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DOJ’s Fraud Division Issues Corporate Enforcement Directive – Continuing to Carve Out a Wider Lane

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Assistant Attorney General Colin M. McDonald of the National Fraud Enforcement Division issued a directive on October 1 providing guidance on the Division’s approach to corporate enforcement. It establishes four corporate enforcement priorities—focused primarily on fraud against the United States—and identifies ten factors governing charging and resolution decisions. It also centralizes review of corporate matters in the Division’s Corporate Enforcement Section and calls for the implementation of a Division whistleblower program. Finally, it signals that responsibility for corporate enforcement within DOJ remains in motion, with the Fraud Division claiming a central role. On October 1, 2026, National Fraud Enforcement Division (Fraud Division) Assistant Attorney General Colin M. McDonald issued Directive 26-12.[1] The directive commits the Division to an “aggressive, all-tools approach” to its “health care, government, tax, and trade fraud priorities,” while pledging to “firmly guard against overbroad corporate enforcement.”[2] It states expressly that the Division aims to avoid “interfer[ing] with legitimate business operations,” and points prosecutors handling corporate matters to the Justice Manual’s Principles of Federal Prosecution of Business Organizations and the Department-wide Corporate Enforcement and Voluntary Self-Disclosure Policy (CEP).[3] Within that framework, the directive does four things:

> (1) Identifies the Division’s corporate enforcement priorities, (2) Enumerates ten factors that must receive “great weight” in charging and resolution decisions, (3) Provides the Division’s Corporate Enforcement Section with responsibility for supporting all corporate matters, from the inception of an investigation through compliance with criminal resolutions, and (4) Orders the development of a whistleblower program.

The directive builds on two earlier policy statements we analyzed in a prior client alert: the Division’s August 13, 2026, priorities memorandum (the Priorities Memo), which devoted two paragraphs to “corporate misconduct” without identifying specific areas of corporate focus, and the August 18, 2026, final rule, which amended the Department’s organizational regulations to define the Division’s jurisdiction (the Fraud Division Rule), giving it concurrent authority with the Criminal Division over most fraud offenses.[4] **What the Directive Does The directive’s corporate priorities track the Division’s four substantive lanes and frame them expansively.** In opening and conducting corporate investigations, prosecutors are to prioritize fraud schemes involving:

- The health care industry, including health care fraud, distribution of controlled substances, and violations of the Federal Food, Drug, and Cosmetic Act (FDCA);
- Public trust or financial integrity of Americans and markets, in connection with procurement, government contracts, and other government functions;
- Significant evasion of internal or external revenue; and
- Tariff evasion, importation of goods or services, or forced labor.[5]

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Health care leads the list and extends broadly to include "the illegal prescribing and dispensing of opioids and other controlled substances"[6] and FDCA violations—areas that fall outside traditional criminal health care fraud enforcement. The Fraud Division's website does not explain how the Division intends to exercise its FDCA enforcement authority or how that authority will intersect with the Criminal Division's White Collar and Corporate Enforcement Section (WCCES), whose Health & Safety Unit currently handles criminal FDCA matters. This creates a potential overlap in enforcement responsibilities; whether DOJ intends to transfer that unit to the Fraud Division or otherwise clarify the allocation of FDCA matters remains unclear. Notably, trade appears twice on the list of priorities: "external revenue" is the Fraud Division Rule's term for customs, duties, and tariffs, and tariff evasion, importation, and forced labor also receive a priority of its own.[7] The priorities are framed largely around fraud that harms the government, taxpayer-funded programs, or the public trust, consistent with the Department's continued framing of the Division as focused on fraud against taxpayer dollars and taxpayer-funded programs.[8]

The ten factors reflect several Administration priorities and frame how the Division will assess the seriousness of corporate misconduct. In recommending outcomes in corporate matters—including whether to bring charges and the terms of any plea or other agreement—Division personnel are to give "great weight" to:

