JONES DAY | One Firm Worldwide®

**Third in a Series**


# WHITE PAPER

June 2024

## 2023 False Claims Act Enforcement in Health Care and Life Sciences, Part III

In February 2024, the Department of Justice ("DOJ") announced the results of its 2023 False Claims Act ("FCA") enforcement efforts. Through those efforts, it obtained more than $2.6 billion in overall recoveries, and of that amount, $1.8 billion came from health care and life sciences ("HCLS") stakeholders alone.

Jones Day is issuing the third installment of its three-part *White Paper*: "2023 False Claims Act Enforcement in Health Care and Life Sciences." In Part I of the *White Paper*, Jones Day provides an overview of DOJ's FCA enforcement in the HCLS industry during 2023, how that enforcement differed from previous years in terms of monetary recoveries, DOJ's case mix, as well as the evolution of DOJ's priorities and judicial decisions impacting this area.

In Part II of the *White Paper*, we cover the major trends identified in Part I in more detail, discussing 2023 FCA matters involving the Anti-Kickback Statute and Stark Law, Medicare Advantage (Part C), cybersecurity, pandemic fraud, as well as the crescendo of public statements from federal regulators about private equity and corporate ownership in the health care and life sciences space.

Now, in Part III, we provide in-depth discussions of key FCA developments from the bench, including *Schutte*, *Polansky*, causation, and other topics.

2023 brought significant FCA developments from the bench. Of particular note, the U.S. Supreme Court weighed in on two high-stakes FCA issues: scienter and the Department of Justice's power to dismiss *qui tam* complaints over relator objections. In *U.S. ex rel. Schutte v. SuperValu Inc.*, the Supreme Court ruled that a defendant's subjective state of mind can be sufficient to establish scienter, rejecting the view that scienter is never possible when the defendant's actions were "consistent with any objectively reasonable interpretation" of the regulatory requirements underlying an FCA claim.

And in *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, the Supreme Court confirmed that the government may dismiss an FCA case over the relator's objection even if the government initially declined to intervene. Perhaps more notably, three Justices raised questions about the constitutionality of the FCA's *qui tam* provisions in separate opinions in *Polansky*.

Also of particular note, the circuit split over causation in FCA cases based on the Anti-Kickback Statute ("AKS") has widened, while the Supreme Court declined to take up the issue.

These issues, as well as notable decisions on materiality, Rule 9(b), public disclosure, and damages, are discussed in this *White Paper*.

## SCIENTER IN *U.S. EX REL. SCHUTTE V. SUPERVALU, INC.*

In 2023, the U.S. Supreme Court decided the consolidated cases *U.S. ex rel. Schutte v. SuperValu, Inc.* and *U.S. ex rel. Proctor v. Safeway, Inc.*, addressing the key question of whether a person can *knowingly* violate the FCA if (s)he acted according to an "objectively reasonable" interpretation of an ambiguous statute or regulation. The Supreme Court held that scienter under the FCA focuses on a defendant's *subjective* intent and, as such, mere post-hoc demonstration of a regulation's ambiguity does not preclude a finding that a defendant acted *knowingly*.

In *Schutte* and *Proctor*, the relators alleged that the defendant pharmacies filed false reports of their "usual and customary" drug prices for Medicare and Medicaid reimbursement by failing to account for certain discounts. In both cases, the district courts agreed with this theory of falsity—but granted summary judgment for the defendants on scienter grounds. The courts held that at the time of the alleged conduct, interpreting "usual and customary" prices to exclude the discounts provided in connection with certain retail programs was "objectively reasonable," and thus the defendants could not have acted "recklessly or knowingly." No. 11-3290, 2020 WL 3577996, at *9–11 (C.D. Ill. July 1, 2020); 466 F.Supp.3d 912, 941 (C.D. Ill. 2020).

