IN THE

SUPREME COURT OF THE UNITED STATES

Docket No. 24-9176

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 3321
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QUESTIONS PRESENTED

1. Does the federal Food, Drug, and Cosmetic Act (FDCA) preempt state products liability immunity exceptions that apply when a medical device manufacturer violates the FDCA, thus preventing injured consumers from obtaining relief for their physical or mental injuries?
2. When a medical device manufacturer's conduct towards the FDA is fraudulent and results in the government funding a claim, may a relator demonstrate via discovery a nexus between that fraudulent conduct and the elements of a False Claims Act violation?

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The District Court's order is unreported, available at *United States ex rel. Riley Ortega v. Mednology, Inc.*, No. 24-cv-12121 (S.D. Trans. Oct. 15, 2023), and set forth in the Record. R. at 2–24. The opinion of the Court of Appeals for the Seventeenth Circuit is also unreported, available at *United States ex rel. Riley Ortega v. Mednology, Inc.*, No. 24-1000 (17th Cir. Apr. 1, 2024), and set out in the Record. R. at 25–42.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves Transylvania's products liability law, set forth at Trans. Comp. Stat. §§ 630.544–630.546 (2024). The most important provision of this law concerns three circumstances in which device manufacturers lose immunity from products liability claims. Trans. Comp. Stat. § 630.546. Because this case asks whether these immunity exceptions are preempted by the Food, Drug, and Cosmetic Act (FDCA), this case also involves the express preemption provision of the Medical Device Amendments of 1976, Pub. L. 94-295, § 2, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k), and the enforcement provision of the FDCA, Pub. L. 75-717, § 307, 52 Stat. 1040, 1046 (1938) (codified at 21 U.S.C. § 337).

This case also involves the connection between fraudulent conduct and the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*. This Act prohibits anyone from knowingly presenting a false or fraudulent claim to a government payor with the intent of collecting payment. In this matter, the conduct began with a change in a medical device, and thus involves the Food and Drug Administration (FDA). Because there is a question of whether a fraud-on-the-FDA theory is viable for an FCA claim,

the sufficiency of the claim must be judged under the plausibility standard of Federal Rules of Civil Procedure Rule 12(b)(6).

The statutes named above are reprinted in the Appendix.

STATEMENT OF THE CASE

STATEMENT OF THE FACTS

United States Army veteran Riley Ortega struggles with sleep. A retired artillery officer from Wohio, Riley has service-related post-traumatic stress disorder (PTSD), insomnia, and sleep apnea. R. at 3. Her traumatic memories also disrupt her ability to function day-to-day. *Id.* To get some sleep, Riley visited her doctor, a somnologist, who prescribed a medical device called Sleepternity. *Id.* Sleepternity is a continuous positive airway pressure (CPAP) machine, manufactured by Mednology, that purports to alleviate sleep apnea and insomnia. R. at 3–5.

The FDA approved Sleepternity as a Class III medical device—the most dangerous type of medical device—on December 30, 2022. R. at 3–4; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77 (1996) (discussing the differences between Class I, II, and III medical devices). After the FDA issued its approval, the Centers for Medicare and Medicaid Services (CMS) started paying for Sleepternity when it was prescribed to Medicare and Medicaid recipients. R. at 4.

Critically, the version of Sleepternity that the FDA approved used a sturdy, silicone-based foam to dampen noise. *Id.* But once the FDA approved Sleepternity, Mednology cut costs by swapping the silicone foam with a less stable, polyester-based polyurethane (PE-PUR) foam. *Id.* According to the FDA, PE-PUR foams can

disintegrate over time, releasing volatile organic compounds (VOCs). *Id.* As the foam disintegrates, the threat to consumers grows, as they can swallow foam chunks or harmful compounds like isocyanate—a VOC that can cause health problems. R. at 4–5. During the year before the FDA approved Sleepternity, these risks led a rival device manufacturer, Philips, to recall CPAP machines with PE-PUR foams. R. at 4. Despite the risks posed by PE-PUR foams, Mednology did not inform the FDA or consumers that it swapped Sleepternity's original silicone foam with PE-PUR foam after the device received FDA approval.

Riley did not know that Sleepternity had PE-PUR foam in it. *Id.* She and her primary care physician knew she was allergic to isocyanate. R. at 5. But they had no reason to suspect that Sleepternity's foam could release such harmful VOCs. *Id.*

After using Sleepternity, Riley experienced asthma attacks so severe that she was rushed to the emergency room, where the physician on call had to stabilize her condition. R. at 4. That physician recommended that Riley stop using Sleepternity, and Riley's primary care physician agreed, sensing that Sleepternity was causing Riley's asthma problems. R. at 5. But because Sleepternity did not have a warning label explaining the risks of isocyanate exposure, none of the doctors could pinpoint why Sleepternity exacerbated Riley's asthma so severely. *Id.*

Riley followed the doctors' orders and stopped using Sleepternity. *Id.* When she did so, her asthma symptoms subsided, but her lungs were chronically inflamed. *Id.* Further, her insomnia and sleep apnea returned. *Id.* So Riley's struggles with sleep continued.

Riley eventually learned from her brother, who is a Mednology assembly manager, that Mednology substituted PE-PUR foams in place of sturdier silicone foams. *Id.* He told Riley that Mednology used silicone foam in Sleepternity devices to secure FDA approval and that Mednology knowingly swapped the silicone foams with PE-PUR foams once it secured that approval. *Id.* Upon further research, Riley learned that degrading PE-PUR foam can release isocyanate and realized that Sleepternity likely caused her destabilizing asthma attack and her chronic lung inflammation. *Id.* Because of Mednology's cost-cutting, Riley's every breath hurt more than before, a new addition to her PTSD-induced insomnia and sleep apnea.

PROCEDURAL HISTORY

Riley reported Mednology's fraudulent conduct to the FDA and brought a products liability suit against Mednology in June 2023. R. at 6. Riley asserted that Mednology breached its duty of care, failed to disclose Sleepternity's modifications to the FDA, and failed to warn consumers about the dangers of PE-PUR foams in Sleepternity devices—all in violation of Transylvania's products liability statute. *Id.* Riley also brought an FCA claim against Mednology using a fraud-on-the-FDA theory; the United States declined to intervene in Riley's FCA claim. *Id.*

After Riley served Mednology, the company recalled Sleepternity from the market. R. at 7. In response, FDA halted its investigation into Mednology and decided to focus its investigatory efforts elsewhere. *Id.* As a result, the FDA never formally found that Mednology violated any FDA requirements. R. at 29.

Transylvania's products liability regime consists of three statutes. One outlines the Transylvania legislature's purpose for codifying a products liability claim. Trans. Comp. Stat. § 630.544. Another outlines manufacturers' duties to consumers. Trans. Comp. Stat. § 630.545. And a third immunizes device manufacturers from products liability claims unless one of three exceptions applies. Trans. Comp. Stat. § 630.546. Under the fraud-on-the-FDA exception, a manufacturer loses immunity if they committed fraud on the FDA. Trans. Comp. Stat. § 630.546(b). Under the failure-to-warn exception, immunity disappears if a manufacturer fails to warn consumers about the dangers posed by a medical device, as required by the FDA. Trans. Comp. Stat. § 630.546(c). And under the compliance exception, a manufacturer loses immunity if their product failed to comply with its FDA approval when it left the manufacturer's control. Trans. Comp. Stat. § 630.546(a).

