No. 20-3425

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA et al., *ex rel.* THOMAS PROCTOR,

Plaintiffs-Appellants,

v.

SAFEWAY, INC.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Central District of Illinois
No. 3:11-CV-3406 (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 DEFENDANT-APPELLEE AND AFFIRMANCE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 20-3425

Short Caption: United States et al. v. Safeway, Inc.

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.

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N/A

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

N/A

Attorney's Signature: /s/ John P. Elwood Date: 04/16/2021

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Attorney's Signature: /s/ Craig D. Margolis Date: 04/16/2021

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Attorney's Signature: /s/ Jayce L. Born Date: 04/16/2021

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** ☑

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Attorney's Signature: /s/ James C. Stansel Date: 04/16/2021

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** ☑

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Attorney's Signature: /s/ Melissa B. Kimmel Date: 04/16/2021

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** ☑

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Attorney's Signature: /s/ Tara S. Morrissey Date: 04/16/2021

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

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Attorney's Signature: /s/ Andrew R. Varcoe Date: 04/16/2021

Attorney's Printed Name: Andrew R. Varcoe

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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 has a 10% or greater ownership interest in it; the Chamber of Commerce of the United States of America states that it has no parent corporation and no publicly held company has a 10% or greater ownership interest in it.

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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 defendant-appellee 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 Chamber is to represent the interests of its members in matters before Congress, 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.

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 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) 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 one of several reasonable interpretations of a provision improperly converts the Act from a fraud prevention statute into something else entirely.

If this Court were to reject the "objectively reasonable" scienter standard adopted by the district court and numerous circuits, it would have far-reaching consequences for *Amici*'s members. Such a decision would harm not just pharmacies like defendant-appellee 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. Relator's position that a party can violate the False Claims Act by adopting an objectively reasonable interpretation of an ambiguous provision would impermissibly broaden the Act's intended scope and threaten the *in terrorem* effect of quasi-criminal 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 (2007), the Supreme Court looked to the common law to hold that whether a person knowingly or recklessly violated the Fair Credit Reporting Act 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.* at 68-70. The district court 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). Because it is impossible to say that a party actually "knows" that an objectively reasonable interpretation of an ambiguous legal obligation is right or wrong absent binding guidance confirming its meaning, *see* 551 U.S. at 70 & n.19, the Supreme Court correctly rejected the idea that "evidence of subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly." *Id.* n.20.

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. SA-60; *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 Relator advances 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. Relator's 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 Relator's proposed subjective standard, 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 presenting or

[2] The Act was adopted in response to allegations of flagrant war profiteering. *United States v. McNinch*, 356 U.S. 595, 599 (1958). Private contractors supporting the

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 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 False Claims Act's intent provision, courts "presume 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.

Union Army were accused of defrauding the federal treasury through flagrantly wrongful acts: "For sugar [the government] often got 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 involving 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.

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. In *Safeco*, as here, the Court was addressing scienter in the context of a disputed legal obligation—whether, in the absence of clear and authoritative guidance, the

defendant had actual knowledge of a purported legal obligation. It is impossible to say that a party actually "knows" that an interpretation of an ambiguous legal obligation is right or wrong absent binding guidance confirming what the legal obligation is, *see id.* at 70 & n.19. The Supreme 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.* n.20. As the Court explained, "Congress could not have intended such a result for those who followed an interpretation that could reasonably have found support in the courts, whatever their subjective intent may have been." *Id.* It is thus of no moment that Relator alleges Safeway had actual knowledge it was acting improperly, or acted with deliberate ignorance. *See* Relator's Br. 63-68.

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). Such concerns fundamentally misunderstand *Safeco*. As *Safeco* explained, a party's subjective thinking has no bearing on whether they have been provided fair notice their conduct is unlawful; either the provision 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; *see also Christopher v. SmithKline Beecham Corp*., 567 U.S. 142, 158-59 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time . . . ."); *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 … civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express." (quoting *Diamond Roofing Co. v. OSHRC*, 528 F.2d 645, 649 (5th Cir. 1976)).

In view of the Supreme Court's 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. It is thus unsurprising that every court of appeals to consider the issue has agreed that *Safeco*'s objective scienter standard applies to the False Claims Act. *See* SA-35 to SA-36 (collecting cases). 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. The Court concluded 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 agency pronouncements 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 "courts of appeals" decisions 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 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," *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, *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" Medicare Provider Reimbursement Review Board decision was not enough to warn 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) (report prepared by former agency official was "not the kind of official government warning" constituting authoritative

guidance); *Purcell*, 807 F.3d at 289 (testimony from former bank employee about 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) (court doubtful that agency's "Business Alert" constituted kind of authority envisioned by *Safeco*).

