NO. 23-2134

IN THE

United States Court of Appeals for the Seventh Circuit

UNITED STATES, ET AL., EX REL.,
RONALD J. STRECK,

Plaintiff-Appellee, Cross-Appellant,

v.

ELI LILLY AND COMPANY,
Defendant-Appellant, Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of Illinois
Case No. 1:14-cv-09412
Hon. Harry D. Leinenweber

BRIEF OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION SUPPORTING DEFENDANT-APPELLANT AND REVERSAL

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Appellate Court No: 23-2134

Short Caption: United States, et al., ex rel., Streck v. Eli Lilly and Company

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Attorney's Signature: /s/Shane Pennington Date: 12/27/2023

Attorney's Printed Name: Shane Pennington

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Attorney's Signature: /s/Cory L. Andrews Date: 12/27/2023

Attorney's Printed Name: Cory L. Andrews

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INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center. WLF promotes free enterprise, individual rights, limited government, and the rule of law. WLF often appears as an amicus curiae in significant cases to argue for the proper construction of the False Claims Act (FCA). *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016); *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010).

The FCA has taken on a life of its own in recent years. Enacted during the Civil War, the statute began as an important, but limited, tool against government procurement fraudsters and wartime opportunists. Today, the opportunists are often not the targets of the statute, but rather its putative enforcers: enterprising relators have weaponized the FCA into a vehicle for debilitating lawsuits over just about anything that arguably touches—even remotely—the federal fisc. Given the statute's

[1] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae* or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

"essentially punitive" character, the Supreme Court has emphasized the importance of "strict enforcement" of the Act's "rigorous" requirements, *Escobar*, 579 U.S. at 182, 192.

This case is about what happens when lower courts ignore that "strict enforcement" mandate. Eli Lilly and Company's (Lilly's) Opening Brief explains in detail how the district court's refusal to "strictly enforce[], several of the FCA's "rigorous" requirements eviscerated key limits on FCA liability inherent in the statutory text and confirmed by settled precedent. WLF focuses on another problem with the district court's rulings: the serious threat they pose both to due process of law and separation of powers.

INTRODUCTION AND SUMMARY OF ARGUMENT

Companies operating in the shadow of the FCA's "essentially punitive" treble-damages regime face a constant threat of suffering "open-ended liability" without fair notice of the legal requirements they are claimed to have violated. The Supreme Court has therefore warned that, in the FCA context, respect for basic due process principles in the FCA context demands "strict enforcement" of the Act's "rigorous" requirements. Whatever else such "strict enforcement" may entail, in a

case like this one where punitive liability hinges on violation of a regulatory standard, it must, at a bare minimum, require that defendants be able to identify what the regulation at issue requires with ascertainable certainty at the time of the conduct at issue.

For three reasons, Lilly did not have that minimal fair notice here. First, the district court's interpretation of the relevant average manufacturer price (AMP) requirements did not exist in an authoritative form until the district court applied it against Lilly here. Second, the agency and its Inspector General knew about Lilly's AMP methodology throughout the relevant period, did not object to it, and at times expressly approved of it. Third, federal court decisions available during the relevant period rejected the district court's interpretation and confirmed the soundness of Lilly's approach. Under each of these three circumstances, courts, including this Court, have consistently held that fair-notice principles bar the imposition of mere civil administrative liability. That same lack of notice barred the district court from imposing treble damages against Lilly for the same conduct.

Nor is that the only constitutional problem with the district court's judgment. Besides the fair-notice issue, the district court's approach to

the FCA also violates separation of powers by making it literally impossible for the Executive to ensure the faithful execution of Administrative Procedure Act provisions essential to the validity, viability, and legitimacy of legislative rules. Section 552(a) of the APA requires agencies to publish "statements of general policy or interpretations of general applicability formulated and adopted by the agency" in the Federal Register and prohibits the Executive from causing any person to be "adversely affected" by such a standard unless and until it has done so. *See* 5 U.S.C. § 552(a). The district court's interpretation of the AMP regulations at issue here indisputably qualifies as one such "interpretation of general applicability." *Id.* Thus, because the agency had not—and still has not—published that interpretation in the Federal Register, Section 552(a) would have prohibited the Executive from bringing an ordinary enforcement action against Lilly based on the conduct at issue here. The district court's decision thus empowers private relators to enforce laws of the United States "in the name of the United States" but in ways that the United States itself may not. This undermines the Executive's ability to ensure compliance with the APA, which, in turn, undermines the core procedural requirements necessary

to maintain democratic accountability in administrative lawmaking and the legitimacy of the administrative state itself under Republican principles.