Riley relied on all three exceptions in her products liability action. *Id.* But Mednology moved to dismiss Riley's claims. R. at 9; *see also* R. at 24 n.7. Mednology asserted that Riley's products liability claim could not move forward because the FDCA preempted Transylvania's immunity exceptions, which meant Mednology was immune from products liability claims. *Id.* Moreover, Mednology asserted that Riley's FCA claim could not rely on a fraud-on-the-FDA theory. *Id.*

The District Court disagreed with Mednology's preemption argument and held that the FDCA did not preempt Transylvania's immunity exceptions. R. at 10–18. But the District Court dismissed Riley's FCA claim and held that FCA claims may not utilize a fraud-on-the-FDA theory. R. at 18–24. Both parties appealed. R. at 25.

On appeal, the Seventeenth Circuit held that the FDCA preempted the fraud-on-the-FDA and failure-to-warn exceptions. R. at 28–31. But the court held that the FDCA did not preempt the compliance exception, so it allowed Riley's products liability claim to proceed because she alleged sufficient facts to show that Sleepternity did not comply with its FDA approval. R. at 32–35. The court also denied Mednology's motion to dismiss Riley's FCA claim. R. at 37–38. Mednology appealed to this Court.

SUMMARY OF THE ARGUMENT

First, this case is about whether the FDCA—a nearly 100-year-old federal law—preempts Transylvania's products liability immunity exceptions, thus preventing an injured veteran from suing a medical device manufacturer for injuries caused by the manufacturer's failure to comply with FDA requirements. None of Transylvania's immunity exceptions are preempted because the FDCA only preempts claims.

Thus, the Seventeenth Circuit correctly held that the FDCA does not preempt Transylvania's compliance exception. But it wrongly held that the fraud-on-the-FDA and failure-to-warn exceptions were preempted. According to the Seventeenth Circuit, these two exceptions are preempted whenever a plaintiff asks a court to find that a device manufacturer violated the FDCA. The court reasoned that this rule prevents states and courts from interfering in the FDA's operations and enforcement activities, which this Court was concerned about in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

The FDCA does not preempt any of Transylvania's immunity exceptions. The FDCA only preempts two types of state tort law: those that impose requirements on device manufacturers that are in addition to, or different from, FDCA requirements; and those that seek to enforce the FDCA. 21 U.S.C. §§ 337(a), 360k(a). As this Court's FDCA preemption cases make clear, the FDCA only preempts *claims*—not immunity exceptions. *See Riegel v. Medtronic*, 552 U.S. 312, 323–24 (2008) (holding that the FDCA expressly preempts some "causes of action"); *see also Buckman*, 531 U.S. at 349 n.4 (holding that the FDCA impliedly preempts *claims* resting solely on FDCA violations). And for good reason: damages are awarded for successful claims, but not for successful immunity exceptions. Since damages cannot be awarded merely because a plaintiff shows that an immunity exception applies, Transylvania's immunity exceptions neither enforce the FDCA nor impose additional requirements on device manufacturers.

Further, immunity exceptions do not raise the Seventeenth Circuit's policy concerns about states and courts interfering with the FDA. The fear of losing a niche state products liability immunity will not motivate device manufacturers to overburden the FDA with paperwork because the FDA already has robust enforcement powers. 21 U.S.C. ch. 9 subch. III (outlining penalties for violating the FDCA). Additionally, by identifying incidents where device manufacturers violated FDA requirements, Transylvania's immunity exceptions allow the FDA to maximize its limited resources by identifying additional cases where it can efficiently bring

enforcement actions. Thus, Transylvania's immunity exceptions help the FDA instead of hindering it.

Second, just as Transylvania's immunity exceptions facilitate the FDA's exercise of its powers to protect the public health, so do relators' actions in fraud-on-the-FDA *qui tam* FCA actions. This Court, in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), explained that liability under the FCA extends to "any person who knowingly presents . . . a false or fraudulent claim for payment or approval." See 31 U.S.C. § 3729(a). The FDA granted approval to Mednology for the original, more stable version of Sleepternity with silicone foam; then Mednology degraded the device by using an unstable PE-PUR foam. Without changing the labeling, lowering the price, or submitting a pre-market approval (PMA) supplement to notify the government of the change from the FDA-approved version to the distributed, less-stable version of Sleepternity, Mednology submitted a claim to CMS, a government payor. Thus, the FCA elements of knowingly presenting a fraudulent or false claim for payment have been met.

Such facts are sufficient to make a plausible claim for relief, as required to deny a defendant's motion to dismiss under Federal Rules of Civil Procedure 12(b)(6). Mednology's request for a motion to dismiss implies that a question of law is at stake; however, the Seventeenth Circuit correctly characterized this matter as a question of fact. Mednology argues that causation has not been sufficiently established in the relationship between CMS's payout procedures and the FDA approval system. The Seventeenth Circuit, exemplified by Judge Ruzich's concurrence, perceived the

nature of this relationship question as one that can be answered through discovery, and thus appropriately denied the motion to dismiss.

Furthermore, the Seventeenth Circuit cited this Court's holding in *Escobar* to support the implied false certification theory in this matter. Using that theory, the court reasoned that CMS's decision to pay for Sleepternity was based on the device's FDA approval. That reliance implied that Mednology used false certification to obtain government funds.

Finally, the District Court incorrectly held that because neither the FDA nor CMS took action against Mednology, Riley's allegations fail to establish a causation element of her FCA claim. The court based this reasoning on the First Circuit's holding in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (2016). But that case and this one are not analogous. This case is significantly distinguished from *D'Agostino*, exactly at the crux of the causation issue. In *D'Agostino*, the inferior medical device stayed in the marketplace, with no FDA recall, past the point when the relator filed suit against the defendant device company. 845 F.3d at 8. Due to the FDA's inaction in that case, the First Circuit held that the relator was precluded from basing the FCA claim on a fraud-on-the-FDA theory. *Id.* at 10. In contrast, here, Mednology pulled Sleepternity off the market shortly after receiving a copy of Riley's complaint. Putting the debatable reasoning of an FDA inaction theory aside, more fact-finding would be necessary to analyze the FDA's record regarding approval of CPAP devices containing PE-PUR foam to apply this theory here. Thus, this Court should affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss Riley's FCA claim.

Therefore, the Seventeenth Circuit was half right. It correctly held that the FDCA does not preempt Transylvania's compliance immunity exception. It also correctly held that Riley's FCA claim may rely on a fraud-on-the-FDA theory. But the Seventeenth Circuit wrongly held that the FDCA preempted Transylvania's fraud-on-the-FDA and failure-to-warn immunity exceptions. Consequently, this Court should affirm in part and reverse in part.

ARGUMENT

I. The FDCA does not preempt state products liability immunity exceptions that apply when a device manufacturer fails to comply with FDCA or FDA requirements.

The FDCA does not preempt Transylvania's products liability immunity exceptions. Preemption is the idea that, when federal law and state law collide, federal law wins. *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1187 (10th Cir. 2023). Here, there is no collision between federal law and Transylvania law: the FDCA regulates standards for medical devices, while Transylvania's immunity exceptions merely allow injured consumers to hold device manufacturers accountable for violating their duty of care and good faith. Trans. Comp. Stat. § 630.545.

