Nos. 22-1491(L), 22-1492

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA and
COMMONWEALTH OF VIRGINIA,

Plaintiffs-Appellants,

v.

WALGREEN CO.,

Defendant-Appellee.

On Appeal from the United States District Court for the
Western District of Virginia, No. 1:21-CV-00032-JPJ

BRIEF OF *AMICI CURIAE* CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE AMERICAN MEDICAL ASSOCIATION, AND THE MEDICAL SOCIETY OF VIRGINIA IN SUPPORT OF APPELLEE AND AFFIRMANCE

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DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST

Under Federal Rule of Appellate Procedure 26.1 and Local Rules 26.1(a)(2)(A) and (a)(2)(C), the Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent entity, and no publicly held corporation or similarly situated legal entity has 10% or greater ownership in the Chamber.

The American Medical Association ("AMA") and the Medical Society of Virginia state that they are each non-profit entities, that they have no parent entities, and that no publicly held corporation or similarly situated legal entity has 10% or greater ownership in them.

Under Local Rule 26.1(a)(2)(B), the Chamber, the AMA, and the Medical Society of Virginia certify that they are unaware of any publicly held corporation or similarly situated legal entity, other than those listed in Defendant's corporate disclosure statement, that has a direct financial interest in the outcome of the litigation by reason of a franchise, lease, other profit sharing agreement, insurance, or indemnity agreement.

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INTERESTS OF AMICI CURIAE

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber often files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

The False Claims Act (FCA) contains *qui tam* and treble damages provisions that create a well-documented potential for abusive litigation that harms businesses and other potential defendants. The FCA's "materiality" standard helps to temper that potential for harm and abuse by ensuring that plaintiffs may not sue for every minor or legally insignificant misrepresentation that they can conjure. The Chamber accordingly has a strong interest in ensuring that the FCA's "demanding" materiality standard is enforced fully and consistently in accordance with Supreme Court precedent.

The objectives of the American Medical Association ("AMA") and its constituent association, the Medical Society of Virginia ("MSV," and together,

"AMA *amici*") are to promote the science and art of medicine and the betterment of public health. The AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA policy making process. The MSV represents the Commonwealth's physicians, residents, PAs and medical students. The MSV also participates in the AMA House of Delegates. Together, AMA *amici* represent tens of thousands of healthcare providers in Virginia and across the country. The AMA and MSV submit this brief on their own behalf and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

AMA *amici* have a strong interest in ensuring that patients covered under Medicaid receive the benefits to which they are legally entitled, and they are concerned with the effect that reversal in this case would have on state-federal healthcare programs. AMA *amici* oppose prior authorization requirements like the ones Virginia imposed in this case, which AMA *amici* conclude restrict access to essential medications for patients living with hepatitis C infections based on cost

rather than medical or health-based considerations. As a result of restrictions like these in Virginia and other states, it is the official policy of the AMA to "advocate, in collaboration with state and specialty medical societies, as well as patient advocacy groups, for the elimination of sobriety requirements, fibrosis restrictions, and prescriber restrictions for coverage of [hepatitis C] treatment by public and private payers." AMA Policy Statement, *Advocacy for Hepatitis C Virus Education, Prevention, Screening and Treatment H-440.845* (2022), https://bit.ly/3xUyQBu. In a recent resolution, the AMA House of Delegates surveyed the medical evidence and concluded that "there are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete [hepatitis C] therapy" and "that initiating therapy in patients with lower-stage fibrosis augments the clinical and public health benefits of virologic cure, and treatment delay may decrease the benefit of virologic cure."[1]

AMA *amici* believe that the government's arguments in this case not only run afoul of the FCA's materiality requirement, but are contrary to Medicaid's goal of providing prescription drug coverage to needy citizens. The government's argument that an FCA defendant cannot assert the illegality of a funding condition

[1] AMA House of Delegates, Resolution 216 (A-22) (2022), https://bit.ly/3raTz0c; *see also* AASLD/IDSA, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis* (Nov. 6, 2019), https://bit.ly/3Sul5Ba.

effectively means that states that impose unlawful conditions on the receipt of Medicaid assistance are entitled to keep their ill-gotten gains (and in fact treble them). Accepting those arguments would incentivize governments to impose illegal funding conditions, with the consequence of denying care to patients who depend on Medicaid. Relatedly, AMA *amici*, like the Chamber, have a strong interest in enforcing the FCA's rigorous materiality standard, as their members are sometimes defendants in FCA suits, and it is both unfair and improper to impose punitive treble damages liability in cases where the statute's materiality standard has not been satisfied.

