No. 20-2241

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA et al., *ex rel.* TRACY SCHUTTE and MICHAEL YARBERRY,

Plaintiffs-Appellants,

v.

SUPERVALU, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of Illinois
No. 3:11-CV-3290 (Hon. Richard Mills)

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

James C. Stansel
Melissa B. Kimmel
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street NW
Washington, DC 20004
(202) 835-3400

Steven P. Lehotsky
Tara S. Morrissey
U.S. CHAMBER LITIGATION CENTER
1615 H Street NW
Washington, DC 20062
(202) 463-5337

John P. Elwood
Craig D. Margolis
Jayce L. Born
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.elwood@arnoldporter.com

Counsel for Amici Curiae

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):
Chamber of Commerce of the United States of America; Pharmaceutical Research and Manufacturers of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:
Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ John P. Elwood Date: 12/07/2020

Attorney's Printed Name: John P. Elwood

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

Address: 601 Massachusetts Ave. NW
Washington, DC 20001

Phone Number: (202) 942-5000 Fax Number: (202) 942-5999

E-Mail Address: john.elwood@arnoldporter.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Chamber of Commerce of the United States of America; Pharmaceutical Research and Manufacturers of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Craig D. Margolis Date: 12/07/2020

Attorney's Printed Name: Craig D. Margolis

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 601 Massachusetts Ave. NW

Washington, DC 20001

Phone Number: (202) 942-5000 Fax Number: (202) 942-5999

E-Mail Address: craig.margolis@arnoldporter.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Chamber of Commerce of the United States of America; Pharmaceutical Research and Manufacturers of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Jayce L. Born Date: 12/07/2020

Attorney's Printed Name: Jayce L. Born

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 601 Massachusetts Ave. NW

Washington, DC 20001

Phone Number: (202) 942-5000 Fax Number: (202) 942-5999

E-Mail Address: jayce.born@arnoldporter.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Pharmaceutical Research and Manufacturers of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ James C. Stansel Date: 12/07/2020

Attorney's Printed Name: James C. Stansel

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 950 F Street NW

Washington, DC 20004

Phone Number: (202) 835-3400 Fax Number:

E-Mail Address: jstansel@phrma.org

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Pharmaceutical Research and Manufacturers of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Melissa B. Kimmel Date: 12/07/2020

Attorney's Printed Name: Melissa B. Kimmel

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 950 F Street NW

Washington, DC 20004

Phone Number: (202) 835-3400 Fax Number:

E-Mail Address: mkimmel@phrma.org

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Chamber of Commerce of the United States of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Steven P. Lehotsky Date: 12/07/2020

Attorney's Printed Name: Steven P. Lehotsky

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 1615 H Street NW

Washington, DC 20062

Phone Number: (202) 463-5337 Fax Number:

E-Mail Address: slehotsky@USChamber.com

rev. 12/19 AK

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-2241

Short Caption: United States et al. v. Supervalu Inc. et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

☐ **PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.**

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing item #3):

Chamber of Commerce of the United States of America

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Arnold & Porter Kaye Scholer LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Tara S. Morrissey Date: 12/07/2020

Attorney's Printed Name: Tara S. Morrissey

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 1615 H Street NW

Washington, DC 20062

Phone Number: (202) 463-5337 Fax Number:

E-Mail Address: tmorrissey@USChamber.com

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation and no corporation or publicly held company owns 10% or more of its stock, and the Chamber of Commerce of the United States of America states that it has no parent corporation and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Page(s)

Cases—Continued

Page(s)

Cases—Continued

Page(s)

Cases—Continued

Page(s)

Cases—Continued

Statutes

Page(s)

Rules & Regulations

Legislative Materials

Other Authorities

Page(s)

Other Authorities—Continued

Page(s)

Other Authorities—Continued

STATEMENT OF INTEREST[1]

Pursuant to Federal Rule of Appellate Procedure 29, Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Chamber of Commerce of the United States of America (the "Chamber") submit this brief in support of defendants-appellees and affirmance.

PhRMA is a voluntary, non-profit association that represents the nation's leading biopharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA's members invest billions of dollars each year to research and develop new drugs, more than 500 of which have been approved since 2000. The members of PhRMA closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, and from every region of the country. An important function of the

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

Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community, including cases involving the False Claims Act (the "Act").

Amici have a strong interest in the question presented here, which is fundamental to the scope of False Claims Act liability. *Amici*'s members, many of which are subject to complex and detailed regulatory schemes, have successfully defended scores of False Claims Act cases in courts nationwide, including the Seventh Circuit, arising out of government contracts, grants, and participation in federal programs. With increasing frequency, private relators (only infrequently joined by the government itself) have asserted that objectively reasonable interpretations of ambiguous statutes, regulations, and contract provisions can give rise to False Claims Act liability, triggering the statute's "essentially punitive" regime of treble damages and penalties, *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784–85 (2000). Imposing liability on a party for adopting a reasonable interpretation of a provision subject to several different interpretations improperly converts the Act from a fraud prevention statute into something else entirely.