Transylvania's legislature gave medical device manufacturers broad immunity from products liability suits, subject to three exceptions. Trans. Comp. Stat. § 630.546. Under the fraud-on-the-FDA exception, manufacturers lose immunity if they intentionally withheld or misrepresented information to the FDA, and the plaintiff proves that the FDA would not have approved or would have withdrawn approval for

the device if it had accurate information. Trans. Comp. Stat. § 630.546(b). Under the failure-to-warn exception, manufacturers lose immunity if they failed to warn consumers of dangers posed by their products as required by the FDA. Trans. Comp. Stat. § 630.546(c). And under the compliance exception, manufacturers lose immunity if their device failed to comply with the terms of its FDA approval when it left the manufacturers' control. Trans. Comp. Stat. § 630.546(a). To succeed on the compliance exception, consumers must also overcome a presumption that the device complied with its FDA approval when the device left the manufacturers' control. *Id.*

The Seventeenth Circuit correctly held that the FDCA does not preempt Transylvania's compliance immunity exception. But it wrongly held that the FDCA preempts the fraud-on-the-FDA and failure to warn exceptions. R. at 29, 31, 35. Had the court engaged in a proper preemption analysis, it would have concluded that none of the immunity exceptions are preempted by the FDCA.[1]

Preemption may be express or implied. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 95 (1992) (plurality). Express preemption occurs when Congress explicitly supersedes state law. *Id.* Implicit preemption occurs when federal and state law conflict, or when Congress enacts a regulatory scheme so pervasive that states have no room to supplement it. *Id.* Express and implied preemption are both possible under the FDCA. 21 U.S.C. § 360k(a) (expressly preempting certain state requirements); 21 U.S.C. § 337(a) (impliedly preempting private attempts to enforce the FDCA).

[1] Preemption is a question of law, which this Court reviews de novo. *Knight v. Boehringer Ingelheim Pharms., Inc.*, 984 F.3d 329, 337 (4th Cir. 2021).

Express FDCA preemption turns on whether a state law imposes requirements on medical devices that are in addition to, or different from, FDA requirements. 21 U.S.C. § 360k(a). As a result, the FDCA does not expressly preempt state laws that mirror FDA requirements. *Lohr*, 518 U.S. at 495. Here, Transylvania's immunity exceptions impose no requirements on device manufacturers. And the exceptions incorporate, and therefore parallel, FDA requirements. Trans. Comp. Stat. § 630.546. Therefore, the FDCA does not expressly preempt Transylvania's immunity exceptions.

Similarly, the FDCA does not impliedly preempt Transylvania's immunity exceptions. The FDCA requires all FDCA enforcement actions to be brought by the United States. 21 U.S.C. § 337(a). As a result, implied FDCA preemption occurs when states or private parties seek to enforce FDA requirements. *Buckman*, 531 U.S. at 349 n.4. Thus, state tort law can allow private individuals to sue for conduct that violates FDA requirements, so long as the tort claim does not solely turn on the fact that the conduct violates those requirements. *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023). Here, Transylvania's immunity exceptions are not impliedly preempted because immunity exceptions cannot enforce FDA requirements; only claims can. Moreover, Riley's underlying claim is not impliedly preempted because she is not suing Mednology to punish their failure to comply with FDA requirements. Rather, she is suing Mednology because they failed to comply with FDA requirements and that failure sent her to the emergency room. R. at 4.

Therefore, this Court should affirm the Seventeenth Circuit's holding that the FDCA does not preempt Transylvania's compliance exception and reverse the Seventeenth Circuit's holding that the FDCA preempts the fraud-on-the-FDA and failure-to-warn immunity exceptions. R. at 29, 31, 35. None of the immunity exceptions impose additional requirements on device manufacturers or allow plaintiffs to enforce FDA requirements. Rather, these exceptions merely allow plaintiffs to walk through otherwise-closed courthouse doors to pursue a traditional state products liability claim. Trans. Comp. Stat. §§ 630.545–630.546.

A. The FDCA does not expressly preempt Transylvania's immunity exceptions.

Transylvania's immunity exceptions do not impose requirements that are in addition to, or different from, FDA requirements. Rather, these provisions incorporate FDA requirements. Therefore, the FDCA does not expressly preempt Transylvania's immunity exceptions.

Express FDCA preemption only occurs when a state imposes requirements on device manufacturers that differ from, or are in addition to, FDCA requirements. 21 U.S.C. § 360k(a). These state requirements can be imposed by statute or common law. *See Reigel*, 552 U.S. at 324. Importantly, claims that are "'equal to, or substantially identical to, requirements imposed under the [FDCA]'" survive express preemption. *Lohr*, 518 U.S. at 496–97 (quoting 21 C.F.R. § 808.1(d)(2) (interpreting the scope of 21 U.S.C. § 360k(a))). Thus, the FDCA does not expressly preempt state tort claims that are premised on a violation of FDCA requirements. *Riegel*, 552 U.S. at 330.

The FDCA only preempts claims, and immunity exceptions are not claims. *See Riegel*, 552 U.S. at 323–24 (holding that the FDCA expressly preempts some "causes of action"). Claims are demands for a remedy to which one is allegedly entitled. *Claim*, *Black's Law Dictionary* (12th ed. 2024). Immunity exceptions, by contrast, merely allow an injured plaintiff's case to proceed against defendants who engaged in certain specified conduct. *See Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985) (noting that immunities can confer immunity from suit or a total defense to liability).[2] Unlike claims, immunity exceptions do not enforce legal obligations. As a result, immunity exceptions cannot impose legally binding requirements on device manufacturers that are in addition to, or different from, FDA requirements. Therefore, immunity exceptions are not expressly preempted by the FDCA.

The distinction between claims and immunity exceptions is exemplified by the contrast between this case and *Riegel v. Medtronic*. In that case, a plaintiff brought several tort claims against a device manufacturer that complied with FDA requirements. *Id.* at 320, 330. The manufacturer's compliance with FDA requirements meant that the plaintiff's claims, if successful, would have imposed state requirements in addition to those imposed by FDA. *Id.* at 324–25. Transylvania's immunity exceptions, however, merely eliminate immunity from products liability claims if a device manufacturer failed to comply with FDA

[2] Neither the District Court nor the Seventeenth Circuit analyzed whether Transylvania's immunity provision grants defendants immunity from suit or immunity from liability. The Second Circuit, however, interpreted similar statutory language from Michigan and concluded that it created an affirmative defense by immunizing device manufacturers from liability. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 96 (2d Cir. 2006). The subtle distinction between complete defenses and affirmative defenses is immaterial for FDCA preemption purposes because neither defense imposes obligations on device manufacturers.

requirements. Trans. Comp. Stat. § 630.546. Unlike in *Riegel*, where the plaintiff essentially sought damages solely because of an FDCA violation, no damages can be awarded here simply because Riley proves that an immunity exception applies. 552 U.S. at 320–21; *see also Uzuegbunam v. Preczewski*, 592 U.S. 279, 291 (2021) ("[A] person who is awarded . . . damages receives relief on the merits of his *claim*.") (emphasis added) (quotations omitted). Thus, Transylvania's immunity exceptions cannot impose any requirements on device manufacturers that are "different from, or in addition to" FDA requirements. 21 U.S.C. § 360k(a).

Moreover, even if this Court analyzes Transylvania's immunity exceptions as if they were claims, the FDCA still would not preempt the exceptions because they mirror FDA requirements. The FDCA does not expressly preempt state claims that mirror or parallel FDA requirements. *Lohr*, 518 U.S. at 496–97. Transylvania's immunity exceptions incorporate, and therefore parallel, FDA requirements. The fraud-on-the-FDA exception, for example, applies when a device manufacturer intentionally withholds or misrepresents information to the FDA, which is an FDCA violation. Trans. Comp. Stat. § 630.546(b); 21 U.S.C. § 331(q)(2). Similarly, the failure-to-warn exception applies when a device manufacturer "fails to warn about the dangers or risks of the drug or medical device *as required by the FDA*." Trans. Comp. Stat. § 630.546(c) (emphasis added). And the compliance exception applies when a medical device *failed to comply with its FDA approval* when it left a manufacturer's control. Trans. Comp. Stat. § 630.546(a) (emphasis added). Thus, even if this Court analyzes the immunity exceptions under its "parallel claims"

jurisprudence, the exceptions parallel FDCA requirements and survive express FDCA preemption.

