



Health Law Developments

The Newsletter of the Health Law Section

State Bar of Georgia

Spring 2025

From the Chair

Aaron M. Danzig



Thank you to all the attendees at our annual Advanced Health Law Seminar on November 1, 2024. We had a packed house with exceptional and insightful panels.

Thanks again to our

sponsors Alston & Bird, Arnall Golden Gregory LLP, Chilivis Grubman LLP, and Parker Hudson Rainer and Dobbs LLP.

Look out for this year's Advanced Health Law Seminar. It will be in October, date and location are being finalized now. If you have an idea for a panel, please submit a proposal to me at aaron.danzig@agg.com by May 1, 2025. Also, the Section will be hosting at lunch-and-learn on Wednesday, April 23, 2024, entitled Private Equity in the Crosshairs: Transactional and Regulatory Considerations for Health Care Investments in 2025. It will be from 12 – 2pm at Alston & Bird, which graciously agreed to host.

In this issue, we have three excellent and timely articles. Robert Buckley and Neena Molavi write about proposed changes to the HIPAA security rule and how they may require changes to business associate agreements; Kara Silverman and Kelsey O'Neill discuss a recent Second Circuit case addressing the Antikickback Statute's "one-purpose rule"; and Scott Grubman assesses the future of False Claims Act *qui tam* cases in light of the *Zafirov* district court case.

[Aaron Danzig](#)

Inside This Issue

Proposed Changes to the HIPAA Security Rule May Require Significant Changes to Business Associate Agreements.....2

Lowering the Bar: Second Circuit Finds "At-Least-One-Purpose" Sufficient for Proving Anti-Kickback Statute Violation.....5

Are the False Claims Act **Qui Tam** Provisions Doomed? The Appointments Clause, Zafirov, and the Future of Whistleblowing.....7

Scenes from 2024 Advanced Health Law Seminar.....10

Save-The-Date!



Health Law Section Lunch-and-Learn

Please mark your calendars for an interesting panel entitled: "Private Equity in the Crosshairs: Transactional and Regulatory Considerations for Health Care Investments in 2025." It will be

Wednesday, April 23 from 12-2 p.m. at Alston & Bird. The panelists are [Matthew Kent](#) (Alston & Bird antitrust partner), [Sarah K. Browning](#) (BakerHostetler healthcare transactions counsel), and [Andrew Hranka](#) (Coker Group Managing Director) and [Sean Sullivan](#), moderator (Alston & Bird healthcare partner). Registration link to be provided separately.

Proposed Changes to the HIPAA Security Rule May Require Significant Changes to Business Associate Agreements

By Robert Buckley and Neena Molavi

On December 27, 2024, over ten years since the last significant revision¹ of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the United States Department of Health and Human Services Office for Civil Rights (“OCR”) released a Notice of Proposed Rulemaking (the “proposed rule”) which would, if finalized and implemented as is, dramatically heighten requirements under the HIPAA Security Rule.² The Security Rule sets forth various administrative, physical, technical, organizational, and documentation³ requirements meant to protect electronic protected health information (“ePHI”). Most standards created by the Security Rule are accompanied by implementation specifications which facilitate compliance with the standard, with some specifications being required and others being “addressable.”⁴ Among the reasons cited for updating the Security Rule is concern for the increase in breaches and cybersecurity incidents in recent years.⁵ Accordingly, the proposed rule aims to modify the Security Rule to address significant changes in technology, changes in breach trends and cyberattacks, OCR observations from enforcement investigations, guidelines and methods for protecting ePHI, and relevant court decisions.⁶

I. Overview of Certain Proposed Changes to the Security Rule

Concerned with the “alarming growth” in cybersecurity breaches affecting large groups,⁷ OCR has proposed a lengthy list of changes to the Security Rule. While the proposed changes would “substantially revise the regulatory text”, OCR believes the updates would not substantially change

existing obligations under the Security Rule and would instead codify “those activities that are critical to protecting the security of ePHI” and provide greater detail for those requirements.⁸ Some of the major changes contemplated by the proposed rule that may affect Business Associate Agreements follow.

