No. 21-1052

In the Supreme Court of the United States

UNITED STATES OF AMERICA, EX REL. JESS POLANSKY, M.D., M.P.H., PETITIONER

v.

EXECUTIVE HEALTH RESOURCES, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

JOHN P. BUEKER
ANDREW J. O'CONNOR
PATRICK T. ROATH
CAMBREY C. DENT
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199

DOUGLAS H. HALLWARD-DRIEMEIER
Counsel of Record
ROPES & GRAY LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes, regulations and rules: Page(s)

Statutes, regulations and rules: Page(s)

Miscellaneous:

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INTEREST OF AMICUS CURIAE*

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical-technology association representing device, diagnostics, and digital-technology manufacturers that are transforming health care through earlier disease detection, less-invasive medical procedures, and more-effective treatments. Its

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

more than 400 member companies span every field of medical science and range from cutting-edge startups to multinational manufacturers. AdvaMed's member companies are dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards.

The question presented by this petition is vital, and recurring, to AdvaMed's members. Namely, qui tam relators often bring False Claims Act (FCA) cases predicated on an alleged violation of the Federal Food, Drug, and Cosmetic Act (FDCA). In such cases, the government's authority to dismiss the case is critically important—even in cases in which it initially declined to intervene. Without the government's authority to dismiss, or when that authority is improperly restricted, relators are enabled to pursue FCA cases even when the government believes it has not been defrauded and regulatory agencies do not believe action is warranted. Such suits substitute lay jurors and judges for the Food and Drug Administration (FDA) in making nuanced policy determinations in connection with the enforcement of the complicated regulatory regimes governing medical devices. Congress specifically precluded private causes of action to enforce the FDCA, and the FCA should not be construed to permit an end-run around that limitation by limiting the government's ability to rein in runaway relators.

SUMMARY OF THE ARGUMENT

The FCA "is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 579 U.S.

176, 194 (2016) (quoting *Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). The court of appeals' ruling that the government retains authority to dismiss initially declined FCA suits is an important part of keeping the FCA within its proper bounds.

The FCA grants a relator a share of the government's recovery for fraudulent claims, but the action is in the name of, and vindicates a wrong to, the government. Many FCA suits filed by relators involve allegations of fraud that are predicated on complicated questions of regulatory compliance that implicate the government's enforcement discretion. Nowhere is that discretion more delicate—a matter of life and death, and promoting innovation—and more explicitly committed to experts than in the life-science context.

Often, relators' claims are predicated on the FDCA, a situation that heightens those concerns. The FDCA confers on the FDA a significant degree of responsibility, and discretion, to weigh competing regulatory interests in the course of exercising its regulatory responsibilities. To preserve FDA's authority and shield it from interference, Congress forbade private litigation, including by state actors, to enforce the FDCA. See 21 U.S.C. 337(a) (no private right of action under the FDCA). Instead, Congress intended that the FDCA's provisions "be enforced *exclusively* by the Federal Government." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (emphasis added).

When the government, which is the alleged victim of fraud, does not believe that the defendant's claims warrant FCA liability, a relator's pursuit of an FCA suit

in the face of the government's opposition is inconsistent with the concept of "exclusive" federal control.

The government may choose to terminate an FCA enforcement action for varied policy reasons: the government may believe that the claims were not false, either because they did not violate the regulatory regime at issue, or because the agency would not have enforced the regulation by barring reimbursement; the government may believe that any potential "falsity" was immaterial to its payment decision under *Escobar*, or the government may believe that other policy interests weigh against enforcement (such as maintaining the availability of a product on the market or chilling innovation). Or the government may find that continuing to litigate the claim imposes inappropriate burdens on government legal resources, for instance by requiring discovery from the very federal agencies in whose name the litigation supposedly is being pursued. These underlying policy choices continue to exist even after the initial decision regarding whether to intervene in an FCA action, and the considerations often change as the litigation progresses and the relator's theory of liability comes more clearly into focus. The court of appeals' decision in this case upholding the government's ongoing authority to dismiss a suit brought on its behalf is essential to preventing relators from undermining the government's regulatory and policy-making interests as well as its prosecutorial discretion.

