Nos. 21-1326, 22-111

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA, ET AL.,
EX REL. TRACY SCHUTTE & MICHAEL YARBERRY,
Petitioners,
v.
SUPERVALU, INC., ET AL.,
Respondents.

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

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

BRIEF OF AMICUS CURIAE TAXPAYERS AGAINST FRAUD IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICUS[1]

Amicus curiae Taxpayers Against Fraud Education Fund ("TAFEF") is a nonprofit public interest organization dedicated to combating fraud against the government and protecting public resources through public-private partnerships. TAFEF is committed to preserving effective anti-fraud legislation at the federal and state levels. The organization has worked to publicize the *qui tam* provisions of the False Claims Act ("FCA"), regularly participates in litigation as amicus curiae, and has provided testimony to Congress about ways to improve the FCA. TAFEF is supported by whistleblowers and their counsel, by membership dues and fees, and by private donations. TAFEF is the 501(c)(3) arm of Taxpayers Against Fraud, which was founded in 1986.

TAFEF has a strong interest in ensuring proper interpretation and application of the FCA. It files this brief to explain how the Seventh Circuit's rule limiting consideration of a defendant's subjective knowledge would severely hinder government antifraud efforts, and to show how the rule's stark evidentiary limitations are inconsistent with how the United States deals with contractors who act on its behalf or provide it goods and services in the marketplace.

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[1] No counsel for a party authored this brief in whole or in part and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

SUMMARY OF THE ARGUMENT

In *United States ex rel. Schutte v. SuperValu* and *United States ex rel. Proctor v. Safeway*, the Seventh Circuit held that a defendant does not knowingly violate the FCA, even if it believes it is submitting false claims, as long as its conduct is consistent with an incorrect-but-textually-possible interpretation of a legal requirement, unless the defendant was warned away from that interpretation by specific binding guidance from the relevant government agency or a court of appeals. The Seventh Circuit imported that rule from *Safeco Ins. Co of America v. Burr*, 551 U.S. 47 (2007), where this Court interpreted a different word in a different statute in an entirely different context.

As Petitioners argue, this rote application of *Safeco* ignores the FCA's text and purpose. The FCA is the government's primary civil anti-fraud tool, and it has been wildly successful, with more than $72 billion recovered on behalf of taxpayers since the statute was revamped in 1986.[2] The Seventh Circuit's rule threatens this success by giving defendants with subjective knowledge of their own wrongdoing a get-out-of-liability-free card, which they or their lawyers can play at any time. If adopted by this Court, the rule would not only rewrite the FCA's knowledge standard, but would also severely hamstring the United States' ability to protect taxpayer dollars from fraud. The Court should reverse and reaffirm the FCA's text, which acknowledges that a defendant's contemporaneous subjective

[2] *See* False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022, *available at* https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022.

knowledge matters. In addition, the Court should reject the Seventh Circuit's narrow view of interpretative guidance and hold that relevant guidance in FCA cases is a context-specific factual question.

TAFEF will not repeat Petitioners' well-reasoned arguments. Instead, this brief will show how the Seventh Circuit's rule ignores the text and context of the FCA. It will also illustrate the practical negative implications of the rule by showing how it would have undermined significant rulings that faithfully applied the FCA's text and purpose. These illustrations show the absurdity of the court's rule and why it cannot be allowed to stand.

Section I explains that, contrary to the Seventh Circuit's holding, the FCA's plain language provides for consideration of a defendant's subjective knowledge.

Section II then shows that the Seventh Circuit was wrong to have limited so-called "authoritative" guidance to binding agency rules or court of appeals opinions. Instead, the scope of relevant guidance in FCA cases should be a context-specific question that considers how the United States and its contractors iron out potential legal uncertainties. Simply put, when the United States pays for lifesaving services or enters the market to purchase commercial goods, it interacts with companies in ways that any normal market participant does—beyond notice-and-comment rulemaking or agency adjudications—and that provide defendants adequate notice that they may be (or are) committing fraud. The Seventh Circuit's rule would ignore the reality of government-as-market-participant and impose limitations that would cripple the United

States' ability to flexibly tackle the nation's complex challenges while also protecting taxpayers from fraud.

Section III then demonstrates, through cases that were decided using the FCA's textual knowledge standard and with reference to appropriate guidance, why the Seventh Circuit's rule is incorrect. The examples all concerned laws, regulations, and contracts with multiple possible interpretations, but also included evidence that suggested that defendants subjectively knew at the time they submitted claims that they were not complying with their legal requirements or were otherwise committing fraud. The cases held defendants accountable for their knowing misconduct, while also addressing any potential "concerns about fair notice and open-ended liability … through strict enforcement" of the FCA's "rigorous" scienter requirements. *See Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016).

This court has recognized that companies must "turn square corners when they deal with the government," *Rock Island, AR & LA R.R. v. United States*, 254 U.S. 141, 143 (1920). The Seventh Circuit rule turns that on its head in a way that will result in harm to the federal Treasury and undermine federal programs. It would allow government contractors to avoid liability for knowing fraud through manufactured ambiguity, free from any duty to clarify that ambiguity and confident that they can later hire attorneys to shield themselves. This Court should reverse.

ARGUMENT

I. Under the FCA's plain language, evidence of subjective knowledge is always relevant to scienter.

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A defendant acts knowingly if it "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A).

