No. 24-9176

In the Supreme Court of the United States

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES EX REL. Riley ORTEGA,

Respondent.

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

BRIEF FOR PETITIONER

3302
Counsel of Record

QUESTIONS PRESENTED

I. Can a state statutory immunity exception for manufacturers that is based on fraudulently obtaining FDA approval or failing to comply with any FDA requirements survive preemption by federal law?

II. Should a *qui tam* False Claims Act claim against a medical device manufacturer based solely on the fraud-on-the-FDA theory of liability be allowed?

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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. at 1–24. The opinion and order of the United States Court of Appeals for the Seventeenth Circuit is unreported and set out in the record. R. at 25–43.

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

This case involves the following provisions of the False Claims Act: 31 U.S.C. §§ 3729; 3730(b), (c). These provisions are set out in Appendix A.

This case involves the following provision of the Food, Drug, and Cosmetic Act: 21 U.S.C. § 360k. This provision is set out in Appendix A.

This case involves the following Transylvania statutes: 21 Trans. Comp. Stat. §§ 630.544; 630.545; 630.546 (2024). These provisions are set out in Appendix A.

This case involves Art. VI, cl. 2 under the United States Constitution:

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

REGULATORY PROVISIONS INVOLVED

This case involves the following provisions of the Code of Federal Regulations Title 21—Food and Drugs: 21 C.F.R. §§ 7.40(b); 814.39. These provisions are set out in Appendix B.

RULES PROVISIONS INVOLVED

This case involves the following provision of the Federal Rules of Civil

Procedure: Fed. R. Civ. P. 12(b)(6). This provision is set out in Appendix C.

STATEMENT OF THE CASE

Statement of Facts

Sleepternity device. Petitioner is the manufacturer of Sleepternity, a continuous positive airway pressure (CPAP) machine. R. at 3. CPAP machines are generally used to reduce the occurrence of sleep apnea. R. at 3. Sleepternity provides several unique features that can help users reduce insomnia, in addition to several features that can help users reduce sleep apnea. R. at 3. On December 30, 2022, the Food and Drug Administration (FDA) granted pre-market approval for Sleepternity as a Class III medical device. R. at 3–4.

Sleepternity contains a sound-dampening foam. R. at 4. Before the FDA granted pre-market approval for Sleepternity, the sound-dampening foam contained in Sleepternity was silicone-based. R. at 4. After the FDA granted pre-market approval for Sleepternity, Petitioner replaced the silicone-based foam with a polyester-based polyurethane (PE-PUR) foam and did not disclose the modification to the FDA. R. at 4. Another medical device company recalled its CPAP devices due to health risks associated with PE-PUR sound abatement foams. R. at 4.

Respondent's symptoms. Respondent was prescribed Sleepternity by a somnologist to treat Respondent's sleep apnea and insomnia symptoms. R. at 3. Respondent experienced asthma attacks and was transported to an emergency room. R. at 4–5. The asthma attacks caused respondent's lungs to be chronically inflamed. R. at 5. The on-call emergency room physician who treated Respondent's

asthma attacks recommended that Respondent stop using Sleepternity. R. at 4–5. Respondent's primary condition agreed with the emergency room physician that Respondent's allergy attacks constituted unknown side effects of Sleepternity. R. at 5. Respondent discontinued use of the features of Sleepternity that can help users reduce sleep apnea, but Respondent continued use of the features of Sleepternity that can help users reduce insomnia. R. at 5.

Respondent's investigations. Respondent's brother is employed as an assembly manager by Petitioner. R. at 5. Respondent's brother informed Respondent that the reason Petitioner replaced Sleepternity's silicone-based foams with PE-PUR foams was to save manufacturing costs. R. at 5. Respondent performed research and discovered that PE-PUR foams can degrade into certain forms of isocyanate. R. at 5–6. Respondent is allergic to isocyanate. R. at 5. Respondent believed that the PE-PUR foams in Sleepternity likely contributed to Respondent's asthma attacks. R. at 5–6. Respondent reported Petitioner's conduct to the FDA. R. at 6.

Respondent's complaint. On June 21, 2023, Respondent filed a complaint against Petitioner. R. at 6. Shortly after Respondent served a summons and copy of Respondent's complaint to Petitioner, Petitioner voluntarily recalled Sleepternity pursuant to 21 C.F.R. § 7.40(b). R. at 7. In response, the FDA discontinued its investigation of Petitioner's conduct. R. at 7.

Nature of Proceedings

Southern District of Transylvania. On June 21, 2023, Respondent brought a

products liability action against Petitioner alleging a breach of its duty to disclose to the FDA the modifications it made to the foams in Sleepternity and its duty to warn about the PE-PUR foams in Sleepternity. R. at 6. Respondent's complaint also contains a False Claims Act (FCA) claim against Petitioner on behalf of the United States under the FCA's *qui tam* provision. *Id.*; 31 U.S.C.§ 3730(b). The United States declined to intervene in the FCA action. R. at 6. Respondent relies solely on the fraud-on-the-FDA theory to bring the FCA action. *Id.*

Petitioner responded with a motion to dismiss under Rule of Civil Procedure 12(b)(6) for failure to state a claim. R. at 9. In response to Respondent's products liability claim, Petitioner insists in the motion to dismiss that federal law preempts Transylvania's state product liability statute. R. at 9. In response to Respondent's FCA claim, Petitioner insists in the motion to dismiss that the fraud-on-the-FDA theory is not a viable basis for bringing such claim. R. at 9.

On the products liability issue, the district court denied Petitioner's motion to dismiss. R. at 18. On the FCA issue, the district court granted Petitioner's motion to dismiss. R. at 19.

Seventeenth Circuit. The circuit court affirmed the district court's motion to dismiss the Petitioner's products liability claims on different grounds. R. at 35. The circuit court reversed the district court's granting of Petitioner's motion to dismiss Respondent's FCA claim. R. at 38. Judge Ruzich concurred with the majority on the FCA issue and dissented on the products liability issue. R. at 38.

SUMMARY OF THE ARGUMENT

Federal law preempts a state statutory immunity exception for manufacturers that is based on fraudulently obtaining FDA approval or failing to comply with any FDA requirements. Federal preemption doctrine is based on the Supremacy Clause and invalidates state laws that conflict with federal law.

The first step of a preemption analysis is to determine whether a presumption against preemption applies. Congress, through the Food, Drug, and Cosmetic Act (FDCA), gives ample powers to the FDA, including specifically to deter fraud against the FDA, which is not a field that states have traditionally occupied. Therefore, the presumption against preemption does not apply to a state statutory immunity exception for manufacturers that is based on fraudulently obtaining FDA approval or failing to comply with any FDA requirements.