If this Court were to reject the "objectively reasonable" scienter standard applied by the district court and adopted by numerous other circuits, it will have

far-reaching consequences for *Amici*'s members. Such a decision will harm not just pharmacies like defendants-appellees in this case, but also the myriad other businesses, non-profit organizations, and even municipalities that perform work for (or financed by) the federal government, or which receive funds through a vast array of federal programs. Relators' position that a party can violate the Act even if its interpretation of an ambiguous provision is objectively reasonable would impermissibly broaden the intended scope of the Act and threaten the *in terrorem* effect of quasi-criminal False Claims Act liability in cases involving the complex statutory and regulatory regimes that *Amici*'s members must navigate every day.

SUMMARY OF ARGUMENT

In *Safeco Insurance Company of America v. Burr*, 551 U.S. 47, 68–70 (2007), the Supreme Court articulated the relevant standard for determining whether a party knowingly or recklessly violated the Fair Credit Reporting Act by looking to the common law meaning of those terms. The Court concluded that whether a person knowingly or recklessly violated the statute should be evaluated against an objective standard under which an objectively reasonable interpretation of an ambiguous provision cannot give rise to liability unless authoritative guidance warned the person away from that interpretation. *Id.*

The decision below correctly applied *Safeco*'s objective scienter standard to the False Claims Act. Like the Fair Credit Reporting Act, the False Claims Act

incorporates the meaning of the common law terms it uses, including what it means to act "knowingly" and "recklessly." A defendant cannot act with the requisite intent to violate the False Claims Act if its claim is "based on [a] reasonable but erroneous interpretation[] of [its] legal obligations." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015).

The district court also correctly concluded that, under *Safeco*, only formal, binding guidance constitutes the "authoritative guidance" sufficient to warn a defendant away from an otherwise reasonable interpretation. *Safeco*, 551 U.S. at 70; *id.* n.19 ("informal staff opinion" insufficient). Adhering to *Safeco*'s insistence on formal, binding agency action promotes careful agency decisionmaking and discourages shortcuts. It also protects the regulated public by discouraging overregulation and ensuring fair notice and an opportunity to comment before important regulatory changes.

The position Relators advance would extend the False Claims Act beyond its intended limits. The Act is a *fraud prevention* statute, and its scienter requirement plays a critical role in cabining its reach. Relators' position raises the prospect of costly litigation, crippling treble damages and statutory penalties, and grave reputational harm based on objectively reasonable interpretations of any one of the countless byzantine regulations or contract provisions to which government contractors, grantees, and federal program participants are routinely bound. Under

the subjective standard Relators propose, such claims would be unlikely to be resolved on the pleadings. Many businesses would be forced to settle even meritless claims rather than face protracted litigation, expansive discovery, and the risk of punitive liability based on disputed legal obligations. If this Court were to split from every other court of appeals and reject the application of *Safeco*'s objective scienter standard, or if it were to broaden the definition of "authoritative guidance," the breadth and uncertainty of resulting litigation would increase the costs of doing business for broad swaths of the U.S. economy—not only for contractors, grantees, and program participants, but also for the government itself and, ultimately, the American taxpayer.

This Court should affirm the district court's judgment.

ARGUMENT

I. *Safeco*'s "Objectively Reasonable" Standard for Scienter Applies to the False Claims Act

The False Claims Act was enacted in 1863 and signed into law by President Lincoln "to prevent and punish *frauds* upon the Government of the United States." Cong. Globe, 37th Cong., 3d Sess. 348 (1863) (statement of Sen. Wilson) (emphasis added).[2] In its current form, the statute imposes liability for knowingly

[2] The Act was enacted in response to allegations of flagrant war profiteering during the Civil War. *United States v. McNinch*, 356 U.S. 595, 599 (1958). Private contractors supporting the Union Army were accused of defrauding the federal treasury through flagrantly wrongful acts: "For sugar [the government] often got

presenting or causing to be presented "a false or fraudulent claim for payment" or knowingly making "a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). The Act defines "knowing" to mean that a person (1) has actual knowledge of falsity, (2) acts in deliberate ignorance of truth or falsity, or (3) acts in reckless disregard of truth or falsity. *Id.* § 3729(b)(1). But it does not explain further what a party must show to prove intent under this standard. *See id.* (specifying only that the statute does not require "proof of specific intent to defraud").

This is where the common law comes in. "[I]t is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (internal quotation marks omitted). As the Supreme Court explained in construing the intent provision of the False Claims Act, the Court "presume[s] that Congress retained all … elements of common-law fraud that are consistent with the statutory text because there are no textual indicia to the contrary." *Id.* at 1999 n.2.

---

sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories." *United States ex rel. Newsham v. Lockheed Missiles & Space Co.*, 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting 1 F. Shannon, *The Organization and Administration of the Union Army*, 1861–1865, at 54–56 (1965)).

