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What Life Sciences Companies Can Expect for Enforcement in 2023

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In 2022, the U.S. Department of Justice (DOJ) continued progressing toward prepandemic levels of enforcement activity. The federal False Claims Act (FCA) remains DOJ's favorite tool to address alleged healthcare fraud, but other federal and state enforcement authorities have increasingly demonstrated interest in using the tools at their disposal, including antitrust laws, to target the healthcare industry. Below are areas the government is likely to view as particularly attractive targets in the coming year.

Use of Antitrust Violations as a Basis for Anti-Kickback Statute and FCA Liability

Over the past few years, DOJ and whistleblowers have actively used the FCA to target conduct they allege to include kickbacks designed to undermine competition and checks on drug pricing. Initially, such allegations primarily focused on drug-company-sponsored patient assistance programs, even though such programs were common, longstanding, and generally understood to be compliant with HHS-OIG guidance. More recently, DOJ has focused on arrangements between or among pharmaceutical companies alleged to have fixed the prices of generic drugs. According to DOJ, certain manufacturers paid and received compensation prohibited by the Anti-Kickback Statute (AKS) through agreements with other pharmaceutical manufacturers on price and allocation of customers.

Whistleblowers have begun to pick up on these themes. In particular, whistleblowers have been pursuing theories of liability under the FCA premised on the allegation that pharmaceutical companies have undertaken anticompetitive actions before the Patent and Trademark Office and/or the Food and Drug Administration (FDA) that are designed to foreclose competitors from entering the market. The result, according to these whistleblowers, is that the claims for the defendants' products are inflated as compared to the price that would have prevailed with competition, therefore rendering them "false" claims under the FCA. Companies have robust legal defenses against this theory. But while this remains a developing area of law, so far courts have demonstrated some willingness to accept the theory of liability, particularly at the motion to dismiss stage.

These enforcement efforts are consistent with a broader focus by the Biden administration on competition issues. In July 2021, the President issued his Executive Order on Promoting Competition in the American Economy, which sparked a multiagency focus on antitrust enforcement in the healthcare industry. Consistent with this pronouncement, late last year, DOJ's Antitrust Division and the Department of Health and Human Services Office of Inspector General (HHS-OIG) signed a memorandum of understanding (MOU) to formalize their efforts to collaborate to address conduct that poses both fraud

and abuse risks and may also harm competition.

In the MOU, the agencies committed to collaborate to "better protect health care consumers and workers from collusion, ensure compliance with laws enforced by [each entity], and promote competitive health care markets."[1] The agencies aim to achieve that goal through four primary activities: information sharing; training, education, and outreach; consultation and coordinated enforcement; and referrals. Although the agencies were always free to coordinate with each other to address conduct potentially implicating the jurisdiction of both the Antitrust Division and HHS-OIG, their decision to memorialize how each agency will encourage earlier information sharing and educate the other on relevant issue spotting suggests greater collaboration.

Scrutiny of Drug Company Relationships With Pharmacy Benefit Managers

Both federal and state governments have increasingly expressed interest in closely scrutinizing the business practices of the relationships between drug companies and pharmacy benefit managers (PBMs), under a variety of legal theories ranging from antitrust to fraud and abuse.

In June 2022, the Federal Trade Commission (FTC) announced "that it will ramp up enforcement against any illegal bribes and rebate schemes that block patients' access to competing lower-cost drugs" and issued a corresponding Policy Statement "put[ting] drug companies and prescription drug middlemen on notice that paying rebates and fees to exclude competitors offering lower-cost drug alternatives can violate competition and consumer protection laws."[2] This new FTC Policy Statement follows another FTC announcement in June, disclosing that the Commission has launched a broad investigation of PBM practices, focusing in particular on the six largest PBMs.[3] While FTC has yet to disclose any findings from this investigation or enforcement actions relating to rebates, these high-profile announcements are an indication that FTC's new leadership prioritized PBM relationships for 2022 and beyond.

FTC's policy statement creates some risk that DOJ and whistleblowers may explore theories of FCA liability premised on the assertion that the rebate practices identified by FTC as "foreclose[ing] competition from less expensive generic and biosimilar alternatives" may inflate the price of drugs. Such a theory could be buttressed by certain comments from HHS-OIG in the preamble to the now-withdrawn "rebate rule" that sought to narrow safe harbor protection under the AKS for drug rebates. [4]

DOJ has other enforcement tools it may turn to as well, such as the Travel Act, which criminalizes the use of interstate commerce with the intent to facilitate any unlawful activity, including bribery as defined by state law. Unlike the FCA, which reaches only federal healthcare programs, the Travel Act can be used to target alleged bribes affecting commercially insured beneficiaries, and indeed DOJ has been leveraging this relatively unknown law with increasing frequency over the past few years.