The second step of the preemption analysis is to determine whether any claims are explicitly preempted. The FDCA contains an explicit preemption provision that preempts state laws that differ in safety and effectiveness requirements. A claim under a state product liability statute regarding fraud by a medical device manufacturer has different requirements from those of the FDCA that relate to safety and effectiveness. Therefore, such a claim is explicitly preempted.

The third step of the preemption analysis is to determine whether any claims are implicitly preempted. Exceptions to state immunity for medical device manufacturers are implicitly preempted by the FDCA because Congress intended

the FDCA to be enforced by the FDA. Without implicit preemption, state courts could substitute their judgment for the judgment of the FDA.

Therefore, the Seventeenth Circuit should be reversed and Petitioner's motion to dismiss Respondent's products liability action should be granted.

A *qui tam* False Claims Act claim against a medical device manufacturer based solely on the fraud-on-the-FDA theory of liability should not be allowed. The Seventeenth Circuit erred in allowing Respondent to base a *qui tam* FCA action against a medical device manufacturer solely on the fraud-on-the-FDA theory of liability. The elements of FCA liability are based on federal statute. Conversely, the fraud-on-the-FDA theory is a common law theory that plaintiffs have asserted in seeking damages under state tort law. The fraud-on-the-FDA theory of liability does not conform with the elements of FCA liability. Furthermore, policy concerns arise when fraud-on-the-FDA theory is relied upon in an FCA claim. For these reasons, fraud-on-the-FDA theory is not a viable basis for bringing a *qui tam* False Claims Act claim against a medical device manufacturer.

Therefore, the Seventeenth Circuit should be reversed and Petitioner's motion to dismiss Respondent's FCA action should be granted.

STANDARD OF REVIEW

The question of whether federal law preempts a state statutory immunity exception for manufacturers that is based on fraudulently obtaining FDA approval or failing to comply with any FDA requirements is a question of law, and as such the Court reviews the circuit court's decision on this question *de novo*. *See Lofton v.*

McNeil Consumer & Specialty Pharms., 672 F.3d 372, 375 (5th Cir. 2012). The question of whether fraud-on-the-FDA theory of liability can be the sole basis for a *qui tam* FCA action against a medical device manufacturer is a question of law, and as such the Court reviews the circuit court's decision on this question *de novo*. *See United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 898 (9th Cir. 2017).

Both questions arise from a motion to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. In reviewing a motion to dismiss, the Court must accept the facts alleged in the plaintiff's complaint as true and make any reasonable inferences in the nonmovant's favor. *Crescent Plaza Hotel Owner, L.P. v. Zurich Am. Ins. Co.*, 20 F.4th 303, 307 (7th Cir. 2021); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To state a claim, a plaintiff's complaint must include enough facts for the claim to be "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when the facts in the plaintiff's complaint allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

ARGUMENT

I. A state statutory immunity exception for manufacturers that is based on fraudulently obtaining FDA approval or failing to comply with any FDA requirements cannot survive preemption by the FDCA.

The Supremacy Clause states that the Constitution and federal laws are "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The Supremacy Clause is the source of preemption doctrine, under which "state laws that are contrary to federal statutes" are invalidated. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1045 (9th Cir. 2022); *See Gibbons v. Ogden*, 22 U.S. 1, 210, 6 L.

Ed. 23 (1824)). Preemption may be either explicit or implicit, depending on whether the intent of Congress is "explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98, 112 S. Ct. 2374, 2383, 120 L. Ed. 2d 73 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

The FDCA contains a two-part preemption provision that applies to state laws or regulations governing medical devices. 21 U.S.C. § 360k. First, the FDCA provides that states cannot establish any requirements that are different from, or in addition to, any FDCA requirement applicable to a medical device. *Id.* Second, the FDCA provides that states cannot establish any requirements concerning the safety or effectiveness of a medical device "or to any other matter included" in a FDCA requirement applicable to a medical device. *Id.*

A. The FDCA provides no federal private right of action for product liability claims against medical device manufacturers.

The Court has interpreted the FDCA preemption provision as "clear evidence" that Congress intended the FDCA to be "enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Furthermore, the Court has been clear that the FDCA does not create, explicitly or implicitly, a private right of action. *Id.*; *See Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 811(1986) (reasoning "Congress did not intend a private federal remedy for violations of the statute that it enacted.").

While the Court has settled the issue of whether there is a federal private right of action for product liability tort regarding medical devices under the FDCA,

the Court has not settled the issue of whether a state private right of action for product liability tort regarding medical devices is preempted by federal law.

B. The FDCA explicitly preempts and bars any claims under a state product liability statute regarding fraud by a medical device manufacturer.

1. The presumption against preemption does not apply to a claim under a state product liability statute regarding fraud by a medical device manufacturer.

a. The Seventeenth Circuit erred in applying a presumption against preemption because policing fraud against federal agencies is not a field that states have traditionally occupied.

In its analysis of federal preemption, the Court begins with a presumption that federal law does not preempt historical state police powers "unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). However, the presumption against preemption does not apply to a field that States have not traditionally occupied. *Buckman*, 531 U.S. at 347.

The Court's decision in *Buckman* illustrates how the presumption against preemption does not apply to state product liability statutes regarding medical device manufacturers. *See id.* In *Buckman*, the plaintiff made a state law claim alleging that the defendant made fraudulent representations to the FDA to get approval for bone screws. *Id.* The Court held that the presumption against preemption did not apply because policing fraud against federal agencies was not a field that States traditionally occupied. *Id.*

Following the Court's decision in *Buckman*, any claim under a state product liability statute regarding a medical device manufacturer must involve a breach of a duty of the medical device manufacturer to the FDA. *See id.* As such claim relates to a relationship between the FDA and the entities regulated by it, the nature of the

claim is inherently federal in nature. *See id.* It would not make sense to apply a presumption against preemption to such claim, because state police powers, the basis of the presumption against preemption, do not extend to federal agencies. S*ee Geo Grp., Inc. v. Newsom*, 50 F.4th 745, 761 (9th Cir. 2022) (reasoning "the presumption does not apply when a state law would interfere with inherently federal relationships.").

b. Federal preemption regarding fraud by a medical device manufacturer does not preclude all state consumer protections against medical device manufacturers because parallel claims are not preempted.

The Court has previously indicated that the FDCA does not preclude state courts from offering state consumers any protections from a defective medical device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996). State law claims can avoid preemption by the FDCA if the claim does not impose additional or different requirements to the federal regulations but is instead parallel to the federal requirements. *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 771 (5th Cir. 2011).