Executive authority to create legislative rules in litigation and then apply them retroactively in the same litigation to impose punitive liability against a regulated party is unheard of and contrary to basic due-process and rule-of-law norms. The United States itself would never be permitted to wield such power in any context. The district court therefore erred by permitting a qui tam relator to wield it here.

For these and other reasons explained in greater detail below, the district court's judgment should be reversed.

ARGUMENT

I. THE DISTRICT COURT'S RULINGS RAISE GRAVE DUE-PROCESS CONCERNS.

A. The FCA Triggers Heightened Due-Process Protections That Demand Strict Enforcement of the Act's Rigorous Requirements.

Before 1986, an FCA violation subjected a company to only double—not treble—damages. *United States v. Bornstein*, 423 U.S. 303, 305 (1976). During that period, FCA damages were considered "compensat[ory]." *Id.* at 314. With "evidence of fraud in Government

programs and procurement [wa]s on a steady rise,"[2] however, Congress amended the FCA in 1986 to provide for treble damages.[3] With that, FCA damages became "essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000). As a result, FCA defendants today enjoy greater due-process protections than they did before 1986.

Along with punitive treble damages, FCA violations may carry criminal penalties. 18 U.S.C. § 287. This also has important implications for the due-process protections afforded defendants in FCA actions because "the relative importance of fair notice and fair enforcement" mandated by the Due Process Clause "depends in part on the nature of the enactment." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). The Supreme Court thus has "greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe." *Id.* at 498-99 (citing *Winters v. New York*, 333 U.S. 507, 515 (1948)).

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[2] *See* S. Rep. No. 99-345, 2, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5267.

[3] *See* False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2(7), 100 Stat. 3153, 3153.

Moreover, because the FCA has both criminal and civil penalties, courts "must interpret the statute consistently, whether [they] encounter its application in a criminal or noncriminal context." *Leocal v. Ashcroft*, 543 U.S. 1, 12 n.8 (2004). "[T]he rule of lenity" therefore applies so that civil and criminal provisions are interpreted consistently. *Id.* (citing *United States v. Thompson/Ctr. Arms Co.*, 504 U.S. 505, 517-18 (1992) (plurality)).

To avoid "'penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule,'" *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (quoting *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987)), courts rely on "strict enforcement" of the Act's "rigorous" requirements, *Universal Health Servs.*, 579 U.S. at 182, 192. Whatever else "strict enforcement" may entail in cases like this one where liability hinges on violation of a regulatory standard, it must require defendants to have at least as much notice of what the regulation forbids as would be necessary to ensure due process in an ordinary civil enforcement action.[4] After all,

[4] This Court has said that because "[t]he FCA imposes civil liability," it generally looks to "civil, not criminal definitions" when assessing how the statute should apply. *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 464 n.6 (7th Cir. 2021)

notice insufficient to justify a civil fine or citation is necessarily insufficient to justify punitive damages and potential criminal liability for exactly the same conduct. And, as described below, courts routinely apply the fair-notice principle in the administrative context to protect regulated parties from the imposition of punitive remedies without due process of law.

B. Defendants Must Be Able to Identify What a Regulatory Standard Requires With "Ascertainable Certainty."

"A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *Fox Television Stations*, 567 U.S. at 253; *see also Johnson v. United States*, 576 U.S. 591, 595 (2015) (due process requires that the law "give ordinary people fair notice of the conduct it punishes"). A punitive statute cannot leave regulated parties to "guess at its

---

(citations omitted), *rev'd on other grounds*, 598 U.S. 739 (2023). That principle makes good sense where, as in *SuperValu*, the Court is assessing statutory standards like the Act's scienter element. *Id.* The same limitation does not apply in the due-process context. Indeed, the Supreme Court has drawn on void-for-vagueness cases decided in the criminal context in establishing the fair-notice standards applicable in civil cases involving regulatory issues. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (holding that "[a] fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required," and, in support of that conclusion, relying on landmark decisions from the criminal context, including *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926); *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939); and *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972).

meaning," *Connally*, 269 U.S. at 39, unable to "know where . . . [to] draw the line between the allowable and the forbidden," *Winters*, 333 U.S. at 519.