Therefore, Transylvania's immunity exceptions are not preempted by the FDCA because they do not impose additional requirements on device manufacturers; rather, they parallel federal requirements. Because the Seventeenth Circuit did not conduct an express preemption analysis, this Court should affirm, albeit on different grounds, the Seventeenth Circuit's holding that the compliance exception is not preempted by the FDCA. Similarly, this Court should reverse the Seventeenth Circuit's holding that the FDCA preempts the fraud-on-the-FDA and failure-to-warn immunity exceptions.

B. The FDCA does not impliedly preempt Transylvania's immunity exceptions.

The FDCA does not impliedly preempt Transylvania's immunity exceptions because immunity exceptions cannot enforce FDA requirements. Implied FDCA preemption only occurs when a private party seeks to enforce duties imposed by the FDCA or FDA. *See Buckman*, 531 U.S. at 349 n.4. Transylvania's immunity exceptions are not claims, so they cannot enforce any duties imposed by the FDA. Further, Transylvania's immunity exceptions do not raise the risk that states or courts will interfere with the FDA's inner workings. Moreover, Transylvania's immunity exceptions are entitled to a presumption against preemption because products liability law is within the states' historic police powers. Therefore, this Court should affirm the Seventeenth Circuit's holding that the compliance exception is not

preempted and reverse its holding that the fraud-on-the-FDA and failure-to-warn exceptions are preempted.

i. The FDCA preempts claims, not immunity exceptions.

The FDCA does not impliedly preempt Transylvania's immunity exceptions. Implied FDCA preemption occurs when a state law allows private parties to enforce FDA or FDCA requirements. *Id.* Transylvania's immunity exceptions cannot enforce any such requirements, however, because immunity exceptions are not claims, and relief can only be awarded for successful claims. *See Uzuegbunam*, 592 U.S. at 291. In other words, only claims can enforce—and be preempted by—the FDCA.

The United States must initiate all FDCA enforcement actions. 21 U.S.C. § 337(a). As the *Buckman* Court noted long ago, state laws authorizing private suits to enforce the FDCA conflict with this categorical mandate. *Buckman*, 531 U.S. at 348. Thus, the FDCA impliedly preempts state statutes creating claims "that exist solely because of an FDCA infraction." *DiCroce*, 82 F.4th at 41. As this Court noted in *Buckman*, implied FDCA preemption preserves the important policy of allowing FDA to choose the best way to balance the FDCA's objectives, without having to worry about state tort claims that can upset that balance. *See* 531 U.S. at 348–49, 353.

Therein lies the crucial distinction between this case and *Buckman*. The question in *Buckman* was whether the FDCA impliedly preempted fraud-on-the-FDA claims. *Id.* at 343–44. But here, the question on certiorari is whether the FDCA preempts Transylvania's *immunity exceptions*—not whether Riley's underlying *claims* are preempted by the FDCA. R. at 43. This Court should follow its past

practices and confine its review to this narrow question. *See Yee v. City of Escondido*, 503 U.S. 519, 538 (1992) (considering only the questions on certiorari); *see also Nynex Corp. v. Discon*, 525 U.S. 128, 140 (1998) (same); *see also Glover v. United States*, 531 U.S. 198, 205 (2001) (same).

Immunity exceptions are not claims, so they are not preempted under *Buckman*. Immunities are legal shields behind which a defendant will never be found liable. *See Uzuegbunam*, 592 U.S. at 291; *see also Immunity*, *Black's Law Dictionary* (12th ed. 2024). Immunity exceptions are holes in the shield, which allow plaintiffs to walk into court. *See* R. at 17. Claims, by contrast, are why a plaintiff is in court; they are the legal interests or remedies a plaintiff seeks to vindicate. *Claim*, *Black's Law Dictionary* (12th ed. 2024). Because relief is awarded for claims and not for immunity exceptions, immunity exceptions cannot enforce FDA requirements or be impliedly preempted by the FDCA.

The Seventeenth Circuit nominally observed that this case involves immunity exceptions instead of claims. R. at 30–31. It even correctly noted that the District Court relied on cases that were inapplicable because they discussed claims rather than immunity exceptions.[3] R. at. 30. And the court rightfully held that the compliance exception was not preempted by the FDCA. R. at 35.

But the Seventeenth Circuit did not analyze whether the compliance exception attempts to enforce the FDCA, as is required for an implied preemption analysis.

[3] The District Court analyzed *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), *Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. 2010), *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), and *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), all of which are inapplicable because they involved claims instead of immunity exceptions. R. at 30.

Rather, it held that the compliance exception was not preempted because, "[w]hen Congress enacted the FDCA, it did not intend to completely shield drug or medical device manufacturers from any form of liability." R. at 35. This Court should affirm the Seventeenth Circuit's conclusion but supplement its reasoning by holding that the compliance exception does not attempt to enforce the FDCA.

By contrast, the Seventeenth Circuit analyzed the fraud-on-the-FDA and failure-to-warn exceptions under the claims-centric rationale of *Garcia v. Wyeth-Ayerst Laboratories*. R. at 28, 31; 385 F.3d 961, 965 (6th Cir. 2004) (noting that the plaintiff could not "prove fraud on the FDA because such claims are preempted by federal law"). Had the Seventeenth Circuit fleshed out the crucial differences between claims and immunity exceptions, it likely would have upheld all of Transylvania's immunity exceptions, rather than just upholding the compliance exception.

Garcia's logic is inadequate because it failed to grapple with the difference between claims and immunity exceptions. In that case, the Sixth Circuit analyzed Michigan's fraud-on-the-FDA immunity exception, which is nearly identical to Transylvania's fraud-on-the-FDA immunity exception. *Garcia*, 385 F.3d at 965; *compare* Mich. Comp. Laws. § 600.2946(5)(a) (1996) *with* Trans. Comp. Stat. 630.546(b). The Sixth Circuit recognized that Michigan's immunity exception was "a somewhat different legal regime from the one invalidated in *Buckman*" because *Buckman* focused on remedies and claims. *Garcia*, 385 F.3d at 965. But confoundingly, in one short, declarative sentence, the Sixth Circuit dismissed the difference between claims and immunity exceptions as "immaterial." *Id.* at 966; *see also Marsh v.*

Genentech, Inc., 693 F.3d 546, 552 n.6 (6th Cir. 2012) (repeating this error). It is anything but; immunity exceptions merely allow a plaintiff to walk into court, while claims enforce legal obligations.

DiCroce v. McNeil Nutritionals shows why the FDCA cannot impliedly preempt immunity exceptions. There, a plaintiff brought a state false advertising claim against a manufacturer that violated FDCA labeling requirements. 82 F.4th at 38, 40. DiCroce's claim existed solely because the manufacturer failed to comply with the FDCA; thus, the court held that her claim was a private attempt to enforce the FDCA. *Id.* at 41. Unlike in *DiCroce*, where the plaintiff's claim tried to enforce the FDCA by seeking damages for violations of that act, damages cannot be awarded to Riley simply because she shows that one of Transylvania's immunity exceptions applies to Mednology. *See* 82 F.4th at 39; *see also Uzuegbunam*, 592 U.S. at 291 (2021) (observing that damages are awarded for successful claims). Further unlike in *DiCroce*, where the plaintiff's claim arose solely from FDCA violations, here Riley's underlying claim does not arise from Mednology's FDCA violations. 82 F.4th at 41; R. at 5. Rather, Riley's claim exists because Mednology violated their "duty of care and good faith, which Riley can prove without pointing to Mednology's FDCA violations.[4] Trans. Comp. Stat. § 630.545.

