No. 15-7

IN THE
Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,
Petitioner,
v.
UNITED STATES OF AMERICA
AND COMMONWEALTH OF MASSACHUSETTS
EX REL. JULIO ESCOBAR AND CARMEN CORREA,
Respondents.

On Writ of Certiorari
to the United States Court Of Appeals
for the First Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* SUPPORTING PETITIONER

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INTEREST OF THE *AMICUS CURIAE*

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.[1] GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals.

GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, and they do so while saving consumers billions of dollars. In 2014, generic drugs accounted for 88% of prescriptions dispensed in the United States, but only 28% of total drug spending, resulting in $254 billion in health savings during 2014 alone and $1.68 *trillion* over the past ten years. Generic Pharmaceutical Association, Generic Drug Savings in the U.S. 1 (7th ed. 2015), *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf. In 2014, generic drugs saved the U.S. health system $4.1 billion in treating cancer, $13.8 billion in treating seizure disorders, and $23.3 billion in treating depression. *Id.* at 3. And savings are not limited to consumers and private insurers: Medicare and Medicaid saved nearly $110 billion in 2014 due to the use of generic drugs. *Id.* at 5.

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

GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See, e.g., Commil USA, LLC v. Cisco Sys., Inc.*, No. 13-896 (U.S.); *Panasonic Corp. v. Samsung Elects. Co.*, No. 14-540 (U.S.); *FTC v. Actavis*, No. 12-416 (U.S.); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* No. 10-844 (U.S.); *Takeda Pharms. U.S.A., Inc. v. Burwell*, No. 15-5021, -22 (D.C. Cir.).

GPhA's members are heavily regulated by the complex set of rules that govern the health care sector generally and the pharmaceutical industry in particular. Generic pharmaceutical manufacturers consider compliance with health care statutes and regulations to be vitally important, and they dedicate substantial resources to ensuring that their own actions comply with the law. But because of the way the federal government pays for pharmaceuticals, a company's own compliance with the law is not enough to be safe from liability under the False Claims Act (FCA). Rather, the implied-certification theory at issue in this case allows relators to sue a pharmaceutical company based even on a *customer*'s noncompliance with a regulatory requirement, and even if the regulatory requirement in question is one of the many complex and ambiguous provisions of federal or state law that are not designed for private enforcement. And because FCA penalties are assessed for each claim for reimbursement submitted to the government, *i.e.*, each medication dispensed, the result is massive yet unforeseeable potential liability.

As targets of such litigation under the FCA, GPhA's members have a strong interest in ensuring

that this Court properly interprets the requirement that claims be "false" or "fraudulent" to be actionable under the FCA. Correctly interpreting that key element preserves the FCA's role as "the primary vehicle by the Government for recouping losses suffered through fraud," *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 700 (7th Cir. 2015), rather than a "blunt instrument to enforce compliance with all medical regulations," *Mikes v.* Straus, 274 F.3d 687, 699 (2d Cir. 2001).

SUMMARY OF ARGUMENT

The False Claims Act is meant to punish fraudsters who pillage the public fisc. It is not designed as extraordinary supplemental punishment for anyone who violates a federal, state, or local regulation and happens also to be a federal contractor, or to do business with one.

But that is the consequence of the theory adopted by the court of appeals and defended by the respondent relator and the government. Any regulatory violation may become an FCA violation on the implied-certification theory, based on a post hoc determination that it was material to government payment. And because the FCA applies to anyone who "causes" a false claim to be submitted, anyone who makes a product that is later *resold* to the government, or reimbursed by the government, becomes a potential target—based on certifications supposedly made to the government *by someone else*.

The disproportionality between the supposed violation and the unavoidable punishment is remarkable. The FCA *mandates* the imposition of penalties for *each and every claim* found in violation, with no upper boundary for total penalties and little

or no room for judicial discretion about the appropriate penalty in any given case. And because it promises relators between fifteen and thirty percent of the damages and penalties awarded in a successful case, there is little incentive to forbear.

Relators are filing lawsuits seeking literally billions, even trillions, of dollars in mandatory penalties based on companies' deficient compliance with regulatory, contractual, and statutory requirements. Many of those requirements are, by their terms, enforceable only by the Government (should the Government exercise its discretion to do so). And those requirements often are designed to be enforced not through massive penalties, but through opportunities to cure, mitigation plans, or more moderate fines. As a result, the implied-certification theory exposes companies and their employees to enormous liability for compliance issues that are meant to be addressed by administrative and executive agencies in a much more careful and deliberate manner.