The Court of Appeals for the Seventh Circuit affirmed, 9 F.4th 455 (2021); 30 F.4th 649 (2022), relying on *Safeco Ins. Co. v. Burr*, 551 U.S. 47 (2007). Interpreting the term "'willfully'" under the Fair Credit Reporting Act ("FCRA"), *id.* at 52, *Safeco* held that evidence of "subjective bad faith" does not support a finding of willfulness where a defendant's conduct comported with an "objectively reasonable" interpretation of an ambiguous statute from which the defendant was not warned away by "authoritative guidance," *id.* at 70 & n.20. In *Schutte* and *Proctor*, the circuit court reasoned that the phrase "usual and customary" was ambiguous and could reasonably have been understood as excluding the discounts at issue—even if that understanding was ultimately wrong. Relying on *Safeco*, the court further held that "a defendant's subjective intent is irrelevant" to scienter under the FCA when the defendant's interpretation of the law was "objectively reasonable" and did not conflict with any "authoritative guidance." *Schutte*, 9 F.4th at 469–72, 470; *Proctor*, 30 F.4th at 659–63.

The Supreme Court granted certiorari and unanimously reversed. The Court noted that the FCA's "three-part test" for scienter—requiring either "actual knowledge," "deliberate ignorance," or "reckless disregard" of the truth or falsity of the information—"largely tracks the traditional common-law scienter requirement for claims of fraud," and "focus[es] primarily on what respondents thought and believed." *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749–51 (2023). Focusing on the present tense of the FCA text ("knowingly *presents*," etc.), the Court held "the focus is not . . . on *post hoc* interpretations that might have rendered the[] claims accurate. It is instead on what the defendant knew when presenting the claim." *Id.* at 752.

The Court rejected the Seventh Circuit's strict application of *Safeco* on a variety of grounds, including that *Safeco* addressed a different scienter standard (willfulness) under a different statute (the FCRA). The Court went on to say that the facial ambiguity of a regulation—here, regarding the meaning

of "usual and customary"—does not always preclude the possibility that the defendants nonetheless knew their claims were false. In other words, the defendants' subjective beliefs were not irrelevant to their scienter simply "because *other* people might [have made] an honest mistake" in interpreting the law. *Id.* at 753 (emphasis in original). For scienter, the Court held "it is enough if [the defendants] believed that their claims were not accurate." *Id.* at 757.

Importantly, however, *Schutte* did not eliminate the argument that a defendant lacks scienter due to regulatory ambiguity, and instead made clear that "honest mistakes" about the meaning of a regulation can indeed negate scienter. The Court noted that because the regulation at issue was less than clear, "it might have been a forgivable mistake if respondents had honestly read the phrase as referring to retail prices, not discounted prices," *id.* at 753, leaving the door open to rebutting scienter based on a genuinely held, though mistaken, interpretation of an ambiguous regulation.

But *Schutte* does raise practical considerations, such as how best to establish a company's actual understanding of a regulation (particularly when that understanding may rest on privileged legal opinions). Also, would a single stray email from a low-level employee be enough to create evidence of the company's scienter? How should one determine whether there is an "unjustifiably high risk" that the company's understanding of a regulation is not "correct"? For example, what type of agency guidance should be considered? Formal agency guidance subject to notice and comment? Or informal or other sub-regulatory guidance? What if the agency guidance is not directly on point? *Schutte* does not address such questions. And the Supreme Court's upcoming decision in *Loper Bright Enterprises v. Raimondo* on the future of the *Chevron* doctrine may affect what type of agency guidance can trigger an "unjustifiably high risk" that the company's regulatory interpretation is wrong.

There will be more to come on scienter in the near future. In the wake of its decision in *Schutte*, the Supreme Court vacated and remanded the decisions in *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022), and *U.S. ex rel. Olhausen v. Arriva Medical, LLC*, No. 21-10366, 2022 WL 1203023 (11th Cir. Apr. 22, 2022). Both appellate courts had affirmed the dismissal of FCA complaints on grounds that involved the interrelation of scienter and objectively reasonable interpretations of statutory requirements. On remand, the defendants in both cases appear poised to argue that, even under the Supreme Court's ruling in *Schutte*, the relators have not adequately alleged their scienter. *See* Defs.' Mot. to Dismiss Am. Compl. at 2–3, *Sheldon*, No. 1:14-cv-02535 (D. Md. 2023) (ECF No. 1122); Appellee's Notice of Supp. Auth at 1, *Olhausen*, No. 21-10366 (11th Cir. 2023) (ECF No. 49). We will be monitoring these and other cases for further developments.

