Nos. 21-1326, 22-111

IN THE

Supreme Court of the United States

UNITED STATES EX REL. TRACY SCHUTTE ET AL.,
Petitioners,
v.
SUPERVALU INC. ET AL.,
Respondents.

UNITED STATES EX REL. THOMAS PROCTOR,
Petitioner,
v.
SAFEWAY, INC.,
Respondent.

On Writs of Certiorari to the United States Court of Appeals for the Seventh Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING RESPONDENTS

John M. Masslon II
Counsel of Record
Cory L. Andrews
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave. NW
Washington, DC 20036
(202) 588-0302
jmasslon@wlf.org

March 27, 2023

QUESTION PRESENTED

Whether the objective knowledge standard this Court articulated in *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007), governs the False Claims Act's scienter requirement where a claim's purported falsity turns on an ambiguous legal obligation.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF AUTHORITIES iv

INTEREST OF AMICUS CURIAE 1

INTRODUCTION 1

STATEMENT 3

I. SUPERVALU..3

II. SAFEWAY 5

SUMMARY OF ARGUMENT....................................5

ARGUMENT 7

I. PETITIONERS' FOCUS ON THE THREE TYPES OF SCIENTER SUPPORTING FCA LIABILITY IS A RED HERRING 7

II. THE CONSTITUTIONAL-DOUBT CANON RESOLVES ANY QUESTION ABOUT *SAFECO*'S APPLICABILITY TO FCA CLAIMS 8

A. FCA Penalties Trigger Heightened Due-Process Protections 9

B. Petitioners' Interpretation Of The FCA Flouts These Heightened Due-Process Protections 12

CONCLUSION...21

TABLE OF AUTHORITIES

Page(s)

Cases

Abraham Lincoln Mem'l Hosp. v. Sebelius,
698 F.3d 536 (7th Cir. 2012)................................19

United States ex rel. Berkowitz v. Automation Aids, Inc.,
896 F.3d 834 (7th Cir. 2018)................................15

Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.,
492 U.S. 257 (1989)..9

Champlin Ref. Co. v. Corp. Comm'n,
286 U.S. 210 (1932)..13

City of Chicago v. Morales,
527 U.S. 41 (1999)..12, 14

Cline v. Frink Dairy Co.,
274 U.S. 445 (1927)..13

Connally v. Gen. Const. Co.,
269 U.S. 385 (1926).................................12, 13, 14

United States ex rel. Garbe v. Kmart Corp.,
824 F.3d 632 (7th Cir. 2016)............................4, 15

United States ex rel. Hagood v. Sonoma Cnty. Water Agency,
929 F.2d 1416 (9th Cir. 1991)..............................16

United States ex rel. Harman v. Trinity Indus. Inc.,
872 F.3d 645 (5th Cir. 2017)................................16

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Hindo v. Univ. of Health Scis./Chi. Med. Sch.,
65 F.3d 608 (7th Cir. 1995).................................16

United States ex rel. Hochman v. Nackman,
145 F.3d 1069 (9th Cir. 1998).............................16

Int'l Harvester Co. of Am. v. Kentucky,
234 U.S. 216 (1914)..12

Lanzetta v. New Jersey,
306 U.S. 451 (1939)..12

Leocal v. Ashcroft,
543 U.S. 1 (2004)..10, 11

Nielsen v. Preap,
139 S. Ct. 954 (2019)...8

United States ex rel. Phalp v. Lincare Holdings, Inc.,
857 F.3d 1148 (11th Cir. 2017)...............16, 17, 18

United States ex rel. Purcell v. MWI Corp.,
807 F.3d 281 (D.C. Cir. 2015)..........................7, 10

Rehab. Ass'n of Va. v. Kozlowski,
42 F.3d 1444 (4th Cir. 1994)...............................19

Safeco Ins. Co. of Am. v. Burr,
551 U.S. 47 (2007).......................................2, 7, 11