Safeco addressed that very issue. There, the Supreme Court examined what the terms "knowing" and "reckless" meant at common law in the context of another statute that involved the same mental states for liability—the Fair Credit Reporting Act. The Court began with recklessness, the lower (and more easily proven) of the two mental states. It explained that "the common law has generally understood [recklessness] in the sphere of civil liability as conduct violating an objective standard: action entailing 'an unjustifiably high risk of harm that is either *known* or so obvious that it *should be known*.'" 551 U.S. at 68 (quoting *Farmer v. Brennan*, 511 U.S. 825, 836 (1994)) (emphasis added); *id.* at 69 (noting the "high risk of harm, objectively assessed, that is the essence of recklessness at common law"). Thus, a party who acts in accordance with an interpretation of an ambiguous statute that is "not objectively unreasonable" *as a matter of law* "falls well short of raising the 'unjustifiably high risk' of violating the statute necessary for reckless liability." *Id.* at 70. What's more, because the standard of proof for establishing a knowing violation is higher still, the Court wrote that where there was "more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Id.* at 70 n.20. The Court therefore rejected the idea that "evidence of subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly." *Id.*

In view of the Supreme Court's explicit embrace of the common law in construing the *mens rea* provisions of the False Claims Act, *see Escobar*, 136 S. Ct. at 1999, *Safeco* is dispositive of the issue before the Court. Therefore, it is not surprising that every federal court of appeals to consider whether *Safeco*'s objective scienter standard applies to the False Claims Act has agreed that it does. [*See* SA 16.] The district court thus correctly concluded that there is no knowing or reckless violation of the False Claims Act if the defendant acted in accordance with an objectively reasonable interpretation of a legal provision, regardless of subjective intent.

II. Only Binding Guidance Can Warn a Party Away from an Otherwise Objectively Reasonable Interpretation of an Ambiguous Provision

As part of its analysis of whether Safeco's interpretation was objectively reasonable, the Supreme Court looked to whether there was "guidance from the courts of appeals" or "authoritative guidance" from the relevant agency that would warn the defendant away from its interpretation. *Safeco*, 551 U.S. at 70. There was not. The courts of appeals had not weighed in, and the relevant agency, the Federal Trade Commission, "has only enforcement responsibility, not substantive rule-making authority, for the provisions in question." *Id.* An "informal staff opinion" "written by an FTC staff member" that was "not binding on the Commission" was not authoritative. *Id.* at 70 n.19. "Given this dearth of guidance" and the ambiguous

statutory text, the Court concluded that Safeco's interpretation of the statute was objectively reasonable. *Id.* at 70.

Safeco's meaning is clear: Only precedential court rulings or formal, binding pronouncements from an agency constitute "authoritative guidance" sufficient to warn a defendant away from an otherwise objectively reasonable interpretation of an ambiguous provision. That is in keeping with the ordinary meaning of "authoritative." *See Authoritative Precedent*, Black's Law Dictionary (11th ed. 2019) ("binding precedent"). And it makes sense as a matter of law. *Safeco* tellingly referred only to decisions by "the courts of appeals" as sufficient to "warn [a party] away from the view it took," because only courts of that level and higher have legally binding effect. *See Van Straaten v. Shell Oil Prods. Co*, 678 F.3d 486, 490 (7th Cir. 2012) ("[D]ecisions of district courts are not authoritative even within the rendering district. They cannot 'settle' any proposition.").

Equally tellingly, *Safeco* referenced "substantive rulemaking authority" and the inadequacy of "informal" non-binding opinions. *Safeco*, 551 U.S. at 70 & n.19. That is consistent with the fact that agencies must act through formal processes before regulated parties can be bound to the agency's interpretation of an ambiguous provision. Only "an interpretation contained in … a formal adjudication or notice-and-comment rulemaking" is sufficient to bind regulated parties to an agency's interpretation of an ambiguous statute. *Christensen v. Harris Cnty.*, 529

U.S. 576, 587 (2000). "[I]nterpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law," are insufficient. *Id.* And an agency's interpretation of an ambiguous regulation must satisfy strict criteria to authoritatively resolve ambiguity: it must "*at the least* emanate from those actors, using those vehicles, understood to make authoritative policy in the relevant context," *Kisor v. Wilkie*, 139 S. Ct. 2400, 2416 (2019) (emphasis added); "the agency's interpretation must … implicate its substantive expertise," *id.* at 2417; it must "reflect fair and considered judgment" rather than merely a "litigating position" or post-hoc justification for action, *id.* (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)); and it must provide regulated parties with "fair warning" before taking effect, *id.* at 2418. Unless the agency's interpretation of a regulation satisfies *all* those requirements, it is not "authoritative guidance" sufficient to dispel ambiguity. *Cf. Safeco*, 551 U.S. at 70 n.19.

This Court has already recognized as much in a case applying *Safeco*'s objective scienter standard: In *Van Straaten*, this Court rejected an agency bulletin as authoritative guidance because "it [was] neither an exercise in notice-and-comment rulemaking nor the outcome of administrative adjudication." 678 F.3d at 488. And so, too, have a number of other courts of appeals. *See also, e.g.*, *United States ex rel. Complin v. N. Carolina Baptist Hosp.*, 818 F. App'x 179, 184 n.6

(4th Cir. 2020) (a "non-precedential and non-binding" decision of the Medicare Provider Reimbursement Review Board was not enough to warn the defendant away from its interpretation); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 880 (11th Cir. 2016) (a report prepared by a former agency official was "not the kind of official government warning" that constituted authoritative guidance); *Purcell*, 807 F.3d at 289 (testimony from a former bank employee about the bank's standards "hardly amounts to the necessary 'authoritative guidance'"); *Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 377 n.3 (3d Cir. 2012) (in a Fair and Accurate Credit Transactions Act case, explaining that it was doubtful an agency's "Business Alert" constituted the kind of authority envisioned by *Safeco*).

