DOJ Pharmaceutical & Medical Device Enforcement Continues In Line With Recent Trends

*Contributed by **Maya Florence** and **Avia Dunn**, Skadden, Arps, Slate, Meagher & Flom LLP*

February 2024

Over the past few years, pharmaceutical and medical device manufacturers may have noted a decline in significant corporate resolutions—i.e., those involving monetary settlements of over $1 million—led by the Department of Justice (DOJ). This downward trend is real: there were 19 such resolutions in 2019, 14 in 2020, 11 in 2021, and six in 2022. While 2023 saw a total of nine such resolutions, slightly up from 2022's total, the number of settlements is still markedly lower than just five years ago.

Faced with this trend, industry observers may rightly wonder what is behind this clear decline in pharma and device-focused enforcement, what it may mean for future enforcement against pharmaceutical and medical device manufacturers, and how manufacturers should best prepare their companies for future enforcement. This article discusses pharma and medical device enforcement trends over the past five years, potential explanations for the recent decline, and what that may mean for future life sciences enforcement, as well as how companies in the industry can best prepare themselves for a potential uptick in the future.

Trends in Recent Pharma & Device Settlements

Upon inspection, several observations emerge that provide greater insight into the noted decline in pharma and device enforcement over the five years since 2019:

Increase in Civil-Only Resolutions. Across the five-year period, the significant majority of enforcement matters were resolved civilly, with only 13 of the 61 total resolutions including a criminal component. While many variables could be driving this, the lean toward civil-only resolutions may be the result of:

- The increase in the percentage of matters arising out of relator-driven qui tam civil False Claims Act (FCA) complaints;
- The trend toward cases involving alleged improper promotion, which historically were often resolved through criminal misbranding charges, instead being resolved almost uniformly through civil FCA settlements premised on causing medically unnecessary claims through false and misleading promotion; and/or
- The similar uptick in cases involving quality and manufacturing concerns forming the basis for civil FCA resolutions rather than criminal Food, Drug & Cosmetic Act cases.

Shift From Pharma to Device Manufacturers. The balance of DOJ-led settlements has shifted over time from predominantly involving pharma manufacturers to predominantly involving device manufacturers. In 2019, two-thirds of the 19 resolutions involved drug manufacturers while one-third involved device manufacturers. By 2022, this statistic had flipped; two-thirds of the resolutions involved device manufacturers and one-third involved drug manufacturers. The ratio in 2023 was again 2:1 in favor of device resolutions. It remains to be seen whether this will be a permanent shift.

Frequency of AKS Theories. Year over year, alleged violations of the Anti-Kickback Statute (AKS)—either as a standalone criminal violation or as a predicate for a civil FCA case, and sometimes in conjunction with other allegations—continue to be the most frequently cited basis for enforcement. The highest percentage of kickback cases in the past five years involved the previously unused theory that pharma manufacturers provided kickbacks to patients by contributing to independent charitable foundations that offered patient co-pay support, and 2023 saw the first case alleging a kickback violation based on a pharma company's provision of free genetic testing to patients. Over the five year period, more traditional kickback cases involving meals, travel, paid engagements, and other forms of remuneration also persisted as well.

Prioritization of False & Misleading Promotion. Non-kickback-related enforcement over the past five years has reflected DOJ's prioritization—codified in the Justice Manual—of matters involving promotion that is false, misleading, or encourages unapproved new uses likely to cause consumer harm, in addition to violations of Food, Drug, and Cosmetic Act (FDCA) good manufacturing practice and adverse event reporting requirements, as well as a steady trickle of drug pricing cases.

What Else Has DOJ Been Focused On?

While it is clear that the past five years have seen fewer—and declining—DOJ enforcement resolutions involving pharmaceutical and medical device manufacturers, it does not mean that DOJ has not been active in healthcare and life sciences enforcement overall. Indeed, over the past five years, DOJ has been vigorously pursuing enforcement in a number of other areas.

It stands to reason that DOJ's activity in these areas, two of which involve major public health crises and others of which involve emerging and expanding industries, has likely resulted in a shift of resources and focus away from more traditional pharmaceutical and medical device manufacturers. Areas of particular DOJ activity over the past five years include the following.

Electronic Health Record (EHR) Vendors

The government began substantially incentivizing the use of EHR systems as far back as 2009, through the Health Information Technology for Economic and Clinical Health (HITECH) Act, which earmarked $27 billion for incentive programs and allocated billions more to train health information technology workers and assist hospitals and providers in implementing EHR systems. As such systems took hold, DOJ began warning that EHR-related fraud was likely to be an area of significant enforcement focus, and in fact, it has been. DOJ has brought at least eight enforcement matters against EHR vendors, with one dating back to 2017, and seven since 2019.