It is time for this Court to put a stop to this practice by rejecting the implied-certification theory of False Claim Act liability. The False Claims Act is not a citizen-suit provision for private enforcement of the entire U.S. Code and the Code of Federal Regulations—much less the Code of Wyoming Rules or the finest print in lengthy Medicaid-provider contracts. This Court should impose a clear limiting principle on False Claims Act suits by interpreting the terms "false" or "fraudulent" "claims" or "statements" to mean what any reasonable person would think these terms mean—claims and statements that contain misrepresentations, not

claims and statements that fail voluntarily to disclose a claimant's lack of compliance with the myriad statutes, regulations, or contractual terms that govern its conduct. Imposing massive punishment based on the contrary reading is wholly inconsistent with the principle of lenity: because the FCA does not mandate the overbroad and punitive reading necessary to sustain the implied-certification theory, that theory must be rejected.

ARGUMENT

I. THE IMPLIED-CERTIFICATION THEORY THREATENS COMPANIES AND INDIVIDUALS EVEN WHEN THEY DO NO BUSINESS WITH THE GOVERNMENT.

The False Claims Act was adopted to stop government contractors from "plundering . . . the public treasury," by "bill[ing] for nonexistent or worthless goods, charg[ing] exorbitant prices for goods delivered, and generally robb[ing the United States] in purchasing the necessities of war." *United States v. McNinch*, 356 U.S. 595, 599 (1958). The implied-certification theory takes the FCA far afield from its historical roots, exposing private companies—and even their employees—to liability for regulatory deficiencies.

Indeed, today companies are routinely exposed to massive potential FCA liability even when they *do not contract with the government* and *do not make any certifications*. GPhA's members are prime examples. When a GPhA member manufactures and sells a bottle of prescription medication to a pharmacy, it has no way of knowing whether that bottle will end up as the subject of a claim to the federal government. Each bottle could be sold to a

customer who pays out of pocket; a customer with private health insurance; or a customer who, through the pharmacy, will file a claim with Medicare, Medicaid, or another federal program. Yet if someone eventually seeks federal reimbursement, FCA liability is possible not just for the pharmacy, but also for the drug company: the FCA applies not only to "any person who . . . presents" false claims, but also to "any person who . . . causes" false claims "to be presented." 31 U.S.C. § 3729(a)(1)(A); *see also id.* § 3729(a)(1)(B) (FCA applies to "anyone who . . . makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"). The consequence is FCA liability based on someone else's claim and someone else's alleged certification.

A number of recent suits against pharmaceutical companies have alleged precisely this type of indirect connection to claims for government reimbursement supposedly containing false certifications. In one long-running case, for example, the plaintiffs allege that pharmacies violated the FCA when they dispensed a prescribed drug in tablet rather than capsule form, preferring the dosage form that Medicaid reimbursed at the higher rate. *United States ex rel. Lisitza v. Par Pharm. Cos.*, No. 06 C 06131, 2013 WL 870623, at *1 (N.D. Ill. Mar. 7, 2013). The plaintiffs sued not only the pharmacies but also the drug company that had sold the pharmacies the alternative dosage forms, alleging that even though the drug company had not submitted any claims itself, its marketing had "'caused' the submission of the false claims within the meaning of the FCA." *Id.* The claims submitted by the pharmacies were not factually false; the

claims identified the drug and dosage form dispensed to patients for legitimate medical conditions. But the government has asserted that they were "legally false" because the claims for reimbursement contained an implied false certification that Medicaid benefits had been provided "economically," which was allegedly violated when the dosage form dispensed was subject to higher Medicaid reimbursement. U.S. Compl. ¶ 118, *Lisitza*, No. 06 C 06131 (N.D. Ill. filed Sept. 9, 2011), ECF No. 41.[2]

FCA liability can be imposed based on even more tenuous connections. While most FCA cases are initially brought against businesses, the FCA applies to "any person," including individuals. Corporate employees have been pursued for FCA penalties from their own pockets, on the theory that they, too, submitted a false claim or "cause[d]" one to be submitted. *See, e.g.*, Nathan A. Huff, *Government Targets Laboratory Chief Executive in False Claims Act Suit – The New Normal in the Wake of the Yates Memo?*, False Claims Act & Qui Tam Law (Oct. 27, 2015), http://www.falseclaimsactlawblog.com/2015/10/government-targets-laboratory-chief.html (noting the government's pursuit of the co-founder and former CEO of Health Diagnostics Laboratory "in a federal qui tam lawsuit seeking hundreds of millions of dollars in damages" even after the company settled for $47 million). Indeed, the Department of Justice has emphasized its pursuit of FCA penalties against individuals. *See* Press Release, U.S. Dep't of Justice, Justice Department Recovers Over $3.5

[2] Although the pharmacies settled the claims against them, the case against the generic drug company is currently in its tenth year of litigation.

Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015; *see also* Memorandum from Deputy Attorney General Sally Quillian Yates re Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015), http://www.justice.gov/dag/file/769036/download. As a result, employees can be held *personally liable* not just for their own conduct, or their company's, but for the regulatory failings of their company's *customers* who submit claims.

