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 IN SUPPORT OF PETITIONER

Team #3320
Counsel for Petitioner,
Mednology, Inc.

ORAL ARGUMENT REQUESTED

QUESTIONS PRESENTED

I. Whether federal law preempts a statutory exception to a manufacturer's state-recognized immunity when the exception is based on the manufacturer fraudulently obtaining FDA approval or failing to comply with any FDA requirements?

II. Whether a relator may rely on the fraud-on-the-FDA theory to bring a False Claims Act claim against a medical device manufacturer under the Act's *qui tam* provision?

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The opinion of the United States District Court for the Southern District of Transylvania is unreported but appears on pages 2–24 of the record where the district court DENIED Petitioner's motion to dismiss Respondent's state law claims and GRANTED Petitioner's motion to dismiss Respondent's FCA claim. The opinion of the United States Court of Appeals for the Seventh Circuit is also unreported but appears on pages 25–42 of the record where the appellate court AFFIRMED the district court's denial of Petitioner's motion to dismiss Respondent's state law claims and REVERSED the district court's granting of Petitioner's motion to dismiss Respondent's FCA claim.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves provisions of the United States Code 31 U.S.C. §§ 3729–3733; 21 U.S.C. § 360k(a); and 21 U.S.C. §337(a). This case also involves a provision from the Code of Federal Regulations C.F.R. § 7.40(b). Finally, this case involves statutes from the State of Transylvania 21 Trans. Comp. Stat. §§ 630.544-46.

STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves a products liability action that Riley Ortega ("Respondent") brought against Mednology, Inc. ("Petitioner" or "Mednology"). R. at 6. Respondent alleges that Petitioner fraudulently produced a product, known as "Sleepternity". R. at 6. Respondent filed claims against Mednology under the State of Transylvania's product liability statute, as well as a False Claims Act (FCA) action based on the fraud-on-the-FDA theory. R. at 6.

Sleepternity. Mednology developed a medical device in order to treat individuals with sleep apnea. Sleepternity is a novel *continuous positive airway pressure (*CPAP) machine that provides a variety of unique features which are meant to optimize device effectiveness and enhance user experience. R. at 3. One such feature includes headphones which are designed to aid users to relax and fall asleep gently by emitting gentle pulses which travel to the user's brain. R. at 3. Sleepternity ultimately helps users to effectively reduce insomnia, in addition to an overall reduction of the occurrence of sleep apnea. R. at 3.

FDA Approval. On December 30, 2022, the FDA approved Sleepternity for marketing as a Class III medical device. R. at 3-4. After its approval by the FDA, the Centers for Medicare and Medicaid Services (CMS) provided coverage to those who were prescribed Sleepternity for the costs of using the device. R. at 4. To reduce manufacturing costs, and thus the overall cost for the device, Mednology altered a material used in the production of the Sleepternity machine. Specifically, in their headphones, Mednology replaced the silicone-based sound-dampening foam with a polyester-based polyurethane (PE-PUR) foam, as polyurethane is a cheaper alternative to silicone. R. at 4.

Riley Ortega's Usage. Riley Ortega was prescribed Sleepternity to help alleviate her sleep apnea and insomnia symptoms R. at 3. During the time that Riley was using Sleepternity, she began to experience asthma attacks. Per doctor recommendation, she stopped use of Sleepternity, which alleviated her asthma attacks, but her sleep apnea returned. R. at 5. Based upon some familial advice and individualized research Riley learned of the PE-PUR foam used in Sleepternity's headphones and the foam's *potential* to degrade into certain forms of isocyanate, to which Respondent is allergic. R. at 5. Based on this possibility, Respondent contributed her asthma attacks and related health issues to the existence of those foams in Sleepternity. R. at 5. As a result,

