Nos. 21-1326, 22-111

In the Supreme Court of the United States

UNITED STATES, ET AL., EX REL. TRACY SCHUTTE & MICHAEL YARBERRY, PETITIONERS

v.

SUPERVALU INC., ET AL.

UNITED STATES, EX REL. THOMAS PROCTOR, PETITIONER

v.

SAFEWAY, INC.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE AMERICAN MEDICAL ASSOCIATION, BUSINESS ROUNDTABLE, THE ILLINOIS STATE MEDICAL SOCIETY, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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IX

INTEREST OF AMICI CURIAE¹

The Chamber of Commerce of the United States of America (the "Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more million companies and professional than three organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, which remain its core purposes. AMA members practice in every medical specialty and in every state. The Illinois State Medical Society ("ISMS") is a non-profit, membership organization that represents its 9,000 physician members across all specialties and practice areas throughout the State of Illinois. Founded in 1840. ISMS has grown into the leading advocate for Illinois physicians and patients, representing the interests of its

¹ No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

member physicians, medical graduates completing residency and fellowship programs, and medical school students, as well as those of patients, promoting the ethical practice of medicine, the betterment of public health, and the delivery of quality, affordable health care. The AMA and ISMS submit this brief on their own behalf and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies, which represent the viewpoint of organized medicine in the courts.

Business Roundtable is an association of chief executive officers of over 230 leading U.S. companies that support 37 million American jobs, generate \$10 trillion in sales activity, and account for 24% of the U.S. GDP. Business Roundtable was founded on the belief that businesses should play an active and effective role in the formulation of public policy. Business Roundtable participates in litigation as *amicus curiae* when important business interests are at stake.

National Association of Manufacturers The ("NAM") is the largest manufacturing association in the States, representing small large United and manufacturers in all 50 states and in every industrial sector. Manufacturing employs over 12.9 million men and women, contributes over \$2.8 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA members have invested more than \$1 trillion in the search for new treatments and cures—including \$102.3 billion in 2021 alone. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and lifeenhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

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 arising out of government contracts, and federal program participation. With grants. increasing frequency, private relators 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. U.S. ex rel. Stevens, 529 U.S. 765, 784-785 (2000). Imposing such liability for adopting one of several reasonable interpretations of an ambiguous provision improperly converts the Act from a fraud-prevention statute into something else entirely.

Rejecting the "objective reasonableness" scienter standard would have far-reaching consequences for *Amici*'s members. Such a decision would harm the myriad 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. Petitioners' position that a party can violate the False Claims Act even where it acts consistent with 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), this Court looked to the common law to hold that whether a person willfully 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. Safeco's objective scienter standard reflects the common law understanding of the very same mens rea options used by the False Claims Act. Absent binding guidance, a party cannot "know" whether an objectively reasonable interpretation of an ambiguous provision is right or wrong. Such a party cannot act with the requisite intent to violate the False Claims Act, "whatever their subjective intent may have been." Id. at 70 n.20.

Safeco does nothing to deprive agencies of recourse when a regulated party receives payment under an interpretation of an ambiguous provision that the government later determines is wrong. It merely ensures that regulated parties receive the minimal fair notice that constitutional due process requires before ambiguous obligations are enforced using severe, punitive *fraud* liability. Petitioners' rule would encourage federal agencies to remain silent in the face of legal ambiguity, or even to issue vague guidance to preserve "strategic ambiguity." U.S. ex rel. Sheldon v. Allergan Sales, LLC, 24 F.4th 340, 354 (4th Cir.) (Wilkinson, J.), vacated on reh'g en banc and aff'g by an equally divided court, 49 F.4th 873 (4th Cir. 2022) (en banc). And it would permit opportunistic relators to belatedly capitalize on regulatory ambiguities regarding practices long known to, and accepted by, the relevant agency.

Adhering to *Safeco*'s insistence that only formal, binding guidance is sufficiently "authoritative" to warn a defendant away from an otherwise reasonable interpretation accords with ordinary principles of what makes agency action binding on the regulated public. It also protects the public by encouraging agencies to act through formal rulemaking rather than informal guidance, thereby ensuring the benefits of public input, reasoned decisionmaking, and fair notice.

