PRATT'S GOVERNMENT CONTRACTING LAW REPORT

VOLUME 8 **NUMBER 7** **July 2022**

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Library of Congress Card Number:

ISBN: 978-1-6328-2705-0 (print)
ISSN: 2688-7290

Cite this publication as:

[author name], [article title], [vol. no.] PRATT'S GOVERNMENT CONTRACTING LAW REPORT [page number] (LexisNexis A.S. Pratt).
Michelle E. Litteken, GAO Holds NASA Exceeded Its Discretion in Protest of FSS Task Order, 1 PRATT'S GOVERNMENT CONTRACTING LAW REPORT 30 (LexisNexis A.S. Pratt)

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MATTHEW BENDER

(2022–Pub.4938)

Editor-in-Chief, Editor & Board of Editors

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POSTMASTER: Send address changes to *Pratt's Government Contracting Law Report*, LexisNexis Matthew Bender, 230 Park Ave. 7th Floor, New York NY 10169.

Multiple Appellate Courts Now Rule That Government and Relator Cannot Take Advantage of Ambiguous Law to File False Claims Act Lawsuit to Obtain Treble Damages and Civil Penalties

By Robert S. Salcido*

In recent developing case law, more than a half dozen appellate courts, based on U.S. Supreme Court precedent, have ruled that when a defendant has a reasonable interpretation of an ambiguous statute, regulation or contract and there is no official governmental guidance to warn defendant away from its reasonable interpretation, there can be no False Claims Act liability. In this article, the author explains that, in light of this trending case law, companies can reduce their exposure to liability by staying actively abreast of the government's rules and regulations regarding payment and, when those rules are ambiguous, adopting a reasonable interpretation of what those rules require and documenting their deliberative process.

The federal government spends more than $1.2 trillion each year financing health expenditures, such as payments made under the Medicare and Medicaid programs.

Multiple volumes in the U.S. Code and Code of Federal Regulations govern how payments shall be made under Medicare and Medicaid. Additionally, the Centers for Medicare & Medicaid Services ("CMS") issues dozens of manuals encompassing tens of thousands of pages of rules and instructions.[1]

Those operating in the health care industry must master this guidance because failure to heed the plethora of rules and regulations in requesting federal payment could result in a violation of the False Claims Act ("FCA").

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[1] *See, e.g., Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019) (noting that CMS's Provider Reimbursement Manual itself exceeds 6,000 pages, and the dissenting opinion, *id.* at 1823, noting that CMS "also publishes more than a dozen other manuals, with tens of thousands of additional pages of instructions governing 'the scope of benefits, the payment for services, [and] the eligibility' of benefits or services.") (citation omitted).

The FCA arms law enforcement officials with a penal remedy of treble damages and civil penalties against those who knowingly or fraudulently present false claims to the government.

It also empowers private citizens (known as relators) to sue on the behalf of the government (known as qui tam actions) and to obtain a substantial bounty if they prevail. In January 2022, DOJ reported that it recovered more than $5.6 billion in FCA recoveries in fiscal year ("FY") 2021, with over $5 billion relating to matters involving the health care industry.

But mastering the volumes of Medicare and Medicaid guidance and instructions is no easy chore. This is true not only because of the plethora of rules and regulations but also because, as more than 50 courts have observed, Medicare and Medicaid statutes and regulations "are among the most completely impenetrable texts within human experience."[2]

Given the "completely impenetrable texts" and the vast riches potentially available under the FCA, there is an almost overwhelming temptation for the government and relators to attempt to take advantage of ambiguities in the impenetrable texts by bringing FCA actions and seeking treble damages and massive civil penalties.

