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

Team 3311

Counsel for Petitioner

QUESTIONS PRESENTED

(1) This Court and Congress have expressed concerns about state laws that place state juries in position to supplant the judgement of FDA. As such, where a state legislature accords blanket immunity to medical device manufacturers, does federal law preempt a state law that would abrogate a device manufacturer's immunity for allegedly misleading the FDA or otherwise failing to comply with FDA requirements based on a state court determination?

(2) The FDA has a variety of enforcement mechanisms to prevent and address fraud against the agency. When the FDA does not take action against a medical device manufacturer despite knowledge of the alleged fraud, is a fraud-on-the-FDA theory a viable basis for a relator to bring a False Claims Act action under the *qui tam* provision?

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The opinion of the United States Court of Appeals for the Seventh Circuit has not yet been published in the Federal Reporter but is included in the Record on Appeal. (R. at 25-42.) The ruling of the district court denying in part and granting in part petitioner's motion to dismiss is unreported but included in the Record on Appeal. (R. at 2-24.)

CONSTITUTIONAL AND STATUTORY PROVISIONS

The **Second Clause of the Sixth Article of the U.S. Constitution, known as the Supremacy Clause**, provides: "This Constitution, and the Laws 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." U.S. Const. Art. VI, cl. 2.

The **Federal Food, Drug, and Cosmetic Act** is established in title 21, chapter 9 of the United States Code. Under § 360k of the Act, States are prohibited from establishing or enforcing any requirements with respect to devices intended for human use that differ from or add to federal requirements under the FDCA. The statute applies to any requirement "which is different from, or in addition to, any requirement applicable" and "which relates to the safety or effectiveness or to any other matter in a requirement applicable to the device under this statute." 21 U.S.C. § 360k. Moreover, Section 337(a) provides, in relevant part, that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C § 337(a).

Sections 3729-3733 of the United States Code establish the **False Claims Act**, which creates liability for persons who cause the government to incur costs by submitting false claims. Section 3730 establishes a *qui tam* provision, which enables private citizens to bring actions on behalf of the government. The relevant provisions are reproduced in App.1a.

Transylvania's product liability statute, 21 TRANS. COMP. STAT. § 545-546, is reproduced at App.1a.

SUMMARY OF THE ARGUMENT

1. Federal law preempts schemes that permit state courts to substitute their judgement for the FDA or otherwise invade the "inherently federal" relationship between the FDA and a regulated party. The Transylvania statute immunizes manufacturers of FDA-approved drugs and medical devices from products liability suits where they are in compliance with FDA requirements but permits plaintiffs to abrogate that immunity by alleging the manufacturer intentionally withheld information from the FDA or otherwise failed to comply with FDA requirements. The statute empowers state courts and juries to determine whether the FDA would have withdrawn approval or would have never given approval in the first place. Because the statute empowers state courts to sit as arbiters of compliance with FDA regulation or otherwise police the relationship between the FDA and a manufacturer, is it not preempted?

2. When bringing a False Claims Act action under the *qui tam* provision, relators must satisfy all necessary elements to sufficiently plead their claim—falsity, scienter, causation, and materiality. In cases of fraud-on-the-FDA, the FDA's decision not to take enforcement action despite knowledge of the alleged fraud casts doubt on the causal nexus between the alleged misrepresentation and the ultimate payment by the government. Though agencies can identify compliance with regulations as a condition of

payment, this Court has insisted that that fact itself is not dispositive on the issue of materiality. If a relator's pleadings neither establish that the misrepresentation was integral to the payment nor that the misrepresentation, should not the Court dismiss the complaint?

STATEMENT

A. FDA APPROVAL PROCESS FOR MEDICAL DEVICES.

Important to the foregoing presented questions is an appreciation of the complexity of the FDA's role and the process of approving and regulating devices.

The application process includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008).

As a result of the increasing volume of submitted material, FDA approval and regulation of medical devices has become a herculean effort. Indeed, over the last 45 years it has only grown more complex with more complex products, requiring more complex review. Jonathan Darrow, *FDA Regulation and Approval of Medical Devices: 1976-2020*, 326 JAMA 420 (2021) ("Darrow 2021"). For devices, the time from initial submission to receipt of decision varies from 300 to 1000 days. *Id.* at 426. For pharmaceuticals under the FDA's purview, that time increases exponentially as the total time from the effective date of a new application to approval was almost 9.1 years between 2008 and 2017. *Id.* Manufacturers submit volumes of data and documentation to support their applications. *Reigel*, 552 U.S. at 318.

Sleepternity, the device at issue in this case, is a Class III medical device. (R. at 3–4.) Class III devices are subject to the most strenuous evaluation as they are deemed to pose the highest risks to patients. FOOD & DRUG ADMIN., PREMARKET APPROVAL. For a Class III device to be approved, it must first receive Section 515 Premarket Approval so that it may begin marketing. *Id.* Premarket Approval is governed by section 814. 21 C.F.R. § 814 (current through March 22, 2024). The PMA process includes mechanisms to deny or withdraw a PMA for a lack of compliance or material misstatement. *Id.* §§ 814.42(e)(1), .45(a)(1) (Denial of Approval of a PMA); *see Id.* § 814.3(i)(definition of "statement of material fact"). Sleepternity was approved for marketing by the FDA on December 30, 2022. (R. at 2-3.)[1]

All of the provisions of the premarket approval process are based on the FDA's authority under the Food, Drug, and Cosmetic Act. 21 C.F.R. § 814.3(a); 21 U.S.C. § 321-392. The enforcement of these provisions is thus strictly the province of the United States. 21 U.S.C. § 337(a).

A Class III medical device is subject to the Section 515 classification process, premarket submission, premarket approval, the premarket submission review process, and then post-market regulatory controls. Nathan Cheng & Debra Fromer, *Understanding the FDA Device Approval Process in FPRMS*, 16 Current Bladder Dysfunction Rep. 46 (2021). To complete the premarket approval (PMA) process, the manufacturer must submit "a summary of the information contained in the

[1] Presumably, the District Court is alluding to Premarket Approval as this is what the FDA commonly refers to as "approval for marketing." *See* Darrow 2021, *supra*, at 421.

application; information regarding product specifications, intended use, manufacturing methods; results of clinical and nonclinical testing and studies; proposed labeling; and samples of the device. Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD & DRUG L.J. 245, 249–250 (2004). The summary must describe: (1) how the device functions; (2) the basic scientific concepts underlying the device; (3) the significant physical and performance characteristics of the device; (4) any alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended; and (5) the foreign and U.S. marketing history of the device, including, at a minimum, a list of all of the countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. *Id.* Once the application is complete, the FDA begins a scientific and technical review of the application. *Id.* at 251-52.

In 2004, the PMA process for a medical device took 1200 hours. *Id.* Device reviews have only grown more complicated. Darrow 2021, supra, at 326.

B. LEGAL HISTORY OF FRAUD-ON-THE-FDA AND FEDERAL PREEMPTION.

In *Lohr*, the Supreme Court made clear that, though the FDCA contains an express preemption provision that bars states from imposing any requirement "in addition to" the federal regime, the FDCA does not bar state claims that parallel federal requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). The Court built on this in *Riegel*, holding that state law claims are preempted "only to the

narrow extent that they add different or extra requirements to the safety and effectiveness." *Reigel*, 552 U.S. at 316.

The FDCA requires that any and all proceedings instituted to enforce it or to restrain violations "shall be by and in the name of the United States." 21 U.S.C § 337(a). Not only is there a bar on private enforcement, but there are concerns that "allowing judges and juries to second-guess FDA decisions . . . strikes at the very heart" of the FDA's regulatory system. *Protecting Patients from Defective Medical Devices Before the S. Comm. on Health, Education, and Pensions*, 111th Cong. 27 (2009) (statement of Peter Barton Hutt, Senior Counsel, Covington & Burling). The Supreme Court's precedent has been consistently concerned with the effects of state law claims on the efficacy of the FDA in accomplishing its mission to regulate drugs and medical devices. *See Buckman Co. v. Plaintiff's Legal Comm.*¸531 U.S. 341, 347–48 (2001). The FDCA sets forth a "comprehensive scheme" of disclosure requirements as part of the approval process. *Id.* at 348. Along with these requirements, the FDCA empowers the FDA to investigate and penalize fraud in a manufacturer's disclosures or elsewhere in the approval process. *Id.* at 348-49. The *Buckman* Court observed that state fraud-on-the-FDA claims also interfere with the FDA's approval process, because the possibility that "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" could lead manufacturers to over submit information and thus burden the evaluation process. *Id.* at 351. Interpreting *Buckman*, courts have tethered these concerns less to the structure of the claim and more to the necessary procedure and activities

associated with proving the issue of misleading the FDA or failing to comply. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012).