In *Hughes*, the state law claim for failure to provide adequate warnings or instructions under Mississippi law did not impose additional or different requirements to the federal regulations. *Id.* The Mississippi duty to provide adequate warnings or instructions was construed by Mississippi courts to provide "reasonable warnings" of risks. *Id.* at 769 (quoting *Thomas v. Hoffman–LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.1992). The federal requirement in question required the manufacturer to "report incidents in which the device may have caused or contributed to a death or 'serious injury,' or malfunctioned in such a way that would likely cause or contribute to death or serious injury if the malfunction recurred." *Id.*

at 766. The Fifth Circuit in *Hughes* held that the claim was not preempted by the FDCA because the state law claim did not add additional requirements and was parallel to the federal requirement. *Id.* at 771. For similar reasons, the courts have held that negligent manufacturing claims also parallel federal requirements and are not preempted. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 2010 WL 5186062 (7th Cir.2010), *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed.Appx. 436, 440–42 (6th Cir.2010).

c. The district court erred in applying a presumption against preemption to Respondent's claims regarding fraud by a medical device manufacturer.

In the instant case, the district court relied on *Lohr* to apply a presumption against preemption. R. at 13. However, unlike the instant case, the plaintiff in *Lohr* alleged negligence and strict liability against a medical device manufacturer, claims parallel to the relationship between the FDA and the regulated entity. *Id.*; *see Lohr*, 518 U.S. at 481. As a result of the parallel claims, the claim in *Lohr* implicated "both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.* at 485.

In contrast, a claim regarding fraud by a medical device manufacturer must allege a breach of duty to the FDA and thus relates to a relationship between the FDA and the regulated entity. R. at 6. Consequently, a claim regarding fraud by a medical device manufacturer does not implicate federalism concerns as do the claims in *Lohr*. 518 U.S. at 485.

In the instant case, the claims regarding fraud by a medical device manufacturer are the alleged breach of duty to disclose to the FDA and the alleged

breach of duty to warn under the Transylvania product liability statute. R. at 6; *see* Trans. Comp. Stat. § 630.545 (2024). Neither claim is parallel to federal requirements.

First, the duty to disclose under Section 630.545 is not parallel to federal requirements because it overlaps with federal requirements for disclosures to the FDA. *Id.* The duty to disclose under Section 630.545 requires "disclosures to appropriate agencies or government officials about any modifications made to the product." *Id.* In contrast, the federal requirement for duty to disclose requires disclosure to the FDA if the modification affects the "safety or effectiveness of the device." 21 C.F.R. § 814.39. Therefore, the duty to disclose under state law is more onerous than the federal requirement. *See id.*; *see* Trans. Comp. Stat. § 630.545 (2024). Consequently, the instant claim for duty to disclose is preempted for adding more to the federal requirements as opposed to being parallel.

For the same reasons, the duty to warn under Section 630.545 is not parallel to federal requirements because it adds more to federal requirements for disclosures to the FDA. *Id.* (requiring "the duty to warn of any dangers or risks associated with the product.").

2. The FDCA's explicit preemption clause bars any claim based on a state product liability claim regarding fraud by a medical device manufacturer.

A claim under state law can be barred when "Congress explicitly preempts state law in the statutory language." *Pennsylvania v. Navient Corp.*, 967 F.3d 273, 287 (3d Cir. 2020). Because Congress included an explicit preemption provision in the FDCA, it follows that the FDCA would bar certain claims under state law. *See*

21 U.S.C. § 360k.

The Court has established a two-step test for determining if a state law claim is explicitly preempted by the FDCA. *White v. Medtronic, Inc.*, No. 18-11590, 2019 WL 1339613, at *3 (E.D. Mich. Feb. 20, 2019) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008)), report and recommendation adopted, No. 18-11590, 2019 WL 1330923 (E.D. Mich. Mar. 25, 2019), aff'd, 808 F. App'x 290 (6th Cir. 2020)). The first step is to determine whether a federal source has established requirements for a medical device. *Id.* The second step is to determine whether the state law claim is based upon requirements that conflict with the federal requirements for the medical device, and whether the federal requirements relate to the safety and effectiveness of the medical device. *Id.*

a. Federal statutes establish requirements for medical devices that have received premarket approval from the FDA.

As noted by the Court in *Riegel*, premarket approval imposes federal requirements for medical device manufacturers. *Riegel*, 552 U.S. at 322. Premarket approval is a rigorous process where the FDA spends an average of 1,200 hours reviewing each premarket approval application. *Riegel*, 552 U.S. at 317–318. The Court has relied upon the federal requirements of a medical device's market entry to determine whether state law claims alleging a medical device is unsafe will survive a federal preemption challenge. *See* Christine A. Gaddis, *Buckman Extended: Federal Preemption of State Fraud-on-the-FDA Statutes*, 69 Food & Drug L.J. 113, 119 (2014).

b. A state product liability law regarding fraud by a medical device manufacturer conflicts with federal requirements for medical device manufacturers.

Common-law causes of action for negligence and strict liability impose requirements and would be preempted by federal requirements specific to a medical device. *Riegel*, 552 U.S. at 323–24 (citing *Lohr*, 518 U.S. at 493–494). The requirements based on such common-law causes of action are considered stricter than the federal requirements specific to the product. *Id.* at 325.

In *Riegel*, the Court determined whether a state law claim regarding a catheter was preempted by the FDCA. *Id* at 315. The complaint alleged that the catheter was "designed, labeled, and manufactured in a way that violated New York common law." *Id.* at 320. The Court held that the FDCA's preemption provision barred the claim for challenging the safety and effectiveness of a catheter that received premarket approval from the FDA. *Id.* at 312. The Court was concerned that "[s]tate tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 325. The Court reasoned that it was implausible that Congress intended the FDCA to grant power to "a single state jury" that exceeded the power granted "to state officials acting through state administrative or legislative lawmaking processes." *Id.* (quoting *Lohr*, 518 U.S. at 504).

Therefore, a state product liability law regarding fraud by a medical device manufacturer satisfies the two-part test for determining if a state law claim is explicitly preempted by the FDCA. *See Nexus Pharms., Inc.*, 48 F.4th at 1044.

C. The Seventeenth Circuit erred in not dismissing Respondent's breach of duty of care and good faith claims because exceptions to state immunity for medical device manufacturers are implicitly preempted by the FDCA.

