Docket No. 24-9176

In The

Supreme Court of the United States

September Term, 2024

MEDNOLOGY, INC.,

Petitioner,

v.

UNITED STATES EX REL. RILEY ORTEGA,

Respondent.

On Petition for Review from the United States

Court of Appeals for the Seventeenth Circuit

BRIEF FOR PETITIONER

Oral Argument Requested

Attorneys for Petitioner

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QUESTIONS PRESENTED

1. Does federal law preempt the exceptions within a state-recognized immunity statute when the statute invokes a federal relationship and requires courts to perform duties that Congress has granted to a federal agency?
2. Can a relator rely on the fraud-on-the-FDA theory to bring an action under the False Claims Act against a medical device manufacturer without establishing the materiality, scienter, and causation elements, and when the FDA has not withdrawn its approval for the device?

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OPINIONS BELOW

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

CONSTITUTIONAL PROVISIONS

Article VI, Clause 2 of the United States Constitution is relevant to this case and reprinted in Appendix A.

STATUTORY PROVISIONS

The following provisions of the United States Code are relevant to this case: 21 U.S.C. § 360k(a); 21 U.S.C. § 337(a); 31 U.S.C. § 3729(a). These provisions are reprinted in Appendix B.

The following provisions of the Transylvania Compensation Statute are relevant to this case: 21 TRANS. COMP. STAT. § 630.546(a)–(c). These provisions are reprinted in Appendix C.

REGULATORY PROVISIONS

The following provisions of the Code of Federal Regulations are relevant to this case: 21 C.F.R. § 740(a)–(b). These provisions are reprinted in Appendix D.

STATEMENT OF THE CASE

Factual Background

Sleepternity Approval. Riley Ortega is an army veteran and a citizen of the state of Wohio. R. at 3. She experiences both sleep apnea and insomnia symptoms. R. at 3. To ease these symptoms, Ortega's doctor prescribed her Sleepternity—an advanced "continuous positive airway pressure (CPAP) machine" designed to induce sleep for restless individuals. R. at 3. Sleepternity includes several carefully curated features such as automatic pressure adjustment, a heated humidifier, and even noise-cancelling headphones. R. at 3. Each feature was thoughtfully selected to increase users' overall comfort levels and gently ease them into a deep sleep. R. at 3. Such innovation helps users reduce not only their sleep apnea but also their insomnia symptoms. R. at 3. The Food and Drug Administration (FDA) approved Sleepternity for advertising as a Class III medical device in December 2022. R. at 3–4.

The Modification. Subsequently, the silicone-based, sound-insulating foam in the Sleepternity machine was replaced with a polyester-based polyurethane (PE-PUR) foam. R. at 4. The modification was not disclosed to the FDA, and Ortega did not know about the change. R. at 4. Sleepternity was modified to decrease manufacturing costs. R. at 4. Six months after the FDA approved Sleepternity, a different medical device company, Philips Respironics (Philips), recalled one of its CPAP machines because of the potential health risks that could be associated with PE-PUR foam. R. at 4. PE-PUR foam can break down over time and release chemical

compounds that may cause harm to CPAP users if inhaled. R. at 4. Philips recalled the machine and replaced the foam with a silicone alternative. R. at 4.

Ortega's Theory. Ortega did not know about the foam replacement in Sleepternity until she underwent treatment at a hospital for an asthma attack. R. at 4–5. Because Ortega developed chronic lung inflammation from her military service, the asthma attack aggravated this condition and reintroduced her sleep apnea symptoms. R. at 5. Although she is allergic to isocyanate, a compound from polyurethane, the physicians did not link her allergy to her asthma attack. R. at 5. Upon her doctors' recommendations, Ortega stopped using the Sleepternity CPAP machine; however, she still uses the headphones to treat her insomnia. R. at 5. Ortega's brother believes the corporation used silicone foam to garner FDA approval and then modified the final design to reduce manufacturing costs. R. at 5. After hearing his theory, Ortega concluded the PE-PUR foam may have contributed to her asthma and exacerbated her existing lung inflammation. R. at 5.

Procedural History

The Southern District of Transylvania. Riley Ortega brought a products liability action in the United States District Court for the Southern District of Transylvania. R. at 6. She alleged Mednology breached its duty to disclose and warn of modifications to the Sleepternity foam under Transylvania's product liability statute. R. at 6. Ortega also purported an action under the False Claims Act (FCA). R. at 6. Because the United States declined to participate in Ortega's FCA action against Mednology, she depends on the Act's *qui tam* provision to sustain her claim. R. at 6.

Ortega believes—based on Phillips recalling a product with PE-PUR foam—that the FDA would not have approved Sleepternity with the PE-PUR foam. R. at 6. The record does not indicate whether the FDA *ordered* the recall or whether the company made a *voluntary* recall as permitted under 21 C.F.R § 7.40(b). R. at 6–7. Upon receiving the summons, Mednology voluntarily recalled Sleepternity. R. at 7. Accordingly, the FDA ceased all inquiries of Mednology to pursue investigations of defective products on the market. R. at 7.

While the Transylvania legislature encourages consumers to bring valid claims under its product liability statute, it also understands the importance of shielding manufacturers from liability when the FDA already approved a device. R. at 7–8. Thus, medical device manufacturers, such as Mednology, are immune from liability under Transylvania law. R. at 8. 21 TRANS. COMP. STAT. § 630.546(a). Ortega attempts to nullify Mednology's immunity under statutory exceptions. R. at 8–9. But because the federal Food, Drug, and Cosmetic Act (FDCA) preempts such statutory exceptions, and because an individual cannot rely on a fraud-on-the-FDA theory to support a claim under the FCA, Mednology filed a motion to dismiss all claims. R. at 9.