In the wake of *Buckman*, *Reigel*, and *Lohr*, Congress has appeared to affirm the interpretation that damages actions—especially those that would seem to enforce the FDCA or police fraud—are preempted. After the Court's ruling in *Reigel*, Senator Kennedy (D-MA), the then-Chair of the Senate Health, Education, Labor, and Pensions Committee, and Rep. Frank Pallone (D-NJ) Chair of the House Energy and Commerce Committee introduced the Medical Device Safety Act of 2009, which would amend the FDCA to include a provision stating that "[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State." S. 540, 11th Cong. § 2 (2009). To date, Congress has never adopted such a provision. Instead, opposition to that provision spoke in the same voice as the court. The ranking member of the subcommittee, Senator Orrin Hatch (R-UT) expressed doubts that "randomly selected jurors have the necessary scientific and clinical knowledge to perform the same level of analysis—and review—as the analysis and review by the experts at the FDA. Yet, in essence, this legislation would supplant the findings of the FDA with those of juries in State courts." *Protecting Patients from Defective Medical Devices Before the S. Comm. on Health, Education, and Pensions*, 111th Cong. 4 (2009) (statement of Senator Orrin Hatch).

The Court and Congress's concerns about the practical realities of courts and juries invading the province of the FDA serve as the bedrock for jurisprudence on the issue of fraud-on-the-FDA suits.

C. THE HISTORY OF THE FALSE CLAIMS ACT AND FRAUD-ON-THE-FDA.

The False Claims Act (FCA), enacted in 1863, was a Congressional response to concerns that Union Army suppliers were defrauding the Government during the Civil War. U.S. DEPT. OF JUST., THE FALSE CLAIMS ACT: A PRIMER 1, 1 (2011). At the time of enactment, violators were liable for double the government's damages plus a $2,000 penalty per claim. *Id.* In 1986, the FCA was amended to increase damages from double to triple the government's incurred cost and raised penalties to range from $5,000 to $10,000. *Id.* The FCA has been amended three times since 1986 and has been interpreted by federal courts on hundreds of occasions. *Id.*

The False Claims Act attaches liability to any person who knowingly "presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "makes, uses, or causes 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). Claims are defined under the act as "any request or demand, whether under a contract or otherwise, for money or property" made to the United States Government. § 3729(b)(2)(A). Under the *qui tam* provision, an individual may pursue a FCA civil action on behalf of themselves and the United States Government. § 3730(b)(1). Thus, the elements of a FCA claim are: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys

due." *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006).

The 1986 amendments re-envisioned the previously restrictive *qui tam* provisions of the FCA, broadening the right of private citizens to pursue actions as a means of combating fraud against the Government. Bryan Lemons, *An Overview of 'Qui Tam' Actions*, FED. LAW ENF'T TRAINING CTR. 1, 3. Prior to this expansion, an amendment in 1943 essentially barred persons employed by the Government to pursue *qui tam* actions, by prohibiting cases brought based on information possessed by the United States or any of its employees. *Id.* The legislative history of these 1986 amendments, as interpreted by the Judiciary Committee, reveals its intent to "allow and encourage assistance from the private citizenry" which can "make a significant impact on bolstering the Government's fraud enforcement effort." S. REP. NO. 99-345, at 8 (1986).

Courts have recognized several theories of recovery available for relators under the False Claims Act, including the fraud-on-the-Agency theory which animates the present controversy before the Court.

D. THE TRANSYLVANIA IMMUNITY-EXCEPTION SCHEME.

The Transylvania legislature codified its common law products liability cause of action in Section 630.545, establishing a statutory duty of care and good faith for the manufacture and distribution of products. 21 TRANS. COMP. STAT. § 630.545 (2024). The goal of this statute was to encourage manufacturers to prioritize the health and safety of consumers and encourage consumers injured by a failure to

exercise care, caution, or good faith to bring suits against those manufacturers. *Id.* § 630.544. The Legislature created a carve-out conferring general immunity on manufacturers of FDA-approved drugs and medical devices. *See Id.* § 630.546(a). This carve-out included two exceptions that would abrogate the general immunity conferred on manufacturers. First, if the defendant, prior to the injury, intentionally withheld information or misrepresented information to the FDA and the FDA would have withdrawn approval or otherwise never granted approval had it had the information. *Id.* § 630.546(b). Second, if the defendant failed to warn about the dangers or risks of the drug or medical device as required by the FDA. *Id.* § 630.546(c). Additionally, the statute is interpreted to abrogate the immunity under section (a) where the plaintiff alleges the device was not in compliance with the FDA's approval at the time it left control of the manufacturer. *Id.* § 630.546(a).

E. THIS CASE PRESENTS SEVERAL CIRCUIT SPLITS FOR THE COURT TO RESOLVE.

The controversy brought before the Court grants occasion to consider and resolve a number of circuit splits as discussed below.

1. *Circuits differ on immunity-exception schemes implicating Fraud-on-the-FDA.*

The first circuit split implicated by this case is between the Sixth and Second analyzing a Michigan statute that is practically identical to subsection (b) of the Transylvania statute. *Compare Garcia v. Wyeth-Ayerst Lab'ies*, 385 F.3d 961 (6th Cir. 2004)("*Garcia II*"), *with Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

The Sixth Circuit observed the "difference" between a general immunity with a specific exception and the state fraud-on-the-FDA claim contemplated by *Buckman* "is immaterial." *Garcia II*, 385 F.3d at 965–66. There, the court noted, agreeing with the district court, that "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (internal citations omitted).

As the district court analyzed in *Garcia*, though the products liability theory relied on in Michigan consisted of different constituent elements, such as demonstrating that the product was unreasonably dangerous at the time it was released, to get to that issue the plaintiff must first prove that the defendant defrauded or misled the FDA. *Garcia v. Wyeth-Ayerst Lab'ies*, 265 F.Supp 2d 825, 831 (E.D. Mich. 2003), *aff'd*, 385 F.3d 961 (6th Cir. 2004)("*Garcia I*"). Notably, the Garcia Court did not wholly reject the scheme, but instead found that the only permissible construction of such a statute would be where the FDA has made an affirmative finding of fraud. *Garcia II*, 385 F.3d at 967.

Conversely, the Second Circuit concluded that, because the claims at issue were premised on traditional tort liability not duties to the FDA, they are subject to the presumption against preemption, and, ultimately not preempted. *Desiano*, 467 F.3d at 94–95. This approach was also embraced by the district court below (R. at 14). In the Second Circuit's opinion, *Lohr*'s view of state common-law tort should control

the question of preemption on these claims. *Desiano*, 467 F.3d at 95.[2] The Second Circuit's approach attempts to distinguish between a Fraud-on-the-FDA claim and an item of rebuttal to an affirmative defense on the basis that proof of fraud against the FDA in the former is alone sufficient to confer liability. *Desiano*, 467 F.3d at 95.

In evaluating this circuit split, the Fifth Circuit followed *Garcia* over *Desiano*, concluding that the FDA must find fraud for such an immunity exception to survive preemption. *Lofton*, 672 F.3d at 378-79. The Ninth Circuit in *Perez* seems to share the perspective of the Fifth and Sixth Circuits. *Perez v. Nidek, Co.*, 711 F.3d 1109 (9th Cir. 2013). There, evaluating a fraud by omission claim related to a failure to disclose facts to patients related to compliance with PMA approval, the court found the claim was preempted because the determination of compliance was "within the enforcement authority of the FDA, not this court." *Id.* at 1119-20.

2. Circuits also differ on state statutes that rely on a failure to comply with Agency regulations to establish liability.

Separately, the case raises a circuit split over the preemption of failure-to-warn claims.

The First, Eighth, and Eleventh Circuits, relying on *Buckman*, have concluded that claims predicated on a duty owed to the FDA are impliedly preempted. *See Bryant v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200, 1205 (8th Cir. 2010); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017); *Plourde v. Sorin*

[2] However, as this Court noted explicitly in *Buckman*, "[*Lohr*] did not squarely address the question of implied preemption." 531 U.S. at 352 (discussing *Lohr*, 518 U.S. at 481).

Grp USA, Inc., 23 F.4th 29 (1st Cir. 2022). Conversely, the Fifth found that failure to warn claims were "not preempted "to the extent" that the claim was "predicated on [defendant's] failure to report 'serious injuries' and 'malfunctions' of the device as required by applicable FDA regulations." *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011). Meanwhile, the Ninth Circuit ruled that failure to warn claims based on failure to report known risks were not impliedly preempted by the medical device amendments because it was a state law claim that existed "independent of the FDA's pre-market approval process that was at issue in Buckman." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013).