To determine implicit preemption, a court must first examine whether Congress intended to displace state law. David C. Vladeck, *Deconstructing Wyeth v. Levine: The New Limits on Implied Conflict Preemption*, 59 Case W. Res. L. Rev. 883, 885 (2009). Examples of congressional intent to displace state law include when Congress wants a "federal regulatory regime to occupy the field," when state law "conflicts with federal dictates," and when state law "would frustrate the attainment of federal objectives." *Id.*

In the instant case, Respondent also that Petitioner breached its duty of care and good faith in violation of Transylvania's product liability statute. R. at 6. *see* Trans. Comp. Stat. § 630.545 (2024). Respondent's claim fails because the FDCA implicitly preempts Transylvania's statutory exceptions to immunity for medical device manufacturers.

As noted in the dissenting opinion in the Seventeenth Circuit, if the exceptions and compliance provisions of Transylvania's manufacturer immunity statute are implicitly preempted, then the Petitioner's motion to dismiss should be granted. R. at 42; *See* 21 Trans. Comp. Stat. § 630.546 (2024); *See Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (holding that a statutory FDA compliance requirement for immunity was preempted and the granting of the motion to dismiss product liability claim was affirmed).

1. The FDCA implicitly preempts the exceptions to the Transylvania product liability immunity statute for claims against medical device manufacturers.

In view of the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Lab'ys*, the exceptions to the Transylvania immunity statute are implicitly preempted by the FDCA. *See Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 967 (6th Cir. 2004). In *Garcia*, the Sixth Circuit found that a similar immunity exception provision was implicitly preempted by the FDCA, and that the fraud-on-the-FDA claim was barred. *Id.* The Sixth Circuit in *Garcia* reasoned that though the FDCA does not implicitly preempt a fraud-on-the-FDA claim relying on the FDA's own determination of fraud, the FDCA does implicitly preempt a fraud-on-the-FDA claim relying on court findings of fraud. *Id.* at 966 (reasoning that allowing a fraud-on-the-FDA claim that relies on court findings of fraud would lead to interbranch meddling).

As in *Garcia*, the instant claim alleging breach of duty to disclose to the FDA raises the same interbranch meddling concerns. If the Court does not view the manufacturer immunity exceptions in the instant case as implicitly preempted, then state courts will have to substitute their own judgment for the judgment of the FDA, which would conflict with the federal statutory scheme enacted by Congress. Congress wanted the FDA to regulate fraud instead of state courts, evidenced by the FDCA "amply empowe[ring] the FDA to punish and deter fraud." *Buckman*, 531 U.S. at 348. Therefore, the FDCA implicitly preempts exceptions to state immunity for medical device manufacturers.

In the instant case, the district court relied on the Second Circuit's decision in

Desiano v. Warner-Lambert & Co. to hold that the immunity exceptions were not preempted by federal law. R. at 10–18; *see Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006), aff'd sub nom. *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008). In *Desiano*, the Second Circuit held that a claim alleging a fraud-on-the-FDA can survive preemption if the claim does not solely depend on the fraud-on-the-FDA. *Id.* The Second Circuit in *Desiano* stated that its decision did not conflict with the Court's decision in *Buckman*. *Id.* (reasoning that the Court's decision *Buckman* only relates to claims that solely depend on fraud-on-the-FDA).

However, the Second Circuit's decision in *Desiano* ignores the underlying federalism concerns the Court identified in *Buckman*. *See id.* In *Buckman*, the Court held that state law fraud-on-the-FDA claims were preempted by the FDCA because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350. Therefore, the Sixth Circuit's decision in *Desiano* conflicts with *Buckman* because the Court in *Buckman* viewed the state fraud-on-the-FDA claims as "an illegitimate state effort to interfere in a purely federal realm." Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 Colum. L. Rev. 1, 36 (2011).

Even if a state law claim does not depend solely on fraud-on-the-FDA, following the Second Circuit's decision in *Desiano* for a state law claim that is partially based on fraud-on-the-FDA will result in state court interference with federal agency decision making. This interference would contradict the existing statutory structure that gives federal courts the power of judicial review. *See Loper*

Bright Enterprises v. Raimondo, 144 S. Ct. 2244, 2261 (2024). In contrast, the Sixth Circuit's decision in *Garcia* still allows for fraud-on-the-FDA claims to avoid preemption when the FDA makes the determination of fraud and thus takes into consideration the Court's concerns in *Buckman*. *Garcia*, 385 F.3d at 966.

2. The FDCA implicitly preempts the compliance provision of the Transylvania product liability immunity statute for claims against medical device manufacturers.

For the same federalism reasons underlying *Buckman*, the FDCA implicitly preempts the compliance provision of the Transylvania immunity statute for claims against medical device manufacturers. As the dissent in the Seventeenth Circuit noted in the instant case, *Marsh* is on point for such claims. R. at 41–42; *see Marsh*, 693 F.3d at 553. In *Marsh*, the Sixth Circuit applied the Court's reasoning in *Buckman* in determining whether a similar compliance provision in an immunity statute was implicitly preempted in relation to a claim alleging non-compliance. *Id.* The Sixth Circuit in *Marsh* held that the FDCA preempted the compliance provision, and that immunity applied. *Id.* at 554. The Sixth Circuit in *Marsh* raised similar concerns to the Court in *Buckman*, viewing a requirement for a court to rule on the adequacy of disclosures to the FDA as "inter-branch meddling" *Id.* at 553.

In the instant case, a decision by the Court against implicit preemption of the compliance provision for manufacturer immunity would result in state courts ruling on whether a company breached its duty to disclose to the FDA. This precedent would allow state courts' judgment to be substituted for the FDA's judgment and therefore would conflict with the statutory scheme that gives the FDA enforcement power. *See id.*; *see Buckman*, 531 U.S. at 347.

II. A *qui tam* False Claims Act claim against a medical device manufacturer should not be allowed when a relator bases the claim solely on the fraud-on-the-FDA theory of liability.

The FCA was enacted during the Civil War to penalize government contractors that took advantage of the war to perpetrate massive frauds, including billing the United States for nonexistent or worthless goods and charging exorbitant prices for goods delivered. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 181–82 (2016) (citing *United States v. Bornstein,* 423 U.S. 303, 309 (1976) and *United States v. McNinch*, 356 U.S. 595, 599 (1958)). The FCA has been interpreted by the Court to cover fraudulent claims for reimbursements under Medicare and Medicaid. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023); *see* 31 U.S.C. § 3729(b)(2)(A) (including requests for reimbursement in the definition of a "claim").