Fortunately, for those operating in the industry, recently a tsunami of more than a half dozen appellate courts have rejected FCA plaintiffs' attempts to enforce the FCA in this fashion. Instead, multiple appellate courts have ruled that a company that has a reasonable interpretation of ambiguous government rules—that is, of the impenetrable texts—has a dispositive defense under the FCA when there is no official governmental guidance to warn the company away from its interpretation.[3]

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[2] *See, e.g., Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). The more than 50 cases can be identified by searching "impenetrable texts" "human experience" and "Medicare or Medicaid" in a legal database.

[3] *See, e.g., U.S. ex rel. Olhausen v. Arriva Med., LLC,* No. 21-10366, 2022 U.S. App. LEXIS 10989, at *5–6 (11th Cir. Apr. 22, 2022) (because defendant had an "objectively reasonable interpretation" regarding whether a beneficiary signature was required for every assignment of benefit and regarding whether call-center locations "furnish" Medicare-covered Durable Medical Equipment, Prosthetics/Orthotics and Supplies and hence needed to be enrolled, plaintiff cannot show defendant had the requisite intent to violate the FCA); *U.S. ex rel. Proctor v. Safeway, Inc.*, No. 20-3425, 2022 U.S. App. LEXIS 9093 (7th Cir. Apr. 5, 2022); *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 343–44 (4th Cir. 2022) ("Because [Defendant's] reading of the Rebate Statute was at the very least objectively reasonable and because it was not warned away from that reading by authoritative guidance, it did not act 'knowingly' under the False Claims Act. As a result, we affirm the district court's dismissal of [Relator's] complaint"); *U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 472 (7th Cir. 2021) ("Because [defendant] had an

Set forth below is a description of the recent decision by the U.S. Court of Appeals for the Fourth Circuit in *U.S. ex rel. Sheldon v. Allergan Sales, LLC*,[4] which recently ruled that a reasonable interpretation of ambiguous law is a dispositive defense under the FCA.

Also set forth is an analysis, as illustrated by multiple other recent appellate courts, of how FCA plaintiffs have sought to take advantage of ambiguity in law to institute FCA actions and reasoning courts have applied to reject those lawsuits.

Finally, in light of the developing case law, concrete steps are provided that companies can take to substantially enhance their opportunity to invoke this defense to eliminate potential exposure to FCA liability.

FOURTH CIRCUIT'S RULING IN *SHELDON* FOLLOWS MULTIPLE OTHER APPELLATE COURTS IN ADOPTING U.S. SUPREME COURT'S REASONABLE INTERPRETATION STANDARD IN *SAFECO*

In *Sheldon*, relator alleged that defendant engaged in a fraudulent price reporting scheme under the Medicaid Drug Rebate Statute by failing to aggregate discounts given to separate customers for purposes of reporting "Best Price."[5] Best Price is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity," which

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objectively reasonable understanding of the regulatory definition . . . and no authoritative guidance placed it on notice of its error, the relators have not shown that [defendant] acted knowingly"); *United States v. Allergan, Inc.,* 746 F. App'x 101, 109–10 (3d Cir. 2018) (finding although the court was not prepared to find that the defendants had the best interpretation of the statute, it found that the plaintiff had failed to plead an FCA cause of action because the defendants had a reasonable interpretation of an ambiguous statute and the relator did not plead that the government had published any official guidance that would "warn" defendants away from their reasonable interpretation); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551 (9th Cir. 2017); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016) (affirming dismissal because the FCA plaintiff had failed to submit any relevant evidence that "the government had warned [the defendant] that the agency interpreted [the relevant regulation] differently" than defendant's interpretation and thus because there had not been sufficient "official government warning," there was not "sufficient evidence of reckless disregard."); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015) (stating that the defendant did not knowingly submit false claims when there was no " 'guidance from the courts of appeals' or relevant agency 'that might have warned [the defendant] away from the view it took.' ") (citation omitted).

[4] *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022).

[5] *Id.* at 343.

"shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates."[6]

Relator and defendant had different interpretations regarding what discounts to report in computing the Best Price.