All parties have consented to the filing of this brief. No party's counsel authored the brief in whole or in part, and no entity or person, other than *amici*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In an effort to control its Medicaid costs, the Commonwealth of Virginia previously imposed a prior authorization regime that purported to restrict patients' eligibility to receive certain hepatitis C medications. As the district court held, and as the Department of Health and Human Services itself has opined, Virginia's requirements (which Virginia has since abandoned) violated federal law. Appellee Walgreen Co. ("Walgreens") explains in its response brief why that conclusion was correct.

Amici submit this brief to underscore what necessarily follows from that conclusion: the government may not profit, via the mechanism of a False Claims Act lawsuit, from a violation of federal law. Because federal law in fact entitled Walgreens to reimbursement for every hepatitis C treatment at issue here, the government may not sue Walgreens for treble damages under the FCA on the basis of those reimbursements. False statements that an individual Walgreens employee made to comply with Virginia's unlawful requirements cannot be "material," because the law required the government to disregard those requirements (and thus disregard the false statements as well). As the Supreme Court has emphasized, the FCA's materiality requirement is "rigorous" and "demanding," and it requires plaintiffs to allege that the misrepresentation at issue "went to the very essence of the bargain." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579

U.S. 176, 192, 193 n.5, 194 (2016) (citation omitted); *accord United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 190 (4th Cir. 2022). But when, as here, the alleged false statement concerns a requirement that is legally null and void, that requirement cannot form *any* part of the bargain, much less its "essence."

The United States and Virginia (together, the government)[2] do not meaningfully dispute that conclusion. They do not cite or discuss *Escobar*, the seminal decision on the FCA's materiality element. Instead, relying primarily on 50-year-old criminal cases, they ask this Court to construct a "no collateral attack" rule that prohibits Walgreens from raising the legality of Virginia's Medicaid restrictions in this suit. But the government's criminal cases did not apply such a rule. They involved challenges to an entire statutory program—the equivalent of Walgreens arguing that the Medicaid program itself is unconstitutional. They neither asked nor answered the question here: whether false statements relating to specific unlawful reimbursement requirements are material to a reasonable government decisionmaker, in the context of a reimbursement transaction that is otherwise *lawful*.

Nor should an approach developed in the criminal context govern interpretation of the FCA, a civil statute. As this Court has "reiterat[ed]," the

[2] Virginia adopts the United States' arguments concerning the FCA's materiality element, *see* Va. Br. at 1, so *amici* focus on the United States' brief.

"primary purpose of the FCA [is] making the government completely whole." *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 408 (4th Cir. 2013). Because Virginia's requirements were unlawful, the government suffered no loss at all; it is already whole. No one paid more than they were legally obligated to pay; and Walgreens received nothing more than what it was owed. That is not a scenario in which the FCA's draconian treble damages remedy applies, nor was it intended to do so. To hold otherwise would create fundamental unfairness for FCA defendants in a wide range of cases involving unlawful payment conditions, effectively relieving the government of its burden to prove materiality in such cases.

Enforcing the FCA's materiality standard does not leave the government without options to combat false statements in situations like the scenario alleged here. It just requires the government to proceed in the right manner against the right defendant. Here, the government did exactly that when it criminally prosecuted the Walgreens employee who lied on forms and falsified laboratory test results to satisfy Virginia's unlawful requirements, and who pleaded guilty to health care fraud under 18 U.S.C. § 1347. The government erred, however, when it took the added step of seeking to piggy-back on that criminal prosecution by pursuing treble damages for losses that it never suffered against an employer, Walgreens, which received only what it was owed.

ARGUMENT

I. The District Court Correctly Applied the FCA's "Demanding" Materiality Standard

For the reasons explained in Walgreens' brief, the district court correctly interpreted Section 1927 of the Social Security Act to hold—consistent with the Department of Health and Human Services' own interpretation of the statute—that Virginia's pre-authorization requirements were unlawful. Op. 25-26. That conclusion compels the dismissal of the government's FCA and related claims: false statements made to comply with an unlawful requirement cannot be material as a matter of law.

