



U.S. Department of Justice

Civil Division
Consumer Protection Branch

Voluntary Self-Disclosure Policy for Business Organizations¹ March 2024

Introduction

The Consumer Protection Branch (CPB) leads Department of Justice efforts to enforce laws that protect Americans' health, safety, economic security, and identity integrity. To accomplish its mission, the Branch brings criminal enforcement cases throughout the country.

CPB's criminal enforcement efforts generally fall into two categories. First, CPB prosecutes cases to protect consumer health and safety. Such cases often involve unlawful conduct related to drugs (including prescription and counterfeit drugs), medical devices, food, dietary supplements, and consumer products and vehicles. Second, CPB prosecutes cases that protect consumer economic security and identity integrity, including cases involving data-privacy violations and fraud schemes affecting large numbers of older adults, immigrants, veterans and servicemembers, or other vulnerable victims.

Importantly, CPB is charged with prosecution and oversight of all criminal matters arising under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, and certain other federal statutes. *See* JM 4-1.313, 4-8.000. U.S. Attorney's Offices must notify and consult with CPB upon opening any criminal investigation involving a possible violation of the FDCA. *See* JM 4-8.200, 9-99.000.

CPB encourages companies to voluntarily self-disclose directly to CPB potential violations of federal criminal law involving the manufacture, distribution, sale, or marketing of products regulated by, or conduct under the jurisdiction of, the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), the Federal Trade Commission (FTC), or the National Highway Traffic Safety Administration (NHTSA), as well as potential misconduct involving failures to report to, or misrepresentations to, those agencies. CPB also encourages companies to report potential violations of federal criminal law related to consumer economic security and identity integrity, as described above.² This policy sets forth the criteria

¹ This policy does not create any privileges, benefits, or rights, substantive or procedural, enforceable by any individual, organization, party, or witness in any administrative, civil, or criminal matter.

² Companies should continue to make voluntary self-disclosures to appropriate regulatory agencies under existing regulations and procedures. It is not the purpose of this policy to alter that practice. However, if a company identifies potentially intentional or willful conduct, but chooses to self-report only to a regulatory agency and not to CPB, the company will not qualify

that CPB uses in determining an appropriate resolution for an organization that timely makes a voluntary self-disclosure in such matters.

Written voluntary self-disclosures covered by this policy should be emailed to CPB at the following address: consumer.disclosure@usdoj.gov.

Benefits of the Policy

Absent the presence of aggravating factors, CPB will not seek a guilty plea as to a company, its subsidiaries, or successors for disclosed conduct if the company has (1) voluntarily self-disclosed in writing directly to CPB; (2) fully cooperated as described in JM § 9-28.700; and (3) timely and appropriately remediated the criminal conduct as described in U.S.S.G. § 8B2.1(b)(7), including providing restitution to identifiable victims and improving its compliance program to mitigate the risk of engaging in future illegal activity. CPB also will not require the imposition of an independent compliance monitor for a cooperating company that voluntarily self-discloses the relevant conduct if, at the time of resolution, the company also demonstrates that it has implemented and tested an effective compliance program as described in U.S.S.G. § 8B2.1.

In addition, CPB will apply a presumption in favor of declining prosecution as to a company that undertakes a lawful, bona fide, acquisition of another corporate entity³ if the acquiring company has (1) voluntarily self-disclosed, in writing directly to CPB, misconduct by the acquired entity that the acquiror uncovered as a result of due diligence conducted shortly before or shortly after the acquisition;⁴ (2) disclosed such misconduct within 180 days of the date of closing;⁵ (3) fully cooperated as described in JM § 9-28.700; and (4) appropriately remediated

for the benefits of a voluntary self-disclosure under this policy in any subsequent CPB investigation.

³ CPB may, in its discretion, apply this policy to a corporate “merger of equals” or other transactional structures, depending on the extent to which the merged or consolidated company differs from the corporate entity where the misconduct occurred, including whether the new entity operates with a significantly more robust compliance function and under new management not associated with the prior misconduct.

⁴ If CPB determines that the acquiror or its agents have presented false information to CPB, including about the extent of their prior knowledge of the acquiree’s misconduct, the acquiror shall not qualify for a presumption in favor of declining prosecution, and CPB also will determine whether a separate criminal investigation into the false statements is warranted.