[4] Because Trans. Comp. Stat. § 630.545 uses "including," which is a term of enlargement, Riley can win her products liability claim by proving that Mednology violated its duty of care by doing something other than violating its duties to warn, disclose, and comply with relevant law. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012) (interpreting "including" to mean that "the examples enumerated in the text are intended to be illustrative, not exhaustive"); *see also* R. at 6 (noting that Riley asserts Mednology violated its duty of care, duty to warn, and duty to disclose modifications to the FDA).

Thus, immunity exceptions cannot enforce the FDCA. Only claims can. Therefore, this Court should affirm that the compliance exception is not preempted and reverse the Seventeenth Circuit's holding that the fraud-on-the-FDA and failure-to-warn exceptions are preempted.

ii. Transylvania's immunity exceptions do not require courts to meddle in the FDA's operations or relationships with device manufacturers.

Transylvania's immunity exceptions also do not raise concerns about states or courts meddling in the FDA's operations. The Seventeenth Circuit held that the FDCA preempted Transylvania's fraud-on-the-FDA and failure-to-warn exceptions because they could potentially interfere with the FDA's internal, investigatory, and enforcement processes. R. at 29, 31. But because Transylvania's immunity exceptions require courts to identify if an FDCA violation occurred—without imposing any penalties for those violations—the immunity exceptions assist the FDA in identifying additional instances in which the FDA can bring enforcement actions. Moreover, Transylvania's products liability law does not intrude on the relationship between device manufacturers and the FDA; instead, it regulates the relationship between device manufacturers and consumers. Therefore, the fraud-on-the-FDA and failure-to-warn immunity exceptions do not incentivize meddling in the FDA's affairs.

Two observations are in order before proceeding. First, a substantial portion of the Seventeenth Circuit's opinion expresses concerns about state courts finding that device manufacturers violated the FDCA. R. at 29, 31. But those concerns are red herrings. Riley initiated suit in a federal district court, so this case has never been to

state court. R. at 6. Second, the Seventeenth Circuit articulated a rule that immunity exceptions are not preempted "whenever a plaintiff relies on federal findings to prove the defendant's fraudulent conduct toward the FDA." R. at 29; *see also id.* at 31 (same). Although these findings are exactly what Riley sought from the District Court, the Seventeenth Circuit nonetheless held that the FDCA preempts Transylvania's fraud-on-the-FDA and failure-to-warn immunity exceptions. R. at 5, 29, 31. This misapplication of the Seventeenth Circuit's own legal rule is cause for reversal, even under the abuse of discretion standard. *Koon v. United States*, 518 U.S. 81, 100 (1996) (holding that courts abuse their discretion when they commit legal errors).

Thus, despite its broad rule regarding federal findings, the Seventeenth Circuit's true rule appears to be that the fraud-on-the-FDA and failure-to-warn exceptions are preempted because Riley did not have FDA findings that Mednology violated the FDCA. R. at 29, 31. Here, too, the Seventeenth Circuit took its lead from the Sixth Circuit, which broadly held that *any* immunity exception premised on FDCA violations is preempted unless a plaintiff relies on FDA findings that a defendant violated the FDCA. *Garcia*, 385 F.3d at 966. Both rules are erroneous.

To start, both courts expressed similar concerns that allowing courts to find FDCA violations would interfere with the FDA's enforcement processes.[5] R. at 29, 31; *Garcia*, 385 F.3d at 966. Specifically, by interfering with FDCA enforcement, states and courts could interfere with how the FDA wants to enforce the FDCA, thus creating "an apparent conflict warranting implied preemption." Grace Zogaib,

[5] The Seventeenth Circuit did not analyze whether the compliance exception raised these concerns. It does not, for the reasons stated in this section.

Preemption After Buckman*: State Law Failure to Warn Claims Based on Lack of Disclosure to the FDA*, 21 Ave Maria L. Rev. 236, 241 (2023). That concern may be warranted where a state tort claim attaches penalties to FDCA noncompliance—but that is not the case here, because no penalties are attached to Transylvania's immunity exceptions.

Instead, immunity exceptions supplement FDA's investigatory and enforcement processes by identifying additional instances in which the FDA can bring enforcement actions against noncompliant device manufacturers. The FDA has limited resources and cannot possibly investigate every potential FDCA violation. *Wyeth v. Levine*, 555 U.S. 555, 578 (2009); *see also Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (observing that agencies lack the resources to enforce every violation of a statute). As a result, the FDA itself has long recognized judicial process as supplementing, not supplanting, its authority to protect consumers. *See Wyeth*, 555 U.S. at 566, 579. Here, Transylvania's immunity exceptions simply reveal FDCA violations, instead of punishing those violations (which the FDCA would impliedly preempt). Trans. Comp. Stat. § 630.546; 21 U.S.C. § 337(a). Thus, the judicial process of adjudicating whether a defendant's conduct fits within one of Transylvania's immunity exceptions enables the FDA to determine additional instances in which to exercise its own enforcement powers. *See id.* at 579 n.12 (noting that state tort actions may prompt agency action).

Upholding Transylvania's immunity exceptions would not impair the FDA's effectiveness or internal operations. In *Buckman*, this Court was concerned that

device manufacturers would deluge the FDA with irrelevant information to avoid violating state laws that punished FDCA violations. *See* 531 U.S. at 351. This concern is misplaced in the context of immunity exceptions. As the Second Circuit recognized in *Desiano v. Warner-Lamber & Co.*, the risk of deluging the FDA with paperwork only appreciably increases when an FDCA violation itself is sufficient to impose tort liability, as it was in *Buckman*. 467 F.3d 85 at 97. Because Transylvania's immunity exceptions do not impose liability, it follows from *Desiano* that they do not interfere in the FDA's internal operations. *Id.*

Moreover, there is no reason to believe that the potential loss of a niche state products liability immunity will lead device manufacturers to deluge the FDA with irrelevant paperwork. As this Court recognized in *Buckman*, the FDA has ample authority to punish violations of FDA requirements. 531 U.S. at 348. Although the threat of potential tort liability may strengthen compliance with FDA requirements, any such effect is practically minimal because the FDA can punish noncompliance through imprisonment, fines, device seizures, debarment, and other substantial penalties. 21 U.S.C. ch. 9 subch. III (outlining penalties for violating the FDCA); Zogaib, *Preemption After* Buckman, *supra*, at 249. And even if this fear of losing a niche state products liability immunity led some device manufacturers to submit a few more documents to the FDA, the same result would occur if a state did not provide for products liability immunity in the first instance—yet no court has argued that states must exempt device manufacturers from these suits.[6]

[6] Michigan notably eliminated its immunity exceptions after *Garcia* and *Genentech*. Mich. Comp. Laws § 600.2946 (2024).

Nor do immunity exceptions raise concerns about states or courts intruding on the FDA's relationship with device manufacturers. The Seventeenth Circuit was concerned that Transylvania's immunity exceptions interfere with the relationship between the FDA and device manufacturers. R. at 28–29. But Transylvania's products liability statute poses no such concerns because it regulates the relationship between device manufacturers and consumers. *See Buckman*, 531 U.S. at 352 (distinguishing fraud-on-the-FDA claims from traditional state tort claims).

