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Recent Decisions and DOJ Policy Announcements Signal Key Changes to FCA Enforcement and Litigation Environment

INTRODUCTION

Recent legal and political False Claims Act ("FCA") developments signal a potentially turbulent time for the defense of investigations and lawsuits brought under the FCA.

From the recent Supreme Court holding in *Wisconsin Bell, Inc. v. United States ex rel. Heath*,[i] ruling that a reimbursement paid by a private corporation may constitute a "claim" for purposes of the FCA when the Government has contributed a portion of the funding at issue, to the First Circuit's opinion in *United States v. Regeneron Pharmaceuticals, Inc.*,[ii] deepening the existing circuit split over the standard of causation in FCA cases based on alleged Anti-Kickback Statute ("AKS") violations, we saw significant judicial action in the month of February alone. Moreover, further review of the constitutionality of the *qui tam* provision is imminent with the Eleventh Circuit's consideration of an appeal from the Middle District of Florida in *United States ex rel. Zafirov v. Florida Medical Associates*,[iii] in which a district judge granted dismissal on the pleadings on the grounds that the FCA's *qui tam* provisions violate Article II of the Constitution's Appointments Clause.

At the same time, the first weeks of the new Trump Administration brought a flurry of moves with implications for FCA enforcement. Unlike its treatment of some other statutes (such as the Foreign Corrupt Practices Act), FCA enforcement is expected to remain a top priority for DOJ; Deputy Assistant Attorney General Michael Granston recently stated, "the [D]epartment plans to continue to aggressively enforce the False Claims Act."[iv] At the same time, FCA enforcement is not

necessarily going to continue without change. Instead, the Trump Administration has signaled its desire to employ the FCA to advance its policy objectives, prioritizing areas such as international trade and diversity, equity, and inclusion ("DEI") for increased FCA enforcement.

While any of these developments would have a significant impact, taken together, these changes underscore the need for companies and counsel to be more proactive than ever in charting the evolving FCA landscape to effectively manage risk and defend investigations and litigation.

WISCONSIN BELL: DEFINING "CLAIMS"

On February 21, 2025, the U.S. Supreme Court decided *Wisconsin Bell, Inc. v. United States ex rel. Heath*, holding that a *qui tam* relator may sue a telecommunications provider under the FCA based on allegations that the provider defrauded the Education Rate (E-Rate) Program by overcharging schools and receiving reimbursement rates higher than the program should have paid. The Court ruled that the reimbursements at issue were "claims" under the FCA because the Government contributed a portion of money to the fund.[v]

The E-Rate fund was established under the Telecommunications Act of 1996 to subsidize internet and other telecommunications services for schools and libraries. Although Congress requires carriers to pay into the fund, it is administered by a private corporation. The relator, a telecommunications auditing consultant,[vi] alleged that Wisconsin Bell defrauded the E-Rate program by overcharging the fund and violating the fair pricing rules set by the program.[vii]

Writing for a unanimous Court, Justice Kagan focused on whether the Government "provided," in its ordinary meaning, the money in question.[viii] Because the Treasury transferred $100 million into the fund, consisting of carriers' delinquent contributions to the fund collected by the FCC and Treasury, as well as civil settlements and criminal restitution payments from the Justice Department, the Government "provided [a] portion of the money" disbursed from the fund.[ix] For that reason, the Court concluded that the reimbursements were "claims" under 31 U.S.C. §3729(a)(1)(A).[x]

The Court's holding was narrower than the Seventh Circuit's conclusion on appeal. The Court's opinion did not address the Court of Appeals' broad "collection and distribution theory," which held that the Government effectively provided all the money in the program through its regulatory and administrative role by requiring private parties to put money into the program. The Court left undecided whether collection and distribution alone would be sufficient to constitute an FCA claim. In his concurrence, Justice Thomas noted that this interpretation could expand the scope of FCA liability to include payments between private parties, such as fraudulent child support payments.[xi] It is likely this question will be brought in other districts and circuits.