1. Knowledge of or involvement in the scheme by corporate management;
2. Efforts to conceal fraud from government agencies or auditors, or otherwise to impede or obstruct a government function or oversight;
3. Conduct furthering a scheme that lasts three years or more;
4. Actions that threaten the safety or security of Americans, including military readiness;
5. Conduct causing substantial financial hardship to a taxpayer-funded program or government function;
6. Conduct affecting multiple taxpayer-funded programs or government functions;
7. Conduct affecting three or more federal districts;
8. Financial harm to twenty-five or more victims, or $25 million or more in loss;
9. Exfiltration of American dollars to support foreign adversaries; and
10. Immigration offenses.[9]

The directive describes the factors as a non-exhaustive supplement to the Justice Manual's charging factors, and emphasizes that the CEP applies "[i]n all circumstances."[10] Several of the factors have antecedents in the Justice Manual, where management complicity, pervasiveness, and obstruction have long informed charging decisions.[11] Two features nonetheless distinguish the directive. First, it attaches numeric thresholds—three years, three districts, twenty-five victims, $25 million—to concepts the Justice Manual leaves qualitative. Second, it introduces considerations that have no analogue among the Justice Manual's traditional factors, such as military readiness, foreign adversaries, and immigration offenses, which reflect priorities the Administration has pressed across DOJ since early 2025.[12] **The directive makes the Corporate Enforcement Section a player in every corporate matter the Division oversees.** Cases remain with the prosecuting sections, but prosecutors must report every ongoing corporate investigation to the Chief of the Corporate Enforcement Section. The Section must be notified of any new investigations and major developments in existing investigations, and will "participate in matters as necessary and appropriate to ensure that the Division is dedicating adequate resources to corporate matters and complying with Department policies regarding corporate enforcement."[13] For companies, this means two sets of DOJ counterparts in any Fraud Division matter, with the Section focusing on ensuring consistency in the application of DOJ policy across the Division's investigations. This support role will likely be similar to the one that has been played by the Corporate Enforcement and Compliance Unit in the White Collar and Corporate

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Enforcement Section (formerly the Fraud Section). The Section will also have "primary responsibility" for evaluating compliance with corporate criminal resolutions, including compliance program enhancements and reporting obligations.[14] According to the directive, vesting this responsibility with the Section "will free up resources in the prosecuting sections to pursue additional individual and corporate cases," and ensure consistency in "assess[ing] compliance with corporate resolutions."[15] Consequently, companies negotiating or operating under a Fraud Division resolution should expect the Corporate Enforcement Section, rather than the prosecution team, to take the lead on compliance program and reporting obligations.[16] **The directive's call for a whistleblower program that expressly reaches culpable participants raises the importance of internal reporting and early self-disclosure.** Noting that the Division is "proactively generating leads and opening new individual and corporate fraud investigations at a rapid pace" through the National Fraud Detection Center, the directive instructs Division leadership to "design and implement policies and programs that appropriately incentivize whistleblowers," including those who participated in the misconduct, with public transparency "to the extent possible."[17] It does not say whether the program will offer monetary awards, as the Criminal Division's Corporate Whistleblower Awards Pilot Program does for tips concerning, among other things, procurement, trade, and immigration offenses.[18] This escalation echoes the broad trend of whistleblower regimes across multi-agencies. Whatever form it takes, companies should expect that employees with knowledge of misconduct will have an incentive to report externally first, and that the Division's analytics detection capabilities may surface the same conduct independently. Both developments compress the window in which a corporate self-disclosure can earn full credit under the CEP, placing a premium on timing.[19] Companies should therefore ensure that internal reporting channels are credible and well publicized, that allegations are triaged quickly, and that escalation protocols allow for a prompt, informed decision on whether to self-disclose. **Observations for Companies** **The directive confirms that the Fraud Division intends to play a major role in corporate enforcement.** The Priorities Memo listed corporate misconduct last among five priorities; in contrast, this month's directive integrates corporate enforcement throughout the Division's substantive work and makes clear that the Division itself will pursue corporate accountability and resolutions. The Division's announcement of a corporate resolution under the CEP in July, the description of its Corporate Enforcement Section as responsible for supporting litigation sections and promoting consistency across the Division's fraud portfolio, and its establishment of a mandatory intake, participation, and post-resolution monitoring regime for corporate cases all demonstrate that the Fraud Division intends to take more aggressive action in the corporate enforcement space.[20] Combined with the Fraud Division Rule's catch-all provisions, which permit the Attorney General or Deputy Attorney General to assign the Division any case or category of cases, the directive signals that the Division's footprint in corporate enforcement is likely to continue to grow.[21] The Division reinforced that message on October 8 in Directive 26-13, a broader memorandum directing an "all angles" approach to fraud enforcement, which reaffirms that the Corporate Enforcement Section will "lead this charge" by applying Directive 26-12's factors to the Division's priorities.[22] **Lastly, the Division's claim to FDCA and trade enforcement signals an expansive view of the types of conduct that qualify as fraud against Americans, and an even greater role for the Division.** *Companies should account for the possibility that more than one DOJ component may claim an interest in the same conduct.* The Fraud Division Rule and Priorities Memo left the Fraud Division and the Criminal Division with concurrent authority over most fraud offenses, and the directive arrives amid reporting on disputes between the two components over their respective scope and authority, including a staffing arrangement reached in May that is due for re-evaluation this fall.[23] The directive adds FDCA and trade to the areas in which that overlap is likely to be felt. In remarks delivered at Gibson Dunn on September 30, Criminal Division Assistant Attorney General Tysen Duva framed the dividing line between the two components around the victim: "in terms of the loss or the intended loss, who was harmed?"[24] If the government was harmed, the matter belongs to the Fraud Division; "[i]f it's anything else," it belongs to the Criminal Division's White Collar and Corporate Enforcement Section. Trade fraud, which deprives the government of customs revenue, falls readily on the Fraud Division's