Further, the Seventeenth Circuit's ruling harms injured consumers. The Seventeenth Circuit would functionally require plaintiffs to rely on FDA findings to prove that a device manufacturer is not entitled to immunity under Transylvania law. R. at 29, 31. But the FDA's limited resources mean that some findings will never be made, so some injured consumers will never get relief for their injuries. *See Wyeth*, 555 U.S. at 578.

This case exemplifies that fact because the FDA refocused its investigatory resources after Mednology recalled Sleepternity from the market. R. at 7. Thus, the FDA never made formal findings regarding Mednology's compliance with the FDCA or Sleepternity's approval. If the Seventeenth Circuit's rule stands, Riley and other injured consumers would have no way of showing that a defendant's conduct fits within Transylvania's fraud-on-the-FDA or failure-to-warn exceptions, unless they were lucky enough to be harmed by a device that was the subject of formal FDA findings. And if the Sixth Circuit's ruling stands, consumers could *never* sue device manufacturers unless they were harmed by one of the few devices manufactured by

a company that FDA formally found to have violated the FDCA. *See* FDA, *Compliance Actions*, https://datadashboard.fda.gov/ora/cd/complianceactions.htm (last visited Sept. 8, 2024) (indicating that fewer than 1,700 medical devices were the subject of an FDA warning letter between 2009 and 2024).

This result is inconsistent with congressional intent because it would "have the perverse effect of granting complete immunity from . . . liability to an entire industry that, in the judgment of Congress, needed more stringent regulation[.]" *Lohr*, 518 U.S. at 487. As the Seventh Circuit put it, "[t]he idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive." *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010).

Thus, Transylvania's fraud-on-the-FDA and failure-to-warn immunity exceptions do not raise concerns about states or courts hindering the FDA. To the contrary, immunity exceptions may help the FDA identify additional instances in which to pursue enforcement remedies while simultaneously enabling injured consumers to seek redress against device manufacturers that violate their duty of care to consumers.

iii. Transylvania's immunity exceptions are entitled to a presumption against preemption.

Transylvania's immunity exceptions also enjoy a presumption against preemption, which Mednology has not overcome. State laws protecting the health and safety of a state's citizens—such as a state's tort laws—are entitled to a presumption

against preemption unless Congress clearly intended to preempt those laws. *Lohr*, 518 U.S. at 475, 485. Nothing indicates that Congress intended to preempt traditional state tort law by passing the FDCA. *Wyeth*, 555 U.S. at 574–75. Therefore, Transylvania's products liability statute and its immunity exceptions are entitled to a presumption against preemption.

This Court has repeatedly stressed that "the purpose of Congress is the touchstone in every preemption case." *E.g. Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). Thus, this Court presumes that federal law does not preempt state police powers—including the power to protect health and safety—unless preemption was the "clear and manifest purpose of Congress." *Lohr*, 518 U.S. at 475, 485; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). The presumption against preemption preserves federalism and "provides assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones*, 430 U.S. at 525 (quotations omitted) (citations omitted). Importantly, state tort law is an integral part of the states' police powers and is thus subject to the presumption against preemption. *Taylor v. Gen. Motors Corp.*, 875 F.2d 816, 823 (11th Cir. 1989).

Mednology cannot overcome the presumption against preemption because nothing in the FDCA indicates that Congress enacted it to preempt state tort law. *Wyeth*, 555 U.S. at 574–75 ("Congress did not regard state tort litigation as an obstacle to achieving [the FDCA's] purposes."). In fact, no legislative report or debate shows that Congress discussed state tort law at all when it passed the FDCA and the

Medical Device Amendments of 1976. Thus, neither statutory text nor legislative history shows that Congress clearly intended to preempt state tort law.

Nonetheless, the Seventeenth Circuit held that Transylvania's fraud-on-the-FDA and failure-to-warn immunity exceptions do not enjoy the presumption against preemption.[7] R. at 27–28. The court correctly noted, like this Court did in *Buckman*, that states' traditional police powers do not include the power to police violations of federal law. *Id.*; *see also Buckman*, 531 U.S. at 347. Thus, state laws that seek to enforce the FDCA do not enjoy a presumption against preemption. *Buckman*, 531 U.S. at 347. But Transylvania's immunity exceptions do not penalize FDCA violations or enforce the FDCA in any way. *See* Trans. Comp. Stat. § 630.546. They do not impose penalties on noncompliant device manufacturers. And Riley's underlying products liability claim does not require proof of FDCA violations. Trans. Comp. Stat. § 630.545. Instead, like the claims upheld in *Medtronic*, Riley's claim enjoys a presumption against preemption because it is based on a device manufacturer violating its duty of care to a consumer. *Id.*; *Lohr*, 518 U.S. at 501; *see also Buckman*, 531 U.S. at 352 (reiterating this point).

Congressional intent—which is the lodestar in preemption cases—is best served by upholding Transylvania's immunity exceptions. *E.g. Cipollone*, 505 U.S. at 516. Congress did not include a private right of action in the FDCA, but it also did not intend to leave consumers with no means of redress for injuries caused by medical devices. *See Lohr*, 518 U.S. at 487 (rejecting a construction of the FDCA that would

[7] The Seventeenth Circuit did not analyze whether the compliance exception enjoys the presumption against preemption. It does, for the reasons set forth in this section.

have granted complete immunity "to an entire industry that, in the judgment of Congress, needed more stringent regulation[.]"). Instead, Congress intended that the FDCA preempt only two types of state laws: those that impose requirements in addition to, or different from, FDA requirements; and those that enforce the FDCA. 21 U.S.C. § 360k(a); *Buckman*, 531 U.S. at 352. Transylvania's immunity exceptions fit into neither category. Thus, invalidating these exceptions is out of step with congressional intent, and, by preempting traditional state police powers, "would result in preemption of a scope that would go far beyond anything that has been applied in the past." *Desiano*, 467 F.3d at 96. Surely Congress would have said something had it intended such expansive preemption of state tort law—yet Congress said nothing.

Therefore, this Court should hold that Transylvania's immunity exceptions enjoy a presumption against preemption. As shown by the FDCA's text, Congress intended that the FDCA only preempt state tort law when it imposes requirements that are different from FDA requirements, or when it tries to enforce the FDCA. Transylvania's immunity exceptions do neither, so they fall squarely within the state's historic police powers. Therefore, this Court should affirm the Seventeenth Circuit's holding that the FDCA does not preempt Transylvania's compliance exception and reverse the Seventeenth Circuit's holding that the FDCA preempts the fraud-on-the-FDA and failure-to-warn exceptions.

II. Relators may use a fraud-on-the-FDA theory to sue under the False Claims Act when they have proven a fraud against the government that resulted in government payment.

Liability under the FCA exists whenever someone commits fraud against the federal government that leads to the government paying a claim.[8] Thus, fraud on the FDA is a viable theory for an FCA claim because CMS reimbursement hinges on the FDA's approval of a given device. *The Dan Abrams Co. LLC v. Medtronic, Inc.*, 850 F. Appx. 508, 510 (9th Cir. 2021). Thus, fraudulent representations to the FDA cause CMS to pay claims for the medical device. *Id.*

The Seventeenth Circuit correctly adopted the Ninth Circuit's stance on the viability of the fraud-on-the-FDA theory in FCA claims. R. at 37; *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). Under the FCA, a company that "knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval" has committed a violation of the Act. 31 U.S.C. § 3729(a)(1)(A). Importantly, the fraud need not be against the payor government agency because the FCA requires 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." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006).

[8] This Court reviews dismissal of FCA claims *de novo*. *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1170 (9th Cir. 2006).