The Seventeenth Circuit. Because Ortega does not have a valid theory on which to rest her FCA claim, the district court partially granted Mednology's motion to dismiss; however, it denied dismissal of her state law claims. R. at 2–3. The Court of Appeals for the Seventeenth Circuit held that the FDCA preempts the statutory exceptions to the Transylvania product liability statute. R. at 26. The appellate court affirmed the district court's decision, however, because the trial court did not consider

whether federal law preempted the compliance provision of Transylvania's immunity statute. R. at 35. Notably, a dissenting judge held the FDCA preempts the compliance component as well. R. at 38. The appellate court subsequently reversed the trial court's decision to grant Mednology's motion to dismiss Ortega's FCA claim. R. at 38. The appellate decision is on petition for review so that this Court may decide the underlying legal issues that will properly determine the outcome of Mednology's motion to dismiss. R. at 2–3.

SUMMARY OF THE ARGUMENT

Preemption of State Law. Preemption stems from the fundamental constitutional doctrine that federal law is the supreme law of the land. While courts begin their preemption analysis with the presumption that preemption does not apply, parties may rebut this presumption when the state law attempts to regulate an area that is inherently federal in nature. The FDA's ability to regulate and oversee the medical device approval process stems from its status as a federal agency and from Congress granting it such power. Ortega will likely claim Transylvania's statute attempts to regulate an area within its police powers. But the state's police powers are not unlimited and cannot intervene in an area Congress specifically delegated to the FDA.

Additionally, Transylvania's immunity exceptions cannot take effect because the FDA has not raised any allegations of fraud, withholding required information, or noncompliance against Mednology. While a narrow gap exists for state law to escape preemption, this gap only applies when the FDA *itself* finds that a manufacturer violated a required provision. Here, it has not. The FDA must raise such concerns

because otherwise courts would be able to set a new standard for FDA compliance based on private parties' allegations. Not only would this push the courts into taking on a role outside its delegated powers, but it would also introduce the possibility of fifty different versions of a single federal standard. Ortega will likely purport that preempting Transylvania's statute will leave similarly situated, future plaintiffs without a remedy. But such plaintiffs could still pursue their state claims if the FDA finds that the manufacturer has violated a required provision. Here, the FDA has not.

Fraud-on-the-FDA Theory. The False Claims Act exists to reimburse the government when it has suffered financially because of a misleading claim. Four things are required: falsity, knowledge, materiality, and causation resulting in the government forfeiting money due. To support an FCA claim, the relator must establish that the defendant knew that they provided a false statement that is material to the government's decision to approve the false claim for reimbursement. Ortega's mere conjecture that Mednology *could have* knowingly deceived the government fails to meet this standard. Equally vital is the materiality element—it is not the intent of the legislature for the Act to cover instances of noncompliance that do not influence the government's payment decisions. When a relator fails to raise a factual dispute over whether the government would have continued to reimburse claims for the defendant's product if it had known of the misrepresentation—like in the present case—the materiality element presents a legal ground for dismissal. The final hurdle FCA claimants must overcome is establishing the requisite causation between the

defendant's misrepresentation and the government's financial loss. She has not made this connection. For these reasons, Ortega fails to meet her evidentiary burden—thus her claim is both untenable and subject to dismissal.

STANDARD OF REVIEW

The legal standard for determining whether federal law preempts a statutory exception to a state immunity statute is a question of law reviewed de novo. *Nickels v. Grand Trunk W. R.R. Inc.*, 560 F.3d 426, 429 (6th Cir. 2009) (citing *Nye v. CSX Transp., Inc.*, 437 F.3d 556, 560 (6th Cir. 2006)).

Similarly, the legal standard for determining whether a relator may bring a claim under the False Claims Act is reviewed de novo. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 898 (9th Cir. 2017) (citing *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1169 (9th Cir. 2006)) (dismissing claims when the relator's purported theory does not support a cause of action under the False Claims Act).

ARGUMENT

I. The presumption against preemption does not apply because regulating devices under the FDCA is inherently federal in nature.

Article VI of the United States Constitution, otherwise known as the Supremacy Clause, establishes the fundamental principle that federal law is "the supreme Law of the Land . . . " U.S. CONST. art. VI, cl. 2. The Supremacy Clause lays the foundation for federal preemption—the legal doctrine that federal law supersedes conflicting state law. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 477 (2018); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). Federal preemption exists to invoke "a rule of decision" when state law clashes with or impedes a federal law. *Armstrong v. Exceptional Child Ctr.*, 575 U.S. 320, 324 (2015).

While preemption acts as a guide when deciding between state and federal law, it is not an unlimited grant of power to Congress. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484–85 (1996). A court begins its analysis with the presumption that federal law will not preempt state law "unless that was the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (illustrating the presumption against preemption) (internal quotations omitted). Therefore, a party can overcome the presumption by demonstrating that Congress intended federal law to supersede state law. *Id.* Congress possesses such intent when it regulates an area that is inherently federal in nature. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48 (2001).

This Court has recognized two forms of preemption: express and implied. *Gade*, 505 U.S. at 98 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Express preemption occurs when Congress includes clear and unambiguous statutory language stating its intent for the federal statute to supersede state law. *Id.* Implied preemption, however, occurs when a federal statute invokes Congress's authority "in its structure and purpose." *Id.* (internal quotations omitted). Conflict preemption, a type of implied preemption, occurs when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (internal quotations omitted). Accordingly, the presumption against preemption does *not* apply when state laws attempt to regulate areas they have not "traditionally occupied"—such as medical device approval and regulation at the federal level—because doing so prevents Congress from granting full effect to the laws it writes. *See Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230).