Despite the unanimous opinion in *Wisconsin Bell*, Justice Kavanaugh wrote a single paragraph concurrence, joined by Justice Thomas, stating that "[t]he [FCA's] *qui tam* provisions raise substantial constitutional questions under Article II" and that "in an appropriate case, the Court should consider the competing arguments on the Article II issue."[xii] (internal citations omitted) The concurrence reiterates Justice Kavanaugh's concurrence and Justice Thomas's dissent in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023).[xiii] In *Polansky*, the eight-Justice majority held that the FCA gave the Government the authority to dismiss a *qui tam* suit over a relator's objection. But Justice Thomas's dissenting opinion in *Polansky* asserted that *qui tam* suits violate Article II by assigning to relators an executive function which should only be carried out by individuals appointed as "Officers of the United States," a question which was not otherwise addressed by the case.[xiv] Justices Kavanaugh and Barrett agreed with Justice Thomas's argument in a separate concurrence. Justice Kavanaugh's *Wisconsin Bell*

concurrence reiterates his previously stated view that the constitutionality of *qui tam* provisions is an important question for future consideration.

We may soon see this question before the Court, as *United States ex rel. Zafirov v. Florida Medical Associates* is before the Eleventh Circuit. In *Zafirov*, Judge Kathryn Kimball Mizelle of the Middle District of Florida held in September 2024 that the *qui tam* provision of the FCA was unconstitutional because it violated the Constitution's Appointments Clause.[xv] Closely tracking Justice Thomas's 2023 *Polansky* dissent, Judge Mizelle's opinion held that the FCA relator was an "Officer of the United States" who had not been properly appointed in accordance with Article II requirements.[xvi] The Government and the relator both appealed, and oral argument before the Eleventh Circuit will likely occur later in 2025. While Judge Mizelle's ruling was a first-of-its-kind outlier among the federal district courts, this argument is now available for assertion by FCA defendants in other jurisdictions—particularly in cases in which the Government declined to intervene and private relators are proceeding to litigate on their own.[xvii] The case lays the groundwork for potential review of the constitutionality of the *qui tam* provisions by the Supreme Court. With Justices Thomas, Kavanaugh, and Barrett having expressed sympathy with the conclusion reached by Judge Mizelle, only one more Justice would have to agree that review of the issue was appropriate for the Court to take it up on certiorari in the *Zafirov* case or in a future case.[xviii]

Against this legal backdrop, during Attorney General Pam Bondi's Senate confirmation hearing, Senate Judiciary Chairman Chuck Grassley (R-IA), a long-time champion for whistleblowers, asked the then-nominee if she was committed to defending the constitutionality of the FCA if confirmed.[xix] In response, Bondi said "[she] would defend the constitutionality, of course, of the False Claims Act," and noted the importance "[of] whistleblowers. . . and the protection and the money [the FCA] brings back to our country."[xx] With the Administration's overall priority of shrinking Government spending, whistleblowers may continue to be seen as important partners in identifying and investigating fraud, but much remains to be seen.

REGENERON: DEFINING CAUSATION IN THE AKS CONTEXT

On February 18, 2025, the First Circuit issued its opinion in *United States v. Regeneron Pharmaceuticals, Inc.*, holding that an FCA plaintiff must prove but-for causation to establish FCA liability based on violations of the Anti-Kickback Statute ("AKS").[xxi] The First Circuit joined the Sixth[xxii] and Eighth Circuits[xxiii] in adopting the but-for causation standard, deepening a circuit split with the Third Circuit, which rejected but-for causation and adopted a more lenient standard under which any claims following an AKS violation arguably are "tainted," irrespective of the alleged kickback's impact on the provider's decision making.[xxiv]

In *Regeneron*, the First Circuit considered allegations that the company violated the FCA by way of the AKS. In the underlying district court case, the Government alleged the company made contributions to a charitable foundation, which then provided co-pay assistance rebates to physicians, thereby inducing the providers to prescribe Regeneron's product, Eylea.[xxv] The Government alleged that the claims "resulted from" the rebates in violation of the AKS, regardless of whether the rebates were the but-for cause of the claims. Regeneron argued that the rebates could render a subsequent claim "false" for purposes of the FCA only if they were the but-for cause of providers' prescriptions of Eylea and subsequent claims for reimbursement to Medicare.[xxvi] The district court granted Regeneron's summary judgment motion but certified the issue for interlocutory review by the First Circuit Court of Appeals.[xxvii]