A. The FCA's "Demanding" Materiality Standard Precludes Liability for False Statements Made to Comply With Unlawful Provisions

The FCA imposes liability only for false statements that are "material." *Escobar*, 579 U.S. at 192. The statute defines "material" misrepresentations as those "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), which means that, for a false statement to satisfy the materiality element, it must go "to the very essence of the bargain," *Escobar*, 579 U.S. at 193 n.5 (quoting *Junius Constr. Co. v. Cohen*, 178 N.E. 672, 674 (N.Y. 1931)).

The Supreme Court has emphasized that the FCA's materiality standard is "demanding" and "rigorous." *Escobar*, 579 U.S. at 192, 194. The high materiality bar serves to "ensure that the False Claims Act does not become 'an all-purpose

antifraud statute or a vehicle for punishing garden-variety breaches of contract.'" *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017) (quoting *Escobar*, 579 U.S. at 194); *see also United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1169 (10th Cir. 2016) (adopting "the materiality requirement as a means to determine which instances of noncompliance [with applicable statutes or regulations] are covered by the FCA").

The limiting function of a materiality element is particularly important in the FCA context, where the statute's treble damages and *qui tam* provisions provide a "strong financial incentive" for relators to bring FCA suits on behalf of the government. *See United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006) ("Rule 9(b) ensures that the relator's strong financial incentive to bring an FCA claim—the possibility of recovering between fifteen and thirty percent of a treble damages award—does not precipitate the filing of frivolous suits.").

To assess the materiality of a false statement, courts must look "to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 579 U.S. at 193 (citation omitted). As this Court has recognized, materiality requires the court to examine how the misrepresentation would affect a "reasonable man . . . determining his choice of action in the transaction in question." *United States v. Raza*, 876 F.3d 604, 621 (4th Cir. 2017) (quoting

Escobar, 579 U.S. at 193); *see also Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 459 (2013) ("materiality is judged according to an objective standard").

In this case, the proverbial "reasonable person" is a reasonable Medicaid employee reviewing Walgreens' claims for reimbursement. *United States ex rel. Am. Sys. Consulting, Inc. v. ManTech Advanced Sys. Int'l*, 600 F. App'x 969, 974, 976 (6th Cir. 2015) (emphasizing that materiality inquiry focuses on a "reasonable government decision-maker"); *see Raza*, 876 F.3d at 620-21. That reasonable employee is presumed to follow federal law. "It is a general principle to presume that public officers act correctly until the contrary be shown." *Ross v. Reed*, 14 U.S. 482, 486 (1816); *see Almy v. Sebelius*, 679 F.3d 297, 309 (4th Cir. 2012) ("The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties." (quoting *United States v. Chem. Found.*, 272 U.S. 1, 14-15 (1926))). Indeed, the "reasonable person" is the epitome of a law-abiding citizen, often *defining* the applicable legal standard. *See, e.g.*, *Parrot v. Wells, Fargo & Co. ("The Nitro-Glycerine Case")*, 82 U.S. 524, 536 (1872) ("'Negligence' has been defined to be 'the omission to do something which a reasonable man, guided by those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and

reasonable man would not do.'"). It would be odd indeed to hold, in the context of a statute aimed at deterring violations of federal law, that the reasonable government employee is one who disregards federal law. *See id.*

Applying the reasonable person materiality standard here compels affirmance. If the government's practice of not enforcing a particular statutory requirement "is very strong evidence that those requirements are not material," *Escobar*, 579 U.S. at 195, then the conclusion that a requirement is *unenforceable* constitutes definitive evidence that the requirement is not material. The materiality question here is thus far easier than the one presented in *Escobar*. There, the Court explained that it is not "*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.* at 194 (emphasis added); *accord Boyko*, 39 F.4th at 194-95 ("[W]hile [plaintiff] has plausibly alleged that compliance with certain state-law requirements was a condition of payment, that alone is insufficient to plead materiality with particularity."). But surely it is *necessary* to a finding of materiality that the government had the legal option of declining to pay on the basis of the false statement. In this case, however, the government had no such option. "[T]he False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations," *Escobar*, 579 U.S. at 196, and violation of a void requirement is definitionally not "significant."

