its use of polyurethane foam. (R. 6).

Transylvania has products liability immunity statute for medical device manufacturers that contains two exceptions. 21 Trans. Comp. § 630.546(a)–(c). First, for defrauding the FDA in the process of obtaining premarket approval and second for failing to warn the FDA of dangers associated with the product. *Id.* §§ 630.546(b)–(c). Ortega alleged that Mednology's conduct activated both exceptions, reliving it of immunity. (R. 8–9).

Mednology moved to dismiss all of Ortega's claims under Federal Rule of Civil Procedure 12(b)(6). First, it argued that the FDCA preempted both exceptions to Transylvania's immunity statute. (R. 9). With both exceptions preempted, Mednology would have general immunity against Ortega's products liability claims. (R. 9). Second, it argued that Ortega could not rely on the fraud-on-the-FDA theory to bring a FCA claim. (R. 23). Accordingly, she failed to state a claim on both issues, and her complaint warranted dismissal. (R. 9). The district court denied Mednology's motion to dismiss the tort claims because the FDCA did not preempt the immunity exceptions. (R. 24). The court granted Mednology's motion to dismiss the FCA claim

because Ortega could not base her claim on "Mednology's fraudulent conduct toward the FDA." (R. 24).

Mednology and Ortega cross-appealed. (R. 25). The Seventeenth Circuit affirmed the denial of Mednology's motion to dismiss Ortega's tort claims, but it concluded that the FDCA preempted both exceptions to Transylvania's immunity statute. (R. 38). Instead, it affirmed because Transylvania's statute conditioning immunity on FDA compliance was not preempted, and Ortega pleaded sufficient facts to overcome the presumption that Mednology was in compliance with FDA regulations. (R. 34, 38). The Circuit then determined that Ortega could rely on the fraud-on-the-FDA theory to bring an FCA claim because she "alleged sufficient facts to plausibly satisfy the materiality element." (R. 38). Accordingly, it reversed the district court's granting of Mednology's motion to dismiss. (R. 38).

SUMMARY OF THE ARGUMENT

The FDCA does not impliedly preempt tort immunity exceptions for defrauding the FDA or failing to warn the FDA. In *Buckman Co. v. Plaintiffs' Legal Commission*, this Court held that the FDCA impliedly preempts standalone fraud-on-the-FDA claims because the claim would conflict with the FDA's enforcement of the FDCA. The Court was concerned that standalone tort claims would interfere with the FDA's ability to manage the delicate balance between statutory and regulatory objectives. What *Buckman* did not say, though, is that the FDCA preempts all proceedings requiring evidence of fraud on the FDA. Indeed, this Court took the time to explain that the plaintiff's failure to rely on a traditional tort

claim in pursuing their fraud-on-the-FDA theory led to its downfall. Despite this Court's careful distinction, two circuits have held that proceedings requiring state courts to find that the FDA was defrauded are preempted based on the concerns of *Buckman*. That view is wrong and misapplies this Court's precedent.

Transylvania's statute is not impliedly preempted on account of *Buckman*. The Second Circuit, addressing whether a statute nearly identical to Transylvania's was preempted by *Buckman*, held that the presumption against preemption applies and that the concerns identified in *Buckman* are not present when the plaintiff is not bringing a standalone fraud-on-the-FDA claim. That view correctly interprets this Court's precedent and addresses the bigger picture—the presumption against preemption applies when states regulate the health and safety of their citizens. Transylvania was regulating the health and safety of its citizens by limiting tort liability, so the Seventeenth Circuit was wrong not to begin with that assumption.

The Second Circuit was also correct in concluding that a plaintiff offering evidence of fraud on the FDA to beat statutory immunity does not implicate *Buckman's* concerns. Although Transylvania's statute conditions immunity on compliance with FDA regulations and contains an additional exception for failing to warn the FDA, the analysis remains the same. In each instance, Transylvania was regulating the health and safety of its citizens by enacting the statute, and courts issuing findings according to the statute do not interfere with the FDA's balance of objectives. Accordingly, this Court should adopt the position taken by the Second

Circuit and conclude that the FDCA does not impliedly preempt Transylvania's tort immunity statute.

A relator can rely on the fraud-on-the-FDA theory to bring a False Claim Act claim. The fraud-on-the-FDA theory supports the FDA's policy of ensuring the safety and efficacy of healthcare products and the FCA's purpose of prosecuting fraud on the government. In *United Health Services v. Escobar*, this Court held that a hospital's misrepresentation about compliance with facility requirements was "so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations." 579 U.S. 176, 196 (2003). The Act covers "statement[s] that misleadingly omit[] critical facts . . . irrespective of whether the other party signaled the importance of the qualifying information." *Id.* This Court assuaged "concerns about fair notice and open-ended liability" associated with the FCA by reinforcing the Act's strict materiality and scienter elements. *Id.*

Relying on *Escobar*, the Ninth Circuit correctly permitted an FCA claim using the fraud-on-the-FDA theory to move past the motion to dismiss stage. The Ninth Circuit was unconcerned that the manufacturer's fraud was directed at the FDA rather than the payor agency because the FDA and the Center for Medicare & Medicaid Service (CMS) are both regulated by the Secretary of Health and Human Services. By defrauding the FDA, the manufacturer defrauded the Department of Health and Human Services. If a lack of FDA intervention is preclusive to bringing

an FCA claim, then the Act's *qui tam* provision is rendered superfluous, and relators may be left without an incentive to alert the government of potential fraud.

Mednology defrauded the FDA by obtaining FDA approval for the Sleepternity device containing silicone-based foam then manufacturing the device with polyurethane foam. FCA liability attaches when a manufacturer knowingly violates a condition for government payment. Mednology knowingly violated the FDA's requirement of obtaining approval for Sleepternity after altering the foam used in the device. The misrepresentation resulted in Sleepternity obtaining FDA approval which CMS relied on in deciding to cover the device. Because Ortega alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations," the FCA's pleading requirements are satisfied and her FCA claim should proceed to trial. *United States ex rel. Campie v. Gilead Sciences*, 862 F.3d 890, 907 (9th Cir. 2017).

ARGUMENT

STANDARD OF REVIEW

A dismissal under Federal Rule of Civil Procedure 12(b)(6) is reviewed de novo. *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F. 3d 1108, 1116 (9th Cir. 2020). The facts in a plaintiff's complaint are accepted as true and must "state a claim to relief that is plausible on its face" with all reasonable inferences resolved in favor of the nonmovant. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). FCA claims, like all

fraud claims, must be plead with particularity. *Winter*, 953 F. 3d at 1116; Fed. R. Civ. P. 9(b).

I. The FDCA does not preempt Transylvania's Tort immunity statute or its exceptions.

Federal law can preempt state law either expressly or impliedly. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484–85 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 438 (2001). The FDCA expressly preempts state requirements "different from, or in addition to, any applicable requirement under [the FDCA]." 21 U.S.C. § 360k(a). Implied preemption occurs if a state law directly conflicts with a federal law or if Congress intended the federal statute to occupy the field on a given subject. *Cipollone v. Ligget Grp., Inc.*, 505 U.S. 504, 516 (1992). Because express preemption is not implicated by the question in this case, the analysis only examines implied preemption.

The Transylvania legislature enacted a products liability immunity statute for manufacturers that comply with FDA regulations. 21 Trans. Comp. § 630.546(a). That said, the legislature carved out two exceptions to immunity. First, if a manufacturer defrauds the FDA in the process of obtaining premarket approval, and the FDA would not have approved the device but for the fraud. *Id.* § 630.546(b). Second, if a manufacturer fails to warn the FDA about the dangers associated with the device. *Id.* § 630.546(c). Courts diverge on whether the FDCA impliedly preempts statutes like Transylvania's because of the holding in *Buckman*—the FDCA preempts standalone fraud-on-the-FDA tort claims. *See Buckman*, 531 U.S. at 343. One side

argues that the concerns identified in *Buckman* require preemption because state court findings of fraud will interfere with the FDA's ability to balance statutory objectives. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012). The other side argues that *Buckman* addressed entirely different circumstances than those implicated by an immunity statute, thus *Buckman*'s concerns are not controlling. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co., LLC. v. Kent*, 552 U.S. 440 (2008).