The Court has applied Section 3729(a)(1)(A) of the FCA as the source of liability for cases involving reimbursements under Medicare and Medicaid. *Schutte*, 598 U.S. at 747; *Escobar*, 579 U.S. at 180. Under Section 3729(a)(1)(A), FCA liability arises for a party that ""knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

Section 3729(a)(1)(A) requires a "false or fraudulent claim" for FCA liability. *Id.* Although neither "false" nor "fraudulent" are defined by Congress, the Court has identified three mechanisms by which a claim can be false or fraudulent. *See Escobar*, 579 U.S. at 187. First, the claim can be "false or fraudulent" because it is factually false. *Campie*, 862 F.3d at 902. An example of a factually false claim in the context of reimbursements under Medicare and Medicaid could be a doctor billing

Medicare for a service that was never performed. See *U.S. v. Krizek*, 111 F.3d 934 (D.C. Cir. 1997). Second, a claim can be "false or fraudulent" because it is legally false due to false certification. *Escobar*, 579 U.S. at 181. False certification can be express or implied. Joan H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that Counts Under the False Claims Act*, 2017 U. Ill. L. Rev. 1811, 1817 (2017). An example of express false certification in the context of reimbursements under Medicare and Medicaid is a healthcare provider signing a statement on an invoice for a Medicare payment that the healthcare provider is compliant with Medicare requirements when the healthcare provider is out of compliance. *See id.*, citing *United States ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1217–18 (10th Cir. 2008). An example of implied false certification in the context of reimbursements under Medicare and Medicaid is a healthcare provider submitting reimbursement claims to Medicaid while omitting that the healthcare provider is out of compliance with Medicaid licensing requirements. *Escobar*, 579 U.S. at 184–185. The third way a claim can be "false or fraudulent" is if it is obtained through promissory fraud, also known as fraudulent inducement. *Campie*, 862 F.3d at 902. An example of FCA promissory fraud could be a contractor misrepresenting themselves, resulting in the award of a government contract, whereafter each claim under the contract is fraudulent because the contract was fraudulently obtained. *U.S. ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006).

Section 3729(a)(1)(A) also requires the fraudulent conduct to be conducted

"knowingly". 31 U.S.C. § 3729(a)(1)(A). The FCA defines this scienter requirement to mean that the fraudulent conduct must be performed with actual knowledge of the fraud, or with deliberate ignorance of truth or falsity, or with reckless disregard of truth or falsity. *Escobar*, 579 U.S. at 181 (citing 31 U.S.C. § 3729(b)(1)(A)).

Another element of FCA liability is that a false or fraudulent claim "must be material to the government's payment decision." *Escobar*, 579 U.S. at 194. The materiality element of FCA liability requires that the false or fraudulent claim significantly influenced the government's decision to pay or withhold payment. *United States ex rel. Harman v. Trinity Industries, Inc.*, 872 F.3d 645, 665 (5th Cir. 2017).

Another element of FCA liability is causation. See *United States ex rel. D'Agostino v. EV3, Inc.*, 845 F.3d 1 (1st Cir. 2016), at 9. For the causation element to be satisfied, a direct connection between the alleged fraudulent conduct and the government's decision to pay or approve a claim must be shown. *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014).

The FCA contains a *qui tam* provision, under which a relator may bring an action on behalf of the United States. 31 U.S.C. § 3730(b)(1). After the FCA *qui tam* action is brought by the relator, the United States has the right to prosecute, dismiss, or settle the action. *Id.* at § 3730(c)(1), (2). If the United States chooses not to proceed with the action, then the relator has the right to proceed with the action. *Id.* at § 3730(c)(3).

The FCA does not contain a liability provision for fraud-on-the-FDA theory.

See 31 U.S.C. § 3729. Fraud-on-the-FDA is a theory of liability that has been relied upon by plaintiffs seeking damages under state tort law. *Buckman*, 531 U.S. at 347–348. Under the fraud-on-the-FDA theory, there exists a private right of action under state tort law for product liability claims where the product is regulated by the FDA and fraudulent misrepresentations have been made to the FDA regarding the product. *Id.* at 348. The Court has held that state-law fraud-on-the-FDA claims are preempted by federal law because the FDA is empowered to punish and deter fraud against the FDA. *Id.*

In the instant case, the district court and the circuit court identified a split between the First Circuit and the Ninth Circuit on whether fraud-on-the-FDA theory can be relied upon by a relator bringing a *qui tam* FCA claim. (R. at 35–36). The First Circuit rejected an FCA claim that relied on fraud-on-the-FDA theory based on the facts alleged in the claim. *D'Agostino*, 845 F.3d 1 (1st Cir. 2016). In its decision in *D'Agostino*, the First Circuit considered the Court's analysis in *Buckman* and raised additional policy concerns surrounding the reliance on fraud-on-the-FDA theory for FCA *qui tam* claims for medical devices. *Id.* at 9. However, the First Circuit stopped short of ruling that the FCA is preempted by the FDCA. *Id.* The Ninth Circuit accepted an FCA claim that involved fraudulent misrepresentations made to the FDA regarding pharmaceuticals, but did not identify the source of liability as fraud-on-the-FDA theory. *Campie*, 862 F.3d 890. The Ninth Circuit instead identified the source of liability as implied certification theory, and based its analysis on the Court's approval of implied certification theory as a source of

liability for FCA claims in *Escobar*. *Id.* at 901 (citing *Escobar*, 579 U.S. 176).

A. The Fraud-on-the-FDA theory, as applied to a medical device manufacturer, does not conform with the elements of FCA liability.

The Seventeenth Circuit based its analysis of all elements of FCA liability on the Ninth Circuit's decision in *Campie*. R. at 36. The Seventeenth Circuit framed its choice of analysis as a dichotomy between following the First Circuit's decision in *D'Agostino* or the Ninth Circuit's decision in *Campie*. *Id.* The Seventeenth Circuit chose to follow the Ninth Circuit's decision in *Campie* because, compared to the First Circuit's decision in *D'Agostino*, the Ninth Circuit's decision in *Campie* more thoroughly applied the Court's implied certification theory analysis from *Escobar*. *Id.*

1. The fraud-on-the-FDA theory, as applied to a medical device manufacturer, does not conform with every mechanism for satisfying the falsity element of FCA liability.

The split between the First Circuit and the Ninth Circuit on whether fraud-on-the-FDA theory can be relied upon by a relator bringing a *qui tam* FCA claim hinges on the application of the falsity element of liability to the respective facts of *D'Agostino* and *Campie*. *See D'Agostino*, 845 F.3d 1; *Campie*, 862 F.3d 890. The circuit court in *D'Agostino* utilized the promissory fraud mechanism of falsity and applied the FCA element of falsity to a fraud-on-the-FDA claim against a medical device manufacturer. *D'Agostino*, 845 F.3d at 7–10. The circuit court in *Campie* utilized all three mechanisms of falsity: factual falsity, implied false certification, and promissory fraud, and applied the FCA element of falsity to multiple fraud-on-the-FDA claims against a large drug producer. *Campie*, 862 F.3d at 902–904.

