No. 08-304

IN THE
Supreme Court of the United States

GRAHAM COUNTY SOIL & WATER CONSERVATION DISTRICT, *et al.*,

Petitioners,

v.

UNITED STATES OF AMERICA *ex rel.* KAREN T. WILSON,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF OF *AMICI CURIAE* THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PETITIONERS

CONAN GRAMES
Counsel of Record
DOUGLAS WAYNE KENYON
HUNTON & WILLIAMS LLP
1900 K Street
Washington, DC 20006-1109
(202) 955-1685

Counsel for Amici Curiae

218695

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

Cases:

Cited Authorities

Cited Authorities

Cited Authorities

STATEMENT OF INTEREST[1]

This *amici curiae* brief in support of Petitioners is filed on behalf of two trade organizations: the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). PhRMA and BIO represent companies that are devoted to discovering new cures for diseases and ensuring patient access to life-saving and life-enhancing therapies.

PhRMA represents the world's leading research-based pharmaceutical and biotechnology companies, each of which is devoted to inventing medicines that allow patients to live longer, healthier, more productive lives. PhRMA members alone invested an estimated $44.5 billion in 2007 in discovering and developing new medicines. PhRMA advocates for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies.

BIO is the largest biotechnology organization in the world, providing advocacy, business development and communications services for more than 1,250 members

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission. The Petitioners have filed a blanket waiver with the Court and the Respondent has consented to the filing of this brief and such consent is being lodged herewith. The parties have been given at least 10 days notice of *amici*'s intention to file.

worldwide. BIO members are involved in researching and developing innovative healthcare, agricultural, industrial and environmental biotechnology products. Corporate members range from entrepreneurial companies developing a first product to Fortune 100 multinationals. BIO also represents state and regional biotech associations, academic centers, venture capital firms, and other service providers to the industry.

Compliance with regulations designed to prevent healthcare fraud is critically important, and *amici's* member companies devote significant resources to internal compliance programs that complement the government's efforts to prevent misconduct. *Amici* fully support appropriate enforcement of the False Claims Act. At the same time, a balance must be maintained, as contemplated by Congress, between encouraging citizens with information otherwise unavailable to the government to come forward and preventing unnecessary litigation that provides no new information to the government.

Amici are concerned that the Fourth Circuit's decision, if not reversed, not only will permit, but actually will encourage, *qui tam* relators to initiate actions without any direct or personal knowledge of the information on which the allegations are based. Indeed, *amici*, whose members are often the targets of *qui tam* suits, anticipate that the Fourth Circuit's decision may well create a new cottage industry wherein individuals rummage through State reports or audits for tenuous allegations of wrongdoing and then file *qui tam* actions based upon the State's own investigative work. *Amici* fear that constantly defending such suits will serve only

to increase their already substantial costs of doing business, which, in turn, may increase pressure on healthcare costs for all Americans and negatively impact patient access to new treatments by impairing industry's ability to develop those treatments. *Amici*, therefore, file this brief in support of the petition for a writ of certiorari.

ARGUMENT

The Fourth Circuit's holding — that the "public disclosure" jurisdictional bar is limited to information in federal, and not State, reports, hearings, audits, and investigations — if allowed to stand, will turn the public disclosure bar on its head and dramatically expand the range of evidence upon which *qui tam* plaintiffs can bring False Claims Act cases in reliance on the government's, rather than their own, investigative work. Such an expansion would lead to substantial unintended and negative consequences for *amici's* members, the patients they serve, and the U.S. healthcare system.

As discussed in Section II below, the most common type of *qui tam* action involves allegations of healthcare fraud. A rule whereby information contained in a publicly-available audit or report prepared by a State pursuant to the federal-state Medicaid program does not trigger the jurisdictional bar will result in initiation of *qui tam* actions in cases where the relator has no direct or personal knowledge of the information on which the allegations are based. Such a rule will encourage the very type of "parasitic" *qui tam* actions that Congress intended to prevent when it enacted the public disclosure jurisdictional bar provision. The Fourth

Circuit's holding, therefore, turns this provision on its head. In construing a provision aimed at encouraging private enforcement lawsuits by those individuals who were either close observers of (or otherwise involved in) the fraudulent activity in such a way as to allow claims by opportunistic plaintiffs who have no personal information to share, the holding of the court below threatens to subvert the clear intent of the statute. Because of the far-reaching implications of such an interpretation, the petition for a writ of certiorari should be granted.