The Justice Department's affirmative civil enforcement policy, which includes False Claims Act enforcement, recognizes a similar principle. In a memorandum issued by the Associate Attorney General in January 2018, the Department adopted a policy limiting reliance on non-binding agency guidance (that is, agency guidance that has not "undergo[ne] the notice-and-comment rulemaking process") in enforcement actions. Memorandum from the Associate Attorney General to the Heads of Civil Litigating Components and United States Attorneys, *Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases* (Jan. 25, 2018), available at

https://www.justice.gov/file/1028756/download. Specifically, the memorandum directed Department litigators not to use "noncompliance with guidance documents as a basis for proving violations of applicable law." *Id.* As implemented through the *Justice Manual*, while guidance documents may provide some evidence of "professional or industry standards," U.S. Dep't of Justice, *Justice Manual*, § 1-20.202, the Department's "general principle[]" is that "enforcement actions … must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation," *id.* § 1-20.100.

Similarly, the Department of Health and Human Services recently issued a final rule providing that "the Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation." Department of Health and Human Services, *Good Guidance Practices* at 60 (Dec. 3, 2020), https://www.hhs.gov/sites/default/files/hhs-eo-13891-final-rule.pdf. The Department explained that the use of such guidance documents by "qui tam relators" in an "attempt[] to impose binding new obligations on regulated parties" was "inappropriate." *Id* at 53.

III. Holding that Only Formal, Binding Guidance Is "Authoritative" Protects Regulated Parties and Encourages Good Agency Practices

"Federal agencies love to publish guidance documents … . They 'come in a variety of formats and names, including interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, advisories, and the like,' and some agencies may even offer guidance 'in new and innovative formats, such as video or audio tapes, or interactive web-based software.'" Sean Croston, *The Petition Is Mightier Than the Sword: Rediscovering an Old Weapon in the Battles over "Regulation Through Guidance,"* 63 Admin. L. Rev. 381, 382 (2011) (footnotes omitted). "Informal advice and guidance is given by administrative agencies in quantities difficult to imagine. The magnitude of this material dwarfs statutes and agency legislative regulations. The forms of advice and guidance are numerous, but include memos, bulletins, staff manuals, letters, and oral responses to questions." William R. Andersen, *Informal Agency Advice—Graphing the Critical Analysis*, 54 Admin. L. Rev. 595, 596 (2002) (footnote omitted). "Agencies sometimes claim they are just trying to be 'customer friendly' and serve the regulated public when they issue advisory opinions and guidance documents. This may, in fact, be true in many cases." Committee on Government Reform, *Non-Binding Legal Effect of Agency Guidance Documents, Report by the Committee on Government Reform*, H.R. Rep. No. 106-1009, at 1 (2000). But sometimes such "guidance documents [a]re intended to bypass the rulemaking

process." *id.*; *accord* Ryan Hagemann, *New Rules for New Frontiers: Regulating Emerging Technologies in an Era of Soft Law*, 57 Washburn L.J. 235, 238 ("guidance documents" used by "many regulatory agencies seeking to circumvent the traditional rulemaking process").

Hewing to *Safeco*'s strict standard encourages good agency practices. A broader reading of "authoritative guidance," like the one Relators advance here, would discourage agencies from undertaking the effort necessary to issue binding pronouncements, using notice and comment and permitting input from regulated parties to clarify ambiguous obligations. *Cf., e.g.*, *Decker v. Nw. Env't Def. Ctr.*, 568 U.S. 597, 620 (2013) (Scalia, J.) (concurring in part and dissenting in part); John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretation of Agency Regulations*, 96 Colum. L. Rev. 612, 662 (1996) (broad powers of agency self-interpretation "reduces the efficacy of notice-and-comment rulemaking"). The result would be less careful administrative action. "Experience has shown … that guidance documents also may be poorly designed or improperly implemented. At the same time, guidance documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review." *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432-01 (Jan. 25, 2007). As one scholar explained:

> Where an agency can nonlegislatively impose standards and obligations that as a practical matter are mandatory, it eases its work greatly in

> several undesirable ways. It escapes the delay and the challenge of allowing public participation in the development of its rule. It probably escapes the toil and the discipline of building a strong rulemaking record. It escapes the discipline of preparing a statement of the basis and purpose justifying the rule. It may also escape APA publication requirements and Office of Management and Budget regulatory review.

Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1317 (1992) (footnotes omitted). Adhering to the *Safeco* standard in this way encourages more careful administrative action by agencies.