Most recently, in *Plourde* and *DiCroce*, addressing putative violations of labeling requirements under the FDCA and state failure to warn claims, the First Circuit fashioned a test where a complaint is preempted unless the conduct it pleads: (1) violates the FDCA requirements and (2) would also violate the state law in question even if the FDCA did not exist. *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023); *Plourde*, 23 F.4th at 29. There, because the claims themselves were predicated on failure to comply with FDCA labeling requirements, the First Circuit found that the claim was preempted. *DiCroce*, 82 F.4th at 41–42.[3]

[3] The Eighth and Ninth Circuits have taken similar approaches. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

3. Circuits differ on whether fraud-on-the-FDA is a viable theory on which to bring a False Claims Act action.

The question of whether the fraud-on-the-FDA is a viable basis for a relator's FCA claim has not yet been decided by this Court and is a point of disagreement among the circuits. The current split between the First and Ninth Circuits highlights the challenges the theory faces in satisfying two key FCA elements: causation and materiality.

The First Circuit, focusing on the causation element, rejected the theory because of an insufficient causal link between the alleged fraud and government payment. *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 3, 10 (1st Cir. 2016).

The Ninth Circuit, on the other hand, briefly mentioned causation but primarily relied on materiality considerations to uphold the theory, viewing it as a form of promissory fraud. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 903 (9th Cir. 2019). For the Ninth Circuit, the implied false certification approach was deemed a matter of proof rather than a matter of law. *Id.* at 907.

4. The weight of authority requires a showing of "proximate cause."

The statutory text of the False Claims Act defines "knowing," "claim," "obligation," and "material," but does not explicitly define cause. 31 U.S.C. § 3729(b). The courts have been left to battle and disagree over the definition and application of "cause" in FCA actions. Which, inevitably, led to a circuit split over the applicable theory of causation. The Third, Fifth, Seventh, Tenth and D.C. Circuits have adopted the proximate cause standard for FCA claims. *See United States v. Hibbs*, 568 F.2d

347, 349 (3d Cir. 1977) (concluding that a "causal connection must be shown between loss and fraudulent conduct and that a broad "but for" test is not in compliance with the statute"); *United States v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981) (following the decision in Hibbs, "The language of the statute clearly requires . . . the United States . . . must demonstrate the element of causation between the false statements and the loss"); *United States v. Luce*, 873 F.3d 999 (7th Cir. 2017) (overturning 25-year circuit precedent of but-for causation standard in FCA claims to adopt a proximate cause standard); *United States ex rel. Sikkenga v. Regence BlueCross BlueShield*, 472 F.3d 702, 715 n.17 (10th Cir. 2006) ("proximate causation standard strikes the proper analytical balance and comports with the rule requiring strict construction of punitive civil suits."); *Cimino v. IBM*, No. 13-cv-00907 (APM), 2019 U.S. Dist. LEXIS 168059, at * 16–17 (D.D.C. Sep. 30, 2019) ("The clear weight of authority . . . is that the element of causation for an FCA claim requires . . . proximate, cause for the loss").

F. PLAINTIFF-RELATOR FILES THE INSTANT SUIT.

Plaintiff-Relator Riley Ortega ("Orgeta" or "Plaintiff-Relator" or "Respondent") brought this suit in the Southern District of Transylvania against Mednology, Inc. ("Mednology" or "Petitioner") under Transylvania's product liability suit for alleged breaches of the duty of care and good faith. (R. at 6.) Additionally, after referring the matter to the Department of Justice under the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733 (2024), and the United States declining to intervene, Ortega brought a *qui tam* action against Mednology alleging Fraud-on-the-FDA. (*Id.*)

The suit relates to Mednology's constant positive air pressure (CPAP) machine, Sleepternity. (R. at 3.) The product was prescribed to Ortega to treat sleep apnea symptoms believed to be tied to her post-traumatic stress disorder. (R. at 3.) Sleepternity's various novel features—including noise-cancelling headphones that encourage sleep—make it an effective treatment for insomnia. (*Id.*) Following approval by the FDA, the Centers for Medicare and Medicaid Services began providing coverage for patients who were prescribed Sleepternity. (R. at 4.)

Ortega alleged that Mednology, after receiving approval by the FDA, replaced the sound-abating silicone-based foam with a polyester-based polyurethane (PE-PUR) and did not disclose the modification to the FDA. (*Id.*) PE-PUR foams can be tied to the release of volatile organic compounds (VOCs)—including isocyanates, which Ortega is allergic to. (*Id.* at 4–5.) Ortega alleged, based on conversations with her brother who is an assembly manager at Mednology, that the company only used the silicone-based foam to secure approval and then switch to PE-PUR to save manufacturing costs. (*Id.* at 5.)

In June 2021, a different manufacturer initiated a recall of its CPAP machines that contained PE-PUR foam due to concerns about the release of VOCs. (R. at 4.) Ortega relies on this recall to assert that the FDA would not have approved Sleepternity had its application been based on devices with PE-PUR foams.[4]

[4] Importantly, the FDA's process for reviewing PE-PUR foams in Philips products is, as of the time of this writing, still ongoing and the FDA has yet to draw a conclusion on the risks associated with PE-PUR foam based on testing associated with the recall. U.S. FOOD & DRUG ADMIN., FOAM TESTING SUMMARY FOR RECALLED PHILIPS VENTILATORS, BIPAP MACHINES, AND CPAP MACHINES (2024).

However, Philips' recall was not an act taken by the FDA nor a violation of FDA standards. The recall was initiated by Philips voluntarily, and after conducting several series of certified testing, Philips has concluded that "the use of the sleep therapy devices is not expected to result in appreciable harm to health in patients." *Explained: The voluntary Philips Respironics sleep and respiratory care devices recall*, PHILIPS.

The FDA requested further testing in October 2023, but has yet to broadly recall devices using PE-PUR foams. (R. at 4, n.1.) In fact, the FDA maintains its position that stopping use of the device may involve greater risk than continuing its use. *Id.*

Ortega alleges that she experienced asthma attacks and had to be transported to the emergency room as a result of the PE-PUR foam in Sleepternity. (R. at 4-5.)

Based on the foregoing allegations, Ortega claims that Mednology's immunity should be abrogated under the Transylvania statute because Mednology misled the FDA about the foams used in Sleepternity or, in the alternative, Mednology failed to warn of dangers as required by the FDA because it did not warn about the risks associated with PE-PUR foams.

G. PROCEDURAL HISTORY.

Mednology brought a motion to dismiss Ortega's claims under Federal Rule of Civil Procedural 12(b)(6) for failure to state a claim. (R. at 2). The District Court denied in part and granted in part. As the basis for its motion, Mednology asserted

that the immunity exception in the Transylvania Statute was preempted. (R. at 8.) The district court denied Mednology's motion to dismiss Ortega's state law claims, finding that Transylvania's immunity statute was not preempted by state law. (R. at 16, 18, 24). The court granted the motion to dismiss Ortega's False Claims Act action, finding the fraud-on-the-FDA theory is not a viable basis for bringing an FCA claim. (R. at 21, 24).

Mednology appealed the preemption issue, and Ortega appealed the FCA claim issue. (R. at 25). The court of appeals for the seventeenth circuit affirmed, on other grounds, the district court's denial of Mednology's motion to dismiss Ortega's state law claims brought under the Transylvania product liability statute. *Id.* Despite finding that both immunity exceptions of the Transylvania statute were preempted by federal law, the court affirmed the denial of the motion to dismiss on the grounds that the immunity statute will not protect defendants if they fail to comply with all FDA approval requirements. (R. at 32) The court held that Ortega alleged sufficient facts to plausibly rebut the presumption that Sleepternity complied with the requirements for FDA approval when it was distributed and sold to the market. (R. 33, 38). The court of appeals reversed the dismissal of Ortega's FCA claim, on the basis that Ortega alleged sufficient facts to plausibly satisfy the materiality element of her FCA claim. (R. at 37, 38).

Judge Ruzich concurred in part and dissented in part from the panel, asserting that Ortega's state law claims should not have been permitted to proceed based on

the compliance exception in subsection (a) as that section, too, should be deemed preempted. (R. at 41.)

Mednology filed a petition for writ of certiorari to the United States Court of Appeals for the Seventeenth Circuit appealing both decisions from the court below. (R. at 43).

