Shifts in Department of Justice Policies Present Opportunities, Pose Risks for FDA-Regulated Companies and Officials

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The first six months of the second Trump administration brought major changes to the Department of Justice (DOJ), with the department announcing major policy overhauls intended to align federal enforcement officials' work with the administration's priorities.

The changes affect a range of criminal and civil enforcement activities undertaken by the DOJ, with special emphasis on new incentives for companies' self-disclosure of misconduct, reforms to the department's policies on monitorships, major changes in Foreign Corrupt Practices Act (FCPA) enforcement, shifts in the priority targets identified for scrutiny under the False Claims Act, and enforcement policies that align with some of the administration's most visible political priorities.

FDA-regulated companies need to be aware of these important shifts in DOJ policies and to reexamine their corporate compliance programs in light of the changes. They also need to keep up with the government's ongoing enforcement activities to make sure that they are prepared for any scrutiny on the part of FDA and DOJ officials as department and agency priorities continue to evolve.

As always, compliance officials and corporate management at all levels in FDA-regulated companies must stay up to date with the government's enforcement activity, assess their firms' risks and the risks faced by individual executives, senior managers and other employees in light of that enforcement activity, and adjust their operations and corporate compliance programs as needed to manage DOJ and FDA enforcement scrutiny effectively.

I. White-Collar Criminal Enforcement Reforms

The DOJ has revamped several of its white-collar criminal enforcement policies to align them to principles of "focus, fairness and efficiency" and to clarify the benefits of self-reporting corporate wrongdoing and cooperating with federal prosecutors.

Speaking in Washington, D.C., on May 12, 2025, at the Anti-Money Laundering and Financial Crimes Conference, sponsored by the Securities Industry and Financial Markets Association (SIFMA), Acting Assistant Attorney General Matthew R. Galeotti, the head of the DOJ's Criminal Division, said that the division "is turning a new page on white-collar and corporate enforcement."

Moving away from "excessive enforcement." "Recently," Galeotti said, the DOJ's white-collar enforcement actions "have come at too high a cost for businesses and American enterprise. Companies need clear guidance and certainty on the concrete benefits that each company, their shareholders, boards and customers can earn through self-reporting, owning up to criminal conduct, remediating, and cooperating with the department."

"Too often," he added, "businesses have been subject to unchecked and long-running investigations that can be costly — both to the department and to the subjects and targets of its investigations — and can unduly interfere with day-to-day business operations."

"If companies continue to assume that the department will be quick and heavy-handed with the stick and stingy with the carrot," he said, "the system will continue to generate lengthy, drawn-out investigations that are ultimately detrimental to companies and the department. This approach has deterred companies from cooperating and allowing the department to more readily target the most culpable actors."

"Excessive enforcement and unfocused corporate investigations stymie innovation, limits prosperity, and reduces efficiency," Galeotti told the conference attendees. "So that ends today. … We are here to prosecute criminals, not law-abiding businesses."

The Criminal Division's new white-collar enforcement plan, he said, will focus on targeting "the most egregious white-collar crime to make our nation safer and more prosperous, vindicate victims' rights, maximize the use of the department's resources, and provide fairness and transparency to individuals and companies alike."

Revised Self-Disclosure Policy

First, Galeotti announced, the Criminal Division has revised its Corporate Enforcement and Voluntary Self-Disclosure Policy (CEP), Justice Manual §9-47.120.

Saying that the policy "had gotten unwieldy and hard to navigate," he reported that the division's Fraud Section and Money Laundering and Asset Recovery Section had simplified the policy and clarified the outcomes that companies can expert.

(1) Benefits of self-disclosure. "Self-disclosure is key to receiving the most generous benefits the Criminal Division can offer," Galeotti stressed. "Coming forward and coming clean lets the department devote its resources to investigating and prosecuting individual wrongdoers and the most egregious criminal schemes."

Moreover, he said, "companies can avoid what we have seen in the past: burdensome, yearslong investigations that inevitably end in a resolution process in which the company feels it must accept the fate the department has ultimately decided."