The materiality test that the government itself proposed in *Escobar* would exclude liability in this case. The government's position was "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be *entitled* to refuse payment were it aware of the violation." *Escobar*, 579 U.S. at 195 (emphasis added). This test cannot be satisfied when the government's withholding of payment is in fact unlawful. And here, Virginia's attempt to restrict the ability of sick patients to receive hepatitis C medication was at all times "void, and … as no law." *Ex parte Siebold*, 100 U.S. 371, 376 (1879); *see, e.g.*, *Cantero v. Bank of Am., N.A.*, No. 21-400, 2022 WL 4241359, at *6 (2d Cir. Sept. 15, 2022) (when a state law conflicts with federal law, "the law of [the state] is from the nature of things inoperative and void" (quoting *Davis v. Elmira Sav. Bank*, 161 U.S. 275, 283 (1896)).

Because Virginia's restrictions were unlawful, an individual employee's false statement relating to those restrictions could not have affected a reasonable Medicaid employee's decision to reimburse for a prescription.

B. The Government's Arguments Misconstrue the FCA's Materiality Test

The government barely engages with the law of materiality. *See* U.S. Br. 21-24. It fails to cite—much less discuss or attempt to distinguish—*Escobar*, the Supreme Court's leading case on the law of FCA materiality. *See* 579 U.S. at 194. Instead, the government primarily argues (at 22-38) that Virginia's requirements

were in fact lawful, a position that the district court thoroughly debunked. If the government's silence on *Escobar* indicates its position that this case turns on the legality of Virginia's Medicaid restrictions, then *amici* agree.

To the extent the government addresses the FCA's materiality element directly, it does not apply anything resembling *Escobar*'s standard. Instead, the government asserts, without further elaboration, that the Walgreens employee's statements were material because, "[i]n the absence of Walgreen's alleged fraudulent conduct, the prescriptions would not have been reimbursed by the government." U.S. Br. 23. But as courts have noted, arguments of this kind "conflate[] materiality with causation, a separate element of a False Claims Act cause of action." *See Petratos*, 855 F.3d at 491. That the Walgreens employee's false statements may have caused Virginia to approve reimbursements does not mean the statements were material to the *reasonable* Medicaid employee who follows the law. *See id.*

Nor can the government evade *Escobar*'s materiality requirement by making assertions about knowledge. *Compare* U.S. Br. 23 (emphasizing "knowingly" requirement in materiality section), *with Thomas*, 820 F.3d at 1172-73 ("[E]ven if [defendant] violated the Contract by altering educational documents for its employees, the undisputed facts show that the violation was not material to

USAID's payment decisions."). Scienter and materiality are distinct elements in the FCA. *Boyko*, 39 F.4th at 188.

II. Enforcing the FCA's Materiality Standard Is Not a Prohibited "Collateral Attack"

Instead of engaging with *Escobar* and its progeny, the government asks this Court to ignore materiality altogether. Specifically, it argues that this Court should invent an exception to the FCA's materiality requirement and hold that Walgreens cannot raise the invalidity of Virginia's coverage exclusions in a so-called "collateral attack." U.S. Br. 16-21. The Court should decline to do so. The government's proposed exception is found nowhere in the statute's text, is inconsistent with basic background principles of law, and is not compelled by any of the precedent the government cites. The government's criminal cases are distinguishable on their face and inapplicable in the civil FCA context. And the few civil cases that it cites are either inapposite, unpersuasive, or both.

A. The FCA's Text and Background Interpretive Principles Preclude the Government's "Collateral Attack" Theory

The text of the FCA is clear: proof of materiality is always required. *See Escobar*, 579 U.S. at 191. Nothing in the FCA purports to alter the usual rule that the plaintiffs bear the burden of proving each element of their case, including by establishing that a false statement could have influenced a reasonable government decisionmaker. Nor does anything in the statute purport to limit the arguments that

defendants may offer in their own defense. The government does not argue otherwise.