On appeal, the First Circuit affirmed the district court's decision. The First Circuit focused on the relevant statutory language, which was added to the AKS by amendment in 2010 and provides that "a claim that includes items or services *resulting from* a violation of [the AKS] constitutes a false or fraudulent claim" under the FCA.[xxviii] The First

Circuit, relying on Supreme Court precedent interpreting similar statutory language,[xxix] determined the plain text of the AKS required a but-for causation standard and concluded that requiring but-for causation would not defeat the purpose of the amendment to the AKS. The court rejected each of the Government's textual and contextual arguments, holding that there was no convincing reason to deviate from the "but-for" causation standard.[xxx] For example, the court was unconvinced by the Government's argument that "prov[ing] why a doctor prescribed a particular drug" can "sometimes be difficult" counseled in favor of a lowered causation standard, noting that other elements of the FCA are also difficult to prove, like scienter.[xxxi]

The First Circuit notably left open the application of a "false certification" theory of falsity under the FCA. The falsity theory at issue on appeal relied on the "resulting from" statutory language. In dicta, the First Circuit suggested that a claim could be false within the meaning of the FCA if it falsely certifies compliance with the AKS even if the claim did not "result from" the alleged AKS violation, because FCA claims relying on a false certification theory "run on a separate track."[xxxii] Of course, if a claim certifies that it does not result from an AKS violation, then there is no daylight between the statutory "resulting from" theory of falsity and a "false certification" theory of falsity – the certification is not false if the claim would have been submitted anyway regardless of the alleged AKS violation. The Government and relators, however, may argue that the submission of a claim should be deemed to convey a broader certification regarding the AKS. Defendants may have strong arguments against reading nonexistent "implied" certifications into claims that are truthful. In addition, while most courts treat claims that "result from" an AKS violation as satisfying the FCA's materiality requirement without separate analysis, defendants may have strong arguments that broader certifications, whether express or "implied," that go beyond whether the claim results from an AKS violation are immaterial.

The Supreme Court denied certiorari when the relator sought review of the Sixth Circuit's 2023 *United States ex rel. Martin v. Hathaway* decision which also held that the "resulting from" statute required but-for causation. But it is possible that the Government could seek the Court's review of the First Circuit's decision.[xxxiii]

TRUMP ADMINISTRATION ANNOUNCEMENTS: UTILIZING THE FCA TO ADVANCE POLICY PRIORITIES

In addition to the significant legal developments described above, the Trump Administration appears to be taking actions that may shift the FCA enforcement and defense landscape. The Trump Administration, including DOJ officials, have committed to "root[ing] out waste, fraud and abuse . . . consistent with the new Administration's stated focus on achieving Governmental efficiency." [xxxiv] We expect aggressive and active FCA enforcement in sectors like life sciences, healthcare and the defense industry. We do not expect the plaintiff's bar to let up on the investigation and filing of *qui tam* FCA complaints unless the relator provision *Zafirov* is struck down by the Supreme Court. Furthermore, with Senator Grassley (R. Iowa) as Chairman of the Senate Judiciary Committee, we can expect DOJ nominees and appointees to be held to commit to FCA enforcement going forward. Beyond traditional areas for enforcement, we also may see more FCA actions tied to the Administration's priorities, including:

1. **Enforcement Focus on Tariffs**: DOJ is expected to make "illegal foreign trade practices" a key focus of FCA enforcement. In his prepared remarks before the Federal Bar Association's annual *qui tam* conference on February 20, 2025, Deputy Assistant Attorney General Michael Granston noted "[y]ou can expect the Department to continue to use the False Claims Act to enforce these trade laws." Since returning to office, President Trump signed Executive Orders ("EOs") initiating tariffs against Mexico, Canada, and China,[xxxv] as well as a presidential proclamation reviving Section 232 tariffs against all countries on aluminum and steel.[xxxvi] Though the tariffs against Canada and Mexico have been subject to multiple stops and starts, subject to rapid (and even daily) change this past week alone, President Trump has committed to imposing tariffs across industries, including

automobiles and semiconductors.[xxxvii] Companies importing goods can expect DOJ to aggressively use reverse false claims theories under the FCA to pursue allegations that importers knowingly failed to pay money that was owed to the Government in the form or tariffs, as well as increased scrutiny from whistleblowers.