Strictly adhering to *Safeco*'s strict standard for "authoritative guidance" also protects the regulated public. "[W]hen the practice of making binding law by guidances, manuals, and memoranda is tolerated," a "costly … tendency to overregulate … is nurtured." *Id.* Moreover, such informal documents can "create major policy shifts that impose significant burdens on industries." John D. Graham & Cory R. Liu, *Regulatory and Quasi-Regulatory Activity Without OMB and Cost-Benefit Review*, 37 Harv. J.L. & Pub. Pol'y 425, 426 (2014). Thus, "informal agency advice comes at a price," including "the imposition of important new requirements on regulated parties without the benefit" of ordinary protections, such as input from regulated parties and, frequently, fair notice. Andersen, *supra*, at 596. In addition, the very informality and offhandedness of the guidance may cause it to escape the notice of regulated parties.

IV. *Safeco*'s Objectively Reasonable Standard Is Critically Important in Cabining Expansive False Claims Act Liability

If this Court were to become the first appellate court to reject *Safeco*'s standard for scienter under the False Claims Act, or if it adopts Relators' broad understanding of what constitutes "authoritative guidance," it would open the door to expansive False Claims Act liability for certifications of compliance with an array of ambiguous and unsettled statutory, regulatory, or contractual requirements. Such a holding would increase the already considerable financial and reputational costs of defending *qui tam* suits, which overwhelmingly result in no recovery to the government. And the risk of crippling treble damages and statutory penalties would force many businesses to settle even meritless cases that, under a subjective standard, could not be resolved on the pleadings.

A. *Qui Tam* Actions Impose Needless Costs on American Businesses—and The Government

False Claims Act liability potentially affects any person or entity, public or private, that receives or handles federal funds in myriad forms. *See, e.g.*, *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (higher education); *United States ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013) (medical manufacturing); *United States ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cnty.*, 712 F.3d 761 (2d Cir. 2013) (fair housing); *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010)

(waste disposal); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010) (consulting services); *United States ex rel. Pritzker v. Sodexho, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (public school-lunch services); *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (healthcare services); *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983) (food stamp program); *United States ex rel. Shemesh v. CA, Inc.*, No. 09-cv-1600, 2015 WL 1446547 (D.D.C. Mar. 31, 2015) (software development); *United States ex rel. Oliver v. Philip Morris USA, Inc.*, 101 F. Supp. 3d 111 (D.D.C. 2015) (cigarette manufacturing), *aff'd*, 826 F.3d 466 (D.C. Cir. 2016); *United States ex rel. Bias v. Tangipahoa Parish Sch. Bd.*, 86 F. Supp. 3d 535 (E.D. La. 2015) (public school ROTC program); *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. 2014) (pharmaceutical manufacturing); *United States v. Americus Mortg. Corp.*, No. 12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014) (mortgage lending); *United States ex rel. McLain v. Fluor Enters., Inc.*, 60 F. Supp. 3d 705 (E.D. La. 2014) (disaster relief construction services); *United States ex rel. Landis v. Tailwind Sports Corp.*, 51 F. Supp. 3d 9 (D.D.C. 2014) (athletic sponsorship); *United States ex rel. Koch v. Koch Indus., Inc.*, 57 F. Supp. 2d 1122 (N.D. Okla. 1999) (crude oil purchasing).

Since 1986, an "army of whistleblowers, consultants, and, of course, lawyers" has been released onto this landscape. 1 John T. Boese, *Civil False*

Claims and Qui Tam *Actions*, at xxi (4th ed. 2011). Over that period, nearly 20,000 False Claims Act actions were filed, and over 13,000 of those were *qui tam* suits. U.S. Dep't of Justice, *Fraud Statistics—Overview: Oct. 1, 1986–Sept. 30, 2019*, at 2 (2019), https://bit.ly/3iI7K5Z. But only a fraction of those suits results in any monetary recovery for the government: "about 10 percent of non-intervened cases result in recovery." *United States ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 1087 (11th Cir. 2018) (citing David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 Nw. U. L. Rev. 1689, 1720–21 (2013)), *aff'd*, 139 S. Ct. 1507 (2019)).

The skyrocketing number of *qui tam* suits underscores the importance of carefully limiting the Act's sweep. Meritless *qui tam* actions can be "downright harmful" to the business community. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010). The Act's treble damages and penalties provisions are "essentially punitive." *Vt. Agency*, 529 U.S. at 784–85 (2000). Businesses face the specter of treble damages and civil penalties of over $23,331 per false claim. Civil Monetary Penalties Inflation Adjustment, 85 Fed. Reg. 37,004-01 (June 19, 2020); 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). Wholly apart from the prospect of an eventual judgment, simply *defending* a False Claims Act case requires a "tremendous

expenditure of time and energy." Todd J. Canni, *Who's Making False Claims, The* Qui Tam *Plaintiff or the Government Contractor? A Proposal to Amend the FCA to Require that All* Qui Tam *Plaintiffs Possess Direct Knowledge*, 37 Pub. Cont. L.J. 1, 11 n.66 (2007). For example, "[p]harmaceutical, medical devices, and health care companies" alone "spend billions each year" dealing with False Claims Act investigations. John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011).