For example, in *Buckman*, a group of patients injured from orthopedic bone screws sued the company that helped the medical device manufacturer obtain FDA approval. *Id.* at 343. The FDA conducted its approval in accordance with the Medical Device Amendments of 1976 within the FDCA. *Id.* at 344. The plaintiffs claimed the company made fraudulent representations to the FDA while obtaining market approval for the screws. *Id.* at 343.

This Court held that the presumption against preemption did not apply to those circumstances because policing fraud against the FDA is not "a field [in] which

the States have traditionally occupied . . . " *Id.* at 347. Additionally, it explained that the relationship between the FDA and the entities "it regulates is inherently federal in character because the relationship *originates from, is governed by, and terminates according to federal law*." *Id.* (emphasis added). As a result, this Court held the FDCA preempted the state fraud statute because the fundamental nature of the FDA demonstrated Congress's intent to have the federal government police fraud in the medical device approval process. *Id.* at 347–48.

Like the company in *Buckman*, Mednology obtained FDA approval for Sleepternity. R. at 3–4. The FDA—as opposed to Transylvania—controlled the approval process from start to finish. R. at 3–4. *See* 21 U.S.C. § 360k(a) (emphasizing that states may not impose additional or different approval requirements for medical devices than what the federal government deems necessary). Thus, the relationship between Mednology and the FDA originates from the power Congress specifically granted to the federal government. *Id.* While Ortega will likely argue that Transylvania's police powers give it the ability to circumvent federal law, she ignores the fact that Mednology obtained the approval on which she rests her products liability claim in a fully federal process. R. at 3–4. Moreover, the relationship between Mednology and the FDA would not exist but for Congress's deliberate decision to delegate approval authority to the federal government. *See* 21 U.S.C. § 360k(a).

A. Ortega cannot rely on subsection (b) of the Transylvania immunity statute because the FDA has not asserted any fraud claims against Mednology.

The federal government is the sole entity that may pursue violations of the FDCA. *See Buckman*, 531 U.S. at 349 n.4 (quoting 21 U.S.C. § 337(a)) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Private litigants do not possess such authority. *See id.* Given Ortega's inability to enforce federal regulations and the intrinsic federal relationship between Mednology and the FDA, the Sixth Circuit's decision in *Garcia* should control how this Court interprets the preemptive status of the FDCA on subsection (b) of Transylvania's immunity statute. *See* 385 F.3d 961, 966 (6th Cir. 2004).

For instance, in *Garcia*, a plaintiff brought a products liability action against a drug manufacturer that subsequently sought immunity under a Michigan statute. *Id.* at 963–64. The plaintiff argued the immunity statute was unconstitutional because it required her to assert fraud against the FDA—an act she could not perform as a private litigant under the FDCA. *Id.* at 965. The court held the statute was only unconstitutional in *some* settings, such as "when a plaintiff asks a state court to find . . . fraud on the FDA." *Id.* at 966. The court explained that states may include federal provisions into their immunity laws, but plaintiffs cannot pursue such avenues unless "*the federal agency itself* determines that fraud marred the regulatory-approval process." *Id.* (emphasis added). Thus, when a plaintiff relies on their own independent

findings of fraud—and asks the state to validate such findings through judicial action—their attempt to invoke an immunity exception cannot move forward. *See id.*

In *Garcia*, the plaintiff did not provide any evidence of federal findings of fraud. *Id.* Instead, she relied on her own allegations. *Id.* Because the FDA neither asserted nor offered proof of fraud, the court concluded that the plaintiff's attempt to bypass the FDCA with private fraud allegations did not fit within the narrow gap to avoid preemption. *See id.*

Like the plaintiff in *Garcia*, Ortega has not provided any evidence of federal findings of fraud. R. at 6–7. Instead, she relies on her own personal assumptions, theories from her brother, and conclusions about Philips's decision to recall its product as proof of fraud against the FDA. R. at 5–6. Moreover, it is inappropriate for Ortega to compare Mednology to Philips when there is no indication in the record of whether Philips voluntarily recalled its product or whether the FDA required it to do so. R. at 6–7.

Ortega believes the FDA would not have approved Sleepternity based on the Philips recall. R. at 6. But responsible companies may *voluntarily* recall products when there is a potential risk to public safety. *See* 21 C.F.R. § 7.40(a)–(b). The FDA does not need to initiate the recall. *Id.* at § 7.40(b). Thus, Ortega's decision to compare the two companies—when she lacks knowledge about who initiated the Philips recall—is not only speculative but also conclusory. R. at 6–7. Even if the FDA had initiated the Philips recall, it would not equate to the FDA finding fraud *in Mednology's case*. R. at 6–7. Additionally, her comparison only further demonstrates that she lacks

any federal findings of fraud on which to rest her claims. R. at 6–7. In bringing her state claims, and thus advocating for a court to apply the immunity exception against Mednology, she asks a court to validate allegations that only the federal agency has the authority to raise. *See* 21 U.S.C. § 337(a).

Ortega may argue that she is simply trying to pursue her state law claims and has no interest in regulating fraud against the FDA. R. at 11. But she cannot enforce subsection (b), and thus pursue her state claims, without at least *attempting* to establish that Mednology defrauded the FDA for approval. *See* 21 TRANS. COMP. STAT. § 630.546(b) ("immunity . . . does not apply if the defendant . . . *intentionally withholds from or misrepresents* to the [FDA] information concerning the . . . medical device that [must] be submitted under the federal Food, Drug, and Cosmetic Act.") (emphasis added); *Garcia*, 385 F.3d at 966 (6th Cir. 2004). And because Ortega cannot rely on the FDA's findings of fraud against Mednology—because none exist—she relies on her own. R. at 8. Thus, the FDCA preempts the immunity exception under subsection (b). *See Garcia*, 385 F.3d at 966.

B. Federal law preempts Transylvania's failure to warn exception when a private party alleges violations of the FDA's disclosure requirements.