The FCA's definition of knowingly, which includes "actual knowledge," allows courts to consider a defendant's subjective intent at the time it submits false claims for payment. As Petitioners' brief articulates, the common law of fraud has long considered a defendants' subjective intent at the time of its false statement. Pet. Br. 23-31. Thus, a defendant that subjectively believes that a claim for payment is false but submits that claim anyway commits fraud under the FCA's "actual knowledge" standard.

The other two prongs of the FCA's knowledge standard also incorporate subjective intent and make it clear that belief in falsity is not necessary if there is a sufficiently high risk of falsity. Thus, when a defendant submits a false claim, it knowingly violates the FCA if it fails to make further inquiry into the truth of its claims when either (1) it subjectively knows that its claims are probably false or (2) a reasonable person in defendant's position would recognize that a claim is likely false. Pet. Br. at 33-38.

This Court has long understood the FCA "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States* v. *Neifert-White Co.,* 390 U.S. 228, 232 (1968)). While the concept of fraud implies a subjective intent, Congress added a definition of knowingly in 1986 to make clear that the FCA is broader than common law fraud and that no specific intent to defraud was required, and that other forms of subjective intent were relevant. S.Rep. No. 99-345 at 9 (1986); *see also* Pet Br. at 23 n.6. The Seventh Circuit's rule runs counter not only to the plain text adopted in 1986, but to the very purpose of the statute.

II. The Seventh Circuit's evidentiary limitations on what authoritative guidance is relevant to determining whether a company was "warned away" from an erroneous interpretation of a statute or regulation does not reflect how the United States expects contractors to handle uncertainty when seeking and receiving taxpayer funds.

This Court made clear that application of the *Safeco* scienter rule interpreting "willfully" depends on context. *See Safeco*, 551 U.S. at 57 ("willfully is a word of many meanings whose construction is often dependent on the context in which it appears.") (cleaned up); *see also Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 n.* (2016) (rejecting application of *Safeco* rule because subjective bad faith is relevant in the context of patent infringement damages). Referring to *Safeco*, the Seventh Circuit held that the only evidence relevant to whether a defendant was "warned away" from

an erroneous interpretation of a legal requirement is "authoritative" government guidance or decisions from courts of appeals. *United States ex rel. Schutte v. Supervalu*, 9 F.4th 455, 470-71 (7th Cir. 2021); *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 661-62 (7th Cir. 2022). [3] The Seventh Circuit also strongly suggested that only "binding" guidance is relevant, and further hinted that only "notice-and-comment rulemaking or binding agency adjudications" constitutes sufficiently authoritative guidance under *Safeco*. *Proctor*, 30 F.4th at 662.

But *Safeco* interpreted "willfully" in the context of the Fair Credit Reporting Act ("FCRA"). The difference between the FCA and the FCRA reveals why the Seventh Circuit's was incorrect to categorically exclude from the knowledge analysis broad swaths of evidence relevant to whether a defendant was warned away from an incorrect interpretation of its legal requirements. The FCRA is a consumer protection statute that regulates the conduct of third parties—that is, companies and consumers. The FCA, by contrast, is only implicated when the United States spends taxpayer dollars, either to fund critical programs or to procure necessary goods and services—situations that involve direct give-and-take between the United States (or its

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[3] The Seventh Circuit made clear in both *Schutte* and *Proctor* that it was only analyzing the federal Medicaid regulations; thus, the relevant guidance it considered was only federal guidance. *See Schutte*, 9 F.4th at 469 n.9 (assuming without deciding that relevant state regulations were consistent with analogous federal regulations); *Proctor*, 30 F.4th at 660 n.12 (rejecting relevance of state Medicaid regulations from states that were not named plaintiffs). The Proctor majority erroneously failed to consider the relevance of the state Medicaid regulations, as there were numerous state Medicaid plaintiffs at involved.

designated intermediaries) and its service providers and suppliers. In the FCA context, then, whether a defendant was "warned away" should be determined with reference to that dialogue and the context surrounding it.

Indeed, the Seventh Circuit's rule kneecaps the United States' ability to clarify its expectations for how taxpayer money is spent, potentially limiting it to the years-long process of notice-and-comment rulemaking, agency adjudication, or appellate court decision making. At the same time, the rule ignores the many avenues that Congress and administrative agencies have opened to private parties participating in government programs or interacting with the United States in the marketplace to work to ensure mutual understanding of legal requirements for the expenditure of taxpayer money. In fact, the Seventh Circuit's rule creates real disincentives for companies to engage with the United States in good faith to iron out ambiguities in those obligations. And finally, it ignores the reality that fraud is often innovative, and flexible solutions are needed to keep it in check.

In short, the Seventh Circuit rule disregards context and converts a rule meant to ensure fair and adequate notice to third-party market participants into one that severely diminishes the United States' ability to participate in the marketplace itself, obviates established mechanisms for ensuring responsible stewardship of taxpayer money, and creates an open season for fraud.

A. Congress and federal agencies have provided many ways for service providers and contractors to clarify any uncertainty in laws, regulations, or contractual requirements, and the Seventh Circuit's narrow rule could potentially undermine many of them.

The Seventh Circuit's narrow rule would severely undermine the procedures that Congress and administrative agencies have put in place to clarify any uncertainty in the meaning of rules, regulations, and contractual terms.