A. *Proposal: Removing the distinction between “addressable” and “required” implementation specifications*

Currently, the Security Rule differentiates between “addressable” and “required” implementation specifications.⁹ “Addressable” implementation standards may be assessed by covered entities or business associates for reasonableness and appropriateness in the environment, and based on that assessment, covered entities or business associates may either implement the specification or, if they find the specification unreasonable or inappropriate, they may implement an alternative measure so long as they document why the measure specified by the Security Rule is not reasonable or appropriate.¹⁰

OCR identified its concern that some regulated entities treat “addressable” specifications as optional, but stated it believes compliance is not and should not be optional.¹¹ The proposed rule would reduce the flexibility afforded to the “addressable” specifications by requiring covered entities and business associates to comply with all standards and implementation specifications.¹²

B. *Proposal: Requiring regulated entities to maintain a written technology asset inventory and network map of electronic information systems and technology assets*

The proposed rule, if finalized, would require regulated entities to “conduct and maintain an accurate and thorough written technology asset inventory and a network map of its electronic information systems and all technology assets that may affect the confidentiality, integrity, or availability of ePHI.”¹³ The network map would identify the location,

1 See Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (Jan. 25, 2013).

2 HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information, 90 Fed. Reg. 898.

3 See 45 C.F.R. §§ 164.308, 164.310, 164.312, 164.314 & 164.316.

4 See, e.g., 45 C.F.R. § 164.308.

5 90 Fed. Reg. at 900.

6 *Id.*

7 *Id.*

8 *Id.* at 901.

9 45 C.F.R. 164.306(d).

10 *Id.* at (d)(3).

11 90 Fed. Reg. at 917.

12 *Id.* at 933.

13 *Id.* at 937.

whether physical or cloud-based, of technology assets.¹⁴ A covered entity would need to consider technology assets used by its business associates in preparing its network map.¹⁵

C. Proposal: Requiring regulated entities to verify business associate compliance with technical safeguards

After finding the lack of a requirement for covered entities to verify that business associates actually take necessary steps to protect ePHI may result in a gap in protection, OCR has proposed requiring regulated entities to obtain written verification documenting business associates' deployment of the Security Rule's technical safeguards.¹⁶ This verification would need to be obtained at least every twelve months and contain an analysis of the business associate's relevant electronic information systems.¹⁷ The Notice of Proposed Rulemaking also reminds regulated entities that subcontractors of business associates are also business associates.¹⁸

D. Proposal: Requiring Patch Management

The proposed rule sets out a new standard which, if finalized, would require written policies and procedures for patching and updating relevant electronic information systems in an effort to strengthen overall security.¹⁹ This standard would be accompanied by six implementation standards for which, as noted above, compliance would be required.²⁰ However, the proposed rule creates exceptions for certain situations, such as when a patch, update or upgrade is not available to address an identified risk or when the only available patch, update or upgrade would adversely affect the confidentiality, integrity, or availability of ePHI.²¹

II. Impact of Proposed Changes on Business Associate Agreements

If finalized as currently proposed, the changes to the Security Rule would become effective sixty days following publication, and regulated entities would have 180 days from the effective date to establish and implement compliant policies and procedures before facing enforcement.²² OCR has, however, proposed an additional transition period under certain circumstances to modify existing business associate agreements.²³ Covered entities would need to adapt existing

- 14 *Id.*
- 15 *Id.*
- 16 *Id.* at 956.
- 17 *Id.*
- 18 *Id.*
- 19 *Id.* at 943.
- 20 *Id.*
- 21 *Id.*
- 22 *Id.* at 900-901.
- 23 *Id.* at 901.

business associate agreements within that timeframe, and depending on the arrangement, the proposed rule could require significant adjustments.

Covered entities and business associates would need to review their current arrangements and, for any addressable implementation specifications they chose to replace with an alternative, they would need to reform their contracts and practices to comply with the implementation specification as it is described in the applicable regulation. For example, if a covered entity and business associate previously determined that an encryption mechanism, as described in 45 C.F.R. § 164.312(e)(2)(ii), was not reasonable or appropriate and instead opted for an alternative mechanism, the arrangement would need to be adjusted to require encryption whenever necessary.²⁴

Regarding the technology asset inventory and network map requirement, while the technology assets used by business associates handling ePHI are not a part of a covered entity's electronic information system, they nevertheless would be required to be included in the covered entity's network map.²⁵ Thus, business associate agreements would likely need to be adjusted to require a business associate's cooperation in developing the network map. The same goes for the requirement that covered entities verify business associate compliance with technical safeguards – business associate agreements would need to ensure that covered entities are given access to the information they need to meet this standard.