The FDCA empowers the federal government to oversee all disclosures as required throughout the approval process. *See Marsh v. Genentech, Inc.*, 693 F.3d 546, 550–51 (6th Cir. 2012) (citing *Buckman*, 531 U.S. at 348–50). Thus, when a court

entertains failure to disclose allegations from a private party, it encroaches on a federal responsibility by purporting a new disclosure standard. *See id.*

For instance, in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, the Fifth Circuit considered whether a federal law preempted a Texas statute requiring a plaintiff to assert a violation of federal disclosure requirements when bringing their failure to warn claim. 672 F.3d 372, 373–74 (5th Cir. 2012). The statute required plaintiffs to prove that the manufacturers withheld required information from the FDA when obtaining FDA approval for their product. *Id.* But only the FDA can allege a violation of federal disclosure requirements. *Id.* at 379. Thus, the court adopted the Sixth Circuit's holding in *Garcia* to guide its analysis. *See id.* at 380 (explaining that *Garcia's* fraud-on-the-FDA preemption theory is analogous to the circumstances in *Lofton* and allows the FDA to better maintain its inherent regulation abilities); *see also Garcia*, 385 F.3d at 966–67.

The court ultimately held that federal law preempted the Texas statute. *Lofton*, 672 F.3d at 381. It explained that letting courts impose liability on drug manufacturers through state statutes—in situations where the FDA has not alleged a manufacturer violated any federal disclosure requirements—would "intrude on the competency of the FDA and its relationship with regulated entities." *Id.* at 380. Essentially, the FDA would be competing with the states to determine what constitutes a required disclosure. *See id.*

Like the plaintiff in *Lofton*, under subsection (c) of the Transylvania immunity statute, Ortega would have to establish that Mednology did not comply with FDA

disclosure requirements when obtaining approval for Sleepternity. *See* 21 TRANS. COMP. STAT. § 630.546(c). But under *Lofton* and *Garcia*, Ortega cannot bring such allegations because doing so would disrupt the approval process that Congress empowered the federal government to oversee. *See Lofton*, 672 F.3d at 380; *Garcia*, 385 F.3d at 966–67; 21 U.S.C. § 360k(a). When a trial court validates a private party's allegations against a manufacturer, it sets a new standard for what is sufficient for disclosures in its jurisdiction. *See Lofton*, 672 F.3d at 380. And such a standard could ultimately contradict or add to what the FDA requires and lead to uncertainty among manufacturers. *See id.* Therefore, limiting allegations of nondisclosure only to those by the FDA limits confusion and maintains the efficiency of the approval process. *See id.* Because Ortega lacks any federal findings of disclosure violations on which to rest her failure to warn claim, the FDCA preempts the immunity exception under subsection (c). *See id.* at 381.

C. Ortega's noncompliance allegations invoke the same preemption barriers as Transylvania's immunity exceptions.

This Court has long adhered to the principle that the three branches of government work together to carry out their independent functions. *Touby v. United States*, 500 U.S. 160, 167–68 (1991) (citing *Mistretta v. United States*, 488 U.S. 361, 380 (1989)). In doing so, it furthers the "basic principle of our constitutional scheme that one branch of the Government may not intrude upon the central prerogatives of another." *Loving v. United States*, 517 U.S. 748, 757 (1996) (citing *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 225–26 (1995)). Such interbranch meddling

contradicts longstanding constitutional history that allows our government to function and best serve its people. *See id.*

1. Allowing courts to determine the adequacy of a manufacturer's compliance with FDA provisions imposes on the agency's power to set approval standards.

Congress empowered the FDA to dictate the necessary approval standards for medical devices. *See* 21 U.S.C. § 360k(a). Given this grant of power, the FDA has the strongest expertise over what actions constitute compliance with its own provisions. *See Marsh*, 693 F.3d at 553–54. Allowing a court to apply state law and set a new precedent for what qualifies as compliance with federal provisions strips the FDA of its exclusive power. *See* 21 U.S.C. § 360k(a).

For example, in *Marsh*, the Sixth Circuit examined the compliance portion of Michigan's immunity statute. 693 F.3d at 549, 552. Its language mirrors Transylvania's compliance provision and grants manufacturers immunity if "the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller." *Id.* at 549; *see* 21 TRANS. COMP. STAT. § 630.546(a). The court held that the FDCA preempted the Michigan compliance provision because the plaintiff's noncompliance allegations were "premised on violation of federal law, implicate[d] the relationship between a federal agency and the entity it regulate[d], and ask[ed] the court to assume a role usually held by the FDA." *Marsh*, 693 F.3d at 555. The court explained that allowing such behavior would lead to the same separation of powers concerns this Court warned of in *Buckman*. *Id.* at 553

(citing *Garcia*, 385 F.3d at 966) (letting courts create new standards for FDA requirements through judicial action would cause confusion among regulated entities); *see also Buckman*, 531 U.S. at 347.

Like the plaintiff in *Marsh*, Ortega's noncompliance allegations invoke reliance on FDA requirements, discuss interactions between a federal agency and the entities it regulates, and threaten inter-branch meddling through judicial action. *See* 693 F.3d at 553. Allowing courts to set new federal standards will not only lead to widespread confusion among manufacturers but will also lead to extensive litigation in each state because of competing standards. *See id.* Additionally, Ortega offers allegations of fraud as allegations of noncompliance in her complaint. R. at 6, 33. The factual reasoning behind her fraud allegations also backs her noncompliance allegations. R. at 6, 33. Thus, the allegations in her complaint are the same "species of fraud" that the FDCA preempts. *Marsh*, 693 F.3d at 553; *see Buckman*, 531 U.S. at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."). R. at 6, 33.

2. Defendants are not completely shielded from liability because the FDA has avenues to punish fraud and enforce adherence to its policies.