In explaining how a doctrine that originated in the criminal-law context came to be "a cardinal rule of administrative law," this Court has turned to an oft-quoted opinion of the D.C. Circuit.

Courts routinely apply this criminal-law principle in the civil administrative context. *See, e.g.*, *Wis. Res. Protection Council v. Flambeau Min. Co.*, 727 F.3d 700, 708 (7th Cir. 2013) (holding that where a "regulation is not sufficiently clear to warn a party about what is expected of it—an agency may not deprive a party of property by imposing civil or criminal liability"). Indeed, this fair-notice requirement is now "thoroughly incorporated into administrative law." *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995). To determine "whether a party received fair notice" of what a regulatory standard requires, "courts frequently look to the regulations and other agency guidance." *Wis. Res. Protection Council*, 727 F.3d at 708. The key question is whether "'by reviewing the regulations, a regulated party acting in good faith would be able to identify, with ascertainable certainty, the standards with

which the agency expects parties to conform.'" *Id.* (quoting *Howmet Corp. v. EPA*, 614 F.3d 544, 553-54 (D.C. Cir. 2010) (internal quotation marks omitted)). If not, "'then the agency has fairly notified a petitioner.'" *Id.*

There are at least three situations, however, where courts uniformly recognize that fair notice is lacking.

1. When the regulatory standard was not authoritatively announced until *after* the defendant acted.

Fox Television Stations clarifies this point. There, the Court assessed whether the FCC violated Fox's and ABC's due-process rights by imposing sanctions for three broadcasts that included "fleeting expletives"—i.e., brief profanity or nudity. After the broadcasts aired, the FCC promulgated guidelines making the conduct in all three instances subject to sanctions. But at the time of the broadcasts, it was unclear whether the brief profanity or nudity was punishable. The Court thus concluded that "the Commission's lack of notice to Fox and ABC that its interpretation had changed so the fleeting moments of indecency contained in their broadcasts were a violation . . . 'failed to provide a person of ordinary intelligence fair notice of what is prohibited.'" 567 U.S. at 254.

Similarly, in *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142 (2012), the Court refused to adopt the Department of Labor's interpretation of the Fair Labor Standards Act about whether pharmaceutical detailers were "outside salesmen" and therefore exempt from overtime requirements. The Department argued that the Court should defer to its statements in a 2009 amicus brief, but the Court held that the amicus brief did not provide fair notice that the exemption applied to the detailers. The brief was written years after the offensive conduct, the pharmaceutical industry's practice was to classify the detailers as exempt employees, and the Department had never initiated an enforcement action for such classifications. Adopting the Department's position "would [have] seriously undermine[d] the principle that agencies should provide regulated parties fair warning of the conduct [a regulation] prohibits or requires." *Id.* at 156 (citations and internal quotation marks omitted). Regulated parties should not have "to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference." *Id.* at 159.

This Court applied the same rule in *United States v. Cinergy Corp.*, 623 F.3d 455, 458 (7th Cir. 2010), to hold that a defendant could not be charged with violating the Clean Air Act when it complied with the published version of a regulation. The EPA had secured Indiana's agreement to amend the regulation, but Indiana had yet to do so. Still, the EPA sought to penalize the defendant for violating the future, amended version of the regulation. This Court rejected the argument that the process was permissible because the defendant was on notice only of what "a straightforward reading of [the regulation] permitted." *Id.*

Finally, in *Gates & Fox v. Occupational Health & Safety Review Commission*, 790 F.2d 154, 156-57 (D.C. Cir. 1986) (Scalia, J.), the D.C. Circuit held that, although the defendant's own safety inspector had warned the company that the regulation at issue prohibited its conduct, the company still did not have fair notice sufficient to support a citation. The regulatory language itself did not expressly foreclose the defendant's interpretation. And the inspector's warning, which "did not come from OSHA," was "not an authoritative interpretation of the regulation." *Id.* at 157. Instead, "[i]t show[ed], at most, that *some* person (and one who

had nothing to lose by an abundance of caution) read the regulation as OSHA suggests." *Id.* That was not enough to cure the fair-notice problem.

