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Client Alert

White Collar Defense

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Two False Claims Act Cases From SDNY Highlight Continuing Bite of Aggressive Healthcare Enforcement

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The U.S. Attorney's Office for the Southern District of New York last week announced the resolution of two significant False Claims Act (FCA) cases—one from a large settlement and the other the result of a jury verdict after trial. As is often the case, both results are cautionary tales: first, because they included damages and penalties totaling hundreds of millions of dollars; and second, because they reflect the Department of Justice's (DOJ) continued enforcement of healthcare cases under the FCA.

One takeaway from the two cases is that DOJ appears to be making good on its promise to continue vigorous healthcare enforcement under the FCA. We had forecasted as much before the current administration took over, and DOJ publicly vowed in February to continue pursuing these kinds of cases. We expect vigorous health care enforcement to continue despite an otherwise uncertain white-collar enforcement landscape.

United States ex rel. Bassan v. Omnicare, Inc.

FCA cases, particularly those that arise from its whistleblower provisions (known as qui tam actions), are often resolved through negotiated settlements between the government and the defendant. This happens principally because the government can leverage the statute's treble (triple) damages provision to extract favorable settlements. Because of the possibility of such steep penalties, FCA cases rarely proceed to trial.

But that happened just last week, and the defendants—Omnicare, Inc. (Omnicare), and its parent, CVS Health Corporation (CVS Health)—paid the price, at least for now. Following a four-week trial, the jury found Omnicare liable for fraudulently dispensing drugs without valid prescriptions to elderly and disabled individuals in assisted-living and other residential long-term care facilities in violation of the FCA.[1] The Government had alleged that Omnicare had dispensed these medications over eight years by automatically assigning new prescription numbers, authorizing refills or dates to invalid prescriptions, and periodically refilling medications in bulk without confirming that the prescriptions were medically necessary and authorized by a physician.[2] The jury ultimately found that Omnicare billed Medicare, Medicaid, and TRICARE (health insurance for the military) for over three million false claims based on these invalid prescriptions.[3] CVS Health was found liable as Omnicare's parent for causing Omnicare to submit the false claims.[4]

The jury found $135,592,814 in damages.[5] As mentioned above, that amount is trebled under the FCA, meaning Omnicare is currently on the hook for up to $406,778,442.[6] The damages verdict represents one of the largest ever after trial in an FCA case.[7] On top of that, the court can assess statutory penalties,[8] which can amount to between a minimum of $14,308 and a maximum of $28,619 per claim.[9]

Both Omnicare and CVS Health can still appeal. And CVS Health might succeed sooner rather than later in vacating the jury's award because U.S. District Judge Colleen McMahon has left pending CVS Health's motion for a directed verdict. Judge McMahon previously said that she "believe[d] there [was] ample evidence to support a reasonable jury's finding that CVS Health Corp. did ***not*** directly participate in Omnicare's submission of false claims," before opting to allow the jury to have the initial word.[10] And in previously denying summary judgment to CVS Health, Judge McMahon noted that she would "not hesitate to grant" a motion for a directed verdict "if the Government does not meet its burden of proving that CVS Health, a holding company, participated in the scheme alleged against its subsidiary Omnicare."[11]

United States ex rel. Bellman v. Gilead Sciences, Inc.

Also last week, DOJ announced that the Government and Gilead Sciences, Inc. (Gilead), had agreed to resolve claims that Gilead offered and paid kickbacks to healthcare practitioners who spoke at or attended Gilead speaker events to induce them to prescribe Gilead's HIV/AIDS drugs.[12] The scheme violated the Anti-Kickback Statute (AKS) and thereby resulted in the submission of false claims for the drugs to federal healthcare programs in violation of the FCA.[13] Under the settlement, Gilead agreed to pay $202 million, with over $176 million to be paid to the United States and the remainder to various states.[14]

The settlement agreement lays bare some egregious examples of Gilead's speaker program. For example, Gilead admitted that, from 2011 to 2017, it held over 17,300 speaker programs for which it engaged 548 healthcare providers involved in the treatment of HIV to present on Gilead's HIV drugs or a topic concerning HIV.[15] Those speakers were often identified by sales representatives—not for their teaching skills or knowledge of the product but because they were high prescribers.[16] Gilead paid more than $23.7 million in honoraria payments to speakers, and 60 such speakers each received over $100,000 in payments.[17] Indeed, one speaker, who received over $300,000 in speaking fees, wrote prescriptions for Gilead's HIV drugs that resulted in $6 million in payments from Medicare, Medicaid, and TRICARE.[18]

The speaker programs also took place at fancy restaurants across the country, and Gilead often paid for travel for practitioners from distant locations.[19] Making matters worse, high-prescribing practitioners attended multiple Gilead programs on the exact same topics, often within a short period of time. For example, over 250 prescribers of Gilead HIV drugs attended speaker programs on the same topic three or more times within a six-month period.[20] One nurse practitioner in New York City attended 75 HIV speaker programs in total, including attending 40 such programs on the same topic three or more times within a six-month period.[21]