A. The presumption against preemption applies because the statute does not implicate an inherently federal relationship.

This Court has routinely recognized that the presumption against preemption applies when Congress legislates "in a field which the States have traditionally occupied." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). When the presumption applies, this Court "'start[s] 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.'" *Lohr*, 518 U.S. at 485 (quoting *Rice*, 331 U.S. at 230). The presumption against preemption applies when a state regulates the health and safety of its citizens. *See Buckman*, 531 U.S. at 348; *Desiano*, 467 F.3d at 93–94.

A state is regulating the health and safety of its citizens when it limits tort liability. In *Medtronic, Inc. v. Lohr*, this Court said that "[s]tates traditionally have had great latitude under their police powers to legislate as to the protection of the

lives, limbs, health, comfort, and quiet of all persons." 518 U.S. at 475 (quoting *Metro. Life Ins. v. Massachusetts*, 471 U.S. 724, 756 (1985)). Accordingly, when the Second Circuit addressed a Michigan immunity statute that withdrew immunity from manufacturers if they defrauded the FDA in the process of receiving premarket approval, it concluded that the presumption should apply because the state was regulating the health and safety of its citizens. *See Desiano*, 467 F.3d at 87–94. The court reasoned that a state's decision to limit tort liability "falls squarely within its prerogative to 'regulat[e] matters of health and safety,' which is a sphere in which the presumption . . . applies, indeed, stands at its strongest." *Id.* at 94 (quoting *Buckman*, 531 U.S. at 348).

By contrast, the presumption does not apply when a state attempts to regulate inherently federal relationships. *See Buckman*, 531 U.S. at 348. In *Buckman*, the plaintiffs brought a standalone fraud-on-the-FDA tort claim to enforce a duty that the manufacturer owed exclusively to the FDA. *Id.* at 343–47. This Court was unwilling to apply the presumption because the claim interfered with the relationship between a federal agency and the manufacturer, and that relationship is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 348.

The presumption against preemption applies because Transylvania was regulating the health and safety of its citizens by limiting tort liability for medical device manufacturers. Like the Michigan statute in *Desiano*, Transylvania's statute grants immunity to manufacturers but withdraws it if the manufacturer defrauds the

FDA or fails to warn the FDA of dangers associated with the product. Unlike *Buckman*, where the plaintiffs' claim interfered with the relationship between the FDA and the manufacturer, Transylvania's statute regulates the relationships between the state, the manufacturer, and the consumer. *See* Johsua D. Lee, Note, *Reconsidering the Traditional Analysis: Should* Buckman *Alone Support Preemption of Fraud-On-The-FDA Exceptions to Tort Immunity?*, 17 N.Y.U. J. Legis. & Pub. Pol'y 1055, 1090 (2014). The Transylvania legislature determined that manufacturers who comply with FDA regulations deserve tort immunity to allow more medical devices to reach Transylvania citizens. At the same time, the legislature realized that manufacturers do not deserve immunity if their devices are on the market because of fraud or failure to warn the FDA of its dangers. Thus, the statute is not an attempt to police fraud on the FDA, but an encouragement to manufacturers to prioritize the health and safety of Transylvania citizens. *See* 21 Trans. Comp. § 630.544. The relationship between Transylvania and the manufacturer originates from, is governed by, and terminates according to Transylvania law. There is no question that there is a fundamental difference between the statutes addressed by *Desiano* and the Seventeenth Circuit—a difference that warrants a differing application of the presumption than that applied in *Buckman*.

Transylvania's statute does not police fraud against a federal agency. It regulates the health and safety of its citizens, which is where the presumption against preemption "stands at its strongest." *Desiano*, 467 F.3d at 94. Accordingly, the presumption against preemption should apply here.

B. The Seventeenth Circuit should have concluded that the exception to Transylvania's statute are not impliedly preempted because they do not act as an obstacle to the federal regulatory scheme.

1. *Buckman* is distinguishable because it addressed a standalone tort claim alleging fraud on the FDA.

In *Buckman*, this Court held only that the FDCA impliedly preempts standalone fraud-on-the-FDA claims. *See* 531 U.S. at 353.

The question in *Buckman* was whether the plaintiffs could bring standalone fraud-on-the-FDA claims or if the FDCA preempted the claim. *See id.* at 343. The plaintiffs alleged that the defendant fraudulently misrepresented the status of its medical device to obtain premarket approval from the FDA, and thus the defendant should be liable for their injuries. *Id.* at 343, 346-47. This Court began its analysis by declining to apply the presumption against preemption because "policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347 (quoting *Rice*, 331 U.S. at 230). It then held that the plaintiff's fraud-on-the-FDA claims conflicted with federal law and were thus impliedly preempted for three reasons. *Id.* at 348. First, the FDA has procedures in place to police fraud on itself that would be hindered by state courts creating liability for manufacturers. *Id.* at 348–50. Second, state court findings might lead manufacturers to fear promoting off-label use of medical devices. *Id.* at 349–50. And third, state court findings of fraud would lead manufacturers to flood the FDA with unnecessary documents when applying for premarket approval, slowing down the approval process. *Id.* at 351.

In *Garcia v. Wyeth-Ayerst Laboratories*, the Sixth Circuit considered a statute like Transylvania's and held that state courts are preempted from issuing a finding of fraud unless the FDA does first. *See* 385 F.3d at 963–66. The court concluded that the difference between the tort claim in *Buckman* and the immunity exemption in the statute was "immaterial." *Id.* at 966. In reaching this conclusion, the Sixth Circuit misinterpreted *Buckman*. This Court never said that only the FDA can find that it has been defrauded. This Court was careful to distinguish between standalone claims and claims associated with state torts. *Id.* at 347–53. The claim in *Buckman* did not rely on any sort of traditional state tort theory—it existed "solely by virtue of the FDCA disclosure requirements." *See id.* at 352–53. Accordingly, this Court distinguished the case before it from *Silkwood v. Kerr-McGee* and *Medtronic Inc. v. Lohr* where the plaintiff's claims sounded in traditional state tort law. *Id.* at 353. The logical implication of this distinction is that, had the plaintiffs in *Buckman* alleged traditional state tort law claims based on defrauding the FDA, those claims would have survived implied preemption. Thus, *Buckman* did not intend to prohibit state courts from considering evidence of fraud on the FDA in all circumstances.

When a plaintiff asks a state court to issue a finding of fraud-on-the-FDA to withdraw immunity, they are not bringing a state law tort claim. The fraud issue is, at most, an extra element of the tort claim, and thus falls outside the scope of the circumstances this Court addressed in *Buckman*. *See Desiano*, 467 F.3d at 94–95. Accordingly, the Sixth Circuit erred in *Garcia* when it decided that the distinction did not matter for purposes of preemption. *See* Jason Murdey, *Preemption of the*

"Fraud on the FDA" Exception to Michigan's Tort Immunity Statute for Drug Manufacturers: Reconsidering Garcia and Design After Levine, 66 Food & Drug L.J. 85, 98 (2011) ("*Garcia* commits the fundamental apprehension that *Buckman* itself took pains to avoid: conflating the preemption of stand-alone "fraud on the FDA" claims with embedded tort claims.")

The formal difference between a state court finding of fraud to withdraw tort immunity and a standalone fraud-on-the-FDA claim cannot be overlooked when applying the preemption analysis. Accordingly, *Buckman* should be read narrowly—as this Court intended—when addressing state statutes removing tort immunity for defrauding the FDA.

2. The FDCA does not preempt the exceptions to Transylvania's statute because the policy concerns identified in *Buckman* do not carry the same weight in this case.

i. The FDCA does not preempt the fraud exception because the exception does not create tort liability for manufacturers, thus avoiding this Court's concerns in *Buckman*.