For example, Congress authorized the Department of Health and Human Services ("HHS") to issue advisory opinions on certain matters relating to the Anti-Kickback Statute ("AKS"). *See* 42 U.S.C. § 1320a-7d(b). The AKS prohibits offering, providing, or receiving remuneration in exchange for referrals of business reimbursable by federal healthcare programs, unless an express safe harbor applies. Under the HHS advisory opinion program, companies can ask HHS whether an innovative healthcare payment system might constitute illegal remuneration under the AKS, or whether it falls within one of the AKS's safe harbors. *See id.* These opinions are binding on HHS and the requesting party, and are available to the public through HHS's website. *See id.*; *see also* Advisory Opinions, *available at https://oig.hhs.gov/compliance/advisory-opinions/*.

The Seventh Circuit's rule would undermine this procedure in two ways. First, if a provider thinks that the AKS's application to a particular business idea is unclear, the Seventh Circuit's rule could discourage

that provider from seeking a binding legal determination, instead incentivizing an unscrupulous provider to take a "heads-I-win" (if the agreement is legally permissible) / "tails-you-lose" (if the agreement is impermissible but the application of the AKS is ambiguous) approach to AKS compliance. Second, it would render the publication of these opinions irrelevant. Although HHS's published advisory opinions would normally be "entitled to respect" based on their "power to persuade," *see Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000), under the Seventh Circuit's rule, these explicitly non-binding opinions would be entirely irrelevant to determining whether a non-requesting defendant had been warned away from a questionable interpretation of the AKS, rather than being considered as one piece in a holistic factual inquiry. The Seventh Circuit's rule would thus undermine an important Congressionally designed mechanism for clarifying how the United States interprets a law meant to shield medical decision making from corrupt influences.

As another example, Federal Acquisition Regulations ("FAR") encourage "[e]xchanges of information among all interested parties, from the earliest identification of a requirement through receipt of proposals" in order "to improve the understanding of Government requirements and industry capabilities, thereby allowing potential offerors to judge whether or how they can satisfy the Government's requirements…" Federal Acquisition Regulation § 15.201(a)-(b). But under the Seventh Circuit's rule, these exchanges of information—which the FAR expressly anticipates would influence both the United States and potential offerors' understandings of government contractual requirements—would be entirely irrelevant to whether a de-

fendant knowingly committed fraud, even if the exchanges shed clear light on the parties' understandings of the relevant contract terms.

These rules are just two among many that reflect Congressional and agency appreciation for the fact that not every rule or contract is crystal clear, and the presumption that private companies and the United States will work together to clarify uncertainty.[4] The Seventh Circuit's rule would severely undermine these procedures and others like them.

B. The Seventh Circuit's evidentiary limitations would turn fraud enforcement into a multi-billion-dollar game of Whack-A-Mole.

Furthermore, the Seventh Circuit's rule, which also requires that guidance be sufficiently "specific," ignores the unfortunate reality that persons contracting with the government can iterate on fraud much faster than formal agency or judicial decision making can address it. The rule would make it impossible for the government to keep ahead of the innovative ways that people cheat the taxpayers by requiring it to anticipate

[4] Congress also regularly grants agencies the ability to provide guidance when government programs require evolving standards to protect taxpayer dollars. *See, e.g.*, 12 U.S.C. § 1708(d)(3) (granting the Secretary of the United States Department of Housing and Urban Development the authority to implement the Federal Housing Administration home loan program through rulemaking as well as mortgagee letters and interim final regulations). FHA rules that govern the origination, underwriting, and servicing of FHA loans are put out through HUD handbooks and mortgagee letters. *See* Housing Handbooks, *available at* https://www.hud.gov/program_offices/administration/hudclips/handbooks/hsgh.

every loophole and address each one with "sufficiently specific" guidance.

As just one example, the nearly $1 trillion Paycheck Protection Program spent hundreds of billions of dollars in 2020 and may have been subject to fraud rates as high as 15% (i.e., tens of billions of dollars).[5] Yet even the relatively fast-moving Department of Justice did not settle its first FCA Paycheck Protection Program case until January 12, 2021,[6] and by March 26, 2021, had filed charges accounting for only about half a billion dollars.[7] Hundreds of millions of dollars is better than nothing, but it is a drop in the bucket in the context of this fast-moving and potentially fraud-riddled program. The Seventh Circuit's rule would invite defendants to argue the PPP program and other programs quickly put together to address the economic fallout from the COVID-19 pandemic are vague, and that any interpretive guidance is irrelevant to their liability under the FCA. It would further encourage defendants to argue that any such guidance is insufficiently specific because the United States did not anticipate every manner of fraud that could apply to these programs to mitigate the impact of the pandemic. This would in turn require the United States,

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[5] 15% of Paycheck Protection Program Loans Could be Fraudulent, Study Shows, *available at* https://www.nytimes.com/2021/08/17/business/ppp-fraud-covid.html.

[6] Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program, *available at* https://www.justice.gov/usao-edca/pr/eastern-district-california-obtains-nation-s-first-civil-settlement-fraud-cares-act.

[7] Justice Department Takes Action Against COVID-19 Fraud, https://www.justice.gov/opa/pr/justice-department-takes-action-against-covid-19-fraud

when faced with similar crises in the future, to either not respond in a timely fashion so as to have enough time to engage in laborious notice-and-comment rule-making and to anticipate any and all permutations of fraud, or subject itself to unscrupulous actors who use "reasonable interpretations" as a sword and shield to swindle the government.