2. When the agency knew of the defendant's conduct and approved of it or at least did not object to it.

In *Wisconsin Resource Protection Council*, this Court held that where "the only available guidance" from the regulator was that the company's conduct was legal, "[t]o hold otherwise, would be inconsistent with the requirements of due process," 727 F.3d at 709, 711. The case involved a mining company that discharged stormwater under a Clean Water Act permit issued by a Wisconsin agency under an EPA-approved permitting program. *Id.* at 702, 704-05. Plaintiffs alleged that although EPA had approved the Wisconsin program initially, it had never formally approved the state's subsequent modification of the program as the Act required. This, plaintiffs contended, rendered the company's permit invalid and its discharges under the permit unlawful. *Id.* at 705.

This Court held that even if plaintiffs were correct that the company's permit was technically invalid, it "[could] not, consistent with the requirements of due process, impose a penalty on [the company] for complying with what Wisconsin deemed a valid . . . permit." *Id.* at 707. The company was not aware of the issue that plaintiffs claimed rendered

its permit invalid, and the state had assured the company repeatedly during the period at issue that the permit was valid. *Id.* at 708-09. Settled due-process principles dictated that the company was "entitled to rely" on those assurances. *Id.* at 710.

The Fourth Circuit's decision in *United States v. Hoechst Celanese Corp.*, 128 F.3d 216 (4th Cir. 1997) is also instructive. There, the EPA sought to levy penalties against an industrial plant for violating Clean Air Act regulations. The regulations imposed emissions standards and reporting requirements on emitters of benzene. The plant owner, Hoechst, argued that the EPA regulations failed to provide fair notice that Hoechst's plant had to comply with the benzene regulations.

The court agreed. In assessing the fair-notice issue, it emphasized the importance of "examin[ing] the particular situation of the defendant, and whether *it* lacked reasonable notice." *Id.* at 224 (emphasis in original). That inquiry revealed that Hoechst had contacted the state regulators enforcing the benzene regulations for the express purpose of determining whether it was in compliance. *Id.* at 225. The state agency told Hoechst and the EPA that the company's approach was lawful. Given the state agency's approval of its interpretation and the EPA's failure to

act in response, the Fourth Circuit held that "the company had reason to believe that its interpretation . . . was accurate." *Id.* at 226. Hoechst therefore "lacked fair notice" of its regulatory obligations and could not be liable for its failure to comply with them. *Id.*

3. When the regulatory requirements are unclear, but agency and/or judicial precedent during the period in question support defendant's approach.

In *Kropp Forge Co. v. Sec'y of Labor*, 657 F.2d 119, 121 (7th Cir. 1981), the Commission had cited Kropp for failing to have an "effective hearing conservation program" at its noisy Chicago plant. According to the Commission, Kropp's program "lacked six necessary elements" to be deemed "effective." *Id.* This Court reversed the Commission's order, holding that because the regulation at issue did not inform Kropp of "the exact contours of its responsibility," the company lacked the fair notice that due process demands. *Id.* at 122 (internal quotation marks and citations omitted).

In reaching that conclusion, the Court emphasized that the Secretary of Labor had previously acknowledged that the regulation did not in fact list all six requirements. *Id.* Indeed, a Labor Department "Guide" to OSHA compliance told regulated parties that because the six

elements were not listed in the regulation itself, they were not binding requirements. *Id.* Finally, agency and judicial precedent supporting the same conclusion. *Id.* Given these facts, the Court reasoned, it would be fundamentally unfair to punish Kropp for failing to comply with all six requirements. *Id.* at 124.