Generic drug companies have a wide variety of customers, including wholesalers, pharmacy warehouses, pharmacies, hospitals, nursing homes, and other providers or resellers of pharmaceutical products. There is simply no way to know whether a particular drug sold may someday draw FCA allegations, because drug companies have no way of knowing whether their products will ultimately be dispensed to a patient with government insurance or to a patient with private insurance. For entities like generic drug companies, which are one step removed from the submission of claims to the government, the possibility of FCA liability based on later implied certifications that they did not even make is particularly concerning.

II. THE IMPLIED-CERTIFICATION THEORY FAILS TO PROVIDE ADEQUATE NOTICE TO POTENTIAL DEFENDANTS ABOUT THE TYPE OF CONDUCT THAT MAY SUBJECT THEM TO FCA LIABILITY.

The FCA requires a "false" or "fraudulent" claim. As petitioner explains, an *implicit* certification

cannot make a claim actually "false" or "fraudulent." Rather, that requires an actual false statement or representation. Pet. Br. 29-33. The contrary rule—imposing liability without any actual "false record or statement" of compliance, *Mikes*, 274 F.3d at 687, 697-98—would impose liability without adequate notice, even for picayune failures to comply with vague or obscure regulatory standards. "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996). The implied-certification theory violates this principle by failing to inform defendants about the type of conduct that could subject them not simply to regulatory enforcement proceedings, but to demands for millions, billions, or even (no hyperbole) *trillions* in damages and penalties. *See* 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9).

A. Highly-Regulated Entities Are Subject To Nearly Countless And Ever-Changing Technical Regulations That Could Serve As The Basis For An Implied-Certification Claim.

Many industries that submit claims for government payment or reimbursement are heavily regulated by particularly complicated regimes—federal, state, and even local—that extend far beyond what federal claims are permissible. *See* Richard Doan, *The False Claims Act and the Eroding Scienter in Healthcare Fraud Litigation*, 20 Annals Health L. 49, 74 (2011) (noting "the maze of 15,000 Medicare regulations, 400 pages of Medicare laws, thousands

of pages of CMS literature, 7,000 CPT codes, and 51 idiosyncratic state Medicaid programs" (footnotes omitted)). For example, pharmacies—generic drug companies' major customers—are governed by overlapping statutory, regulatory, and contractual layers. The conduct of a pharmacy in New Jersey that submits claims for Medicaid reimbursement may be governed by the federal Medicaid Act, counterpart state statutes, regulations promulgated by the Centers for Medicare and Medicaid Services (CMS), the New Jersey Board of Pharmacy regulations, *and* Medicaid provider agreements, all of which change over time. These nearly countless requirements create ample avenues for a hopeful relator searching for a compliance failure on which to base an FCA claim.

Deficient compliance with very technical regulatory requirements often serves as the basis of a relator's FCA claim. For example, in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011), a relator alleged that every claim for payment the company submitted was false because the company had not submitted accurate "VETS-100 reports," a required tally of how many veterans it employed, by September 30 of each year. *Id.* at 404-05.

Health care and pharmaceutical manufacturing are particularly rife with complex regulations that may allow relators to second-guess compliance. For example, one relator alleged that claims for prescription drugs were "false" because those pharmaceuticals were repackaged (into patient-friendly blister packs) at a facility that also processed penicillin, whereas FDA Current Good Manufacturing Practices call for penicillin to be

handled at a separate facility. *See United States ex rel. Rostholder v. Omnicare, Inc.*, No. CCB-07-1283, 2012 WL 3399789, at *5 (D. Md. Aug. 14, 2012). Another relator asserted an implied-certification claim based on a pharmacy's alleged sale of medication that had been repackaged and redispensed allegedly without fully complying with a New Jersey Board of Pharmacy regulation. The relator contended that the state regulation permitted redispensing only "[i]f a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact." *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 435, 442 (3d Cir. 2004) (quoting N.J. Admin. Code § 13:39-9.15(a)(2)).

Transforming arguable regulatory noncompliance into FCA liability creates a particularly acute fair-notice concern when used against defendants who make no certification. Defendants like generic drug manufacturers are typically sued not for their own implied certifications, but for the implied certifications of their customers that, long after purchasing generic drug products from a manufacturer, submit a claim for government reimbursement. A manufacturer must not only police its customers and their *express* certifications, but also acquire encyclopedic knowledge of every statute and regulation with which its customers will *impliedly* certify compliance and monitor its customers to ensure that there are no regulatory lapses.

This type of regulatory burden puts undue pressure on the generic pharmaceutical industry. Generic drug manufacturers operate on a very low

profit margin. Indeed, this profit margin is the reason they are able to save consumers so much money. While they rigorously comply with the regulations that govern *them*, they cannot master and monitor their *customers'* compliance with myriad *other* statutes and regulations, not to mention the provisions in contracts that are not a matter of the public record—all of which courts have found to contain requirements that could give rise to an FCA claim.