As another example, consider how alleged violations of the Higher Education Act ("HEA") evolved in response to government enforcement efforts. The HEA prohibits schools from paying recruiters and admissions personnel based on the number of students enrolled or the amount of student financial assistance obtained. Two successive FCA cases against ITT Education Services ("ITT"), first *United States ex rel. Graves v. ITT Educ. Servs.*, 284 F. Supp. 2d 487 (S.D. Tex. 2003) and later *Leveski v. ITT Educ. Servs.*, 719 F.3d 818 (7th Cir. 2013), show how the United States may be one step behind, and how the Seventh Circuit's rule would limit access to valuable scienter evidence. In the earlier case, the *Graves* relator alleged that ITT paid bonuses of 5-10% of "earned revenue," which allegedly took into account factors prohibited by the HEA. *Graves*, 284 F. Supp. 2d at 490. The district court dismissed the case against ITT because it determined that compliance with the HEA's incentive compensation ban was not a "condition of payment" for government funds. *Id.* at 502.[8] Nevertheless, several years later, the relator in *Leveski* alleged a "much more sophisticated—and harder to detect—violation" of HEA rules in which ITT allegedly compensated her through employee job evaluations that the relator alleged were a

[8] This narrow focus on conditions of payment was rejected thirteen years later in *Escobar*, 579 U.S. at 181

"sham" meant to hide the only true metric: "the number of applications, enrollments, and starts." *Leveski*, 719 F.3d at 830, 821. Although the United States did not intervene in the *Leveski* matter, the Department of Education later barred ITT from enrolling new students receiving federal aid, and ITT declared bankruptcy shortly thereafter.[9] The United States ultimately discharged over $3.9 billion in federal loans for students who had attended ITT.[10]

The Seventh Circuit's rule would leave the government ill-equipped to deal with this kind of innovation in at least two ways. First, the proposed rule would make irrelevant the evidence that a defendant specifically responded to government investigations not by correcting its prior misconduct, but by trying to hide that misconduct in layers of sham paperwork. Second, any rule that the United States passed to address the first fraud might not be sufficiently "specific," in the Seventh Circuit's formulation, to cover the follow-on fraud. *See Proctor*, 30 F.4th at 660 (finding that a CMS example in the Medicare manual was sufficiently specific to warn Safeway away from its interpretation of one type of price match program, but not the other, even though both were designed for the same essential purpose). The Seventh Circuit's rule would allow unscrupulous actors to constantly change their fraud to

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[9] ITT Education Services Files for Bankruptcy After Aid Crackdown, *available at* https://www.nytimes.com/2016/09/18/business/itt-educational-services-files-for-bankruptcy-after-aid-crackdown.html.

[10] Education Department approves $3.9 billion group discharge for 208,000 borrowers who attended ITT Technical Institute, *available at* https://www.ed.gov/news/press-releases/education-department-approves-39-billion-group-discharge-208000-borrowers-who-attended-itt-technical-institute.

fall outside of any "specific" guidance and take taxpayer money they are not entitled to so long as their attorneys can find some daylight between the guidance and the wrongdoing.

III. Adopting the Seventh Circuit's rule, which requires courts to ignore a defendant's subjective knowledge of falsity, would expose the United States to extensive fraud, while faithfully applying the FCA's text allows for "rigorous" application of the False Claims Act's scienter standard.

To illustrate how the Seventh Circuit's rule runs counter to the text and purpose of the FCA, we have included five examples of the many cases in which enforcement would have been hampered had the rule been in place. In each of these cases, defendants argued that a legal requirement was ambiguous, but courts properly considered the defendants' contemporaneous subjective knowledge of falsity.

The first three cases illustrate how a decision adopting the Seventh Circuit's rule could dramatically undermine programs that provide healthcare to the elderly and disabled by allowing defendants to pilfer tens of millions of taxpayer dollars. The fourth case illustrates the same concern in non-healthcare government procurement. The last case, by contrast, demonstrates how the correct application of the FCA definition of knowingly adequately protects defendants that lack actionable knowledge from FCA liability.

Two important threads run through each of these cases. First, in each case there was evidence that defendants knew that they were, at best, wading into

uncertain waters and adopting tenuous interpretations of their legal requirements. Second, each matter involves critical government programs with substantial amounts of taxpayer money at stake. The integrity of these programs is essential to carrying out these important and often lifesaving governmental functions—whether providing healthcare to government-insured patients, procuring critical IT software, or feeding soldiers deployed overseas. Affirming the Seventh Circuit's scienter rule would severely limit the United States' ability to protect federal programs from fraud that undermines them.

A. *United States ex rel. Walker v. R & F Props. of Lake County, Inc.*, 04-15283 (11th Cir.)

Given the broad mandate of the Medicare program—to provide beneficiaries with reasonable and necessary health care services—Medicare statutes and regulations allow for flexibility as the practice of medicine and delivery of care changes over time. This flexibility occasionally results in rules that do not specifically address every nuance of the practice of medicine. But facial ambiguities in Medicare statutes or regulations can often be resolved by reference to government and industry guidance, which is widely available to care providers. In *United States ex rel. Walker v. R & F Props. of Lake County, Inc.* the Eleventh Circuit recognized that such guidance is relevant to the FCA scienter inquiry.