This Court applied a similar principle in reversing another Occupational Health and Safety Review Commission citation for lack of fair notice in *In re Metro-East Mfg. Co.*, 655 F.2d 805 (7th Cir. 1981). Key to the Court's conclusion was the fact that the agency did not clarify its regulation even when another federal court had interpreted it to permit the conduct at issue. *Id.* at 811-12. "The responsibility to promulgate clear and unambiguous standards is upon the Secretary," this Court explained. *Id.* at 810 (internal quotation marks and citations omitted). "The test is not what he might possibly have intended, but what he said." *Id.* (internal quotation marks and citations omitted). Because "[t]he Secretary has the means and obligation to amend" the regulation to clarify its meaning, his failure to do so in the face of a judicial decision adopting a contrary interpretation was decisive of the fair-notice issue. *Id.* at 810, 811-12.

C. Under These Settled Principles, Lilly Lacked Fair Notice That Its AMP Calculations Violated Regulatory Requirements.

All three lines of cases discussed above confirm that Lilly lacked fair notice that its AMP calculations were improper.

First, even if Relator's and the district court's construction of the applicable regulatory standards is correct, Lilly did not have fair notice of that interpretation when it submitted the claims at issue. *See Fox Television Stations*, 567 U.S. at 253; *Christopher*, 567 U.S. at 595.

Just as Cinergy Corp. could not be held liable for violating an amended regulation the agency had not yet promulgated, *see Cinergy Corp.*, 623 F.3d at 458, Lilly should not have been held liable for violating a regulatory standard that did not yet exist in any authoritative form when it submitted the claims at issue. Indeed, the due-process problem here is significantly more serious than the one in *Cinergy Corp.* There, the defendant was at least aware of EPA's intention to amend the regulation at issue in a way that would prohibit the company's conduct. *Id.* No such bread crumbs were available to Lilly here. It is thus no exaggeration to say that the imposition of punitive liability on Lilly here epitomized "the kind of 'unfair surprise' against which [the Supreme]

Court has long warned." *Christopher*, 567 U.S. at 144 (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170-171 (2007)).

Relator might respond that Lilly was in fact on notice because Relator himself has long championed the interpretation eventually adopted by the district court. But Relator is not the agency, so his views are not authoritative and therefore could not supply the necessary fair notice. *See Gates & Fox*, 790 F.2d at 156-57.

Second, Lilly repeatedly disclosed its AMP calculation methodology to the agency, and the agency never objected to it. On the contrary, as Lilly's Opening Brief explains (at 46), the agency and its Office of Inspector General approved of, or at least acquiesced in, Lilly's approach. That renders any attempt to establish fair notice here dead on arrival. *See Wis. Res. Protection Council*, 727 F.3d at 708-09; *Hoechst Celanese Corp.*, 128 F.3d at 224-26. This issue is especially important given its direct bearing on materiality. *See Escobar*, 579 U.S. at 195 (courts must strictly enforce materiality to ensure fair notice under the FCA); *id.* (fact that Government knew about defendant's wrongful

conduct but took no corrective action is "very strong evidence" that the conduct is "not material").

Third, during the period when Lilly was submitting the claims at issue, two courts had rejected the district court's interpretation of the regulations. Furthermore, and as already mentioned, the agency and its Office of the Inspector General signaled their approval of Lilly's AMP methodology during the same period. Lilly's Opening Brief at 46. Just as the agency and judicial precedent during the relevant period barred this Court from concluding that the defendants in *Kropp Forge* and *In re Metro-East Mfg. Co.* had fair notice of the requirements the government claimed they had violated, so, too, did Lilly's receipt of confirmations of the soundness of its AMP methodology from courts and the agency. *Kropp Forge*, 657 F.2d at 122-24; *In re Metro-East Mfg. Co.*, 655 F.2d at 810, 811-12. To hold otherwise, would cause "the practice of administrative law to come to resemble 'Russian Roulette.'" *See Trinity Broad. of Fla.,*

Inc. v. FCC, 211 F.3d 618, 630 (D.C. Cir. 2000) (quoting *Satellite Broad.*, 824 F.2d at 4).

