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First Circuit Requires But-For Causation for FCA Liability Based on AKS Violations

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Key Takeaways

- The First Circuit ruled in *United States v. Regeneron Pharmaceuticals, Inc.*, that the government must prove but-for causation to establish False Claims Act (FCA) liability based on violations of the Anti-Kickback Statute (AKS).
- This decision aligns with the Sixth and Eighth Circuits while rejecting the Third Circuit's more lenient standard, which allowed claims to be deemed false even if an AKS violation had no actual impact on provider decision-making.
- The ruling raises the bar for FCA enforcement, making it harder for the government and whistleblowers to establish liability for claims that merely followed an alleged kickback.

The First Circuit's Ruling in *Regeneron*

In *Regeneron*, the government alleged that the company violated the AKS by covering patient copayments through a charitable foundation, thereby inducing physicians to prescribe Eylea. The government argued that any Medicare claims for Eylea that followed these payments were false under the FCA, regardless of whether the alleged kickback actually influenced a physician's prescribing decision.

Regeneron countered that a claim is only "false" under the FCA if an AKS violation actually caused the submission of the claim – meaning the claim would not have been submitted but for the kickback. The First Circuit agreed with Regeneron, ruling that the phrase "resulting from" in the FCA's 2010 amendment to the AKS imposes a but-for causation requirement.

The court relied on Supreme Court precedent in *Burrage v. United States*, which interpreted similar statutory language as requiring actual causality rather than a mere association between events. Applying this reasoning, the First Circuit rejected the government's argument that a claim could be deemed false solely because it followed an AKS violation. Instead, the government must prove that the alleged kickback was the determining factor in the claim's submission.

This ruling removes a powerful tool the government and whistleblowers previously used in FCA litigation – the broad "tainted claim" theory – which presumed FCA liability whenever a claim followed a financial incentive, regardless of whether that incentive actually influenced the provider's decision-making.

The First Circuit's Alignment With the Sixth and Eighth Circuits – And Its Rejection of the Third Circuit's Standard

The First Circuit's ruling in *Regeneron* joins a growing consensus among appellate courts in favor of requiring but-for causation in FCA cases based on AKS violations. The Sixth Circuit, in *United States ex rel. Martin v. Hathaway*, and the Eighth Circuit, in *United States ex rel. Cairns v. D.S. Medical LLC*, both held that an FCA claim is only false if an AKS violation directly caused the submission of a claim.

These decisions contrast sharply with the Third Circuit's ruling in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.* (2018), which held that an AKS violation tainted all claims that followed, even if the kickback had no effect on provider decision-making. The *Greenfield* standard effectively allowed the government to establish FCA liability without proving that the alleged unlawful payment had any actual impact on the claims process.

By siding with the Sixth and Eighth Circuits, the First Circuit has reinforced a stricter standard that requires the government to prove a direct link between an AKS violation and a claim submission. This shift narrows the scope of FCA liability and makes it harder to bring cases based on speculative theories of causation.

Implications for Health Care and Life Sciences Companies

The First Circuit's decision significantly raises the burden for the government and whistleblowers in FCA cases based on AKS violations. This ruling reinforces stricter standards for proving causation and will have broad implications for health care and life sciences companies.

1. Increased Difficulty for FCA Enforcement and Whistleblower Claims

With the First Circuit now requiring but-for causation, it will become increasingly difficult for the government and whistleblowers to establish FCA liability based on financial arrangements that do not clearly result in improper claims. This shift is particularly significant for pharmaceutical manufacturers, medical device companies, and health care providers that offer financial incentives or discounts in compliance with industry norms. The government will no longer be able to rely on broad "tainted claim" theories that presume FCA liability whenever a claim follows an AKS violation; instead, it will need to demonstrate that a kickback directly caused a provider to submit a claim. Similarly, whistleblowers bringing qui tam actions will face higher hurdles in proving that a defendant knowingly engaged in unlawful conduct rather than merely structuring business arrangements in a way that could be interpreted as financially beneficial to providers.

2. Deepening Circuit Split and the Likelihood of Supreme Court Review

The First Circuit's ruling in *Regeneron* aligns with the Sixth and Eighth Circuits, which have adopted a stricter interpretation of the FCA's connection to AKS violations. However, the Third Circuit continues to apply a more lenient standard that allows for FCA liability even in cases where an AKS violation had no demonstrable impact on a provider's prescribing or purchasing decisions. This growing division among the circuits makes it increasingly likely that the Supreme Court will be asked to resolve the issue. If the Court grants certiorari, its ruling could reshape the landscape of FCA enforcement, either reinforcing the trend toward a higher burden of proof or restoring a more flexible standard that favors government enforcement efforts. Until such a ruling is issued, companies operating in multiple jurisdictions must be aware of the different standards applied by courts and adjust their compliance strategies accordingly.

3. Importance of Compliance Programs and Safe Harbor Protections

Given the heightened standard for FCA liability, compliance programs will play an even more critical role in mitigating risk. Companies should ensure that their financial arrangements with providers and third parties are structured to comply with AKS safe harbors and that all incentives offered can be justified by legitimate business purposes. The Department of Health and Human Services (HHS) has established more than 35 safe

harbors that exempt certain financial relationships from AKS liability, and organizations should regularly review these protections to determine whether their arrangements fall within them. Advisory opinions from HHS can also provide valuable guidance in navigating complex compliance issues. By proactively aligning their practices with regulatory guidance, companies can not only reduce the risk of FCA liability but also strengthen their ability to defend against future enforcement actions.

4. Proactive Risk Management in Business Transactions

The First Circuit decision highlights the need for health care and life sciences companies to take a proactive approach to managing regulatory risk. Organizations should carefully assess the structure of their financial relationships with providers, vendors, and third parties to ensure that they avoid even the appearance of improper inducements. This includes conducting internal audits, reviewing contractual arrangements, and ensuring that any discounts, rebates, or financial incentives comply with AKS requirements. Training programs for sales and marketing teams should emphasize the importance of structuring business transactions in ways that avoid any suggestion of improper intent. In addition, internal documentation should clearly reflect legitimate business justifications for financial arrangements, which can serve as a critical defense if a company's practices are later questioned in an FCA investigation. By taking these proactive steps, companies can position themselves to comply with the evolving legal landscape while continuing to operate effectively in the health care marketplace.

Conclusion

The First Circuit's decision in *Regeneron* marks a significant shift toward a stricter standard in FCA cases based on AKS violations. By requiring *but-for causation*, the ruling limits the government's ability to impose liability based on broad "tainted claim" theories.

With a growing split between circuits, a Supreme Court review now seems inevitable. In the meantime, health care and life sciences companies should continue to prioritize AKS compliance and proactively manage regulatory risks to protect against potential FCA liability.

For more information on how this decision impacts your organization, please contact our [Government Enforcement and Investigations](#) team and our [Health Care and Life Sciences Litigation](#) team.