The court of appeals suggests *Marsh* cannot control this Court's decision because then plaintiffs like Ortega would not have relief against manufacturers who allegedly violate FDA requirements. R. at 34–35. But this assertion ignores the principle that plaintiffs like Ortega could pursue their tort claims if the *FDA itself* finds

evidence of fraud or noncompliance. *Garcia*, 385 F.3d at 966; *see Buckman*, 531 U.S. at 354 (Stevens, J., concurring) (distinguishing claims rooted in speculation from those in which the FDA explicitly found fraud). Moreover, the FDA has several ways to "detect[ ], deter[ ], and punish[ ]" fraud and noncompliance throughout its approval processes. *Buckman*, 531 U.S. at 349. The FDA may investigate suspected fraud, seek injunctions and civil penalties, and seize devices. *Id.* (listing various remedies in the United States Code). The FDA can also order recalls. 21 C.F.R. § 7.40(a)–(c) ("Recall is generally more appropriate and affords better protection for consumers than seizure, when [products] have been widely distributed."). The numerous enforcement options available to the FDA demonstrate that defendants will not automatically escape liability for fraud or noncompliance. *Buckman*, 531 U.S. at 349. If the FDA suspects a violation, it can pursue it. *Id.* And consequently, plaintiffs can still pursue their claims—and impose further liability—if they can link the claim to a federal finding. *See id.* at 354 (Stevens, J., concurring); *Garcia*, 385 F.3d at 966. Ortega cannot. R. at 8.

II. The fraud-on-the-FDA theory is not a viable basis for an FCA claim against Mednology because Ortega fails to establish its requisite elements.

The False Claims Act of the United States Code imposes general liability on persons or entities who (a) "knowingly present[ ], or cause[ ] to be presented, a false or fraudulent claim for payment or approval," or (b) "knowingly make[ ], use[ ], or cause[ ] to be made or used, a false record or statement material to a false or

fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). The recognized purpose behind the FCA is to effect reimbursement for financial loss to the government as a result of a finding of fraud. *See United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) ("[The FCA is] intended to reach all types of fraud, without qualification, that might result in financial loss to the Government."). Because the FCA protects the government from financial loss, misleading statements or misrepresentations *without* that effect are not covered under the FCA. *See id.* To bring a proper FCA claim, a relator has the burden of proving four elements: (1) falsity, (2) knowledge, (3) materiality, and (4) causation resulting in the government to pay out or forfeit money due. *See* 31 U.S.C. § 3729; *Cantrell v. N.Y. Univ.*, 326 F. Supp. 2d 468, 471 (N.Y. Dist. 2004). Ortega has failed to meet this burden. R. at 22–24.

A. Ortega has failed to show that Mednology knowingly or intentionally failed to disclose its use of PE-PUR foams to the FDA.

Ortega appears to buttress her claim on a theory of implied false certification. R. at 36. According to this Court in *United States Health Services v. United States ex rel. Escobar*, the implied false certification theory can only be a basis for liability under the FCA when the defendant who submits the claim "makes specific representations about the goods or services provided, but fails to disclose noncompliance with *material* statutory, regulatory, or contractual requirements that make those representations misleading with respect to those goods or services." 579 U.S. 176, 177 (2015) (emphasis added). *Escobar* created the rule under which the implied false certification theory can be a basis for liability:

> [We] hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: First, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements to make those misrepresentations misleading half-truths.

Id. at 190. Notably, the element of materiality is crucial. *See id.* It is also demanding. *Id.*; *see Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008). Expressly referenced in the FCA and inherent in the materiality element is the "scienter" or knowledge requirement—the plaintiff must prove that "the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Allison*, 553 U.S. at 665. Failure to show the intent to defraud results in an unfounded and baseless claim. *See id.* ("Contrary to the decision of the Court of Appeals below, we hold that it is insufficient for a plaintiff asserting a § 3729 claim to show merely that '[t]he false statement's use . . . result[ed] in obtaining or getting payment or approval of the claim . . . '"). Mere conjecture of knowledge and intent cannot meet the clear and convincing standard. *See Horn & Assocs. v. United States*, 123 Fed. Cl. 728, 755 (2015).

Countless plaintiffs have sought and failed to base FCA claims on misrepresentation without scienter. *See, e.g.*, *id.*; *Ulysses, Inc. v. United States*, 117 Fed. Cl. 772, 781 (2014). For instance, in *Horn*, the government's FCA claim failed because it could not establish that a contractor intended to deceive the government by allegedly overstating incurred costs in a breach of contract lawsuit. 123 Fed. Cl. at 750. The Federal Claims Court held that, instead of proving the scienter requirement, the

government wove up a story like a "patch on a suit of clothes"—"it may be made out of the same cloth . . . but it is not the original garment." *Id.* at 755. Mere conjecture that the contractor *could have* knowingly deceived the government in overstating breach of contract costs did not meet the clear and convincing standard required for an FCA claim. *Id.*

In *Ulysses*, another FCA claim failed where the government fell short of showing that the defendant knowledgeably deceived the government by misrepresenting its ability to manufacture a product according to the terms of their contract. 117 Fed. Cl. at 781. The government's interpretation of the plaintiff's conduct was merely "an overreaction unsupported by legal authority." *Id.* at 780. The lack of evidentiary basis pertaining to knowledge rendered the government's FCA claim baseless. *See id.*

In the present case, Ortega had the burden of establishing that Mednology knowingly defrauded the government to even qualify for bringing an FCA suit. *See* U.S.C. § 3729(a)(1)(A)–(B). However, like the plaintiffs in *Horn* and *Ulysses*, the only evidence that Ortega has shown is mere conjecture, which is not enough to meet her burden. R. at 6. She has presented no other evidence beyond a suspicion that Mednology *might* have waited to substitute its silicone-based foams with PE-PUR foams to induce FDA approval prior to switching to a cheaper supply product. R. at 6. She has only relied on her own claims. R. at 6. In order to prove the plausibility of her claim, she would need to contribute enough direct or circumstantial evidence to show that Mednology *knowingly and intentionally* waited to substitute the silicone-based foams with PE-PUR foams so that the FDA would approve the device; furthermore,

she would need to show that the failure to report this substitution was based on the defendant's knowledgeable misrepresentation. *See* U.S.C. § 3729(a)(1)(A)–(B). Because Ortega has failed to plead any plausible evidence supporting the scienter requirement, she has no viable FCA claim. *See id.*

B. The FDA's inaction and the government's continued coverage for Sleepternity indicates a lack of materiality.

1. An FCA claimant must provide factual evidence showing that the defendant's alleged materiality was relevant to the government's disbursement decision.