2. **Prohibition on Sub-Regulatory Guidance**: AG Bondi's memorandum, "*Reinstating the Prohibition on Improper Guidance Documents*"[xxxviii] expressly withdrew former Attorney General Merrick Garland's "*Issuance and Use of Guidance Documents by the Department of Justice*" memorandum.[xxxix] AG Bondi's memorandum explains DOJ's stance that "[g]uidance documents violate the law when they are issued without undergoing the rulemaking process established by law yet purport to have a direct effect on the rights and obligations of private parties governed by the agency or otherwise act as a substitute for rulemaking."[xl] The memorandum does not, however, clarify whether guidance can be used to establish scienter in FCA cases. The U.S. or relators often attempt to establish scienter by showing an FCA defendant had knowledge of agency guidance. Even in the first Trump Administration, Associate Attorney General Rachel Brand issued a memo permitting the use of guidance documents in a limited set of "proper purposes" and instructed "the Department may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate."[xli] However, in 2024, the Supreme Court held in *Loper Bright Enterprises v. Raimondo* that agency interpretation of laws are not entitled to deference unless clearly established by statute. The ruling may require Bondi's memo to be implemented even more narrowly than the Session and Brand policies from the previous Administration.[xlii] However, Bondi's DOJ may provide further clarification yet, since the memorandum directs the Associate Attorney General (the third-highest ranking official within DOJ) to report on "strategies and measures that can be utilized to eliminate the illegal or improper use of guidance documents," within 30 days.[xliii]

3. **Potential FCA Liability for DEI Programs**: On January 21, 2025, President Trump issued EO 14173, "Ending Illegal Discrimination and Restoring Merit-Based Opportunity."[xliv] The EO aims to eliminate Diversity, Equity, and Inclusion ("DEI") policies in Government agencies and companies that do business with the federal Government and makes clear that the Trump Administration intends to use the FCA to accomplish these objectives. The EO requires that all federal contracts include "a term requiring such counterparty or recipient to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws." The EO requires these contracts also include "a term requiring the contractual counterparty or grant recipient to agree that its compliance in all respects with all applicable Federal anti-discrimination laws is material to the Government's payment decisions for purposes" of the FCA. By requiring both a certification and materiality term in all future federal contracts with private companies, the Administration is setting up enforcement of its policies regarding DEI through the FCA.[xlv]

   To enforce this EO, AG Bondi issued a memorandum titled, "*Ending Illegal DEI and DEIA Discrimination and Preferences*."[xlvi] The memo directs DOJ's Civil Rights Division and Office of Legal Policy to jointly submit a report to the Associate Attorney General by March 1, 2025.[xlvii] This report must include "proposals for criminal investigations and for up to nine potential civil compliance investigations of entities that meet the criteria" of those private sector entities defined by the EO (e.g., including large non-profit corporations). The EO sets up the FCA as a tool for these investigations. Together, these actions create fertile ground for whistleblower activity given the polarizing and public nature of these potential DEI investigations.

