Novartis Warping Kickback Standard In FCA Case, DOJ Says

By **Jeff Overley**

Law360 (September 19, 2018, 3:54 PM EDT) -- Novartis Pharmaceuticals Corp. has flatly "misstated the law" in its bid to escape a whistleblower's False Claims Act suit alleging illicit kickbacks aimed at boosting Medicare Part D business, the U.S. Department of Justice told a New Jersey federal court Tuesday.

In a statement of interest, the DOJ accused Novartis of baselessly asserting that discounts it provided to pharmacy benefit manager Express Scripts Inc. are immune from Anti-Kickback Statute liability because there's no evidence that they were commercially unreasonable or didn't reflect fair market value.

"As a matter of law, the AKS does not require that remuneration in the form of a discount be commercially unreasonable or inconsistent with fair market value," the DOJ said Tuesday.

The FCA suit was filed by former Novartis account director Joseph Perri, who says he was fired for attempting to stop improper discounts for multiple sclerosis drug Gilenya. Perri says that Novartis gave discounts to Express Scripts for Gilenya purchased by commercial insurance plans, and that in return, Express Scripts provided favorable coverage of Gilenya in Medicare Part D.

In a recent motion to dismiss, Novartis said the suit is doomed because Perri "has not adequately alleged that the discounts provided by Novartis were unreasonable, which is a prerequisite to establishing illegal remuneration" under the AKS.

The DOJ, which has not intervened in the case, used its statement of interest to push back forcefully against that assertion. It argued that AKS liability is determined by examining whether "one purpose" of a payment was to drum up referrals of Medicare business.

"In the Third Circuit, remuneration is illegal under the AKS if one purpose of the remuneration was to induce referrals, regardless of whether the remuneration may have also had a legitimate purpose, such as paying fair market value for services," the DOJ wrote.

According to the statement of interest, an AKS violation is established by showing that a company knowingly made a payment with the intention of influencing referrals of Medicare patients.

"Nothing more is required," the DOJ said.

The DOJ's statement of interest offered a hypothetical example of why fair market value cannot, by itself, show that a payment was not an unlawful kickback. Under the example, a hospital selects one physician over another because the physician agrees to increase patient referrals, but still pays the physician a commercially reasonable fee.

"The transaction would still give rise to concerns about the physician gaining an unfair competitive advantage by trading on referrals and making unnecessary and excessive referrals to retain his position at the hospital," the DOJ wrote. "This goes to the very heart of what the AKS was designed to prevent."

Perri echoed the DOJ's arguments in a recent filing that opposed Novartis' motion to dismiss.

"The propriety of remuneration is dictated by its purpose, not its value," Perri said. "And where, as here, the remuneration is intended to induce Medicare referrals, fair market value cannot legitimize the payment."

In his complaint, Perri argued that "swapping" commercial discounts for Medicare Part D business has the effect of inflating Part D costs "because the savings are diverted away from the Part D plan to the commercial plan." Perri contends that Novartis was motivated to offer discounts because of the debut of a rival MS drug, Biogen Inc.'s Tecfidera.

Attorneys for Novartis did not respond to requests for comment.

The U.S. is represented by Joseph H. Hunt, Craig Carpenito, Andrew A. Caffrey III, Michael D. Granston, Jamie A. Yavelberg and Arthur S. Di Dio of the DOJ.

Novartis is represented by Philip S. May, Matthew J. O'Connor, Michael M. Maya and Patrick M. Phelan of Covington & Burling LLP.

The U.S. ex rel. Perri v. Novartis Pharmaceuticals Corp. et al., case number 2:15-cv-06547, in the U.S. District Court for the District of New Jersey.

--Editing by Aaron Pelc.

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