These kinds of abuses were the result of an ill-equipped compliance program. Indeed, as part of the resolution, Gilead admitted that its compliance program failed to prevent the kickbacks.[22] For example, before 2016, Gilead did not place any limits on repeat attendance at its speaker programs or on whether speakers could attend programs multiple times on the same topics they had already presented on.[23] Gilead also failed to monitor the data it did have on these programs. According to documents filed in the case, Gilead maintained or could access data on its speaker programs, including information about the venues, costs, and attendees.[24] Yet Gilead failed to detect the speaker program abuses relating to expensive meals, inappropriate venues, and excessive repeat attendance over an extensive period.[25] That said, the resolution here does not include an independent compliance monitor, which suggests that by the time of the resolution, Gilead had convinced DOJ that it had implemented an improved and strengthened compliance program that included sufficient internal controls to prevent these kinds of abuses in the future.

Speaker programs have long been on DOJ's radar as ripe for potential abuse. In fact, the Health and Human Services' Office of Inspector General issued a Special Fraud Alert in November 2020 highlighting the compliance risks associated with hosting programs at which high-prescribing speakers are paid to present at venues, like fancy restaurants, that are not typically conducive to educational events. (It is not surprising that Gilead's speaker program took place before this 2020 guidance was issued.) Companies should take extreme care before putting on any speaker programs and should ensure that such programs are fully vetted, approved, and closely monitored by their compliance departments.

Please reach out to the Lowenstein Sandler White Collar Defense group if you have any questions about a speaker program or other healthcare compliance issues.

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[1] Press Release, U.S. Att'y's Off. SDNY, Statement of U.S. Attorney Jay Clayton on the Verdict in U.S. v. Omnicare and CVS Health Corporation (Apr. 29, 2025), https://www.justice.gov/usao-sdny/pr/statement-us-attorney-jay-clayton-verdict-us-v-omnicare-and-cvs-health-corporation.

[2] *See United States ex rel. Bassan v. Omnicare, Inc.*, No. 15 Civ. 4179 (CM) (VF), Dkt. 17 ¶¶ 121–41, 162–73 (SDNY Dec. 17, 2019).

[3] Press Release, U.S. Att'y's Off. SDNY, Statement of U.S. Attorney Jay Clayton on the Verdict in U.S. v. Omnicare and CVS Health Corporation.

[4] *Id.*

[5] *Id.*

[6] *Id.*; 31 U.S.C. § 3729(a)(1).

[7] Press Release, U.S. Att'y's Off. SDNY, Statement of U.S. Attorney Jay Clayton on the Verdict in U.S. v. Omnicare and CVS Health Corporation.

[8] *Id.*

[9] 31 U.S.C. § 3729(a)(1) (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note, Pub. L. No. 101-410).

[10] *Omnicare, Inc.*, Dkt. 756 at 23 (SDNY Apr. 24, 2025) (emphasis added).
[11] *Omnicare, Inc.*, Dkt. 671 at 10 (SDNY Feb. 19, 2025).
[12] Press Release, U.S. Att'y's Off. SDNY, U.S. Attorney Announces $202 Million Settlement with Gilead Sciences For Using Speaker Programs to Pay Kickbacks to Doctors to Induce Them to Prescribe Gilead's Drugs (Apr. 29, 2025), https://www.justice.gov/usao-sdny/pr/us-attorney-announces-202-million-settlement-gilead-sciences-using-speaker-programs; *United States ex rel. Bellman v. Gilead Sciences, Inc.*, No. 16 Civ. 6228 (PAE), Dkt. 32 at 1–2 (SDNY Apr. 28, 2025).
[13] Press Release, U.S. Att'y's Off. SDNY, U.S. Attorney Announces $202 Million Settlement with Gilead Sciences For Using Speaker Programs to Pay Kickbacks to Doctors to Induce Them to Prescribe Gilead's Drugs; *Gilead Sciences, Inc.*, Dkt. 32 at 2.
[14] Press Release, U.S. Att'y's Off. SDNY, U.S. Attorney Announces $202 Million Settlement with Gilead Sciences For Using Speaker Programs to Pay Kickbacks to Doctors to Induce Them to Prescribe Gilead's Drugs; *Gilead Sciences, Inc.*, Dkt. 32 at 3, 6.
[15] *Gilead Sciences, Inc.*, Dkt. 32 at 3-4.
[16] *Id.* at 4.
[17] *Id.*
[18] *Id.*
[19] *Id.* at 4-5.
[20] *Id.* at 5.
[21] *Id.*
[22] *Id.* at 6.
[23] *Id.*
[24] *Id.*
[25] *Id.*

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