## *U.S. EX REL. POLANSKY V. EXECUTIVE HEALTH RESOURCES*

Section 3730(c)(2)(A) of the FCA permits the government to seek dismissal of a *qui tam* complaint over the relator's objection, but the government did not use this mechanism with much frequency until after the issuance of the "Granston Memo"[1] in 2018—which brought new relevance to a longstanding circuit split[2] over the standard to be applied to these dismissal motions. In *U.S. ex rel. Polansky v. Executive Health Resources*, 599 U.S. 419 (2023), the Supreme Court stepped in to resolve this circuit split, and also to address whether the government had the right to seek dismissal if it had initially declined to intervene in the case.

In an 8–1 decision, the *Polansky* Court held that the government retains its right to dismiss an FCA suit, even if it initially declines to intervene in the action within the seal period.[3] The Supreme Court further held that Federal Rule of Civil Procedure 41 (governing voluntary dismissal) applies when the government moves to dismiss a *qui tam* action. Perhaps of greater significance, three Justices—Justice Thomas in a dissent, and Justices Kavanaugh and Barrett in a concurrence—questioned the constitutionality of the FCA's *qui tam* provisions, inviting further arguments on that issue (as are already being seen in the lower courts).

### Government Intervention and Dismissal

In the lower court proceedings in *Polansky*, the government elected not to intervene, and the relator chose to proceed with the litigation. However, after years of discovery, which gave rise to extensive discovery demands and privilege disputes involving the government, the government decided the "varied burdens of the suit outweighed its potential value" and moved to dismiss the case over the relator's objection. *Id.* at 428. The district court granted the request, holding that the government

had "'thoroughly investigated the costs and benefits of allowing [the relator's] case to proceed and ha[d] come to a valid conclusion based on the results of its investigation.'" *Id*. The relator appealed, and argued the government could not dismiss after initially declining to intervene during the seal period. The Third Circuit affirmed, holding the government could dismiss the action even if it declined to intervene during the seal period, as long as it intervened "sometime later." *Id*. The Court held that Federal Rule of Civil Procedure ("FRCP") 41(a) was the proper standard for evaluating such a dismissal motion.

The Supreme Court affirmed. The Court held that the government could move to dismiss as long as it intervened at some point, i.e., including after the expiration of the seal, noting that "the Government's interest in the suit" is the "predominant one . . . [and] that interest does not diminish in importance because the Government waited to intervene." *Id.* at 434–35. The Court then held that such motions should be analyzed under the standards generally governing the voluntary dismissal of suits pursuant to FRCP 41. The Court emphasized that a motion to dismiss by the government will satisfy this standard "in all but the most exceptional cases." *Id.* at 437. The Court reasoned that because an FCA "suit alleges injury to the Government alone[,]" and because "the Government, once it has intervened, assumes primary responsibility for the action[,] . . . a district court should think several times over before denying a motion to dismiss. If the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion." *Id.* at 437–38.

**Possible Challenges to the Constitutionality of *Qui Tam* Suits**

Notably, Justice Thomas's dissent in *Polansky* may be of more immediate interest. Along with Justices Kavanaugh and Barrett's concurrence, it shows that at least three Justices may be open to arguments challenging the constitutionality of the FCA's *qui tam* provisions.

In his dissent, after disagreeing with the majority's reading of Section 3730(c)(2) and (3), Justice Thomas opined that there are "substantial arguments" that *qui tam* actions are inconsistent with Article II of the Constitution because they put relators in the position of "conducting civil litigation . . . for vindicating public rights," thereby invading an "executive function" to be carried out only by the President or duly appointed officers. *Id.* at 449–50 (quoting *Buckley v. Valeo*, 424 U.S. 1, 138–40 (1976)). Justices Kavanaugh and Barrett concurred with the majority opinion, but also added that they agreed with the dissent's view that there are "substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation"—and that the Court "should consider the competing arguments on the Article II issue in an appropriate case." *Id.* at 442.