I. The Fourth Circuit's Holding Will Significantly Undermine the Twin Goals of the Public Disclosure Bar.

Congress amended the False Claims Act ("the FCA") in 1986 to include a public disclosure jurisdictional bar. *See* 31 U.S.C. § 3730(e)(4)(A). The twin goals of the provision are (1) to encourage private enforcement of suits by individuals who have personal knowledge of fraudulent activity, and (2) to discourage opportunistic plaintiffs who have no personal information to share. *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 649-51 (D.C. Cir. 1994) (describing the twin purposes of the public disclosure bar). Section 3730(e)(4)(A) recognizes three categories of "public disclosure[s]" that will trigger the Act's jurisdictional bar: first, disclosures in a "criminal, civil, or administrative hearing"; second, disclosures in "a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation"; and third, disclosures in "the news media."

As for the first category, the circuit courts are united in holding that a State court proceeding constitutes a public disclosure under the Act. *See United States ex rel. Wilson v. Graham County Soil & Water Conservation District*, 528 F.3d 292, 303 (4th Cir. 2008) (collecting cases). The second category, however, has split the circuits and is the subject of the present certiorari petition. *Compare United States ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 917-18 (9th Cir. 2006) (holding that a State administrative report constitutes a public disclosure), *cert. denied*, 2008 U.S. LEXIS 1142 (2008); *Battle v. Bd. of Regents*, 468 F.3d 755, 762 (11th Cir. 2006) (same); and *Hays v. Hoffman*, 325 F.3d 982, 988 (8th Cir. 2003) (same), *cert. denied*, 540 U.S. 877 (2003), *with United States ex rel. Wilson v. Graham County Soil & Water Conservation District*, 528 F.3d 292, 306 (4th Cir. 2008) (holding that a State administrative report does not constitute a public disclosure); and *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 745 (3d Cir. 1997) (same).

As the Fourth Circuit candidly acknowledged, the second category is not limited by its literal language to *federal* reports, hearings, audits, and investigations. (Pet. App. 22a.) That court, however, nevertheless decided to so limit the second category based on its application of the doctrine *noscitur a sociis*. While not repeating here the Petitioners' sound critique of that doctrine and its misapplication by the Fourth Circuit (Pet. 22-26), we point out that the court's reading of the word "federal" into the public disclosure bar would lead to several unintended and anomalous results.

First, numerous *federal* programs have been, and continue to be, adopted based on the "cooperative federalism" model of legislation, i.e., legislation in which the federal government encourages State and local governments to implement its programs. *See*, *e.g.*, *Schaffer v. Weast*, 546 U.S. 49, 52 (2005) (observing that the Individuals with Disabilities Education Act "is frequently described as a model of cooperative federalism") (citation and internal quotation marks omitted); *New York v. United States*, 505 U.S. 144, 167-68 (1992) (collecting cases demonstrating that "a program of cooperative federalism is replicated in numerous federal statutory schemes[,]" including the Clean Water Act, the Occupational Safety and Health Act of 1970, the Resource Conservation and Recovery Act of 1976, and the Alaska National Interest Lands Conservation Act) (internal citations and quotation marks omitted); *California v. United States*, 438 U.S. 645, 650 (1978) ("If the term 'cooperative federalism' had been in vogue in 1902, the Reclamation Act of that year would surely have qualified as a leading example of it."); *Batterton v. Francis*, 432 U.S. 416, 431 (1977) (noting that the Aid to Families with Dependent Children program involved the "concept of cooperative federalism").

Many of these and other federal-state programs require the States to audit, investigate, and report on compliance with federal law. Take, for example, the Medicaid program, in which many members of *amici* participate and which this Court has observed "is designed to advance cooperative federalism." *Wisconsin Dep't of Health and Human Servs. v. Blumer*, 534 U.S. 473, 495 (2002) (citation omitted). According to the

Centers for Medicare and Medicaid Services ("CMS"), the Medicaid program's aggregate expenditure on prescription drugs in 2006 (the latest historical year for which such data are available) amounted to $19.4 billion. CMS, Office of the Actuary, National Health Expenditure Projections tbl. 11, *available at http://www.cms.hhs.gov/National*HealthExpendData/03_NationalHealthAccountsProjected.asp.[2]

The Medicaid program, which provides joint federal and State funding of healthcare for millions of low-income individuals, was launched in 1965 with the enactment of Title XIX of the Social Security Act, as added 79 Stat. 343, 42 U.S.C. § 1396 *et seq. Arkansas Dep't of Health and Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006). The statute vests authority for the program's administration in the Secretary of Health and Human Services ("HHS"), who has delegated such authority to CMS.[3] *Id.*

Although States are not required to participate in Medicaid, all of them have chosen to do so. *Id.* The Medicaid "program is a cooperative one; the Federal Government pays between 50% and 83% of the costs the State incurs for patient care, and, in return, the

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2. CMS projects that by 2017, such expenditures will amount to $47.1 billion. CMS, Office of the Actuary, National Health Expenditure Projections tbl. 11, available at http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp.