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[i] *Wisconsin Bell, Inc. v. U.S. ex rel. Heath*, No. 23-1127, 2025 WL 567337, at *2 (U.S. Feb. 21, 2025).
[ii] *U.S. v. Regeneron Pharmas., Inc.,* No. 23-2086, 2025 WL 520466, at *1 (1st Cir. Feb. 18, 2025).
[iii] *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, No. 8:19-CV-01236-KKM-SPF, 2024 WL 4349242, at *18 (M.D. Fla. Sept. 30, 2024).
[iv] *See* Daniel Wilson, *DOJ Official Flags 'Aggressive' FCA Approach Under Trump*, LAW360 (Feb. 20, 2025), *available at* https://www.law360.com/articles/2300751/doj-official-flags-aggressive-fca-approach-under-trump.
[v] *Wisconsin Bell, Inc. v. U.S. ex rel. Heath*, No. 23-1127, 2025 WL 567337, at *2 (U.S. Feb. 21, 2025).
[vi] Heath is referred to as "a consultant who audits telecommunications bills for several school districts," in at least one lower court decision. *U.S. ex rel. Heath v. Wisconsin Bell, Inc.*, No. 08-CV-00724, 2012 WL 4128020, at *1 (E.D. Wis. Sept. 18, 2012).
[vii] Congress established that the E-Rate program would be managed and executed by the Universal Service Administrative Company. Per the E-Rate program, the Federal Communications Commission ("FCC") regulates the collection and distribution of the E-Rate funding to the beneficiaries of the program. The FCC also sets the "lowest corresponding price" rule to prohibit carriers from charging schools or libraries more than they would a similarly situated residential customer. *See* 47 C.F.R. § 54.500. In *Wisconsin Bell*, the whistleblower alleged that Wisconsin Bell overcharged schools and libraries and then sought reimbursement from the fund at that inflated rate.
[viii] *Id.* at *6.
[ix] *Id.* at *6.
[x] *Id.* at *8.
[xi] *Id.* at *11-12 (Thomas, J., concurring).
[xii] *Id.* at *13 (Kavanaugh J., concurring).
[xiii] In *Polansky*, the eight-Justice majority held that the FCA gave the Government the authority to dismiss a relator's *qui tam* suit.
[xiv] U.S. CONST. art. II, § 2, cl. 2.
[xv] *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, No. 8:19-CV-01236-KKM-SPF, 2024 WL 4349242, at *18 (M.D. Fla. Sept. 30, 2024), *appeal docketed*, No. 24-13581 (1st Cir. Nov. 13, 2024).
[xvi] *See id.* The majority opinion in *Polansky* did not reach the issue of whether an FCA relator constituted an "Officer of the United States."
[xvii] At least one district court has already expressly disagreed with the holding in *Zafirov*. *See U.S. v. Chattanooga Hamilton Cnty. Hosp. Auth.*, No. 1:21-CV-84, 2024 WL 4784372, at *2-3 (E.D. Tenn. Nov. 7, 2024) (explaining that the Sixth Circuit has "unambiguously held that the FCA is constitutional") (citing *U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994)).
[xviii] *See Polansky*, 599 U.S. at 452 (Thomas, J., dissenting) (noting the constitutionality of the *qui tam* provision raises "complex questions, which I would leave for the parties and the court below to consider after resolving the statutory issues that have been the focus of this case up to now").
[xix] *The Nomination of the Honorable Pamela Jo Bondi to be Attorney General of the United States Before the S. Comm. on the Judiciary*, 119th Cong. (2025), *available at* https://www.judiciary.senate.gov/committee-activity/hearings/the-nomination-of-the-honorable-pamela-jo-bondi-to-be-attorney-general-of-the-united-states.
[xx] *Id.*
[xxi] *Regeneron Pharmas., Inc.*, 2025 WL 520466, at *1.
[xxii] *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023).
[xxiii] *U.S. ex rel. Cairns v. D.S. Med., LLC*, 42 F.4th 828 (8th Cir. 2022).
[xxiv] *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96-98 (3d Cir. 2018).
[xxv] *See Regeneron Pharmas., Inc.*, 2025 WL 520466, at *2.
[xxvi] *See id.* at *2.
[xxvii] *See id.* at *3.
[xxviii] 42 U.S.C. § 1320a-7b(g) (2022).
[xxix] *See Paroline v. U.S.*, 572 U.S. 434 (2014) (holding that though the statute contained the language "as a result of," which would normally impose a "but for" causation standard, that standard was inappropriate because it would defeat the purpose of the statute).
[xxx] *See Regeneron Pharmas., Inc.*, 2025 WL 520466, at *10.
[xxxi] *Regeneron Pharmas., Inc.*, 2025 WL 520466, at *9.
[xxxii] *Id.* at *8.
[xxxiii] *United States ex rel. Martin v. Hathaway*, 144 S.Ct. 224 (2023) (*cert. denied*).
[xxxiv] *See* Daniel Wilson, *DOJ Official Flags 'Aggressive' FCA Approach Under Trump*, LAW360 (Feb. 20, 2025), *available at* https://www.law360.com/articles/2300751/doj-official-flags-aggressive-fca-approach-under-trump.
[xxxv] Exec. Order No. 14,193, 90 Fed. Reg. 9113 (Feb. 1, 2025), *available at* https://www.whitehouse.gov/presidential-actions/2025/02/imposing-duties-to-address-the-flow-of-illicit-drugs-across-our-national-border/; https://www.whitehouse.gov/presidential-actions/2025/02/imposing-duties-to-address-