ARGUMENT

For the following reasons, this Court should affirm the court below's ruling that subsections (b) and (c) are preempted and reverse its ruling that subsection (a) can support Ortega's suit. Moreover, this Court should reverse the court below's holding that Ortega's fraud-on-the-FDA theory properly established the elements required to bring an action under the False Claims Act.

I. IMMUNITY EXCEPTIONS BASED ON ALLEGED FRAUD OR NON-COMPLIANCE INVADE THE FOOD AND DRUG ADMINISTRATION'S PROVINCE TO POLICE VIOLATIONS OF THE FDCA.

A state law that conflicts with the laws of the United States is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). As Justice Breyer observed candidly in *Egelhoff*, the true test of federalism is "'not in the occasional constitutional effort to trim Congress' commerce power at its edges . . . but rather in those many statutory cases where courts interpret the mass of technical detail that is the ordinary diet of the law." *Egelhoff v. Egelhoff ex. rel Breiner*, 532 U.S. 141, 160 (2001) (Breyer, J., dissenting). The technical operation of the immunity exception scheme underlying this dispute vividly demonstrates the important task of the Court to delve into the minutia of statutes to comprehend their true relationship to federal power. And, where the operation of state schemes impermissibly impede federal power, it is the mandate of the Constitution that this Court designate such state laws as preempted.

As the court below aptly noted, the issue in this case is whether federal law preempts the *immunity exception* provided under subsections (b) and (c), not whether

it preempts Respondent's *state law claims* brought under Transylvania's product liability statute. (R. at 27.)

Fundamental to the inquiry of preemption is a determination of the proper structure of the inquiry. This Court and its circuits have been divided over which analytical framework should attach to the statutory scheme at issue. The conflict first begins at whether this is a scheme policing an agency's relationship with a regulated party, as in *Buckman*, 531 U.S. 341 (2001), or is it a matter of a state exercising its historic police powers over health and safety, as in *Lohr*, 518 U.S. 470 (1996), or *Wyeth v. Levine*. 555 U.S. 555 (2009).

Petitioner agrees with the Sixth Circuit that the issue at bar is about the interference with the agency's relationship in a federally regulated field—not a question of state' policing health and safety.

A. The Court should clarify the proper preemption analysis structure.

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2. This clause serves as the cornerstone on which the federal preemption doctrine is constructed. The preemption doctrine is comprised of two veins: implied and express. *Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992). In considering whether a state law is preempted, the first consideration is whether the state law in question is preempted by an express preemption provision in the relevant federal law. *Chamber of Commerce of the U.S. v. Whiting*, 131 S. Ct. 1968, 1977 (2011) (*quoting CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). In such cases, the Court has prescribed that one must examine the plain wording of the

clause which "necessarily contains the best evidence of Congress' preemptive intent." *Id.*

In the absence of express preemption, the Court must look to the implications of the statutory scheme to determine preemptive intent. Indeed, preemptive intent can be inferred if the scope of a statute indicates that Congress intended federal law to occupy the legislative field, or if there is a conflict between the state and federal law. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76-77 (2008). Moreover, preemptive intent can be inferred where a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000).

Preemption analysis must be conducted "statute by statute, line by line." *Egelhoff*, 141 U.S. at 160 (Breyer, J., dissenting). On this technical understanding, Transylvania's immunity exception functions to create a *de facto* fraud-on-the-FDA tort and is therefore, on the line-by-line, foreclosed by this Court's analysis in *Buckman*. *Id.*

B. This Court should abrogate the presumption against preemption.

Important to the consideration of whether a statute is preempted is the consideration of whether it is subject to the presumption against preemption. Indeed, part of the circuit split is concerned with the application of the presumption against preemption to this issue—as the courts below, too, were divided on. (R. 14, 27.) Petitioner contends first, that as *Garcia II, Buckman* and the circuit court below held,

the presumption does not apply, and, second, the Court should take this opportunity to sever such a presumption from implied preemption analysis altogether.

The court below began with the assumption that the historic police powers of the States are not to be superseded absent the clear and manifest intention of Congress to do so. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The presumption underlying *Rice*, though rhetorically poignant, has always been weak. Ernest A. Young, *'The Ordinary Diet of the Law': The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 307 (2011). There, the Court stepped off the presumption that state exercise of historic police powers would be valid, only to find any state regulation on a subject regulated by a federal to be preempted, even on a relatively feeble showing of Congressional intent. *Id.* Importantly, this case provides this Court the opportunity to do away with *Rice*'s presumption.

Indeed, the *Reigel* Court's decision to find no-preemption without analyzing whether such a presumption applied is demonstrative of this Court's abrogation of *Rice* particularly as it relates to the field occupied by the FDA. *Altria Grp., Inc.*, 555 U.S. at 102 (Thomas, J., dissenting) ("Given the dissent's [in *Riegel*] clear call for the use of the presumption against pre-emption, the Court's decision not to invoke it was necessarily a rejection of any role for the presumption in construing the statute."); *accord Reigel*, 552 U.S. at 333–34 (Ginsburg, J., dissenting). Additionally, in *Whiting*, despite contemplating a conflict between federal immigration law and a core power

of states (licenses) this Court made no mention of the *Rice* presumption. *See generally, Chamber of Commerce v. Whiting*, 563 U.S. 582 (2011).

The court below relied on *Buckman* and *Rice* to find that because this is not a field that states have traditionally occupied, it cannot be presumed state actions would not be preempted. (*See* R. at 27.) The *Rice* Court held that a state's effort to assert the right to regulate a matter is preempted if that matter is "in any way regulated by the Federal Act." *Rice*, 331 U.S. at 236. There, the only provisions saved by the "presumption" were those that the Secretary had made no effort to regulate. *Id.* Here, the relationship between manufacturers and the FDA is heavily regulated—including fraud, misrepresentation, and noncompliance—indicating that even if the presumption is applied it would be overcome. *Id.*; *see also* 21 C.F.R. § 814. 42(e)(1).

This Court should reject the *Rice* presumption altogether as incompatible with the actual language of the Supremacy Clause. It is impossible to give full effect to the Supremacy Clause, binding judges in every state to the laws of the United States—"any *Thing* in the Constitution or Laws of any State to the contrary notwithstanding"— while presuming somehow that some *Thing* under a state law would withstand the supremacy of the laws of the United States. *See* U.S. Const. Art. VI, cl. 2.

The Supremacy Clause should be understood as a *non obstante* clause in the same drafting tradition as it was constructed in. Caleb Nelson, *PREEMPTION*, 86 VA. L. REV. 225 (2000). The tradition of the *non obstante* clause, as it was understood by the framers, was to ensure that any conflicting provision would fall away instead

of relying on the prior *doctrine of repeals* which effectively permitted a subsequent law to be given its natural effect at the expense of the prior law. *Id.* at 231–32. Importantly, understanding the text of the Supremacy Clause as a *non obstante* provision makes it wholly incompatible with any presumption against preemption. *Id*. at 290. Indeed, the Supremacy clause "rejects a general presumption that federal law does not contradict state law." *Id.* at 293.

In the alternative, as *Buckman* makes clear, where a state law invades the relationship between the federal agency and the regulated party, it is not subject to any presumption against preemption. Moreover, this Court has a more concise set of principles it may apply to make determinations of implied preemption. As enunciated in *Geier*, the ordinary principles of conflict preemption turn solely on whether a State has upset the regulatory balance struck by the federal agency. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000). Building on this, the Court can add a contour for the concept of obstacle preemption based on the bases advanced in *Buckman*, that state laws that "exert an extraneous pull on the scheme established by Congress" are preempted by that scheme. *Buckman*, 531 U.S. at 353.

The presumption, based on the status of the Supremacy Clause as a *non obstante* clause should be that: where a federal agency is exercising valid authority according to a scheme established under Congress's constitutional powers, any state law that upsets the regulatory balance struck by that agency is preempted. *Geier*, 529 U.S. at 869; *Buckman,* 531 U.S. at 348, (after the FDA has struck "a somewhat delicate balance of statutory objectives" and determined that petitioner submitted a

valid application to manufacture a medical device, a State may not use common law to negate it); *International Paper Co. v. Ouellette,* 479 U.S. 481 (1987) (after the Environmental Protection Agency has struck "the balance of public and private interests so carefully addressed by" the federal permitting regime for water pollution, a State may not use nuisance law to "upse[t]" it); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.,* 450 U.S. 311, 321 (1981) (after an agency struck a "balance" between competing interests to allow abandonment of railroad lines, a State may not use statutory or common law to negate it); *Rice*, 331 U.S. at 236 ("The test, therefore, is whether the matter on which the State assets the right to act is in any way regulated by the Federal Act. If it is, the federal scheme prevails"). After all, "Congress has power to assume not only some control, but paramount control" where it has been conferred Constitutional plenary power. *Colorado v. United States*, 271 U.S. 153, 165-66 (1926) (Brandeis, J.).