The Justice Department's affirmative civil enforcement policy, which includes False Claims Act enforcement, recognizes a similar principle. The Department has adopted a policy, formally codified in the *Justice Manual*, limiting reliance in enforcement actions on non-binding agency guidance (that is, agency guidance that has not "undergo[ne] the notice-and-comment rulemaking process"). 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. Department litigators are not to use "noncompliance with guidance documents as a basis for proving violations of applicable law." *Id.* 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 issued a final rule providing that "HHS may not . . . use any guidance document for purposes of requiring persons or entities outside HHS to take any action or to refrain from taking any action beyond what is already required by the terms of an applicable statute or regulation." Department of Health and Human Services, *Good Guidance Practices*, 85 Fed. Reg. 78,770, 78,776 (Dec. 7, 2020). The Department explained that the use of such guidance documents by "qui tam relators" to "impose binding new obligations on regulated parties" was "inappropriate[]." *Id.* at 78,784.

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 . . . 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." 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 (2018) ("guidance documents" used by "many regulatory agencies seek[] 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 Relator advances, 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," and "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 encourages 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 of the guidance may cause it to escape the notice of regulated parties.

IV. *Safeco*'s Objectively Reasonable Standard Limits Expansive False Claims Act Liability

If this Court were to become the first appellate court to reject *Safeco*'s scienter standard under the False Claims Act, or if it adopts Relator's 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. Meritless *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) (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); *United States ex rel. Pritzker v. Sodexho, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (public school lunches); *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001) (healthcare); *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983) (food stamps); *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. Bias v. Tangipahoa Parish Sch. Bd.*, 86 F. Supp. 3d 535 (E.D. La. 2015) (public school ROTC programs); *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); *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, over 13,000 of them *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 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.

Relators are thus keenly aware that mere allegations, regardless of 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 creates intense pressure 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 *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" "rigorous" scienter and materiality requirements. *Escobar*, 136 S. Ct. at 2002. The "objectively reasonable" scienter standard 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 that businesses routinely face when they assist the government in implementing programs—as contractors, grantees, or simply as program participants. 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] Contractual agreements regularly incorporate "thousands of pages of other federal laws and regulations" of comparable complexity. *United States v. Stanford-Brown, Ltd*, 788 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]

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[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).

[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)).

Virtually every interaction that businesses undertake with the government is thus likely to involve complex provisions whose meanings are unsettled. 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 statutory penalties, and reputational harm whenever a provision is subject to dispute. That risk is particularly pronounced in programs like the one here, where the supposed "false claim" involves not a single contract or transaction with a government agency, but untold thousands of repeated transactions, all implicating the same basic interpretive question.

"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)). Making regulated parties civilly liable based upon 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

the provision gave adequate notice. *Safeco*, 551 U.S. at 70 (analyzing whether guidance warned party away).

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 sensor joints 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 to credit supplier rebates to the government (about which the Office of Management and Budget and the relevant Office of Inspector General had "differing

[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).

opinions");[11] and whether highway inspectors met minimum requirements under "ambiguous" and "inconsistent sets of qualifications" set forth in a number of contract attachments.[12] In each case, courts ruled for the defendants on motions to dismiss or at summary judgment because their positions were objectively reasonable. Indeed, *this case* aptly illustrates the kind of disputed regulatory minutiae that under Relator's reading could expose businesses to crippling liability based on supposed meanings that are anything but plain. Relator seeks punitive sanctions because Safeway failed to count prices offered solely to customers who join member-only clubs as prices offered to "the general public." But as this Court has explained, things available only to customers who enroll in special programs are not "for . . . the general public." *ON/TV of Chi. v. Julien*, 763 F.2d 839, 842-43 (7th Cir. 1985) (subscription TV programming not "broadcasting for the use of the general public").

The *Safeco* standard helps control the costs of *qui tam* litigation, because an objective scienter standard can stop meritless claims early, at the motion to dismiss or summary judgment stage. Indeed, in *Safeco*, the federal government advocated an

[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] *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).

objective scienter standard because "[t]hat purely legal inquiry . . . can, and generally should, be undertaken at an early stage in the case." U.S. Br., *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 Rule 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 Relator advocates 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 Relator's position, defendants would 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 correct.

Relator's standard 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). 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 "place[] 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).

Relator's rule 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 Relator's 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 to 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 defendant-appellee's brief, the district court's decision should be affirmed.

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Respectfully submitted,

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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 6,970 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: April 16, 2021

/s/ John P. Elwood
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CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2021, 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: April 16, 2020

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