The court of appeals, however, erred to the extent it relied on Federal Rule of Civil Procedure 41(a) as supplying the proper standard for adjudicating a motion to dismiss filed by the government after it has declined to

intervene at an earlier stage in the litigation. The apposite standard, as explained in the Brief for the United States, see U.S. Br. 45-46, is in fact contained in the FCA itself, which provides that "[t]he Government may dismiss the action notwithstanding the objections of the [relator] if the [relator] has been notified by the Government of the filing of the motion and the court has provided the [relator] with an opportunity for a hearing on the motion," 31 U.S.C. 3730(c)(2)(A). Rule 41(a), which generically governs the voluntary dismissal of a civil action, does not bear on the more precise issue addressed by Section 3730(c)(2)(A).

A contrary ruling by this Court would materially weaken the government's ability to police litigation that encroaches on the authority of regulatory agencies, such as the FDA, to make a measured response to suspected fraud. Such a ruling would, in effect, empower lay juries to second-guess expert agencies and find fraud where those agencies do not believe any wrongdoing was committed. Curtailing the United States' ability to dismiss such suits would transfer the power to make significant policy judgments regarding the scope and enforcement of complex regulatory regimes from expert agencies to private litigants. In the case of FCA litigation predicated on FDCA violations, petitioner's rule would defeat the central holding of *Buckman* that reserved these enforcement prerogatives for the Federal Government.

ARGUMENT

I. ADMINISTRATIVE AGENCIES, INCLUDING FDA, OVERSEE HIGHLY TECHNICAL REGULATORY FRAMEWORKS, INCLUDING THE ONE GOVERNING MEDICAL DEVICES

The rule urged by petitioner, which would preclude the government from dismissing post-declination FCA cases, would materially diminish the government's ability to maintain its authority over nuanced questions of regulatory application. In the context of FCA suits predicated on alleged FDCA violations, such a ruling would permit precisely what Congress sought to avoid in 21 U.S.C. 337(a) by expressly precluding private litigation to enforce the FDCA. It would likewise interfere with the need, recognized by this Court in *Buckman*, for FDA to make the sensitive policy choices regarding enforcement of the complicated statutory schemes it oversees. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

A. Regulatory Regimes In The Healthcare Industry Are Highly Complex, And Their Enforcement Requires The Exercise of Discretion By Agency Experts

This Court has previously encountered an FCA claim predicated on alleged violation of a highly complicated regulatory regime administered by FDA—the Current Good Manufacturing Provisions (cGMP), which establish a framework governing drug and medical device manufacturing in the United States. See *United States ex rel. Campie* v. *Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017), cert. denied, 139 S. Ct. 783 (2019). Pur-

suant to authority provided by the FDCA, FDA requires drug manufacturers to comply with the cGMP framework, which establishes the standards for the methods, facilities, and controls used in manufacturing and processing drugs. See 21 U.S.C. 371; 21 C.F.R. 210, 211. These regulations and agency guidance documents set forth a highly technical regulatory regime aimed at fostering quality procedures in drug manufacturing, and preventing the production of unsafe or ineffective products. See *ibid.*

The cGMP framework is not designed to be interpreted, let alone enforced, by non-experts. Rather, assessing compliance with the interacting layers of cGMP regulation and FDA guidance demands FDA's unique expertise and judgment. See 43 Fed. Reg. 45,014, 45,018 (Sept. 29, 1978) ("The accumulated knowledge and experience of FDA in the area of current good manufacturing practice is reflected in a body of information * * * which is the basis for agency expertise.").

The identification of some cGMP violations are a routine feature of almost any FDA inspection of a manufacturing facility. Yet the government only orders a recall or directs that the plant cease production in the most extreme circumstances. Instead, the government prioritizes dependable supply of medicines and supplies, where the issue does not present an immediate danger to public health. In 2021, the FDA conducted thousands of inspections, covering biologics, devices, drugs, food and cosmetics, tobacco, and veterinary products. Although the FDA possesses authority to take formal enforcement action to enforce the FDCA, 5,051 of these inspections resulted in "No Action Indicated," 2,577 re-

sulted in "Voluntary Action Indicated," and only 370 resulted in an "Official Action." U.S. Food & Drug Admin., Data Dashboard, https://datadashboard.fda.gov/ora/cd/inspections.htm. An Official Action means that regulatory and/or administration actions will be recommended. This could include a warning letter, an injunction, or prosecution. The decision which level of enforcement action to pursue requires an exercise of FDA's discretion, including assessing and weighing the threat to patient well-being posed by the technical violations and, conversely, the burdens imposed on the manufacturer and, in extreme cases, the threat to patient health if products were removed from the market or became scarce.