In fact, the basic common-law principles on which the FCA draws refute the government's argument that courts must assume the validity of unlawful payment conditions in assessing FCA materiality. That argument runs headlong into the longstanding rule that unlawful contractual provisions are void and unenforceable. *See Kaiser Steel Corp. v. Mullins*, 455 U.S. 72, 77 (1982) ("illegal promises will not be enforced in cases controlled by the federal law"); *id.* at 83 ("a federal court has a duty to determine whether a contract violates federal law before enforcing it"). Courts accordingly will not enforce contractual provisions that violate the law or are contrary to public policy. *See, e.g.*, *Pryor v. Nat'l Collegiate Athletic Ass'n.*, 288 F.3d 548, 569 (3d Cir. 2002) ("A contract term or condition that violates public policy is void and is thus unenforceable."); *RLM Commc'ns, Inc. v. Tuschen*, 831 F.3d 190, 198 (4th Cir. 2016) ("Because the Noncompete is unenforceable and cannot be mended by blue-penciling, the district court properly dismissed the associated claim for breach of contract."); *see also Weil v. Neary*, 278 U.S. 160, 167 (1929) ("[W]e are of opinion that the contract sued on is clearly contrary to public policy and does not sustain the challenged judgment.").

In each of these cases, the party later challenging the contractual provision as void had previously agreed to comply with that provision. But that fact was

irrelevant. It is "long established in the jurisprudence of both this country and England, that a court will not lend its aid, in any way, to a party seeking to realize the fruits of an agreement that appears to be tainted with illegality," as the government is attempting to do here. *See Continental Wall Paper Co. v. Louis Voight & Sons Co.*, 212 U.S. 227, 262 (1907). Because Virginia's coverage exclusions for hepatitis C patients were invalid, the general rule in civil cases is that this Court should not enforce them.

Lacking any textual hook or common-law precedent for enforcing unlawful requirements in a fraud lawsuit, the government argues, in essence, that it is bad policy to allow defendants to challenge a regulation in an FCA lawsuit. *See* U.S. Br. 20-21. If anything is bad policy, though, it is a legal rule that would allow the government to decline to bring an administrative recoupment action for overpayment—where Walgreens would of course have been permitted to explain that it received no overpayment—and then pursue treble damages instead while prohibiting Walgreens from defending itself. A legal rule of this kind would provide windfalls to both the government and private relators in a wide array of FCA suits founded on illegal payment requirements. *Cf. United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 383 (4th Cir. 2008) (holding that relators may not use the FCA to avoid contractual provisions). More to the point, however, "policy arguments cannot supersede the clear statutory text."

Escobar, 579 U.S. at 192. The FCA requires materiality. That should end the matter.

B. The Government's Criminal Cases Do Not Require Courts to Disregard Valid Materiality Arguments

None of the decades-old Supreme Court cases the government cites use the term "collateral attack." *See* U.S. Br. 16-18 (citing *United States v. Kapp*, 302 U.S. 214 (1937); *United States v. Knox*, 396 U.S. 77 (1969); *Kay v. United States*, 303 U.S. 1 (1938); *Dennis v. United States*, 384 U.S. 855 (1966); *Bryson v. United States*, 396 U.S. 64 (1969)). Nor do these cases undercut the district court's application of the FCA's materiality element in this case. Rather, even assuming that those criminal cases apply in the civil context (as explained below, that proposition is dubious), they are readily distinguishable.

Fundamentally, the government's cases do not apply here because they do not analyze materiality under the *Escobar* standard; that is, they do not engage with the importance of the alleged misrepresentation *to the transaction at issue*. *See Escobar*, 579 U.S. at 194. They instead dealt with defendants who challenged the validity of an entire statutory scheme. None of the defendants argued, like Walgreens here, that the misrepresentation was immaterial because the transactions at issue would necessarily have proceeded anyway. To the contrary, successfully pressing such challenges would have invalidated every reimbursement or other transaction under the statutory scheme.

The Government's lead case is *Kapp*, which illustrates this distinction nicely. *Kapp* involved the defendants' conspiracy "to cheat the United States by selling hogs to the government at premium prices" under the Agriculture Adjustment Act ("AAA") based on misrepresentations about the hogs' origin and ownership. 302 U.S. at 215. After the Supreme Court held (in a different case) that the entire AAA was unconstitutional,[3] the defendants argued that their representations about the origin of the hogs "cease[d] to be a material fact, [because] the provisions of the [AAA] are void." *Id.* at 216. The Supreme Court rejected that reasoning, explaining that the fact that "the statute providing for [particular] claims and payments is found to be invalid" does not immunize an "attempt to defraud the United States by obtaining the approval of claims and benefit payments through false representations." *Id.* at 217.