Here, the FDCA is a valid exercise of Congressional commerce power. *United States v. Walsh*, 331 U.S. 432, 434 (1947). The FDA's regulation of its relationship with regulated parties is a derivative part of that Congressional scheme. *Buckman*, 531 U.S. at 353. As such, where, as here, the operation of statutes upsets the regulatory balance struck by the FDA (that is, how it seeks to regulate parties, the information it seeks, and the stability of its determinations) those statutes should be preempted.

C. Subsection (b) of Transylvania's scheme is impliedly preempted.

Subsection (b) abrogates the immunity of drug and device manufacturers where they intentionally withhold from or misrepresent to the FDA any information that is required to be submitted under the FDCA and with that withheld information the drug would not have been approved, or the FDA would have withdrawn approval had the information been accurately submitted. 21 TRANS. COMP. STAT. § 630.546(b).

In *Buckman*, the Court ruled that where a state law tort implicated the relationship between a federal agency and regulated parties it was impliedly preempted because such a relationship was inherently federal because "the relationship originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347. The Court refused to apply any presumption against preemption as it does not apply to state law claims that implicate a field that states have never occupied—such as policing the relationship between an agency and a regulated party. *Id.* at 347-48 (citing *Lohr*, 518 U.S. at 485). The state law in question here is no different.

Here, to sue a medical device manufacturer, a plaintiff must prove first that the manufacturer withheld information from or misled the FDA and then that they were injured as a byproduct of the breach of the various duties underlying the products liability statute. *See* §§ 630.545, .546(b). Though this is procedurally distinct from fraud-on-the-FDA being the whole substance of the claim as in *Buckman*, that does not erase its functional similarity. Just as these statutes are preempted because they second-guess the authority of the FDA, the obstacles to federal objectives created

these schemes arise from the normal process of litigation that underlies proving up such claims and the anticipated response to such proceedings. *Lofton*, 672 F.3d at 380.

This Court has made clear that policing fraud on a federal agency is not a field in which states are entitled to a presumption against preemption as it is a unique federal area of regulation. *See Buckman*, 531 U.S. at 347; *Whiting*, 563 U.S. at 604. Indeed, so did Congress. Section 337(a) of the FDCA clearly articulates that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. 21 U.S.C. § 337(a). This forecloses private causes of action that seek to enforce the terms of the FDCA or vindicate purported violations thereof. *Mink,* 860 F.3d at 1327.

Further, the scheme itself rests on the same impermissible invasion of a federal agency's inherently federal relationships as the preempted torts in *Buckman*. Just as in *Buckman*, subsection (b) "exert[s] an extraneous pull on the scheme established by Congress" and should be deemed preempted. *Buckman*, 531 U.S. at 353.

Though the fraud-on-the-FDA component here is in the form of rebutting an immunity scheme instead of a standalone tort, that is a distinction without difference. As the Sixth Circuit observed when addressing a nearly identical immunity provision in Michigan, the "difference" between a general immunity with a specific exception and the state fraud-on-the-FDA claim contemplated by *Buckman* "is immaterial." *Garcia II*, 385 F.3d at 965–66. There, the court observed that "*Buckman* teaches that

state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (internal citations omitted).

Conversely, the Second Circuit's approach fundamentally misunderstands the "extraneous pull" that fraud-on-the-FDA schemes create. *See Buckman*, 531 U.S. at 353. Though the products liability claim is not itself a fraud-on-the-FDA claim, to get to underlying tort the plaintiff must still demonstrate the defendant defrauded or misled the FDA. *Garcia I*, 265 F. Supp. 2d at 831; *Lofton*, 672 F.3d at 379 (concluding that similar Texas provision was a Fraud-on-the-FDA provision because it required, as a matter of course, for the Plaintiff to "establish that the drug maker 'withheld from or misrepresented . . . required information.'"). Because the operative effect of the statute in question presents an obstacle this Court plainly observed in *Buckman*, the "technical detail" of the statute would counsel that it be deemed preempted. *Egelhoff*, 132 U.S. at 160 (Breyer, J. Dissenting). As the Fifth Circuit critiqued, the approach advanced in *Desiano* "overlooks the reality of trial practice." *Lofton*, 672 F.3d at 380. Importantly, where the state statute requires state juries to make determinations about what is material or relevant to the FDA under its own requirements, the statute runs afoul of *Buckman*'s counsel. *Id.*

Indeed, the same mechanistic threats to the FDA's regulation observed in *Buckman* happen here. There, the Court noted that permitting state lawsuits based on a fraud-on-the-FDA would cause manufacturers to comply with the FDA's regime in the "shadow of 50 States' tort regimes." *Buckman*, 531 U.S. at 351. The crux of this is that disclosures to the FDA may be deemed sufficient by the agency, but later

second-guessed in state court. *Id.* Moreover, anticipating potential litigation, manufacturers would submit a deluge of documentation the FDA neither wants nor needs resulting in greater burdens on the government as it seeks to pursue its various objectives. *Id.* Indeed, "the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." *Lofton*, 672 F.3d at 380. Indeed, as the Statement, *supra* at 16, discusses, the FDA process is complicated and already entails mountains of information. Statutes that ask state courts to determine if the FDA would have not granted approval or would have withdrawn its approval—whether as an element of an independent claim or threshold question to relief—requires the Court to ask whether a state court or jury is properly equipped to stand in the shoes of scientific experts who have spent 1200 hours evaluating a product. Congress has already answered this question: they are not. *See* Sen. Hatch remarks, *supra* at 21.

Subsection (b) requires state judges to ask the same questions that the *Buckman* Court deemed improper: did the manufacturer mislead or misrepresent information? 21 TRANS. COMP. STAT. § 630.546(b). Would the device still have been approved by the FDA had the information been provided? *Id.* Would the FDA have revoked its approval? *Id.* Jurors and state courts cannot competently step into the shoes of the FDA to answer these questions on behalf of the agency without usurping and displacing its decision-making authority. *Buckman*, 531 U.S. at 354 (Stevens, J., concurring).

Moreover, it is federal law that determines what information the regulated party would submit and the federal agency that would determine whether compliance is proper—rendering disclosures to the FDA and decisions about those disclosures uniquely federal. *Lofton*, 672 F.3d at 378-79.

As such, the Court should read *Buckman* to proscribe immunity-exception schemes that seek to implant the fraud-on-the-FDA theory as a threshold question. Therefore, the Court should affirm the finding that subsection (b)'s fraud-on-the-FDA provision is preempted.

D. Subsection (c)'s Failure to Warn scheme is, too, impliedly preempted.

Subsection (c) of the Transylvania code abrogates section 630.546(a)'s immunity where a "defendant fails to warn about the dangers or risks of the . . . medical device as required by the FDA." 21 TRANS. COMP. STAT. § 630.546(c).

The Medical Device Amendments to the FDCA include an express preemption clause which forbids any state "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 application 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.A. § 360k (West, through P.L. 118-78). In effect, a state-law claim is expressly preempted under section 360k(a) when "the FDCA imposes a federal requirement on the device and the contested state or local rule imposes any obligation that differs from or adds to those in the FDCA." *Plourde*, 23 F.4th at 33. The *Lohr* Court

stressed that Section 360k should not be read to curtail a state's right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. *Lohr*, 518 U.S. at 495. But *Buckman* counsels that any law that would seek to enforce a party's duty to the FDA is preempted. *Mink*, 860 F.3d at 1327 (discussing *Buckman*, 531 U.S. at 348).

The First Circuit's contemplation of failure-to-warn claims in *Plourde* and *DiCroce* is illuminative of how this Court should think about the claims at issue here. There, because the claims themselves were predicated on failure to comply with FDCA labeling requirements, the First Circuit found that the claim was preempted. *Id.* at 41–42.[5]

The Ninth Circuit's approach, too, steps off from the requirement that all actions enforcing the FDCA must be taken by the government through its myriad authority to investigate and pursue injunctions or civil or criminal penalties. *Perez*, 711 F.3d at 1119 (citing 21 U.S.C § 337(a)).

Subsection (c) creates, as a threshold question to liability, whether or not the manufacturer failed to comply with FDA warning requirements. 21 TRANS. COMP. STAT. § 630.546(c). Because "that violation of the FDCA 'is a critical element'" in Transylvania's statute, this Court must find that it is impliedly preempted. *DiCroce*, 82 F.4th at 42.