There have been challenges to the constitutionality of the *qui tam* provision over the years, and those have, to date, been unsuccessful. *Polansky*, however, has reinvigorated those efforts. *See, e.g.*, *U.S. ex rel. Wallace v. Exactech, Inc.*, No. 7:18-CV-01010, 2023 WL 8027309, at *6 (N.D. Ala. Nov. 20, 2023) (rejecting argument that the FCA's *qui tam* provisions violated Article II); *U.S. ex rel. Zafirov v. Florida Medical Associates LLC*, Case No. 8:19-cv-1236-T-KKM-SPF (M.D. Fla.) (currently considering challenge to *qui tam* provision's constitutionality).

## CIRCUIT SPLIT OVER CAUSATION

As part of the 2010 Patient Portability and Affordable Care Act ("PPACA"), Congress amended the AKS to make clear that claims submitted to the government that "result[ed] from" violations of the AKS could be a predicate for liability under the FCA. 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." (emphasis added)). But courts have split on the type of causal link that can satisfy this "resulting from" requirement.

**"Causal Link" versus "But For" Causation**

Generally, a statute requiring causation is presumed to require "but for" causation unless the statutory language shows that it does not "follow[] the general rule."[4] Nonetheless, in 2018 and 2019, the First and Third Circuits rejected "but for" causation in interpreting the PPACA amendment to the AKS and instead applied a looser causal requirement. This "looser" standard is, at least, more stringent than the essentially standardless approach advocated by the government and relators, in that the courts required some sort of "causal link" between the alleged kickback and the subsequent claim for reimbursement. *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018); *Guilfoile v. Shields*, 913 F.3d 178, 190

(1st Cir. 2019). Nonetheless, it is a departure from the more exacting "but for" test that typically applies.

In July 2022, however, the Eighth Circuit departed from the Third Circuit and First Circuit's "causal link" test by holding that plaintiffs who allege violations of the AKS must demonstrate but-for causation between a kickback and claim for reimbursement in order to establish claims "resulting from" the kickbacks. *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022). In that case, at trial, the government relied solely on the 2010 amendment to the AKS to show false claims. The jury was instructed that for the government to prevail on causation, "'it is enough for the United States to show that the claim failed to disclose the Anti-Kickback Statute violation.'"

The Eighth Circuit reversed, holding that the jury was instructed on the wrong causation standard. Considering the AKS's "resulting from" language, the court concluded that, to find FCA liability based on an AKS violation, the jury must find that "a defendant would not have included particular 'items or services' but for the illegal kickbacks." *Id.* at 836. The court pointed out that the Supreme Court had previously concluded that the ordinary meaning of "'results from' imposes . . . a requirement of actual causality"—specifically, "but for" causation, *id.* at 835 (citing *Burrage v. United States*, 571 U.S. 204, 210–11 (2014))—and that but-for causation is the "'default' or 'background'" rule when a statute does not indicate otherwise, *id.* (citing *Comcast Corp.*, 589 U.S. at 332).

In March 2023, the circuit split deepened with the Sixth Circuit joining the Eighth Circuit in holding that the "resulting from" provision requires showing "but for" causation. *See U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023). There, the lower court dismissed the relator's claim that the defendant had violated the AKS and thus the FCA. The Sixth Circuit affirmed, finding that the plaintiffs failed to allege causation. The court reasoned that the ordinary meaning of "resulting from" is but-for causation. *Id.* at 1052–53. The court found that the defendants merely continued a past practice of referrals for which "the alleged scheme did not change anything," such that it did not sustain an AKS-based FCA claim. *Id.*[5] The Supreme Court declined to review this decision.