Respondent brought a products liability action against Mednology for its alleged fraudulent production of Sleepternity. R. at 6. Respondent claims that Mednology violated Transylvania's product liability statute when it breached its duty of care and good faith; breached its duty to disclose to the FDA the modifications it made to the sound abatement foams; and breached its duty to warn about the dangers and risks associated with the PE-PUR foams in the Sleepternity device. R. at 6. In addition to her state law claims, Respondent relies on the fraud-on the FDA theory to bring a False Claims Act action under the Act's qui tam provision. R. at 6. The United States declined to intervene in Respondent's FCA action against Mednology. R. at 6. After Mednology was made aware of Respondent's complaint, the company voluntarily recalled Sleepternity from the market and the FDA discontinued its investigation of the company's allegedly fraudulent conduct. R. at 7.

II. PROCEDURAL HISTORY

District Court. Alleging that Mednology, Inc. ("Mednology" or "Petitioner") fraudulently produced a product called Sleepternity, Riley Ortega ("Respondent") brought action against Mednology under both state and federal law. Respondent filed claims against Mednology under the State of Transylvania's product liability statute, relying on the exceptions in the statute to overcome Mednology's state-recognized immunity. Respondent also brought a False Claims Act (FCA) action under the Act's *qui tam* provision against Mednology based on the fraud-on-the-FDA theory.

Mednology filed a motion to dismiss Respondent's claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, which Respondent challenged. Mednology based its motion to dismiss on the theories that the FDCA preempts the exceptions to Transylvania's

state-recognized immunity, and that the alleged fraudulent conduct toward the FDA cannot serve as a valid basis for Respondent's False Claims Act claim.

The District Court granted Mednology's motion to dismiss in part and denied it in part. Specifically, the Court DENIED Mednology's motion to dismiss Respondent's state law claims, finding that federal law does not preempt any provision that would neutralize Mednology's immunity under the state statute. On the other hand, the Court GRANTED Mednology's motion to dismiss Respondent's claim under the False Claims Act, finding that the False Claims Act action cannot be based entirely on Mednology's conduct of fraudulently obtaining FDA approval for its medical device.

Appellate Court. Respondent appealed the district court's granting of Mednology's motion to dismiss Respondent's claim under the False Claims Act. Mednology appealed the district court's denial of its motion to dismiss Respondent's state law claims brought under Transylvania's product liability statute.

The Appellate Court determined that the relevant provisions under Transylvania's product liability statute were preempted by Federal law. Nevertheless, the Court AFFIRMED the district court's denial of Mednology's motion to dismiss Respondent's state law claims, finding that Respondent alleged sufficient facts to plausibly rebut the presumption that Sleepternity was in compliance with FDA approval. Additionally, the Appellate Court REVERSED the district court's granting of Mednology's motion to dismiss Respondent's FCA claim, finding that Respondent alleged sufficient facts to plausibly satisfy the materiality element of the FCA claim.

SUMMARY OF THE ARGUMENT

This Court should reverse the Appellate Court's denial of Petitioner's motion to dismiss Respondent's state law claims because federal law preempts the statutory exceptions to a

manufacturer's state-recognized immunity even when the exception is based on the manufacturer fraudulently obtaining FDA approval or failing to comply with any FDA requirements. This Court should also reverse the Appellate Court's denial of Petitioner's motion to dismiss Respondent's FCA claim because the Respondent did not meet the causality and materiality elements required to bring the implied false certification theory under the False Claims Act.

I.

Respondent's state claims are based on Transylvania's product liability statute, which provides immunity to manufacturers if their medical device has been approved by the FDA. There are two exceptions to this immunity related to fraudulent behavior or failure to comply with FDA requirements. These exceptions are preempted by federal law, specifically the FDCA, which governs FDA-related issues. The presumption against preemption, which would negate Petitioner's immunity, does not apply in this case. Additionally, case law supports the conclusion that the immunity exceptions in Transylvania's product liability statute cannot be overcome without a finding of fraud or violation against the FDA, which is a determination that must be made by the FDA. There is no evidence or finding by the FDA to support Respondent's claims of fraud, violation, or non-compliance; therefore, Respondent has not brought a claim under which she can recover, so the Court should grant Petitioner's motion to dismiss Respondent's state claims.