Petitioners' position would extend the False Claims Act beyond its intended limits. The Act is a *fraud* prevention statute. "[S]trict enforcement" of its "rigorous" scienter requirement, *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192 (2016), plays a critical role in keeping its reach within appropriate limits. Petitioners' position would convert the Act into a mechanism for opportunistic relators to profit from unsettled questions regarding the statutory, regulatory, and contractual minutiae that government contractors and program participants regularly face under sometimes byzantine federal programs.

As the government itself noted in *Safeco*, an objective scienter standard helps control litigation costs by permitting early resolution of meritless claims. See 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. By contrast, petitioners' subjective standard would impose enormous litigation costs because "questions of subjective intent * * * rarely can be decided by summary judgment." *Harlow* v.

Fitzgerald, 457 U.S. 800, 816 (1982). Relators—only infrequently joined by the government—would exploit the routine disagreements of defendants' employees about ambiguous provisions to claim that any uncertainty represents a triable issue of recklessness or even knowing fraud.

Even weak False Claims Act cases are tremendously expensive to litigate. The prospect of expensive and risky litigation and unwarranted settlements has a chilling effect on potential contractors, reducing competition and agencies' choice and increasing contractor prices. Rejecting *Safeco*'s objective scienter standard thus increases costs not only for contractors, grantees, and program participants, but also for the federal government itself—and, ultimately, the American taxpayer. This Court should affirm.

ARGUMENT

A. *Safeco's* "Objective Reasonableness" Scienter Standard Should Apply To The False Claims Act

1. The False Claims Act imposes liability for knowingly 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.

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. U.S. ex rel. Escobar,

579 U.S. 176, 187 (2016) (internal quotation marks omitted). As this Court explained in *Escobar*, 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 187 n.2.

Safeco addressed that very issue. There, this Court examined what the term "willfully" meant at common law in the context of interpreting the Fair Credit Reporting Act, and held that it encompasses both "acts known to violate the [law]" and "reckless [violations] as well," 551 U.S. at 56-57-mens rea levels identical to those covered by the False Claims Act.² 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] * * * 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." Id. at 68 (quoting Farmer v. Brennan, 511 U.S. 825, 836 (1994)); id. at 69 (objective risk assessment defines "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

² Courts have long held that actual knowledge incorporates willful blindness or deliberate ignorance. See *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 766-768 (2011).

such interpretation as a knowing or reckless violator." *Id.* at 70 n.20.

In Safeco, as here, the Court addressed 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 establishing what the legal obligation is, see id. at 70 & n.19. Unlike an observed fact (which one *can* "know"), a person cannot "know" what an ambiguous provision means, but at most can try to predict how authoritative decisionmakers might interpret it. 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." Ibid.

2. The government has voiced concerns about a False Claims Act defendant "escap[ing] liability by identifying a post hoc rationale for its prior representations," regardless of whether it contemporaneously embraced that position. U.S. *Amicus* Br. 16.

But defendants cannot "escape liability" by pointing to merely any "post hoc rationale." *Safeco* provides two meaningful safeguards against creative, after-the-fact interpretations. First, a court must agree that the governing legal requirement is ambiguous. Second, a court must agree that the defendant's interpretation is objectively reasonable. Given these constraints, the government's concerns that defendants will be able to exploit *Safeco* are overblown. Dishonest defendants cannot count on their lawyers coming up with an afterthe-fact construction of an ambiguous provision that not only exonerates them, but that the court will deem *objectively reasonable*. Indeed, it is far more likely that any objectively reasonable reading will occur to participants at the time they are puzzling over ambiguous provisions and hazy guidance—and frequently, when they are trying without success to obtain definitive guidance from the agency.