Relator alleged that all discounts provided along distribution chains must be aggregated in calculating Best Price. For example, if defendant furnished a 20 percent discount to a patient's insurance company and a 10 percent discount to the same patient's pharmacy, two different entities on the distribution chain, defendant was required to aggregate these discounts and report a Best Price of 70 percent and provide Medicaid a 30 percent rebate.[7]

Defendant read the statute differently. It believed that it did not need to aggregate these discounts because they were given to different entities. Defendant reported a Best Price of 80 percent (based on the highest discount given to a single entity).[8]

Because defendant had a reasonable interpretation of what was, at most, an ambiguous statute regarding whether certain discounts must be aggregated in determining Best Price and there was no official governmental guidance to warn defendant away from its interpretation, the court affirmed the dismissal of relator's action at the pleading stage.[9]

The court based its ruling upon the Supreme Court's decision in *Safeco Insurance Co. of America v. Burr*.[10] In *Safeco*, the Court construed reckless disregard consistently with its common law meaning to hold that one cannot act "knowingly" if it bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from that interpretation by authoritative guidance.[11]

Aside from being anchored in Supreme Court precedent, the common law, and the precedent of six other appellate courts, the court identified several significant policy interests that bolstered its construction of the FCA.

First, the court's rule ensures that individuals and industry have notice of what the law requires and due process. As the court observed, it "is profoundly troubling to impose such massive liability on individuals or companies without

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[6] *Id.* at 345.

[7] *Id.* at 346.

[8] *Id.*

[9] *Id.* at 343–44.

[10] *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007).

[11] *See Sheldon*, 24 F.4th at 347–48.

any proper notice as to what is required," and if "the government wants to hold people liable for violating labyrinthine reporting requirements, it at least needs to indicate a way through the maze."[12] Defendants should not read the agency's official position for the first time in an FCA complaint seeking treble damages and massive civil penalties. "After all, [a] defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false if the requirements for that claim are unknown."[13]

Second, the court's ruling protects individuals and industry from arbitrary agency action. As the court acknowledged, "CMS may not wish to specify its position on the issue" because "[c]lear regulations constrain regulatory power and limit future flexibility" but "such reasons are not necessarily permissible."[14] Retaining "ambiguity in order to expand potential liability for regulated entities cannot pass muster" because "allowing agencies to take advantage of companies like this would not be right."[15] In short, government agencies should not draft amorphous rules and regulations to enhance flexibility but then use the ambiguity they created to bring fraud actions.

Third, it protects individuals and industry from FCA abuse. As the court noted, the FCA should "not assess liability through ambush."[16] If courts permitted FCA actions based upon ambiguous guidance, the government and private, financially self-interested relators would be empowered to invoke the FCA to recover treble damages and massive civil penalties regarding each ambiguity in the impenetrable, multivolume health care governmental texts. As multiple courts have now recognized, neither the government nor private whistleblowers should be able to take advantage of ambiguity that the government itself creates to recover a windfall of treble damages and civil penalties.

FOURTH CIRCUIT JOINS SIX OTHER CIRCUITS IN RULING REASONABLE INTERPRETATION OF AMBIGUOUS LAW PROVIDES DISPOSITIVE FCA DEFENSE

The Fourth Circuit's decision in *Sheldon* represents a significant growing trend of appellate court decisions applying *Safeco* to the FCA to rule that a reasonable interpretation of ambiguous guidance is a dispositive defense.

Now more than a half dozen appellate courts have embraced that position. As described below, these courts, like *Sheldon*, identified that the governing law

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[12] *Id.* at 350.

[13] *Id.* (internal quotation and citation omitted).

[14] *Id.* at 356.

[15] *Id.*

[16] *Id.*

or certification the FCA plaintiff claimed was breached was ambiguous, that defendant's interpretation fell within a reasonable construction of the rule and concluded that plaintiff could not establish the FCA's knowledge element.