Similarly, the Centers for Medicare & Medicaid Services (CMS), a federal agency within the United States Department of Health and Human Services, enforces the Clinical Laboratory Improvements Amendments (CLIA). See 42 U.S.C. 263a; 42 C.F.R. Part 493. CLIA sets laboratory standards to ensure the safety, efficacy, reliability, and accuracy of test results. *Ibid.*

Enforcing CLIA requires CMS and delegated professional organizations to engage in routine inspections, issue deficiency notices to regulated labs, and weigh the risks and benefits of commencing an enforcement action. See 42 C.F.R. 493.1806, 493.1834(d)(2). When a laboratory does not comply with one or more CLIA requirements, CMS may impose sanctions of increasing severity. 42 C.F.R. 493.1806, 493.1807. Not every CLIA violation is severe enough to require the suspension of laboratory testing and associated billing privileges; in fact, such violations are the exception, not the rule. See, *e.g.*, 42 C.F.R. 493.569(a), 493.1806, 493.1834(d)(2). CLIA

reserves for CMS, not private litigants, the finely calibrated judgments regarding which sanctions, if any, are appropriate in light of competing policy objectives.

B. The Regulation of Medical Devices is Particularly Complicated

Most relevant to AdvaMed members is the FDA's oversight of the regulatory regime governing the marketing of medical devices in the United States. All medical devices used in the United States are regulated by the FDA in a two-part process. First, a medical device is grouped into one of three classes depending on its risk profile. Second, the device's risk profile is used to determine what review process and controls are needed to provide a reasonable assurance of safety and effectiveness. Both determinations require the FDA to make fact-intensive and technical inquiries. To do this, the FDA heavily relies on its experts to provide professional advice on the various complex scientific, technical, and policy issues that arise in this process.

1. Classification of medical devices

FDA categorizes medical devices into one of three classes. Class I devices are low-risk devices such as scalpels, bandages, and medical gloves. For these devices, general regulatory controls are deemed "sufficient to provide reasonable assurance of safety and effectiveness." 21 U.S.C. 360c(a)(1)(A). These controls include but are not limited to cGMP standards and prohibitions against adulteration. These controls are applicable to all classes of devices.

Class II devices are devices for which, the FDA has decided general regulatory controls are insufficient to

ensure patient safety. For these devices, the FDA has established research-based "special controls" to provide safety assurance. 21 U.S.C. 360c(a)(1)(B). These special controls can include clinical data, promulgation of performance standards, post-market surveillance, and patient registries. *Ibid.* Examples of Class II devices are ultrasonic diagnostic equipment, x-ray machines, and insulin pumps.

Class III devices are subject to the most regulatory scrutiny. These devices are used to support or sustain life, but they can also involve risk of illness or injury. Pacemakers, heart valves, and hemodialysis machines are all examples of Class III devices. General regulatory controls are insufficient to provide a reasonable assurance of safety and effectiveness, for these devices, and the FDA lacks the necessary information to create "special controls." 21 U.S.C. 360c(a)(1)(C). All Class III devices are therefore subject to the FDA's pre-market approval process (PMA) unless a statutory exception applies. This process, which is the FDA's most stringent pathway for approving medical devices, typically requires human clinical trials and laboratory testing.

2. The 510(k) process

For devices first marketed after 1976 (which are presumptively Class III devices), FDA may reclassify the device into Class I or Class II if it determines the device is "substantially equivalent" to an existing device in that classification. 21 U.S.C. 360c(f)(1)(A)-(B).

The analysis of whether a device is "substantially equivalent" to another device is known as the "510(k) process" after the relevant section in the FDCA. As this

Court has recognized, the 510(k) process is itself a "comprehensive scheme" that enables the FDA to balance the key factors in determining whether a device is safe and effective for public use. See *Buckman*, 531 U.S. at 348-349. "[T]he § 510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception." *Ibid.*

To receive 510(k) clearance from FDA, manufacturers must establish its substantial equivalence. See 21 U.S.C. 360c(i); 21 C.F.R. 807.92(a)(3). "Substantial equivalence" means that the device has the same intended use as the predicate, and that any different characteristics from the predicate "do[] not raise different questions of safety and effectiveness." 21 U.S.C. 360c(i)(1)(A)(ii); see also 21 C.F.R. 807.100(b).

FDA's review under the 510(k) process involves numerous, highly technical steps. FDA must, for example, analyze substantial equivalence by considering whether the new and predicate devices have the same "intended use[s]," 21 C.F.R. 807.100(b)(1), whether the design, materials, and energy source of the devices have the same technological characteristics, 21 C.F.R. 807.100(b)(2)(i), (ii)(A), and whether any different technological characteristics raise different questions of safety and effectiveness, 21 C.F.R. 807.100(b)(2)(ii)(C).