In any event, such concerns are far outweighed by the due process principles animating Safeco. As Safeco explained, a party's subjective thinking has no bearing on whether it has received fair notice that its conduct is unlawful because the provision either provided regulated parties adequate notice, or it did not. See Safeco, 551 U.S. at 70 n.20. The government has no business imposing quasi-criminal liability for acting consistent with an objectively reasonable interpretation of an ambiguous obligation. Fundamental notions of due process prohibit "penalizing a private party for violating" a rule without first providing adequate notice of the substance of the rule." U.S. ex rel. Purcell v. MWI Corp., 807 F.3d 281, 287 (D.C. Cir. 2015) (quoting Satellite Broad. Co. v. Fed Comme'ns Comm'n, 824 F.2d 1, 3 (D.C. Cir. 1987)). As then-Judge Scalia explained, "[i]f 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." Gates & Fox Co. v. OSHRC, 790 F.2d 154, 156 (D.C. Cir. 1986).

3. The *Safeco* rule protects regulated parties from unfair surprise resulting from the common practice of agencies failing to provide definitive guidance about ambiguous obligations—whether because of inertia or indecision, to preserve enforcement and implementation discretion, or for other reasons entirely. Courts have criticized agencies for "conspicuous inaction" for failing to act regarding regulatory ambiguities even in the face of longstanding industry practices implicating them. E.g., Perez v. Loren Cook Co., 803 F.3d 935, 942-943 (8th Cir. 2015) (en banc); United States v. Moss, 872 F.3d 304, 214 (5th Cir. 2017); see also Romero v. Barr, 937 F.3d 282, 296 (4th Cir. 2019). The government and petitioners assert that uncertainties can be readily addressed by "mak[ing] inquiries [of agencies] to ensure compliance," U.S. Br. 34; Pet. Br. 21, but agencies are not so forthcoming. Courts have recognized that agencies sometimes even "refuse[] to respond to manufacturer requests for clarification," in an effort to "thereby maintain[] strategic ambiguity" about the obligations of regulated parties. Sheldon, 24 F.4th at 354, 356. And any assistance comes at a high cost: The government maintains that "a claim of reliance on the statements or advice of a government official * * * result[s] in waiver of [attorney-client] privilege." Plaintiffs' Mem. Supporting Mot. to Compel at 21, Dkt. 505-3, U.S. ex rel. Poehling v. UnitedHealth Group, Inc., No. CV-16-08697 FMO (C.D. Cal. June 3, 2022).

Adopting petitioners' rule would encourage federal agencies to remain silent in the face of legal ambiguity, creating a series of landmines for well-intentioned businesses that strive to comply with a myriad of regulations and requirements every day. Worse still, the government is not the only party that can detonate those landmines. Enterprising relators routinely exploit regulatory ambiguity, even when the relevant agency has not determined that a defendant has violated the law, or has even acquiesced in a known practice for years. Indeed, that is what happened here. Resp. Br. 2, 6, 11, 42; see also *Sheldon*, 24 F.4th at 354 (*qui tam* suit brought to challenge practice well known to agency, whose status agency failed to clarify despite requests).

This Court has recognized that forgiving (or even rewarding) agency ambiguity "creates a risk that agencies will promulgate vague and open-ended regulations that they can later interpret as they see fit." Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 158 (2012); accord Loren Cook, 803 F.3d at 941-942 ("Allowing such an interpretation to prevail could create the risk that the Secretary may never provide more specific interpretative guidance so as to avoid limiting his future ability to construe his own ambiguous regulations."); Matthew C. Stephenson & Miri Pogoriler, Seminole Rock's Domain, 79 Geo. Wash. L. Rev. 1449, 1461 (2011) ("[A]n administrative agency that writes vague regulations knows that it will be able to control their subsequent interpretation.").

As this Court has recognized, "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 liable when the held agency announces its interpretations for the first time * * *." Christopher, 567 U.S. at 158-59. And it is another thing entirely when intentional ambiguity becomes the basis to impose "essentially punitive" fraud liability, Stevens, 529 U.S. at 784-85, on a regulated party that failed to correctly divine an unspoken agency interpretation. Yet, that is exactly what petitioners ask this Court to do.