These courts also underscored that the determination regarding whether the law is ambiguous and defendant's interpretation is reasonable is an issue of law, that defendant's subjective intent was not material to the analysis and that defendant need not develop its reasonable interpretation prior to the submission of any claim.

In *Allergan,* the ambiguity related to the statute governing the definition in the Medicaid Drug Rebate Program ("MDRP") of "Average Manufacturer's Price" ("AMP"). The issue concerned whether defendants knowingly breached the MDRP when they excluded certain credits they received from their customers in calculating an AMP.[17]

Specifically, after the initial sale, some customers were obligated to provide credits when after they purchased drugs from drug manufacturers, the drug manufacturers raised their prices and the customers were able to sell the products at a higher price and retain the profits.[18]

The court noted that each version of the MDRP during the relevant time mandated the calculation of the AMP as the average price paid by entities dealing directly with the manufacturer, but the MDRP during the relevant time never addressed whether post-sale credits must be added to the calculation. Hence, there was no ultimate answer as to whether the relator was correct that price appreciation credits that remits value back to the manufacturer could be considered a component of the cumulative value a manufacture receives for a drug or whether the defendants were correct that "price" as used in the statute related to the initial price paid and not the cumulative price.

The court concluded that although it was not prepared to find that defendants had the best interpretation of the statute, it found that relator had failed to plead an FCA cause of action because defendants had a reasonable interpretation of an ambiguous statute and relator did not plead that the government had published any official guidance that would "warn" defendants away from their reasonable interpretation.[19]

In *Schutte*, the ambiguity related to Medicaid's requirement that pharmacies report their "usual and customary" ("U&C") drug prices when seeking

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[17] 746 F. App'x at 103.

[18] *Id.* at 104.

[19] *Id.* at 109–10.

reimbursement under Medicare and Medicaid.[20] Medicaid regulations define U&C as the price the pharmacy "charges to the general public."[21] In determining the U&C, defendants did not include as charges to the general public discount prices under their price-match program which they provided to customers to match prices their competitors charged.[22] Relators contended that these discounts should be included because the "clear" purpose of the regulation was to ensure that the government receive the benefit of the "prevailing retail market price" that pharmacies provide to consumers.[23]

The court noted that federal regulations were ultimately silent on this issue. They did not provide pharmacies with guidance on identifying the "general public" when they charge customers various prices for the same prescription.[24] The court noted that U&C might mean the prices that are "charged" most frequently for a drug or it could mean the retail rather than a discount price.[25]

Further, it could mean that discount prices only apply if applied to all consumers, or discounts could only apply if they constitute the price most frequently charged to consumers, or it could apply to all discounts programs offered to the public.[26]

The court concluded that the government's definition of U&C "is open to multiple interpretations."[27] The court ruled that because defendants had an

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[20] 9 F.4th at 459.

[21] *Id.* at 469.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.* Recently, the U.S. Court of Appeals for the Seventh Circuit, in *U.S. ex rel. Proctor v. Safeway, Inc.*, No. 20-3425, 2022 U.S. App. LEXIS 9093 (7th Cir. Apr. 5, 2022), noted that in its decision in *Schutte* it resolved the issue that during the relevant time period the meaning of U&C pricing was "open to many reasonable interpretations." *Id.* at *19. The court concluded that defendant's interpretation was reasonable unless there was authoritative guidance warning that defendant's interpretation was not objectively reasonable. As to the meaning of authoritative guidance, the court found that it must examine the source of the guidance and its specificity.