Considering the FCA element of falsity, Seventeenth Circuit erred in favoring the Ninth Circuit's decision in *Campie* over the First Circuit's decision in *D'Agostino* for two reasons. First, *Campie* is a drug case, while *D'Agostino* is a medical device case, and the question in the instant case involves medical device manufacturers, not drug producers. Second, *Campie* applies the implied certification theory to FCA liability, while *D'Agostino* applies the fraud-on-the-FDA theory to FCA liability, and the question in the instant case involves the fraud-on-the-FDA theory, not the implied certification theory.

a. The Seventeenth Circuit erred in performing its analysis of the falsity element of FCA liability for fraud-on-the-FDA theory claims against a medical device manufacturer based on analysis of FCA claims against drug producers.

The Court stated in *Escobar* that the application of the falsity element of FCA liability is a common law issue. *Escobar*, at 187 (citing *Sekhar v. United States*, 570 U.S. 729, 732 (2013) and *Neder v. United States*, 527 U.S. 1, 22 (1999)). Common law is created in the process of applying new rules retroactively to existing facts arising from a case. Frederick Schauer, *Is the Common Law Law*, 77 Calif. L. Rev. 455 (1989). Common law also extends to modifying or replacing existing rules when applying the existing rule to the case at hand would "generate a malignant result." *Id.* The Ninth Circuit in *Campie* heeded these principles in applying the common law implied certification theory set forth by the Court in *Escobar*, a case involving a medical provider billing for services, to a new set of facts involving a drug producer. *See Campie*, 862 F.3d 890. However, the Seventeenth Circuit did not heed these principles of common law, and instead rigidly applied the implied

certification theory from the Ninth Circuit's decision in *Campie* to a case with different facts, the most glaring difference being that the instant case involves a medical device manufacturer. R. at 35–38.

As noted by the district court, the facts of the instant case are analogous to those of *D'Agostino*. R. at 20. Unlike *Campie*, in *D'Agostino*, like the instant case, the defendant's products were medical devices. R. at 20–24. Also, unlike Campie, in which the defendant's alleged fraudulent conduct was hiding failed tests and the production of pharmaceuticals in violation of FDA regulations, in *D'Agostino*, like the instant case, the defendant's alleged fraudulent conduct was making misrepresentations to receive FDA pre-market approval. *Id.* The Seventeenth Circuit is mistaken in following *Campie* and disregarding *D'Agostino*, for its stated reason that *Campie* applies "*Escobar*'s clarifications to a case like ours," because *Campie* is not a case more like ours than *D'Agostino*. (R. at 36). The similarity between *Campie* and the instant case that the Seventeenth Circuit utilizes to support its reasoning is the Seventeenth Circuit's own assertion that implied certification theory applies, which is not a similarity between the facts of the respective cases but rather between the legal theories that the Ninth Circuit and the Seventeenth Circuit chose to apply to the facts. *Id.* Even if implied certification theory applies in the instant case, as the Seventeenth Circuit assumes, then the implied certification theory factors from *Escobar* should be applied to the facts of this case with less reliance on the Ninth Circuit's reasoning in *Campie*, and with due consideration given to the First Circuit's reasoning in *D'Agostino*, a case with

more similar facts to the instant case. *See id.*

b. The Seventeenth Circuit erred in performing its analysis of the mechanisms of the falsity element of FCA liability for claims relying on a fraud-against-the-FDA theory of FCA liability against a medical device manufacturer based on an implied certification theory of FCA liability.

The Seventeenth Circuit inferred that Respondent is relying on an implied certification theory of FCA liability because CMS's decision to pay or reimburse for the use of Sleepternity was based on FDA approving the device for marketing and distribution. (R. at 36). It is important to note that implied certification theory and implied false certification are two distinct legal concepts. Implied false certification is a type of false certification, which is one of the mechanisms through which a claim can meet the falsity requirement for FCA liability. On the other hand, implied certification theory is a theory of liability that can be applied to all elements of FCA liability and can also be utilized in analysis of non-FCA causes of action. *See Escobar*, 579 U.S. at 190; *see* Krause, 2017 U. Ill. L. Rev. at 1817. The two distinct concepts are illustrated by the Ninth Circuit's decision in *Campie*, where the Ninth Circuit identified an implied certification theory of FCA liability and applied it in its analysis of the mechanisms for the falsity element of FCA liability, including implied false certification. *Campie*, 862 F.3d at 902–904.

The Seventeenth Circuit erred in conflating implied certification theory with implied false certification. The question in the instant case involves a relator's reliance on the fraud-on-the-FDA theory, not implied certification theory. R. at 43. Like implied certification theory, fraud-on-the-FDA theory is a theory of liability that can be applied to all elements of FCA liability and can also be utilized in

analysis of non-FCA causes of action. *Buckman*, 531 U.S. at 347–348. However, the Seventeenth Circuit applied implied certification theory instead of fraud-on-the-FDA theory. R. at 35–38.

The Seventeenth Circuit's error arises because the fact that CMS's decision to pay or reimburse for the use of Sleepternity was based on FDA approving the device for marketing and distribution is evidence of an implied false certification mechanism of FCA falsity, but is insufficient to infer that implied certification theory should apply to all elements of FCA liability. *Id.* In *Escobar*, the Court established two conditions for FCA liability under implied certification theory: (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 579 U.S. at 190. The fact that CMS's decision to pay or reimburse for the use of Sleepternity was based on FDA approving the device for marketing and distribution can be inferred to, at most, only satisfy the first condition of implied certification theory liability from *Escobar*. *See* R. at 36.

Therefore, because the question in the instant case is whether a relator may rely on the fraud-on-the-FDA theory to bring a False Claims Act claim against a medical device manufacturer, the Court should disregard the Seventeenth Circuit's analysis in favor of one that actually applies fraud-on-the-FDA theory to the facts of the instant case.

c. Fraud-on-the-FDA theory does not conform with every mechanism for satisfying the FCA element of falsity when applied to a medical device manufacturer.

Fraud-on-the-FDA theory does not conform with the factual falsity mechanism for FCA falsity, because it is factually true that the defendant has FDA approval. *See Campie*, 862 F.3d at 902.

Fraud-on-the-FDA theory does not conform with the express false certification mechanism for FCA falsity as applied to a medical device manufacturer because courts are highly unlikely to encounter a set of facts where, in a claim for reimbursement under Medicare or Medicaid, a defendant would be required to expressly certify that the defendant did not fraudulently obtain FDA approval. *See* Krause, 2017 U. Ill. L. Rev. at 1817.