The government has tried reverting to the pre-2010 approach to litigating AKS-based FCA claims, under which, instead of leveraging the "resulting from" provision, it would rely upon a false certification of AKS compliance. For example, in *U.S. ex rel. Fesenmaier v. Cameron-Ehlen Group., Inc.*, the district court distinguished between these theories of liability—holding that the causation requirement imposed by the "resulting from" language did not apply to FCA claims predicated on a "material falsity" theory, and that "but for causation is only required 'when a plaintiff seeks to establish falsity or fraud **through the 2010 amendment**.'" *U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-cv-03003, 2023 WL 36174, at *3 (D. Minn. Jan. 4, 2023) (emphasis in original) (quoting *Cairns*, 42 F.4th at 831, 836–37).[6]

But this alternative approach raises its own complications, particularly when the defendant paying the alleged kickbacks was not itself submitting any claims for payment. Indeed, older, conflicting case law on that issue is partly why Congress sought in the PPACA to simplify establishing falsity in AKS-based FCA cases.

More cases are making their way up to the circuit level on this issue. The First Circuit recently accepted interlocutory appeals to resolve conflicting decisions out of the District of Massachusetts on the issue of causation under the 2010 amendments. *See, e.g., United States v. Teva Pharms. USA, Inc.*, No. 23-8028 (1st Cir. Nov. 17, 2023). We will be monitoring this circuit split as it continues to develop.

## PLEADING WITH PARTICULARITY UNDER RULE 9(b) AND ARTIFICIAL INTELLIGENCE

Another 2023 case made headlines more for its alleged facts than legal conclusions. In *Doe I v. eviCore Healthcare MSI LLC*, the Second Circuit affirmed the dismissal of a complaint under FRCP 9(b) that broadly alleged that the use of "artificial intelligence" ("AI") and other practices to assist in claim submission constituted "worthless services." No. 22-CV-530, 2023 WL 2249577 (2d Cir. Feb. 28, 2023). There, the defendant provided reimbursement services to insurers for federal beneficiaries. The relators alleged that the defendant caused the submission of false claims—first, by requiring its reviewers to "auto-approve" all requests relating to certain medical services, and second, by using AI to approve certain requests based on flawed criteria.

The district court found the relators had not alleged falsity because the services the defendant provided were not so "worthless" that they were "the equivalent of no performance at all." *Id.* at *2. But the Second Circuit affirmed on the more routine ground that the relator had failed under Rule 9(b) to "identify even a single instance" of a procedure on a specific date that was fraudulent or unnecessary, rejecting the relator's contention that the volume of the defendant's approvals made it inevitable that fraudulent claims were approved. *Id*. For this reason, the circuit court found it unnecessary to reach the issue of whether the relators pleaded falsity under a worthless services theory. *Id.* at *2 n.3.

## MATERIALITY

In *Universal Health Services, Inc. v. U.S. ex rel. Escobar,* 579 U.S. 176 (2016), the Supreme Court held that misrepresentations and omissions must be "material" to the government's decision to pay a claim in order to violate the FCA. Writing for a unanimous Court, Justice Thomas characterized the FCA's materiality standard as "rigorous" and "demanding." Providing guidance on how to assess materiality, the Court identified a series of non-exhaustive factors for courts to consider, such as: whether the government has identified compliance with a specific rule as a condition of payment; whether the government generally refuses to pay claims that fail to meet the requirement; whether the government has continued to pay claims despite actual knowledge of noncompliance with the requirement; and whether the alleged noncompliance is considered minor or insignificant, or if it goes to the "very essence of the bargain." Since then, the lower courts have grappled with how much weight to give these and other factors in their materiality analyses.

In 2023, the Third Circuit considered the importance of the government's continued payment of claims to the FCA's materiality requirement. In *U.S. ex rel. Druding v. Care Alternatives, Inc.*, 81 F.4th 361 (3d Cir. 2023), the relator alleged that a hospice provider had violated the FCA by submitting claims to Medicaid without adequate clinical documentation supporting medical necessity. The district court granted summary judgment, finding that the government's continued reimbursement of the defendant's claims even after being made aware of its deficient documentation precluded materiality. The Third Circuit reversed, holding that the district court had erred by granting dispositive weight to the government's continued payment of the defendant's claims. Notwithstanding these continued payments, the court found that the documentation requirement the defendant had allegedly violated was "a foundational part of the Government's Medicare hospice program," and that a reasonable jury could find that the defendant's violations were material if they went to the "'essence of the bargain': patients' medical need for hospice care." *Id.* at 371–73 (quoting *Escobar*, 579 U.S. at 193 n.5, 194).