3. Prior to 2001, CMS was known as the Health Care Financing Administration (HCFA). *See* 66 Fed. Reg. 35437; *Ahlborn*, 547 U.S. at 275 n.2.

State pays its portion of the costs and complies with certain statutory requirements for making eligibility determinations, collecting and maintaining information, and administering the program." *Id.* (citing 42 U.S.C. § 1396a; footnote omitted). One such requirement is that the State Medicaid agency must audit records of payments to vendors. 42 C.F.R. § 447.202. State Medicaid agencies are also required to have methods for identifying and investigating suspected fraud cases. *Id.* § 455.13. The agency must conduct a preliminary investigation whenever it "receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices." *Id.* § 455.14. The agency is required to report to the federal government the number of complaints of fraud or abuse that warrant preliminary investigation. *Id.* § 455.17(a).

After conducting a preliminary investigation, if the State Medicaid agency has reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation. *Id.* § 455.15(c). For each case that warrants a full investigation, the agency must report to the federal government the provider's name and number; the source of the complaint; the type of provider; the nature of the complaint; the approximate range of monetary losses involved; and the legal and administrative disposition of the case. *Id.* § 455.17(b).

Yet, as Petitioners observe, the Fourth Circuit's construction of the public disclosure bar would lead to the anomalous result that a formal report prepared by a State Medicaid official pursuant to federal Medicaid laws and regulations and then widely disseminated would

not trigger the public disclosure bar, while a one-paragraph article in a little-known weekly paper of limited circulation would. (Pet. 24.)

Amici disagree with the position the United States put forward as intervenor in *Hays v. Hoffman*, 325 F.3d 982 (8th Cir. 2003). In that case, the United States argued that a State Medicaid audit report may not constitute a public disclosure under the federal FCA because "[m]any [S]tate and local reports, audits, and investigations . . . never come to the attention of federal authorities and, accordingly, they do not put the federal government in a position to pursue on its own the fraud they disclose." Br. for U.S. as Intervenor, 2002 WL 32181440, at *38-41 (May 2002).[4] However, as discussed

4. In its *amicus curiae* brief in *United States ex rel. Bly-Magee v. Premo*, 470 F.3d 914 (9th Cir. 2006), the United States spends six pages discussing the legislative history of section 3730(e)(4). Br. for U.S. as Amicus Curiae, 2007 WL 4613626, at 9-14 (Dec. 2007). However, John Boese has observed that:

> [A]pplicable legislative history explaining versions not adopted is of little help in deciphering this provision. Because Section 3730(e)(4) was drafted subsequent to the completion of the House and Senate Committee reports on the proposed False Claims Act Amendments, those reports, which contained discussion of altogether different bars, cannot be used in interpreting it. And the sponsors' interpretations of the provision ultimately enacted, which are preserved in the Congressional Record, are spare, often incorrect, and wide-ranging enough to provide some support for almost any construction of its many ambiguities.

John T. Boese, *Civil False Claims and Qui Tam Actions* § 4.02[A], at 4-47 to 4-48 (3rd ed. 2008).

above and in the Eighth Circuit's opinion in *Hays*, the Medicaid program is a cooperative federal-state program that requires the State Medicaid agency to report to the federal government information regarding the State agency's investigations of alleged Medicaid fraud and abuse. *Hays*, 325 F.3d at 988-89. State Medicaid fraud investigations and their outcomes are readily available to Department of Justice attorneys as potential sources of the allegations in FCA suits brought by the government itself. *See id.*; *see also In re Natural Gas Royalties Qui Tam Litig.*, 467 F. Supp. 2d 1117, 1143 (D. Wyo. 2006) ("The Court finds that this State-generated report that investigates gas measurement of gas streams, including those from federal leases, would likely place the federal government on notice of fraudulent activities impacting the federal fisc.").