Fraud-on-the-FDA theory does not conform with the implied false certification mechanism for FCA falsity as applied to a medical device manufacturer because the implied false statement must be made in the claim for CMS reimbursement. For CMS, FDA approval is a condition for payment. How the FDA approval was obtained is not a condition for payment. Therefore, fraud-on-the-FDA theory does not conform with implied false certification because the implied false statement is made to the FDA in order to obtain FDA approval, and, while linked to the claims for reimbursement made to CMS, are separate statements from the claims for reimbursement made to CMS. See *D'Agostino*, 845 F.3d at 7–10. Although *Campie* applied implied false certification to a case involving fraudulent FDA approval, the implied false statements in *Campie* arose from the claims to CMS for reimbursement. *Campie*, 862 F.3d at 902–904. The issue for implied false

certification was that the numerous violations of FDA regulations resulted in the drugs being contaminated, and the claims for reimbursement implied that the drugs were not contaminated. *Id.*

Fraud-on-the-FDA theory may conform with the promissory fraud mechanism for FCA falsity as applied to a medical device manufacturer. For promissory fraud, "liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained" through false or fraudulent conduct. *Hendow*, 461 F.3d at 1173. This standard is the most relevant to the question in the instant case. Respondent alleges that Petitioner obtained the government benefit of FDA approval fraudulently, and therefore every subsequent CMS payment for Sleepternity is fraudulent. R. at 2–3. Therefore, Fraud-on-the-FDA theory may conform with the promissory fraud mechanism because the promissory fraud mechanism applies when fraud is conducted when a government benefit is obtained that allows claims to be made later, rather than when the claims are made. *Hendow*, 461 F.3d at 1173.

2. The Seventeenth Circuit erred in failing to apply the fraud-on-the-FDA theory to the scienter element of FCA liability.

The Seventeenth Circuit omitted from its analysis any consideration of the scienter element of an FCA claim. R. at 35–38; *see* 31 U.S.C. §§ 3729(a)(1)(A) (providing for FCA liability when false or fraudulent claims are made "knowingly"), 3729(b)(1)(A) (defining "knowingly"). The FCA provides three mechanisms for the scienter element to be satisfied: the fraudulent conduct must be performed with actual knowledge of the fraud, or with deliberate ignorance of truth or falsity, or

with reckless disregard of truth or falsity. *Escobar*, 579 U.S. at 181 (citing 31 U.S.C. § 3729(b)(1)(A)).

The fraud-on-the-FDA theory does not conform with the scienter element of FCA liability as applied to medical device manufacturers because the defendant must have knowledge of three of the other elements of FCA liability at the time the conduct is performed: falsity, materiality, and causation. First, the defendant must have knowledge that the defendant's conduct is false or fraudulent at the time the conduct is performed. *See Escobar*, 579 U.S. at 191 (providing, as an example of FCA scienter, a firearm manufacturer who has knowledge that its firearms "do not shoot" at the time the manufacturer supplies the United States with said nonfunctioning firearms). Second, it must be shown that the defendant intended that the false or fraudulent conduct be material to the Government's decision to pay or approve a claim. *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F.Supp.2d 310, 350–351 (D. Mass. 2011). Third, the scienter element of FCA liability is only satisfied when it is shown that the defendant knew that healthcare providers would submit false claims for reimbursement as a "natural, ordinary, and reasonable consequence of its" fraud. *Nowak*, 806 F.Supp.2d at 349–350.

Therefore, fraud-on-the-FDA theory applied to FCA scienter for medical devices is next to impossible. If a medical device manufacturer presented a device to the FDA for approval that did not meet FDA standards at the time, the FDA would not grant approval. As in the instant case, for medical devices, fraud-on-the-FDA could only be met after FDA approval was granted, which would not conform with

the FCA scienter element. R. at 4.

3. The Seventeenth Circuit erred in failing to apply the fraud-on-the-FDA theory to the materiality element of FCA liability.

For FCA liability to apply, a false or fraudulent claim "must be material to the government's payment decision." *Escobar*, 579 U.S. at 194; *Harman*, 872 F.3d at 663; see *Rostholder*, 745 F.3d at 700. The FCA defines materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C § 3729(b)(4). For FCA medical device claims, a false or fraudulent claim is material if it can influence a decision of the government body to which the claim was addressed. *Nowak*, 806 F.Supp.2d at 350 (citing *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 394 (1st Cir. 2011)).

The Court in *Escobar* clarified that the FCA is not "an all-purpose antifraud statute" and that materiality "cannot be found where noncompliance is minor or insubstantial." *Escobar*, 579 U.S. at 194. The Court in *Escobar* put forth examples to help illustrate its demanding standard for FCA materiality. *Id.* at 194–195. First, materiality can be proven through "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.* Second, the materiality element of FCA liability is unlikely to be satisfied "[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id.* at 195. Third, the materiality element of FCA liability is unlikely to be satisfied "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." *Id.*

The Seventeenth Circuit analyzed the materiality element of FCA liability in the instant case in the context of a motion to dismiss for failure to state a claim. R. at 36–38. The Seventeenth Circuit focused on the issue of whether Respondent alleged sufficient facts for the materiality element of FCA liability to be a matter of proof. *Id.* The Seventeenth Circuit erred in that it did not apply the fraud-on-the-FDA theory to the materiality element of liability. *See id.*

4. The Seventeenth Circuit erred in failing to apply the fraud-on-the-FDA theory to the causation element of FCA liability.

For a defendant to be liable under the FCA, the defendant must have "presented or caused to be presented" the false or fraudulent claim. 31 U.S.C § 3729(a)(1)(A). To satisfy this causation element of FCA liability, a direct causal link between the defendant's conduct and the government's decision to pay or approve a claim must be shown. *See Rostholder*, 745 F.3d at 701.

In *D'Agostino*, the First Circuit reasoned that the fraud-on-the-FDA theory does not conform with the causation element of FCA liability:

> We reject this argument because alleging that the fraudulent representations "could have" influenced the FDA to approve Onyx falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS. If the representations did not actually cause the FDA to grant approval it otherwise would not have granted, CMS would still have paid the claims. In this respect, D'Agostino's fraudulent inducement theory is like a kick shot in billiards where the cue ball "could have" but did not in fact bounce off the rail, much less hit the targeted ball.

D'Agostino, 845 F.3d at 9.

The Seventeenth Circuit, in the instant case, acknowledges that *D'Agostino*

considers the causation element of FCA liability when analyzing whether the fraud-on-the-FDA theory can be relied upon for an FCA claim. R. at 36. The Seventeenth Circuit's analysis of causation starts and ends with this acknowledgement. The Seventeenth Circuit erred in failing to consider that, as demonstrated in D'Agostino, fraudulently obtained FDA approval would not cause CMS not to pay a claim for an FDA-approved device.