[5] The Eighth and Ninth Circuits have taken similar approaches. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

E. The non-compliance clause of subsection (a) relied on by the Circuit Court below is also preempted.

Finally, the Circuit Court's end-around attempt to preserve Ortega's claims on the basis of the statute's compliance clause is foreclosed.[6] As the Sixth Circuit noted in *Marsh* that procedural non-compliance is arguably a species of fraud-on-the-FDA. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012). The justification for this is relatively elementary. The statute there, as here, does not define compliance, but instead requires the court to determine the adequacy of disclosures and this would usurp the agency's role and go beyond the court's institutional expertise. *Id.* at 553-554. Moreover, *Buckman* and the FDCA must be understood to bar private suits that seek to privately enforce compliance or other duties owed to the FDA. *Mink*, 860 F.3d at 1327.

As the Ninth Circuit observed, applying *Buckman*, whether the defendant's use of a laser was in violation of the FDCA depends upon a number of considerations all of which "rest within the enforcement authority of the FDA, not this Court." *Perez*, 711 F.3d at 1120.

As such, permitting Ortega's claims to persist on her purported ability to demonstrate non-compliance relies on the same meddlesome and violative fact-finding efforts that the *Buckman* Court and Congress found repugnant.[7] Therefore,

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[6] The District Court did not reach this question. (R. at 24 n. 7.)

[7] The Circuit Court's justification for this was that because Ortega had alleged that Sleepternity included the same foam as the Philips recall, it could be inferred that the FDA would not have approved it. (R. at 33.) This bare assertion is directly at odds with the "invasion" of investigatory processes that Circuit Court expressed concerns about in deeming subsection (c) preempted. (R. at 31.)

the Court should reverse the court below's ruling that Ortega's claims could proceed under subsection (a).

F. The Court is faced with two remedies: severance or constitutional avoidance.

Finding that the immunity exception is preempted the Court has the power to fashion a remedy or remand for the circuit court to determine the proper step forward. As this is a scheme that has been repeated, *see Garcia II* and *Lofton*, Petitioner urges the Court to also establish the proper remediation for this form of preemption. The Court has two options.

i. The Court could sever the offending provisions.

A state has the authority to create, abolish, and modify common law causes of action. *Ferri v. Ackerman*, 444 U.S. 193, 198 (1979). As part of this authority, states are free to define defenses to those claims, including immunity. *Id.* Indeed, where the state legislature has created immunity from liability for a certain group of potential tortfeasors, the invalidity of the statutory exceptions to that immunity does not vitiate the immunity itself. The Court should continue its practice of limiting the solution to the problem. *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183, 2209 (2020).

As such, the Court should sever subsections (b) and (c) from the statute as they impermissibly create obstacles for the FDA's regulation and encroach on a field Congress has demonstrably reserved for the federal government. That the consequence of that decision is that manufacturers like Mednology are not susceptible to tort suits should not be a persuasive argument to the contrary. First, the FDA

retains all enforcement power if there is a finding of wrongdoing. Second, as, the *Garcia* Court observed, severing the immunity provision merely places the responsibility for prosecuting fraud in the hands of the FDA or the federal government instead of state courts. *Garcia II*, 385 F.3d at 968.

ii. In the alternative, the Court can avoid any constitutional dispute altogether by affirming the construction counseled in *Garcia II*.

When confronted with two competing constructions of a statute, the Court may select, even a less straightforward interpretation of the statute, to avoid any constitutional violation. Anita S. Krishnakumar, *Passive Avoidance*, 71 STAN. L. REV. 513, 577–78 (2019). The Court can see the competing interpretations of an altogether similar immunity scheme in *Marsh* and *Garcia*. *Marsh* would counsel that the exception be severed while *Garcia* would permit states to incorporate federal standards into tort law when the agency itself makes a determination of fraud. *Garcia II*, 385 F.3d at 966.

As Justice Stevens noted in his concurrence in *Buckman*, if the FDA determines that fraud has occurred, state damages would supplement and facilitate the federal enforcement scheme. *Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring). This is also the approach prescribed in *Garcia II*, permitting actions that require a showing of fraud to proceed, where and only where, the federal agency has made such a finding. *Marsh*, 693 F.3d at 551 (discussing subsequent developments in the application of *Garcia II*).

Marsh sees an immunity exception scheme based on noncompliance as itself preempted, and would not permit the court below's decision to remand as the scheme in its totality is violative of Federal supremacy. In *Marsh*, the sixth circuit ruled, though finding an exception preempted may leave a plaintiff without adequate remedy because of the remaining immunity provision, that was a consequence of the state's scheme—not the court's making. *Marsh*, 693 F.3d at 546, 554 ("Although preemption principles do not foreclose state-law failure-to-warn claims once the FDA has approved a drug, Michigan law does so.") This would find the immunity-exception preempted and in violation of the constitution, though leaving the remainder of the immunity provisions undisturbed.

Conversely, *Garcia II* understood the immunity exception itself as not preempted, but instead contemplated who the proper fact finder for such compliance or fraud ought to be. In the view of the *Garcia* Court, state courts could abrogate immunity under such a statute where, and only where, the determination of fraud or noncompliance was itself made by the FDA or other regulatory authority. *Garcia II*, 385 F.3d at 967.

The court below adopted this, in part, out of a reticence to leave plaintiffs like Ortega without remedy. However, the Court's belief that individuals should not be left without remedy is one that should be left to the purview of the state legislature in question. The Transylvania Legislature should have written a scheme that didn't rely on courts to impermissibly construct and construe its terms to afford its citizens relief.

As this Court made clear in *Lohr*, traditional tort liability is not foreclosed or preempted by the FDCA is not itself preempted, so long as it does not create any duty in excess of those prescribed by the Act. The Transylvania legislature can instead seek to expose medical device manufacturers in the normal course of tort liability and rely on courts to determine which claims are preempted by the FDCA.

The Transylvania legislature wanted a scheme that would simultaneously afford relief to plaintiffs like Ortega while also enabling medical device manufacturers to operate with predictable levels of insulation from liability so long as their products are approved by the FDA. 21 TRANS. COMP. STAT. § 630.544-.545. Though *Marsh* is perhaps most consistent with the black letter understanding of the supremacy clause, this Court's avoidance jurisprudence would suggest that the construction adopted by the *Garcia II* and *Lofton* Courts is the most prudent approach that balances the efficiency goals of the marketplace with the need for consumers to vindicate injuries while still preserving the FDA's exclusive governance of its relationship with regulated parties. This also embraces the balance sought by the *Buckman* concurrence. *Buckman*, 531 U.S. at 355 (Stevens, J., concurring). There, Justices Stevens and Thomas lamented that it would be likely outside the objective of Congress to foreclose all damages remedies for plaintiffs harmed by manufacturer misconduct where there is a demonstrated finding by the agency and would permit such claims to come forward where the agency has made such an affirmative finding. *Id.*

Additionally, there is perhaps a substantial policy argument for accepting the Circuit Court and *Garcia II*'s construction. That is, if legislatures like Transylvania are precluded from permitting immunity to be abrogated through some demonstration of non-compliance or fraud, they may be tempted to offer no immunity at all. This could open the door to medical device and drug manufacturers being exposed to greater volumes of litigation. There has long been a concern that increased litigation increases healthcare costs. *See* U.S. DEPT. OF HEALTH & HUMAN SERVS., ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE (2003), (finding that increasing litigation costs in healthcare are often passed on to consumers leading to higher prices).

Therefore, in the alternative, the Court ought to adopt the narrower view arising from *Garcia II* and urged by the Court below that immunity-exception schemes based on establishing fraud, non-compliance, etc. be permitted to proceed where, and only where, the FDA has made such a finding.

II. THE FRAUD-ON-THE-FDA IS NOT A VIABLE THEORY TO BRING A FALSE CLAIMS ACT UNDER THE ACT'S *QUI TAM* PROVISION AGAINST A MEDICAL DEVICE MANUFACTURER IN CASES OF FDA INACTION BECAUSE THE THEORY NECESSARILY FAILS TO SATISFY THE REQUIRED ELEMENTS OF CAUSATION AND MATERIALITY.

A. The Circuit Court's emphasis on Escobar *neglected Causation.*

The fraud-on-the-FDA theory seeks to extend liability for fraudulently obtained government payments by linking the FDA approval process to federal healthcare programs, like CMS, which generally require FDA approval for

reimbursement coverage of drugs or devices. Thus, the fraud-on-the-FDA theory relies on the contention that the FDA would not have granted pre-market approval without the alleged fraudulent claims.