Thus, not only does the implied-certification theory put government contractors in an untenable position, it puts *non-contractors* in an impossible one. *Cf. United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011) ("[A]nyone examining Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them."). And even if such compliance were possible, it would be prohibitively expensive in light of the low profit margins on which generic manufacturers operate.

B. Implied-Certification Claims Are Often Based On Vague Regulatory And Statutory Standards.

Not only are the provisions governing the conduct of regulated entities practically innumerable, they are also at times quite vague. In several cases, FCA liability has hinged on whether a pharmacy's conduct meets an extraordinarily imprecise standard, such as whether the dispensation of a particular medication was "reasonable," 42 U.S.C. § 1395y(a)(1)(A), "necessary," *id.*, or "provided economically," *id.* § 1320c-5(a). Notably, many cases involve no allegations that treatments are being prescribed

without any medical indication or that frivolous and unnecessary tests are being ordered solely to rack up an expensive bill. Instead, these cases involve medical judgments about whether the particular treatment prescribed and dispensed was appropriate, or whether a different treatment would have been preferable.

For instance, FCA litigation can turn on issues that would be debatable even in an employee-benefits appeal or in the design of a prescription-drug formulary—contexts that do *not* carry multibillion-dollar penalties or the threat of criminal liability. One recent example turned on whether the prescription drug Plavix was just as good as aspirin or another alternative drug. The relator, using an implied-certification theory, alleged that the company's allegedly false marketing campaign caused physicians to submit claims for Plavix, rather than aspirin or another alternative drug. *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, No. CIV.A. 13-1039 FLW, 2015 WL 4997077, at *2, *12 (D.N.J. Aug. 20, 2015). The relator alleged that those claims were "false" because alternative drugs were "as effective" at a lower cost, and thus the claims failed to comply with Medicaid and Medicare Part D requirements that treatments be "medically necessary" or "reasonably necessary." *Id.* at *13.[3] The *Lisitza* case raises similar allegations: by marketing an alternative dosage form that was reimbursed at a higher rate by Medicaid, the generic manufacturer allegedly caused pharmacies to submit

[3] The district court dismissed the claim, but only after determining, on the merits and as a matter of law, that the drugs at issue were "reasonable and necessary" as defined by Medicare Part D. *In re Plavix*, 2015 WL 4997077, at *16.

false claims based on an implied certification that the drug was dispensed "economically." U.S. Compl. ¶ 118, *Lisitza*, No. 06 C 06131 (N.D. Ill. Sept. 9, 2011), ECF No. 41.

Indeed, FCA litigation can turn on medical or clinical concepts that are even broader in scope—and just as vague in content—as the debate over drug efficacy in *Plavix*. In another prominent FCA case, the government alleged (under an implied-certification theory) that a psychiatric hospital had failed to comply with statutes and regulations requiring that patients receive an "appropriate quality of care" in a "safe and secure environment." *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485, 1487 (W.D. Okla. 1996). The district court denied the hospital's motion to dismiss notwithstanding the vague nature of the governing standards, stating that "'[i]t may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its services meet 'professionally recognized standards for health care,'" but concluding that this "problem of measurement" was no bar to the government's FCA claim. *Id.* at 1488.[4]

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[4] *See also Mikes*, 274 F.3d at 701 (implied-certification claim for failure to comply with the Medicare statute's requirement that services provided thereunder must "be of a quality which meets professional recognized standards of health"); *United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 370 (E.D. Pa. 2014) (discussing a TRICARE regulation "which generally does not cover off-label prescriptions unless 'review[ed] for medical necessity, [which] requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective and in accordance with nationally accepted standards

Because relators can turn compliance with any standard, no matter how vague, into the subject of an *implied* certification, liability for massive FCA penalties is based on a post-hoc determination of what these standards mean and whether compliance with these standards was material to government payment. If the relator's view of the standards prevails—for instance, if the court agrees with the relator's *medical* judgment that a particular prescription is "reasonable," "necessary," "safe," or "effective"—then the certification and therefore the claim are rendered "false." Such an interpretation makes little sense, particularly in the context of a fraud statute imposing *mandatory* penalties on a per-claim basis if a claim is determined to be "false." *See Mikes*, 274 F.3d at 702 (declining to adopt interpretation of the FCA that would require "federal courts to step outside their primary area of competence and apply a qualitative standard measuring the efficacy of [medical] procedures. The quality of care standard of § 1320c-5(a) is best enforced by those professionals most versed in the nuances of providing adequate health care").

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of practice in the medical community'" (alterations in original)); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1262 (D.C. Cir. 2010) (implied-certification claim against a government contractor premised on violation of a conflicts of interest regulation, which prohibited a contractor from taking on work that "(1) [m]ay diminish its capacity to give impartial, technically sound, objective assistance [to the Nuclear Regulatory Commission] and advice or may otherwise result in a biased work product, or (2) may result in its being given an unfair advantage") .