For its part, the Fourth Circuit recently considered whether a defendant's violation of an allegedly unlawful government requirement could be material for purposes of FCA liability. *United States v. Walgreen Co*., 78 F.4th 87 (4th Cir. 2023). In that case, the government alleged that the defendant's employee had submitted falsified records to Virginia's Medicaid program regarding patients' eligibility for certain medications that were subject to state-imposed coverage restrictions. The district court granted the defendant's motion to dismiss for failure to plead materiality, in part based on evidence that Centers for Medicare and Medicaid Services had raised concerns that state-imposed coverage restrictions may be in violation of the Medicaid Act. *See id.* at 91. The trial court held that the government had not pleaded materiality because "the falsified records *should not have* . . . influenced the [government's] decision-making because the drugs should have been covered . . . regardless of the information contained on the falsified records." *Id.* (emphasis in original).

The Fourth Circuit reversed, holding "[t]he legality of Virginia's eligibility requirements might be relevant to whether the misrepresentations had a natural tendency to influence, or could influence, the decisionmakers," but were not dispositive. *Id.* at 93 (citing *Escobar*, 579 U.S. at 190). Indeed, "the very act of falsifying records to feign compliance with requirements suggests that [the defendant] itself thought that those requirements were material." *Id.* at 94. Lastly, the fact that the government itself was the first plaintiff to bring the suit, rather than a relator, was a "strong[] indicator of materiality." *Id.*

## PUBLIC DISCLOSURE BAR

In 2023, there were three notable circuit court decisions relating to the public disclosure bar of the FCA. These three cases considered the extent to which prior disclosures must overlap

with the relator's allegations before those disclosures can act as a bar to the relator asserting an FCA claim.

In March 2023, the Second Circuit continued to apply the public disclosure bar's stringent requirements to prevent parasitic FCA cases.[7] In *Piacentile v. U.S. Oncology Inc*., No. 22-18, 2023 WL 2661579 (2d. Cir. Mar. 28, 2023), the court held that the public disclosure bar required dismissal of the relator's suit where the kickback scheme alleged had been revealed in three prior lawsuits, although none had specifically identified the defendant by name. Even though the relator's lawsuit was the first instance in which the specific defendant had been named and in which the specific alleged kickbacks were identified, the court dismissed because claims "based in any part upon publicly disclosed allegations or transactions" are barred "even if the prior disclosure does not identify a defendant by name," as long as the disclosure "identif[ied] enough about a transaction that additional parties are discoverable." *Id.* at *2.

In December 2023, the Fifth Circuit came to a similar conclusion, ruling that a *qui tam* suit was "substantially the same" as certain prior public disclosures even though those disclosures did not mention the defendants by name. *U.S. ex rel. Vaughn v. Harris Cnty. Hosp. Dist*., No. 22-20659, 2023 WL 8649876 (5th Cir. Dec. 14, 2023). In *Vaughn*, the relator's suit specifically identified the defendants and the mechanism of the alleged fraud in much more detail than any of the public disclosures. The court nevertheless held these prior public disclosures were sufficient to preclude the more specific allegations of the relator's complaint. *Id.* at *3–4. The court rejected the relator's argument that his suit should survive because he alleged specific examples of the conduct: "the crux of the public disclosures unearths the possible fraud," and "offering specific examples of [ ] conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed." *Id.* at *5.