Transylvania's tort immunity statute contains an exception for defrauding the FDA when obtaining premarket approval for a medical device. 21 Trans. Comp. § 630.546(b). The statute withdraws immunity if a manufacturer "intentionally withholds from or misrepresents to the [FDA] information concerning the . . . medical device that is required to be submitted" by the FDCA, and the FDA "would not have approved" or "would have withdrawn approval for the . . . medical device if the information were accurately submitted." *Id.* In *Buckman* this Court was concerned that standalone fraud-on-the-FDA claims would interfere with the FDA's

ability to regulate itself for three reasons. First, the plaintiff's claim was an attempt to police fraud on the FDA, and the FDA is adequately empowered to police itself. *Buckman*, 531 U.S. at 348–50. Second, standalone tort claims might discourage off-label use of medical devices. *Id.* at 349–50. And third, standalone tort claims might lead to manufacturers over-submitting documents to the FDA for fear of state courts considering their submissions to the FDA insufficient. *Id.* at 151. Those concerns do not carry the same weight here because the fraud exception to Transylvania's tort immunity statute does not create tort liability for manufacturers, so it does not interfere with the FDA's ability to police fraud, does not affect off-label use, and does not create an increased incentive to over-submit documents to the FDA.

Tort immunity exceptions for defrauding the FDA are not attempts to police fraud on the FDA, and thus they do not interfere with the FDA's ability to police fraud on itself. In *Desiano*, the Second Circuit held that the formalistic difference between the standalone tort claim in *Buckman* and the Michigan immunity exception for defrauding the FDA demonstrated that the state was not attempting to police fraud on the FDA. 467 F.3d at 94–97. Rather than attempting to police fraud, the Michigan fraud exception encouraged compliance with FDA regulations to ensure that only those products declared safe by the FDA would reach Michigan citizens. *Cf.* 21 Trans. Comp. §§ 630.544, 630.546(a). By contrast, the Sixth Circuit reached the opposite conclusion; tort immunity exceptions for defrauding the FDA are no different than standalone tort claims. *See Garcia*, 385 F.3d at 966.

Accordingly, it held that the FDCA preempts the exception unless the FDA issues a finding of fraud first. *See id.* Justice Stevens, concurring in *Buckman*, said that state court damage remedies after the FDA issues a finding of fraud "supplement and facilitate . . . the federal enforcement scheme." 531 U.S. at 354 (2001) (Stevens, J., concurring). Although he advocated for the position taken by the Sixth Circuit, the underlying reasoning of his argument is even stronger under these circumstances. Tort immunity exceptions for defrauding the FDA facilitate the federal enforcement scheme by encouraging compliance. They do not interfere with the FDA's ability to police itself—instead, they complement the FDA's enforcement mechanisms.

Fraud exceptions to tort immunity will not discourage off-label use of medical devices. *Buckman* felt that standalone claims would lead manufacturers to stop pursuing approval for devices with "potentially beneficial off-label uses for fear that such use might expose the manufacturer . . . to unpredictable civil liability." *Id.* at 351. That is not the case with fraud exceptions because the finding of fraud does not create civil liability for manufacturers. Thus, the concern is inapplicable.

This Court's concern in *Buckman* that standalone fraud-on-the-FDA claims would lead manufacturers to flood the FDA with unnecessary documents "prove[s] too much." *Desiano*, 467 F.3d at 97. As the Second Circuit pointed out, there is no difference between allowing state courts to address fraud-on-the-FDA when examining tort immunity statutes and allowing plaintiffs to introduce evidence of fraud on the FDA to prove their state law tort claim. *See id.* This Court's caselaw

permits the latter, but the Sixth Circuit concluded that the concerns in *Buckman* require a finding that the FDCA preempts the former. *See Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 966 (6th Cir. 2004). Such a conclusion is illogical and cannot stand. "Only when proof of fraud is by itself sufficient to impose liability . . . does the incentive to flood the FDA appreciably escalate." *Desiano*, 467 F.3d at 97 (emphasis in original).

Transylvania's immunity exception for defrauding the FDA should not be preempted. Transylvania courts are not attempting to police fraud against the FDA by enforcing the statute. The Transylvania legislature determined it wanted to grant general immunity to medical device manufacturers unless the manufacturer defrauded the FDA in gaining marketing approval. *See* 21 Trans. Comp. Stat. § 630.546(a)–(b). Under this statute, a state court finding of fraud on the FDA does not create liability for the manufacturer. Such a finding merely allows a plaintiff to move forward with their state law tort claim. The state court finding does nothing to interfere with the FDA's ability to use the processes provided by Congress to police fraud. Rather, the state court finding of fraud complements the statutory scheme by encouraging compliance with FDA regulations.

Similarly, the Transylvania statute will not lead manufacturers to flood the FDA with unnecessary documents. As the Second Circuit pointed out, evidence of fraud on the FDA is introduced in other circumstances, so Transylvania courts issuing findings of fraud to remove tort immunity will not create a new incentive to submit additional documents to the FDA. On the contrary, the current standard of

allowing fraud evidence in state law tort claims creates a greater incentive because liability can immediately follow the court's ruling. When courts issue a finding of fraud in accordance with a tort immunity exception, the case is merely ushered to the next stage of litigation.

Transylvania's fraud exception is not an attempt to police fraud on the FDA, so it does not conflict with the FDA's "responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman*, 531 U.S. at 350. Nor does it incentivize manufacturers to flood the FDA with extra documentation. Accordingly, *Buckman*'s concerns do not mandate a finding that the FDCA impliedly preempts state court findings of fraud under tort immunity exceptions.

ii. The FDCA does not preempt the failure to warn exception because the exception does not conflict with the FDA's regulatory processes.

Transylvania's immunity statute contains an exemption for failing to warn the FDA that states, "The immunity granted under subsection (a) does not apply if the defendant fails to warn about the dangers or risks of the . . . medical device as required by the FDA." 21 Trans. Comp. § 630.546(c). The Seventeenth Circuit improperly concluded that this Court's concerns in *Buckman* required preemption because the exception interferes with the FDA's ability to "police the conduct of regulated entities." (R. 31). The District Court correctly applied *Desiano* to find that the FDCA does not preempt the exception because the concerns identified in *Buckman* are not implicated here.

First, a state court withdrawing immunity by finding that a manufacturer failed to warn the FDA does not create inter-branch meddling. Like the analysis for the fraud exception in section B.2.i, when a state court addresses a defense to immunity based on the failure to warn, the court is not creating liability for the manufacturer. Thus, the state court is not attempting to "police the conduct of regulated entities." (R. 31). Rather, it is simply removing the state-created immunity and permitting plaintiffs to pursue their state law claims. Unlike in *Buckman* where the Court found that the relationship between the FDA and the manufacturer is "inherently federal," 531 U.S. at 348, the relationship between the state and manufacturer is inherently local for purposes of removing tort immunity. The entire basis of immunity exists because of state law, and thus a state court is not meddling with the FDA's ability to police its regulated entities by determining whether that immunity should be granted.

The Fifth Circuit addressed a tort immunity exception like Transylvania's in *Lofton v. McNeil Consumer and Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012). There, a Texas statute withdrew tort immunity if a device manufacturer failed to warn the FDA, and the plaintiff was required to provide evidence of fraud on the FDA to invoke the exception. *See id.* at 374–75. In deciding whether the FDCA preempted the statute, the court examined the distinction drawn by the Second Circuit in *Desiano* between standalone tort claims and immunity exceptions. *See id.* at 377–78. The court declined to follow *Desiano* and instead adopted the Sixth Circuit's position that the distinction is immaterial for purposes of

preemption. *See id.* at 378–81. Both the Fifth and Sixth Circuits overlooked the meaningful difference between a standalone fraud-on-the-FDA claim and a state court finding that removes tort immunity. *See Desiano*, 467 F.3d at 94–97; *Tigert v. Ranbaxy Pharmaceuticals, Inc.*, No. 12-00154, 2012 WL 6595806, at *4 (D. N.J. Dec. 18, 2012); *Yocham v. Novartis Pharmaceuticals Corp.*, 736 F. Supp. 2d 875, 887 (D. N.J. 2012). One creates tort liability for the manufacturer, thus interfering with the FDA's ability to use the procedures allocated by Congress to police fraud. The other revokes state-created immunity because of a state-created exception. One interferes with the FDA's regulatory processes; the other complements the federal enforcement scheme.