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side of that line. The Division's claim to FDCA enforcement is less clear-cut, because FDCA violations frequently harm patients and consumers rather than the government—and Duva himself acknowledged that health care and procurement fraud matters may implicate both components. Companies should take this into account in evaluating risk and in considering whether and where to self-disclose potential misconduct. While the new CEP promises to credit a good-faith disclosure to one appropriate component even if the matter is later handled by another, companies should consider which component is best positioned to receive a disclosure and whether disclosing to multiple components is most protective to ensure proper disclosure credit. [25] *FDCA Enforcement Remains in Flux.* Criminal prosecutors experienced in FDCA enforcement moved in late 2025 from the Civil Division's former Consumer Protection Branch to a Health & Safety Unit within the Criminal Division's Fraud Section (since renamed the White Collar and Corporate Enforcement Section), while civil FDCA enforcement remained with the Civil Division's Consumer Protection Branch (since renamed the Enforcement & Affirmative Litigation Branch).[26] When DOJ renamed the Fraud Section on August 10, a Department spokesperson identified "Food, Drug, Cosmetic Act violations" as among the Criminal Division's Fraud Section's continuing priorities.[27] The directive now places FDCA violations within the Fraud Division's first enumerated corporate priority. Because the priority is framed around "fraud schemes," the Division's FDCA focus will likely be on matters involving an intent to defraud or mislead or potentially adulterated or misbranded products paid for by federal health care programs.[28] Indeed, some of the DOJ's largest historical corporate resolutions have involved misbranded drugs and medical devices paid for by Medicare and Medicaid. As noted above, the Fraud Division's FDCA authority potentially overlaps with the Criminal Division's expertise in this area. Whether the Fraud Division will assume any of that unit's responsibilities or bring its prosecutors into the Division is not yet known, and the unresolved overlap could create friction between the two divisions. The directive thus potentially positions the Fraud Division as a third FDCA enforcer at Main Justice—in addition, of course, to the U.S. Attorney's Offices—alongside the Criminal Division's Health & Safety Unit and the Civil Division's Enforcement & Affirmative Litigation Branch. Companies in the life sciences, medical device, food, and consumer health sectors should assume that FDCA exposure may be evaluated by Fraud Division prosecutors applying the directive's priorities and factors, along with prosecutors in the WCCES Health & Safety Unit or elsewhere. *Trade enforcement shows a similar pattern.* Trade fraud is an area of concurrent Fraud Division and Criminal Division authority under the Fraud Division Rule, but the Fraud Division leads the interagency Trade Fraud Task Force, co-signed its July 2026 enforcement resource guide, and, as noted, returns to trade twice in the directive.[29] Importers and companies with cross-border supply chains should treat customs valuation, classification, country-of-origin, and forced-labor compliance as corporate criminal risk, not solely as a customs-compliance function. *Gibson Dunn's White Collar Defense and Investigations, FDA and Health Care, Consumer Protection, International Trade Advisory and Enforcement, and Sanctions and Export Enforcement Practice Groups are available to advise clients on these developments. Our lawyers include former senior Department of Justice officials who led or supervised components whose work now falls, in whole or in part, within the Division's purview—among them a former Acting Assistant Attorney General of the Criminal Division, a former Senior Deputy Chief of the Criminal Division's Fraud Section and Chief of its FCPA Unit, and the former Director of the Civil Division's Consumer Protection Branch—as well as a former Assistant Secretary of Commerce for Export Enforcement. We are available to help clients assess exposure under the directive's priorities and factors, calibrate compliance programs and internal reporting channels in anticipation of the Division's whistleblower program, evaluate self-disclosure decisions under the CEP, and navigate investigations and resolution negotiations in which the Division has an interest.*