On the other hand, the Ninth Circuit reversed a district court's dismissal under the public disclosure bar. There, the complaint alleged that the defendant manufacturer had fraudulently obtained certain patents to prolong its monopoly and charge an "artificially high price" for the drug at issue. *Silbersher v. Valeant Pharms. Int'l, Inc.*, 76 F.4th 843, 851 (9th Cir. 2023). The defendant moved to dismiss on the basis of various prior disclosures. Among other holdings, the court held that an *inter partes* review ("IPR") of the patents at issue did not qualify as a "public disclosure" under the bar and that the remaining relevant public disclosures "do not disclose a combination of facts sufficient to permit a reasonable inference of fraud." *Id.* at 856. The court wrote that "the scattered qualifying public disclosures each contain a piece of the puzzle, but none shows the full picture." *Id.* at 857.

The defendants filed a petition for rehearing *en banc*, arguing that the panel's decision conflicted with precedent in the Ninth Circuit and 11 other circuits that held that the misrepresented state of facts and true state of facts need not appear in the *same* public disclosure in order to trigger the public disclosure bar, but instead may be dispersed across several sources. The court denied the petition but issued a revised opinion to make clear that "the scattered disclosures when viewed together possibly reveal some of these true and misrepresented facts, *but nothing in combination from which fraud can reasonably be inferred.*" *Silbersher v. Valeant Pharms. Int'l, Inc.*, 89 F.4th 1154, 1168 (9th Cir. 2024) (emphasis added). It amended its previous decision to say that each public disclosure "may each contain a piece of the puzzle, but *when pieced together*, they fail to present the full picture of fraud. In his *qui tam* action, [the relator] filled the gaps by stitching together the material elements of the allegedly fraudulent scheme." *Id.* (emphasis added).

While the Ninth Circuit declined to reverse its original determination, the revised opinion at least facially corrected course for the court's approach to the bar, including rejoining the consensus view that individual disclosures need not contain *all* of the material elements of an alleged scheme. On April 8, 2024, the defendant filed a petition for a writ of certiorari on the issues of whether a relator can avoid the public disclosure bar by "stitching together" public disclosures and whether IPR constitutes a channel for public disclosure. *See* Petition for Writ of Certiorari, *Valeant Pharms. Int'l, Inc., et al. v. Silbersher*, No. 23-1093 (filed April 8, 2024).

## CALCULATION OF DAMAGES

In August, the Ninth Circuit addressed the calculation of damages and penalties in the government-contracting context and, in doing so, reined in the plaintiffs' maximalist approach to damages. *U.S. ex rel. Hendrix v. J-M Mfg. Co*., 76 F.4th 1164 (9th Cir. 2023). In *Hendrix*, the plaintiffs brought suit under the

FCA and state analogs against a pipe manufacturer, alleging that the defendant sold its pipes to public agencies while falsely certifying that they complied with industry standards. *Id.* at 1168. In a bifurcated trial, the jury found the defendant had violated the FCA because it had changed its manufacturing processes and falsely represented that the piping uniformly complied with industry standards. *Id.* at 1169. In Phase Two of the trial, the jury failed to come to a verdict on damages. The district court granted judgment as a matter of law, denying actual damages. Nevertheless, it then awarded civil penalties for each of the 26 projects at issue, although not on every individual piece of pipe at issue. On appeal, the Ninth Circuit affirmed. *Id.* at 1172–73.

The circuit court declined the plaintiffs' request that the court impose a separate penalty for each individual piece of pipe that was stamped with the certification. The court held that the "jury's finding of falsity and materiality did not mean that every stick of pipe was non-compliant. That jury found only that [the defendant] did not uniformly comply with industry standards and could have delivered some non-compliant pipe. [The] [p]laintiffs did not establish how much non-compliant pipe was received nor were they able to identify any specific piece of non-compliant pipe." *Id.* at 1172. On the basis of the failure of proof on the actual volume of purportedly defective pipes and the substantial authority awarding FCA damages on the basis of contracts or projects, the court held that the 26 projects, rather than the individual pieces of pipes sold pursuant to those projects, provided the proper metric for calculating penalties under the FCA. *Id.* at 1173.