II. THE DISTRICT COURT'S INTERPRETATION OF THE FCA VIOLATES SEPARATION OF POWERS.

More than 20 years ago, the Supreme Court "express[ed] no view on the question whether qui tam suits violate Article II." *Vt Agency of Nat. Res.*, 529 U.S. at 778 n.8. The scope of FCA liability has expanded exponentially since, however, making the issue harder and harder to ignore. *See Polanksy*, 599 U.S. at 442 (Kavanaugh, J., concurring); *id.* at 443 (Thomas, J., dissenting). Although the FCA already strains Article II boundaries, permitting relators to bring claims like those here would irreparably transgress them. The Court can therefore reverse the district court's rulings for this reason as well.

A. The Constitution Vests the Right to Control Litigation in the Executive Branch.

The Constitution's central innovation is the "separation of governmental powers into three coordinate Branches." *Mistretta v. United States*, 488 U.S. 361, 380 (1989). The division "was not simply an abstract generalization in the minds of the Framers." *Buckley v. Valeo*, 424 U.S. 1, 124 (1976) (per curiam). Rather, it entails "a carefully crafted system of checked and balanced power within each Branch," *Mistretta*,

488 U.S. at 380-81, the "ultimate purpose of [which] is to protect the liberty and security of the governed," *Metro. Wash. Airports Auth. v. Citizens for Abatement of Aircraft Noise, Inc.*, 501 U.S. 252, 272 (1991). Within this tripartite system, "the executive power—all of it—is vested in a President." *Seila Law, LLC v. CFPB*, 140 S. Ct. 2183, 2191 (2020) (internal quotation marks omitted); U.S. Const. art. II, § 1.

Splitting the executive authority, by contrast, "might impede or frustrate the most important measures of the government, in the most critical emergencies of the state" or divide the nation into "irreconcilable factions." Alexander Hamilton, *The Federalist* No. 70 at 429 (Bantam ed. 2003). Consolidating the executive power in one Executive protects against those outcomes and ensures national uniformity. "The vesting of the executive power in the President was essentially a grant of power to execute the laws." *Myers v. United States*, 272 U.S. 52, 117 (1926). To that end, the President's "most important constitutional duty" is to "take Care that the Laws be faithfully executed." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559 (1992) (citing U.S. Const. art. II, § 3). That duty includes the "exclusive authority and absolute discretion to decide whether to prosecute a case." *United States v. Nixon*, 418 U.S. 683, 693 (1974). And

it extends to both criminal and civil matters. *See Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (explaining that the Court has "recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion").

"Time and again," the Supreme Court has "reaffirmed the importance in our constitutional scheme of the separation of governmental powers into the three coordinate branches." *Morrison v. Olson*, 487 U.S. 654, 693 (1988) (citations omitted). One branch cannot "possess directly or indirectly, an overruling influence over the others in the administration of their respective powers." James Madison, *The Federalist* No. 48 at 300 (Bantam ed. 2003). A statute violates that precept when it "either accrete[s] to a single Branch powers more appropriately diffused among separate Branches or . . . undermine[s] the authority and independence of one or another coordinate Branch." *Mistretta*, 488 U.S. at 382. In the particular context of Executive intrusions, the inquiry is whether a law "impermissibly undermines the powers of the Executive Branch, or disrupts the proper balance between the coordinate branches by preventing the Executive Branch from

accomplishing its constitutionally assigned functions." *Morrison*, 487 U.S. at 695 (internal quotation marks and citations omitted). The Supreme Court has "not hesitated to invalidate provisions of law which violate th[ese] principle[s]," *id.* at 693, including congressional delegations of Executive power to other actors, *e.g.*, *Printz v. United States*, 521 U.S. 898, 922 (1997), and to Congress itself, *e.g.*, *Bowsher v. Synar*, 478 U.S. 714, 726 (1986) ("The structure of the Constitution does not permit Congress to execute the laws" or permit Congress to retain "control over the execution of the laws."). Only when the Executive Branch retains "sufficient control" over litigation can a law "ensure that the President is able to perform his constitutionally assigned duties." *Morrison*, 487 U.S. at 696.