(2) Declination. Under the new policy, companies that voluntarily self-disclose and meet other DOJ criteria — including fully cooperating, "timely and appropriately" remediating, and having no aggravating circumstances — "will receive a declination, not just a presumption of a declination," Galeotti announced.

Companies meeting the requirements "will not be required to enter into a criminal resolution," he said. "This is a clear path to declination."

(3) Aggravating circumstances. If a company has aggravating circumstances — such as involvement by executive management in the misconduct, significant profits from the misconduct, egregiousness or pervasiveness of the misconduct within the company, or criminal recidivism — but otherwise meets the criteria, Galeotti said, "you may still be eligible for CEP declination based on weighing the severity of those aggravating circumstances and the company's cooperation and remediation."

(4) Delayed self-closure. Galeotti added that the revised policy — which includes a flowchart of the criteria involved with self-reporting — should "provide enhanced clarity and benefits for companies who in good faith self-disclose either not quickly enough or after — unbeknownst to them — the department has already become aware of the misconduct." He noted that the new CEP "put[s] an end to the guessing game companies previously faced under these circumstances."

Those companies "are still eligible to receive significant benefits," he said — including a non-prosecution agreement with a term of fewer than three years, a 75% reduction in the criminal fine, and avoiding the appointment of a compliance monitor.

Monitor Selection Policy

The Criminal Division has also modified its policy on the selection of compliance monitors, Galeotti announced — saying that "the value monitors add is often outweighed by the costs they impose."

"Unrestrained monitors can be a burden on businesses that are frequently making self-directed improvements and investing significant amounts in their own compliance programs to solve problems internally and proactively," he told the conference attendees.

Without proper oversight by the Criminal Division, he said, monitors "can create an adversarial relationship with the companies they monitor, impose significant expense, stray from their core mission, and unduly interfere with business."

"At times," he said, "the money companies spend on their monitor could be better spent investing in their compliance programs or, if they haven't already, making victims whole."

(1) Cost-benefit analysis. Under the new monitor selection policy, Galeotti said, the DOJ will ensure that the benefits of the monitor will outweigh its costs — "both monetary costs, as well as burdens on the business's operations."

"A monitor's costs must be proportionate to the severity of the underlying conduct, the profits of the company, and the company's present size and risk profile," he said.

(2) Factors to consider. To make this calculation, he added, the DOJ will consider:

- the nature and seriousness of the conduct, and the risk that it will happen again — considering chiefly "harms to Americans and American business";
- the availability of other effective independent government oversight — specifically, oversight by regulatory agencies;
- the efficacy of the company's compliance program and compliance culture at the time of the resolution; and
- the maturity of the company's controls, and its ability to test and update its compliance program.

"When a monitor is imposed," Galeotti said, "that monitor must understand that she or he serves the public by ensuring the company will not reoffend and has an appropriate compliance program."

Using its revised monitor selection policy, he added, the DOJ is reviewing each preexisting monitorship "in an effort to narrow their scope or, where appropriate, terminate a monitorship altogether, based on a totality-of-the-circumstances review."

Moreover, he said, the Criminal Division will require a fee cap for monitors, approve the budgets for workplans, and require biannual meetings of the DOJ, the monitor and the company.

Revised Corporate Whistleblower Program

Galeotti also announced changes to the DOJ's corporate whistleblower program — applicable to cases resulting in a forfeiture — that are intended to reflect the department's focus on "the worst actors and the most egregious crimes."

Under the DOJ's Corporate Whistleblower Awards Pilot Program, a whistleblower who provides the Criminal Division with original and truthful information about corporate misconduct that results in a successful forfeiture may be eligible for an award.

Specifically, Galeotti said, the DOJ has added new priority areas for whistleblower tips:

- procurement and federal program fraud;
- trade, tariff and customs fraud;
- violations of federal immigration law; and
- violations including sanctions, material support of foreign terrorist organizations, or facilitating cartels and transnational criminal organizations (TCOs), including money laundering narcotics and violations of the Controlled Substances Act.