Second, *Buckman*'s concern that allowing state courts to make similar determinations will lead to manufacturers flooding the FDA with unnecessary information is relevant here, but not dispositive. Because this exception is based on failing to warn the FDA about the inherent dangers of a product, manufacturers may be inclined to submit more information to retain the immunity granted by the state. But as the Second Circuit pointed out in *Desiano* regarding evidence of fraud on the FDA, *see Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2d Cir. 2006), state courts can already consider evidence of manufacturers failing to warn the FDA via state tort claims. *See Hughes v. Boston Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011) (holding that failure to warn claims avoid preemption); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (holding that failure to warn claims avoid preemption). *But see Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017)

(holding that failure to warn claims are preempted); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010) (holding that failure to warm claims are preempted). Thus, there would be no increased incentive to over-supply documentation to the FDA by allowing a state court to remove immunity for failing to warn the FDA.

In *Lofton*, the Fifth Circuit attempted to distinguish *Desiano* on this point, holding that state court findings of failure to warn interfere with the FDA's investigatory processes when there are close questions of withholding or misrepresentation. This Court need not address that concern to resolve this case. This Court can hold that when the failure to warn the FDA is clear and unambiguous, then the FDCA does not preempt the immunity exception. Ruling in this way will affect many cases because the question of whether a manufacturer warned the FDA of the dangers associated with the product will often be easy. To obtain premarket approval, a medical device manufacturer must submit documentation of tests run on the product to guarantee its safety. *See* 21 U.S.C. § 360e(c)(1); *see also id.* § 360c(f)(4). Thus, a state court will often be able to look at these documents to determine whether the manufacturer informed the FDA of any known dangers or risks. State courts will not need to wade into the murky waters of whether a submission was adequate or not; they can resolve the question by examining whether the manufacturer provided any warning to the FDA.

Transylvania's tort immunity exception for failing to warn the FDA does not interfere with the FDA's regulatory processes. Just as Transylvania was not attempting to police fraud on the FDA via its fraud exception, it was not trying to do

so via this exception either. Despite the conclusions of the Fifth and Sixth Circuits, the formal difference between standalone tort claims and tort immunity exceptions is meaningful. There is no question that this difference mandates a different result than that of *Buckman*.

This case presents an easy example of a manufacturer failing to warn the FDA; Ortega demonstrated that Mednology did not warn the FDA about the dangers associated with Sleepternity because it did not disclose its use of polyurethane foam. Ortega pleaded that—shortly before Mednology marketed Sleepternity with polyurethane foam—Philips Respironics removed its CPAP machines containing polyurethane foam from the market because of the potential for serious health risks. Mednology did not include a warning about its use of polyurethane foam in Sleepternity because it was hiding that fact from the FDA. Accordingly, this is not an instance where the state court is meddling with the FDA's regulatory processes. This is a clear question that does not require the FDCA to preempt the immunity exception.

Contrary to the Seventeenth Circuit's conclusion, the FDCA should not preempt the failure to warn exception based on the concerns identified in *Buckman*. The cases the Seventeenth Circuit relied on to reach its conclusion overlook important differences between this case and *Buckman*. This Court should resolve the issue by holding that the FDCA does not preempt the exception when the question of failure to warn is clear and unambiguous as it was here.

3. Adopting the Sixth Circuit's position would produce unreasonable results because the FDA does not give teeth to its enforcement mechanisms.

Due to its limited resources, the FDA is slow to act or may not act at all. Accordingly, this Court should not adopt a rule that only allows plaintiffs to recover when the FDA exercises its police power to punish manufacturers.

Requiring plaintiffs to wait to bring tort claims until the FDA issues a finding of fraud against a manufacturer will leave many people without a remedy. Congress did not imagine such a result, and that result would be inconsistent with this Court's analysis of products liability preemption under the FDCA. *See Lohr*, 518 U.S. at 487 ("Medtronic's argument [that Congress intended consumers to have no remedy for injuries caused by medical devices] is not only unpersuasive, it is implausible."). Although this Court said that the FDA was adequately capable of policing fraud against itself in *Buckman*, that same conclusion cannot reasonably be made today. *See Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009) (citing four FDA statements to Congress that the agency lacks sufficient resources to carry out its duties to the public).

Although the FDA is empowered to police fraud, it is not clear that it always takes advantage of that power. The FDA has its prerogatives and chooses to investigate and punish certain actors based on allocation of its limited resources. State tort liability exists to give citizens a remedy. A federal agency's inability to pursue every violation of its regulations is not a legitimate reason to limit that remedy. The lack of a formal finding of fraud by the FDA does not make a

manufacturer's violation of the FDCA any less real or an injured plaintiff's right to a remedy any less valid. Accordingly, the *Desiano* rule creates reasonable results by allowing plaintiffs to pursue legitimate tort claims even if the FDA is paralyzed by lack of resources. By recognizing the differences between the circumstances of *Buckman* and cases like *Desiano* or *Garcia*, the Second Circuit's rule prohibits medical device manufacturers from being shielded by preemption principles when there is no conflict between state and federal law. And although this rule allows plaintiffs in states with liability defenses (like Michigan or Transylvania) to move forward with their claims, it does not overburden manufacturers because plaintiffs are still subjected to the preemption principles expressed in *Lohr*, *Buckman*, and *Reigel v. Medtronic, Inc. See* 518 U.S. 470; 531 U.S. 341; 552 U.S. 312 (2008).

Applying the *Garcia* rule to Ortega's case shows how unreasonable the result can be. Ortega alleged a number of state law tort claims against Mednology for injuries she suffered due to Mednology using polyurethane foam in its CPAP machines. Because Transylvania granted medical device manufacturers general tort immunity, Ortega must also take the additional step of showing that Mednology defrauded the FDA in the process of obtaining premarket approval from the FDA. Mednology quickly recalled its device from the market, so the FDA ceased its investigation into Mednology's fraudulent conduct. If this Court adopts *Garcia*'s rule, manufacturers will be incentivized to violate FDA regulations then recall their products quickly based on the low likelihood of the FDA using its punishment

mechanisms. Ortega will have no remedy and Mednology will go unpunished for its violations of both state torts and federal law.

The *Garcia* rule encourages device manufacturers to recall their devices from the market to avoid FDA investigation and to continue reaping the benefits of violating FDA regulations. Until the FDA establishes that it is capable of policing the entities it regulates, this Court should not adopt a rule that gives it the power to limit injured plaintiffs' ability to bring state torts.

C. Even if the FDCA preempts one or both exceptions, it does not preempt Transylvania's general grant of immunity conditioned on compliance with FDA regulation because the condition is not an obstacle to federal law.

Transylvania's grant of tort immunity, conditioned on compliance with FDA regulations, is not impliedly preempted.

Conditioning immunity on compliance is within the state's province. For the same reasons discussed in sections 2.B.i. and 2.B.ii., conditioning immunity on compliance does not interfere with the FDA's ability to police its regulated entities, nor does it implicate the relationship between the manufacturer and the agency. First, conditioning immunity on compliance with FDA regulations complements the federal regulatory scheme by encouraging manufacturers to comply with FDA regulations. *Cf. Buckman*, 531 U.S. at 354 (Stevens, J., concurring). Second, the immunity condition only implicates the relationships between the state, the manufacturer, and the consumer. Although the Sixth Circuit has held that conditioning immunity on compliance with FDA regulations implicates the

relationship between the manufacturer and the agency, its holding does not address the question presented in this case. *See Marsh v. Genetech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012). There, the plaintiffs alleged that a manufacturer failed to comply with general post-approval reporting requirements. *Id.* at 552. In a footnote, it explicitly said it was not answering the question of "whether an allegation of *substantive non-compliance* that . . . more directly involves a consumer, such as a chemical variance or an inaccurate label, would be preempted . . . ." *Id.* at 554 n.4 (emphasis added).