The dispute in *Walker* turned on whether defendant had fraudulently billed the United States for nurse and physician assistant services as "incident to the service of a physician" under Medicare rules. Medicare pays 15% more when a nurse or physician assis-

tant's services are "incident to the service of a physician." *United States ex rel. Walker v. R & F Props. of Lake County, Inc.*, 433 F.3d 1349, 1352-54 (11th Cir. 2005). The relator contended that a physician had to be present in the clinic where the nurses and physician assistants were providing services in order to bill Medicare in this way. *Id.* The relator alleged that the defendant filed false claims by billing Medicare for services provided by nurse practitioners and physician assistants as "incident to the service of a physician" even when there was no physician present in the clinic. *Id.* at 1353-54. Relator thus argued that the defendant's misconduct overcharged the United States by 15%. *See id.* at 1352-53.

The defendant argued that the "incident to" standard was unclear, and the district court agreed that "the Medicare statutes and regulations in effect [at the time] did not adequately define the phrase," and therefore it was ambiguous. *Id.* at 1354. Following a rule very similar to the one adopted by the Seventh Circuit nearly two decades later, the district court held that the phrase's ambiguity meant the defendant could not knowingly have violated the rule, and therefore granted defendant summary judgment. *Id.*

While the Eleventh Circuit agreed that the phrase was ambiguous (at least for the period in question), it disagreed that that was the end of the analysis. *Id.* at 1356. Instead, the Court of Appeals noted that the relator had introduced substantial extra-regulatory evidence that showed that the defendant knew that the proper interpretation of the "incident to" phrase required a physician to be present in the office suite for nurse and physician assistant services to be

billed at the higher "incident to" rates. *Id*. The Eleventh Circuit favorably cited to forms of Medicare guidance later rejected by the Seventh Circuit, such as the Medicare Carrier's Manual and Medicare bulletins. *Id*. The Court of Appeals also implicitly held that common industry practice was also relevant guidance, referring to information that originated outside the government, including the relator's evidence of "seminar programs, expert testimony … [and] two notes written by [defendant's] employee that paraphrase a billing consultant's advice." *Id*. The Court therefore reversed and remanded, and the case later resolved for $287,500. *See Walker, et al. v. R & F Properties*, 5:02-cv-131(M.D. Fla), ECF No. 314, Ex. A.

Under the Seventh Circuit's rule, most or all of this highly probative evidence would have been discarded. The defendant, who had later cherry-picked an interpretation of the "incident to" rule that served to increase its profits at the expense of taxpayers, would have unjustly pocketed over a quarter of a million taxpayer dollars.

This pre-*Safeco* opinion recognizes the importance of context in evaluating what guidance is relevant. Medicare conditions of payment are set forth in statute, implemented by regulations, and clarified through handbooks and bulletins. Private Medicare Administrative Contractors process claims, develop rules, and issue local coverage determinations of what constitutes reasonable and necessary care. Private physicians, nurses, and other medical professionals provide medical care based on medical best practice. Billers and coders submit claims to CMS using internationally developed standards for reporting diagnoses and procedures. Medicare statutes and regulations

concern the enormous and ever-changing healthcare industry, and therefore do not always have the Seventh Circuit's narrowly defined "authoritative guidance," but that uncertainty can be clarified by reference to the vast sea of official and unofficial guidance. Jettisoning everything but notice-and-comment rulemaking, agency adjudications, and court of appeals decisions would ignore the realities of this and other complex programs where taxpayer dollars are given to private entities to support a public purpose.

B. *United States ex rel. Bahnsen et al. v. Boston Scientific*, 11-cv-1210 (D.N.J.)

Congress has recognized that there must be a balance between the certainty of notice-and-comment regulations and the flexibility to clarify uncertainties in those regulations. To that end, Medicare statutes expressly contemplate that CMS will issue guidelines and clarifications through manuals and require CMS to "publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretive rules, statements of policy, and guidelines of general applicability" not published as regulations. 42 U.S.C. § 1395hh. In *United States ex rel. Bahnsen et al. v. Boston Scientific*, 11-cv-1210 (D.N.J.), a district court properly looked to the Medicare Provider Integrity Manual ("PIM") and the defendant's subjective understanding of that manual to determine the defendant's liability under the FCA.

In *Bahnsen*, the relators alleged that defendant Boston Scientific Neuromodulation Corporation ("BSNC") knowingly submitted false claims for supplies for an implantable medical device characterized

as "DMEPOS."[11] The relators alleged, among other things, that in order to bill Medicare for the supplies, BSNC needed a detailed physician order for those supplies on file. The rule requiring a detailed written order comes from statute (42 U.S.C. § 1395m(a)(11)(b)(i)) and the PIM. Relator alleged that defendants submitted claims without such an order, and that BSNC concealed defects in the devices, resulting in the use of defective medical devices in patients, the continued concealment of those defects, and marketing of defective devices to doctors and patients.