State enforcement scrutiny may continue as well. Since 2019 the Attorney General of Ohio has been aggressively investigating PBM practices, and in March 2022 his office announced new subpoenas to the major PBMs. Throughout the year several drug companies disclosed in Securities and Exchange Commission (SEC) filings that they had received inquiries from the Ohio and Illinois Attorneys General relating to trade and pricing practices and PBM relationships. This flurry of activity is consistent with a pattern of increasingly active state Attorneys General, who have often launched independent investigations that mirror or expand federal probes.

Fraud-on-the-FDA as a Theory of FCA Liability

For the past decade, relators have increasingly attempted to convert alleged misconduct before FDA into theories of FCA liability. The so-called fraud-on-the-FDA theory of liability has been met with some skepticism by courts, and DOJ has never litigated the theory on its own. Nonetheless, in the past year, DOJ appears to be showing a renewed interest in supporting this theory.

Fraud-on-the-FDA is an expansion of the longstanding fraudulent inducement theory, which posits that claims for payment are false if the defendant induced a government entity to enter the contract based on fraudulent conduct. However, the fraud-on-the-FDA theory takes this causal chain one step further. Relators advancing this theory claim that fraudulent conduct or false statements submitted to FDA can render false the claims for payment submitted to a separate government entity, such as the Centers for Medicare and Medicaid Services.

Although DOJ under the last administration dismissed a fraud-on-the-FDA case over a relator's objections and otherwise largely ceased filing supportive amicus briefs, in June 2022 DOJ once again filed a statement of interest encouraging a court to deny the defendant's motion to dismiss in a fraud-on-the-FDA case. And in December 2022, DOJ announced a $12 million settlement with a cochlear implant manufacturer based on allegations that the company misled FDA. According to the settlement's covered conduct, the manufacturer allegedly represented in a Premarket Approval Application that its devices satisfied an internationally recognized standard for radio frequency (RF) emissions, when in fact the devices were not in compliances with that standard. The government alleged that the claims submitted to federal healthcare programs for these devices "were false, regardless of whether or not there were safety issues with the" devices as a result of inconsistency with the RF standard.

Although DOJ's renewed interest in the fraud-on-the-FDA theory of liability may encourage additional relators to pursue this theory and may even suggest a willingness from DOJ to intervene and litigate such a case, not all courts agree it is a viable cause of action. Last year, the U.S. Court of Appeals for the Second Circuit affirmed the dismissal of a fraud-on-the-FDA case. The district court had concluded that a "fraudulent inducement theory based on FDA approval lies on a shaky legal foundation." However, Second Circuit declined to comment on the fraud-on-the-FDA theory's validity. Instead, the panel affirmed the dismissal based on the plaintiff's failure to "plausibly allege that any misrepresentation by [defendant] materially impacted the Government Healthcare Programs' payment determination."

With no signs that DOJ is backing away, life science companies with complex or novel questions within the FDA's regulatory authority may face suits based on the fraud-on-the-FDA theory. To mitigate risk, companies should transparently engage with FDA to ensure the agency can make informed decisions. Thorough documentation of FDA engagement will prepare companies to produce these materials to DOJ in the future as needed.

Enforcement Focused on Misconduct in Clinical Trials

Risks associated with clinical trial misconduct have been steadily growing over the years and have now also become the focus of significant enforcement attention. Specific types of misconduct are myriad, ranging from outright falsification or manipulation of subject-level data, failing to properly protect subject safety, and misrepresentation of results in publications or regulatory submissions to more subtle issues such as failing to publicly register studies and report results on ClinicalTrials.gov or concealing conflicts of interest. These actions may come to light in a number of ways including routine monitoring, whistleblower complaints, audits, or inspections.

FDA is responsible for overseeing clinical trials to ensure the safety and welfare of participants and the quality and integrity of the data. FDA achieves this by ensuring compliance with good clinical practice regulations, which include requirements related to informed consent, institutional review board oversight, and overall trial and data integrity. If FDA finds that a sponsor, or third party conducting trial activities on behalf of a sponsor, fails to comply with these requirements, FDA has the authority to initiate enforcement action. Actions may include sending untitled or warning letters, rejection of data, seizure of investigational product, injunction, civil monetary penalties, or other prosecution under the Federal Food, Drug, and Cosmetic Act (FDCA) or other federal statutes.

There is rising concern that FDA is failing to adequately address misconduct in clinical trials. Into that breach has stepped DOJ. DOJ has said in its public statements that clinical trial fraud is an enforcement priority. In both December 2020 and December 2021, the Deputy Attorney General for the Consumer Protection Branch noted that clinical trial fraud was an area where enforcement would be “aggressive,” with a focus on “liability for submitting false information and failing to submit required reports.” We expect this scrutiny to continue in 2023, with additional scrutiny of companies that are alleged to have identified — but failed to address and disclose — other misconduct or that failed to implement adequat guardrails to discover and eliminate such misconduct.