Moreover, the mere existence of allegations (however tenuous) that a company "defraud[ed] our country sends a message" and "[r]eputation[,] … once tarnished, is extremely difficult to restore." Canni, *supra*, at 11; *accord United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105–08 (7th Cir. 2014) ("[A] public accusation of fraud can do great damage to a firm."). For companies that do significant government work, "the mere presence of allegations of fraud may cause [federal] agencies to question the contractor's business practices." Canni, *supra*, at 11. And a finding of False Claims Act liability can result in suspension and debarment from government contracting, *see* 2 C.F.R. § 180.800—"equivalent to the death penalty" for many government contractors, Ralph C. Nash & John Cibinic, *Suspension of Contractors: The Nuclear Sanction*, 3 Nash & Cibinic Rep. ¶ 24 (Mar. 1989), as well as exclusion from participation in federal healthcare programs, *see* 42 U.S.C. § 1320a-7(b). False Claims Act

allegations can also trigger satellite litigation, such as shareholder derivative suits. *E.g.*, Stipulation of Settlement at 1, *In re Oracle Corp. Derivative Litig.*, No. 10-cv-3392 (N.D. Cal. May 28, 2013) [ECF No. 95].

Given the financial and practical pressures, relators are keenly aware that mere allegations, regardless of their merit, can "be used to extract settlements." Sean Elameto, *Guarding the Guardians: Accountability in* Qui Tam *Litigation Under the Civil False Claims Act*, 41 Pub. Cont. L.J. 813, 824 (2012). Punitive liability and the potential that lawsuits will drag on for years creates intense pressure on defendants to settle even "questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011). This pressure will only intensify if government contractors, grantees, and program participants face the specter of crippling liability based on an objectively reasonable interpretation of one of the many ambiguous contractual, statutory, or regulatory provisions that govern their conduct.

B. The Objective *Safeco* Standard Is Essential to Cabining Expansive False Claims Act Liability

"The [False Claims Act] is a fraud prevention statute," and a violation of a statute, rule, or regulation is not fraud "unless the violator knowingly lies to the government about [it]." *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). Scienter thus plays an important role in limiting the Act's reach. As the Supreme Court has explained, "concerns about fair notice

and open-ended liability" in False Claims Act cases should be "addressed through strict enforcement of the Act's" scienter requirement. *Escobar*, 136 S. Ct. at 2002. The "objectively reasonable" scienter standard the district court applied in this case plays a critical role reining in open-ended liability under the Act. "Strict enforcement of the [Act]'s knowledge requirement helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into [False Claims Act] liability … ." *Purcell*, 807 F.3d at 287.

The need for strict enforcement of the scienter requirement is particularly critical because of the complex contractual and regulatory schemes businesses routinely face when they are assisting the government in implementing government programs—as contractors, as grantees, or simply as participants in federal programs. It is common, even typical, for those assisting the government in implementing its programs to be subject to detailed statutory, regulatory, and contractual obligations. Those legal regimes are at minimum "complex" (Federal Family Education Loan Program),[3] if not "complex [and] poorly-worded" (Small Disadvantaged Business regulations).[4] Agreements with the government regularly "incorporate[] by reference thousands of pages of other federal laws and regulations" of comparable complexity. *United States v. Stanford-Brown, Ltd*, 788

[3] *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011).

[4] *H.B. Mac, Inc. v. United States*, 36 Fed. Cl. 793, 816 (1996), *rev'd on other grounds*, 153 F.3d 1338 (Fed. Cir. 1998).

F.3d 696, 707 (7th Cir. 2015). Many federal regulatory regimes are so reticulated and challenging that courts and scholars routinely describe them as "byzantine[] and all-encompassing" (Agricultural Marketing Agreement Act of 1937),[5] "intricate" and "almost unintelligible" (the Social Security Act),[6] and "onerous and impenetrable" and "byzantine to the point of incomprehensibility" (government procurement rules).[7] That brings us to the Medicare and Medicaid programs at issue here, which this Court and others have described as "among the most completely impenetrable texts within human experience."[8]

Virtually every interaction businesses undertake with the government is therefore likely to involve complex provisions whose meanings are unsettled and subject to interpretation. It would create tremendous risk to allow businesses' objectively reasonable interpretations of unsettled obligations to expose them to the risk of lengthy and costly litigation, potentially crippling treble damages and

[5] *United States ex rel. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1329 (E.D. Cal. 1995).

[6] *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981).

[7] Steven R. Koltai, *How the Healthcare.gov Mess Happened and How To Fix It*, Brookings Inst. (Nov. 25, 2013), https://brook.gs/3oaOkdr (referencing "onerous and impenetrable procurement rules"); David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616, 672 n.180 (2013) (referencing the "byzantine" two-thousand-page Federal Acquisition Regulations governing federal government contracting and procurement).