BSNC argued in its motion for summary judgment that it could not have knowingly submitted false claims because the relevant portions of the PIM that applied to DMEPOS supplies were ambiguous, and that the PIM could be read to support defendant's position regarding written orders. *United States ex rel. Bahnsen et al. v. Boston Scientific*, 11-cv-1210 (D.N.J.), ECF No. 299-29 at 35-58. BSNC conceded that some of its internal documents showed that "the company's understanding [of the relevant rules] evolved over time," *id.* at 56, but nevertheless urged the district court to adopt a rule like the Seventh Circuit's rule precluding consideration of that "evolving" understanding. In opposition to summary judgment, the relators pointed to evidence showing that at the time it submitted claims to the United States BSNC did not subjectively hold the view argued by its attorneys in its summary judgment motion. That evidence included deposition testimony from BSNC's corporate representative, internal

[11] DMEPOS standards for "Durable Medical Equipment, Prosthetics, Orthotics and Supplies," which are covered under Medicare Part B. *See generally* 42 C.F.R. § 414.200 *et seq.*

company documents, and descriptions of its own internal audits all suggesting the company knew it was submitting false claims. *Bahnsen* Docket, ECF No. 313 at 37-43. Pointing to this evidence, the relators contended that BSNC knew at the time that the PIM required detailed physician orders for DMEPOS supplies, but that BSNC did an about-face "as soon as it faced a lawsuit for its rampant fraudulent billing practices." *Id.* at 43.

The district court conducted a careful review of the relevant requirements, and ultimately agreed with BSNC that the rules regarding DMEPOS supplies were subject to multiple interpretations. *United States ex rel. Bahnsen et al. v. Boston Scientific*, 2017 U.S. Dist. LEXIS 206512, at *26-33 (D.N.J. Dec. 15, 2017). But the district court denied BSNC summary judgment, finding that the company provided "no evidence that it sought outside guidance or legal advice as to the reasonableness of its interpretation during the time that it was actually submitting the claims," while citing favorably to the relators' evidence showing that BSNC subjectively knew that it had submitted false claims. *Id.* at 33-34.

If the Seventh Circuit's rule had been in place when *Bahnsen* was decided, a defendant who believed it was submitting false claims and was correct in that belief would have escaped liability based on the creativity of its lawyers—and not even when it was submitting claims, but at summary judgment.

Bahnsen also demonstrates why the Seventh Circuit's rule fails from a practical perspective, as it ignores the context of modern government programs. Congress expressly authorized CMS to issue guidance and policy clarifications in manuals; both parties in *Bahnsen* agreed that the PIM provided the relevant

rules for the supplies at issue; and the district court fairly considered its impact on the defendant's knowledge. Imposing artificial limits on what types of guidance are relevant ignores how government-funded programs function and what guidance is available to government contractors.

C. *United States ex rel. Ross v. Independent Health Corp. et al.*, 12-cv-00299 (W.D.N.Y.)

Traditional Medicare is a fee-for-service program in which providers submit claims to private Medicare Administrative Contractors, who process those claims on behalf of the government. Beginning in the 1980s and continuing to today, Congress has experimented with alternative Medicare delivery models, including the use of private insurers to provide coverage under Medicare Part C. Under Part C, the United States pays private Medicare Advantage Plans a fixed monthly amount to insure Medicare beneficiaries, with the amount adjusted by a risk score for each patient determined through demographic factors and health status. *United States ex rel. Ross v. Independent Health Corp.*, 12-cv-00299, 2023 U.S. Dist. LEXIS 390, at *6 (W.D.N.Y. Jan 3, 2023). Health status is determined using diagnostic codes from the ICD system, which is an international standard for medical coding published by the World Health Organization. *See id.* Thus, under Part C, Medicare rules and regulations govern the provision of services by private insurers using an international NGO's standards. The district court in *United States ex rel. Ross v. Independent Health Corp.* properly looked to defendants' subjective knowledge by referencing a broad array of government and non-governmental guidance.

In *Ross*, the government intervened in a case against a Medicare Advantage plan, Independent Health ("IH"), its subsidiary, DxID, and DxID's founder and CEO, Betsy Gaffney. The United States alleged that the defendants fraudulently obtained higher monthly Part C payments by making its beneficiaries look less healthy than they actually were by, among other things, submitting historical diagnoses that were not confirmed to still exist and by submitting pre-filled addenda to doctors that encouraged those doctors to indicate that their patients had certain high-value diagnosis codes, even when the codes were not supported by the patients' medical records. *See United States ex rel. Ross v. Independent Health Corp. et al.*, 12-cv-00299 (W.D.N.Y.), ECF No. 142.

Defendants made a host of arguments in their motion to dismiss, including that the Medicare Advantage program's diagnostic coding guidance was ambiguous and that the United States was forcing providers to rely only on high-level guidance from ICD coding criteria that did not provide Medicare Advantage plans with sufficient notice about proper diagnosis coding. *See Ross* Docket, ECF 154-1 at 9. Defendants argued that submitting historical diagnosis codes and using addenda to capture codes was one reasonable interpretation of the allegedly ambiguous rules and open-ended guidance. *Id.* at 25-47.

The district court rejected this argument, noting that the reasonableness of the defendants' interpretations of the coding guidance required further factual development, and that the United States had alleged that defendants were warned away from their erroneous interpretations "by administrative guidance, third-party audits, internal complaints, and the practices of

other health-care organizations." *Ross*, 2023 U.S. Dist. LEXIS 390, at *31. Indeed, the United States' complaint in intervention was full of evidence of the defendants' subjective knowledge on the coding issue and other allegations in the complaint, including:

- IH ignored warnings about DxID's and its CEO's practices, including concerns from employees and another insurance company about DxID's and its CEO's coding practices. *Ross* Docket, ECF 142 ¶ 111, 124, 263-264.