Additionally, business associate agreements would need to set forth patch management policies and procedures. This would include identifying which parties will be responsible for assessing the systems and applying patches as well as ensuring proper access to electronic systems is given.

III. State-Level Health Data Laws

The Notice of Proposed Rulemaking contends that “a patchwork of State-specific laws may create difficulties for regulated entities that are located or operate in multiple States.”²⁶ For example, the Washington My Health My Data Act went into effect in 2024, intending to provide heightened protections for Washington's health data.²⁷ Nevada has enacted a law governing consumer health data.²⁸ Connecticut also enacted a similar law in 2023.²⁹ New York's Assembly recently passed a bill titled the “New York Health Information Privacy Act,”³⁰ which if enacted, would further

- 24 *Id.* at 968.
- 25 *Id.* at 937.
- 26 *Id.* at 900.
- 27 Wash. Rev. Code § 19.373.005.
- 28 Nev. Stat. § 603A.400 *et seq.*
- 29 *See* Conn. Gen. Stat. § 42-515 *et seq.*
- 30 <https://www.nysenate.gov/legislation/>

add to the patchwork.

Despite OCR's desire to avoid "a patchwork of State-specific laws,"³¹ states have proceeded to set their own separate requirements. While the stricter standards of the proposed rule may curb further state legislation on the matter moving forward, covered entities and business associates in many states will nevertheless have to assess the applicability of various laws to their individual arrangements.

IV. Conclusion

In the event the proposed rule is finalized as-is, covered entities and business associates would have limited time to evaluate compliance and accordingly adjust their agreements and implement any necessary changes. As the proposed changes summarized above are only a sampling of those set forth in the Notice of Proposed Rulemaking, regulated entities will likely have a multitude of additional requirements with which they would need to comply beyond their business associate agreements. The rise in state legislation imposing additional requirements further complicates the compliance landscape, and health care entities are advised to navigate these changing laws with care.

bills/2025/S929

31 90 Fed. Reg. at 900.



Robert Buckley



Neena Molavi

Robert Buckley is a Partner at Aligned Health Law. Robert is an IAPP Certified Information Privacy Professional (CIPP/US) and Certified Information Privacy Manager (CIPM) and he counsels healthcare clients on privacy and compliance issues. Neena Molavi is a recent graduate of Georgia State University College of Law's Health Law Certificate program. Her focus is on healthcare regulatory compliance and transactions. They can be reached at rbuckley@alignedhl.com and neenamolavi@gmail.com.



The State Bar has three offices to serve you.

HEADQUARTERS

104 Marietta St. NW
Suite 100
Atlanta, GA 30303
404-527-8700
800-334-6865
Fax 404-527-8717

SOUTH GEORGIA OFFICE

244 E. 2nd St.
Tifton, GA 31794
229-387-0446
800-330-0446
Fax 229-382-7435

COASTAL GEORGIA OFFICE

18 E. Bay St.
Savannah, GA 31401
912-239-9910
877-239-9910
Fax 912-239-9970

Lowering the Bar: Second Circuit Finds “At-Least-One-Purpose” Sufficient for Proving Anti-Kickback Statute Violation

By Kara Silverman and Kelsey O'Neill

On December 27, 2024, the United States Court of Appeals for the Second Circuit joined other federal circuit courts in adopting the “at-least-one-purpose” rule (generally shortened to the “one purpose rule”).¹ Under this rule, defendants violate the Anti-Kickback Statute (“AKS”)² when at least one purpose (as opposed to the “sole” or “primary purpose”) of the alleged arrangement was to induce patient referrals, even if there were other, legitimate reasons for offering remuneration.³ This rule lowers the bar for proving AKS violations considerably, which in turn impacts routine business practices, and ultimately patient care.