the-flow-of-illicit-drugs-across-our-national-border/; Exec. Order No. 14,194, 90 Fed. Reg. 9117 (Feb. 1, 2025), *available at* https://www.whitehouse.gov/presidential-actions/2025/02/imposing-duties-to-address-the-situation-at-our-southern-border/; Exec. Order No. 14,195, 90 Fed. Reg. 9121 (Feb. 1, 2025), *available at* https://www.whitehouse.gov/presidential-actions/2025/02/imposing-duties-to-address-the-synthetic-opioid-supply-chain-in-the-peoples-republic-of-china/.

[xxxvi] Proclamation No. 10896, 90 Fed. Reg. 9817 (Feb. 10, 2025), *available at* https://www.whitehouse.gov/presidential-actions/2025/02/adjusting-imports-of-steel-into-the-united-states/.

[xxxvii] John Liu & Elisabeth Buchwald, *Trump plans to impose 25% tariffs on autos, chips and pharmaceuticals*, CNNBUSINESS (Feb. 19, 2025), *available at* https://www.cnn.com/2025/02/19/economy/us-new-tariff-plans-trump-intl-hnk/index.html.

[xxxviii] *See* Memorandum of U.S. Attorney General Pamela Bondi to All Department Employees on Reinstating the Prohibition on Improper Guidance Documents (Feb. 5, 2025), *available at* https://www.justice.gov/ag/media/1388511/dl?inline.

[xxxix] *See* Memorandum of U.S. Attorney General Merrick Garland to Heads of All Department Components on Issuance and Use of Guidance Documents by the Department of Justice (July 1, 2021), *available at* https://www.justice.gov/d9/2022-12/attorney_general_memorandum_-_issuance_and_use_of_guidance_documents_by_the_doj712021.pdf.

[xl] *See* Memorandum of U.S. Attorney General Pamela Bondi to All Department Employees on Reinstating the Prohibition on Improper Guidance Documents (Feb. 5, 2025), *available at* https://www.justice.gov/ag/media/1388511/dl?inline.

[xli] Memorandum of Associate Attorney General Rachel Brand to Heads of Civil Litigating Components, United States Attorneys, and Regulatory Reform Task Force on Limiting the Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *available at* https://www.justice.gov/archives/opa/press-release/file/1028756/dl?inline.

[xlii] *See* 603 U.S. 369 (2024).

[xliii] Memorandum of U.S. Attorney General Pamela Bondi to All Department Employees on Reinstating the Prohibition on Improper Guidance Documents (Feb. 5, 2025), *available at* https://www.justice.gov/ag/media/1388511/dl?inline.

[xliv] *See* Exec. Order No 14,173, 90 Fed. Reg. 8633 (Jan. 21, 2025).

[xlv] *But see*, *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016) (holding that "a misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment" and that "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive").

[xlvi] *See* Memorandum of U.S. Attorney General Pamela Bondi to All Department Employees on Ending Illegal DEI and DEIA Discrimination and Preferences (Feb. 5, 2025), *available at* https://www.justice.gov/ag/media/1388501/dl?inline.

[xlvii] At the time of publication, this report has not yet been publicly released.

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