These cases have generally involved allegations that EHR vendors falsely represented their systems' capabilities and offered kickbacks to induce the use of their systems, and have been brought by DOJ's Commercial Litigation Branch working with US Attorneys' Offices. However, DOJ also has pursued allegations that pharma companies paid kickbacks to EHR vendors to implement clinical decision support (CDS) alerts in EHR software that were designed to increase prescriptions for manufacturers' drug products.

Clinical Laboratories

The past five years have seen a steady, and increasing, drumbeat of major resolutions involving clinical laboratory companies. Indeed in 2022, DOJ announced five major enforcement resolutions involving clinical laboratories, almost the same as the number of announced resolutions involving pharmaceutical or medical device manufacturers—six in total. 2023 saw a similar pattern; DOJ announced nine major enforcement resolutions involving pharma or device companies and almost the same number—seven in total—involving large clinical laboratories, in addition to a number of smaller matters involving more regional lab companies or single laboratories.

These matters have involved a mix of allegations that are specific to clinical laboratories—e.g., improper application of the Medicare "14-day Rule" for laboratory billing—as well as allegations that laboratories improperly induced the use of their tests or caused the submission of claims for medically unnecessary testing, and have likewise been brought by DOJ's Commercial Litigation Branch working with US Attorneys' Offices.

Opioid-Related Enforcement

Throughout the past five years, DOJ's Consumer Protection Branch (CPB), working with US Attorneys' Offices throughout the country, has focused substantial resources on combatting the nationwide opioid epidemic through criminal and civil enforcement. CPB officials have repeatedly cited opioid enforcement as a primary enforcement focus. The branch has pursued matters involving large corporate defendants as well as a very high percentage and volume of cases involving local pharmacies and opioid prescribers.

Notably, CPB is the DOJ component charged with enforcement of the FDCA and the Controlled Substances Act. As such, it stands to reason that CPB's understandable focus on opioid-related enforcement may have diverted resources away from more traditional matters involving alleged FDCA violations.

Covid-19 Fraud

The unexpected Covid-19 outbreak in early 2020 led to the rapid availability of various government funds intended to assist businesses and individuals in withstanding the economic impact of the global pandemic. DOJ responded by shifting resources to focus on identifying and recovering misused Covid-19 relief funding.

Among other things, this resulted in a March 2021 announced takedown of 474 defendants charged with criminal offenses, the creation of a Covid-19 Fraud Enforcement Task Force in May 2021 and additional Covid-19 Fraud Strike Force Teams in September 2022. In August 2023, DOJ announced that its Covid-19 fraud enforcement efforts through that date had resulted in the seizure of over $1.4 billion in Covid-19 relief funds and the charging of over 3,000 defendants with crimes. These cases have involved a variety of DOJ components, including the Criminal and Civil Fraud Sections, CPB, and various US Attorneys' Offices.

Telehealth Fraud

In addition to an influx of available government funds, the Covid-19 pandemic also led to a relaxing of restrictions on the use of telehealth. While DOJ had already begun to focus enforcement resources on telehealth fraud prior to the pandemic, there is no question that the pandemic led to an uptick in such fraud, and a corresponding increase in DOJ's telehealth-related enforcement.

This enforcement has taken the form of a number of large nationwide operations, including Operation Brace Yourself in 2019, Operation Double Helix, also in 2019, Operation Rubber Stamp in 2020, and telehealth components of the 2021 and 2022 National Health Care Fraud Enforcement Actions. In July 2022, DOJ announced criminal charges against 36 defendants for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes. These cases have largely been directed by Criminal Division Strike Forces working with various US Attorneys' Offices.

What Does This Mean For Potential Future Enforcement?

As these areas of activity make clear, the DOJ components that have historically pursued matters involving pharma and device manufacturers—CPB and the Commercial Litigation Branch, which investigates and litigates FCA complaints filed by qui tam relators—have been focusing investigative and enforcement resources on other actors. This has been driven by public health needs—in the case of the Covid-19 pandemic and opioid epidemic—as well as areas of expanded activity, such as telehealth, EHR systems, and clinical laboratories.

These areas of expanded activity are likely to remain a fixture of healthcare delivery, and thus presumably a focus of DOJ enforcement and general government scrutiny, going forward. In this regard, it is notable that the Department of Health and Human Services Office of Inspector General (HHS-OIG) recently announced that it anticipates publishing an industry segment-specific compliance program guidance for clinical laboratories, likely in 2025. On the other hand, it is reasonable to assume that Covid-19 and opioid-related enforcement may abate as those public health crises hopefully recede. As such, there is reason to suspect that DOJ resources that have been trained on other actors may, over time, turn back to more traditional cases involving pharma and device manufacturers.

To be prepared for a potential uptick in enforcement, companies in this space should be cognizant of what DOJ has said publicly regarding its expectations for corporate compliance.

Increased Focus on Self-Disclosure

In the first quarter of 2023, DOJ announced a number of important updates to its policies regarding the prosecution of corporate crimes. These included revisions to the Criminal Division's Corporate Enforcement Policy (CEP) designed to—among other things—increase the incentives for voluntary self-disclosure of criminal violations.