II.

The Respondent, here, argues that since CMS began to provide coverage to individuals who were prescribed Sleepternity for the costs of using the device, due to the fact the device was approved for marketing by the FDA, the idea that the device fraudulently obtained approval constitutes a False Claims violation for such reimbursements. The present case requires a

balancing of the District Court and Court of Appeals opinions with respect to the causality and materiality elements of the fraud on the FDA theory and the implied false certification theory to address the relator's reliance on such theories in bringing a FCA claim. While the District Court correctly highlights the First Circuit's opinion in *D'Agostino* with respect to the casual element of this issue, the Court of Appeals rightly relies on *Escobar's* clarification of the FCA to best determine this issue.

ARGUMENT AND AUTHORITIES

STANDARD OF REVIEW. The Supreme Court of the United States reviews questions of law de novo. *Monasky v. Taglieri, 140 S. Ct. 719, 730 (2020).* This appeal raises two legal questions. Whether a federal law preempts subsections (b) and (c) of Transylvania's immunity statute is a question of law that shall be reviewed *de novo*. See *Lofton v. McNeil Consumer & Specialty Pharms.,* 672 F.3d 372, 375 (5th Cir. 2012) ("Questions of law regarding preemption are reviewed de novo."). Further, whether the dismissal of claim under the False Claims Act relating to a relator's reliance on the Fraud on the FDA theory to bring such a claim under the FCA's *qui tam* provision is reviewed *de novo*. *United States ex rel. Campie v. Gilead Scis.,* 862 F.3d 890, 898 (9th Cir. 2017).

I. PETITIONER'S MOTION TO DISMISS RESPONDENT'S STATE LAW CLAIMS SHOULD BE GRANTED BECAUSE EXCEPTIONS BASED ON A MANUFACTURER FRAUDULENTLY OBTAINING FDA APPROVAL [§ 630.546(B)] OR FAILING TO COMPLY WITH ANY FDA REQUIREMENTS [(§ 630.546(C)] ARE PREEMPTED BY FEDERAL LAW PETITIONER

Respondent brought claims against Petitioner under Transylvania's product liability statute, alleging that Respondent fraudulently produced the Sleepternity device. R at 6; 21 Trans.

Comp. Stat. § 630.545 (2024). The State's product liability statute is followed by an immunity provision that protects manufacturers from liability if the medical device was approved by the FDA. 21 Trans. Comp. Stat. § 630.546(a). There are two exceptions to this immunity, which Respondent relies on to overcome Petitioner's immunity. The exceptions negate the immunity granted under §630.546(a) if: (b) the manufacturer intentionally withholds from or misrepresents information about the medical device that was required, under the FDCA, to be submitted to the FDA, or (c) the manufacturer fails to warn about the dangers and risks associated with the FDA. 21 Trans. Comp. Stat. § 630.546(b-c). Respondent is not able to meet these exceptions to the immunity provision and therefore, Respondent's claims are preempted by the FDCA. 21 U.S.C. § 337(a).

A. Presumption Against Preemption Does Not Apply in This Case

The appellate court correctly relied on the *Buckman* analysis and determined that the presumption against preemption, which would negate Petitioner's immunity, does not apply in this case. R at 27. The *Buckman* analysis involves a scenario analogous to the one at hand. In *Buckman*, the plaintiffs allege that a medical device manufacturer made false representations to the FDA to obtain FDA approval. *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The plaintiffs brought their claim under state tort law, asserting that but for those false representations, the FDA would not have approved the device and plaintiffs would not have been injured. *Id* at 343. The Supreme Court in *Buckman* held that no presumption against preemption applied and that plaintiffs' claims were preempted by the FDCA because federal law, not state law, must govern fraud allegations against a federal agency. *Id* at 346. Similarly, in the case at hand Respondent claims that Petitioner fraudulently obtained FDA approval for Sleepternity by making false representations, and but-for those alleged false representations, the FDA would not have approved

Sleepternity. R at 19. Given the stark similarities in the two cases, the analysis in Buckman should apply to this case.

