PRATT'S GOVERNMENT CONTRACTING LAW REPORT

VOLUME 7 **NUMBER 1** **January 2021**

LexisNexis®

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Library of Congress Card Number:

ISBN: 978-1-6328-2705-0 (print)
ISSN: 2688-7290

Cite this publication as:

[author name], [article title], [vol. no.] PRATT'S GOVERNMENT CONTRACTING LAW REPORT [page number] (LexisNexis A.S. Pratt).
Michelle E. Litteken, GAO Holds NASA Exceeded Its Discretion in Protest of FSS Task Order, 1 PRATT'S GOVERNMENT CONTRACTING LAW REPORT 30 (LexisNexis A.S. Pratt)

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MATTHEW BENDER

(2021–Pub.4938)

Editor-in-Chief, Editor & Board of Editors

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Life Sciences Enforcement Trends in 2020 and Outlook for 2021

By Sarah K. diFrancesca and Courtney M. White*

The authors of this article examine Department of Justice life sciences enforcement trends and look ahead to 2021.

Although the U.S. Department of Justice ("DOJ") reported a slight decrease in settlements with life sciences companies in FY2019 (the most recent year for which data is available),[1] this likely will be a temporary trend. Several significant settlements and investigations in 2020 provide key insights into government enforcement priorities as we look toward 2021.

Enforcement actions are a valuable educational tool for legal and compliance teams looking to minimize corporate risk and ensure an effective compliance program that stays up to date with industry trends. Four key themes in 2020 enforcement actions to date are:

1) Industry relationships with charitable foundations;
2) Speaker programs;
3) Other kickbacks; and
4) Drug pricing.

INDUSTRY RELATIONSHIPS WITH CHARITABLE FOUNDATIONS

The DOJ has continued its multi-year focus on donations made by pharmaceutical companies to charitable entities that provide financial assistance to low-income individuals for out-of-pocket health care costs. The lessons learned from several key settlements and investigations in 2020 continue to inform the industry on structuring and monitoring their relationships with charitable foundations.

Inappropriate coordination between pharmaceutical companies and the charitable foundations to which they donate has been a DOJ enforcement priority. This trend continued in 2020, when Novartis agreed to pay over $51 million to settle allegations that it violated the False Claims Act ("FCA") by

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[1] https://oig.hhs.gov/publications/docs/hcfac/FY2019-hcfac.pdf.

engaging in three separate schemes involving charitable foundations to pay the copays of Medicare patients taking Novartis' drugs between 2010–2014.[2] According to the DOJ, this included:

1) Coordinating with the contractor of its free drug program and a charitable foundation to transition 374 patients in a manner that resulted in a disproportionate share of Novartis' funding going to Gilenya patients;

2) Instructing a foundation to narrow its eligibility definition in a way that ensured a greater amount of Novartis' copay assistance would support patients taking its drug Afinitor; and

3) Requesting that another charitable foundation open a fund to cover copays exclusively for Afinitor, a Novartis drug used to treat progressive neuroendocrine tumors ("PNET"), despite the fact the U.S. Food and Drug Administration ("FDA") had approved a competing drug to treat PNET.

The DOJ also reached several industry settlements related to pharmaceutical companies that use charitable foundations as a "conduit" to pay the copays of Medicare patients taking a company's drug.

For example, in February 2020, Sanofi-Aventis paid $11.85 million to resolve allegations it violated the FCA by using a charitable foundation as a conduit to pay kickbacks to patients using its drug Lemtrada. The DOJ alleged (i) Sanofi made contributions to a charitable foundation when the foundation's multiple sclerosis fund was closed to new patients due to a lack of funding, and (ii) coordinated with its third-party reimbursement hub for Lemtrada patients to apply for assistance from the foundation's multiple sclerosis fund when it reopened so they would be first on the list to receive funding. This scheme resulted in Lemtrada patients receiving a disproportionately large share of the grants issued by the charitable foundation, the DOJ asserted.

Similarly, in September 2020, Gilead Sciences paid $97 million to resolve claims it violated the FCA by using a charitable foundation as a "conduit" to pay the Medicare copays of patients using its drug Letairis from 2007–2010.[3] The DOJ alleged that Gilead obtained data from the foundation detailing the number of Letairis patients receiving support and used this data to determine

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[2] https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.

[3] https://www.justice.gov/opa/pr/gilead-agrees-pay-97-million-resolve-alleged-false-claims-act-liability-paying-kickbacks.

the amount of future donations. The DOJ also alleged that Gilead referred Medicare patients to the foundation, which resulted in claims to Medicare to cover the cost of Letairis.

The DOJ also continued its trend of reaching settlements with charitable foundations that the DOJ alleges acted as conduits for pharmaceutical companies.[4]

For example, in January 2020, Patient Services Inc. paid $3 million to resolve allegations it violated the FCA by enabling pharmaceutical companies to provide kickbacks to Medicare patients using the respective company's drugs.[5] The foundation allegedly coordinated with pharmaceutical companies to operate funds in a manner that would minimize the possibility that the companies' contributions to the foundation would go to patients taking competing drugs made by other companies.