In keeping with these policy changes, during 2023, DOJ components with prosecutorial authority, including notably for pharma and device manufacturers, CPB and the US Attorneys' Offices, each announced formal Voluntary Self-Disclosure policies. Along the same lines, inOctober 2023, Deputy Attorney General Lisa Monaco announced the creation of a new safe harbor policy involving a presumption of declination of prosecution for companies that identify and voluntarily self-disclose misconduct within six months of the closing of a merger or acquisition, cooperate in DOJ's investigation, and engage in appropriate remediation, restitution and disgorgement.

This clear DOJ focus on self-disclosure suggests that pharma and device manufacturers should ensure that they have a thoughtful, systematic process in place for evaluating whether misconduct identified through their compliance programs may warrant potential self-disclosure.

Emphasis on Compliance Programs & Empowered Compliance Officers

DOJ's Criminal Fraud Section revamped its former Strategy, Policy, and Training Unit into the Corporate Enforcement, Compliance, and Policy (CECP) Unit, and CBP—which sits within the Civil Division—announced the creation of a Corporate Compliance and Policy (CCP) Unit. DOJ has announced that both of these Units have increased their headcounts and are led by management with experience in compliance and corporate prosecutions.

During 2022, DOJ's Criminal Division announced that for all corporate guilty pleas, deferred prosecution agreements, and non-prosecution agreements, it will consider requiring both the Chief Executive Officer and the Chief Compliance Officer (CCO) to sign a certification at the end of the term of the agreement certifying that the company's compliance program is reasonably designed, implemented to detect and prevent violations of the law, and is functioning effectively.

In describing this plan in March 2022, then-Assistant Attorney General for the Criminal Division, Kenneth Polite, **described this certification** as "the type of resource that compliance officials, including myself, have wanted for some time, because it makes it clear that [compliance officials] should and must have appropriate stature in corporate decision-making" as well as the "data, access, and voice within the organization to ensure" that their companies have "an ethical and compliance focused environment." The DOJ Criminal Division's early 2023 updates to its Evaluation of Corporate Compliance Programs guidelines similarly underscore DOJ's high expectations for effective compliance programs.

At the same time, in November 2023, HHS-OIG released its long-awaited revised, modernized General Compliance Program Guidance (GCPG) for health care stakeholders. Among other things, the GCPG includes a number of recommendations for strengthening compliance programs, including that chief compliance officers should report directly to company CEOs and not be responsible for other company functions such as legal, billing, or finance, that compliance committees should play an active role in the development, implementation, and evaluation of a compliance program, and that a company's compliance program should include performance measures and other incentives to encourage and reward compliance-oriented activities and behaviors.

All of these developments reflect the government's view that strong compliance programs and empowered compliance officials are key to preventing misconduct and ensuring that it is swiftly addressed when it occurs.

Forward-Looking Compliance Obligations in CPB Resolutions

CPB has taken this focus on effective compliance programs even further, publicly confirming that its CCP Unit is responsible for developing and implementing compliance-focused terms in both criminal and civil resolution agreements led by CPB, and enforcing those requirements going forward. Forward-looking compliance provisions have been included in at least four CPB plea and deferred prosecution agreements entered between 2018 and 2021, and CPB officials have indicated that a standardized template for forward-looking compliance obligations is under development.

Those implemented to date have included provisions that extend beyond the conduct at issue in a particular resolution and focus on the structure, content and effectiveness of compliance programs. For example, recent agreements have included requirements around the development of policies, periodic reviews and certifications related to FDCA and fraud and abuse compliance, quarterly board reports by the CCO, annual management reviews and certifications, and annual board reviews and certifications. In this regard, they bear similarities to the types of programmatic requirements historically included in corporate integrity agreements imposed by HHS-OIG and—given their focus on FDCA compliance—to consent decrees imposed by the Food and Drug Administration.

Conclusion

Given the magnitude of federal health care spend associated with pharmaceutical and medical device products and the presumption that their manufacturers therefore have deep pockets, it seems likely that DOJ enforcement may refocus on pharma and device companies as recent public health crises hopefully recede. Among other things, recent enforcement trends suggest that both clinical laboratories and healthcare technology vendors are likely to be the subject of continued scrutiny, which may extend to pharma and device manufacturers who have arrangements with these entities. Regardless of whether pharma and device corporate enforcement resolutions return to historic levels or not, it is clear that companies that face DOJ investigations should anticipate increased scrutiny of the prominence of corporate compliance programs and the degree to which compliance personnel are empowered to prevent, identify, and remediate misconduct.

Companies looking to best prepare themselves for potential enforcement should therefore continue to evaluate the structure and resources of their corporate compliance programs and the qualifications of their compliance personnel, and ensure those personnel are given an appropriate seat at the table.