- IH hired a third party to audit DxID's predecessor (Cognisight), which was formerly run by DxID's CEO, finding that 9 of 14 HCCs were erroneous (a 68% error rate), with particularly high error rates for chronic kidney disease ("CKD"), a particularly lucrative diagnosis code. IH hired Gaffney to form DxID despite knowing about these high error rates in her coding practices. *Id.* ¶¶ 115-118, 121.

- After IH had worked with DxID for more than two years, Cognisight notified IH that, while Gaffney was CEO of Cognisight, it improperly coded CKD from lab reports only. Although IH deleted CKD codes for service year 2010 and repaid CMS accordingly, it continued to implement the same coding practices for CKD and did not inquire into whether erroneous codes were submitted in other service years or for other conditions. *Id.* ¶¶ 313-326.
- IH knew that Gaffney and DxID implemented policies that added incorrect conditions on addenda—for example, Gaffney stated that "when a married couple has any disease, both were assigned to that disease" and that DxID "load[ed]

in renal failure" on to addenda because "it is worth a ton of money." IH also knew that providers often relied upon the addenda prompts instead of conducting their own review of the records. *Id.* ¶¶ 362, 371-377.

- Although IH had concerns about the addenda process and temporarily stopped using DxID for a few months in 2015, it resumed DxID's services in 2016. *Id.* ¶ 378.

This case illustrates the serious practical concerns that the Seventh Circuit's rule ignores. That rule would exclude all evidence of what sophisticated private parties actually believed at the time they were submitting claims, and preclude reliance on relevant and well-accepted international standards. More fundamentally, the Part C program relies on private health insurers to administer the program, and the United States must be able to rely on their honest reporting. The Seventh Circuit's rule would make it harder for the United States to prove a defendant was acting dishonestly (and committing fraud) by excluding highly probative evidence of that dishonesty.

D. *United States ex rel. Kamal Mustafa Al-Sultan v. Agility Public Warehousing Co., K.S.C. et al.*, No. 1:05-cv-2968-GET (N.D. Ga.)

The government spends hundreds of billions of dollars a year on goods and services other than healthcare[12] and its contracting decisions are subject

[12] *See* A Snapshot of Government-wide Contracting for FY 2021, *available at* https://www.gao.gov/blog/snapshot-government-wide-contracting-fy-2021-interactive-dashboard (August 25, 2022) ("In fiscal year 2021, the federal government spent about $637 billion on contracts").

to a substantial body of statutory, regulatory, and other governmental rules. It has also spawned an expansive roster of non-governmental experts who advise entities doing business with the United States on how to comply with the law. Against this backdrop, courts interpreting contracts that later may be subject to claims of ambiguity must look at the same evidence that courts look to for all contracts with imprecise provisions: the intent of the parties. The district court in *U.S. ex rel. Kamal Mustafa Al-Sultan v. Agility Public Warehousing Co., K.S.C. et al.* did just that, and concluded that subjective intent must matter in interpreting government contracts.

The *Agility* case started in 2005 when a whistleblower filed a *qui tam* action alleging that the defendants overcharged the United States military on ongoing supply contracts for troops overseas. One of those contracts was for "Local Market Ready Items," or LMRI, including perishable goods. Under the contract, the military ordered perishable goods from the defendants, who were required to obtain the goods locally and allowed to bill the government for the invoice price from the goods' "manufacturer/supplier," with an additional charge for distribution costs and profit. *See United States ex rel. Kamal Mustafa Al-Sultan v. Agility Public Warehousing Co., K.S.C. et al.*, No. 1:05-cv-2968-GET (N.D. Ga.), ECF 78.

The United States intervened and alleged that, instead of charging the invoice price from the goods' manufacturer/supplier, defendant Agility Public Warehousing Co. ("PWC") used a middleman, referred to as TSC, to purchase the goods, grossly inflate the prices, and issue inflated invoices to PWC. *Id.* PWC then charged the United States based on the inflated TSC

invoices, hiding the price TSC paid. *Id.* The United States alleged that PWC knew that the prices it was charging the military were not the prices that its intermediary had paid to the manufacturer/suppliers of the LMRI, and that its middleman was not a manufacturer/supplier. Among other evidence referenced by the United States in its Amended Complaint in Intervention, it alleged that PWC itself described TSC as a "consolidator or distributor," not a manufacturer or supplier. *Id.* ¶ 54. The United States also referenced an internal PWC communication in which one of the company's assistant general managers suggested that PWC should just "submit TSC invoices"—invoices it knew did not reflect the manufacturer/supplier price—and "then wait for a request for further documentation." *Id.* In other words, the evidence suggested that PWC knew the rules but chose to gamble that it would not get caught.

PWC moved to dismiss, arguing that its contract with the government was ambiguous because it did not define either "manufacturer" or "supplier," and that it reasonably interpreted the terms to allow for the markup it charged. *Agility* Docket, ECF No. 163-1 at 46-48. The district court agreed that the evidence in the complaint could be read to support the defendants' interpretation of those terms. *United States ex rel. Kamal Mustafa Al-Sultan v. Agility Public Warehousing Co., K.S.C. et al.*, 2017 U.S. Dist. LEXIS 37643, at *25-26 (N.D. Ga. Mar. 16, 2017). Rather than stop its analysis at the first sight of ambiguity, however, the district court acknowledged that it needed more evidence to determine the meaning of the contract. *Id.* at *26. Shortly thereafter, defendant PWC settled the

matter for $95 million, and further agreed to forego administrative claims against the government worth $249 million.[13]

The *Agility* case illustrates why the Seventh Circuit's scienter rule is especially unworkable in the context of government contracting. *Agility* involved contracts worth nearly $10 billion. *Agility* Docket, ECF No. 78 ¶ 10(a). To interpret the agreements and determine their meaning, the court needed to consider evidence other than binding court of appeals precedent or narrowly defined agency guidance; it needed to look to communications between the United States and its suppliers, internal party discussions regarding the meaning of the relevant terms, industry practices, and potentially a host of other evidence, much of it originating outside the government. Under the Seventh Circuit's rule, that same supposedly "non-authoritative" evidence would be irrelevant and instead, because the defendant's attorneys put forward a reasonable alternative interpretation, the defendant would have kept almost $100 million in taxpayer money that it knew it was not entitled to receive.