⁵ If the acquiring company possesses evidence of misconduct that endangers national security or presents an ongoing or imminent harm, the company will disclose that misconduct expeditiously rather than wait until the end of the 180-day post-closing window. CPB will not apply a presumption in favor of declining prosecution when a company fails to disclose such misconduct

the criminal conduct within one year as described in U.S.S.G. § 8B2.1(b)(7), including the payment of any restitution or forfeiture arising from the misconduct at issue.⁶ CPB will subject any extensions of these deadlines to a reasonableness analysis, depending on the specific facts, circumstances, and complexity of the particular transaction. This presumption applies only to the acquiror, not to the acquired entity.⁷ CPB also will not factor any misconduct so disclosed in a future recidivist analysis for the acquiring company.

Voluntary Self-Disclosure

In evaluating self-disclosure, CPB will make a careful assessment of the circumstances of the disclosure. CPB will require the following items for a company to receive credit for voluntary self-disclosure of wrongdoing:

- The company discloses the conduct in writing directly to CPB “prior to an imminent threat of disclosure or government investigation,” U.S.S.G. § 8C2.5(g)(1);⁸
- The company discloses the conduct directly to CPB “within a reasonably prompt time after becoming aware of the offense,” U.S.S.G. § 8C2.5(g)(1), with the burden being on the company to demonstrate timeliness;
- The company has no pre-existing obligation to disclose, such as pursuant to regulation, contract, or a prior Department or regulatory resolution;
- The company’s disclosure is accompanied by timely preservation, collection, and production of relevant documents and/or information; and

expeditiously, and will consider the seriousness of the harm or potential danger when assessing how expeditious the disclosure should be.

⁶ Prior to declining a prosecution under such circumstances, CPB will consult with the Antitrust and National Security Divisions to ensure that a potential declination would not interfere or be inconsistent with any civil or administrative process related to the acquisition. To the extent an acquiror discloses violations of the Sherman Act by the acquired entity to CPB, CPB will refer such disclosures to the Antitrust Division for further evaluation before determining if a presumption of declination applies.

⁷ To the extent that the acquired company remains a distinct legal entity following the acquisition and faces potential criminal liability for its prior misconduct, CPB will credit the acquiring entity’s timely disclosure and will consider whether the acquired entity otherwise qualifies for benefits under this voluntary self-disclosure policy.

⁸ If a company makes a disclosure before it becomes aware of an ongoing nonpublic government investigation, the company will be considered to have made a voluntary self-disclosure.

- The company discloses all relevant facts known to it at the time of the disclosure, including as to any individuals substantially involved in or responsible for the misconduct at issue and as to any third parties involved in the misconduct at issue.⁹

Credit for voluntary self-disclosure is not in any way predicated upon waiver of the attorney-client privilege or work product protection, and none of the requirements above require such waiver.

Potential Aggravating Factors¹⁰

Due to the wide variety of criminal enforcement matters CPB pursues, it is not possible to identify all potential aggravating factors that may apply in a particular matter to influence the application of this policy. CPB prosecutors also must balance the goal of encouraging disclosures against the goal of deterring very serious offenses. However, the following non-exhaustive list of circumstances, if present to a significant degree, could result in a more stringent resolution for an organization:

- Conduct that is deeply pervasive throughout the company;
- Intentional or willful conduct that places consumers at significant risk of death or serious bodily injury;
- Conduct that intentionally or willfully targets older adults, immigrants, veterans and servicemembers, or other vulnerable victims; and
- Knowing involvement of upper management in the criminal conduct.

Conclusion

This policy will serve to further deter violations of federal law that affect Americans' health, safety, economic security, and identity integrity; encourage companies to implement strong compliance programs to prevent and detect such violations; and increase the ability of CPB to prosecute individual wrongdoers whose conduct might otherwise have gone undiscovered or been impossible to prove.

⁹ CPB recognizes that a company may not be in a position to know all relevant facts at the time of a voluntary self-disclosure, especially where only preliminary investigative efforts have been possible. In such circumstances, a company should make clear that it is making its written disclosure based upon a preliminary investigation or assessment of information, but it should nonetheless provide a fulsome disclosure of the relevant facts known to it at that time.

¹⁰ Where a voluntary disclosure meets the other requirements for disclosure related to a merged or acquired company, the presence of aggravating factors at the acquired company will not impact the benefits available to the acquiring company.