The district court incorrectly held that the presumption against preemption did apply to Respondent's claims, then went on to improperly rely on the analysis in *Medtronic, Inc. v. Lohr* to resolve the preemption issue. R at 13; *Medtronic, Inc. v. Lohr*, 518 U.S. 475 (1996). Although the appellate court correctly overturned the district court's finding of the presumption against preemption, it did not address why the district court's application was incorrect. The district court incorrectly relied on *Medtronic, Inc. v. Lohr* when it determined that the presumption against preemption existed in this case. The district court argues that Respondent's claims are based on "traditional state tort law rather than fraud-on-the-FDA," so the state has the authority to "exercise its police power to protect the health and safety of its citizens." R at 13; *Medtronic, Inc. v. Lohr*, 518 U.S. 475 (1996). The district court failed to acknowledge one of the main takeaways from *Medtronic*, which is that preemption should occur if the state law interferes with a federal interest and is "different from, or in addition to" federal requirements. *Id* at 500. Application of the presumption against preemption in this case would certainly interfere with federal interests, specifically interests of the FDA. The FDA was made aware of Petitioner's alleged misconduct but chose not to pursue action when Petitioner removed Sleepternity from the market. Applying the presumption against preemption in this case would allow Respondent to rely on the immunity exceptions (21 U.S.C. §630.546(a)-(c)), which are based on Petitioner's alleged fraud and violation of FDA requirements, thus creating a new state cause of action to prove such violations, after blatantly ignoring the FDA's clear intent not to continue investigating Petitioner's alleged fraudulent conduct.

B. Federal Law Preempts The Immunity Exceptions In Subsections (B) And (C) Of Transylvania's Immunity Statute

The appellate court was correct in its application of *Garcia v. Wyeth-Ayerst Labs.*, and by extension *Buckman*, in resolving the preemption issue. R at 28; *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). *Garcia* involved an immunity exception provision nearly the same as one of the immunity exceptions at issue here (21 U.S.C. §630.546(b). The pertinent exception in Garcia provides that state-recognized immunity may be overcome "if the manufacturer intentionally withheld or misrepresented material information concerning the drug that is required to be submitted under the FDCA and the drug would not have been approved, or approval would have been withdrawn if the information was accurately submitted to the FDA." *Id* at 964. The court in Garcia acknowledged that the plaintiff's claims were not solely based on allegations of fraud-on-the-FDA, as was the case in Buckman where the claims were preempted by the FDCA, but nevertheless determined that the Buckman analysis should apply. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 966 (6th Cir. 2004). *Garcia* considered both the concern for a state's authority to govern its citizens and the FDA's responsibility to police fraud in line with the Agency's judgment and goals, then came up with a solution that was beneficial to each objective. *Id*. *Garcia* agreed with *Buckman's* reasoning "that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims," but also acknowledged that it is not reasonable for *Buckman* to preempt the exemptions in all applications. *Id*. The court in Garcia concludes that "exceptions on the basis of state court findings of fraud on the FDA are preempted" because that type of proceeding lies under the authority of the FDA; however, when the FDA itself determines that a fraud has been committed on the agency, then a state claim can be brought in reliance on the federal finding. *Id*.