Over ninety percent of the medical devices marketed in the United States are approved through the 510(k) process. As this Court recognized in *Buckman*, and as we discuss further below, FDA has been charged not only with administering the regime to approve or

clear new devices for marketing, but also with determining what, if any, enforcement action is appropriate if it determines that there was some problem in the process that led to a device being marketed. 531 U.S. at 348-351.

II. Private Enforcement Of The FDCA Through The FCA Is Inconsistent With Congressional Intent, Especially When The United States Opposes The Litigation

The FDCA does not include a private right of action under which members of the public can sue to enforce the Act. See 21 U.S.C. 337(a). Rather, as this Court has observed, Congress specified that the FDCA's provisions "be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352 (citing same).

In *Buckman*, the Court observed that FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration," including "by seeking injunctive relief, 21 U.S.C. 332, and civil penalties, 21 U.S.C. 333(f)(1)(A); seizing the device, 21 U.S.C. 334(a)(2)(D); and pursuing criminal prosecutions, 21 U.S.C. 333(a)." 531 U.S. at 349. More importantly, the Court observed that "[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives," which include ensuring that, "if [a] device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time," and that FDA's regulation does not "intrud[e] upon decisions statutorily committed to the discretion of health care professionals." *Id.* at 349-350. FDA must likewise ensure that its enforcement not "impede competition among predicate devices and delay

health care professionals' ability to prescribe" a product for appropriate uses, or "discourag[e manufacturers] from seeking § 510(k) approval of devices with potentially beneficial off-label uses." *Id.* at 350-351. Private suits predicated on violation of FDA's Section 510(k) process (in *Buckman*, state-law fraud-on-the-FDA claims) "inevitably conflict with the FDA's responsibility to police [regulatory non-compliance] consistently with the Administration's judgment and objectives." *Id.* at 350.

Notwithstanding *Buckman*'s admonition that private suits predicated on FDCA violations could frustrate FDA's careful balancing of competing interests, courts have in many instances permitted private relators to use the FCA as a vehicle to allege violations of the FDCA and FDA regulations as the basis for asserting that claims under federal health insurance programs were fraudulent, thereby frustrating the intent of Congress and upsetting the balance of the regulatory schemes overseen by FDA. See, *e.g.*, *Dan Abrams Co.* v. *Medtronic Inc.*, 850 F. App'x 508 (9th Cir. 2021) (mem.) (unpublished); *United States ex rel. Campie* v. *Gilead Scis., Inc.*, *supra*. For the same reasons articulated in *Buckman*, private civil attempts to leverage the FCA as a method to enforce provisions of the FDCA is improper, particularly when the government agency assigned responsibility to enforce the regulatory regime has not seen fit to take enforcement action itself. See, *e.g.*, *Buckman*, 531 U.S. at 354 (Stevens, J., concurring) (noting that the outcome might be different if FDA had "taken the necessary steps to remove the harm-causing product from the market").

D'Agostino v. *EV3, Inc.*, 845 F.3d 1 (1st Cir. 2016), demonstrates this potential for the FCA to be used in a manner that subverts FDA's enforcement discretion. There, a relator alleged that the defendants made false statements during the FDA approval process for certain medical devices. *Id.* at 4-6. The relator alleged that these misstatements influenced FDA's decision to approve the devices, which was a prerequisite to reimbursement by the Centers for Medicare & Medicaid Services. *Id.* at 7. In other words, although the device had in fact been cleared for marketing by FDA and had never been removed from the market, the qui tam relator proposed to ask a lay jury to decide that FDA's clearance had been premised on misrepresentations and that the clearance should therefore be disregarded in determining whether the product was eligible for CMS reimbursement.

The First Circuit disagreed that relator's theory was actionable under the FCA. Applying the FCA's materiality requirement, the First Circuit held that the alleged false claims could not be deemed material because the government did not withdraw its approval of the medical device at issue after the supposedly false allegations had been brought to light. The court noted that "[i]n the six years since [relator] surfaced the alleged fraud, the FDA has apparently demanded neither recall nor relabeling of [the device at issue]," notwithstanding the range of enforcement options available to FDA. *D'Agostino*, 845 F.3d at 8. The court held that "the FDA's failure actually to withdraw its approval of [the device at issue] in the face of [relator's] allegations precludes [relator] from resting his claims on a conten-

tion that the FDA's approval was fraudulently obtained." *Ibid.* Citing *Buckman*, the court went on to observe that "[t]he collateral effects of allowing juries in qui tam actions to find causation by determining the judgment of the FDA when the FDA itself has not spoken are akin to those practical effects that counsel in favor of not allowing state-law fraud-on-the-FDA claims." *Ibid.*