Equally important to the scienter requirement is the materiality element of an FCA claim. *See* 31 U.S.C. § 3729(a)(1)(A)–(B). It is not within legislative intent for the FCA to encompass instances of noncompliance that do not influence the government's payment decisions. *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). Likewise, the FCA "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." *Id.* Courts have consistently held that "[a] false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the [FCA] unless payment is conditioned on that certification." *United States ex rel. Seiwick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *see Mikes*, 274 F.3d 687 at 696. The materiality requirement is designed to ensure that the FCA does not become "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481,

489 (3d Cir. 2017) (quoting *Escobar*, 579 U.S. at 178). Therefore, the plaintiff raising the FCA claim must show convincing evidence that the defendant's misrepresentation was material to the government's decision to approve or fund the *object* of the lawsuit. *See id.*

In tort law, a matter is material in only two circumstances: (1) if "a reasonable man would attach importance to [it] in determining his choice of action in the transaction" or (2) if "the maker of the representation knows or has reason to know that its recipient regards or is likely to regard the matter as important in determining his choice of action, although a reasonable man would not so regard it." RESTATEMENT (SECOND) OF TORTS § 538 (Am. L. Inst. 1977). Nondisclosure alone is not enough to be actionable—the defendant must generally know or believe the nondisclosure is materially misleading due to his "failure to state additional or qualifying matter." *Escobar*, 579 U.S. at 188.

In 2016, this Court issued a decision regarding materiality under the FCA in *Escobar*. *See id.* at 178–88. According to the opinion, the primary consideration involving liability under the FCA is "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 181. Conversely, FCA claims involving misrepresentations that are not material to reimbursement decisions are not actionable. *Id.*

Escobar characterized an undisclosed fact as material if "[n]o one can say with reason that the plaintiff would have signed [the] contract if informed of the likelihood [of the undisclosed fact]." *Id.* at 178 (quoting *Junius Constr. Co. v. Cohen*, 178 N.E.

672, 674 (N.Y. 1931). Notably, the materiality requirement is stringent. *See id.* A contractual requirement, even if it is labeled a condition of payment, is not automatically considered material. *Id.* at 191. While materiality can be found in undisclosed facts that are not labeled conditions of payment, it does not exist when noncompliance is minor. *Id.* at 178. In contrast, if the government fully pays a specific claim "despite its actual knowledge that certain requirements were violated," the court has strong evidence before it that those requirements are immaterial. *Id.*

The individual facts of *Escobar* differ significantly from Ortega's case. *Id.* at 183–85. *Escobar* involved the death of a seventeen-year-old teenager after being treated by unlicensed and unqualified medical professionals who represented themselves as qualified. *Id.* at 183–84. The plaintiff brought a *qui tam* FCA claim against the counseling establishment, alleging that it defrauded the government by submitting claims for reimbursement from the Medicaid program under false pretenses that its therapists were licensed and qualified. *See id.* at 184. Specifically, the Medicaid program that funded the establishment required the facilities to have standard licensing requirements and certified clinicians in order to approve their claims. *Id.* at 185. Consequently, the defendant's knowing misrepresentation of compliance with statutory mental health facility requirements was "so central" to the purpose of providing mental health counseling that the government program would not have funded the claims if it knew that the defendant was violating the statutory provisions. *Id.* at 176.

The Ninth Circuit Court of Appeals in *Campie* held that the relator met the material fraud requirement where the defendant intentionally misbranded their drugs and substituted false data regarding the derivation of the primary active ingredient in three of their marketed drugs to induce FDA approval. 862 F.3d at 896. The Ninth Circuit concluded that the provision of nonconforming goods can be a basis for FCA liability, but such a claim must still include "an intentionally false statement of fraudulent course of conduct that [is] *material* to the government's decision to pay." *Id.* at 901 (citing *United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th Cir. 1956) and *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)) (emphasis added).

In *Petratos*, the Third Circuit Court of Appeals dismissed a similar FCA claim due to the plaintiff's failure to provide any factual evidence that the Centers for Medicare and Medicaid Services (CMS) would not have reimbursed the defendant's claims if their reporting deficiencies had been corrected. 855 F.3d at 485. *Petratos* involved a widely prescribed cancer treatment drug with side-effects that the defendant concealed and suppressed to maintain FDA approval and submit claims to Medicare. *Id.* Still, the plaintiff's allegations did not meet the high materiality standard because they lacked any factual allegations showing that CMS would not have reimbursed the claims if it had knowledge of the deficiency. *Id.* at 490.

The Third Circuit went on to interpret the *Escobar* decision as "militat[ing] against a finding of materiality." *Id.* Even the assertion that the misrepresentation was a condition of payment was not enough to establish materiality. *Id.* If the plaintiff

had succeeded in showing that CMS routinely refused to pay claims similar to theirs if it had the knowledge of the falsity, they might have had a plausible basis for the materiality element of their claim. *Id.* With no such showing present, however, the court correctly dismissed the case. *Id.*

2. Under *D'Agostino*, an FCA claim that does not raise a factual issue regarding materiality presents a legal ground for dismissal.