B. The Fraud-on-the-FDA theory, as applied to a medical device manufacturer, does not conform with the FCA's *qui tam* provision.

1. The Seventeenth Circuit erred in failing to address policy concerns arising from relying on the Fraud-on-the-FDA theory for *qui tam* actions.

In the instant case, the Seventeenth Circuit failed to consider the policy arguments against allowing relators to rely on the fraud-on-the-FDA theory for *qui tam* actions against medical device manufacturers. *See* R. at 35–38.

The First Circuit's decision in *D'Agostino* identified negative "collateral effects of allowing juries in qui tam actions to find causation by determining the judgment of the FDA when the FDA itself has not spoken." *D'Agostino*, 845 F.3d at 8–9, citing *Buckman* 531 U.S. at 349–51. The First Circuit also identified that courts would encounter practical problems of proof when relators rely solely on the fraud-on-the-FDA theory for *qui tam* FCA actions against medical device manufacturers. *D'Agostino*, 845 F.3d at 8–9.

In the instant case, the district court considered the First Circuit's analysis of the intent of the FCA, and in doing so reasoned that the purpose of the FCA is not to second-guess the FDA's judgment. R. at 22. The Seventeenth Circuit erred in failing to consider the issue.

2. The Seventeenth Circuit erred in failing to address the issue of damages to the government arising from relying on the Fraud-on-the-FDA theory for *qui tam* actions.

Another element of FCA liability is that the false or fraudulent conduct must link to a "claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The requirement of a claim for payment or approval implies that FCA enforces damages sustained by the government arising when the government pays or approves the claim. *See id.* But when the relator relies on a fraud-against-the-FDA theory for *qui tam* actions, there arises an issue of the existence of damages sustained by the government. The Seventeenth Circuit erred in failing to consider this issue. In the instant case, there are likely no significant damages sustained by the government, evidenced by the fact that the United States declined to proceed with the relator's *qui tam* action.

CONCLUSION

By enacting the FDCA and giving the FDA ample enforcement powers, Congress intended for the FDA to be the primary enforcement agent of the FDCA. Because Congress did not intend to prevent state courts from offering any sort of relief for a private right of action against a medical device manufacturer, the FDCA's express preemption provision does not preempt claims that parallel federal requirements. However, the instant claims are not parallel claims, and as such are preempted by the FDCA. Therefore, there is no viable basis for Respondent's products liability claims and the Seventeenth Circuit erred in denying Petitioner's motion to dismiss for failure to state a claim.

The FCA contains provisions for liability that have been interpreted by the

Court in cases involving *qui tam* FCA actions against medical device manufacturers. The FCA elements of liability conflict with the fraud-on-the-FDA theory when applied to medical device manufacturers. Further, policy concerns caution against allowing relators to base *qui tam* FCA actions on fraud-on-the-FDA theory. Therefore, there is no viable basis for Respondent's FCA claim and the Seventeenth Circuit erred in denying Petitioner's motion to dismiss for failure to state a claim.

It is for these reasons that that this Court should reverse the Court of Appeals for the Seventeenth Circuit and grant the Petitioner's motion to dismiss.

Respectfully submitted,

/s/ 3302

Attorneys for Petitioner

CERTIFICATE OF SERVICE

We certify that a copy of Petitioner's brief was served upon Respondent, Riley Ortega, through the counsel of record by certified U.S. mail return receipt requested, on this, the 10th day of September, 2024.

/s/ 3302

Attorneys for Petitioner

APPENDIX A

Statutory Provisions

Food, Drug, and Cosmetic Act (FDCA)

21 U.S.C. § 360k State and Local Requirements Respecting Devices

(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.

False Claims Act (FCA)

31 U.S.C. § 3729 False Claims

(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;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces,

who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

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.

(2) Reduced damages.--If the court finds that--

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the

Government sustains because of the act of that person.

(3) Costs of civil actions.--A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(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.

(c) Exemption from disclosure.--Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

31 U.S.C. § 3730(b), (c) Civil Actions for False Claims

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

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure.1 The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

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

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

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

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

(c) Rights of the parties to qui tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any

administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

Transylvania Statutes

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. § 630.544 (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. § 630.546 (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.

APPENDIX B

Regulatory Provisions

Title 21 Food and Drug

21 C.F.R. § 7.40(b) Recall Policy

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

21 C.F.R. § 814.39 Premarket approval of FDA devices: PMA supplements

(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.

(e)(1) FDA will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under paragraph (a) is not required. FDA will identify such a change in an advisory opinion under § 10.85, if the change applies to a generic type of device, or in correspondence to the applicant, if the

change applies only to the applicant's device. FDA will require that a change for which a PMA supplement under paragraph (a) is not required be reported to FDA in:

(i) A periodic report under § 814.84 or

(ii) A 30–day PMA supplement under this paragraph.

(2) FDA will identify, in the advisory opinion or correspondence, the type of information that is to be included in the report or 30–day PMA supplement. If the change is required to be reported to FDA in a periodic report, the change may be made before it is reported to FDA. If the change is required to be reported in a 30–day PMA supplement, the change may be made 30 days after FDA files the 30–day PMA supplement unless FDA requires the PMA holder to provide additional information, informs the PMA holder that the supplement is not approvable, or disapproves the supplement. The 30–day PMA supplement shall follow the instructions in the correspondence or advisory opinion. Any 30–day PMA supplement that does not meet the requirements of the correspondence or advisory opinion will not be filed and, therefore, will not be deemed approved 30 days after receipt.

(f) Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30–day notice. A 30–day notice shall describe in detail the change, summarize the data or

information supporting the change, and state that the change has been made in accordance with the requirements of part 820 of this chapter. The manufacturer may distribute the device 30 days after the date on which FDA receives the 30–day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate. If the notice is not adequate, FDA shall inform the applicant in writing that a 135–day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of days under review as a 30–day notice shall be deducted from the 135–day PMA supplement review period if the notice meets appropriate content requirements for a PMA supplement.

(g) The submission and grant of a written request for an exception or alternative under § 801.128 or § 809.11 of this chapter satisfies the requirement in paragraph (a) of this section.

APPENDIX C

Rules Provisions

Fed. R. Civ. P.12(b)(6) Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

(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:

(1) lack of subject-matter jurisdiction;

(2) lack of personal jurisdiction;

(3) improper venue;

(4) insufficient process;

(5) insufficient service of process;

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

(7) failure to join a party under Rule 19.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.