An earlier district court case, *United States ex rel. Nowak* v. *Medtronic, Inc.*, reflects a similar attempt to end-run the FDCA's bar against private enforcement, and FDA's policy judgments, by asserting FCA liability based on the premise that the devices in question should not have been cleared. 806 F. Supp. 2d 310 (D. Mass. 2011). In *Nowak*, a district court dismissed an FCA claim grounded on the theory that the defendant device maker "falsely presented its biliary stents to health care providers as effective for use in the vasculature despite knowing both that the devices were not approved for such a use because they may not be safe and effective for such a use." *Id.* at 349. In dismissing the relator's false certification claims, the court noted that "the government, the medical community, and the media were aware of off-label promotion of biliary stents for use in the vascular system," *id.* at 328, and that FDA had continued to clear such "biliary" stents because others were already offered on the market, see *id.* at 322.

While *D'Agostino* and *Nowak* reached the right result, other cases demonstrate the creativity of relators in bringing suit under the FCA predicated on alleged FDCA violations and the willingness of other courts to accept such theories of FCA liability.

In *United States ex rel. Campie* v. *Gilead Sciences, Inc.*, *supra*, for example, the Ninth Circuit reversed a district court decision granting a motion to dismiss relator's FCA claim premised on alleged drug impurities introduced by cGMP violations and improper laboratory conditions. The Ninth Circuit held that the relator's allegations of drug product contamination could proceed to trial despite the fact that FDA was aware of the allegations yet took no steps to remove the impacted drug from the market. 862 F.3d at 906. The court acknowledged that "other courts have cautioned against allowing claims under the False Claims Act to wade into the FDA's regulatory regime," *id.* at 905 (citing, *inter alia*, *D'Agostino*, 845 F.3d at 9), but held that "to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake," *id.* at 906.

In *Dan Abrams Co.*, the Ninth Circuit permitted a "fraud on the FDA" case to advance to trial on the theory that the defendant's medical devices were allegedly only susceptible to uses that should have been subjected to the more rigorous PMA review process rather than the more streamlined 510(k) regime. 850 F. App'x at 511. The Ninth Circuit reached this decision notwithstanding the fact that the products had never been removed from the market and FDA had, in the intervening period, cleared similar medical devices for the purportedly "true" indication under the 510(k) process. See *United States ex rel. Dan Abrams Co.* v. *Medtronic, Inc.*, No. LA CV15-01212, 2019 WL 12536543, at *3 (C.D. Cal. July 23, 2019), rev'd in part, 850 F. App'x 508 (9th Cir.).

In a slightly different context, in *United States ex rel. Holland* v. *DaVita, Inc.*, a district court denied a motion to dismiss a relator's FCA suit premised on the theory that "[d]efendants deviated from pre-approved test methods without performing method validations for these modifications, as required by CLIA regulations." No. 17-cv-1592, 2020 WL 12813696, at *2 (M.D. Fla. June 25, 2020). The court allowed the relator to use complicated and nuanced CLIA regulations as a springboard for asserted FCA liability despite the fact that the defendants' facilities had been inspected numerous times during the relevant period and that the inspectors, while noting certain CLIA deficiencies, never withdrew the facilities' accreditation. See *United States ex rel. Holland* v. *DaVita, Inc.*, No. 17-cv-1592, 2021 WL 4948076, at *1 (M.D. Fla. Aug. 10, 2021). Ultimately, the district court awarded the defendant summary judgment based on "the uncontroverted evidence * * * that CLIA violations—including of the type Relators allege—are common, yet rarely lead to the revocation of accreditation or the cancellation of payment." *Id.* at *6. But the case nonetheless exemplifies the risk that private actors can use the FCA to threaten massive liability for purported violations of highly nuanced regulatory regimes, even when the federal agency charged with enforcing those regulations, in a manner consistent with broader policy goals, had never taken enforcement action.