Transylvania's statute does not interfere with the FDCA's regulatory scheme. Rather, it complements the scheme by encouraging manufacturers to comply with federal regulations without subjecting them to liability for violations of those regulations. *See* 21 Trans. Comp. §§ 630.545, 630.546(a)–(c). This is within the state's province, and Mednology has not shown enough evidence to overcome the presumption against preemption here.

Moreover, the Seventeenth Circuit correctly distinguished *Marsh* and concluded that the condition is not preempted. Ortega alleged that Sleepternity was marketed with a different and more dangerous foam than approved by the FDA. Thus, she alleged that Sleepternity was substantively non-compliant with FDA regulations when it left Mednology's control—the exact question left open by the Sixth Circuit. Accordingly, *Marsh*'s holding carries no weight for this Court's analysis.

Transylvania's statute conditioning immunity on compliance with federal regulations does not interfere with the federal statutory scheme. Accordingly, the

Seventeenth Circuit was correct in concluding that the FDCA does not preempt the statute.

II. A relator can rely on the fraud-on-the-FDA theory to bring a claim under the False Claims Act.

The FCA holds liable those who knowingly present a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a). A "claim" is any request or demand to the government for payment or property, including "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 (2019); *see* 31 U.S.C. § 3729(b)(2)(A).

Federal healthcare funding programs, such as Medicare and Medicaid, require FDA approval for drugs and medical devices before providing reimbursement coverage for the cost of a medical device. *See* U.S. Dep't Health & Hum. Servs., Medicare Benefit Policy Manual, ch. 14, § 10 (2021) (stating that medical devices may be covered by Medicare and Medicaid). CMS' responsibilities extend beyond device approval, encompassing the administration of the Medicare and Medicaid programs which serve more than 160 million Americans. *Id.* Because of CMS' extensive coverage responsibilities, it generally defers to FDA determinations about a device's safety and efficacy. *Id.* As such, "[v]iolations of the FDA regulatory regime have ramifications beyond FDA enforcement actions." *United States ex rel. Campie v. Gilead Sciences*, 862 F.3d 890, 907 (9th Cir. 2017).

The fraud-on-the-FDA theory connects a manufacturer's fraud executed during the FDA approval process to the device's resulting government coverage. Kelly Carty Zimmerer, *Health Fraud Form FDA Approval to CMS Payments: Why Fraud-on-the-FDA Should be a Viable Form of Liability Under the False Claims Act*, 62 U. Louisville L. Rev. 713, 716 (2024). By reinforcing the validity of the fraud-on-the-FDA theory, this Court can ensure that the FCA holds companies accountable for fraudulently obtaining FDA approval resulting in Medicare coverage that causes "healthcare companies to submit reimbursement claims to the government for payment." *Id.*

A. Ortega survives the motion to dismiss her False Claims Act claim because she pleaded sufficient facts to establish all four of the Act's elements.

Under Federal Rule of Civil Procedure 12(b)(6), an FCA claim can be dismissed only when there is an "absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). To survive a motion to dismiss, a plaintiff must plead sufficient 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 relator's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555.

The FCA has four elements, "(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 mon[ies] due." *United States v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006). Because the Act requires the materiality of the false

statement to have caused government payment, courts consider the third and fourth elements together. *See Escobar*, 579 U.S. at 193.

To prevail on a 12(b)(6) motion to dismiss an FCA claim, a relator must plausibly and particularly allege all four elements of the Act "by a preponderance of the evidence." 31 U.S.C. § 3731(d). A relator can plead each FCA element "with plausibility and particularity . . . by, for instance, pleading facts to support allegations of materiality." *Escobar*, 579 U.S. at 196 n.6. The relator must "allege enough facts to raise a reasonable expectation that discovery will reveal evidence of the misconduct alleged." *United States ex rel. Stenson v. Radiology Ltd., LLC*, No. 22-16571, 2024 WL 1826427, at *1 (9th Cir. April 26, 2024) (quoting *Cafasso v. Gen Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011)). Furthermore, because fraud is an element of the Act, a relator is required "to state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

1. Mednology fraudulently misrepresented its use of silicone-based foam in Sleepternity by not disclosing to the FDA that it changed the foam to polyurethane-based foam after premarket approval.

Submitting a claim for payment that intentionally fails to disclose noncompliance with a regulatory requirement is actionable under the FCA. Congress did not explicitly define "false" or "fraudulent" in the FCA context, so the Court "incorporate[s] the well-settled meaning of the common law terms it uses." *Escobar*, 579 U.S. at 187 (quoting *Sekhar v. United States*, 570 U.S. 729, 732 (2013)).

Under the common-law definition of fraud, misrepresentations by omission can give rise to FCA liability. *Escobar*, 579 U.S. at 177. For example, in *Escobar*, "a teenage beneficiary of Massachusetts' Medicaid program," died from a seizure caused by medication complications while at a mental health facility. *Id.* at 176. The teen's parents discovered that many of the facility's employees were not licensed to provide mental health counseling or prescribe medication without supervision. *Id.* The petitioners alleged that Universal Health Services (Universal) violated the FCA by defrauding the Medicaid program through the submission of reimbursement claims with misleading representations about the services provided and the providers' qualifications. *Id.* The parties disputed "whether submitting a claim without disclosing violations of statutory, regulatory, or contractual requirements constitutes such an actionable misrepresentation." *Id.* at 188. The realtor argued that when a billing party submits a claim for government reimbursement, it "impliedly certifies compliance" with program requirements and entitlement to payment. *Id.* at 180. This Court agreed, finding that Universal's claims for payment constituted "half-truths . . . omitting critical qualifying information" and thus were actionable under the FCA. *Id.* at 188.

Misrepresentations about the manufacturing process can be considered fraudulent statements under the FCA. In *United States ex rel. Campie v. Gilead Sciences*, three former employees of Gilead Sciences alleged that the company "made false statements about its compliance with [FDA] regulations regarding certain HIV drugs" resulting in the payment of billions of government dollars. 862 F.3d 890, 902

(9th Cir. 2017). The court held that the realtors sufficiently pled the fraudulent claim element of the FCA by alleging that Gilead misrepresented that active ingredients in its drugs were manufactured at approved facilities when they were not. *Id.* Despite Gilead's noncompliance, they continued to submit claims for government payment of the "FDA approved" drugs. *Id.* at 904. The court held that Gilead's misrepresentations "[fell] squarely within the rule of half-truths" established in *Escobar*. *Id.*

Like Universal's misrepresentations by omission in *Escobar* and Gilead's misrepresentations about FDA regulatory compliance in *Campie*, Ortega sufficiently alleged that Mednology's use of polyester-based polyurethane foam was fraudulent. CPAP machines are covered by the Centers for Medicare and Medicaid Services (CMS) under the Durable Medical Equipment benefit. 42 U.S.C. § 1395x(n). CMS reimbursement claims can be submitted by the patient beneficiary, health care provider, or the service supplier. 42 C.F.R. § 424.5(a)(5). When the FDA approved Sleepternity as a Class III medical device, its sound-dampening foam was silicone-based. (R. 4). After obtaining FDA approval and CMS coverage, Mednology swapped the silicone-based foam with polyurethane-based foam without notifying either agency. (R. 4). Despite the change, Sleepternity continued to be advertised and prescribed as a device containing silicone-based foam. (R. 4).