4. This is not a question of whether agencies will have recourse when a regulated party acts in accordance with an interpretation of an ambiguous provision that is later determined to be wrong. Agencies have numerous tools at their disposal to address contractor errors and noncompliance, including mechanisms that allow the government to recover payments that are later determined to have been improperly made. See, *e.g.*, *U.S. ex* rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1220 (10th Cir. 2008) (noting administrative scheme for bringing hospitals back into compliance); U.S. ex rel. Howard v. Lockheed Martin Corp., 14 F. Supp. 3d 982, 1014 (S.D. Ohio 2014) (government issued Corrective Action Requests upon discovering noncompliance).

The only question is whether regulated parties should be liable for *fraud*, under the False Claims Act's punitive liability scheme, for acting consistent with an objectively reasonable interpretation of an obligation that was never made clear to them. They should not. Holding otherwise 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); see also *Purcell*, 807 F.3d at 287 ("Strict enforcement of the [False Claims Act]'s knowledge requirement helps *** avoi[d] the potential due process problems" of inadequate notice).

B. Requiring Proof Of Formal, Binding Guidance To "Warn Away" From An Objectively Reasonable Interpretation Encourages Good Agency Practices And Protects Regulated Parties

1. In determining whether the regulated parties' interpretation of the Fair Credit Reporting Act in *Safeco* was objectively reasonable, the 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. 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 rulemaking authority, for the provisions in question." *Ibid.* 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 the regulated parties' interpretation of the statute was objectively reasonable. *Id.* at 70.

Safeco's meaning is clear: Only precedential appellate 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 decisions of courts at that level and higher have precedential 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.").

Equally tellingly, *Safeco* distinguished "authoritative guidance," promulgated by agencies with "substantive rulemaking authority," from non-authoritative "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. *Ibid.* 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); "the agency's interpretation must *** implicate its substantive expertise," *id.* at 2417; it must reflect "considered judgment" rather than merely a "litigating position" or post hoc justification, *ibid.* (quoting *Christopher*, 567 U.S. at 155); and it must provide regulated parties with "fair warning" before taking effect, *id.* at 2418. Unless the agency's interpretation satisfies those requirements, it is not "authoritative guidance" sufficient to dispel ambiguity. Cf. *Safeco*, 551 U.S. at 70 & n.19.

Several courts of appeals have recognized as much when applying Safeco's objective scienter standard. In Van Straaten, for example, the Seventh Circuit rejected an agency bulletin as authoritative guidance because "it [was] neither an exercise in notice-and-comment the outcome of rulemaking nor administrative adjudication." 678 F.3d at 488; see also, e.g., U.S. ex rel. Complin v. N. Carolina Baptist Hosp., 818 F. App'x 179, 184 n.6 (4th Cir. 2020) ("non-precedential and nonbinding" Medicare Provider Reimbursement Review Board decision insufficient to warn defendant away); U.S. ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC, 833 F.3d 874, 880 (11th Cir. 2016) (report prepared by former agency official "not the kind of official government warning" to be authoritative); Purcell, 807 F.3d at 289 (testimony from former bank employee "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) (expressing doubt that agency's "Business Alert" was authoritative).

The Justice Department's policy regarding the use of guidance documents in enforcement actions, including those involving the False Claims Act, recognizes a similar principle. The Department has adopted a policy, formally codified in the Justice Manual, that agency guidance (meaning guidance that has not undergone the notice-and-comment process) cannot by itself form the basis for an enforcement action "because such documents cannot 'impose any legally binding requirements' on private parties." Justice Manual § 1-19.000, available at http://bit.ly/3TnysEY (quoting *Kisor*, 139 S. Ct. at 2420 (plurality opinion)). "Instead, enforcement actions must be based on the failure to comply with a binding obligation, such as one imposed by the Constitution, a statute, a legislative rule, or a contract." *Ibid*.