The DOJ also reached a similar settlement with a specialty pharmaceutical company in August 2020.[6]

We anticipate the DOJ's focus on relationships between charitable foundations and pharmaceutical companies to continue to be a priority for the DOJ in 2021. The DOJ filed complaints this year against two pharmaceutical manufacturers for purportedly using charitable foundations as conduits to cover Medicare copays for their respective drugs.[7] The DOJ asserted in both complaints that these companies used data obtained from charitable foundations to determine the amount of future payments to be made to those foundations in order to cover the copays of patients using their respective drugs.

SPEAKER PROGRAMS

Promotional speaker programs are a longstanding enforcement priority of the DOJ, and this trend continued in 2020. Most notably, Novartis paid over $591

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[4] *See, e.g.*, https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare; https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicar; https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks.

[5] https://www.justice.gov/opa/pr/patient-services-inc-agrees-pay-3-million-allegedly-serving-conduit-pharmaceutical-companies.

[6] https://www.justice.gov/usao-ma/pr/specialty-pharmacy-advanced-care-scripts-agrees-pay-35-million-resolve-allegations-it.

[7] https://www.justice.gov/usao-ma/pr/united-states-files-suit-against-drug-manufacturer-regeneron-paying-kickbacks-through-co; https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals.

million and forfeited over $38 million to resolve FCA allegations that it paid kickbacks to doctors in the form of speaker programs to induce them to prescribe numerous Novartis drugs.[8] Specifically, the government alleged that Novartis "hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors."

The specific allegations included paying honoraria for speaker programs that in reality were social events held at expensive restaurants with little or no educational value.[9] These events frequently exceeded the company's $125 meal limit. The government further alleged some of the speaker events never took place and were used to pay a fee to the speaker as an inducement to prescribe Novartis drugs. The government also alleged that Novartis sales representatives were instructed to select high-volume prescribers to serve as speakers to encourage or pressure them to write more prescriptions for Novartis drugs. Novartis conducted return-on-investment ("ROI") analyses on these speaker programs and encouraged repeat attendance at promotional events.

As part of the settlement, Novartis entered into a five-year corporate integrity agreement ("CIA") with the Department of Health and Human Services Office of Inspector General ("OIG") that includes notable new provisions related to speaker programs.[10] Under the CIA, Novartis is limited to conducting external speaker programs in a remote format for 18 months following FDA approval of a new product or a new indication for a product. Additionally, there is a limit of $100,000 in total remuneration for speaking and speaker training and a $10,000 total remuneration cap per speaker.

In another DOJ settlement, DUSA Pharmaceuticals, Inc. ("DUSA"), a subsidiary of Sun Pharmaceutical Industries, Inc., paid $20.75 million to resolve FCA allegations that it knowingly promoted an administration process for its drug Levulan Kerastick that contradicted the product instructions approved by the U.S. Food and Drug Administration ("FDA") and was unsupported by sufficient clinical evidence.[11] Among other things, the govern-

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[8] https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians. Novartis also agreed to pay over $48 million to resolve state Medicaid claims.

[9] https://www.justice.gov/usao-sdny/press-release/file/1291316/download.

[10] https://oig.hhs.gov/fraud/cia/agreements/Novartis_Corporation_06302020.pdf.

[11] https://www.justice.gov/opa/pr/dusa-pharmaceuticals-pay-us-2075-million-settle-false-claims-act-allegations-relating.

ment alleged that DUSA used speaker programs and health care professional ("HCP") peer-to-peer programs to promote this off-label use of Levulan Kerastick.

OTHER KICKBACKS

Several other notable enforcement actions this year make it clear kickbacks remain an enforcement priority for federal and state enforcement authorities. For example, medical device maker Merit Medical Systems Inc. ("MMSI") paid $18 million to resolve FCA allegations it paid kickbacks to physicians and hospitals to induce the use of its products.[12] The government alleged that MMSI provided free advertising, practice development, and practice support services under the guise of an internal "Local Advertising Program" to induce certain high-volume prescribers to purchase and use MMSI products. HCPs also received luxury trips and consulting fees, which the company disguised as educational grants.

Notably, the action against MMSI arose from a *qui tam* whistleblower complaint by the company's former chief compliance officer, who warned the company that these activities may violate the federal Anti-Kickback Statute ("AKS"). The relator alleged that the company created a "chili pepper" scale from 1–3 to assess how much "heartburn" a particular action would give the company regarding compliance and ethics.[13]

Additionally, the DOJ's largest industry FCA settlement to date involving Purdue Pharmaceuticals and members of the Sackler family include allegations Purdue violated the AKS. The DOJ alleges, among other things, Purdue made payments to an electronic health records company in exchange for referring, recommending, and arranging for the ordering of Purdue's extended-release opioid products and entered into contracts with certain specialty pharmacies to fill prescriptions for Purdue's opioid drugs that other pharmacies rejected as potentially lacking medical necessity.[14]

State enforcement authorities also are active in pursuing kickback allegations. For example, AbbVie Inc. entered into a settlement with the California Department of Insurance ("CA Department") to resolve allegations that it

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[12] https://www.justice.gov/usao-nj/pr/medical-device-maker-pay-18-million-settle-allegations-improper-payments-physicians.