C. Implied-Certification Claims Often Allege Technical Violations That The Responsible Agency Would Not Pursue And That Private Plaintiffs May Not Pursue Directly.

Enterprising relators have turned the implied-certification theory into a vehicle to litigate compliance with regulations that are not privately enforceable, and not meant to be. Exacerbating the notice problem inherent in an implied-certification theory, these lawsuits threaten to create liability even where the responsible agency would see none, or would make a considered and discretionary judgment not to pursue it.

For instance, as this Court has repeatedly held, Congress made quite clear that the FDCA is to be enforced by the United States alone, not by each and any citizen of the United States. 21 U.S.C. § 337(a). Congress recognized that it would be untenable to have a regulated business's compliance with the FDCA or FDA regulations, "although deemed appropriate by the Administration," be second-guessed by a court at the instance of a private plaintiff.[5] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001). The agency has special expertise in deciding "whether the particular enforcement action [that may be] requested" by people outside the agency "fits the agency's overall policies." *Heckler v. Chaney*, 470 U.S. 821, 832

[5] The Court in *Buckman* rejected private enforcement of the FDCA in state court at the initiation of private plaintiffs claiming actual injury from a medical device—whereas the implied-certification theory permits private enforcement of the FDCA by private litigants who have suffered no personal injury whatsoever.

(1985). Having those expert judgments second-guessed—whether by a private relator, or by generalist FCA litigators at the Department of Justice, both of whom seek to maximize monetary recovery—can easily "skew[]" the "somewhat delicate balance of statutory objectives" that the FDA strikes. *Buckman*, 531 U.S. at 348.

Yet the implied-certification theory permits just that sort of litigation. As just discussed, no one may bring a private lawsuit to enforce the FDA's Current Good Manufacturing Practices. Yet relators have sought to use the implied-certification theory to dodge that plain statutory bar. For instance, in *Rostholder*, the relator alleged that a corporation that provides pharmacy services to long-term care facilities did not comply with Current Good Manufacturing Practices when they repackaged drugs in the same facility that handled penicillin. *See* 2012 WL 3399789, at *5. Compliance with current standards for good manufacturing calls for a classic agency judgment, yet the implied-certification theory under the FCA allows it to be litigated in a different, inappropriate forum.

Similarly, even though this Court has regularly held that "off-label" use of a drug or device is "generally accepted," *Buckman*, 531 U.S. at 350-51, FCA litigants regularly seek to allege that *every claim* for Medicare or Medicaid reimbursement for an off-label use was caused by unlawful off-label marketing and, therefore, a false claim on an implied-certification theory. For instance, the court in *Bergman v. Abbott Laboratories* sustained an action against a drug company for allegedly causing physicians to submit claims for reimbursement for off-label uses of drugs based on the drug

manufacturer's violations of 21 U.S.C. § 355(d) and physicians' violations of 42 U.S.C. § 1395y(a)(1)(A). 995 F. Supp. 2d at 368-70. Such exposure to "unpredictable civil liability" naturally threatens manufacturers' willingness to bring to market products "with potentially beneficial off-label uses." *Buckman*, 531 U.S. at 350.

Declining to provide a private right of action in a statute generally reflects a legislative determination that it is in the public's best interest for agencies to exercise discretion about when and how to enforce these requirements based on the statutory tools available to them, such as imposing fines, continuing performance of the current agreement but declining to renew it at the end of its term, providing an opportunity to cure any lack of compliance, requiring a plan of correction, requiring mitigation, removing the noncompliant entity from the government program, or instituting an administrative adjudication for lack of compliance. As the Office of Legal Counsel has noted, "it is frequently in the Government's interest, as it would be in the interest of any contracting party, to avoid excessive concern over minor failings that might threaten a useful course of dealing with the other party," particularly if "the contractor's performance otherwise has been adequate." Office of Legal Counsel, *Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 U.S. Op. Off. Legal Counsel 207, 220 (1989).

Agencies may exercise their discretion to punish the worst offenders in the most significant way and address more minor violations with a scalpel, rather than a sledgehammer. *See* 21 U.S.C. § 336 (permitting the Secretary to provide a written notice or warning for violations of the FDCA, rather than

imposing criminal or civil penalties, "whenever he believes that the public interest will be adequately served" by a more minor punishment); 42 U.S.C. § 1320c-5(b)(1)-(3) (violation of Medicare health-care provider obligations may be enforced solely by the Secretary with an appropriate penalty, but only after the organization "has been given a reasonable opportunity to enter into and complete a corrective action plan" and has "failed in a substantial number of cases substantially to comply with any obligation imposed on him" or "grossly and flagrantly violated any such obligation in one or more instances").[6] Agencies can also harmonize compliance across multiple programs. *Astra USA, Inc. v. Santa Clara Cnty.*, 131 S. Ct. 1342, 1349-50 (2011).