Satellite Broad. Co. v. FCC,
824 F.2d 1 (D.C. Cir. 1987).................................10

Screws v. United States,
325 U.S. 91 (1945)...13

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Skilling v. United States,
561 U.S. 358 (2010)....................14

St. Louis, I. M. & S. R. Co. v. Williams,
251 U.S. 63 (1919)....................9

State Farm Fire & Cas. Co. v. United States ex rel. Rigsby,
580 U.S. 26 (2016)....................1

United States v. Bornstein,
423 U.S. 303 (1976)....................9

United States v. Brookdale Senior Living Communities, Inc.,
892 F.3d 822 (6th Cir. 2018)....................18

United States v. Harriss,
347 U.S. 612 (1954)....................14

United States v. L. Cohen Grocery Co.,
255 U.S. 81 (1921)....................13

United States v. Reese,
92 U.S. 214 (1875)....................12

United States v. Sci. Apps. Int'l Corp.,
626 F.3d 1257 (D.C. Cir. 2010)....................15

United States v. Thompson/Ctr. Arms Co.,
504 U.S. 505 (1992)....................10

Universal Health Servs., Inc. v. United States ex rel. Escobar,
579 U.S. 176 (2016)....................1, 15

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489 (1982) 10

Vt. Agency of Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000) 9

Statutes

18 U.S.C. § 287 .... 10, 11

31 U.S.C.
§ 3729(a)(1)(A) 2, 8, 11, 17
§ 3729(b)(1)(A)(i) 2, 7
§ 3729(b)(1)(A)(ii) 2, 7
§ 3729(b)(1)(A)(iii) 2, 7

False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 .... 9, 17

Okla. Stat. § 7255 (1921) 13

Other Authorities

Douglas W. Baruch et al., *In False Claims Act Cases, Government Must Provide Full Discovery Regarding Materiality*, WLF LEGAL OPINION LETTER (Dec. 6, 2018) 1

H.R. Rep. No. 99-660 (1986) 18

S. Rep. No. 99-345, *as reprinted in* 1986 U.S.C.C.A.N. 5266 .... 9, 17, 18

TABLE OF AUTHORITIES
(*continued*)

Page(s)

Stephen A. Wood, Res Judicata *in* Qui Tam *Litigation: Why Government Should Be Bound by Judgments in Non-Intervened Cases*, WLF WORKING PAPER (Apr. 22, 2021)............................1

INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae in important False Claims Act cases. *See, e.g.*, *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26 (2016); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016).

WLF's Legal Studies Division also regularly publishes papers on FCA issues. *See, e.g.*, Stephen A. Wood, Res Judicata *in* Qui Tam *Litigation: Why Government Should Be Bound by Judgments in Non-Intervened Cases*, WLF WORKING PAPER (Apr. 22, 2021); Douglas W. Baruch et al., *In False Claims Act Cases, Government Must Provide Full Discovery Regarding Materiality*, WLF LEGAL OPINION LETTER (Dec. 6, 2018).

WLF believes that these cases are an attempt at expanding the FCA beyond its purpose.

INTRODUCTION

Congress enacted the FCA during the Civil War to deter war profiteers from intentionally bilking the government out of much-needed funds. Today, the FCA limits similar abuse in the ever-growing healthcare industry. But unlike in the past, today a

---

* No person or entity, other than Washington Legal Foundation and its counsel, paid for the brief's preparation or submission.

cottage industry of lawyers pursues actions against companies for objectively reasonable conduct.

A key element of any fraud claim is scienter. That is why the FCA requires plaintiffs to prove that defendants "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To act knowingly, defendants must (1) have "actual knowledge" that the information is false, (2) show "deliberate ignorance of the truth or falsity of the information," or (3) show "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A)(i-iii). Without this showing of scienter, government contractors may still be liable for their breach of contract. But a lack of scienter eliminates the threat of criminal penalties, treble damages, attorneys' fees, and costs under the FCA. The scienter requirement therefore serves as a critical due-process protection.