[8] *Abraham Lincoln Mem. Hosp. v. Sebelius*, 698 F.3d 536, 541 (7th Cir. 2012) (quoting *Rehabilitation Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)).

statutory penalties, and reputational harm whenever a provision connected to payment is subject to dispute. "Strict enforcement of the [False Claims Act]'s knowledge requirement helps to ensure that *innocent mistakes made in the absence of binding interpretive guidance* are not converted into [False Claims Act] liability, thereby avoiding the potential due process problems posed by 'penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.'" *Purcell*, 807 F.3d at 287 (quoting *Satellite Broad. Co. v. Fed Commc'ns Comm'n*, 824 F.2d 1, 3 (D.C. Cir. 1987)) (emphasis added); *see also Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.) ("If a violation of a regulation subjects private parties to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express." (citation omitted)). Making regulated parties civilly liable based upon the views of officials embodied in informal guidance documents would undermine the "fundamental principle … that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required," *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

An objective scienter requirement upholds this fundamental principle by asking whether, at the time of the alleged violation, the applicable provision gave a party adequate notice of what was required of it. *Safeco*, 551 U.S. at 70 (analyzing whether authoritative guidance might have warned a party away from the view it

took). Some stray district court opinions have voiced concerns about a False Claims Act defendant "escap[ing] liability by identifying any reasonable interpretation of the statute at issue, regardless of whether the defendant followed that interpretation or believed it to be correct." *E.g.*, *United States ex rel. Suarez v. AbbVie, Inc.*, No. 15 C 8928, 2020 WL 7027446, at *16 (N.D. Ill. Nov. 30, 2020). But, respectfully, such concerns fundamentally misunderstand *Safeco*. As *Safeco* explained, a party's subjective knowledge at the time of their action has no bearing on whether they have been provided fair notice their conduct is unlawful; the provision either provided adequate notice to regulated parties, or it did not. *See Safeco*, 551 U.S. at 70 n.20; *see also*, *e.g.*, *Fuges v. Sw. Fin. Servs., Ltd.*, 707 F.3d 241, 250 (3d Cir. 2012) (plaintiff's argument that defendant's interpretation was only a post hoc rationalization was "in essence, an assertion about the defendant's intent or subjective bad faith, and, as such, … was expressly foreclosed by *Safeco*" (internal citation and quotation marks omitted)). *Safeco* is thus necessary to "avoid[] the potential due process problems posed by penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." *Purcell*, 807 F.3d at 287 (internal citation and quotation marks omitted). If the defendant was not provided fair notice, then it cannot be penalized, regardless of its subjective belief. As the D.C. Circuit explained, "[h]ad the government

wanted to avoid such consequences, it could have defined its regulatory term to preclude them." *Id.* at 291.

If the decision below is reversed, a statute enacted to address flagrant acts of fraud such as the provision of patently worthless goods, *see supra* note 2, would instead be used to pursue treble damages based on unsettled and disputed questions involving statutory, regulatory, or contractual minutiae, such as whether a roofing subcontractor knowingly "violated the Davis-Bacon Act by deducting Trust contributions from the paychecks of employees whose rights to fringe benefits had not yet vested" (when an agency manual addressed only insurance plans, not trust contributions);[9] whether braised joints on sensors for military helicopters met requirements for diametrical clearance, masking, and stop-off and flux removal (about which there was a reasonable "difference in interpretation");[10] whether a school lunch contractor was required by regulations to credit supplier rebates to the government (about which the Office of Management and Budget and the relevant

[9] *United States ex rel. Sheet Metal Workers Int'l Ass'n, Local Union 20 v. Horning Invests.*, 828 F.3d 587, 594 (7th Cir. 2016) (affirming grant of summary judgment because relator failed to prove subcontractor knowingly violated Davis-Bacon because there was "enough ambiguity" "that we cannot infer that [defendant] either knew or must have known that it was violating [it]").

[10] *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 562 (7th Cir. 2015) (affirming grant of summary judgment for manufacturer of military helicopter parts, explaining that defendant lacked requisite knowledge because of "difference in interpretation" about braising requirements).

Office of Inspector General had "differing opinions");[11] whether the regulatory requirement that a drug manufacturer must disclose to regulators the "best price" for a drug has to "aggregate discounts offered to different entities" even if no single entity actually received all discounts;[12] and whether highway inspectors met minimum credential requirements under "ambiguous" and "inconsistent sets of qualifications" set forth in a number of contract attachments.[13] In each case, courts ruled for the defendants early in the litigation on motions to dismiss or at summary judgment because their positions were objectively reasonable. Under the position Relators advance, however, that would no longer be possible.

The *Safeco* standard helps to control the costs of *qui tam* litigation, because an objective scienter standard can cut off meritless claims early in litigation, at the motion to dismiss or summary judgment stage. Indeed, in *Safeco*, the federal government advocated an objective scienter standard because "[t]hat purely legal

---

[11] *United States v. Sodexho, Inc.*, No. 03–6003, 2009 WL 579380, at *17 (E.D. Pa. Mar. 6, 2009) (granting defendant's motion to dismiss because defendant's interpretation of regulatory requirements was reasonable and OMB and Inspector General disagreed about propriety of action).

[12] *United States ex rel. Sheldon v. Forest Labs., LLC*, No. ELH-14-2535, 2020 WL 6545854, at *19–20 (D. Md. Nov. 6, 2020) (granting motion to dismiss because there were several reasonable understandings, and "the plain and natural reading" supported defendant's argument that Best Price did not require "manufacturers to aggregate discounts from multiple transactions," and "guidance was not so clear as to warn Forest away from its interpretation").

