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DOJ Hints at Broad Potential AKS Liability for Commission-Based Contractor Sales Relationships

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This year the Fourth Circuit Court of Appeals affirmed a Department of Justice ("DOJ") victory in a False Claims Act ("FCA") case predicated on commission-based sales contracts found to have violated the Anti-Kickback Statute ("AKS"). More noteworthy than the panel's opinion was DOJ's press release, which broadly characterized commission-based sales force compensation arrangements unprotected by a safe harbor—standard in some sectors of the healthcare and life sciences industries—as unlawful remuneration given to "recommend" products. This stance departs from DOJ's recent practice of moderating its enforcement positions in an effort to comply with judicial recognition of First Amendment protections for truthful, non-misleading commercial speech. The pronouncement also underscores the importance of structuring commission-based sales force arrangements to comply with a safe harbor where possible.

In 2015, DOJ intervened in an FCA suit filed against a blood testing laboratory, its owner, and leadership from the lab's independent contractor sales company, BlueWave. Only the lab owner and two BlueWave executives litigated the case to conclusion. There were three theories of alleged AKS violations at issue in the case: "processing and handling" fees paid by the lab to ordering physicians, commission-based compensation paid by the lab to BlueWave for sales of the lab's blood tests, and commission-based compensation paid by BlueWave to its independent contractor sales representatives.

The AKS prohibits offering or paying remuneration "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering" any federally reimbursable item or service. AKS cases often focus on remuneration in exchange for purchases, prescriptions, or orders of reimbursable items and services, but in this case, the less frequently litigated "arranging for or recommending" language formed the crux of the government's case.

DOJ's complaint-in-intervention took aim at the lab's contract with BlueWave, which included a monthly base fee plus a percentage-based commission on revenue generated from sales in BlueWave's territory. DOJ alleged that BlueWave "arranged for and recommended that physicians order laboratory tests from" the defendant lab, and that in return for these referrals, the lab paid BlueWave increasingly large commissions. DOJ pointed out that as an independent contractor, BlueWave could not take advantage of the employee safe harbor, which protects payments made to bona fide employees, and that the personal services safe harbor was also unavailable because the arrangement failed to comply with that safe harbor's requirements that aggregate compensation be set in advance,[1] be consistent with fair market value, and not take into account the volume or value of referrals.

DOJ criticized not just the incentive compensation the lab paid to BlueWave, but also the compensation BlueWave paid to its own independent contractor sales force. Individual sales representatives received percentage-based commission payments tied to sales revenue from the lab's tests. DOJ took the position that because this compensation also "varied depending on the volume or value of the referrals the sales

representatives…arrang[ed] for or recommend[ed]," that it, too, was a further downstream violation by BlueWave and its executives of the AKS.

DOJ's complaint-in-intervention makes clear that there was more going on than simply commission-based payments that could not be safe harbored: BlueWave allegedly pushed physicians—including by promoting the lab's "processing and handling" fees as a revenue generator—to order vast amounts of medically unnecessary tests, yielding millions of dollars a year in incentive compensation. But the press release's portrayal of the AKS violations that were affirmed by the Fourth Circuit is far more generic and consistent with commonplace incentive-based compensation arrangements that can be lawfully implemented. Of the alleged AKS violations, DOJ stated: "these volume-based commissions" from the lab to BlueWave violated the AKS, because they "constituted 'remuneration' intended to induce BlueWave's sales representatives to sell as many blood tests as possible" and furthermore the AKS "prohibited BlueWave from paying its salespeople for recommending the tests."[2]

These descriptions in the press release are wholly inconsistent with the nuanced, facts-and-circumstances analysis that the Department of Health and Human Services Office of Inspector General ("OIG") has articulated when assessing the legality of sales force compensation arrangements that do not satisfy a safe harbor. OIG has identified certain "suspect characteristics" that "appear to be associated with an increased potential for program abuse," including "compensation based on percentage of sales," direct billing of federal healthcare programs by the seller, "direct contact between" the seller's sales agents and federal healthcare program beneficiaries or physicians who can order the seller's items, and use of sales agents who are healthcare professionals (i.e., so-called "white coat marketing").[3] OIG explained that it will subject arrangements to greater scrutiny when more factors are present, but that a violation of the AKS is still contingent on the requisite intent to induce referrals. In other words, contrary to the impression one might glean from DOJ's press release, OIG's position is that arrangements under which independent contractors receive a commission to sell, and thus recommend, federally reimbursable products are not necessarily unlawful. But while the underlying BlueWave case is indeed consistent with many of OIG's "suspect" factors, DOJ's description of the misconduct adopts a much blunter approach than OIG's more nuanced framework of analysis.

The proposition that the AKS "prohibited BlueWave from paying its salespeople for recommending the tests" is not only overbroad but also in tension with judicial recognition in off-label promotion cases that commercial speech is protected by the First Amendment when it is truthful and not misleading. Since suffering major court losses in this context, DOJ has noticeably elected to focus its off-label promotion efforts on cases involving false and/or misleading statements about off-label uses.

Similarly, DOJ has historically exercised its enforcement discretion under the AKS in a way that steers clear of potential First Amendment battles over truthful speech that recommends products. Accordingly, the government has primarily expressed concern over "white coat marketing" by physicians to patients, implying that it can be misleading because patients in these circumstances "may have difficulty distinguishing between professional medical advice and a commercial sales pitch."[4] Notably, First Amendment defenses were not presented to or resolved by the Fourth Circuit.

DOJ's press release presents a troubling departure from past practice and suggests that the government may become more interested in scrutinizing financial arrangements between providers and life sciences companies and their independent contractor sales personnel. To avoid getting caught flat-footed by a shift in enforcement discretion, companies should review their sales force compensation arrangements and ensure that, where possible, they are in compliance with the employee or personal services safe harbors. Where that is not possible, it is more important than ever to confirm that compliance guardrails are in place to ensure the compensation arrangement does not

appear to be inducing medically unnecessary sales, and that the sales representatives' statements are truthful and not misleading.

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[1] This safe harbor element was amended effective January 2021 to require only that the methodology for determining the compensation be set in advance. See 85 Fed. Reg. 77,684, 77,839 (Dec. 2, 2020).
[2] Press Release, DOJ, Fourth Circuit Court of Appeals Affirms $114 Million Judgment Against 3 Defendants Found Liable of Defrauding Medicare and Tricare (Mar. 8, 2021), **https://www.justice.gov/usao-sc/pr/fourth-circuit-court-appeals-affirms-114-million-judgment-against-3-defendants-found**.
[3] OIG, Advisory Op. No. 99-33 (Mar. 1993), **https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm**.
[4] See, e.g., OIG, Advisory Op. No. 11-08 (June 14, 2011), **https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/advopn11-08.pdf**.

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