



U.S. Department of Justice

Civil Division
Consumer Protection Branch

Voluntary Self-Disclosure Policy for Business Organizations¹ *February 2023*

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.

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 (1) the company has voluntarily self-disclosed 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.

In addition, CPB 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.

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 directly to CPB “prior to an imminent threat of disclosure or government investigation,” U.S.S.G. § 8C2.5(g)(1);³
- 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;⁴

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

³ 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.

⁴ When a company undertakes a merger or acquisition, uncovers misconduct by the merged or acquired entity through thorough and timely due diligence or, in appropriate instances, through post-acquisition audits or compliance integration efforts, and voluntarily self-discloses the misconduct and otherwise takes action consistent with this policy (including, among other requirements, the timely implementation of an effective compliance program at the merged or

- The company has no pre-existing obligation to disclose the conduct to the Department, such as pursuant to a prior resolution;
- The company's disclosure is accompanied by timely preservation, collection, and production of relevant documents and/or information; and
- 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.⁵

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 Factors

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;
- Knowing involvement of upper management in the criminal conduct.

acquired entity), there will be a presumption against a guilty plea in accordance with and subject to the other requirements of this policy.

⁵ 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 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.

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.