Ortega alleged that Mednology "initially utilized silicone-based foams to secure marketing approval from the FDA and that it replaced such foams with [polyurethane-based] foams to save manufacturing costs before packaging and

sending Sleepternity to its distributors." (R. 5). This allegation establishes fraud under the FCA. By distributing Sleepternity without disclosing the presence of polyurethane-based foam, Mednology omitted qualifying information that would impact user's claims for Medicare reimbursement just as Universal did in *Escobar*. Accordingly, Mednology's omission of critical qualifying information fits squarely into *Escobar*'s "rule of half-truths."

2. Mednology knowingly used polyurethane-based foam in Sleepternity because the foam made it cheaper to manufacture.

The FCA's scienter element asks whether the defendant knowingly violated a requirement that is "material to the Government's payment decision." *Escobar*, 579 U.S. at 192. To plead scienter, a realtor must "allege a false statement or course of conduct made knowingly and intentionally." *Campie,* 862 F.3d at 904; *see* 31 U.S.C. § 3729(b)(1). The Act defines "knowledge" as "actual knowledge," "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); *see Escobar*, 579 U.S. at 182.

A relator's pleadings must allege a manufacturer's knowledge or guilty intent to satisfy the FCA's scienter element. In *Campie*, the realtors pointed to intentional actions Gilead took to perpetrate its fraud, including, "altering test results, batch numbers, and Inventory Control Numbers, and representing that nonapproved FTC came from approved facilities." 862 F.3d at 904. Because the realtors alleged that Gilead made statements about its drugs that were "'intentional, palpable lie[s],' made

with 'knowledge of the falsity and with intent to deceive," scienter was adequately pled.'" *Id.* (quoting *United States ex rel. Hopper v. Anton*, 911 F.3d 1261, 1265, 1267 (9th Cir. 1996)).

An intent to deceive can be inferred from a manufacturer's actions. In *United States v. Aerodex, Inc.*, the manufacturers denied an intent to "cheat" the government by selling the Navy engine bearings that were of similar quality to the bearings contracted for. 469 F.2d 1003, 1007 (5th Cir. 1972). The court was unpersuaded, finding that there was an intent to cheat a government agency through "deliberate misbranding" of the bearings provided. *Id.* If the manufacturers believed the bearings were interchangeable, they could have requested permission to deliver the substituted parts or "at least, could have disclosed to the Navy the manner in which they thought they could comply with the contract." *Id.* Without such permission or disclosure, the behavior "indicates nothing less than an intention to deceive." *Id.* Similarly, the D.C. Circuit Court of Appeals determined that if a company "knowingly submitted false progress reports" indicating adequate software delivery to the government when in fact it was not, "the[ ] progress reports would constitute false statements in support of false claims and would trigger the [False Claims] Act's civil penalty." *United States ex rel. Schwedt v. Planning Rsch. Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) ("Though PRC did not submit a bill for the software, its goal of receiving payment was implicit in the submission of the goods, and the accompanying progress reports has the purpose of 'getting . . . [the] claim . . . approved.'") (alteration

in original). Therefore, the plaintiff's scienter allegations were sufficient to allow the FCA claim to proceed. *Id.* at 199.

In this case, Ortega adequately pleaded that Mednology knowingly and intentionally obtained FDA approval for Sleepternity based on a misrepresentation of its components. Mednology secured FDA approval for Sleepternity containing silicone-based foam, yet manufactured and marketed Sleepternity knowing that its representation was untrue. Beyond those allegations, like the court in *Aerodex*, this Court can reasonably infer that altering a component of a medical device after FDA approval—but before distribution—suggests Mednology's intent to deceive the FDA, Sleepternity users, and government payors. As the *Aerodex* court reasoned, Mednology could have disclosed the change and attempted to obtain FDA approval for the updated device. And like the fraudulent progress reports in *Schwedt*, Ortega alleged that Mednology's fraudulent procurement of FDA approval had the implicit goal of ensuring CMS coverage of Sleepternity. Ortega's explicit allegations of scienter paired with Mednology's implicit intent to deceive users and payors satisfy the Act's scienter element.

3. Mednology's fraudulent misrepresentation was material in causing Medicare coverage for Sleepternity because CMS relies on FDA approval when deciding to provide medical device coverage.

Under the FCA, a falsehood is "material" if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Materiality is a stringent requirement and "cannot rest on a

single fact or occurrence as always determinative." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)). Traditional tort law principles require the FCA's causation element to be analyzed using a proximate cause test "to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 714 (10th Cir. 2006). The strict causation test filters out "claims with only attenuated links between the defendants' specific actions and the presentation of the false claim." *Id.*

Both the FDA and CMS are managed by the Department of Health and Human Services and the agencies work together to navigate the "complex regulatory approval process" for medical devices. Katie Adams et. al., Bipartisan Policy Center, *Strengthening Regulatory Collaboration Between FDA and CMS* 6 (2024). The FDA is responsible for ensuring that medical products meet United States safety requirements before being marketed. *Id.* CMS is responsible for determining the eligibility of therapies for reimbursement." *Id.* Medicare makes its device coverage determinations based on specific statutory coverage provisions; however, any Medicare Part B recipient can obtain coverage for durable medical equipment "as long as the equipment is medically necessary." Department of Health and Human Services, Medicare Coverage of Durable Medical Equipment & Other Devices 2 (2024). Therefore, FDA approval of a medically necessary equipment essentially guarantees CMS' coverage for Medicare Part B recipients.

i. Mednology's failure to comply with the FDA's statutory requirements induced the government to pay for nonconforming goods.

A fraudulent claim is not limited to express misrepresentations in a payment contract. *Escobar*, 579 U.S. at 178 ("A defendant can have 'actual knowledge' that a condition is material even if the Government does not expressly call it a condition of payment."). In *Escobar*, the Court posited that policy concerns about the FCA—including fair notice and open-ended liability—"can effectively be addressed through strict enforcement of the Act's materiality and scienter requirements." *Id.* at 192 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (2010)).

This Court has held that "proof 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." *Id.* at 194–95. The materiality inquiry should include whether the government pays a claim despite knowing "that certain requirements were violated," because "that is very strong evidence that those requirements were not material." *Id.* at 195. On the other hand, "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.*

Escobar stands for the proposition that when "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omission can be a basis for liability if they render

the defendant's representations misleading with respect to the goods or services provided." *Id.* at 187.

To illustrate the materiality inquiry, this Court offered the analogy of a manufacturer selling guns to the government. *Id.* at 191. The government may not overtly tell the manufacturer that the guns are expected to shoot, but the manufacturer is aware "that the Government routinely rescinds contracts of the guns that do not shoot," thus, he "has 'actual knowledge'" that functionality of the guns is a condition of payment. *Id.* A reasonable person selling guns to the government "would realize the imperative of a functioning firearm" and that "the 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." *Id.* (quoting 31 U.S.C. § 3729(b)(1)(A)).

Inducing the government to pay for nonconforming goods is a basis of FCA liability. In *Campie*, Gilead Sciences attempted to circumvent liability by claiming that the FDA continued to approve the drugs at issue after learning of Gilead's noncompliance. *Campie*, 862 F.3d at 906. The relator argued that if "continued approval" by the FDA could shield Gilead from liability, any company could use fraudulently-obtained FDA approval to do the same. *Id.* The Ninth Circuit determined that issues of payment "are matters of proof, not legal grounds to dismiss relators' complaint[s]." *Id.* at 907. Instead, to survive a motion to dismiss, the court required that "relators allege more than the mere possibility that the government

would be entitled to refuse payment if it were aware of the violations . . . ." *Id.* Because that condition was met, Campie's claim survived the motion to dismiss. *Id.*

By failing to comply with the FDCA, Mednology's violation fits squarely into the *Escobar*'s parameters. Like Universal's misrepresentations in *Escobar*, the specific type of foam used in Sleepternity is not an express condition of payment. Instead, Mednology's misrepresentation is an omission of a violation of statutory, regulatory, or contractual requirement. Medical devices are required to obtain premarket approval by the FDA before distribution. 21 U.S.C. § 360(e). Because Sleepternity is a Class III device that has obtained premarket approval, Mednology is required to abide by the FDCA's requirement of submitting a supplemental application for any change in the device "that affects safety or efficacy." *Id.* § 360e(d)(5)(A)(i). And as the gun manufacturer referenced in *Escobar* would reasonably know that the guns he was producing were expected to shoot, a medical device manufacturer reasonably knows that fraudulently procuring FDA approval will impact Medicare's coverage of a device. Mednology's misrepresentation is a basis for FCA liability because it misled Sleepternity users, FDA regulators, and government payors about the quality and contents of the device.