2. In an age when statutes are intentionally written broadly to vest agencies with ample discretion to interpret statutes and thereby set policy, the *Safeco* standard encourages agencies to address ambiguous legal obligations. See pp. 10-11, *supra*. Adhering to *Safeco*'s authoritativeness standard encourages federal agencies to address ambiguities the *right way*: through well considered, formal decisionmaking that brings agency expertise to bear in promulgating rules that are honed by the notice-and-comment process.

a. Some "[f]ederal agencies love to publish guidance documents * * *. They 'come in a variety of formats and including interpretive memoranda, policy names, 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." 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 *** serve the regulated public when they issue *** guidance documents." House Committee on Government Reform, Non-Binding Legal Effect of Agency Guidance Documents, H.R. Rep. No. 106-1009, at 1 (2000). But sometimes such "guidance documents [a]re intended to bypass the rulemaking process." *Ibid.*

Hewing to Safeco's standard encourages good agency practices. Broadening the type of guidance that counts as "authoritative" in False Claims Act cases would discourage agencies from undertaking the effort necessary to issue binding pronouncements, soliciting input from regulated parties and using formal noticeand-comment rulemaking to announce authoritative positions. 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 toAgency Interpretation of Agency Regulations, 96 Colum. L. Rev. 612, 662 (1996) (broad powers of agency selfinterpretation "reduces the efficacy of notice-andcomment 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 thus encourages careful administrative action.

In addition, "when the practice of making binding law by guidances, manuals, and memoranda is tolerated," a "costly *** tendency to overregulate *** is nurtured." *Ibid.* 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). And the very informality of the guidance may cause it to escape the attention of regulated parties. Thus, "informal agency advice comes at a price" to regulated parties. Andersen, *supra*, at 596.

C. Safeco's Objective Reasonableness Standard Appropriately Limits Expansive False Claims Act Liability

Any person or entity, public or private, that receives or handles federal funds in myriad forms potentially falls within the False Claims Act's reach. Petitioners' subjective standard would expose a broad cross-section of businesses, individuals, nonprofits, and governmental entities³ to protracted litigation and potentially crippling liability, increasing the already considerable financial and reputational costs of *qui tam* suits. This potential expansion of liability underscores the importance of rigorously applying the False Claims Act's scienter standard.

The False Claims Act is a "fraud prevention statute," U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999), enacted during the Civil War to address flagrant procurement fraud: "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

³ See, e.g., U.S. ex rel. Vermont Nat'l Tel. Co. v. Northstar Wireless, LLC, 34 F.4th 29 (D.C. Cir. 2022) (telecommunications services); U.S. ex rel. Schweizer v. Canon, Inc., 9 F.4th 269 (5th Cir. 2021) (office equipment); U.S. ex rel. Tzac, Inc. v. Christian Aid, No. 17-cv-4135, 2021 WL 2354985 (S.D.N.Y. June 9, 2021) (charitable aid organization); United States v. Sanford-Brown, Ltd., 840 F.3d 445 (7th Cir. 2016) (higher education); U.S. ex rel. Steury v. Cardinal Health, Inc., 735 F.3d 202 (5th Cir. 2013) (medical manufacturing); U.S. ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cnty., 712 F.3d 761 (2d Cir. 2013) (housing); U.S. 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); U.S. ex rel. Pritzker v. Sodexho, Inc., 364 F. App'x 787 (3d Cir. 2010) (public school lunches); Grand Union Co. v. United States, 696 F.2d 888 (11th Cir. 1983) (food stamps); U.S. ex rel. Shemesh v. CA, Inc., No. 09-cv-1600, 2015 WL 1446547 (D.D.C. Mar. 31, 2015) (software development); U.S. ex rel. Bias v. Tangipahoa Parish Sch. Bd., 86 F. Supp. 3d 535 (E.D. La. 2015) (public school JROTC programs); United States v. Americus Mortg. Corp., No. 12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014) (mortgage lending); U.S. ex rel. McLain v. Fluor Enters., Inc., 60 F. Supp. 3d 705 (E.D. La. 2014) (disaster relief); U.S. ex rel. Landis v. Tailwind Sports Corp., 51 F. Supp. 3d 9 (D.D.C. 2014) (athletic sponsorship).

experimental failures of sanguine inventors, or the refuse of shops and foreign armories." U.S. ex rel. Newsham v. Lockheed Missiles & Space Co., 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting 1 Fred A. Shannon, The Organization and Administration of the Union Army, 1861–1865, at 54-56 (1965)).