In keeping with the spirit of cooperative federalism through which Medicaid and many other federal programs operate, State reports addressing allegations of fraudulent conduct in federal or cooperative programs should trigger the jurisdictional bar of section 3730(e)(4)(A). This will serve the Act's twin goals of precluding parasitic *qui tam* suits brought by opportunistic would-be relators that the federal government can itself prosecute without undermining the incentive provided to legitimate whistleblowers to bring claims that the government would be unable to bring on its own. *See*, *e.g.*, *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649-51 (D.C. Cir. 1994). By strictly limiting the public disclosure bar to information contained in federal reports, hearings, audits, and investigations, the Fourth Circuit has opened the door to *qui tam* actions based

on information plucked from audits and reports prepared by State actors. As a result, *qui tam* actions may be initiated in cases where the relator has no direct or personal knowledge of the information on which the allegations are based. Ironically, while the Fourth Circuit's decision is based on a doctrine (*noscitur a sociis*) designed to divine congressional intent, its interpretation will encourage the very type of parasitic *qui tam* actions that the public disclosure bar was intended by Congress to prevent.

As Petitioners note, by reading the word "federal" into the public disclosure bar, the Fourth Circuit has potentially undermined the first goal of the public disclosure bar as well, i.e., it may be harder for individuals who have personal knowledge of fraudulent activity to bring *qui tam* suits. Under the first-to-file provision of the Act, the filing of a *qui tam* suit by one plaintiff prevents the filing of a subsequent *qui tam* suit by another plaintiff. 31 U.S.C. § 3730(b)(5). Under the Fourth Circuit's construction of the public disclosure bar, therefore, an individual who closely observed the fraudulent activity could have her *qui tam* action blocked by an individual whose earlier-filed *qui tam* action was based on information found in a State report or audit.

II. The Fourth Circuit's Holding Will Benefit Opportunistic Relators at the Expense of the Public Interest.

For the reasons detailed above, the Fourth Circuit's holding clearly will benefit opportunistic relators. The cost of such an interpretation, however, will be borne by *amici's* members, the patients that they serve, and the U.S. healthcare system at large. If the FCA's public disclosure bar is held to apply only to federal administrative reports, audits, and investigations, *see United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 528 F.3d 292, 302-03 (4th Cir. 2008); *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 745 (3d Cir. 1997), then the continued discovery of, and assurance of patient access to, innovative treatments will be jeopardized.

FCA cases involving alleged healthcare fraud predominate over such cases involving alleged fraud in defense contracting and other industries. *See* Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in out-of-Control Qui Tam Litigation under the Civil False Claims Act*, 76 U. Cin. L. Rev. 1233, 1243-49 (Summer 2008). In 2007, 196 qui tam claims were filed alleging healthcare fraud, compared to 66 claims alleging fraud in defense contracting. U.S. Dep't of Justice, Civil Div., Fraud Statistics—Overview, October 1, 1986 - September 30, 2007, at 3-4 (2007), *available at http://www.taf.org/stats-fy-2007.pdf*. In that same year, healthcare fraud *qui tam* cases resulted in approximately $1.1 billion in settlements and judgments, compared to approximately $32 million for *qui tam* claims alleging fraud in defense contracting. *Id.*

Given how much money is at stake with the prospect of collecting treble damages under the FCA, and considering that the healthcare sector is the primary target of would-be relators, the number of such claims in certain jurisdictions would skyrocket if relators could potentially obtain a windfall by reviewing investigation reports prepared by State Medicaid agencies. Forcing pharmaceutical and biotechnology companies to defend against a slew of new *qui tam* claims based on State reports rather than the relator's personal knowledge (coupled with the nature of such claims) would divert time, capital, and other critical resources from companies' research and development efforts and would significantly increase the already substantial costs of developing and marketing new treatments that treat, cure, or prevent so many debilitating and life-threatening diseases and conditions. If the Fourth Circuit's holding dramatically increases the number of *qui tam* suits initiated against pharmaceutical and biotechnology companies – as would be expected – patients may be the ones to suffer.

Furthermore, because FCA cases carry with them the potential for substantial penalties, treble damages, and, even worse, the threat of mandatory exclusion from participating in all federal healthcare programs, pharmaceutical and biotechnology companies may elect to settle many of these new *qui tam* actions almost regardless of merit, rather than assume the risk of litigation. The significant costs associated with the prospect of company settlements ultimately may impact the decisions of individual companies as to how to price their products or how to allocate resources for new research and development projects, with potentially

negative consequences not just for individual patients, but for the broader healthcare system and society at large.

In short, the Fourth Circuit's extra-statutory interpretation of the FCA's public disclosure bar would encourage opportunistic relators at the expense of the public interest.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

CONAN GRAMES
Counsel of Record
DOUGLAS WAYNE KENYON
HUNTON & WILLIAMS LLP
1900 K Street
Washington, DC 20006-1109
(202) 955-1685

Counsel for Amici Curiae