These cases present a straightforward legal question about the scienter requirement: Does the test this Court outlined in *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007) for willfulness under the Fair Credit Reporting Act apply to FCA actions? The courts of appeals to have considered this question are unanimous—yes.

Petitioners and their amici, however, ask this Court to upend this well-settled rule. True, sometimes the courts of appeals are wrong when they unanimously interpret a statute or this Court's precedent. But that is a rare occasion and did not happen here. The appellate courts correctly interpreted the FCA to require courts to use the

Safeco test when deciding whether relators met the FCA's willfulness requirement.

Even a jurist who dissented in the court of appeals only attacks *Safeco* when arguing that it does not apply in FCA actions. *See* Oral Argument at 1:22:10-1:22:25, *United States ex rel. Sheldon v. Allergen Sales, LLC*, 49 F.4th 873 (4th Cir. 2022) (en banc) (per curiam) (No. 20-2330) (Judge Wynn suggesting that this Court's *Safeco* decision was "judicial activism"). This Court should not abandon *Safeco*'s test for willfulness just because it makes it harder for the plaintiffs' bar to extort settlements from companies for objectively reasonable conduct. Government contractors' due-process rights, of course, trump the ability of some lawyers to craft a niche business by suing under the FCA. Those due-process concerns require affirming the Seventh Circuit's decisions.

STATEMENT

I. SUPERVALU

Between 2006 and 2016, SuperValu controlled over 800 pharmacies. During that time, SuperValu tried to compete with pharmacies like Wal-Mart, which began offering prescription drugs at deep discounts. But rather than match Wal-Mart's prices for all customers, SuperValu instead matched the price only when customers asked for a price match of a nearby pharmacy. The pharmacist then applied the discount and matched the other pharmacy's price after confirming that pharmacy's price. The sales were coded as cash sales rather than third-party payor sales.

SuperValu did not use the price matches when seeking reimbursements from Medicare and Medicaid. Rather, it used the retail prices. This price submission is known as the usual and customary (U&C) price.

Twelve years ago, two relators sued SuperValu arguing that excluding the price matches when calculating the U&C price violated the FCA. They claim that the price-match program tried to retain customers while maintaining revenue by charging Medicare, Medicaid, and other insurers the drugs' full prices.

While the suit was pending, the Seventh Circuit held that pharmacies had to include membership club discounts when calculating the U&C prices for drugs. *See United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 643-45 (7th Cir. 2016). SuperValu immediately followed that decision and included the price matches in its U&C prices.

Still, the District Court granted SuperValu's motion for summary judgment. It held that *Safeco*'s test also applied in the FCA context. Because SuperValu's construction of the statute and regulations was objectively reasonable, the relators could not show the scienter needed to prevail in an FCA action.

In a divided opinion, the Seventh Circuit affirmed. It agreed with the District Court—and every other circuit to consider the issue—and held that *Safeco*'s test applies in the FCA context. Although the United States had declined to take over

the case, the Solicitor General urged this Court to hear this case and the Court agreed to do so.

II. SAFEWAY

Between 2006 and 2015, Safeway also tried to compete with low-cost pharmacies. Safeway pharmacists could—but did not have to—match competitors' prices when customers asked for price matches of nearby pharmacies. In 2008, Safeway started another program that helped customers receive cheaper prescriptions. After filling out a form and paying cash, customers received generic drugs for $4 per 30-day supply. Safeway did not use sales under either program when calculating drugs' U&C prices.

In 2011, a relator sued Safeway under the FCA arguing that Safeway violated the FCA when it requested reimbursement from Medicare and Medicaid because it did not properly calculate the drugs' U&C prices. The District Court granted Safeway summary judgment for the same reason that it granted SuperValu summary judgment; the relator failed to prove scienter under the *Safeco* test. Applying its *SuperValu* decision—decided during the pendency of the appeal—the Seventh Circuit affirmed. This Court then agreed to hear the case together with *SuperValu*.