In pursuing this enforcement priority, DOJ has expanded beyond the confines of the FDCA, bringing charges against individuals involved in clinical trials for wire fraud, mail fraud, false statements, and conspiracy to commit fraud, falsify clinical trial data, and defraud the United States. In recent cases, individuals have been sentenced to prison and required to pay restitution greater than $1 million. Clinical trial sponsors are increasingly coming under the microscope for perceived misconduct. Beyond DOJ enforcement action, life sciences companies can be exposed to congressional investigations, SEC enforcement action, and shareholder litigation for alleged failure to identify and/or disclose misconduct as well as allegedly material misstatements or omissions when discussing trial results.

With the potential for increased enforcement and other forms of scrutiny, companies should maintain robust policies to ensure proper conduct of trials. Policies should cover all trial phases — from pre-trial screening and vetting to post-trial data collection, analysis, and discussion of results — and assure compliance with ClinicalTrials.gov requirements for trial registration and results reporting. Further, policies and procedures should assure thorough monitoring to detect misconduct as early as possible. If misconduct is discovered, companies should act quickly to characterize issues and implement appropriate Corrective and Preventative Actions (CAPAs).

Additional considerations may be present for certain companies. For example, companies that rely on Contract Research Organizations (CROs) for their clinical trials may be at increased risk and will need to ensure both that the CROs have adequate controls to meet FDA requirements and that their work is adequately monitored. Early-stage companies are especially at risk due to heavy reliance on third parties for trial-related activities.

Enforcement Arising From Inspections

FDA has resumed inspections at prepandemic levels, and the number of inspections continues to rise because the agency is seeking to clear a major backlog of inspections that developed from 2020 to 2022. In doing so FDA is continuing to make use of tools it pioneered or increased the use of during travel lockdowns, such as remote regulatory assessments (RRAs). This will likely lead to increased

enforcement in connection with good manufacturing practice (GMP) compliance. Unfortunately, inspection readiness at some manufacturing sites has declined due to a lack of experience and practice in managing inspections, likely from the extensive delay between inspections resulting from the pandemic. In many cases this has been compounded by the loss of key personnel or subject matter experts at sites.

In addition to managing RRAs, FDA has also begun conducting unannounced inspections of foreign manufacturers, particularly in India, a major source of pharmaceuticals for the U.S. market. Unannounced inspections in China are also likely to materialize once travel restrictions in the country are lifted. Companies whose pharmaceutical supply chains rely on manufacturing sites located in India or China should therefore take steps to assess and ensure that these sites are GMP compliant and to shore up their operations or consider alternative manufacturing sites for key materials.

We also predict more public regulatory actions by the FDA, including the increased use of warning letters and import alerts. Many of these are likely to focus on the product quality issues that are being reviewed now during inspections and RRAs but originally occurred during the pandemic; in many cases, these issues actually manifested themselves due to COVID-related staffing and supply chain restrictions. Data integrity (DI) also remains an inspectional priority for the FDA in its enforcement activities. Both prior to and following the agency's issuance in 2018 of guidance on DI, the agency has shown a willingness to refer DI issues found during inspections to the DOJ for possible enforcement action.

The decline in inspections in recent years may have also created a lack of urgency at some sites, and in some places this is manifesting itself in backlogs in closing quality investigations or implementing Corrective and Preventative Actions (CAPAs). Sites should be on alert for such backlogs developing because a failure to execute on such matters in a timely fashion can lead to repeat problems, closer FDA scrutiny during inspections or RRAs, and whistleblower risks.

In 2023, we will likely see the wider economic slowdown start to affect manufacturers and companies and in turn reduce workforces. As a result, we expect there to be an increase in the number of whistleblowers. We already saw a number of large government investigations stemming from whistleblower complaints in the second half of 2022, and we expect this trend to continue. Indeed, in recent years, whistleblowers have attempted to expand the playing field of potential FCA cases by making the following allegations:

- violations of GMP or Quality Systems Regulations (QSR), leading to the shipment of adulterated products
- the FDA's postmarketing oversight being hindered by material violations of GMP/QSR in the complaints handling and investigation process
- fraud-on-the-FDA, an allegation that the FDA would not have approved a product had it been aware of undisclosed GMP/QSR violations

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[1] DOJ & HHS-OIG, Memorandum of Understanding Between the Antitrust Division of the U.S. Department of Justice and the Office of the Inspector General of the U.S. Department of Health and Human Services (Dec. 9, 2022), **https://www.justice.gov/opa/press-release/file/1556856/download**.

[2] **https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes**.

[3] **https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry**.

[4] 85 Fed. Reg. 76,666, 76,679 (Nov. 30, 2020).

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