Moreover, Riley may base her claim on a fraud-on-the-FDA theory because this Court has held that both the FCA and its own prior decisions indicate that a "rigid, restrictive reading" of the FCA is erroneous. *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). *See also Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 247 (2003) (explaining that "Congress wrote expansively" regarding the types of fraud that the FCA was meant to prohibit). In *Neifert-White*, this Court held that the defendant submitted false information in order to obtain a government loan, and that even if a loan is not a "claim" within the meaning of the FCA, the intent behind the FCA permits such a complaint. *Id*. at 230.

Riley's claim delineates enough facts about Mednology's conduct as to plausibly allege an FCA violation. Accordingly, this Court should affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss. R. at 38. When reviewing a 12(b)(6) motion to dismiss, courts must construe the alleged facts as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Riley's facts reveal that Mednology's conduct plausibly meets the elements of an FCA claim because Mednology knowingly submitted fraudulent claims to, and accepted payments from, CMS. R. at 6. Therefore, this Court should affirm the Seventeenth Circuit and allow Riley's FCA claim to proceed.

A. FCA liability exists whenever fraud against the federal government leads to a government entity paying a claim.

The Seventeenth Circuit correctly held that FCA liability exists whenever a company commits fraud against the federal government and that fraud results in the

government paying a claim. Fraud against the payor government entity is sufficient, but not required, for FCA liability.

As a result, the Seventeenth Circuit correctly adopted the Ninth Circuit's stance on the viability of the fraud-on-the-FDA theory in FCA claims. R. at 37; *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). In *Campie*, two of the defendant drug company's employees filed a *qui tam* suit alleging that the company violated the FCA. *Id.* at 896. The employees alleged that the defendant made false statements to the FDA regarding certain HIV drugs, which the FDA approved. *Id*. Meanwhile, the defendant never notified the FDA of bad test results, contamination and adulteration of those products. *Id*. The Ninth Circuit applied the FCA text to these facts and held that the relators "adequately satisfied the falsity requirement" because the defendant requested payment and made false representations about the drugs. *Id*. at 902. In response to the lower court's rejection of the claim because the fraud was on one agency (FDA) and the payor was a different agency (CMS), the Ninth Circuit reversed that holding and reasoned that the False Claims Act "imposes no such limitation." *Id*. at 903 (citing 31 U.S.C. § 3729(a)(1)(B) ("extending liability to those who cause false claims to be used.")). The Ninth Circuit correctly based its holding on the FCA's text.

On the other hand, Mednology asks this Court to look to the First Circuit's holding in *D'Agostino v. ev3, Inc.*, which is more rigid than the text of the statute. R. at 20. In that case, the defendant medical device company created artificial liquid material to treat malformed blood vessels in the brain. *D'Agostino*, 845 F.3d at 3. The

defendant sought approval for one of them, Onyx, and submitted the required documents for PMA. *Id*. The relator, a sales representative, alleged that the defendant did not abide by its promises to the FDA regarding marketing, product testing, and physician training. *Id*. at 4. CMS then paid physicians who performed procedures using Onyx and paid the hospitals where their work took place. *Id*. at 7. The relator filed a *qui tam* FCA claim, and the district court granted a motion to dismiss. *Id*. at 6. The First Circuit cited the statutory language, stating that "FCA liability attaches to a 'false or fraudulent claim for payment or approval,'" but then the court steered away from that broad language to unreasonably focus on the possibility that the defendant's false representations "could have" influenced the FDA to grant approval. *Id*. at 7. This idea begs the question of what else is meant to influence the FDA's decision if it is not the representations of the company.

When the District Court in this case cited the First Circuit in *D'Agostino*, it overlooked a key difference between the facts of that case and this one: soon after Riley's complaint, Mednology voluntarily recalled Sleepternity from the market. R. at 7. The FDA did not have a chance to act while it was on the market. This difference provides another reason that this Court should not follow the First Circuit's lead and should instead uphold the Ninth Circuit's more statute-based reasoning.

Regardless of this difference in the two cases, this Court's decision in *Neifert-White* demonstrates that there are not so many hurdles to jump in an FCA claim; it stated that such claims apply to "all types of fraud, without qualification, that might

result in financial loss to the Government." 390 U.S. at 232. Therefore, the First Circuit's scrutiny of causation in FCA claim cases is unwarranted.

Here, Mednology has not denied that it knowingly degraded the device's foam content for its marketed product without approval from the FDA, a deceit that fits the legal definition of "fraud," which is "a knowing misrepresentation of the truth or concealment of a material fact to induce another to act to his or her detriment." *Fraud*, *Black's Law Dictionary* (11th ed. 2019).

The Ninth Circuit pointed to the importance of this scienter requirement in fraud-on-the-government cases in *Hendow* when it held that "[s]o long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." *Hendow*, 461 F.3d at 1172. For example, the court explained that the defendant, the University of Phoenix, "knowingly made false promises" to comply with government requirements in the Program Participation Agreement so that it would receive Title IV funds from the Department of Education. *Id*. at 1166. Specifically, the defendant did not ban incentive compensation (a recruiting tactic) because such a ban prevents certain abuses of power among recruiters. *Id.* at 1175. The defendant conducted the deceit by having one truthful set of files that were not compliant with the program separate from another fictional set of files that were compliant. *Id.* at 1169.

The relators in that case alleged an FCA violation because the defendant requested and received the Title IV government funds while conducting the deceit.

Id. At the district court level, just as in this case, the court was short-sighted in granting the 12(b)(6) motion to dismiss. But then that grant was overturned by the Ninth Circuit which had cited to this Court's broad interpretation of the purpose of the FCA: that it is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Id*. at 1170 (citing *Neifert-White Co.*, 390 U.S. 232).

Thus, this Court should affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss Riley's FCA claims. Under the FCA, the critical issue is whether fraud was committed against the federal government and that fraud led to the government paying a claim; not whether fraud was committed against the payor government agency. The Ninth and Seventeenth Circuits correctly recognized this fact. Therefore, this Court should affirm the Seventeenth Circuit and allow Riley's FCA claim to proceed to discovery.

B. The Seventeenth Circuit correctly held that Riley's fraud-on-the-FDA basis for Riley's FCA claim is viable because the facts meet the required elements to prove CMS paid Mednology based on a fraudulent claim.

This Court should affirm that the "fraud-on-the-FDA" theory is a viable basis for an FCA claim because Riley plausibly pled enough facts about Mednology's conduct to satisfy all the elements for FCA liability.

To survive a motion to dismiss under Federal Rules of Civil Procedure 12(b)(6), this Court has ruled that a complaint must provide enough facts in its claim to be "plausible on its face." *Ashcroft*, 556 U.S. at 662. This Court has also clarified that

the facts need not be "detailed." *Id* at 663–64 (citing *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007)). Rather, plausibility is present when the facts presented "allow the court to draw a reasonable inference that the defendant is liable for the misconduct alleged." *Twombly*, 550 U.S. at 556. The claim must not be "mere speculation" or just contain "labels and conclusions" but should "set forth enough factual matter to suggest a cognizable cause of action." *Id*. at 555. Furthermore, a complaint alleging fraud must "state with particularity the circumstances constituting fraud" under Federal Rules of Civil Procedure 9(b). *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1275 (11th Cir. 2018). The complaint cannot merely describe a possible scheme with a "belief that claims requesting illegal payments must have been submitted." *Id*. The plaintiff must "allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions." *Id.* (citing *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005)). In this case, Riley has an abundance of facts answering these questions regarding Mednology's fraudulent conduct towards the FDA and CMS.