II. Foreign Corrupt Practices Act

The DOJ has also issued new guidelines for investigations and enforcement actions conducted under the FCPA.

The department said that the new guidelines are intended to limit "undue burdens" on U.S. companies that operate abroad and to ensure that enforcement actions pursued under the statute target conduct that directly undermines U.S. national interests.

In the past, FDA-regulated companies have frequently come under FCPA enforcement scrutiny, particularly in connection with allegedly illicit transactions involving non-U.S. health care providers and facilities that are part of state-run health care systems.

Issued by Deputy Attorney General (DAG) Todd Blanche on June 9, 2025, the DOJ's "Guidelines for Investigations and Enforcement of the Foreign Corrupt Practices Act" (https://www.justice.gov/dag/media/1403031/dl?inline) are intended to "prioritize American interests, American economic competitiveness with respect to other nations, and the efficient use of federal law enforcement resources," as directed by an executive order issued by President Trump on Feb. 10, 2025 (Executive Order 14209, "Pausing Foreign Corrupt Practices Act Enforcement To Further American Economic and National Security," 90 Fed. Reg. 9587).

The executive order directed the DOJ to ensure that the FCPA is not "stretched beyond proper bounds and abused in a manner that harms the interests of the United States," used "against American citizens and businesses ... for routine business practices in other nations," or enforced in a manner that "harms American economic competitiveness and, therefore, national security."

Factors To Balance

Speaking on June 10, 2025, in New York at the Global Anti-Corruption, Ethics and Compliance Conference, sponsored by the American Conference Institute, Acting Assistant Attorney General Galeotti outlined the provisions of the new FCPA guidelines.

The guidelines provide evaluation criteria and a non-exhaustive list of factors for federal prosecutors to balance when deciding whether to pursue an FCPA case, Galeotti noted.

The factors include but are not limited to the following:

- ***Whether the alleged conduct deprived specific and identifiable U.S. entities of fair access to compete.*** "In addition to distorting markets and undermining the rule of law," the guidelines state, "companies that bribe foreign officials to obtain business can put their law-abiding competitors, including U.S. companies, at a serious economic disadvantage. By bribing foreign officials to obtain lucrative contracts and illicit profits — at times hundreds of millions of dollars — corrupt competitors skew markets and disadvantage law-abiding U.S. companies and others for many years. … Another important factor prosecutors shall consider is whether the alleged misconduct deprived specific and identifiable U.S. entities of fair access to compete and/or resulted in economic injury to specific and identifiable American companies or individuals."

- ***Whether the alleged conduct involves key infrastructure or assets.*** "When this corruption occurs in sectors like defense, intelligence or critical infrastructure," the guidelines state, "American national security interests may be harmed. FCPA enforcement will therefore focus on the most urgent threats to U.S. national security resulting from the bribery of corrupt foreign officials involving key infrastructure or assets."

- ***Whether the alleged conduct bears strong indicia of corrupt intent tied to particular individuals and serious misconduct.*** "FCPA investigations and enforcement actions shall not focus on alleged misconduct involving routine business practices or the type of corporate conduct that involves de minimis or low-dollar, generally accepted business courtesies," the guidelines specify. "Rather, the focus of FCPA enforcement will be on alleged misconduct that bears strong indicia of corrupt intent tied to particular individuals, such as substantial bribe payments, proven and sophisticated efforts to conceal bribe payments, fraudulent conduct in furtherance of the bribery scheme, and efforts to obstruct justice. To prioritize cases that warrant investigation by U.S. authorities, FCPA prosecutors should also consider the likelihood (or lack thereof) that an appropriate foreign law enforcement authority is willing and able to investigate and prosecute the same alleged misconduct."

- ***Whether the alleged conduct is associated with the criminal operations of a cartel or TCO.*** "One primary consideration in deciding whether to pursue an FCPA investigation or enforcement action," the guidelines state, "is whether the alleged misconduct (1) is associated with the criminal operations of a cartel or TCO; (2) utilizes money launderers or shell companies that engage in money laundering for cartels or TCOs; or (3) is linked to employees of state-owned entities or other foreign officials who have received bribes from cartels or TCOs."