The implied-certification theory undermines the discretion granted to agencies tasked with administering complicated regulatory regimes or sensitive government contracts in a careful and deliberate manner. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008) (expressing concern that an overly broad reading of the FCA could "undermine the government's own administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into compliance when they fall short of what the Medicare regulations and statutes require"); *Wilkins*, 659 F.3d at 310 ("It is ironic[] that if we allowed appellants, though they are ostensibly

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[6] Despite the carefully crafted enforcement mechanism built into 42 U.S.C. § 1320c-5 and the lack of a private right of action, violations of this section have repeatedly been the subject of implied-certification claims. *See, e.g.*, *Aranda*, 945 F. Supp. at 1488 (holding that allegations of a provider's failure to comply with § 1320c-5(b)(1) can form the basis of an FCA claim).

acting on behalf of the Government, to bring suit based on United Health's non-compliance with marketing regulations, we would short-circuit the very remedial process the Government has established to address non-compliance with those regulations.").[7]

Relators do not have the same incentives that agencies have to exercise discretion in pursuing claims based on regulatory or statutory deficiencies, because "[a]s a class of plaintiffs, 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). FCA suits can be incredibly lucrative for a successful relator, who is guaranteed by statute to walk away with between 15 percent and 30 percent of the proceeds of the FCA judgment or settlement. 31 U.S.C. § 3730(d)(1)-(2). Over the past three years alone, relators have made nearly $1.5 *billion* simply by being plaintiffs in FCA cases. FY 2015 Fraud Statistics, U.S. Dep't of Justice, http://www.justice.gov/opa/file/796866/download (Nov. 23, 2015 11:56 AM). And individual relators have obtained tens of millions of dollars, typically following settlement of an FCA claim. See, e.*g.*, Press Release, U.S. Dep't of Justice, Nearly 500 Hospitals Pay United States

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[7] *See also United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (permitting an FCA claim based on the violation of a statute could "unilaterally divest[] the government of the opportunity to exercise precisely the discretion that is among the key differentiations of voidness from voidability: the discretion to accept or disaffirm the contract on the basis of complex variables reflecting the officials' views of the government's longterm interests").

More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices (Oct. 30, 2015), http://www.justice.gov/opa/pr/nearly-500-hospitals-pay-united-states-more-250-million-resolve-false-claims-act-allegations ($38 million relator award); Press Release, U.S. Dep't of Justice, Amerigroup to End Appeal and Pay $225 Million to United States and Illinois to Settle Pregnancy Discrimination Case (Aug. 14, 2008), http://www.justice.gov/archive/usao/iln/chicago/2008/pr0814_01.pdf ($56 million relator award).

Given these incentives, relators simply cannot exercise the judgment that an agency can. Without that judgment, more relators and more FCA suits are not always, *per se*, a good thing. *Cf. Astra*, 131 S. Ct. at 1348-49 (rejecting disruptive private enforcement even though it would "spread the enforcement burden").

If Congress intended, by passage of the False Claims Act, to enact a broad citizen-suit provision for private enforcement of any statutory or regulatory commitments (or an unspecific subset of those commitments) of anyone who contracts with the government, "it did so with a peculiar choice of language and in an unusually backhanded manner." *Williams v. United States*, 458 U.S. 279, 287 (1982) (declining to interpret a statute making it a crime to "knowingly mak[e] any false statement or report . . . for the purpose of influence in any way the action of [certain financial institutions]" to cover the depositing of bad checks, because a "check" is not a "statement," *i.e.*, "factual assertion at all, and

therefore cannot be characterized as 'true' or false.'").[8]

III. IN LIGHT OF THE EXTRAORDINARY PENALTIES THAT ACCOMPANY FCA CLAIMS, THE RULE OF LENITY CALLS FOR CONDITIONING LIABILITY ON AN *EXPRESS* CERTIFICATION, WHICH SERVES A NECESSARY GATEKEEPING ROLE.

Given the FCA's unique penalty provisions and the strong incentives they provide for plaintiffs to bring and pursue even marginal cases, FCA cases that survive a motion to dismiss create enormous settlement pressure. And some elements of the cause of action simply cannot be tested on a motion to dismiss (*e.g.*, the bare allegation of scienter). The implied-certification theory impermissibly heightens the probability of significant payments even in meritless suits and is contrary to lenity principles.

Under the FCA's penalties provisions, once a factfinder determines that a defendant violated the Act, courts have no choice but to award three times the amount of damages sustained by the government as a result of the fraud, *plus* civil penalties of between $5,500 to $11,000 for *each* false claim submitted, *plus* the relator's attorneys' fees and costs. 31 U.S.C. §§ 3729(a), 3730(d); 28 C.F.R. § 85.3(a)(9).

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[8] Indeed, by all indications Congress knows how to clearly make a statutory violation cognizable under the False Claims Act when it wants to do so. In 2010, it amended the Anti-Kickbacks Statute to expressly provide that a violation of that statute is a false claim under the FCA. 42 U.S.C. § 1320a-7b(g).

