Supreme Court Removes 'Potent' Defense Option for Health Care Firms Accused of Fraud

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In a unanimous 9-0 vote, the Supreme Court on June 1 overturned a lower court's decision pertaining to the False Claims Act (FCA) and allegations that two large pharmacy chains overcharged the federal government for prescription medications. Experts tell AIS Health, a division of MMIT, that the ruling is significant for health insurers because the FCA disproportionately impacts the health care industry.

The Department of Justice (DOJ), for instance, said it obtained more than $2.2 billion in settlements and judgments involving fraud and false claims for the 12 months through Sept. 30, 2022. More than $1.7 billion of that total involved the health care industry.

The decision was "an unalloyed win for the government and whistleblowers in these two cases but also in future cases" and "very clearly and cleanly shut down a potentially potent defense going forward," according to Michael Podberesky, a partner and co-chair of McGuireWoods's FCA team and a former DOJ attorney. However, Jordan Kearney, a partner at Hooper, Lundy & Bookman, P.C., says that the ruling only applies to the FCA's knowledge, or scienter, requirement and not other aspects of the legislation.

The two consolidated cases — U.S. ex rel. Schutte v. SuperValu Inc. and U.S. ex rel. Proctor v. Safeway, Inc. — involve arguments over what constitutes usual and customary (U&C) drug prices that pharmacies report to the government for reimbursement. The whistleblowers alleged that the pharmacies were overcharging Medicare and Medicaid with U&C prices that they offer to people without insurance when they should have been setting U&C prices based on the lower, discounted prices that the pharmacies often charge customers to match competitors' prices. For instance, they said that after Walmart in 2006 began offering 30-day supplies for many generic drugs, SuperValu and Safeway matched those prices for individuals but still charged Medicare and Medicaid the higher, non-discounted prices.

Kearney says the government contended that Safeway and SuperValu "knew [the U&C prices they submitted for reimbursement] were wrong, they did it anyway, and after the fact they said, 'Well, a reasonable person could have thought that this was OK.'" She notes the lower court ruled in the pharmacies' favor and "said an objectively reasonable person could have been confused about what usual and customary means, therefore [the pharmacies] couldn't have had actual knowledge. But [the Supreme Court] said, 'You actually did know, so it doesn't matter that other people might not have known.'"

If the Supreme Court had ruled the other way, Podberesky says there would be many more early dismissals of cases and more favorable settlement discussions for defendants. He notes lawyers would cite the Supreme Court's decision and argue their clients did not have knowledge that what they were doing was wrong.

He adds that most FCA cases never make it to trial and are settled because defendants face major penalties if they lose. Companies or individuals that lose an FCA case are subject to so-called "treble" — or triple the government's damages — as well as up to more than $27,000 per claim. That could total tens or hundreds of millions of dollars for large health care companies that handle tens of thousands or more claims per year.

"[A decision the other way] would really strengthen defendants' hands in settlement discussions," Podberesky says. "I think it would have had a very significant impact. This case shuts that down."

JUSTICE THOMAS OVERTURNS LOWER COURTS' DECISION

Justice Clarence Thomas, writing the Supreme Court's decision, noted that "two essential elements of an FCA violation are (1) the falsity of the claim and (2) the defendant's knowledge of the claim's falsity."

The district court ruled against SuperValu on the first matter, noting that the chain was in fact overcharging the government, but Thomas wrote that "the court granted SuperValu summary judgement based on the scienter element, holding SuperValu could not have acted knowingly." The court granted Safeway summary judgment in a separate case on the same basis. The Seventh Circuit Court of Appeals affirmed the District Court's rulings.

Thomas wrote that whistleblowers can establish scienter by showing the companies knew the prices they submitted were not their U&C prices; were aware there was a substantial and unjustifiable risk that their retail prices were not their U&C prices but intentionally avoided learning whether their U&C prices were accurate; or were aware of the substantial and unjustifiable risk but still submitted the claims.

"If petitioners can make that showing, then it does not matter whether some other, objectively reasonable interpretation of usual and customary would point to a respondent's higher prices," Thomas wrote. "For scienter, it is enough if respondents believed that their claims were not accurate. We need not address any of the other factual or legal disputes involved in these cases."

RULING IMPACTS HEALTH CARE INDUSTRY

Thomas remanded both cases to the Seventh Circuit Court of Appeals, meaning judges will reconsider their earlier rulings. Kearney predicts that the cases will then get sent back to district courts and says Safeway and SuperValu are now "going to be really incentivized to try to settle" the cases.

"If they feel strongly that the assumptions that had to be made in these cases are incorrect, maybe they will litigate it," she says. "But these can be really expensive cases."

She points to a recent case in which a district court judge ruled that Precision Lens, a cataract surgery lens distributor, and its owner, Paul Ehlen, violated the False Claims Act and owed more than $487 million in damages.

As for the long-term implications of the SuperValu and Safeway cases for the health care industry, Kearney says the ruling did not have to do with other elements of the FCA such as companies or individuals acting in deliberate ignorance or reckless disregard of the truth. The Supreme Court considered if the companies "subjectively knew what they were doing was a no-no, but [regarding whether] objectively it's possible a person could have not known, does that violate the False Claims Act? That's a pretty narrow question."

Podberesky, meanwhile, says “Justice Thomas took pains in his opinion to say we’re not opining on other aspects of the case, on whether the whistleblowers’ allegations are true, whether Safeway and SuperValu actually did have knowledge that the discounted prices should have been provided. That’s all still left to be resolved.”

While the federal government and whistleblowers mostly benefited from the Supreme Court’s ruling, Podberesky notes that “there is a silver lining for defendants here. Justice Thomas in his opinion writes some pretty helpful language that the knowledge requirement is all about subjective belief. And if a defendant made a mistake and they misinterpreted an ambiguous provision, but they had an honest belief that they were doing the right thing, then they won’t have False Claims Act liability.”

He adds that defendants in future cases “can take comfort that if they’re trying to do the right thing here, then even if they ended up making a mistake and misinterpreting an ambiguous provision, they’re not going to have False Claims Act liability if they honestly believe they were doing the right thing.”

Still, hospitals, insurers and others were closely following the Supreme Court’s decision, as they are disproportionately involved in FCA issues. Podbersky estimates that the health care industry accounts for 70% to 75% of FCA cases and recoveries.

Several health insurers have had FCA cases with the government in recent years pertaining to their Medicare Advantage plans, including The Cigna Group, UnitedHealth Group and In an amicus brief filed in March, insurer trade group AHIP and the American Hospital Association argued that a ruling in the government’s position in the Safeway and SuperValu cases “would create a Wild West of ramifications for any well-intentioned and legitimate hospital or insurance provider that seeks to serve Americans in partnership with the government.”

They added that “participation in Medicare and Medicaid carries substantial risk of FCA suits, which inevitably result in expensive litigation, reputational harm, and the possibility of punitive treble damages and statutory penalties. That risk falls heavily on hospitals and health insurance providers, to the ultimate detriment of patients, enrollees, and taxpayers.”

By Tim Casey