INTRODUCTION AND OVERVIEW

The Anti-Kickback Statute is a federal criminal statute that prohibits knowingly and willfully offering or providing remuneration for the purpose of inducing the recipient to purchase a good or service for which payment may be made under a federal program.⁴ Remunerations can be anything of value, including cash, gifts, meals, discounted medical supplies, excessive compensation for medical directorships or consultancies, referral fees, and insurance reimbursement.⁵ Any remuneration or offer of remuneration may form the basis of an AKS violation, and both the payor and recipient of the remuneration could face liability.⁶ Criminal penalties for violating the AKS include fines, jail terms, and exclusion from participating in federal healthcare programs.⁷ Additionally, under the Civil Monetary Penalties Law (“CMP”), anyone who pays or accepts kickbacks could face penalties of up

to \$50,000 per claim plus treble damages.⁸ And, a violation of the AKS can support a violation of the False Claims Act (“FCA”).⁹

The AKS itself does not define what constitutes an “inducement” of referrals. Instead, courts have adopted various standards of interpretation, including the “primary purpose” rule and the “one purpose” rule. Under the “primary purpose” rule, a person would only be in violation of the AKS if his or her motivation to induce referrals was the primary or sole purpose of payment of remuneration. The “one purpose” rule, however, broadens the scope of potential AKS violations by treating remuneration as an illegal inducement when “one purpose” of the remuneration is to gain referrals, even where other legitimate reasons existed for the payment of the remuneration.

THE SECOND CIRCUIT OPINION

In *United States ex rel. Camburn v. Novartis Pharmaceuticals Corporation*, Relator-Appellant Steven M. Camburn (“Camburn”) filed a qui tam action against Novartis Pharmaceuticals Corporation (“Novartis”) under the FCA alleging that Novartis engaged in an illegal kickback scheme to induce physicians to prescribe Gilenya, a drug used to treat multiple sclerosis.¹⁰ Specifically, Camburn alleged that Novartis’ speaker programs, marketing materials, office outfittings, and one-on-one physician dinners were “shams,” “lavish,” and “extravagant” and provided little educational value.¹¹ According to Camburn’s allegations, these Novartis-funded events functioned as a pretext for inducing physicians to prescribe Gilenya in violation of the AKS.¹²

The district court dismissed Camburn’s complaint with prejudice, holding that Camburn did not plead the existence of a kickback scheme with adequate particularity.¹³ The United States Court of Appeals for the Second Circuit upheld the dismissal of the majority of Camburn’s claims, but

1 United States ex rel. Camburn v. Novartis Pharms. Corp., 2024 U.S. App. LEXIS 32722, at *4 (2d Cir. Dec. 27, 2024).

2 42 U.S.C. § 1320a-7b(b).

3 Camburn, 2024 U.S. App. LEXIS 32722, at *11.

4 42 U.S.C. § 1320a-7b(b); *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 808 (11th Cir. 2015).

5 See e.g., *United States v. Goldman*, 607 Fed. Appx. 171, 2015 U.S. App. LEXIS 5631 (3d Cir. 2015); *United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021).

6 42 U.S.C. § 1320a-7b(b).

7 42 U.S.C. § 1320a-7b(b).

8 42 U.S.C. § 1320a-7a.

9 42 U.S.C. § 1320a-7b(g).

10 Camburn, 2024 U.S. App. LEXIS 32722, at *7-9.

11 *Id.* at *13-14.

12 *Id.* at *6.

13 *Id.* at *4-5.

vacated and remanded the case regarding three categories of allegations related to Novartis’s speaker programs: “(1) speaker programs with no legitimate attendees; (2) excessive compensation of speakers for canceled events; and (3) the selection and retention of certain speakers deliberately to induce a high volume of prescriptions of Gilenya.”¹⁴ Importantly, in its remand order, the Second Circuit adopted and applied the “one purpose” rule as the pleading standard for the first time.¹⁵ This means that relators need only allege that at least one purpose of the remuneration from Novartis was to induce prescriptions, without alleging a cause-and-effect relationship between the payments and the physicians’ prescribing habits.¹⁶ Notably, though, the Second Circuit’s opinion did not provide a detailed explanation as to why it was applying the “one purpose” rule, other than noting that this rule “aligns with that of our sister circuits.”¹⁷