First, as to the source, the authoritative guidance "must come from a source with authority to interpret the relevant text." *Id.* at *21 (internal quotations and citations omitted). That means that authoritative guidance must stem from a governmental source or be binding precedent from the courts of appeals or appropriate guidance from the relevant agency. *Id.* Definitions of regulatory text in private contracts would be insufficient. *Id.* (noting that pharmacy benefit managers and pharmacies are "free to agree to their own definitions by contract," but "doing so does not convert a 'garden-variety breach[] of contract' into a false claim." *Id.* (citing *Escobar*).

objectively reasonable understanding of the regulatory definition and no authoritative guidance placed them on notice that their construction was in error, relators did not show that defendants acted knowingly.[28]

In *Donegan*, the ambiguity related to a regulation that provided that the anesthesiologist must personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence.[29] If the anesthesiologist did not participate in emergence, the procedure must be billed at a lower rate. Defendant and relator offered conflicting definitions of when emergence occurs. For example, defendant defined "emergence" to include the patient's recovery in the recovery room.[30]

Relator, by contrast, viewed emergence as excluding time in the recovery room.[31] The court concluded that CMS had not issued guidance regarding the meaning of "emergence" in the law and that "the regulation is ambiguous on this essential question."[32] The court ruled that defendant's interpretation of emergence in the regulation was "objectively reasonable" and affirmed the district court because a defendant's reasonable interpretation of an ambiguous regulation belies the scienter necessary to establish a fraud claim under the FCA.[33]

In *MWI Corp.*, the ambiguity related to language in a Supplier's Certificate defendant was required to provide stating that defendant had not paid "any discount, allowance, rebate, commission, fee or other payment in connection

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Similarly, guidance from states that is inconsistent with federal law has no bearing on the analysis.

Second, aside from source, the authoritative guidance must be specific. *Id.* at *22–23 (noting that provision in CMS Manual did not apply because provision was not "sufficiently specific to warn [defendant] that customer-initiated price-matching fell within the definition of U&C"). Ultimately, the court concluded that it need not rule regarding whether non-binding agency guidance, like a CMS Manual, could ever satisfy *Safeco*'s scienter standard because the relevant provision—a solitary footnote in a lengthy, nonbinding manual that changed over time—was not sufficiently authoritative. The court reasoned that "[i]n light of the totality of the circumstances, we are not convinced that treble damages liability should hinge on a single footnote in a lengthy manual that CMS can, and did, revise at any time. Such an outcome would raise serious due process concerns because defendants may not receive adequate notice of the agency's shifting interpretation." *Id.* at *26 (footnote omitted).

[28] 9 F.4th at 472.

[29] 833 F.3d at 876–77.

[30] *Id.* at 878–79.

[31] *Id.* at 878.

[32] *Id.*

[33] *Id.* at 879.

with the sale," except "*[r]egular commissions* or fees paid or to be paid in the ordinary course of business to [its] sales agents."[34]

The government alleged that the certification was false because nonregular commissions had been paid, pointing to $28 million in commissions—more than 30 percent of the loan amount—that the defendant had paid to its long term (more than 12 years) sales agent. The defendant believed that its commission was regular, and hence its certification was accurate, because the amount paid was what it regularly paid to this particular agent over their longstanding relationship. The court ruled that the precise legal question regarding the meaning of "regular commissions" is ambiguous and that the defendant's interpretation was reasonable.[35]

The court noted that the term "regular commission" could imply at least three different inquiries:

- What is a regular commission industrywide?
- What is a regular commission for the company?
- What is a regular commission as to the company and the specific agent it used?[36]

The court found that the defendant's interpretation—that the regular commission it had paid this particular agent over their longstanding relationship was the appropriate benchmark—was objectively reasonable.[37] The court noted that the defendant only learned that the government possessed a different interpretation once the government announced the term's meaning in the litigation.

Significantly, these courts also set forth a number of principles related to the application of the reasonable interpretation of law defense.

First, since the reasonable interpretation question is directly linked to the legal text, courts can determine the issue at the pleading stage.[38]

Second, defendant's subjective intent is not relevant to the analysis because if the law is unclear and there is no official governmental guidance to warn

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[34] 807 F.3d at 284.

[35] *Id.* at 288.

[36] *Id.*

[37] *Id.* at 284, 288–89.