[13] https://www.massdevice.com/former-merit-medical-executive-claims-physician-kickbacks-in-whistleblower-lawsuit/.

[14] https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

violated the California Insurance Frauds Prevention Act ("CA Act") in the marketing of its drug HUMIRA.[15]

Among other things, the CA Department alleged the AbbVie Nurse Ambassadors program interfered with the flow of doctor-patient communications and other kickbacks were provided to HCPs in violation of the CA Act, such as meals and drinks to HCPs provided outside the context of speakers programs.

In addition to paying $24 million in civil fines, AbbVie agreed to implement and maintain the several non-monetary terms with respect to its HUMIRA Complete Program (including product support and ambassador programs), including the following:

- Require nurse ambassadors to disclose to patients that they are provided by AbbVie and do not work under the direction of the patient's HCP;
- Prohibit HUMIRA sales representatives from inviting HUMIRA-prescribing HCPs to offsite business meals, except as part of AbbVie speaker programs;
- Require nurse ambassadors to direct patients to the medication guide and their HCP regarding side effects and safety risks for HUMIRA;
- Provide guidance and training that nurse ambassadors will not have patient-specific discussions with providers who prescribe AbbVie;
- Prohibit AbbVie employees from describing nurse ambassadors to HCPs as "extensions of their offices" and providing HCPs with contact information for such ambassadors who interact with HUMIRA patients; and
- Prohibit AbbVie employees and nurse ambassadors from actively participating in conversations between patients and insurance companies.[16]

We expect kickbacks to remain a top priority for government enforcers and *qui tam* relators in 2021. This likely will include enforcement actions against life sciences companies, their executives and employees involved in the kickbacks, and HCPs who request or receive such kickbacks, including speaker programs, consulting fees, and sham educational grants.

DRUG PRICING

Drug pricing continues to be a hot topic for the Trump administration, as evidenced by the U.S. House Oversight and Reform Committee's ongoing

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[15] https://www.insurance.ca.gov/0400-news/0100-press-releases/2020/release071-2020.cfm.

[16] https://www.insurance.ca.gov/0400-news/0100-press-releases/2020/upload/Settlement-Agreement-signed-Execution-Copy.pdf.

investigation into the drug pricing practices of 12 pharmaceutical companies. The Committee also issued a subpoena to AbbVie in September 2020, demanding AbbVie produce documents related to the pricing of HUMIRA and IMBRUVICA, two of the most profitable medicines in the United States.[17] The high cost of drugs, combined with frequent price increases and multitude of patent applications filed by certain pharmaceutical companies with the presumed intent of preventing competition in the United States, prompted the government's scrutiny into this area.[18]

The DOJ also has been active in this area. Sandoz, Inc. paid a $195 million criminal penalty to settle claims it participated in four criminal antitrust conspiracies with other pharmaceutical companies to allocate customers, rig bids, and fix prices for generic drugs from 2013–2015.[19] This settlement represents the largest settlement for a domestic antitrust case in U.S. history. As part of the settlement, Sandoz agreed to cooperate fully with the DOJ's ongoing investigation into anticompetitive conduct in the generic pharmaceutical industry

The focus on rising drug prices is not unique to the federal government. In 2018, California enacted a drug price transparency law that requires companies to report and justify drug price increases on a quarterly basis. As of April 2020, California imposed fines totaling $17.5 million on over a dozen drug manufacturers for failing to report drug price increases.[20]

Drug pricing is a topic that has garnered bipartisan support. We expect drug pricing to be a top priority in the Biden administration.

2021 OUTLOOK

We expect the DOJ's enforcement efforts to continue focusing on life sciences companies in 2021. These actions likely will continue to be based on various FCA theories with an increased emphasis on underlying AKS allegations. We further expect aggressive relators' counsel to continue advancing FCA theories related to kickbacks buoyed by several successful settlements in 2020 and the increased scope of Open Payments data beginning in 2021.

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[17] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-09-01%20AbbVie%20Subpoena%20Memo.pdf.

[18] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.

[19] https://www.justice.gov/opa/pr/major-generic-pharmaceutical-company-admits-antitrust-crimes.

[20] https://www.beckershospitalreview.com/pharmacy/california-fines-drugmakers-17-5-million-for-failing-to-report-price-hikes.html.

Additionally, we expect the DOJ will continue identifying and prosecuting individuals responsible for problematic conduct. This will include company executives, key employees, and HCPs who participate in schemes that increase fraud, waste, and abuse to health care programs. We also expect to see a continued ramp-up in the number of cases involving state and local government investigators in FCA investigations, consumer protection, and other regulatory enforcement.