In the case at hand, Respondent its attempting to rely, in part, on the immunity exception in subsection (b) of Transylvania's product liability statute, which negates a manufacturer's immunity if "the manufacturer intentionally withholds from or misrepresents information about the medical device that was required to be submitted under the FDCA, and the drug or medical device would not have been approved, or approval would have withdrawn approval for the drug or medical device if the information were accurately submitted. 21 Trans. Comp. Stat. § 630.546(b). This exception is nearly identical to the provision in *Garcia*, so the Court should apply the holding from *Garcia*. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 964 (6th Cir. 2004). The FDA has already declined to pursue any further action against Petitioner, which means that the FDA did not conclude that any fraud had been committed against the agency. R at 7. Similarly, the exception in subsection (c) requires a finding of violation against the FDA, which lies under the authority of the FDA. Respondent has not presented any evidence, because no such evidence exists, of findings by the FDA that Petitioner committed fraud or violations against the FDA. Without a determination of fraud or violation by the FDA, Respondent is essentially relying on her state court proceeding to find evidence of fraud against the FDA and evidence of violations of FDA requirements, which is a determination that lies under the authority of the FDA. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 966 (6th Cir. 2004) The immunity exception under subsections (b) and (c) cannot be overcome without a finding of fraud or violation by the FDA, which has not occurred in this case; therefore 21 Trans. Comp. Stat. § 630.546(b)-(c) is clearly preempted by the FDCA.

C. Petitioner's Motion to Dismiss Should be Granted Because Respondent Cannot Overcome Immunity

The appellate court incorrectly determined that Respondent alleged sufficient facts to rebut the presumption that Sleepternity complied with FDA requirements when it was approved by the

FDA and therefore, Petitioner's motion to dismiss Respondent's state claims should still be denied. R at 32. To support this conclusion, the appellate court relies on *Ashcroft v. Iqbal*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). *Ashcroft* is a well-known Supreme Court case that requires a plaintiff's "complaint to contain factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* While this is certainly an applicable case, the appellate court failed to recognize that the Respondent has not presented sufficient facts, given the circumstances in this case. The appellate court should have looked to a case that specifically addressed a plaintiff's ability to plead sufficient facts to overcome an agency decision, such as *Marsh v. Genentech, Inc.*, 693 F.3d 546 (6th Cir. 2012).

The appellate court argues that *Marsh* should not apply because the manufacturer in *Marsh* never changed the drug that had been approved by the FDA, whereas in the case at hand, Petitioner made changed to Sleepternity after it was approved by the FDA. R at 34. Although the drug in Marsh was never altered, the plaintiff's "complaint alleges that the manufacturer intentionally and negligently *failed to update* the application with *new information about the product* that would affect the statement of contraindications, warnings, precautions, or adverse reactions." *Marsh v. Genentech, Inc.*, 693 F.3d 546, 552 (6th Cir. 2012) (emphasis added). This language in *Marsh* about "*failing to update* with *new information"* is suggestive of a change occurring after FDA approval and therefore, *Marsh* should inform the Court's decision regarding the sufficiency of Respondent's alleged facts. In *Marsh*, the plaintiff alleged that a drug manufacturer "made multiple material misrepresentations to the FDA, falsely and deceptively reporting that the drug was safe for continuous usage," thus fraudulently obtaining approval by the FDA. *Marsh v. Genentech, Inc.*, No. 1:11-CV-688, 2011 WL 5089467, at *1 (W.D. Mich. Oct. 26, 2011), aff'd, 693 F.3d 546 (6th Cir. 2012). The court in *Marsh* recognized that the state considers a drug "not defective or

unreasonably dangerous" if it has been approved by the FDA, so the plaintiff must overcome the immunity statute in order to bring a claim of noncompliance. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 555 (6th Cir. 2012).

Although Respondent alleges that Sleepternity was not in compliance with FDA requirements for approval, or that Sleepternity became noncompliant when it changed a material included in manufacturing, Sleepternity is presumed to be in compliance because it was approved by the FDA. 21 Trans. Comp. Stat. § 630.546(a). As discussed in the previous section, the Respondent is not able to overcome Petitioner's state recognized immunity and therefore, Transylvania's product liability statute prevents Respondent from being able to bring a claim of noncompliance. *Id*.