In 2016, the Ninth Circuit and the First Circuit Courts of Appeals encountered a split involving whether the issue of materiality presents a matter of proof or a legal ground for dismissal. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 4 (1st Cir. 2016); *Campie*, 862 F.3d at 896. The First Circuit in *D'Agostino* dismissed a relator's FCA claim when the relator failed to include a factual recitation as to the materiality element of his claim. *D'Agostino*, 845 F.3d at 12 ("[T]he lesser included factual recitation in the third amended complaint fails . . . . [w]e therefore have no need to consider the district court's alternative reasons for rejecting D'Agostino's claims."). The complaint did not enumerate any specific information regarding instances of noncompliance—it simply failed to demonstrate materiality "beyond possibility." *Id.*; *see generally Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (describing in general a plaintiff's burden of bringing enough facts to establish a claim that is facially plausible).

The Ninth Circuit in *Campie* considered the issue of materiality as a matter of proof when there was a factual dispute over whether the government would have continued to reimburse claims for the defendant's product if it had been aware of the misrepresentation. *See Campie*, 862 F.3d at 906. For the issue to raise a matter of

proof, the relator still needed to provide a genuine issue of material fact regarding materiality. *Id.* (quoting *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017) ("[The Plaintiff] has failed to establish a genuine issue of material fact regarding . . . materiality")). However, the crucial difference between the two cases is that in *Campie*, the relator presented enough evidence to create a genuine factual dispute over the materiality of the misrepresentation, whereas in *D'Agostino*, the relator did not. *See id.*; *D'Agostino*, 845 F.3d at 12 ("This case presents no need to decide whether such a theory is tenable. The proposed complaint simply does not allege facts making it plausible that all Axium devices—or even most—were defective.").

In an even more recent case, the Fifth Circuit Court of Appeals addressed the plaintiff's burden of providing probative evidence to create an issue involving materiality. *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019). In *Lemon*, the Fifth Circuit considered an express violation of a condition of payment as probative evidence of materiality, even if it was not conclusive. *Id.* In contrast, without the condition of payment acting as probative evidence of materiality, the relator would likely lack a viable FCA claim. *Id.*

In the present case, Ortega appears to rely on the Ninth Circuit's decision in *Campie* to allege that Mednology's fraud was material: "[M]ateriality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Campie*, 862 F.3d at 906. Ortega alleges that because Philips had previously recalled its CPAP

machine due to health risks associated with the PE-PUR foam, Mednology must have known that the FDA would have never approved its use of PE-PUR foam if it was aware of the substitution. R. at 6. However, one single instance of PE-PUR foam recall—especially when the record is silent as to whether Philips's recall was voluntary or at the FDA's request—is not enough to draw such an inference or show a pattern of consistent refusal due to noncompliance. *See Campie*, 862 F.3d at 906. This allegation also fails to consider other factors that might have affected Philips's decision to recall the device based on its association with PE-PUR foams: What were the foams specifically used for? Was PE-PUR being mixed with other chemicals leading to uncontemplated hazards? Was the FDA involved with this decision? The answers to these questions remain absent from the record.

Meanwhile, there is no indication that either the FDA or CMS have made any changes to their approval or funding for Sleepternity. R. at 21. Unlike the defendant in *Lemon*, Ortega has shown no evidence that CMS expressly conditioned its reimbursements to Mednology on the use of the original silicone-based foam. *See Lemon*, 924 F.3d at 161. There is no other probative evidence of materiality to survive a dismissal. *See id.* Moreover, the FDA's inaction in recalling its approval for Sleepternity, paired with CMS's decision to continue funding Mednology's claims, creates strong evidence that the alleged noncompliance with the FDA's requirements was immaterial to the FDA's decision to approve the device. *See Escobar*, 579 U.S. at 178.

Because the facts of *D'Agostino* closely align with the present case, and because Ortega has failed to provide any probative evidence to the issue of materiality, this

Court should follow the First Circuit's reasoning and dismiss her FCA claims for failing to establish the requisite element of materiality. *See* 845 F.3d at 12. To survive the motion to dismiss, Ortega would need to plausibly establish that Mednology's misrepresentation was material to the FDA's decision to approve the medical device. *See id.*; *Ashcroft v. Iqbal*, 556 U.S. 665, 677 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."). However, the evidence tends to negate Ortega's complaints—the FDA has not withdrawn its approval of Sleepternity, and CMS continues to reimburse claims. R. at 21. The only "evidence" she has alleged towards the materiality of the misrepresentation is the uncorroborated accusation from her own brother. R. at 5. Because Ortega has failed to provide any plausible claim towards the materiality element, there are legal grounds for dismissing her FCA claims. *See Ashcroft*, 556 U.S. at 677–84.

C. Ortega has otherwise failed to establish any causation.

To prevail on an FCA claim, the relator must show that the government relied on the misrepresentation in its decision to reimburse the product, and had the defendant's alleged conduct not occurred, the government would not have suffered a financial loss. *See* 31 U.S.C. § 3729(a)(1)(B) ("[The defendant must] knowingly make[ ], use[ ], or cause[ ] to be made or used, a false record or statement material to a false or fraudulent claim . . . "); *United States ex rel. Westrick v. Second Change Body Armor, Inc.*, 128 F. Supp. 3d 1, 18 (D.D.C. 2015). Courts have characterized this element of "inducement" or "reliance" as an element of causation. *See United States ex rel.*