No one factor is necessary or dispositive, Galeotti noted.

Focus on U.S. interests. "The through line is that these guidelines require the vindication of U.S. interests," Galeotti said. "People have speculated about the meaning of that phrase, but the DAG's memo makes it clear. It is not about the nationality of the subject or where the company is headquartered."

"In plain terms," he told the conference attendees, "conduct that genuinely impacts the United States or the American people is subject to potential prosecution by U.S. law enforcement. Conduct that does not implicate U.S. interests should be left to our foreign counterparts or appropriate regulators."

Where U.S. interests are not implicated, however, "the Criminal Division won't hesitate to work with our foreign counterparts or domestic regulators to provide assistance and ensure that those countries and regulators can vindicate their interests and pursue their mandates," Galeotti added.

"Common-sense principles." The guidelines also direct "other common-sense principles," Galeotti added, "such as focusing on specific misconduct of individuals, rather than collective knowledge theories."

"The focus of FCPA enforcement will be on alleged misconduct that bears strong indicia of corrupt intent tied to particular individuals," the guidelines state, "such as substantial bribe payments, proven and sophisticated efforts to conceal bribe payments, fraudulent conduct in furtherance of the bribery scheme, and efforts to obstruct justice."

"All of these propositions are not controversial," Galeotti noted. "In fact, we've heard them many times from counsel advocating on behalf of their clients."

Review of Ongoing FCPA Actions

As the guidelines acknowledged, the executive order directed the DOJ not to initiate any new FCPA investigations for a period of 180 days — until Aug. 9, 2025 — unless the attorney general determined that an individual exception should be made.

Moreover, the executive order directed the department to review all existing FCPA investigations and enforcement actions and take appropriate action "to restore proper bounds on FCPA enforcement."

Galeotti reported that the DOJ "has reviewed FCPA matters, closing certain cases and proceeding with others by applying the criteria set forth in the guidelines."

"With these guidelines now in place, and consistent with the executive order, the Criminal Division will enforce the FCPA — firmly but fairly — by bringing enforcement actions against conduct that directly undermines U.S. national interests without losing sight of the burdens on American companies that operate globally," he said.

III. DOJ Civil Division Enforcement Priorities

On June 11, 2025, Assistant Attorney General Brett A. Shumate, the head of the DOJ's Civil Division, issued a memorandum outlining the division's enforcement priorities, which are intended to advance the Trump administration's policy objectives.

Civil Division attorneys were directed "to prioritize investigations and enforcement actions advancing these priorities."

Two of the five enforcement priority areas identified in the memorandum may affect FDA-regulated companies.

(1) "Combatting Discriminatory Practices and Policies." Shumate announced the Civil Division's intention to "use all available resources to pursue affirmative litigation combatting unlawful discriminatory practices in the private sector," in particular targeting "illegal private sector [diversity, equity and inclusion (DEI)] preferences, mandates, policies, programs and activities."

(2) "Protecting Women and Children." Shumate noted in the memorandum that Attorney General Pam Bondi had directed the Civil Division to "act decisively to protect our children and hold accountable those who mutilate them under the guise of care" and "to undertake appropriate investigations of any violations of the [Federal] Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones or any other drug used to facilitate a child's so-called 'gender transition.'"

The assistant attorney general cited Executive Order 14168, "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," issued on Jan. 20, 2025 (90 Fed. Reg. 8615), and Executive Order 14187, "Protecting Children From Chemical and Surgical Mutilation," issued on Jan. 28, 2025 (90 Fed. Reg. 8771).

Shumate said that the Civil Division would "use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with these directives. These efforts will include, but will not be limited to, possible violations of the [Federal] Food, Drug, and Cosmetic Act and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition and (2) dealers such as online pharmacies suspected of illegally selling such drugs."