A violation of a statute, rule, or regulation is not fraud "unless the violator knowingly lies to the government about [it]." *Lamers*, 168 F.3d at 1020. The "objective reasonableness" scienter standard plays a critical role reining in open-ended liability under the Act by "help[ing] to * * * avoid[] the potential due process problems posed by" inadequate notice. *Purcell*, 807 F.3d at 287, 290. And this Court has noted that "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*, 579 U.S at 192.

The need for strict enforcement of the scienter requirement is particularly critical because of the complex contractual and regulatory schemes that businesses, nonprofits, and even governmental entities routinely face when they assist the federal 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. As courts have recognized, those legal regimes are at minimum "complex" (Federal Family Education Loan Program),⁴ if not "complex [and] poorly-worded" (Small

⁴ U.S. ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 799 (8th Cir. 2011) (citation omitted).

Disadvantaged Business regulations).⁵ Government contracts regularly incorporate "thousands of pages of other federal laws and regulations" of comparable complexity. *United States* v. *Sanford-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),⁶ "intricate" and "almost unintelligible" (the Social Security Act),⁷ and "onerous and impenetrable" and "byzantine to the point of incomprehensibility" (government procurement rules).⁸ That brings us to the Medicare and Medicaid programs at issue here, which this Court has described as involving "a massive, complex * * program," "embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations,"⁹ and which *seven* federal courts of appeals

⁵ 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).

⁶ U.S. ex rel. Sequoia Orange Co. v. Sunland Packing House Co., 912 F. Supp. 1325, 1329 (E.D. Cal. 1995).

 $^{^7}$ Schweiker v. Gray Panthers, 453 U.S. 34, 43 (1981) (citation omitted).

⁸ 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 "byzantine" two-thousand-page Federal Acquisition Regulations governing federal government procurement).

⁹ Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 13 (2000); see also Wisc. Dep't of Health & Fam. Servs. v. Blumer, 534 U.S. 473, 497 (2002) ("complex and highly technical regulatory program" (citation omitted)); NFIB v. Sebelius, 567 U.S. 519, 581 (2012) (Medicaid is an "intricate statutory and administrative

have deemed to be "among the most completely impenetrable texts within human experience."¹⁰ Businesses' interactions with the government commonly involve complex webs of laws, rules, regulations, and miscellaneous guidance documents containing provisions with unsettled or unclear meanings. See *Personal Care Prods.*, 635 F.3d at 159 n.18 (noting that "the complexities of these statutes and regulations *** create compliance *** problems" for providers).

It would create tremendous risk to allow a business's actions that accord with an objectively reasonable interpretation of an unsettled obligation to expose it to False Claims Act liability whenever a provision's meaning 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.

If the decision below is reversed, a statute enacted to address blatant acts of fraud such as the provision of patently worthless goods, see pp. 18-19, *supra*, would instead be used to pursue treble damages based on unsettled and disputed questions involving statutory, regulatory, or contractual minutiae. But cf. *Escobar*, 579

regime[]"); Fischer v. United States, 529 U.S. 667, 679 (2000) (Medicare is "intricate").

¹⁰ Atrium Med. Center v. Dep't of Health & Hum. Servs., 766 F.3d 560, 564 (6th Cir. 2014) (quoting Rehab. Ass'n of Va., Inc. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994)); accord Sunshine Haven Nursing Operations, LLC v. Dep't. of Health & Hum. Servs., 742 F.3d 1239, 1258 (10th Cir. 2014); Parra v. PacifiCare of Ariz., Inc., 715 F.3d 1146, 1149-50 (9th Cir. 2013); Abraham Lincoln Mem. Hosp. v. Sebelius, 698 F.3d 536, 541 (7th Cir. 2012); Personal Care Prods., Inc. v. Hawkins, 635 F.3d 155, 159 n.18 (5th Cir. 2011); Cooper Univ. Hosp. v. Sebelius, 636 F.3d 44, 45 (3d Cir. 2010).