[1] Memorandum from Colin M. McDonald, Assistant Att'y Gen., Nat'l Fraud Enf't Div., U.S. Dep't of Just., *Directive 26-12: Corporate Enforcement in the Fight Against Fraud* (Oct. 1, 2026) [hereinafter Directive 26-12]; Press Release, U.S. Dep't of Just., *Assistant Attorney General Colin M. McDonald Issues Memorandum on the National Fraud Enforcement Division's Corporate Enforcement Priorities* (Oct. 1, 2026). [2] Directive 26-12 at 1–2. [3] Directive 26-12 at 2 (citing Justice Manual § 9-28.000); *see also* U.S. Dep't of Just., *Corporate Enforcement and Voluntary Self-Disclosure Policy* (Mar. 10, 2026)

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[hereinafter CEP]. [4] Memorandum from Colin M. McDonald, Assistant Att'y Gen., Nat'l Fraud Enf't Div., U.S. Dep't of Just., *The Fraud Division's Enforcement Priorities* (Aug. 13, 2026) [hereinafter Priorities Memo]; Establishing the National Fraud Enforcement Division, 91 Fed. Reg. 53,357 (Aug. 18, 2026) (codified at 28 C.F.R. §§ 0.1, 0.13, 0.55, 0.70, 0.71); Gibson Dunn, *The National Fraud Enforcement Division – Final Answers?* (Aug. 20, 2026). The rule amends the Department's organizational regulations in 28 C.F.R. Part 0; it does not modify the Justice Manual, which the directive applies as written. *See* Directive 26-12 at 2, 4 (citing Justice Manual §§ 9-28.000, 9-28.300). [5] Directive 26-12 at 3–4. [6] U.S. Dep't of Just., Nat'l Fraud Enf't Div., *Sections and Offices*, "Health Care Fraud Section" (last visited Oct. 7, 2026). [7] Directive 26-12 at 3–4. [8] *See* Memorandum from Todd Blanche, Acting Att'y Gen., U.S. Dep't of Just., *Creation of the National Fraud Enforcement Division*, at 1 (Apr. 7, 2026) [hereinafter Blanche Memo] (describing the Division's "core mission" as "to zealously investigate and prosecute those who steal or fraudulently misuse taxpayer dollars"); 91 Fed. Reg. at 53,357 (preamble describing the same core mandate); U.S. Dep't of Just., Crim. Div., *White Collar and Corporate Enforcement Section* (last visited Oct. 5, 2026) (listing the section's Securities, Market, and Private Fraud Unit); *DOJ Renames Fraud Section Following White House Driven Shakeup*, Bloomberg Law (Aug. 11, 2026) (reporting a Department spokesperson's description of the renamed section's priorities, including cyber scams, Ponzi schemes, corporate enforcement, and foreign corruption). [9] Directive 26-12 at 4. [10] *Id.* [11] *See* Justice Manual § 9-28.300; *see also* Memorandum from Matthew R. Galeotti, Head of the Crim. Div., U.S. Dep't of Just., *Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime* (May 12, 2025) [hereinafter Galeotti Memo] (directing Criminal Division prosecutors to prioritize schemes involving senior-level personnel, demonstrable loss, and efforts to obstruct justice); Gibson Dunn, *DOJ Announces White Collar Enforcement Priorities* (May 19, 2025). [12] *See* Galeotti Memo, *supra* note 8 (identifying national security offenses among the Criminal Division's priority areas and extending the Corporate Whistleblower Awards Pilot Program to immigration violations); Gibson Dunn, *DOJ Announces White Collar Enforcement Priorities*, *supra* note 8. [13] Directive 26-12 at 3. [14] Directive 26-12 at 2–3. The directive does not reach matters handled by District Fraud Counsel for a U.S. Attorney's Office unless the Division also supervises them. *See id.