IV. False Claims Act Working Group

Increased coordination between the DOJ and the Department of Health and Human Services (HHS) in using the federal False Claims Act to target health care fraud may result in more data-driven enforcement activity by the federal government against FDA-regulated companies and other entities.

Among the priorities set for a newly reestablished interdepartmental working group are combatting illegal drug- and device-related kickbacks, as well as fraud related to "materially defective medical devices."

On July 2, 2025, the DOJ's Civil Division and HHS announced a renewal of the False Claims Act Working Group, which is intended to strength the ongoing collaboration between the two departments "to advance priority enforcement areas" under the statute.

The announcement signals the revival of a DOJ-HHS enforcement collaboration initiated in December 2020 in large part to combat fraud against the government in connection with the COVID-19 public health emergency.

The new iteration of the Working Group will include officials from the HHS Office of General Counsel, the Centers for Medicare and Medicaid Services (CMS) Center for Program Integrity, the HHS Office of Inspector General (OIG) Office of Counsel, and the DOJ Civil Division, with designees representing U.S. Attorneys' Offices.

Heading the working group will be the HHS general counsel, the chief counsel to the HHS OIG, and the deputy assistant attorney general heading the DOJ's Commercial Litigation Branch.

Working Group Priorities

Through the Working Group, HHS plans to refer to the DOJ potential violations of the False Claims Act that reflect Working Group priorities.

Identified as priorities in the July 2025 announcement were the following:

- Medicare Advantage;
- drug, device or biologics pricing, including arrangements for discounts, rebates, service fees, and formulary placement and price reporting;
- barriers to patient access to care, including violations of network adequacy requirements;
- kickbacks related to drugs, medical devices, durable medical equipment, and other products paid for by federal health care programs;
- materially defective medical devices that impact patient safety; and
- manipulation of electronic health records systems to drive inappropriate utilization of Medicare-covered products and services.

Alignment with Civil Division enforcement priorities. Other priorities for the Working Group are the DOJ Civil Division's enforcement priorities related to the False Claims Act, which were announced in the June 11, 2025, memorandum issued by Assistant Attorney General Shumate.

In the memorandum, Shumate specified that the division would use the False Claims Act in enforcement actions advancing the Trump administration's policies regarding allegedly illegal private-sector policies and mandates regarding DEI, seeking treble damages and penalties under the statute against recipients of federal funds "that knowingly violate civil rights laws."

He also said that the division would investigate and pursue civil enforcement against false claims submitted to federal health care programs for any noncovered services related to what Attorney General Bondi called "radical gender experimentation."

Moreover, Shumate said, the Civil Division would use the False Claims Act to target "health care providers that bill the federal government for impermissible services … includ[ing], for example, providers that attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes."

'Cross-Agency Collaboration'

The Working Group announced its intention to "maximize cross-agency collaboration to expedite ongoing investigations in these priority areas and identify new leads, including by leveraging HHS resources through enhanced data mining and assessment of HHS and HHS OIG report findings."

Also, the Working Group will consider whether in particular cases HHS should implement payment suspensions under 42 C.F.R. Part 405 Subpart C, which authorizes Medicare to suspend payment to

providers and suppliers or services "in cases of suspected fraud … if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the [DOJ], and determined that a credible allegation of fraud exists against a provider or supplier" (42 C.F.R. §405.371(a)(2)).

Moreover, the Working Group will consider "whether DOJ shall move to dismiss a qui tam complaint" under 31 U.S.C. §3730(c)(2)(A) and Justice Manual §4-4.111, which authorizes the department to seek to block suits brought under the False Claims Act by private whistleblowers to prevent "interference with the agency's policies" or to control litigation brought on behalf of the United States, among other reasons.

The Working Group encouraged whistleblowers "to identify and report violations of the federal False Claims Act involving priority enforcement areas." It also encouraged health care companies to identify and report violations of the statute in accord with the DOJ's guidelines for taking targeted companies' disclosures, cooperation and remediation into account in False Claims Act actions (Justice Manual §4-4.112).

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