U.S. at 196 ("[T]he False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations."). Examples include:

- 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," but the agency manual addressed only insurance plans, not trust contributions.¹¹
- Whether brazed sensor joints met requirements for diametrical clearance, masking, and stop-off and flux removal. There was a reasonable "difference in interpretation" about these brazing requirements.¹²
- Whether a school lunch contractor was required to credit supplier rebates to the government. Even the Office of Management and Budget and the relevant Office of Inspector General had "differing opinions" on this issue.¹³

¹¹ U.S. 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]").

¹² U.S. ex rel. Marshall v. Woodward, Inc., 812 F.3d 556, 562 (7th Cir. 2015) (affirming grant of summary judgment for manufacturer of helicopter parts, explaining that defendant lacked requisite knowledge because of "difference in interpretation" about brazing requirements).

¹³ United States v. Sodexho, Inc., No. 03-6003, 2009 WL 579380, at *17 (E.D. Pa. Mar. 6, 2009) (granting motion to dismiss because OMB and Inspector General disagreed about regulatory requirements and defendant's interpretation was reasonable).

• Whether highway inspectors met minimum requirements under "ambiguous" and "inconsistent sets of qualifications" set forth in a number of contract attachments.¹⁴

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 apply illustrates the kind of disputed regulatory minutiae that under petitioners' reading could expose businesses, nonprofits and governmental entities to crippling liability based on interpretations that are anything but obvious. Petitioners seek punitive sanctions because Safeway and SuperValu failed to count prices offered solely to customers who join member-only clubs, or prices given under "price-matching" programs, as prices offered to "the general public." But things available only to customers who enroll in special programs are not "for *** the general public." ON/TVof Chi. v. Julien, 763 F.2d 839, 842-843 (7th Cir. 1985) (subscription TV programming not "broadcasting for the use of the general public"). Cases like these are not the kind of cases that the False Claims Act was intended to cover, and the Act should not be construed so broadly as to bring them within its scope.

D. Safeco's Objective Reasonableness Standard Reduces Needless And Burdensome Litigation Costs—Including The Costs Of Litigating Subjective Good Faith

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

¹⁴ U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g, 567 F. App'x 166, 167, 170 (3d Cir. 2014) (affirming summary judgment for defendant based on lack of scienter because contract language setting pay rates for highway inspectors was ambiguous).

Tam Actions, at xxi (4th ed. 2011). Over that period, more than 21,000 False Claims Act actions were filed, nearly 15,300 of them qui tam suits. U.S. Dep't of Justice, Fraud Statistics—Overview: Oct. 1, 1986-Sept. 30, 2022, at 3 (2023), https://bit.ly/3IXOVLg. But only "about 10 percent of non-intervened cases result in recovery" for the government. U.S. ex rel. Hunt v. Cochise Consultancy, Inc., 887 F.3d 1081, 1087 (11th Cir. 2018), aff'd, 139 S. Ct. 1507 (2019)); Ralph C. Mayrell, Digging Into FCA Stats: In-House Litigation Budget Insights, Law360 (July 13, 2021), https://bit.ly/3hUp89K.

Meritless qui tam actions are "downright harmful" to the business community. See Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 298 (2010). Businesses face the specter of treble damages and civil penalties of over \$27,018 per false claim, which can quickly mushroom (e.g., in health-care matters involving thousands of patient claims). Civil Monetary Penalties Inflation Adjustment, 88 Fed. Reg. 5776 (Jan. 30, 2023); 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). And 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).

1. 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 itself advocated an objective scienter standard because "[t]hat purely legal inquiry * * * can, and generally should, be undertaken at an early stage in the case." U.S. Safeco Br. at 23. Courts and jurists have noted that Safeco's 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, 803-804 (7th Cir. 2010) (affirming Rule 12(b)(6) dismissal in part because 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).

The subjective standard that petitioners advocate would impose far greater litigation costs on defendants, effectively eliminating both motions to dismiss and motions for summary judgment as mechanisms for screening out unmeritorious claims. "[Q]uestions 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.").