SUMMARY OF ARGUMENT

I. Petitioners' and Senator Grassley's argument that the Seventh Circuit should have examined all three levels of scienter is a red herring meant to distract from the fact that they are asking this Court to implicitly overturn *Safeco*. Failure to

satisfy the *Safeco* test dooms a plaintiff's claim that a defendant acted with any level of scienter required for FCA liability. The Court should thus reject Petitioners' argument that the Seventh Circuit went astray by focusing on the lowest level of scienter here.

II.A. FCA violations carry the potential of treble damages. Unlike ordinary or even double damages, treble damages are punitive and trigger heightened due-process protections for parties accused of FCA violations. Similarly, FCA violations carry potential criminal penalties. As with treble damages, the threat of criminal penalties also triggers heightened due-process protections.

B. Petitioners' proposed rule ignores these due-process protections. At the heart of due process of law is the right to know what conduct is prohibited. The impenetrable Medicare and Medicaid regulations make it so that even the most conscientious company will eventually breach those rules. But Respondents did not have fair notice that they could face treble damages and criminal penalties until a binding interpretation issued. The *Safeco* test ensures that parties are punished only when they had proper notice of prohibited conduct. It provides this critical due-process protection while still ensuring that companies do not bury their heads in the sand.

ARGUMENT

I. PETITIONERS' FOCUS ON THE THREE TYPES OF SCIENTER SUPPORTING FCA LIABILITY IS A RED HERRING.

Petitioners and Senator Grassley insist that the Seventh Circuit erred by focusing on whether Respondents exhibited "reckless disregard of the truth or falsity of the" submitted claims. 31 U.S.C. § 3729(b)(1)(A)(iii). According to Petitioners and Senator Grassley, the Seventh Circuit also had to examine whether Respondents had "actual knowledge" of the falsity of the submitted claims or showed "deliberate ignorance" to the truth or falsity of the submitted claims. *Id.* § 3729(b)(1)(A)(i-ii). But because Petitioners could not satisfy the *Safeco* test, it was impossible for them to prove any of the three levels of scienter required for FCA liability.

Under *Safeco*, when deciding whether a defendant acted knowingly, courts consider whether the defendant had "an objectively reasonable" interpretation of a provision susceptible to competing interpretations and whether there was "interpretive guidance that might have warned the defendant away from the view it took." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) (cleaned up); *see Safeco*, 551 U.S. at 70.

It is impossible to have "actual knowledge" of the falsity of a claim if these requirements are satisfied. If the defendant had "actual knowledge" that a claim was false, it could not have had an objectively reasonable interpretation of a provision open to differing interpretations. Similarly, a

defendant could not have acted with "deliberate ignorance" absent some guidance warning away from the defendant's objectively reasonable interpretation.

To be liable under the FCA a defendant must have "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Yet Petitioners and Senator Grassley spill much ink on the difference between actual knowledge and reckless behavior. Their doing so is a distraction because they should understand that the Seventh Circuit properly held that failure to satisfy the *Safeco* test was fatal to Petitioners' claims because they could not prove knowledge.

II. THE CONSTITUTIONAL-DOUBT CANON RESOLVES ANY QUESTION ABOUT *SAFECO*'S APPLICABILITY TO FCA CLAIMS.

"[T]he canon of constitutional avoidance" "provides that when a serious doubt is raised about the constitutionality of an act of Congress, this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Nielsen v. Preap*, 139 S. Ct. 954, 971 (2019) (cleaned up). Here, even if two reasonable interpretations exist for the FCA's scienter requirement, this Court should adopt the interpretation incorporating *Safeco*'s test. The other possible interpretation—advanced by Petitioners—would raise serious doubt about the FCA's constitutionality.