Mednology's misrepresentation about the presence of polyurethane-based foam in Sleepternity fraudulently induced FDA approval where it otherwise would not have been granted. As this Court stated in *Escobar,* proof of materiality can include the government's consistent refusal to pay certain claims. In June 2021, Philips Respironics recalled certain CPAP machines containing polyurethane-based foam. (R.

4). The FDA highlighted the dangers of polyurethane-based foam and its ability to break down over time—"[i]f the foam breaks down, black pieces of foam, or certain chemicals that are not visible, could be breathed in or swallowed by the person using the device." FDA, *Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, (Apr. 2024), https://www.fda.gov/medical-devices/respiratory-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines; (R. 4). The recall affected fifteen million devices worldwide and those impacted "remain a top priority for the agency as the FDA continues to take steps to protect the health and safety of individuals using these devices." *Id.* Only a year and a half later, Mednology obtained FDA approval for Sleepternity by claiming to use silicone-based foam in the device. (R. 3–4).

Given the recent and widespread recall of Philip's devices because of the presence of polyurethane-based foam, this Court can reasonably conclude that the FDA would not have approved the Sleepternity device containing polyurethane-based foam. Knowing that FDA approval is necessary for CMS coverage, Mednology's misrepresentation to the FDA resulted in Medicare coverage for the nonconforming device. Because of the Philips recall, "Riley assert[ed] in her complaint that the FDA would not have approved Sleepternity if the device contained [polyurethane] foams instead of silicone foams" during the premarket approval process. (R. 6). Thus, Ortega sufficiently pled materiality of Mednology's fraud and survives the motion to dismiss.

ii. The circuit split should be resolved in favor of the Ninth Circuit because fraud directed at the FDA can be material in causing CMS coverage for a medical device.

Two circuits have addressed the viability of the fraud-on-the-FDA theory. The First Circuit split from the Ninth Circuit on whether fraud directed at the FDA can establish the materiality and causation elements of the FCA. In *D'Agostino v. ev3*, the relator alleged that a device manufacturer induced government payment for a medical device by making fraudulent representations to the FDA to secure the device's premarket approval. 845 F.3d 1, 7 (1st Cir. 2016). Relying on the fraudulent inducement theory, the relator alleged that the defendants "disclaimed uses for the device they later pursued, overstated the training they later provided, and omitted critical safety information about the molecule, including its failure in the . . . device." *Id.*

The First Circuit was concerned that the FDA itself did not make the payments at issue and therefore, the FCA's causation element was not met. *Id.* In response, D'Agostino highlighted that "FDA approval is a precondition to CMS reimbursement" and that the misrepresentations made to the FDA "could have" influenced the device's approval. *Id.* The court determined that the fraudulent inducement claim "[fell] short of pleading a causal link between the representations made to the FDA and the payments made by CMS." *Id.* Just because the manufacturer's misrepresentations to the FDA could cause FDA approval, does not clearly indicate that the misrepresentation did cause government payment. *Id.*

D'Agostino argued that the FCA clearly states that a misrepresentation is material if it has "a natural tendency to influence, or is capable of influencing, the payment or receipt of money or property." *Id.* (quoting 31 U.S.C. § 3729(b)(4)). The First Circuit rejected this argument, reinforcing the demanding nature of the materiality standard by reiterating that the "FCA requires that the fraudulent representations be material to the government's payment decision itself." *D'Agostino*, 845 F3d at 7 (citing *Escobar*, 579 U.S. at 194). Ultimately, the First Circuit determined that D'Agostino's claim failed due to a break in the causal chain; "if the FDA would have approved [the device] notwithstanding the alleged fraudulent representations, then the connection between those representations to the FDA and a payment by CMS relying on FDA approval disappears." *Id*. at 8.

Practical questions also influenced the First Circuit's holding in *D'Agostino*. First, D'Agostino's fraud claims surfaced six years before being heard by the First Circuit. *Id.* During those six years, the FDA neither demanded a recall nor relabeling of the device at issue, "notwithstanding the agency's option to impose postapproval requirements," "suspend approval temporarily," or withdrawal approval. *Id.*; 21 C.F.R. §§ 814.82(a), 814.47(a), 816.46(a). The court found the lack of FDA intervention preclusive to D'Agostino's claim. *D'Agostino*, 845 F.3d at 8. If the FDA had reason to believe that their approval was fraudulently procured, the agency surely would have, and could have, intervened. Ruling otherwise would allow a court to supersede the authority of the FDA to regulate medical devices. *Id.* The court also questioned how a relator could "prove that the FDA would not have granted approval

but for the fraudulent representations made by the applicant." *Id.* at 9. Such concerns resulted in the court holding that "causation is an element of the fraudulent inducement claims D'Agostino alleges and that the absence of official action by the FDA establishing such causation leaves a fatal gap in this particular proposed complaint." *Id.* This interpretation of FCA liability is wrong.

The First Circuit itself recognized that its holding in *D'Agostino* effectively requires a relator "to alert the FDA—to secure withdrawal of approval—before the relator could allege causation." *Id.* This rule undermines the FCA's *qui tam* provision because FDA intervention makes it more likely the government will bring the FCA action first, "thereby arguably precluding the whistleblower from qualifying for a share of the recovery under 31 U.S.C. § 3730(d)." *Id.* The *qui tam* provision grants a relator up to 30% of the proceeds of an FCA action or settlement. 31 U.S.C. § 3730(d). Statutory awards incentivize private individuals to bring FCA claims quickly, benefiting both individual patients and government payors harmed by the alleged fraud. If a relator cannot bring a fraud-on-the-FDA claim without waiting for FDA intervention, the financial incentive is to report such fraud is lost, and individuals are forced to bring a private tort action against a manufacturer or file a complaint with the FDA in hopes of eventually seeing the device recalled.

Permitting fraud-on-the-FDA claims under the FCA will not impede the FDA's regulating authority if materiality is strictly required by the Act. In *Campie*, the Ninth Circuit acknowledged the First Circuit's concern for "allowing claims under the False Claims Act to wade into the FDA's regulatory regime. *Campie*, 862 F.3d at 905.

Campie clarified that "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.* Because of their different regulatory purposes, "[m]ere FDA approval cannot preclude False Claims Act liability, especially where, as here, the alleged false claims procured certain approvals in the first instance." *Id.*

Instead, the Ninth Circuit, following *Escobar*'s rule, held that courts must maintain a high materiality bar for determining whether a relator's allegations sufficiently connect the purported fraud to government payment. *Id.* at 906. The relators in *Campie* argued that reading "too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake." *Id.* Doing so "would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud." *Id.* Beyond that, "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs." *Id.* Because the *Campie* relators alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations" materiality was sufficiently pleaded at the 12(b)(6) stage. *Id.* at 7.