The constitutional argument the defendants offered in *Kapp* had nothing to do with their false statements. They did not contend that misrepresentations about the origins of their hogs were immaterial because compensation was required regardless of the origins of their hogs. Quite the opposite; their argument that the entire "statute providing for [AAA] claims and payments" was "invalid" was an additional reason they were *not* entitled to compensation, rather than a reason why

[3] *See United States v. Butler*, 297 U.S. 1, 78 (1936).

a reasonable government employee would have approved the transaction at issue. *See id.*

Walgreens' argument is one the *Kapp* defendants never made: Walgreens contends that its alleged misrepresentations were immaterial on the theory that the reimbursements were in fact *valid*—i.e., that a reasonable person would have approved the "transaction[s]" at issue regardless of the misrepresentations. *Escobar*, 579 U.S. at 193. Put differently, Walgreens argues that the alleged misrepresentation could not have prompted a reasonable person to approve rather than disapprove the "transaction" at issue. *Id.* The invalidity of Virginia's coverage exclusions means that Walgreens' Medicaid reimbursements were valid and lawful transactions: Walgreens' patients were legally entitled to coverage for the medications that doctors prescribed, and Walgreen was legally entitled to reimbursement for providing those medications. Neither this Court nor the Supreme Court has ever ruled that a defendant could be barred from raising such an argument.

The Supreme Court's decision in *Kay* likewise failed to address the "materiality" element of the crime and involved an attack on an entire statutory program rather than the particular requirement that was the subject of the misrepresentation. *See Kay*, 303 U.S. at 6 ("Petitioner's main argument is that the whole scheme of the statute is invalid; that Congress had no constitutional

authority to create the Home Owners' Loan Corporation—to provide for the conduct of a business enterprise of that character. There is no occasion to consider this broad question as petitioner is not entitled to raise it.").

The government's next case, *Knox*, did not discuss materiality at all. The defendant there had falsified information on a tax form relating to the number of employees involved in his gambling business. *Knox*, 396 U.S. at 78. He argued that he could not be prosecuted for lying because the statute requiring filing of the tax form violated his Fifth Amendment privilege against self-incrimination. *Id.* The Court simply held that fear of self-incrimination did not authorize the defendant to falsify documents, a holding that has nothing to do with this case. *Id.* at 80-84; *accord Bryson*, 396 U.S. at 72.

That leaves *Dennis*, which did not involve any materiality requirement and in any event turned on unique factual circumstances not present here. In *Dennis*, the defendant trade union officials were convicted of falsely certifying that they were not communists, a requirement they said was unconstitutional. Importantly, however, the fraud statute under which they were charged was 18 U.S.C. § 371. *See Dennis*, 384 U.S. at 860. Courts have held that "materiality is not an element of a section 371 offense," *United States v. Toussaint*, 84 F.3d 1406, 1407 (11th Cir. 1996), and *Dennis* accordingly did not hold that the defendants were barred from contending that the invalidity of the certification requirement rendered it

immaterial to any government payment (or other) decision. Rather, the Supreme Court noted that § 371 reaches conspiracies to defraud the United States "in any manner or for any purpose," not just frauds that result in government action or payment, and "is not confined to fraud as that term has been defined in the common law." 384 U.S. at 861. Moreover, *Dennis* noted that, at the time the defendants submitted their false certifications, the Supreme Court itself had just upheld the certification requirement against the same constitutional challenge. *Id.* at 867. The Court's ruling barring the defendants from raising the illegality of that requirement was confined to "circumstances like those before us," where the defendants made false statements about a requirement that "carrie[d] the fresh imprimatur of this Court" and the defendants had "flout[ed]" the Court's decision. *Id.*; *see also id.* at 865 n.11. No similar circumstances are present here.

Finally, in *Bryson*, the Court simply reiterated the holding in *Dennis*. The defendant did not raise any materiality defense, and the Court did not mention materiality. The Court rather simply noted that "none of the elements of proof necessary for petitioner's conviction … has been shown to depend on the validity of" the challenged statute. 396 U.S. at 68-69.