* at 3 n.2. [15] Directive 26-12 at 3. [16] *Id.* at 3. [17] *Id.* at 4–5. [18] U.S. Dep't of Just., Crim. Div., *Corporate Whistleblower Awards Pilot Program* (as amended May 12, 2025); *see also* Gibson Dunn, *DOJ Announces White Collar Enforcement Priorities*, *supra* note 8 (describing the May 2025 expansion of the program's subject areas). [19] *See* CEP, *supra* note 3; Gibson Dunn, *Key Takeaways from DOJ's First Ever Department-Wide Corporate Enforcement and Voluntary Self-Disclosure Policy* (Mar. 19, 2026). [20] Press Release, U.S. Dep't of Just., *Fraud Division Resolves Fraud Investigation of Eye Care Group Under New Corporate Enforcement Policy* (July 29, 2026); U.S. Dep't of Just., Nat'l Fraud Enf't Div., *Sections and Offices* (last visited Oct. 1, 2026); Directive 26-12 at 2–3. [21] 28 C.F.R. § 0.70(g), (l). [22] Memorandum from Colin M. McDonald, Assistant Att'y Gen., Nat'l Fraud Enf't Div., U.S. Dep't of Just., *Directive 26-13: A Comprehensive Approach in the Fight Against Fraud*, (Oct. 7, 2026); Press Release, U.S. Dep't of Just., *Assistant Attorney General Colin M. McDonald Issues Memorandum on the National Fraud Enforcement Division's Comprehensive Approach in the Fight Against Fraud* (Oct. 8, 2026). [23] *See, e.g.*, Dave Michaels & Sadie Gurman, *Trump's Fraud Squad Is Hobbled by Internal Strife*, Wall St. J. (Aug. 14, 2026); *DOJ Leaders Clash on Expanding Fraud Division to Financial Crime*, Bloomberg Law (May 6, 2026); *DOJ Restores Financial Crime Team in Latest Fraud Office Shakeup*, Bloomberg Law (May 28, 2026) (reporting that the arrangement would be re-evaluated in six months); *DOJ Rule Expands Fraud Division Powers, Restrains Criminal Chief*, Bloomberg Law (Aug. 17, 2026). [24] Gaspard Le Dem, *Fraud Section Shake-Up an "Opportunity" to Rebuild, DOJ Official Says*, Glob. Investing. Rev. (Sept. 30, 2026); Global Investigations Review, *GIR Live: Annual Investigations Meeting New York 2026* (Sept. 30, 2026). [25] CEP, *supra* note 3, at 2 n.5. [26] *See* Press Release, U.S. Dep't of Just., *The Department of Justice Creates New Civil Division Enforcement & Affirmative Litigation Branch* (Sept. 25, 2025); U.S. Dep't of Just., Crim. Div., *Fraud Section Year in Review 2025*; U.S. Dep't of Just., Crim. Div., *White Collar and Corporate Enforcement Section*, *supra* note 5. [27] *DOJ Renames Fraud Section Following White House Driven Shakeup*, *supra* note 5. [28] *See* 21 U.S.C. § 333(a)(2). [29]

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28 C.F.R. § 0.70(c); Trade Fraud Task Force, *A Resource Guide to Trade Fraud Enforcement* (July 2026).

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