The forthcoming discussion will address the legal error of court below and then address the legal inadequacy of the Fraud-on-the-FDA theory to satisfy the causation and materiality elements. We urge this Court to resolve the circuit split regarding the fraud-on-the-FDA theory and find it not viable in cases where the FDA fails to act despite knowledge of the alleged fraud.

B. The Court of Appeals improperly analyzed Escobar and neglected the First Circuit's analysis in Nargol.

When faced with the aforementioned circuit split, the district court below correctly relied on *D'Agostino*, finding relator's fraud-on-the-FDA claim failed because she failed to link the causation chain, "[s]ince CMS's decision to provide coverage for Sleepternity was based on the FDA's approval of the medical device, [Ortega] must establish that the FDA would have recalled the device from the market had they known about Mednology fraudulently replacing the PE-PUR foams with the approved silicone-based foams." (R. at 21). Without alleging that the FDA took action, Ortega could not establish sufficient causation to state a claim. (R. at 23.) This is intuitive. The actions of the manufacturer are targeted at influencing doctors to prescribe their products, not at causing the submission of false Medicare claims. Ralph F. Hall & Robert J. Berlin, *When You Have A Hammer Everything Looks Like*

A Nail: Misapplication of the False Claims Act to Off-Label Promotion, 61 FOOD & DRUG L.J. 653, 666-67 (2006).

In its analysis of the circuit split, the court of appeals below preferred the *Campie* approach because *D'Agostino* predated this Court's analysis of materiality in *Escobar*. (R. at 36.); *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 188–93 (2016). This emphasis on *Escobar* led the Court below to erroneously focus only on the materiality element of Ortega's FCA claim. The court below found *Escobar* instructive for resolving the issue at hand because Ortega "appears to be relying on an implied false certification theory to bring her FCA claim against Mednology." (R. at. 36). The court disproportionately relied on Escobar's "demanding" materiality standard, while neglecting the importance and necessity of establishing a causal link between a defendant's alleged fraudulent conduct and the government's decision to pay (R. at 37, 39.)(Ruzich, J., dissenting)(citing *Escobar*, 579 U.S. at 194-195)). Moreover, the court below erroneously analyzed the *D'Agastino-Campie* divide as if the First Circuit never took occasion to evaluate its approach in the wake of *Escobar* or respond to *Campie*. *See Nargol*, 865 F.3d at 36. Petitioner would direct this Court to the First Circuit's analysis in *Nargol*. *Id.*

Following *Escobar*, the First Circuit ruled on *Nargol*, in which it balanced the materiality and causation elements of fraud-on-the-FDA claims previously seen in *D'Agostino* and *Campie*. *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017)(*"Nargol"*). The court applied the demanding materiality standards while also showcasing the missing causal link in instances where the FDA

is aware of allegedly fraudulent behavior but has not acted. *Id.* at 34-35. The court noted that when the FDA inaction despite actual knowledge of fraud, "it is not plausible that the conduct of the manufacturer in securing FDA approval constitutes a material falsehood capable of proximately causing the payment of a claim by the government." *Id.* at 35. Where *Escobar* focused almost exclusively on the materiality element, implicitly using a "holistic materiality review," the approach explained in *Nargol* clarifies the connection between the causation and materiality elements and thus should be the standard applied.

C. The Court should bar qui tam *suits based on Fraud-on-the-FDA in the absence of FDA action.*

Fatal to Respondent's theory to establish all the elements of a claim under a Fraud-on-the-FDA theory. Particularly, it is fails the causation and materiality elements.

1. A Fraud-on-the-FDA theory absent FDA action inherently fails the causation element

The causation element, although currently ill-defined, is a critical element of FCA actions because it goes towards proving that a defendant's alleged fraudulent conduct was the direct link to the government's decision to pay. Without this direct link, the FCA could be used to target minor or immaterial misstatements, overreaching the bounds of the statute. Causation is essential to preventing the FCA from being used to punish garden variety regulatory violations. *See Escobar*, 579 U.S. at 194.

Given the unique and expansive role of the FDA as a regulatory agency with specialized expertise and enforcement authority, the causation element is especially important when faced with alleged fraud-on-the-FDA. Requiring relators to adequately satisfy the causation element assists in maintaining the separation of FCA regulatory and government payment decisions. It also preserves the unique spheres of regulation that govern manufacturers and medical billers. *Hall & Berlin*, 61 FOOD & DRUG L.J. at 674-75. The FDA is tasked with the primary role of evaluating the safety and efficacy of medical products, while the government's decision to pay for those products through programs like CMS is approved through the agency's own independent process. Since FDA approval alone does not automatically entitle a product to government reimbursement, proving that the alleged fraudulent conduct *caused* the government to pay claims requires showing that the fraud was *integral* to both the FDA's approval process and the subsequent payment decision.

It is both difficult and essential to analyze how the causation element is affected by FDA inaction - cases where the FDA is aware of the alleged fraud but chooses not to take action - as the causal link becomes more tenuous.

The FDA's regulatory framework is designed to address and remediate instances of fraud through a structured set of enforcement mechanisms. As articulated by the Supreme Court in *Buckman*, the FDA has "a variety of enforcement options that allow it to make a measured response to suspected fraud upon the

Agency." 531 U.S. at 349. Recall additionally, that enforcement of the provisions of the FDCA is exclusively of the province of the government. 21 U.S.C. § 337(a).[8]

Merely an allegation of antecedent fraud in the causal chain prior to payment does not itself render a claim false. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 491 (2017). Instead, the falsity must be *integral* to the submitted claim. *Hendow*, 461 F.3d at 1174.

The statement already laid out portions of the critical intensity of the FDA approval process. Discussion of FDA Approval Process, *supra* at 16. Importantly, however, CMS payments do not begin and end with FDA approval. Rather, the decision for payment, which hinges on the claim being "reasonable and necessary," requires the claim to be "reasonable and necessary for [the] individual patient" based on "accepted standards of medical practice and the medical circumstances of the individual case." CTRS. FOR MEDICARE AND MEDICAID, MEDICARE BENEFIT POLICY MANUAL, CH. 15, § 50.4.3. Other Medicare provisions and regulations underscore the critical role of the physician in Medicare's payment and reimbursement scheme. The regulations provide that "[t]he physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay." 42 C.F.R. § 424.10(a). This importantly establishes that there are a number of decisions and actions that occur between a manufacturer's purported fraud and CMS's decision to

[8] That a *qui tam* suit is in the name of the government does not escape this principle as the statute states "by and in the name of." *Id.* The conjunctive means the government is the only proper arbiter of suits to enforce the FDCA.

pay. What if a prescribing doctor who knew of the foam change determined that, despite the risk of VOCs, Sleepternity was still reasonably necessary for the care of the patient? Ortega's pleadings are silent on this issue as she has made no effort to illuminate if the only reason that the payments were made was the result of FDA approval—and that's because she, like other relators asserting this theory, simply cannot do so. Indeed, as the District Court noted Ortega does not even establish that the FDA would not have approved the machine. (R. at 23.)

The court below attempts to cure this by asserting that Ortega "asserts that CMS's payment for Sleepternity was conditioned on the FDA's approval." (*Id.* at 37.) However, this is a materiality issue, not a causation issue. The Third Circuit cautioned that the collapsing of materiality and causation elements would render the causation element surplusage in contravention of traditional statutory interpretation. *Petratos*, 855 F.3d at 491.

As the Third Circuit noted in *Petratos*, general approvals by CMS and the FDA demarcate what treatments can be considered "reasonable and necessary," and are thus a necessary condition for reimbursement. Meanwhile, the doctors are best suited to evaluate each patient and determine whether a treatment is "reasonable and necessary for [that] individual patient." *Petratos*, 855 F.3d at 489.

As discussed at length, the weight of the circuits is behind not simply a but-for cause of antecedent fraud, but rather a proximate cause. *See Hibbs*, 568 F.2d at 349; *Miller*, 645 F.2d at 475-76; *Luce*, 873 F.3d at 999. As a matter of law, the causal chain from premarket approval to marketing to diagnosis to prescription to review to

payment is simply too attenuated to permit relators to establish the element of causation on the basis of alleged misrepresentations during PMA.

When the FDA, despite knowledge of alleged fraud, chooses not to exercise these enforcement tools—such as suspending or withdrawing approval of a device—it fundamentally disrupts the causal chain necessary to support an FCA claim. This was underscored by the First Circuit in *Nargol* where the court held that the FDA's decision not to act on allegations of fraud resulted in a "break in the causal chain" between the alleged misrepresentations and the submission of false claims. *Nargol*, 865 F.3d at 34 (*citing D'Agostino, Inc.*, 845 F.3d at 8). Therefore, without FDA intervention, the required causation element for an FCA claim under the fraud-on-the-FDA theory cannot be established.