B. The District Court's Rulings Would Impermissibly Impede the Executive's Take Care Powers.

By permitting self-interested private relators who are neither beholden to DOJ policy nor accountable to the American people to investigate and commence litigation "for the person and for the United States Government," 31 U.S.C. § 3730(b)(1), FCA qui tam claims strain Article II's limits. Once a qui tam claim is filed, the Executive must either intervene or allow the relator to proceed with the case. *Id.* §§ 3730(c)(1),

3730(c)(3). The FCA thus obliges the Executive to expend resources investigating a case it otherwise might not have investigated, and then to either litigate or cede control to a private citizen. And if the government does not intervene, relators shape the arguments and litigation according to their own whims.

Moreover, the interests of these deputized private citizens diverge sharply from the government's. As the Supreme Court has explained, "qui tam relators are different in kind than the Government. They are motivated primarily by prospects of monetary reward rather than the public good." *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997). They are "private persons acting . . . under the strong stimulus of personal ill will or the hope of gain." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.5 (1943).

Placing Executive power into the hands of financially motivated profiteers was apparently intentional: Congress "sought to disperse some quantum of executive authority amongst the general public." *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 750 (9th Cir. 1993). Indeed, in 1986, when Congress greatly expanded relators' powers, legislators candidly acknowledged that Congress was displeased with how the

Executive Branch was performing its constitutionally assigned duties. One legislator, for example, said that "the Government bureaucracy [was] unwilling to guard against or aggressively punish fraud," and another lamented that the "Department of Justice has not done an acceptable job of prosecuting defense contractor fraud." William P. Barr, *Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 Op. OLC 207, 230 (1989) (quoting 131 Cong. Rec. 22,322 (daily ed. Aug. 1, 1985); 132 Cong. Rec. H6482 (daily ed. Sept. 9, 1986) (statement of Rep. Berman)). Congress's solution? Transfer even more Executive power to private relators.

These infractions have triggered challenges to the FCA's constitutionality. The Executive's own Office of Legal Counsel, for example, has warned that the statute "effectively strips [the authority to enforce the laws] away from the Executive and vests it in private individuals, depriving the Executive of sufficient supervision and control over the exercise of these sovereign powers" "even under [*Morrison*'s] most lenient standard for judging threats to separation of powers." Barr OLC Memo at 210, 229. Courts have thus far stopped short of holding that the FCA violates "Article II's Take Care Clause" or "the principle of

separation of powers," but only "because of the United States' significant control." *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1312 (11th Cir. 2021); *cf. Sierra v. City of Hallandale Beach*, 996 F.3d 1110, 1135 n.14 (11th Cir. 2021) (Newsom, J., concurring) ("One possible explanation" for the constitutionality of qui tam suits is that they "didn't raise Article II problems because the executive branch retained full control over them.").

The district court's rulings here undermine Executive control over qui tam cases, severely weakening the foundation on which the FCA has, to date, survived these broader constitutional challenges. Key to Executive control over qui tam litigation is the Attorney General's right to intervene in the action within 60 days of receiving service of the complaint from the relator. When the government intervenes within this 60-day window, it has "primary responsibility for prosecuting the action." 31 U.S.C. § 3730(c)(1). The relator nevertheless has "the right to continue as a party to the action." *Id.*

In theory, this right to intervene gives the Executive the option to exercise primary control over any qui tam prosecution. Here, however, by permitting Relator to bring claims in the name of the United States that

the APA and longstanding DOJ policy prohibit the United States from prosecuting itself, the district court rendered this putative control entirely illusory.

Section 552(a)(1)(D) of the APA provides that "each agency shall separately state and currently publish in the Federal Register for the guidance of the public . . . statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D). Section 552(a)(1)(E) then requires each agency to do the same for "each amendment, revision, or repeal of the foregoing." The statute then forbids the government from causing any "person . . . in any manner [to] be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published" unless the person "has actual and timely notice of the terms thereof." *Id.* § 552(a).

Because the district court's interpretation of the AMP regulations here indisputably qualifies as a "statement[] of general policy or interpretations of general applicability," the agency would have been obligated under Section 552(a)(1)(D) to publish it in the Federal Register had the agency "formulated and adopted" it. Furthermore, until the

agency did so, Section 552(a) would have barred it from "adversely affect[ting]" a regulated party by bringing an FCA claim based on the regulated party's violation of that standard.