II. THE RELATOR CANNOT RELY ON FRAUD ON THE FDA THEORY TO SERVE AS A VALID BASIS FOR BRINGING AN FCA CLAIM, UNDER THE ACT'S *QUI TAM* PROVISION.

A. The Court incorrectly relied upon the Ninth Circuit's Decision in Campie to determine the question of reliance upon the fraud on the FDA theory to bring a FCA claim.

The Respondent, here, argues that since CMS began to provide coverage to individuals who were prescribed Sleepternity for the costs of using the device, due to the fact the device was approved for marketing by the FDA, the idea that the device fraudulently obtained approval constitutes a False Claims violation for such reimbursements. The District Court in the case at hand was correct in asserting that the Respondent may not rely on fraud on the FDA theory to serve as a valid basis for bringing an FCA claim. R. at 24. Further, the Court of Appeals incorrectly relies upon the Ninth circuit's decision in *United States ex rel. Campie v. Gilead Scis*., 862 F.3d 890, 907 (9th Cir. 2017) as the relevant comparative case to determine the validity of the

Respondent's claims in the present case. R. at 36. The Ninth circuit in *Campie*, relies on the "implied false certification theory" which provides that when a "defendant submits a claim that it impliedly certifies compliance with all conditions of payment, can be a basis for liability under the False Claims Act (FCA), at least where two conditions are satisfied: (1) the claim does not merely request payment, but also makes specific representations about the goods or services provided; and (2) the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths; abrogating *U.S. v. Sanford–Brown, Ltd*., 788 F.3d 696. 31 U.S.C.A. § 3729(a)(1)(A)*." Universal Health Servs., Inc. v. United States, 579 U.S. 176, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016); See generally,* 31 U.S.C.A. § 3729.

1. Campie Provides A Weaker Factual Comparison To The Present Case Compared To D'Agostino.

The Court's reliance on *Campie* was due to the Ninth Circuit's discussion of *Escobar* which helped determine that the relator's reliance on the implied false certification theory, led them to allege sufficient facts to state a claim for relief under the FCA which is plausible on its face." R. at 36. The Court upholds *Campie's* analysis since *Campie* applies *Escobar's* 'clarifications of the FCA to another case similar to Campie" R. at 36. However, the Ninth Circuit decision is arguably a weaker comparison to the case at hand in comparison to the *D'Agostino* case. For instance, the Respondent in *Campie* never acknowledged or notified the FDA regarding the test results or adulteration issues. *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 896 (9th Cir. 2017) Despite becoming aware of such manufacturing problems with the Synthetics China products, the Respondent allegedly released said products to its respective contract manufactures prior to FDA

approval of the Synthetics China facility. *United States ex rel. Campie v. Gilead Scis*., 862 F.3d 890, 896 (9th Cir. 2017).

Campie illustrates a circumstance where fraudulent activity was evident prior to any FDA approval being granted to the Respondent, whereas in the present case, the Petitioner's alleged fraudulent conduct occurred after FDA approval of the Sleepternity device. This distinction is critical because the Petitioner in the present case had acquired FDA approval and only then changed their device, but even so, there is no evidence to indicate that Mednology was aware of any defects within their specific products that would compromise the integrity of their product. R. at 7. Conversely, in *Campie* the Respondent had sold the alleged faulty products with the knowledge that those products were defective. (*United States ex rel. Campie v. Gilead Scis*., 862 F.3d 890, 896-97 (9th Cir. 2017). Thus, despite its use of Escobar's principles, the factual circumstance in *Campie does* not serve as the most relevant analogy to the present case.

B. The Court Should Have Relied Upon the First Circuit's Decision In D'Agostino To Determine The Casual Link Requirement Of The Implied-False Certification Theory.