In sum, none of the Supreme Court cases on which the government relies involve an alleged fraud for purposes of obtaining a reimbursement that in fact was

valid and lawful.[4] For purposes of FCA materiality, that distinction makes all the difference. *See supra* § I. The Supreme Court has never held that defendants may be barred from pointing to the invalidity of a particular statutory requirement as a reason why the government has failed to meet its burden to show materiality.

C. The Government's Criminal Cases Are Inapplicable in the FCA Context

Even if the criminal cases on which the government relies were factually analogous to this case, this Court should decline to extend them to the FCA, a civil context that is fundamentally different. Tellingly, the government fails to identify a single Supreme Court decision applying a "no collateral challenge" argument in the context of a civil fraud claim.

The purposes of criminal law and the civil FCA differ in important ways. Criminal laws are inherently punitive. *See United States v. One Assortment of 89 Firearms,* 465 U.S. 354, 362 (1984) (contrasting "a forfeiture proceeding [that] is intended to be, or by its nature necessarily is, criminal and punitive" with one that is "civil and remedial"); *see also One Lot Emerald Cut Stones & One Ring v. United States*, 409 U.S. 232, 237 (1972) (similar). And while the civil FCA's treble damages and penalties are "essentially punitive" in nature, *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000), they also "have a

[4] Nor do the court of appeals cases the government cites. U.S. Br. 19 n.1.

compensatory side, serving remedial purposes in addition to punitive objectives," *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 130 (2003). That is, "the treble damages provision of the statute," in part, "account[s] for the fact that some amount of money beyond actual damages is 'necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims.'" *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 388 (4th Cir. 2015) (quoting *Cook Cnty.*, 538 U.S. at 130); *see also United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 408 (4th Cir. 2013) ("reiterat[ing]" that the "primary purpose of the FCA [is] making the government completely whole"); *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 734 (4th Cir. 2010) (purpose of the FCA is "to protect the government from loss due to fraud") (quotation marks omitted).

The compensatory aspect of the FCA's scheme illustrates why the government's criminal cases are inapplicable to the FCA. Both the United States and Virginia are already "whole" under any understanding of the term. *See Bunk*, 741 F.3d at 408. In contrast, the government's theory would allow it to recover payments that do not qualify as a "loss" at all. It argues that "a [FCA] defendant cannot submit false information to the government to obtain the payment of claims or other benefits and then challenge the underlying requirement to avoid liability for the fraudulent submission." U.S. Br. 14. But that position would allow the

recovery of treble damages for the "loss" of monies to which the government is not entitled—in other words, monies of which the government was not actually defrauded.

Accordingly, the government's argument does not serve any of the FCA's core purposes. Instead, reversal would confer a windfall on the government, which seeks to recover treble damages and civil penalties based on payments *it was legally obligated to make*. *See* Op. 37 ("The lack of materiality dooms this claim, along with a lack of resulting damage, given that the plaintiffs were obligated to pay the patients' claims for the relevant drugs."). In the same vein, Walgreens has not been unjustly enriched through its former employee's alleged crimes; it has received payment only for those prescriptions that were reimbursable under the statute, i.e., those to which it was lawfully entitled. And there is no need for additional deterrence in this case, because it is undisputed that Walgreens' former employee has been criminally punished (and served prison time) for her false statements. Nor is there a need to deter future misrepresentations concerning Virginia's *specific* pre-authorization provisions because—as explained by the district court—those requirements are a legal nullity, and Virginia has abandoned them in any event.

To the contrary, concerns about deterrence counsel strongly against a rule requiring courts to disregard valid materiality arguments. This case arises, as FCA

claims so often do, in the context of Medicaid, a program aimed at providing medical care, including prescription drug coverage, to needy citizens. Virginia denied vulnerable hepatitis C patients coverage based on "disease severity and alcohol and drug abstinence" conditions, U.S. Br. 14, which, as Walgreens explained, was not lawful. Adopting a rule that allows the government to reap the benefits of illegal funding conditions—"recovering" not only the costs of its illegally denied reimbursements, but treble damages—would only incentivize governments to impose illegal funding conditions more frequently in the future, and would also increase the risk of denial of care in cases where the law in fact requires the government to provide funding. No similar concern is present in the criminal context, where the government reaps no comparable pecuniary benefit from prosecuting an individual who has made a false statement.