In another limitation to the plaintiffs' approach to damages, the circuit court also disagreed with the plaintiffs' assertion they were entitled to the entire value of their contract, holding instead that "entire value" damages are appropriate only where the contract is proven to be entirely valueless. Because the FCA imposes liability for "'the amount of damages which the Government sustains because of the' false claim," and because the plaintiffs had not presented "evidence from which a jury could reasonably determine the value of the pipe that [the government] received" as compared to what it paid for, the government had not shown any damages as a result of the defendant's FCA violations. *Id.* at 1173–76.

## LAWYER CONTACTS


**Rebecca C. Martin**
New York
+1.212.326.3410
rcmartin@jonesday.com

**Rajeev Muttreja**
New York
+1.212.326.8367
rmuttreja@jonesday.com

**Heather M. O'Shea**
Practice Leader
Chicago
+1.312.269.4009
hoshea@jonesday.com

**B. Kurt Copper**
Dallas
+1.214.969.5163
bkcopper@jonesday.com

**Laura F. Laemmle-Weidenfeld**
Washington
+1.202.879.3496
lweidenfeld@jonesday.com

**Traci L. Lovitt**
Practice Leader
New York
+1.212.326.7830
tlovitt@jonesday.com

**Kristen Pollock McDonald**
Atlanta
+1.404.581.8498
kmcdonald@jonesday.com

**Matthew Rubenstein**
Minneapolis
+1.612.217.8846
mrubenstein@jonesday.com

**Eric Tung**
Los Angeles
+1.213.243.2151
etung@jonesday.com

*Associates Rachel E. Page, Marielle C. Coutrix, Mary Katherine Hickey, and Sophie Leff contributed to this* White Paper.

## ENDNOTES

1 DOJ, "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)" (Jan. 10, 2018). This memorandum was authored by Michael Granston, Director of the Civil Fraud Section of the Commercial Litigation Branch.

2 *Compare Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003) (government has an "unfettered right" to dismiss a *qui tam* action under § 3730(c)(2)(A)), *with U.S. ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998) (requiring evidentiary hearing and a rational relationship between the dismissal and a valid governmental purpose), *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936 (10th Cir. 2005) (same).

3 Under the FCA, *qui tam* complaints are filed by the relator under seal. 31 U.S.C. § 3730(b)(2). The complaint remains under seal for 60 days, during which time the government may elect to intervene in the action. *Id.* This 60-day period, and any extensions of that period granted by the court, are referred to as the "seal period."

4 *Comcast Corp. v. Nat'l Assoc. of Afr-Am.-Owned Media*, 589 U.S. 327, 332 (2020) ("This ancient and simple 'but for' common law causation test, we have held, supplies the 'default' or 'background' rule against which Congress is normally presumed to have legislated. . . .").

5 The Sixth Circuit also considered whether the defendant hospital's choice to continue a longstanding practice of mutual referrals constituted "remuneration" within the meaning of the AKS. The court answered this in the negative, reasoning that remuneration means only "payments and other transfers of value," such as monetary kickbacks, bribes, or rebates, and does not include other acts that someone may consider valuable. *Id.* at 1048. The hospital's decision not to hire its own doctor, while indirectly benefitting the outside doctor who would continue to receive its referrals, did not constitute a transfer of value in the way the AKS intended. *Id.* at 1051. The court thus affirmed the dismissal of the case on the ground that the relator failed to plead a cognizable theory of remuneration.

6 Following a two-month trial, the jury concluded that an ophthalmic supply company and its founder violated the AKS by offering trips, meals, and other inducements to physicians, who would then purchase medical supplies from the defendants and bill Medicare for reimbursement. The jury determined the defendants caused the submission of 64,575 false claims, resulting in more than $43 million in actual damages to the Medicare program, which after trebling and statutory penalties, resulted in a total award of $487 million. That amount was reduced by the district court, largely under the Excessive Fines Clause, to just under $217 million. *U.S. ex rel. Fesenmaier*, No. 13-cv-3003, 2024 WL 489708 at *13. The case is on appeal.

7 *See US ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings,* No. 21-2117 (2d Cir. Dec. 20, 2022) (the defendant's securities filings had previously revealed the same corporate transactions on which the relator later based its *qui tam* suit and, thus, the False Claim Act's public disclosure bar compelled dismissal of the suit).