A. FCA Penalties Trigger Heightened Due-Process Protections.

1. Before 1986, an FCA violation subjected companies to only double—not treble—damages. *United States v. Bornstein*, 423 U.S. 303, 305 (1976). The Court therefore said that FCA damages were "compensat[ory]." *Id.* at 315. But "evidence of fraud in Government programs and procurement [wa]s on a steady rise." S. Rep. No. 99-345, 2, *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5267. So Congress amended the FCA to provide for treble damages. False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2, 100 Stat. 3153, 3153.

This changed the nature of FCA damages. After the 1986 amendments, the Court held "the current version of the FCA imposes damages that are essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000). This transformation of FCA damages from compensatory to punitive removes any doubt about whether the critical due-process protections that constrain the government's power to punish apply to the FCA.

The "Due Process Clause places outer limits on the size of a civil damages award made pursuant to a statutory scheme." *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 276 (1989) (citing *St. Louis, I. M. & S. R. Co. v. Williams*, 251 U.S. 63, 66-67 (1919)). Purely compensatory damages cannot violate substantive due-process protections if supported by sufficient evidence. Yet FCA damages can violate the Due Process Clause because they are punitive. Besides procedural due-process protections,

then, courts consider substantive due-process principles when analyzing the FCA's scienter requirement. *See Purcell*, 807 F.3d at 287 (citing *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987)).

2.i. Along with punitive treble damages, FCA violations may carry criminal penalties. 18 U.S.C. § 287. This also shapes the due-process protections afforded defendants in FCA actions. "[T]he relative importance of fair notice and fair enforcement" mandated by the Due Process Clause "depends in part on the nature of the enactment." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982).

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

ii. The Seventh Circuit said that the FCA's criminal penalties had no bearing on interpreting the scienter required for civil FCA liability. Schutte Pet. App. 14a n.6. This overlooked the key difference between the Fair Credit Reporting Act's criminal provision and the FCA's criminal provision.

In the Seventh Circuit's view, *Safeco*'s discussion of criminal liability under the FCRA bars

consideration of the FCA's criminal provision. But in *Safeco*, the Court focused on the term of art in the FCRA's criminal provision. *See Safeco*, 551 U.S. at 60. This Court cited three statutes that, like the FCRA, paired the words "knowingly and willfully." As this term of art has a distinct meaning in the criminal context, the Court found that the language of the FCRA's criminal provision differed significantly from the FCRA's civil provision. *Id.*

The FCA's criminal provision does not contain this term of art. Rather, it uses only the term knowingly. 18 U.S.C. § 287. There is no sign of the word willfully. *See id.* This key distinction is what the Seventh Circuit overlooked.

The FCA's criminal and civil provisions have the same scienter requirement. *Compare* 31 U.S.C. § 3729(a)(1)(A) *with* 18 U.S.C. § 287. So under *Leocal*, the Court should give the language the same meaning. 543 U.S. at 12 n.8. This is particularly true because there is no term of art in the FCA's criminal provision as in the FCRA's criminal provision.

The Seventh Circuit thus should have considered the FCA's criminal provision when deciding the scienter required for a civil FCA violation. Although it eventually reached the right result—joining every court of appeals to consider the issue—this Court can also use the FCA's criminal provisions to support Respondents' construction of the FCA's scienter requirement.

B. Petitioners' Interpretation Of The FCA Flouts These Heightened Due-Process Protections.

The FCA therefore requires heightened due-process protections for two reasons. Both the punitive nature of the FCA's treble damages and the criminal penalties for FCA violations require enhanced due-process protections. Yet Petitioners ask this Court to sidestep Respondents' due-process rights and hold them liable despite Petitioners' failure to satisfy the *Safeco* test.

The key constitutional problem with Petitioners' proposed standard is that it deprives Respondents of the right to fair notice of the conduct that could lead to criminal penalties and punitive civil sanctions. Fair notice of what conduct is prohibited is at the core of the Due Process Clause. *City of Chicago v. Morales*, 527 U.S. 41, 58 (1999) (citing *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939)).