[38] Because the objective reasonable inquiry hinges on the text of applicable law that the defendant allegedly violated, it is a question of law. *See Olhausen,* 2022 U.S. App. LEXIS 10989, at *4 ("the analysis of whether an interpretation of ambiguous law is reasonable is an objective one"); *SuperValu Inc.*, 9 F.4th at 468; *Donegan*, 833 F.3d at 879 (determination of objective reasonableness "is an issue of law"); *Purcell*, 807 F.3d at 288.

defendant away from the reasonable interpretation, defendant could not know that there is a violation of law.[39] That is, a court or government agency could arrive at precisely the same conclusion that defendant did given, under the rule, there is no official governmental guidance to warn defendant away from its interpretation. Similarly, if the interpretation is reasonable or permissible, as must be found under this analysis, defendant could not have acted with reckless disregard or deliberate ignorance regarding what the law is because the law is actually undefined.[40]

Third, it does not matter whether defendant's reasonable interpretation occurred before or after the actual claim is presented to the government because regardless of the timing of defendant's reasonable interpretation, defendant could not have acted with actual knowledge or reckless disregard or deliberate ignorance of a statutory, regulatory or contractual breach of a standard that does not exist and has never been published that plaintiff is seeking to enforce against defendant in an FCA proceeding.[41]

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[39] *Proctor*, 2022 U.S. App. LEXIS 9093, at *16 ("a defendant's subjective intent is irrelevant for purposes" of *Safeco* analysis); *SuperValu Inc.*, 9 F.4th at 470 (quoting Supreme Court in *Safeco* that "defendant's subjective intent does not matter for [the court's] scienter analysis—the inquiry is an objective one"); *Purcell,* 807 F.3d at 284 (ruling that defendants did not violate the FCA because they "could reasonably have concluded" that their conduct complied with the law, even though they believed—and testified that they "knew"—it did not).

[40] In conducting a *Safeco* analysis, courts, for the most part, have focused on the FCA's reckless disregard standard and not its deliberate ignorance standard. *Cf. Sheldon*, 24 F. 4th at 349; *Schutte*, 9 F.4th at 469 (noting standards share common requirement and *Safeco* covers all three of the FCA's scienter standards). But, even applying the deliberate ignorance standard, the result is the same. For example, as a practical illustration, take the legal issue in *Schutte*. There the court identified multiple reasonable interpretations of what could constitute U&C charges to the general public, such as: (i) the charge must be frequently made; (ii) the retail charge; (iii) the discounted charge available to all customers; or (iv) discounted charges if they constitute the price most frequently charged. *Id.* at 469. In the context of a fraud action, how can a defendant be deliberately ignorant regarding which of these four reasonable interpretations is the correct one if the government has neither enacted a statute or regulation setting forth its interpretation nor published authoritative guidance regarding, which one is correct? One cannot be deliberately ignorant of a law or interpretation that does not exist.

[41] *Schutte*, 9 F.4th at 470 (rejecting contention that for an erroneous interpretation to be objectively reasonable, defendant must have held it at the time that it submitted its false claim because even "if the Relators can raise an issue of fact on this point, it is irrelevant. The FCA establishes liability only for *knowingly* false claims—it is not enough that a defendant suspect or believe that its claim was false") (emphasis supplied).

STEPS DEFENDANTS CAN UNDERTAKE TO ESTABLISH REASONABLE INTERPRETATION DEFENSE

This case law provides defendants an opportunity to ensure that they will have a dispositive FCA defense notwithstanding uncertainty in the law. As the case law makes clear, when FCA plaintiffs predicate their action upon an ambiguous rule, courts have refused to apply the FCA.

Thus, if companies carefully study the relevant government rules governing payment and develop reasonable interpretations notwithstanding the underlying ambiguity, they will have a valuable defense to FCA liability. If the company has a reasonable interpretation, the government then must show that it has issued formal guidance—such as official agency action or court decisions—that the government contends should have warned the company away from its reasonable interpretation of the ambiguous rule.