In sum, any policy considerations that might support applying a judge-made rule about "collateral attacks" in the criminal context provide no such support in the FCA context. Such a rule would provide a windfall to governments by virtue of the imposition of unlawful payment conditions, and in this case would undermine the core purposes of the Medicaid program.

D. The Government's Civil Cases are Unpersuasive, Factually Distinguishable, or Both

The government, for its part, does not explain why the text or purpose of the FCA support a "no collateral attack" rule that would require courts to disregard

arguments that a misrepresentation was immaterial. It observes in passing that the FCA targets "cheating the government," U.S. Br. 16, 20, but it does not explain how the government has been cheated when it legally owed Walgreens reimbursement. Nor does the government explain how its argument can be squared with *Escobar*'s admonition that the FCA is not an "all-purpose antifraud statute." 579 U.S. at 194. Instead, the government claims that the "principle" of *Kapp* and other cases has been "consistently" applied in civil cases. U.S. Br. 18. In support of this "consistent" practice the government musters three decisions over the last 50 years. U.S. Br. 18-19 & n.1. Those cases are inapposite, not binding, unpersuasive, or all of those put together.

This Court's decision in *Acanfora v. Board of Education of Montgomery County*, 491 F.2d 498 (4th Cir. 1974), simply did not address materiality. There, the plaintiff was a schoolteacher who lied about his sexual orientation to obtain a job and later sued for reinstatement. 491 F.2d at 504. The court held that "[Plaintiff] cannot now invoke the process of the court to obtain a ruling on an issue that he practiced deception to avoid." *Id.* But defendants in FCA cases are not "invok[ing] the process of the court"; they are defending against a suit initiated by the government (or a relator suing on behalf of the government), arguing that the government (or, as it may be, the relator) cannot meet its burden to show that an unlawful payment condition is material. This Court did not hold, for example,

that the school district could have sued the plaintiff to recoup his salary while precluding him from raising the validity of his discharge. In any event, as Walgreens notes, there are good reasons not to extend *Acanfora* beyond its specific facts.

Cedars-Sinai Medical Center v. Shalala, 125 F.3d 765 (9th Cir. 1997), did not address any materiality argument either. The Ninth Circuit observed in *dicta* that a successful challenge to a Medicaid rule would not be a defense in a separate *qui tam* "action pending elsewhere" that was not before the court. *Id.* at 769. But that *dicta* lacks any persuasive value here: the decision predated *Escobar* and did not even use the word "material" or "materiality," much less consider how a finding of the rule's invalidity would affect the materiality of the alleged misrepresentation. *See id.*

That leaves *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010 (N.D. Cal. 2020), the only civil case the government identifies in which a defendant attempted to raise the invalidity of an administrative rule as a defense. *Id.* at 1067. But defendants in *Sutter Health* argued that the statutory rule of "actuarial equivalence" defeated the FCA's *scienter* element in that case, not materiality. *Id.* at 1060. The court invoked *Cedars-Sinai* as part of its rejection of that scienter argument. *Id.* at 1067-68. The court's discussion of materiality

occurs nearly 20 pages later in the opinion, *id.* at 1085-86, and it contains no mention of *Cedars-Sinai* or collateral attacks at all.

In sum, no case supports the remarkable proposition that the government articulates here: that Walgreens is categorically prohibited from raising the validity of Virginia's coverage exclusions to defeat FCA materiality. In the absence of such authority, this Court should decline the invitation to create such a sweeping, atextual rule out of whole cloth.

CONCLUSION

For the foregoing reasons, *amici* respectfully urge the Court to affirm the decision of the district court.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Circuit Rule 32-1, I certify that this brief is proportionally spaced, has a typeface of 14 points and contains 6,342 words.

DATED: October 3, 2022

/s/ *Elisabeth S. Theodore*
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CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2022, I electronically filed the foregoing with the Clerk of the United States Court of Appeals for the Fourth Circuit using the CM/ECF system, which sent notification of such filing to all registered CM/ECF users.

DATED: October 3, 2022

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