IMPLICATIONS

The Second Circuit joins other federal circuit courts in applying this less stringent requirement in pleading AKS violations.¹⁸ The “one purpose” rule lowers the bar by finding it sufficient for a relator to show that any purpose of the remuneration was to induce referrals — even if the remuneration was also intended to compensate for professional services or any another legitimate purpose. Importantly, the “one purpose” rule does not diminish the requirement that plaintiffs satisfy the heightened pleadings requirement under Federal Rule of Civil Procedure 9(b).¹⁹ The Second Circuit made clear that whether a complaint survives a motion for summary judgment depends heavily on the strength and particularity of the allegations, and the court’s “context-specific” analysis of the specific facts alleged in each case.²⁰

In the day and age of “big data” where the poor word choice of any one salesperson could potentially be imputed to malintent for the entire organization, the adoption of the “one purpose” rule could result in virtually all beneficial healthcare arrangements as suspicious pay-for-patient schemes. Additionally, broadly criminalizing the ability of medical providers to refer patients to another medical professional, medical device, or drug could jeopardize routine business practices followed by the healthcare industry across the country, to the detriment of patients benefiting from these innocuous practices.



Kara Silverman



Kelsey O’Neil

Kara Silverman is a partner at Arnall Golden Gregory LLP. Both focus their practices on government investigations and litigation, particularly in healthcare law. Kelsey O’Neill is a litigation law clerk at Arnall Golden Gregory LLP. They can be reached at kara.silverman@agg.com and Kelsey.ONeill@agg.com

¹⁴ Id. at *5.

¹⁵ Id. at *11.

¹⁶ Id.

¹⁷ Id.

¹⁸ See *Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019); *United States v. Greber*, 760 F.2d 68, 69, 72 (3d Cir. 1985); *United States v. Mallory*, 988 F.3d 730, 741 (4th Cir. 2021); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Borrasi*, 639 F.3d 774, 781-82 (7th Cir. 2011); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000).

¹⁹ “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b).

²⁰ *Camburn*, 2024 U.S. App. LEXIS 32722, at *3-5, 9, 18-19.

Are the False Claims Act **Qui Tam** Provisions Doomed? The Appointments Clause, Zafirov, and the Future of Whistleblowing

By Scott Grubman

2024: Another Record Year for Qui Tam Actions

In mid-January 2025, the United States Department of Justice (DOJ) issued its annual False Claims Act (FCA) statistics, announcing that FCA settlements and judgments had exceeded \$2.9 billion in fiscal year 2024 (which ended on September 30, 2024). This marked the 20th straight year that FCA settlements and judgments exceeded \$1 billion, and the 16th straight year that they have exceeded \$2 billion.

Notable among the DOJ's 2024 statistics – although certainly not surprising – was that 83% of the total (\$2.4 billion) was the result of whistleblower lawsuits brought under the FCA's qui tam provisions. This continued a general trend; since 2006, qui tam actions have represented the majority of annual FCA settlements and judgments every year except one. The only exception came in 2021, when the government reached a \$2.8 billion non-qui tam FCA settlement with Purdue Pharma. In fact, since 1987 (the year after the FCA's qui tam provisions were strengthened), over 70% of all FCA settlements and judgments came as a result of qui tam lawsuits.

In addition to the nearly \$3 billion recovery, the DOJ announced that fiscal year 2024 saw a record number of new qui tam filings; 979 to be exact, the highest ever. For context, prior to 2024, the highest number of new annual qui tams was 757 in 2013.

It is obvious, then, that the FCA owes its position as the government's most powerful civil tool against fraud and abuse to the nearly 17,000 whistleblowers who have filed FCA suits over the last 37 years.

The Zafirov Decision

So, in October 2024, when a federal district court judge in Tampa Florida declared the FCA's qui tam provisions unconstitutional, attorneys from across the FCA spectrum took notice. In *United States ex rel. Zafirov v. Florida Medical Associates, LLC*,¹ District Judge Kathryn Kimball Mizelle granted the defendants' motion for judgment on the pleadings and dismissed the

qui tam lawsuit, concluding that the qui tam provisions violated the Constitution's Appointments Clause.