1. The Court has long recognized the importance of fair notice under the Due Process Clause. It has explained that "[e]very man should be able to know with certainty when he is committing a crime." *United States v. Reese*, 92 U.S. 214, 220 (1875). Almost 100 years ago, the Court described the fair notice requirement as "the first essential of due process of law." *Connally v. Gen. Const. Co.*, 269 U.S. 385, 391 (1926) (citing *Int'l Harvester Co. of Am. v. Kentucky*, 234 U.S. 216, 221 (1914)).

General Construction Company highlights why disregarding *Safeco* violates Respondents' due-process rights. There, an Oklahoma statute required

that firms performing under contract with the State pay their workers "the current rate of per diem wages in the locality where the work is performed." Okla. Stat. § 7255 (1921). Finding that the statute violated the Due Process Clause, the Court explained that the term "current rate of wages" was "indeterminate[]" and obscure. *Gen. Const. Co.*, 269 U.S. at 394. And because the statute was "so uncertain that" it could "reasonably admit of different constructions," it violated the Due Process Clause. *Id.* at 393.

The FCA regulates economic agreements between private companies and the federal government. To serve as a government contractor, businesses must agree not to submit false claims. *General Construction Company* is not the only case in which the Court considered whether economic regulations provided inadequate notice of illegal conduct. *See generally, e.g.*, *Champlin Ref. Co. v. Corp. Comm'n*, 286 U.S. 210 (1932) (Oklahoma Curtailment Act); *Cline v. Frink Dairy Co.*, 274 U.S. 445 (1927) (Colorado antitrust law); *United States v. L. Cohen Grocery Co.*, 255 U.S. 81 (1921) (Lever Act). These early 20th-Century cases show that the Court has long guaranteed the right to fair notice.

The Court kept recognizing the importance of fair notice during World War II. It explained that "[t]he constitutional requirement that a criminal statute be definite serves a high function. It gives a person acting with reference to the statute fair warning that his conduct is within its prohibition." *Screws v. United States*, 325 U.S. 91, 103-04 (1945). The next decade, the Court reiterated that "a criminal statute" which fails to give "fair notice that his contemplated conduct is forbidden by the statute"

violates the Due Process Clause. *United States v. Harriss*, 347 U.S. 612, 617 (1954).

The trend continued at the end of the 20th Century. The Court said that "the fair notice requirement" ensures individuals are not placed "at peril of life, liberty or property" because they must "speculate as to the meaning of penal statutes." *Morales*, 527 U.S. at 58 (quotation omitted).

A recent case reveals what fair notice requires when heightened due-process protections apply. In *Skilling v. United States*, the Court held that the defendant received fair notice that bribery and kickbacks violated the honest-services statute. 561 U.S. 358, 412 (2010). The Court explained that this was "as clear as a pikestaff." *Id.* (quotation omitted). But other conduct was not so clear. And because the defendant did not receive fair notice that his conduct violated the statute, the Court vacated the conviction. *Id.* at 413-14.

Yet under Petitioners' proposed standard, FCA penalties could be imposed against a defendant whose conduct adhered to an objectively reasonable interpretation of statutes, regulations, or contracts that could "reasonably admit of different constructions." *Gen. Const. Co.*, 269 U.S. at 393. If this Court were to adopt Petitioners' proposed standard, it would raise serious questions about the FCA's constitutionality.

Although it was "clear as a pikestaff" that submitting factually inaccurate prices for prescription drugs violated the FCA, that is not what happened here. Instead, it was unclear what

constituted a drug's U&C price. No binding guidance counseled against Respondents' objectively reasonable interpretations of the term. They therefore lacked fair notice that they must include the price match and membership club discounts in U&C calculations until *Garbe* gave a broad interpretation to the term. *See* 824 F.3d at 643-45.