The concerns raised in *D'Agostino* are not at issue in Ortega's case. First, the FDA's inaction in Ortega's case is not dispositive. Unlike the relator in *D'Agostino* whose FCA action was pending for six years, Ortega brought her claim in June 2023, just over one year ago. (R. 6). In *D'Agostino*, the device at issue was never recalled by the manufacturer and the FDA never attempted to intervene. The First Circuit

determined that the lack of FDA intervention demonstrated indifference to Gilead's misrepresentation, leaving a "fatal gap" in the causation element required for FCA liability. Here, Mednology immediately recalled Sleepternity after Ortega brought her claim, making FDA intervention impossible. (R. 7). After Mednology removed Sleepternity from the market, "the FDA decided not to continue investigating Mednology's alleged fraudulent conduct to focus on investigating other allegedly defective products in the marketplace that have not been recalled." (R. 7). The termination of FDA investigation of Mednology does not convey a lack of concern about the alleged fraud; it demonstrates the FDA's heightened concern over products that are still available to consumers. It is for this exact reason that the fraud-on-the-FDA theory must exist. The FDA is not capable of consistently pursuing retribution for all fraud committed against it and ensuring that harmful products are quickly removed from the marketplace.

Second, conflating the holding of *D'Agostino* with the denouncement of the fraud-on-the-FDA theory unnecessarily constrains the FCA. The FCA's rigorous materiality and causation standards safeguard the FDA's regulatory judgment from outsider overreach. *See Escobar*, 579 U.S. at 194–95. Instead of FDA intervention being dispositive, courts can simply use FDA intervention, or lack thereof, as a relevant fact to the Act's materiality element. Rejecting every FCA claim where the FDA failed to intervene allows manufactures to use "fraudulently-obtained FDA approval as a shield against liability for fraud." *Campie*, 862 F.3d at 906. Furthermore, FDA concerns are not always in alignment with government payment

agencies. The FDA has a variety of interests from ensuring access to medical devices to allowing competition between device producers. *See* 21 U.S.C. § 393(b). The FDA may be less motivated to intervene when one of its primary objectives is not threatened. The FDA has the authority to regulate fraud against it, but there is a "discrepancy between the FDA's formal policing powers and the agency's actual enforcement activity. Namely, the agency may not have the resources or centralized focus to fully address fraud, especially when it is complex and attached to a billion-dollar industry." Kelly Carty Zimmerer, *Health Fraud Form FDA Approval to CMS Payments: Why Fraud-on-the-FDA Should be a Viable Form of Liability Under the False Claims Act*, 62 U. Louisville L. Rev. 713, 713 (2024).

Finally, the causal connection between Mednology's fraud on the FDA and Medicare's coverage of Sleepternity is clear. Less than two years ago, Philips recalled their CPAP machines because they contained polyurethane-based foam. Given the factual similarities and proximity in time, the FDA would not have approved Sleepternity had it known that it would be manufactured and distributed using polyurethane-based foam.

A decision that thoroughly weighs the four essential elements of the FCA does not encroach on the FDA's regulatory authority. If the trier of fact conclusively determines that the manufacturer's misrepresentations caused CMS to pay for Sleepternity, the FCA's requirements are satisfied. Elevating the FDA's regulatory authority over the Government's right to punish fraud against it does not resolve the injury done to both device users and Government payors. Mednology's immediate

recall of Sleepternity cannot absolve Mednology of FCA liability. Permitting such action sets a dangerous precedent for how medical device manufacturers can defraud the FDA to obtain Medicare coverage and clashes with the intention of the FCA. For these reasons, the fraud-on-the-FDA theory of liability should be affirmed as capable of establishing materiality under the FCA.

B. If CMS had known of the polyurethane foam in Sleepternity it would not have covered the device because it is unreasonable and unnecessary.

After the FDA approves a medical device, CMS must then determine whether the device is "reasonable and necessary" for coverage among Medicare beneficiaries. Centers for Medicare & Medicaid Services, *Medicare Coverage Determination Process*, (Sept. 5, 2024, 4:00 PM), https://www.cms.gov/medicare/coverage/determination-process.

Medicare Parts A and B are "prohibited by law from paying for any medical products or procedures that are not 'reasonable and necessary'" for the Medicare populations they are designed to serve. *Id.* (citing 42 U.S.C. § 1395y(a)(1)(A)). Meaning that durable medical equipment must be "necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member." Centers for Medicare & Medicaid Servs., Dep't of Health and Human Servs., *Medicare Benefit Policy Manual*, ch. 15 § 110.1(C). Medical equipment is "necessary" if it is "expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member." *Id.* § 110.1(C)(1). Reasonableness requires a balancing of whether the

expense of the device is proportionate to its benefit, if the device is "substantially more costly" than a reasonable alternative, and whether the device serves the same purpose as available equipment. *Id.* § 110.1(C)(2).

1. Sleepternity cannot make a meaningful impact to CPAP users' lives because of the harmful effects of polyurethane foam.

CMS bars payment "for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function . . . ." *Id.* § 110.1(C).

Sleepternity is not "necessary" because it can cause users to inhale volatile compounds like isocyanate. The presence of polyurethane-based foam in Sleepternity renders the device unable to "make a meaningful contribution to" a CPAP user's condition. Polyurethane-based foam is known to break down over time and release volatile organic compounds. (R. 4). CPAP users are especially vulnerable to these degraded foam particles which can be breathed in and can result in irritation to the respiratory system, asthma, and "toxic or cancer-causing effects." FDA, *Recommendations for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, (Apr. 2024), https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/recommendations-recalled-philips-ventilators-bipap-machines-and-cpap-machines#risk.

In Ortega's case, Sleepternity's degraded polyurethane-based foam was releasing isocyanate, a known allergen of Ortega's. (R. 5). She was unable to avoid encountering the compound because "Sleepternity's warning label did not contain any

information about the presence of isocyanates in the device." (R. 5). Ortega's use of Sleepternity resulted in asthma attacks requiring hospitalization, chronic inflammation of her lungs, and persistent sleep apnea symptoms. (R. 4-5). Sleepternity's failure to properly perform its therapeutic function, "to reduce the occurrence of sleep apnea," rendered it unnecessary for Ortega and any other patient requiring a CPAP machine.

2. It would be unreasonable for Medicare to pay for Sleepternity because is expense is disproportionate to its therapeutic benefits.

Even if durable medical equipment "serves a useful medical purpose" device processors "must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed." Centers for Medicare & Medicaid Servs., Dep't of Health and Human Servs., *Medicare Benefit Policy Manual*, ch. 15, § 110.1(C)(2). The test for "reasonableness" asks whether "it would be reasonable for the Medicare program to pay for the item prescribed." *Id.* CMS considers whether "the expense of the item to the program [would] be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment." *Id.*

Misrepresentations relating to compliance with a statutory, regulatory, or contractual requirements must be "material to the Government's payment decision in order to be actionable under the False Claims Act." 31 U.S.C.S. § 3729 et seq.; *Escobar*, 579 U.S. at 181. The use of polyurethane-based foam in Sleepternity renders it less therapeutically beneficial than CPAP machines using higher quality materials.

Based on the FDA's concerns about degraded polyurethane, the expense of Sleepternity is vastly disproportionate to the therapeutic benefit it provides.

By law, Medicare cannot cover a device that is not reasonable and necessary. Because Sleepternity does not qualify as either, Medicare would not have provided coverage for the device containing polyurethane-based foam.

CONCLUSION

The FDCA does not preempt Transylvania's tort immunity statute or its exceptions. The statute complements the FDA's enforcement scheme, unlike the standalone tort claim in *Buckman* that acted as an obstacle to federal objectives. Thus, this Court should adopt the Second Circuit's position and hold that state courts can make findings of fraud on the FDA when addressing state immunity statutes.

Additionally, relators can rely on the fraud–on–the FDA theory to bring a False Claims Act claim. The language of the FCA and this Court's application of the Act demonstrate that establishing all four elements is sufficient to survive a 12(b)(6) motion to dismiss. Ortega sufficiently pleaded that Mednology's misrepresentations about the foam in Sleepternity caused the device to obtain FDA approval which CMS relied on when providing Medicare coverage for Sleepternity.

Accordingly, this Court should affirm the Seventeenth Circuit on both issues and remand for further proceedings.

Respectfully submitted,

/s/ 3310

ATTORNEYS FOR RESPONDENT