Pursuant to the Appointments Clause of the United States Constitution, an "Officer of the United States" must be nominated by the President, subject to advice and consent of the United States Senate.² The Supreme Court of the United States has provided a two-step framework for assessing whether an individual is an "Officer of the United States": the individual "must occupy a continuing position established by law and must exercise significant authority pursuant to the laws of the United States."³

The defendants in *Zafirov* argued that because a qui tam relator holds the power to act on behalf of the United States, such a person is, by definition, an "Officer of the United States," subject to the procedure laid out in the Appointments Clause. And because qui tam relators are not appointed pursuant to this constitutionally mandated procedure, the defendants argued, the FCA's qui tam provisions are unconstitutional.

The Broader Legal Landscape

The defendants in *Zafirov* were not the first to make this argument, and Judge Mizelle was not the first federal jurist to accept it, although she was the first to do so outside of a dissenting opinion. In 2023, the same argument was adopted by Justice Clarence Thomas in his dissenting opinion in *United States ex rel. Polansky v. Executive Health Resources, Inc.*,⁴ where Justice Thomas explained why he believed that the qui tam provisions were constitutionally suspect under the Appointments Clause and seemingly invited FCA defense lawyers to tee up that issue. Two other Justices – Kavanaugh and Barrett – joined Justice Thomas in this view.

FCA defense lawyers from across the country took

Justice Thomas up on his invitation and began filing motions to dismiss various pending qui tam actions based on the Appointments Clause. Although Judge Mizelle (who had previously clerked for Justice Thomas) was the first district court judge to accept the argument, she was not the first to address it post-Polansky. In fact, just two weeks before Judge Mizelle issued her decision in *Zafirov*, District Judge Donald Middlebrooks of the Southern District of Florida issued a decision in *United States ex rel. Butler v. Shikara*,⁵ rejecting the same argument and holding that “it would be difficult to justify reaching the opposite conclusion from the very Framers themselves.” Similarly, just a few months after Justice Thomas issued his dissenting opinion in *Polansky*, District Judge Scott Coogler of the Northern District of Alabama issued a decision in *United States ex rel. Wallace v. Exactech, Inc.*,⁶ also rejecting the constitutional argument and finding that a qui tam relator is not an “Officer of the United States” because a qui tam relator’s position is “temporary and exist[s] only for the duration of a particular lawsuit.”

And although the Eleventh Circuit – in which all of the above-referenced district courts reside – has not yet ruled on this issue, various other circuit courts (specifically the 5th, 6th, 9th, and 10th Circuits) have, all of them holding that the qui tam provisions pass Article II muster.⁷ The Second Circuit does not appear to have addressed this exact issue, but did reject a similar Article III challenge to the qui tam provisions in 1993.⁸

The DOJ and the “Father of the Modern FCA” Chime In

In the aftermath of Judge Mizell’s decision in *Zafirov*, numerous stakeholders have filed position briefs in the Eleventh Circuit Court of Appeals, where the case is now pending. On January 6, 2025, the DOJ filed its brief, urging the Eleventh Circuit to reverse the district court’s dismissal. In its brief, the government cited the cases mentioned above, stating that “[e]very court of appeals to have addressed the question has held that the False Claims Act’s qui tam provisions are consistent with Article II, including the Appointments clause.” And, the government states, “[s]o has every other district court that has addressed the question, including within this Circuit.”

In support of its argument, the government argues that qui tam relators do not exercise executive power when they sue under the FCA, but instead “are pursuing a private interest in the money they will obtain if their suit prevails.” The government also points to the history of qui tam provisions in general, noting that such provisions find their origins in common law England. This, the government argues, is evidence that the Framers would have been familiar with and accepted laws which, like the FCA, “provided both a bounty and an express cause of action.” The government also argues that Judge Mizelle erred because the Appointments Clause applies only to government officeholders, not private citizens such as qui tam relators; relators do not exercise “significant government authority”; and relators do not “occupy a continuing position established by law.”