Typically, corporate law and compliance departments are responsible for interpreting legal requirements. In responsible organizations, it is likely that at least one employee or agent considering an ambiguous provision will construe it consistent with the reading the government (or relator) later favors, or at least acknowledge that such a reading may be correct. Cf. *Purcell*, 807 F.3d at 290 ("In the face of an undefined and ambiguous regulatory requirement, it is no wonder that employees of the regulated entity were concerned."). In such a scenario, the government, or a self-interested relator—not infrequently, the very person who endorsed that reading—will then point to evidence of that single opinion to argue there is an issue of fact whether the company recklessly disregarded an alleged falsity or even made knowingly false statements, even if everyone else in the organization thought that view was incorrect.

There may well be vigorous internal debate about what the requirements are-indeed, that is something the law should encourage to promote responsible corporate decision-making. Yet, such debate is often privileged. Petitioners' standard thus may force defendants to waive privilege in order to demonstrate their subjective belief regarding a disputed legal obligation. Indeed, the Justice Department routinely asserts that "a [defendant]'s assertion of good-faith belief in the legality of its conduct" waives attorneyclient privilege, regardless of whether it relies on or even references the existence of counsel's advice. *Poehling* Mem. Supporting Mot. to Compel at 12-14. Tellingly. both the government and petitioner acknowledge their subjective test would involve evidence of legal advice "a defendant received from * * * attorneys." U.S. Br. 34 n.5; id. at 18; Pet. Br. 36, 51.

This illustrates how "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," *ibid.*, 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, and costly, attorney-client privilege issues. U.S. *Safeco* Br. at 23. Petitioners' standard thus would subject defendants 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. That prospect has the very real possibility of forcing defendants to settle even spurious claims to avoid burdensome discovery and the risk of disastrous treble damages and penalties.

2. Moreover, the mere existence of allegations (however tenuous) "can do great damage to a firm." U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc., 772 F.3d 1102, 1105-08 (7th Cir. 2014). "[T]he 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 burdensome 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.

3. 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); see also Smith v. Duffey, 576 F.3d 336, 340 (7th Cir. 2009) (discovery costs alone "can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak"); *Haroco, Inc.* v. American Nat. Bank & Tr. Co., 747 F.2d 384, 399 n.16 (7th Cir. 1984) (noting the "in terrorem settlement value that the threat of treble damages may add to spurious claims"). 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 any one of the many ambiguous contractual, statutory, or regulatory provisions that govern their conduct.

The prospect of expensive and risky litigation and unwarranted settlements has a very real chilling effect on companies and individuals that are evaluating whether to do business with the federal government. In turn, a reduction in qualified entities and individuals willing to deal with the government deprives the government of choice, and reduced competition means that the government very likely will pay higher prices and receive lesser products or services. See, e.g., United States v. Data Translation, Inc., 984 F.2d 1256, 1262 (1st Cir. 1992) (Breyer, C.J.) ("[S]ignificantly increasing competitive firms' cost of doing federal government business[] could result in the government's being charged higher *** prices."); Memorandum from Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, U.S. Dep't of Just., to Attorneys, Commercial Litig. Branch, Fraud Section at 5 (Jan. 10, 2018) ("[T]here may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry.").

Because the costs of False Claims Act litigation are passed on to the government, both directly and indirectly, those costs ultimately will be borne by the taxpayer. For instance, cost-based contractors can pass on to the government up to 80% of their legal expenses from litigating non-intervened *qui tam* cases when they prevail. FAR 31.205-47(a)(3), (e). And contractors undoubtedly pass costs to taxpayers by increasing the prices they charge to account for the risk of costly litigation.

Adopting the *Safeco* objective reasonableness standard will mitigate these substantial costs. This standard appropriately cabins expansive False Claims Act liability and holds the Act true to its intended purpose as a statute designed to address *fraud*.

CONCLUSION

For these reasons, and those in respondents' brief, the decision below should be affirmed.

Respectfully submitted.

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