In *D'Agostino v. ev3*, Inc., 845 F.3d 1(2016), the relator brought a False Claims Act action against the defendant corporation which "discovered, developed, manufactured, and marketed medical devices. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 3 (2016). The defendant in *D'Agostino* sought FDA pre-market approval for Onyx (an artificial liquid material used to treat malformed blood vessels in the brain). *Id.* Here, the FDA approved the Onyx label but in restricted circumstances. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 4 (2016). Further, the FDA had not withdrawn its approval of Onyx, which was similar to the FDA's actions in the present case where the FDA did not withdraw approval for Sleepternity. R. at 7. Thus, *D'Agostino* serves as a more relevant situation

to the case at hand, compared to *Campie* based upon the similarities of the factual circumstances as well as the fundamental issues the courts focused upon in each case. *Id.*

1. The causal link requirement is critical to determining the materiality requirement of the implied-false-certification theory.

The impact of the alleged fraudulent inducement claims here cause the First Circuit to consider not only the materiality, but also the causation elements of this analysis. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 8 (2016). This means that the defendant's conduct must "cause the government to make a payment or to forfeit money owed." *D'Agostino*, 845 F.3d 1, 8 (citing *United States ex rel. Westrick v. Second Change Body Armor Inc.*, 128 F. Supp. 3d 1, 18 (D.D.C. 2015); *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005)). For instance, if the FDA would have approved the defendant's medical device notwithstanding the alleged fraudulent representations, then the causal connection between the fraudulent representations to the FDA and CMS's payment that is contingent on FDA approval disappears. *Id.* Since the FDA did not demand either recall or relabeling of Onyx in the six years since the relator alleged the defendant's fraudulent conduct, the First Circuit concluded that the FDA's failure to withdraw its approval of Onyx foreclosed the relator's ability to base his FCA claim on the assertion that the FDA's approval was fraudulently obtained. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 8 (2016). Thus, the causal link fails to become established without FDA action which inherently precludes the recognition of materiality in such situations. *Id*.

2. D'Agostino provides critical policy considerations that uphold the FDA's authority when making determinations regarding the casual link in the fraud-on-the-FDA theory.

The D'Agostino case applies critical policy considerations for the why the fraud on the FDA theory may not be utilized in such cases were the FDA failed to withdraw approval of the device

in question. *Id.* The First Circuit explain that "to rule otherwise, would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely ne withdrawn from the market even when the FDA sees no reason to do so."(*Id*.) Essentially, the First Circuit advocates for the FDA to maintain its purpose and authority to render such expert decision to determine factual issues and their supposed effect upon original conclusions. *Id*.; See *also* King v. Collagen Corp., 983 F 2d 1130, 1140 (1st Cir. 1993). Furthermore, the impact of allowing juries within qui tam actions to find causation by determining FDA judgment when the FDA has not spoken on those matters is similar to the practical implications that lean in favor of not allowing state-law fraud on the FDA claims. *Id*.; See also *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 349-51, 121 S.Ct. 1012, 148 L.E.2d 854 (2001). For the case at present, allowing a relator to rely upon the Fraud- on-the-FDA theory to bring a FCA claim may deter certain actors from bringing such claims for fear of violating the FCA; or may overwhelm the FDA with large 'data dumps' stemming from overly cautious actors seeking approval for a new product/device. *D'Agostino v. ev3*, Inc., 845 F.3d 1, 8 (2016).

C. The Court Should Apply The First Circuit's Causal Link Requirement In Coordination To With Escobar's Clarification Of The Materiality Requirement To Uphold The Petitioner's Motion To Dismiss.

Since the importance of the First Circuit's causal link requirement was previously discussed, the following discussion emphasizes the impact of both requirements with respect to the Petitioner's motion to dismiss the Respondent's FCA claim. The Court of Appeals correctly emphasizes *Escobar's clarifications* as influential to the discussion of the materiality requirement. However, as previously mentioned, the Court of Appeals incorrectly emphasized *Campie's* application of the law because the analysis within *Escobar* suffices in relevance to the present case.