Iowa Senator Chuck Grassley – often known as the “father” of the modern day (i.e., post-1986 amendments) FCA – also filed an amicus brief. Senator Grassley’s brief goes through a history of the FCA – from its origins in 1863 when it was passed “to deter and punish war profiteers who defrauded the Union Army during the Civil War,” through the modern era, where Senator Grassley’s sponsored amendments strengthened the FCA and turned it into the fraud-fighting tool that it is today. According to Senator Grassley, “[t]he FCA is the flagship anti-fraud statute, standing for over a century and a half. There is no reason, legal or otherwise, to undo it now.”

In fact, the fallout from Judge Mizelle’s decision in *Zafirov* even found its way into the confirmation hearings for Pam Bondi, who was nominated by Donald Trump to serve as 87th Attorney General of the United States. During Bondi’s confirmation hearing on January 15, Senator Grassley – who chairs the Judiciary Committee – questioned her about her commitment to FCA enforcement and to defending the FCA from constitutional attacks. Bondi responded that she understood the importance that FCA whistleblowers play in recovering money for the United States, and assured Senator Grassley that she would defend the constitutionality of the FCA. Senator Grassley took to social media platform X (formerly Twitter) soon thereafter, giving Bondi his support, expressly noting that he was “glad [to] hear her commit to defending the constitutionality of the False Claims Act.”

What's Next? Will the Qui Tam Provisions Survive?

So, what happens next to the FCA's qui tam provisions? Although Judge Mizelle's decision in *Zafirov* currently represents the sole exception to the overwhelming majority of federal courts upholding the constitutionality of the FCA's qui tam provisions, we know that at least 3 Supreme Court Justices agree with Judge Mizelle and would presumably uphold her decision if given the opportunity. Whether the Supreme Court ever decides to take the case or another one that presents the same issue and, if it ever does, whether Justices Thomas, Kavanaugh, and Barrett, will find two more Justices to join their position, remains unseen. What is certain, however, is that if the FCA's qui tam provisions are, indeed, deemed unconstitutional by a higher court, billions of dollars in annual FCA recoveries will be eliminated, at least until Congress can find a

- 1 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024).
- 2 U.S. Const. art. II, § 2, cl. 2.
- 3 *Lucia v. Sec. & Exch. Comm'n*, 138 S. Ct. 2044, 2047 (2018) (cleaned up, internal citations omitted) (emphasis added).
- 4 599 U.S. 419, 449 (2023) (Thomas, J., dissenting).
- 5 2024 WL 4354807 (S.D. Fla. Sept. 6, 2024).
- 6 703 F. Supp. 3d 1356 (N.D. Al. 2023).
- 7 See *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001), *United States ex rel. Taxpayers Against Fraud v. General Electric Co.*, 41 F.3d 1032 (6th Cir. 1994), *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743 (9th Cir. 1993), and *United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787 (10th Cir. 2002).
- 8 *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148 (2d Cir. 1993).



Scott Grubman

Scott Grubman is a partner with the law firm of Chilivis Grubman, where he represents business and individuals in connection with False Claims Act investigations and litigation. He also serves as an Adjunct Professor of Law at Georgia State University School of Law, where he co-teaches a course on healthcare fraud and abuse. He can be reached at sgrubman@cglawfirm.com.



Find your people.

Georgia Lawyers Helping Lawyers (LHL) is a confidential peer-to-peer program that provides colleagues who are suffering from stress, depression, addiction or other personal issues in their lives, with a fellow Bar member to be there, listen and help.

If you are looking for a peer or are interested in being a peer volunteer, visit www.GeorgiaLHL.org for more information.

**GEORGIA
LAWYERS
HELPING
LAWYERS**



Scenes from 2024 Advanced Health Law Seminar



(L to R) Rajesh Shah (McKinsey & Company), Hon. Keith R. Blackwell (Alston & Bird), Robert Brennan (Parker Hudson Rainer & Dobbs).



(L to R) Scott Grubman (Chilivis Grubman), Anthony DeCinque (U.S. Attorney's Office), Lynn M. Adam (Adam Law), Aaron M. Danzig (Arnall Golden Gregory)



(L to R) Valerie Rock (PYA), Daniel J. Felz (Alston & Bird)



(L to R) Dr. Anjali Deshmukh (GSU College of Law), Rachel King (Health Law Strategists)