For 150 years, this Court has repeatedly returned to the idea of fair notice. Each time, the Court has explained why this fair-notice requirement is critical to due process of law. As explained above, the FCA's civil provisions are punitive. An FCA violation also carries potential criminal liability. So the Court's heightened fair-notice requirements should also govern in FCA cases. Otherwise, the FCA's constitutionality would be in doubt. Because Respondents' construction of the FCA—employing the *Safeco* standard—avoids these constitutional concerns, this Court should reject Petitioners' proposed standard.

2. Fair notice is at the core of these heightened due-process protections. Unsurprisingly, therefore, both this Court and the courts of appeals have acknowledged that the scienter requirement is critical in FCA litigation.

"[C]oncerns about fair notice and open-ended liability in FCA cases" are "effectively addressed through strict enforcement of the" FCA's "scienter requirement[]." *Escobar*, 579 U.S. at 192 (citing *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)); *see United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 842 (7th Cir. 2018). Allowing for lax application of the

scienter requirement raises serious due-process concerns. And that is what Petitioners and their amici ask this Court to do by rejecting the *Safeco* test in FCA cases.

The Government, for example, argues that relators can satisfy the FCA's scienter requirement by showing that a company was aware of a substantial risk that it might be wrong and failed to further investigate the issue. This is a wolf dressed in sheep's clothing. The effect of the Government's disguised standard is that negligent conduct satisfies the FCA's scienter requirement because objectively reasonable conduct under an ambiguous legal obligation is at most negligence. So although they disclaim the position, Petitioners and the Government are asking this Court to adopt a test that has the effect of punishing negligent conduct.

Due-process concerns are why "[t]he scienter requirement is critical to the operation of the [FCA]." *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998). As the Seventh Circuit explained, "[i]nnocent mistakes or negligence are not actionable under" the FCA. *Hindo v. Univ. of Health Scis./Chi. Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) (citing *United States ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1420 (9th Cir. 1991)).

Courts are unanimous that negligent submission of claims does not trigger FCA liability. *See, e.g.*, *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 657 (5th Cir. 2017) (FCA's scienter "requirement is not met by mere negligence" (quotation omitted)); *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir.

2017) (citation omitted). These decisions flow naturally from the FCA's plain language requiring that a defendant "knowingly" submit a false claim. 31 U.S.C. § 3729(a)(1)(A). This language reflects Congress's acknowledgment that serious due-process concerns would arise if the FCA imposed treble damages and criminal penalties for the mere negligent submission of false claims. Petitioners' and the Government's proposed standard, however, would have the effect of punishing negligent conduct.

The legislative history of the FCA's current scienter requirement reflects this well-settled due-process principle. First, Congress amended the FCA's scienter requirement in the same enactment that provided for treble damages. *See* False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2, 100 Stat. at 3153-54. When it increased FCA damages to a punitive level, Congress knew that not defining the level of scienter would cause due-process problems.

During hearings on the FCA amendments, the Department of Justice understood the proposed scienter standard to mean "that mere negligence could not be punished by an overzealous agency." S. Rep. No. 99-345 at 21, 1986 U.S.C.C.A.N. at 5286. The Senate Judiciary Committee agreed with this statement. *See id.*

Both DOJ and the Senate focused on government-initiated actions. They did not consider the possibility of overzealous qui tam counsel and litigants seeking windfalls for a company's negligence. This is because the vast qui tam bar did not exist in 1986. Today, however, it is hard not to

encounter advertisements promising big rewards for those willing to serve as clients for qui tam counsel.

Courts often look to this legislative history when discussing the FCA's scienter requirement. *See, e.g.*, *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 837 (6th Cir. 2018); *Lincare Holdings, Inc.*, 857 F.3d at 1155. This Court can do the same when deciding whether the *Safeco* test applies in FCA actions.