Thomas v. Siemens AG, 991 F. Supp. 2d 540, 569 (E.D. Penn. 2014); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943); *see also Westrick*, 128 F. Supp. 3d at 19 (associating the relator's claim with the "fraudulent inducement theory"). This requirement is rudimentary—because the purpose of the FCA is to remediate losses to the government, the plaintiff must first establish that the government suffered a financial loss from the defendant's alleged misconduct. *See Hess*, 317 U.S. at 543. In essence, the contract with the government must be procured by fraud. *Thomas*, 991 F. Supp. 2d at 571. It is not enough to simply assert that the contract was potentially based on a misleading statement. *Id.* For those reasons, a fraud-on-the-FDA theory that fails to establish the requisite chain of causation is not a viable basis for bringing such a claim. *See id.*

In *D'Agostino,* the relator claimed that the defendant fraudulently misrepresented its device and failed to honor commitments made to the FDA in the pre-approval process. 845 F.3d at 4. The failures included overstating training requirements and omitting critical safety information about the device. *Id.* The First Circuit nonetheless held that the plaintiff could not establish a causal link between the defendant's misrepresentations and the government's claims for reimbursement because the FDA did not withdraw approval for the medical device, nor did CMS discontinue reimbursements for its use. *Id.* The court emphasized that the plaintiff's claim that these fraudulent representations "could have" influenced the FDA's approval was not enough to establish the causation element of his FCA claim. *Id.* ("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.").

Even if the plaintiff's claims establish some kind of causation, they must go a step further and establish that the misrepresentation itself caused the government to make payments or forfeit money due. *See Westrick*, 128 F. Supp. 3d at 18 (holding that the relator could not establish causation because they failed to demonstrate that the government relied on certain manipulated data in their contract to reimburse body armor equipment). In *Westrick*, a relator sued on behalf of the government alleging that the defendant body armor company made misrepresentations about the degradation rate of its products by manipulating the data trend lines. *Id.* at 19. Although there was no dispute that the manufacturer made false misrepresentations with a likely purpose of making the product appear more favorable to the government, the relator failed to present any evidence that the government *relied* on the manipulated data when deciding whether to reimburse claims for the product. *Id.*

Similar to the relator in *D'Agostino*, Ortega falls short of linking a causative chain to Mednology's alleged actions or omissions. *See* 845 F.3d at 4. Instead of alleging specific facts that can be disputed, Ortega has made conclusory statements without providing a basis on which they can stand. R. at 6. Specifically, Ortega had the burden of establishing that if the FDA had known that Mednology would replace the silicone-based foams with PE-PUR foams after being granted approval for the device, it would never have given approval in the first place. R. at 21. While she does allege this, her complaint fails to substantiate this theory—making it little more than a

conspiracy. R. at 6. Meanwhile, the FDA has willingly chosen to prioritize investigating other companies and products and has still not withdrawn its approval for Sleepternity. R. at 7.

Furthermore, to recover under the FCA, Ortega needed to go a step beyond and establish that Mednology's replacement of silicone-based foams with PE-PUR foams resulted in the government suffering a financial loss. *See Westrick*, 128 F. Supp. 3d at 18. While there is no dispute that CMS provided coverage for Sleepternity prior to the events of this lawsuit, there are no facts in the record to indicate that CMS has stopped providing such coverage or planned to as a result of the foam replacement. R. at 4. Ortega's failure to provide any facts that attempt to link this chain of causation leads to an FCA claim that is both illusory and implausible. R. at 4. The trial court did not err in granting Mednology's motion to dismiss Ortega's FCA claim for her reliance on the fraud-on-the-FDA theory because it is not a viable basis for establishing the requisite causation.

CONCLUSION

The presumption against preemption does not apply to inherently federal contexts. As a federal agency, the FDA has the authority to oversee the medical device approval process and set approval standards. Thus, it maintains an intrinsically federal relationship with the entities it regulates. Additionally, Mednology is immune from liability under Transylvania's immunity statute because the FDA has not raised any fraud or failure to disclose allegations regarding Sleepternity's approval. Similarly, only the FDA may assert noncompliance with the approval process. To allow

another entity to step in and dictate new federal standards would impose on the agency's power. Such usurpation is both unconstitutional and unnecessary when the FDA has various ways to enforce adherence to its policies and hold manufacturers accountable.

To prevail on an FCA claim, the claimant must show that the alleged misrepresentation was material to the government's reimbursement decision, the defendant had knowledge of the materiality, and the misrepresentation caused the government a financial loss. A fraud-on-the-FDA theory that does not raise evidence regarding the materiality, scienter, and causation elements is not viable. Because Ortega's allegations are conclusory and do not raise a genuine factual issue regarding any of the elements, her fraud-on-the-FDA theory fails and her FCA claim is subject to dismissal. Furthermore, the FDA's failure to repudiate its approval for Sleepternity and CMS's continued coverage for the device indicates that there was no materiality or causation resulting from Mednology's alleged misrepresentation.

It is for these reasons that this Court should reverse the decision of the Seventeenth Circuit Court of Appeals.

CERTIFICATE OF SERVICE

We certify that a copy of Petitioner's brief was served upon Respondent, United States ex. rel. Riley Ortega, through the counsel of record by certified U.S. mail return receipt requested, on this, the 9th day of September, 2024.

/s/ Team #3301

Attorneys for Petitioner

APPENDIX A

Constitutional Provisions

U.S. CONST. art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, [anything] in the Constitution or Laws of any State to the Contrary notwithstanding.

APPENDIX B

Federal Statutory Provisions

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.

21 U.S.C. § 337 Proceedings in name of the United States; [. . .]

(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. [. . .]

31 U.S.C. § 3729(a) False claims

(1) In general.—Subject to paragraph 2, any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [. . .]

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

APPENDIX C

State Statutory Provisions

21 TRANS. COMP. STAT. § 630.546

(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[ ] 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 D

Regulatory Provisions

21 C.F.R. § 7.40 Recall Policy

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(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.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a

recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.