If this Court endorses the implied-certification theory, whether liability for these damages attaches to FCA claims will depend on the subjective view of the agency at issue (to determine whether the contractual, statutory, or regulatory term that was violated was material to the government's decision to pay a claim, *see* 31 U.S.C. § 3729(a)(1)(B)), and the scienter of the defendant (to determine whether the defendant knowingly violated said term, *id.* § 3729(a)(1)(A)-(B)). These types of questions are generally fact-specific inquiries not subject to resolution at the pleadings stage. *See In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989) ("Materiality and scienter are both fact-specific issues which should ordinarily be left to the trier of fact."). Likewise, whether an FCA defendant's conduct actually fell below the statutory or regulatory standard asserted as the basis of the plaintiff's implied-certification theory often cannot be resolved on the pleadings, particularly in the case of vague standards like "reasonable" or "necessary." *See e.g.*, *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *3 (C.D. Cal. July 10, 2014) ("Whether or not any particular use is 'supported' by the compendia is a complex, case-by-case inquiry not susceptible to resolution on a motion to dismiss, and expert testimony is often necessary to discern whether a mention in a compendium in fact constitutes sufficient support.")

Given the enormous penalties at stake in FCA cases, rolling the dice on how a factfinder might view the facts (and concepts like "reasonableness" or "economical") and what inferences they might draw is a risk that, for many companies, is simply

impossible to take.[9] This is particularly true in implied-certification cases, in which *every* individual claim submitted based on programmatic regulatory or contractual failures will be "false."[10] A company that files a single $1 million claim for reimbursement will therefore be on the hook for no more than $11,000 in civil penalties, while a company that files 1000 claims for $5 each (only $5,000 in total payment by the government) faces between $5.5 million and $11 million in civil penalties.

Relators do not hesitate to exploit this penalty structure, often seeking exorbitant civil penalties for hundreds or thousands of claims that were all filed during a time in which a company was operating in violation of a statutory or regulatory standard. *See, e.g.*, *Conner*, 543 F.3d at 1216 (plaintiffs alleged that defendant "presented false claims because it was in violation of various regulations and statutes establishing Medicare conditions of participation at all times from 1987 until the present day" (footnote

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[9] Enormous penalties are not a mere hypothetical possibility; prior cases relying on an implied-certification theory have resulted in hundreds of millions in FCA settlements and judgments. *See, e.g.*, *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 727 (N.D. Ill. 2007) (imposing approximately $300 million in FCA damages and penalties under implied-certification theory for submitting health-care claims while engaging in discriminatory marketing practices).

[10] By contrast, in the factual fraud context, each claim arises out of distinct fraudulent conduct. Similarly, FCA claims based on express certifications each arise out of distinct fraudulent statements. As a consequence, implied-certification cases can result in much greater penalties than claims for conduct that formed the reason for the FCA's enactment in the first place—contractors' "rob[bing] the public treasury" by, for example, "bill[ing] for nonexistent or worthless goods." *McNinch*, 356 U.S. at 599.

omitted)); *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 741 (N.D. Ill. 2007) (imposing treble damages and statutory penalties for each of 18,130 claims submitted while discriminating against a pregnant woman and ill individuals in violation of contractual nondiscrimination requirements); *Schindler Elevator Corp.*, 563 U.S. at 417 (2011) (alleging false certification by elevator company's failure to meet an annual reporting requirement of providing information on the number of veterans it employed, thus rendering false "hundreds of . . . claims for payment" valued at $100 million).

Thus, unlike in typical tort or breach-of-contract cases that involve actual damages, the penalties and damages that could attach to FCA liability often eclipse, many times over, the value of the goods or services that were provided to the government. *See Conner*, 543 F.3d at 1221 (noting that under the relator's implied-certification theory, "[a]n individual private litigant, ostensibly acting on behalf of the United States, could prevent the government from proceeding deliberately through the carefully crafted remedial process and could demand damages far in excess of the entire value of Medicare services performed by a hospital").

This is a particular risk for generic pharmaceutical companies. In the context of generic drugs, the dollar amounts at stake are relatively small (in some instances, as little as a few dollars per prescription), but the sheer number of claims (submitted each time medication is dispensed) is enormous. Even the minimum penalty is many, many times the amount of money that a generic company (or its pharmacy customer) makes from the

sale. Adoption of the implied-certification theory could thus allow the government to obtain valuable and useable goods and services, potentially for years, and also recover penalties that exceed, by scores, the value of the goods and services received even where the government is not damaged by the defendant's non-compliance. The FCA is supposed to be "the primary vehicle by the Government for recouping losses suffered through fraud," *Sanford-Brown,* 788 F.3d at 700, not a vehicle by which the government or relators are unjustly enriched. The implied-certification theory poses an unacceptable risk of a grossly disproportionate penalty for the allegedly unlawful conduct at issue.