[13] *U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g*, 567 F. App'x 166, 167 (3d Cir. 2014) (affirming summary judgment for defendant based on lack of scienter because contract language setting pay rates for highway inspectors was ambiguous).

inquiry … can, and generally should, be undertaken at an early stage in the case." Br. for the United States, *Safeco Ins. Co. of Am. v. Burr*, Nos. 06-84, 06-100, at 23 (Nov. 13, 2006) ("U.S. *Safeco* Br."), https://bit.ly/3mkinP7. Courts and jurists have noted that *Safeco*'s objective reasonableness standard is amenable to resolution on a motion to dismiss. *See Van Straaten*, 678 F.3d at 491 (Cudahy, J., concurring) (noting that scienter under *Safeco* can be "determined as a matter of law and without trial"); *Shlahtichman v. 1-800 Contacts, Inc.*, 615 F.3d 794, 803-04 (7th Cir. 2010) (affirming 12(b)(6) dismissal in part because the defendant's interpretation was objectively reasonable). And "[r]eliance on … objective reasonableness … should … permit the resolution of many insubstantial claims on summary judgment." *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982). Moreover, as the government noted in *Safeco*, using an objective reasonableness standard would "minimize the significant intrusions on attorney-client privilege that often attend inquiries into subjective good faith compliance with the law." U.S. *Safeco* Br. 23–24.

The subjective standard Relators advocate would impose far greater litigation costs on defendants. To begin with, "questions of subjective intent … rarely can be decided by summary judgment." *Harlow*, 457 U.S. at 816; *Silverman v. Motorola, Inc.*, 798 F. Supp. 2d 954, 968 (N.D. Ill. 2011) ("determinations as to a lack of scienter are typically—though not categorically—inappropriate at the

summary judgment stage"); *SEC v. Church Extension of Church of God, Inc.*, No. 02-1118-CH/S, 2004 WL771171, *2 (S.D. Ind. Mar. 23, 2004) ("In general, where the evidence permits an inference of fraudulent scienter, questions of intent are questions for the trier of fact."). Moreover, "substantial costs attend the litigation of … subjective good faith." *Harlow*, 457 U.S. at 816. "Judicial inquiry into subjective [understanding] … may entail broad-ranging discovery and the deposing of numerous persons," *id.*, making it "peculiarly disruptive." *Id.* at 817. And, as the government noted in *Safeco*, a subjective standard may raise issues of good-faith reliance on attorneys that can implicate difficult attorney-client privilege issues. U.S. *Safeco* Br. 23. Under the position Relators advocate, defendants would likely be subject to significantly higher legal and discovery costs. Defendants may even be required to go to trial to resolve questions of subjective intent, subjecting them to unpredictable, fact-intensive, hindsight judgments about whether their interpretation of unclear provisions was the correct one.

The standard Relators advocate could effectively eliminate motions to dismiss (or even motions for summary judgment) as a mechanism for screening out unmeritorious claims, forcing some defendants to settle even spurious claims to avoid burdensome discovery and the risk of disastrous treble damages and penalties. Discovery costs alone in "complex litigation can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak."

Smith v. Duffey, 576 F.3d 336, 340 (7th Cir. 2009). And that is to say nothing about the well-recognized "*in terrorem* settlement value that the threat of treble damages may add to spurious claims." *Haroco, Inc. v. American Nat. Bank & Tr. Co.*, 747 F.2d 384, 399 n.16 (7th Cir. 1984). As one of the False Claims Act's leading commentators observed, the statute's treble damages and penalty structure "places great pressure on defendants to settle even meritless suits." John T. Boese & Beth C. McClain, *Why* Thompson *Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 Ala. L. Rev. 1, 18 (1999).

Relators' rule thus would increase the costs of virtually all federal programs and services, given the government's pervasive reliance on contractors to provide goods and services—from national defense, healthcare, and medical manufacturing, to software development, waste disposal, telecommunications, mortgage lending, disaster relief, and consulting services. The inherent uncertainty of Relators' position may lead responsible companies to charge higher prices to compensate for the increased costs and risks of far-reaching and potentially catastrophic False Claims Act liability, or even decline to bid on contracts or participate in programs.

Adopting the *Safeco* standard here will mitigate these substantial costs. The objective reasonableness standard the district court employed appropriately cabins

expansive False Claims Act liability and holds the Act true to its intended purpose as a *fraud prevention* statute.

CONCLUSION

For these reasons, and those set forth in defendants-appellees' brief, the district court's decision should be affirmed.

Dated: December 7, 2020

Respectfully submitted,

/s/ John P. Elwood

John P. Elwood
Craig D. Margolis
Jayce L. Born
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
(202) 942-5000
john.elwood@arnoldporter.com

James C. Stansel
Melissa B. Kimmel
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street NW
Washington, DC 20004
(202) 835-3400

Steven P. Lehotsky
Tara S. Morrissey
U.S. CHAMBER LITIGATION CENTER
1615 H Street NW
Washington, DC 20062
(202) 463-5337

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

1. The foregoing Brief of Amici Curiae complies with the type-volume limitations of Seventh Circuit Rule 29 because the brief contains 6,947 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. The brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

Dated: December 7, 2020

/s/ John P. Elwood
John P. Elwood

CERTIFICATE OF SERVICE

I hereby certify that on December 7, 2020, I electronically filed the foregoing document with the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: December 7, 2020

/s/ John P. Elwood
John P. Elwood