If the government cannot identify any, case law instructs that the government should receive, if its interpretation of the rule is correct, no more than single damages on an overpayment claim, but not treble damages and substantial civil penalties under the FCA, because, under these circumstances, the government cannot satisfy the FCA's knowledge element.

Hence, companies can reduce their exposure to liability by:

- Staying actively abreast of governmental rules and regulations regarding government payment and forming a reasonable understanding of what those rules require.
- Monitoring official governmental pronouncements and court decisions to evaluate whether that guidance contains any information that would "warn" the company "away" from its reasonable interpretation.
- Maintaining centralized and retrievable records of the rules, regulations, and governmental guidance; communications with the government; and the company's deliberative process to interpret and apply those materials to the company's operations and claims submissions.

CONCLUSION

This body of unanimous appellate court determinations that plaintiff cannot take advantage of ambiguous law to bring an FCA action has not been without dissent. One dissenting Judge referred to the *Safeco* doctrine as applied to the FCA as "a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a post hoc legal rationale that can pass a laugh test."[42] Another dissenting Judge noted that this doctrine violates the principle that "culpability

[42] *Schutte*, 9 F.4th at 473 (Hamilton, J., dissenting).

is generally measured against the knowledge of the actor at the time of the challenged conduct. It also allows the most culpable offenders . . . to craft their own get-out-of-jail-free cards whenever they like."[43]

These dissents, of course, are mistaken in that they assume the conclusion that a defendant can know that its reasonable interpretation of law (which the doctrine requires) can be wrong when there is no clear law providing that they are wrong and no authoritative guidance to warn them away from its reasonable interpretation.[44] Lacking clairvoyance, how can a defendant act with reckless disregard or deliberate ignorance when it has undisputedly acted in accordance with a reasonable interpretation of law and there is no published law to tell it that its interpretation is wrong?

A fundamental problem those in the health care industry confront is that they must certify compliance with voluminous legal rules and regulations that "are among the most completely impenetrable texts within human experience." And, what magnifies the problem is that if the law, as multiple appellate court decisions have noted, is generally incomprehensible, industry confronts being sued by either the government or a private party under the FCA for treble damages and massive civil penalties.

Fortunately, for industry, multiple appellate courts have erected a firewall to prevent FCA plaintiffs from taking advantage of ambiguities in the law for either public or private enrichment. These court decisions are founded upon Supreme Court precedent and common law principles and bolstered by public policies, such as, those charged with violating the law should have notice of the law, government agencies should not engage in arbitrary actions, and essentially penal statutes, like the FCA, should not applied "through ambush."[45]

Collectively, these multiple appellate court rulings instruct that the government and relator can no longer seize upon legal ambiguities to bring FCA actions seeking treble damages and massive civil penalties and that if the

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[43] *Allergan*, 24 F.4th at 369 (Wynn, J. dissenting) (internal citation and quotations omitted).

[44] Indeed, courts have not been reluctant to rule that defendants' interpretation of law is objectively unreasonable. *See, e.g., U.S. ex rel. Streck v. Takeda Pharms. Am., Inc.*, No. 14 C 9412, 2022 U.S. Dist. LEXIS 34392, at *39–40, *43–44 (N.D. Ill. Feb. 28, 2022) (ruling defendant's interpretation of AMP "objectively unreasonable" and granting summary judgment regarding the FCA's falsity element because defendant's "AMP calculations and related certifications were factually and legally false"); *U.S. ex rel. Streck v. Bristol-Myers Co.*, 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019) (finding "nothing ambiguous" in definition of bona fide service fees and ruling that relator provided sufficient scienter, even under the "objectively unreasonable" standard).

[45] *Sheldon*, 24 F.4th at 356.

government wants to bring an FCA action, rather than an overpayment or breach of contract action, it will need to write clear rules to guide industry's conduct.