This Court can reasonably infer Mednology's liability under the FCA through the facts alleged because Mednology's conduct towards the FDA and CMS was a fraud that led to a false claim. Mednology submitted a product composed of a more chemically stable foam for FDA approval and then palmed off to the marketplace and to CMS a lower-quality product that could release VOCs. R. at 5. In this case, VOCs are known to be released if the PE-PUR foam breaks down without warning in an unsuspecting patient's CPAP machine. R. at 4. In fact, the FDA has reported on this

dangerous characteristic of the foam, and a rival medical device company, Philipps, recalled their CPAPs containing PE-PUR foam. R. at 4. Mednology chose not to submit a PMA supplement to the FDA, nor did it notify CMS that the Sleepternity on the market was a substantially different product than that which the FDA approved. R. at 4; *see also* 21 C.F.R. § 814.39 (relating to PMA supplements). Thus, the scienter requirement of an FCA claim has been met.

Additionally, the Seventeenth Circuit relied on this Court's holding in *Escobar* to equate the materiality issue of the claim to that of an issue of fact, not law. R. at 37; *see also* 579 U.S. at 194–95. "Materiality" is defined in the FCA as "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Campie*, 862 F.3d at 904–05 (citing 31 U.S.C. § 3729(b)(4)). In *Escobar*, this Court explained that "proof of materiality can include . . . evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance." 579 U.S. at 194–95.

Here, Riley should have the opportunity to present evidence of government payors' reliance on FDA approval. The Seventeenth Circuit thus properly denied Mednology's motion to dismiss.

The deceit in this case is in Mednology's conduct after Sleepternity gained FDA approval. A manufacturer seeking to change the components of a medical device must earn FDA approval by submitting a PMA supplement to the FDA. 21 C.F.R § 814.39. A device's FDA approval status is important because government agencies such as CMS will not pay claims for unapproved medical devices. *See International Rehab.*

Scis. Inc. v. Sebelius, 688 F.3d 994, 1002 (9th Cir. 2012) (clarifying that FDA approval "is necessary, but not sufficient, for Medicare coverage.") Furthermore, according to a notice in Federal Register, "CMS adopts FDA determinations of safety and effectiveness." Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003). Thus, when CMS pays for devices that a manufacturer deceitfully presents as FDA-approved, a viable fraud-on-the-FDA basis supports the finding of an FCA violation.

The Ninth Circuit reversed the motion to dismiss in *Campie*, whose facts, discussed above, mirror those in this case. Here, the altered Sleepternity device did not have FDA approval, yet Mednology filed claims for it as if it had marketed the FDA-approved version of the device. R. at 4. As the Ninth Circuit and Seventeenth Circuit have supported the fraud-on-the-FDA basis, so too should this Court by affirming the Seventeenth Circuit's denial of Mednology's motion to dismiss.

C. When government funds are paid under fraudulent circumstances, the *qui tam* provision of the FCA is another tool to protect the public welfare.

The FCA was originally enacted in 1863 to combat widespread fraud against the government as it spent heavily to fund the Union troops during the Civil War. S. Rep. 99-345, at 4 (1986). Then and now, fraud against the government, regardless of the form the fraud takes, harms taxpayers by reducing funds available in the public treasury. *See State v. Altus Fin.*, 116 P.3d 1175, 1186 (Cal. 2005). The role of the *qui tam* relator has proven to be vital to the successful recovery of funds. *Id*. During the period between the first FCA amendment in 1943, which restricted the role of the

private relator and reduced incentives, and the second amendment to the FCA in 1986, fraud against the government surged. S. Rep. 99-345, at 14 (1986). One witness at the Senate Judiciary Committee's Subcommittee on Administrative Practice and Procedure of 1985 stated that "an effective vehicle for private individuals to disclose fraud is necessary both for meaningful fraud deterrence and for breaking the current 'conspiracy of silence' among Government contractor employees." *Id.* The government, in other words, needs private relators to fight fraud against the American Taxpayer.

Additionally, the Department of Justice has expressed its support of the fraud-on-the-FDA theory in *qui tam* actions because such actions are the government's "primary civil tool for prosecuting fraud against the government." United States' Statement of Interest as to Defendant's Motion to Dismiss at 1, *United States ex rel. Patricia Crocano v. Trivadia Health Inc.*, 615 F. Supp. 3d 1296 (S.D. Fla. 2022) (Case No. 22-CV-60160-RAR).

If the fraud-on-the-FDA theory is not viable in FCA *qui tam* actions, then the medical products industry could only be liable for representations made directly to the payor government entity and for injuries suffered by hapless consumers. The potential consequences are illustrated by the facts of this case. Mednology sought to cut costs while avoiding oversight by the FDA; in the process, Mednology caused Riley to have an asthma attack so severe that she was admitted to her hospital's emergency room. Moreover, Mednology's false claim to CMS requested payment for the more expensive and safer FDA-approved version of Sleepternity. By over-spending taxpayer money for a degraded and unsafe Class III medical device and by skirting

FDA PMA supplement approval, Mednology attempted a multi-faceted deceit upon the federal government.

Thanks to relators like Riley who pursue *qui tam* actions, such conduct can be duly investigated, potentially resulting in restitution to the public treasury. Discovery should thus proceed, and this Court should affirm the Seventeenth Circuit's denial of Mednology's motion to dismiss Riley's FCA claim.

CONCLUSION

This Court should affirm in part because the Seventeenth Circuit correctly held that the FDCA does not preempt Transylvania's compliance immunity exception and that Riley's FCA claim may rely on a fraud-on-the-FDA theory, but this Court should also reverse in part because the FDCA does not expressly or impliedly preempt Transylvania's immunity exceptions.

Respectfully submitted,

/s/_____

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APPENDIX

21 Trans. Comp. Stat. § 630.544 (2024)

It is the goal of the legislature to encourage manufacturers and distributors of various products to prioritize the health and safety of its consumers when manufacturing or distributing such products. It is also the goal of the legislature to encourage consumers who believe their injury resulted from a manufacturer and/or distributor's failure to exercise care, precaution, or good faith in manufacturing and/or distributing the product to bring a valid claim against the manufacturer and/or distributor.

21 Trans. Comp. Stat. § 630.545 (2024)

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 (2024)

(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.

21 U.S.C. § 360k

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 337(a)

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

F.R.C.P. 12(b)(6)

(b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(6) failure to state a claim upon which relief can be granted;

31 U.S.C. § 3729

(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 104-4101), 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.

21 C.F.R. § 814.39

(a) After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted or is of a type which, under section 515(d)(6)(A) of the act and paragraph (f) of this section, does not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

(1) New indications for use of the device.

(2) Labeling changes.

(3) The use of a different facility or establishment to manufacture, process, or package the device.

(4) Changes in sterilization procedures.

(5) Changes in packaging.

(6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

(7) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. If the protocol has been approved, the change shall be reported to FDA under paragraph (b) of this section.

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, e.g., an editorial change in labeling which does not affect the safety or effectiveness of the device, or if the change is consistent with a predetermined change control plan (PCCP) approved under section 515C of the act.

(c)(1) All procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under § 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit a PMA supplement in electronic format and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional information, if requested by FDA, in electronic format. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in § 814.40 for a PMA.

(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, that information may be included by referencing a previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

(i) The PMA supplement and its mailing cover are plainly marked "Special PMA Supplement—Changes Being Effected";

(ii) The PMA supplement provides a full explanation of the basis for the changes;

(iii) The applicant has received acknowledgement from FDA of receipt of the supplement; and

(iv) The PMA supplement specifically identifies the date that such changes are being effected.

(2) The following changes are permitted by paragraph (d)(1) of this section:

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

(ii) Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.

(iii) Labeling changes that delete misleading, false, or unsupported indications.

(iv) Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.