E. *United States ex rel. Morsell v. Symantec Corp.*, 12-cv-800 (D.D.C.)

Under the Seventh Circuit's rule, the cases above would have resulted in defendants that subjectively knew that they were violating the relevant laws, regulations, and rules keeping taxpayer money despite their knowing fraud. By contrast, applying the FCA's

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[13] *See* Defense Contractor Resolves Criminal, Civil and Administrative Liability Related to Food Contracts, https://www.justice.gov/opa/pr/defense-contractor-resolves-criminal-civil-and-administrative-liability-related-food (May 26, 2017).

text, which contemplates consideration of subjective knowledge, excuses a defendant who did not have a subjective belief that their representation was false, as exemplified in *United States ex rel. Morsell v. Symantec Corp.*

In *Morsell*, the federal government alleged, among other things, that Symantec knowingly submitted false statements to the General Services Administration ("GSA") by failing to accurately and completely disclose its commercial sales practices and the prices that it charged to commercial customers, in violation of government contracting rules. All GSA contracts must include a Price Reduction Clause ("PRC") that accounts for changes in a company's pricing over time. *See* 48 C.F.R. § 552.238-75. The GSA PRC ensures that the government is kept apprised of a company's discounting practices and gives the United States the opportunity to take advantage of those discounts. The United States alleged that Symantec not only failed to provide the discounts offered to commercial customers, but also that "Symantec, the fourth largest software developer in the world in 2013 based on revenues, neither developed nor implemented any software in its purchasing system to automatically ensure its pricing to GSA and commercial customers complied with the requirements of its Contract" with the United States. *United States ex rel. Morsell v. Symantec Corp.*, 12-cv-800 (D.D.C), ECF No. 70 ¶ 9.

Symantec argued in a motion for summary judgment that the PRC in its contract was ambiguous, and that Symantec reasonably interpreted the PRC not to include certain types of discounts the company offered to its commercial customers. *Morsell* Docket, ECF No. 156-1 at 62-71. The district court agreed that the PRC

was ambiguous as applied in the Symantec contract with the United States, and also agreed that Symantec's reading of the contract was reasonable. *United States ex rel. Morsell v. Symantec Corp.*, 471 F. Supp. 3d 257, 293-94, 304-05 (D.D.C. 2020). Nevertheless, the district court denied summary judgment because the United States established a dispute of material fact as to whether Symantec actually held that reasonable interpretation at the time the contract was formed. *Id.* at 305. The United States pointed to, among other things, Symantec's own internal audit, which stated that the company's policies "could create a situation whereby GSA discounts are no longer competitive or in compliance with contractual terms…" *Id.* Evidence therefore suggested that the defendant knew the risk that it was not in compliance with its contract.

With this material factual dispute as to Symantec's subjective knowledge, the parties headed to a bench trial. In exhaustive findings of fact and conclusions of law, the district court again emphasized that "the reasonableness of any given interpretation of [a contractual phrase] is more than a matter of purely legal statutory or textual interpretation—it involves disputed questions of fact regarding the contract negotiations." *United States ex rel. Morsell v. NortonLifelock, Inc.*, Civil Action No. 12-800 (RC), 2023 U.S. Dist. LEXIS 9526, at *153 (D.D.C. Jan. 19, 2023). In weighing those disputed facts, the court held that some of Symantec's interpretations of the contract were not reasonable, but ultimately concluded that the company subjectively believed that much of its conduct fell out-

side the reporting requirements of the PRC, and therefore lacked knowledge sufficient for liability (at least on that issue).[14] *Id.* at 159-167.

Morsell illustrates how application of the FCA's definition of "knowingly" allows for rigorous application of the scienter requirement by considering what a defendant actually believed at the time it submitted claims for payment. In short, the textual interpretation of the FCA ensures that persons who have a subjective belief that their representations are false are held accountable while adequately protecting defendants who do not and who reasonably believe their actions are consistent with their legal obligations, taking into account the context and available guidance.

CONCLUSION

The decisions below should be reversed, and the court should adopt a rule that acknowledges that subjective intent always matters for FCA knowledge. This would properly reaffirm this Court's long held position that companies must "turn square corners when they deal with the government," *Rock Island*, 254 U.S. at 143, and that the United States has a full toolbox to root out and prevent fraud on taxpayers.

Respectfully submitted,

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[14] The district court found in favor of the United States on some of its claims, and ultimately awarded roughly $1.2 million in damages. *Morsell* Docket, ECF No. 362. The United States has recently moved to amend or correct the court's findings pursuant to Rule 52, 59, or to appoint a special master under Rule 53. *Morsell* Docket, ECF No. 364.

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