That Relator's claims ignore a bedrock limit on Executive enforcement authority expressly designed to ensure that the regulated public has "actual notice" of what the law requires and forbids *before* they may "in any manner be required" even to "resort to"—much less "be adversely affected by"—such a regulatory requirement only underscores the extent of the fair-notice problems already discussed. *Id.* § 552(a). Yet it also highlights another constitutionally problematic feature of the district court's rulings. By greenlighting qui tam relators to bring enforcement actions that the United States cannot bring, the district court created a monster: a new class of FCA claims that private relators can bring in the name of the United States even though federal law bars the United States itself from pursuing them.

Left unchecked, the district court's rulings will wreak havoc on the Executive's Take Care powers. The same APA prohibition that prevents the Executive from prosecuting these claims also presumably bars it from intervening in the lawsuit to exercise primary control over the

proceedings. Stripped of one of its primary levers of control in the qui tam context, the Executive would therefore be left to choose between either letting the claim proceed under the relator's sole control or requesting that the district court dismiss the case. Either way, core authority reserved by Article II to the Executive exclusively falls into someone *else*'s hands—either the qui tam relator's or the court's.

The danger this impermissible intrusion on core Article II power poses is very real. After all, "the Constitution diffuses power the better to secure liberty." *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 635 (1952) (Jackson, J., concurring); *see also* James Madison, *The Federalist* No. 47 at 373-74 (Bantam ed. 2003) ("[T]the accumulation of all powers, legislative, executive, and judiciary, in the same hands . . . may justly be pronounced the very definition of tyranny."); Montesquieu, *The Spirit of the Laws*, 38 Great Books of the Western World 70 (Hutchins ed. 1952) ("When the legislative and executive powers are united in the same person, or in the same body of magistrates, there can be no liberty.").

Empowering private qui tam bounty hunters to enforce the laws of the United States in ways that the Executive itself may not undermines

the Executive's Take Care powers in two ways. First, by permitting qui tam claims that violate core APA protections, the district court's rulings guarantee that the APA will not be "faithfully executed" no matter how much "care" the Executive "takes." And because a qui tam suit like this one will almost always "adversely affect" the defendant long before the Government can even move to dismiss, the Attorney General's ability to request dismissal could not cure the problem even if district courts immediately granted every motion he filed.

Second, the district court's approach gives the force and effect of law to a qui tam relator's view of the regulatory scheme that was never subjected to the APA's rulemaking procedures. In doing so, it impermissibly blesses a judicial usurpation of the Executive's authority to establish policy under complex regulatory schemes in the first instance. Short-circuiting the public-participation process the APA requires for the announcement of legislative rules in this way impedes the Executive Take Care powers and undermines the quality and legitimacy of the administrative state that the APA's procedural requirements promote.

Put simply, the district court's rulings here threaten to transform the FCA from a punitive statute of questionable constitutionality into a separation-of-powers disaster. This case exemplifies the sort of nightmare scenario that, without this Court's intervention, will play out more and more frequently: a private qui tam bounty hunter using the judicial system to establish a never-before-seen rule of law without any of the APA's procedural safeguards and then apply that newly-minted rule *retroactively* in the same case to impose treble damages on a regulated party that could never have seen it coming. The FCA was not designed to punish "insignificant regulatory or contractual violations." *Escobar*, 579 U.S. at 194, 196. Nor does it create an APA-free zone for private relators to create law without Executive oversight and without observing the procedural norms that would otherwise protect the public, ensure agency expertise is brought to bear on important policy questions arising in the administrative state, and imbue administrative law with some modicum of democratic accountability and legitimacy.

The district court's rulings threaten to impede Executive authority to set policy under complex regulatory regimes and to upset the reliance interests of the regulated public whose fair-notice and basic procedural

rights the APA protects in the process. This Court should therefore reverse.

CONCLUSION

The judgment should be reversed.

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Respectfully submitted,

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/s/ Shane Pennington
Shane Pennington

December 27, 2023

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I certify that on December 27, 2023, I electronically filed the foregoing document with the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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December 27, 2023