III. The Government Must Retain Authority To Dismiss FCA Claims That Undermine FDA's Authority And Hand Decision-Making Authority To Civil Juries

As the above discussion illustrates, private relators have been permitted to pursue FCA claims predicated

on regulatory violations of the FDCA and similar statutory regimes, motivated exclusively by private monetary reward and without any consideration of the government's competing policy objectives. Under *Buckman*, there is a strong argument that such claims should not be permitted to proceed at all, as the First Circuit held in *D'Agostino*. At the very least, the United States must retain authority to dismiss those qui tam actions if it determines that they are inconsistent with the government's broader policy goals. The government's decision not to intervene at an early stage of an FCA action should not preclude it from dismissing the suit at a later stage when, in light of the development and evolution of the litigation, the government determines that pursuing a claim based on purported injury to the United States is not in the government's interest.

Consistent with the government's residual authority, the appropriate standard for a court's consideration of a relator's objection to a motion to dismiss filed by the government is supplied by the FCA itself, in Section 3730(c)(2)(A), and not by Federal Rule of Civil Procedure 41(a), as the court of appeals ruled in this case. The court's reliance on a general procedural rule that imposes a more rigorous substantive standard than the FCA itself is at odds with the statute and threatens to undermine the scheme that Congress enacted. As the Brief for the United States establishes, the FCA does not impose statutory constraints on the government's ability to dismiss qui tam actions. U.S. Br. 37-46. It would be in appropriate and unwise for this Court to do so. Contrary to petitioner's contentions (Br. 41), that does not render the opportunity for a hearing meaningless. Rather, as the United States explains (Br. 44), the

relator has an opportunity at the hearing to convince the United States is should not dismiss or to convince the court that the government is motivated by an unconstitutional purpose.

Notably, in one of the cases discussed above that exemplifies the risks of FDCA-based litigation under the FCA, the government affirmatively touted its ability to supervise and terminate unwarranted qui tam suits. In *Campie*, the United States successfully advocated against review by this Court of the court of appeals' decision on the basis of its stated intention to dismiss the claim on remand to the Ninth Circuit. See Brief for the United States as Amicus Curiae at 15, No. 17-936, *Gilead Scis., Inc.* v. *United States ex rel. Campie* (2017) ("Pursuant to that authority, the Department of Justice has determined that, if this case is remanded to the district court, the government will move to dismiss respondents' suit under Section 3730(c)(2)(A).").

Had the relator in *Campie* succeeded on her theory that any cGMP violation at all rendered the product "adulterated" and ineligible for reimbursement, the result would have been wild over-deterrence. Every company faced with any kind of cGMP deficiency notice—however unremarkable—would have had to immediately cease production for fear of massive FCA liability. FDA would have lost, as a practical matter, its ability to calibrate the proper response to the identifying a cGMP issue during a site visit.

Similarly, in *Nowak*, had the district court not dismissed the litigation, a finding of FCA liability could have led manufacturers to pull from the market all de-

vices cleared as biliary stents, leaving healthcare providers without any stents for performing other vasculature procedures, including life-saving procedures to open cardiac valves with stents. 806 F. Supp. 2d at 352-358. The government had specifically opted *against* so dramatic an enforcement option, precisely because of the need to preserve supply of valves for those procedures. See *id.* at 321 (noting that "[i]n March 2007, the FDA took the unusual step of calling a meeting of biliary-stent manufacturers to convey the government's concerns regarding off-label use and promotion of biliary stents in the peripheral vascular system"). But for the district court's decision, a single civil plaintiff, pursuing private financial gain, could have undone FDA's deliberate work and dramatically undermined the provision of quality healthcare in America.

This Court, in *Buckman*, acknowledged these precise concerns in the context of state-law tort claims. *Buckman* noted that FDA's enforcement "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." 531 U.S. at 349.

The careful balance that Congress enacted, by precluding private plaintiffs and state governmental enforcement of the FDCA would be rendered largely nugatory if qui tam relators are allowed to pursue FCA claims threatening potentially hundreds of millions, if not billions, in liability predicated on alleged violations of FDA regulations and statutes. Barring such qui tam claims entirely is the result most consistent with Congress's decree that the FDCA may only be enforced "*by and* in the name of the United States." 21 U.S.C. 337(a)

(emphasis added). At the very least, private qui tam relators cannot insist on pursuing FCA liability based on alleged FDCA violations when the United States actively opposes the litigation. The United States must, therefore, retain its authority to dismiss a qui tam action, even when the threat to the government's interests is not evident until after the initial decision not to intervene has been made.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

DOUGLAS H. HALLWARD-DRIEMEIER
JOHN P. BUEKER
ANDREW J. O'CONNOR
PATRICK T. ROATH
CAMBREY C. DENT
ROPES & GRAY LLP

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