A 2005 False Claims Act case filed against generic drug companies illustrates the absurdity of the implied-certification theory in this context. *See* Compl., *United States ex rel. Ven-A-Care of the Florida Keys v. Actavis Mid Atlantic LLC*, No. 1:08-cv-10852 (D. Mass.), ECF No. 1. The plaintiffs sued virtually every major generic drug company in the country, alleging that they reported inflated price data to the national pharmaceutical pricing compendia, thereby causing claims to be submitted and reimbursed at inflated (and therefore implicitly false) rates. The plaintiffs sought penalties for, essentially, each one of these pills dispensed in the United States over a ten-year period. When added up, the claims allegedly at issue would result in *mandatory* penalties of between $3.3 and $6.7 *trillion*. *See, e.g.*, *id.* ¶ 82 ("Approximately 30,075,004.00 'NDC' specific prescription claims were paid or approved by State Medicaid programs for ALPHARMA DRUGS during the six years preceding the commencement of this action against ALPHARMA through 2005 and each was caused to

be false or fraudulent by the said price reporting."); *United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009) ("The Complaint alleges that Defendants engaged in a fraudulent scheme involving tens of thousands of Medicaid claims, over a thousand NDCs, and reimbursements of billions of dollars from Medicaid over the course of a decade."); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, No. CIV.A.05-11084-PBS, 2008 WL 163644, at *1 (D. Mass. Jan. 16, 2008) ("The *Dey* case involves thousands of claims for reimbursement spanning approximately fourteen years, from 1992 to 2006."). The potential exposure for civil penalties is almost comically absurd, except that it is entirely plausible under the implied-certification theory based on the FCA's mandatory civil penalties provisions.

Even if the False Claims Act were susceptible to a construction that encompasses the implied-certification theory, the rule of lenity would preclude the adoption of such an interpretation. *See United States v. Universal C. I. T. Credit Corp.*, 344 U.S. 218, 221-22 (1952)("[W]hen choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite."). Indeed, this Court has already invoked the rule of lenity in interpreting the meaning of the ambiguous term "claim" in the False Claims Act, because even in a civil action the Court is "actually construing the provisions of a criminal statute." *McNinch*, 356 U.S. at 595, 598; *see also Williams*, 458 U.S. at 286 (expressing "reluctan[ce] to base an expansive reading" of a criminal statute "on inferences drawn from subjective and variable 'understandings'" of

whether a "false statement" could plausibly encompass a bad check).

The rule of lenity applies here because the statutory language being construed applies to conduct that is also punishable criminally under the FCA's criminal provision, which also applies to presentment of a "false" or "fraudulent" claim for payment. The criminal provision today is codified at 18 U.S.C. § 287, separately from the civil provision at issue here, but the two sections cannot be divorced from one another. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943) (FCA civil and criminal provisions are construed together). Indeed, the civil and criminal provisions originally were a single statute, and were only separated through the process of codification. *Rainwater v. United States*, 356 U.S. 590, 592 n.8 (1958); *see McNinch*, 356 U.S. at 598 & n.5.

As a result, the rule of lenity applies here with full force. Whether the statute is invoked in a civil case (as here) or a criminal one, there can be only one consistent interpretation—the one consistent with the rule of lenity. *Yates v. United States*, 135 S. Ct. 1074, 1088 (2015) (rule of lenity applies when interpreting the meaning of "tangible object" no matter "whether the offense subject to investigation is criminal or civil"); *Leocal v. Ashcroft*, 543 U.S. 1, 12 (2004) ("[T]he statute at issue] has both criminal and noncriminal applications. Because we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies.").[11]

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[11] *See also United States v. Thompson/Ctr. Arms Co.*, 504 U.S. 505, 517-18 (1992) (plurality opinion); *id.* at 519 (Scalia, J.,

Lenity principles would apply here even if violations did not carry a potential prison sentence. The FCA's treble-damages and civil-penalty provisions are punitive in their own right—indeed, considerably more punitive than some criminal statutes. *See Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000) (FCA damages "are essentially punitive in nature"). The rule of lenity prescribes that "*penal*" statutes shall be strictly construed, and a statute imposing a penalty of this magnitude certainly qualifies. That is why this Court has construed even much more modest civil-penalty statutes using the rule of lenity. *Commissioner v. Acker*, 361 U.S. 87, 91 (1959) (civil penalty for "substantial underestimate" of tax).

In light of the FCA's damages and civil penalty provisions, the potential and uncertain liability could force some companies to simply decline to do business with the government, thereby depriving the government and the public of needed goods and services and of competitive bids for such goods and services. But for businesses like generic drug companies that cannot control if their customers make claims to the government based on the goods that drug companies sell to them, liability in any one case could force them out of business altogether.

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concurring in the judgment); *Crandon v. United States*, 494 U.S. 152, 158 (1990).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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January 26, 2016

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