The legislative history also shows why the *Safeco* test furthers Congress's other goals in defining "knowingly." The House Judiciary Committee explained that "those who play 'ostrich'" would be held liable under the new definition. H.R. Rep. No. 99-660, 21 (1986). The Senate echoed these sentiments. S. Rep. No. 99-345 at 21, 1986 U.S.C.C.A.N. at 5286 ("an individual [who] has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted" would be liable under the knowingly definition).

The *Safeco* test ensures that companies cannot bury their heads in the sand to avoid FCA liability. It does so by asking whether the relevant governmental agency or courts of appeals issued binding guidance warning away from the objectively reasonable interpretation. Here, for example, if CMS or another body with appropriate statutory authority had promulgated binding regulations showing that the U&C price for prescription drugs must include price-matching programs, Respondents could not plead ignorance. Rather, under *Safeco*, they could be held liable for FCA violations because they acted knowingly. The same holds true if Respondents had

failed to conform their conduct after the Seventh Circuit clarified the effect of price matching on U&C prices.

But that is not what happened here. No binding guidance led Respondents away from their objectively reasonable interpretations of the contractual terms. *Safeco* provides Respondents with due process by not penalizing them for mere negligence. *Safeco* does so while accomplishing Congress's goal of ensuring that companies do not bury their heads in the sand when submitting claims for reimbursement.

Petitioners and their amici do not explain why using the *Safeco* test fails to accomplish both goals. They stress the importance of deterring companies from burying their heads in the sand. But the *Safeco* test accomplishes this goal. Petitioners and their amici also avoid meaningful discussion of Congress's first stated goal—ensuring due process by not imposing FCA liability for negligent acts. Applying *Safeco* is the best way to satisfy this objective. In contrast, Petitioners' proposed standard raises serious constitutional concerns that can be avoided by applying the *Safeco* test in FCA actions.

3. "[T]he complex and technical Medicare and Medicaid programs * * * are among the most completely impenetrable texts within human experience." *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 698 F.3d 536, 540-41 (7th Cir. 2012) (quotation omitted). Reading and understanding the regulations is "tortur[e]." *Rehab. Ass'n of Va. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). This maze of statutes and regulations is important because

it shows that Petitioners' proposed standard would wreak havoc on the medical industry.

Even the largest, most well-resourced companies in the world will take objectively reasonable positions when submitting Medicare or Medicaid claims under ambiguous laws that are later determined to be incorrect. Most errors are just negligence. Despite rigorous checks, companies will read a complex regulation in a manner that courts will eventually reject. But if the regulation is amenable to multiple interpretations, the interpretation is objectively reasonable, and no binding guidance cautions against that objectively reasonable interpretation, the company has not committed fraud. Rather, it has committed negligent acts for which it should reimburse the government.

The company should not have to pay treble damages and potentially face criminal liability for mere negligence. That, however, is the effect of Petitioners' argument. Petitioners ask this Court to reject the *Safeco* standard, which is critical to meaningful due-process protections. They seek a standard that would severely punish companies for mere negligence. That standard would set a trap for the wary and unwary alike.

* * *

The FCA's plain language supports applying *Safeco*'s test. But even if the FCA is ambiguous, this Court should use the constitutional-doubt canon and apply *Safeco* here. The criminal penalties and treble damages accompanying FCA liability mean that FCA defendants are entitled to heightened due-process

protections. The Court has long recognized these protections include fair notice of what conduct is prohibited. The legislative history shows that Congress acknowledged this right to heightened due-process protections when amending the FCA in 1986. Applying *Safeco* in FCA cases therefore accomplishes the FCA's goals while providing constitutionally mandated due-process protections.

CONCLUSION

This Court should affirm.

Respectfully submitted,

John M. Masslon II
Counsel of Record
Cory L. Andrews
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave. NW
Washington, DC 20036
(202) 588-0302
jmasslon@wlf.org

March 27, 2023