See United Health Services, Inc., v. U.S., 579 U.S. 176 (2016). Ultimately, when determining the materiality requirement under the FCA, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* 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." *United Health Services, Inc., v. U.S., 579 U.S. 176, 195-96 (2016*). Further, if the Government does pay a certain claim in full, without its actual knowledge that requirements were violated, this indicates strong evidence that those requirements were not material. *United Health Services, Inc., v. U.S., 579 U.S. 176, 196 (2016*). Additionally, if the Government regularly pays a particular type of claim in full, notwithstanding knowledge that requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material. *Id*. Essentially, "the government's decision to withdraw payment for the defendant's product must be based on the defendant's violation of a particular requirement that serves as a condition for payment." R. at 39. Here, the materiality requirement would have to be proved by some showing that CMS withdrew its coverage of Sleepternity based on the Petitioner's nondisclosure of the change in material within the device. However, based upon the definitions proscribed in *Escobar* and the fact that CMS had not withdrew its coverage of Sleepternity at any point prior to the Petitioner's own actions in recalling the product from the market upon notice of the Respondent's summons; it arguably does not appear that nondisclosure of the utilization of the PE-PUR foam would be considered material.

1. The Petitioner's motion to dismiss the Respondent' FCA claim should be upheld.

The Dissent draws a note to the establishment of the casual link between a "defendant's conduct of fraudulently completing a requirement for receiving payment and a government's decision withdraw payment upon discovering such fraud is necessary for satisfying the materiality requirement clarified in *Escobar."* R. at 39-40. While the Dissent raises an important consideration to understanding the relationship between the materiality and causal link requirements, like the Court of Appeals, it is incorrect to reverse the district court's decision to grant the Petitioner's motion to dismiss the Respondent's FCA claim. Based on *D'Agostino's* discussion of the causal link standard, the court holds that "absence of official action by the FDA establishing such causation leaves a fatal gap in such proposed complaints." *D'Agostino v. ev3*, Inc., 845 F.3d 1, 9 (2016). The Court declines to decide whether the gap may be sufficiently sustained by official FDA comment upon the matter. *Id*. However, lack of FDA action in withdrawing the device in question, precludes a causal link from being established. *See generally, D'Agostino v. ev3*, Inc., 845 F.3d 1, 9-10 (2016).

Thus, the lack of a causal link and arguably no materiality requirement met, means that the District Court's decision to grant the Petitioner's motion to dismiss the Respondent's FCA claim should be upheld. Despite the Court of Appeals and Dissent's reliance on *Campie's* discussion that the materiality requirement involved "the matter of proof rather than a legal ground to dismiss a relator's complaint"; the First Circuit's analysis in D'Agostino correctly upholds the authority of the FDA's to guide decisions surrounding causal link determinations, such that these causal links are shown by removal of the product from the market. Thus, the Petitioner's motion to dismiss the Respondent's FCA claim should be sustained.

CONCLUSION

Respondent's state claims which rely on exceptions to Transylvania's product liability statute are preempted by federal law, specifically the FDCA, which governs FDA-related matters. Since there is no FDA finding of fraud or violation to support the exceptions, Petitioner's immunity cannot be overcome, and the Court should grant Petitioner's motion to dismiss Respondent's state law claims. The Respondent wishes to rely upon the fraud-on-the-FDA theory to bring a FCA claim against the Petitioner under the Acts *qui tam* provision. The Court should not allow the Petitioner to rely on the theory under the FCA *qui tam* provision since she does not meet the materiality and causal like requirements under the implied false certification theory. The Court may find for this holding by considering the causal link analysis from *D'Agostino* and the materiality certification requirements from *Escobar* described above. Accordingly, the Court should uphold the Petitioner's motion to dismiss Respondent's FCA claim and REVERSE the Court of Appeals decision for this issue.

Respectfully submitted,

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ATTORNEYS FOR PETITIONER

MEDNOLOGY, INC.