In *D'Agostino* ,a factually similar case, the court rejected the relator's alleged fraudulent inducement claims for failure to establish the causal link: "alleging that the fraudulent representations 'could have' influenced the FDA to approve [the drug] falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS." *D'Agostino*, 845 F.3d at 7. In the present case, Ortega presents no evidence that Sleepternity being manufactured with silicone-based foam was the cause of FDA approval. Ortega relies on the Philips recall to support her assertion that the FDA would not have approved Sleepternity if the device contained PE-PUR foams instead of silicone foams.

Based on the fact that the Philips' recall was voluntarily initiated and not an action taken by the FDA, the recall is not a valid basis for the presumption that the

FDA would not have approved Sleepternity if it had been manufactured with PE-PUR foams at the time of application for approval. Moreover, the Philips recall occurred just a year and a half prior to Sleepternity gaining FDA approval. It is highly unlikely to infer that Mednology knew of the recall and alleged health risks of PE-PUR foams and used that information to intentionally defraud the FDA within that time period—particularly given the aforementioned duration of the PMA process which for class III devices lasts on average 399 days. Darrow 2021, *supra*, at 426. For the foregoing reasons, Ortega is unable to prove that Mednology knew its approval would be negatively affected by using PE-PUR foams rather than silicone-based foams. Thus, she is unable to positively establish the causal connection between the type of foam used at the time of FDA approval and the FDA's approval decision itself.

In sum, the fraud-on-the-FDA theory fundamentally fails to overcome the burden of establishing causation. As established in *D'Agostino,* speculative claims about what might have influenced the FDA fall short of proving the necessary causal link.

Furthermore, Ortega's reliance on the Philips recall to argue that the FDA would not have approved Sleepternity if it had been manufactured with PE-PUR foams is fundamentally flawed because the recall was a voluntary action by Philips, not mandated by the FDA. Additionally, the timing of the recall in relation to Sleepternity's FDA approval makes it implausible to infer that Mednology acted with fraudulent intent by submitting devices manufactured with silicone-based foams for approval. Therefore, at bottom, even if the Court were to find fraud-on-the-FDA to be

viable theory to establish an FCA claim, it should still render judgement that Ortega has not met the causation element of her individual claim and dismiss her FCA claims.

2. FDA inaction fails to satisfy the "demanding" materiality standard set forth in Escobar

The term "material" is defined by the FCA 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). This Court has explained "[t]he materiality standard is demanding. The False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194. A misrepresentation is not considered "material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* "Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* "Materiality . . . cannot be found where noncompliance is minor or insubstantial." *Id.*

In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. *Id.* at 194–95 Conversely, if the Government pays a particular claim in full despite

its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. *Id.* Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material. *Id.* at 195.

"Such very strong evidence becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *Nargol*, 865 F.3d at 35. "In such a case, it is not plausible that the conduct of the manufacturer in securing FDA approval constituted a material falsehood capable of proximately causing the payment of a claim by the government." *Id.*

The materiality factors this Court has identified are: "(1) whether the government expressly designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; (2) the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision; and (3) whether the defendants' alleged noncompliance was 'minor or insubstantial.'" *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 110 (2d Cir. 2021) (summarizing *Escobar*).

The Court should follow the approach of the First Circuit in *D'Agostino* and *Nargol*. "[W]hen the FDA concludes that it has been misled because an "application contained or was accompanied by an untrue statement of a material fact," it can commence an "informal" hearing and withdraw its approval allowing the marketing

of a device." *D'Agostino*, 845 F.3d at 8. However, "since D'Agostino surfaced the alleged fraud, the FDA has apparently demanded neither recall nor relabeling." *Id.* Thus, "[t]he FDA's failure actually to withdraw its approval . . . in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained." *Id.*

Likewise, in *Nargol*, "there [was] no allegation that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations." *Nargol*, 865 F.3d at 35. In fact, "the FDA allowed the device to remain on the market until DePuy, on its own volition, discontinued the device." *Id.* "The FDA . . . possesses a full array of tools for 'detecting, deterring, and punishing false statements made during ... approval processes.'" *Id.* (quoting *Buckman*, 531 U.S. at 349). "Its decision not to employ these tools in the wake of Relators' allegations . . . renders a claim of materiality implausible." *Id.*

Conversely, the Ninth Circuit in *Campie* considered the materiality issues to be "matters of proof, not legal grounds to dismiss." *Campie*, 862 F.3d at 907. However, *Campie* fails to address any of the policy issues that using the FCA in this way creates. Not only is the reasoning of *Campie* expressly rejected in *Nargol*:

Campie offers no rebuttal to *D'Agostino*'s observation that six jurors should not be able to overrule the FDA. *See D'Agostino*, 845 F.3d at 8. And it offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything. *Nargol*, 865 F.3d 36.

Similar reasoning to *Nargol* is shared by the Third and Fourth Circuits. "When an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.'" *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014). To follow *Campie* would "sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *Id.* In *Petratos*, since the Plaintiff "concede[d] that the expert agencies and government regulators . . . [would have] deemed the[] violations insubstantial . . [the Third Circuit did] not think it appropriate for a private citizen to enforce these regulations through the False Claims Act. *Petratos,* 855 F.3d at 490 (applying the *Escobar* materiality factors).

Here, as in both *D'Agostino* and *Nargol* the FDA has not taken any action against Mednology and declined to intervene in Relator's case. (R. at 6.) Sleepternity was *voluntarily* recalled. Relator's claim thus necessarily fails on materiality where the FDA has not exercised its investigative power and jurisdiction. To decide otherwise would "turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval." *D'Agostino*, 845 F.3d at 8.

D. Permitting Fraud-on-the-FDA theories to persist invades the investigatory powers of the FDA.

The policy concerns of infringement upon FDA function expressed by the First Circuit in *D'Agostino* and *Nargol* are not merely judicial conjecture but shared by the United States government itself. Following the Ninth Circuit's decision in *Campie*, Gilead petitioned to this Court for review. On review, the Government filed an amicus brief in which it expressed concerns that permitting a relator's suit to proceed would result in burdensome discovery on the FDA and would "impinge on agency decision making and discretion and would disserve the interests of the United States." *United States ex rel. Campie v. Gilead Scis., Inc.*, No. 11-CV-00941-EMC, 2019 WL 5722618, at *3 (N.D. Cal. Nov. 5, 2019)

Permitting fraud-on-the-FDA to serve as a basis for liability under the FCA in cases where the FDA declines to act risks undermining the FDA's regulatory authority, dilutes the FCA's focus, and could lead to legal challenges that strain judicial resources without effectively curbing government healthcare expenditures. Allowing this theory to serve as a basis for FCA liability shifts the focus from prosecuting clear cases of fraudulent claims to second-guessing regulatory decisions made by the FDA, which could result in inconsistent enforcement and increasing legal uncertainty for manufacturers. Moreover, relying on fraud-on-the-FDA to address healthcare costs may ultimately be counterproductive, as it could lead to increased litigation costs that are passed on to consumers, rather than achieving meaningful reductions in healthcare spending.

CONCLUSION AND PRAYER

For the foregoing reasons, the judgement of the circuit court should be reversed. Consistent with that reversal, the Court should render judgement that the motion to dismiss granted.

Respectfully submitted,

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COUNSEL FOR PETITIONER

APPENDIX

1a

21 TRANS. COMP. STAT. § 630.544:

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

21 TRANS. COMP. STAT. § 630.545:

Manufacturers and distributors of a product owe a duty of care and good faith to their consumers throughout the manufacturing and distribution of such product, including the duty to warn of any dangers or risks associated with the product, the duty to comply with all the state and federal laws and regulations governing the manufacturing and distribution of the product, and the duty to make disclosures to appropriate agencies or government officials about any modifications made to the product. Any resulting injury or death that would not have occurred but for the breach of any of the aforementioned duties shall serve as adequate basis for liability under this statute.

21 TRANS. COMP. STAT. §§ 630.546(a)-(c):

(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.

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; . . .

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

(b) Definitions. For purposes of this section . . .

(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; . . .

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

31 U.S.C. § 3730. Civil Actions for false claims:

(b) Actions by private persons.

(1) A person may bring a civil action for a violation of section 3729 [31 USCS § 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) [Rule 4(i)] of the Federal Rules of Civil Procedure. 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.

. . .

(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). . . .

(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 . . .

(d) Award to qui tam plaintiff.

. . .

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.