

Responding to Government Investigations of Fraud and Abuse: Legal and Practical Issues

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Overview

- **General Background Observations**
- **Government's Major Tools for Investigating Fraud & Abuse**
- **Key Challenges for Companies Involved in a Government Investigation**
- **Preparing for a Government Investigation**

General Background Observations

- Medical device companies face scrutiny (and exposure) from many sources
 - Department of Justice
 - HHS (OIG)
 - State Attorneys General
 - Postal Investigators
 - DOD
 - Veteran's Administration
 - Private *qui tam* plaintiffs
- Federal government has heightened its commitment to enforcement
 - Increased number of enforcement actions
 - Increased funding
 - Expanded statutory framework
- Recent (March '05) subpoenas

Government's Major Tools for Investigating Fraud and Abuse

- Tools for gathering information *(See APPENDIX for more detailed information.)*
 - Search warrants
 - Grand jury subpoenas
 - Administrative subpoenas
 - DOJ Civil Investigative Demands
 - DOJ Authorized Investigative Demands
 - Informal document requests
 - Contacts between government agents and company employees
 - FDA inspection authority
- Statutes

Key Challenges for Companies Involved in a Government Investigation

- Easy to be caught unprepared
- High stakes
- Challenges created by Thompson Memo

Preparing for a Government Investigation

- Devise responses to full range of potential investigative issues (policies and procedures)
- Education and training
- Create “checklists”

APPENDIX

Investigative Tools:

Search Warrants

- Court order, pursuant to application from a prosecutor or agent, authorizing agents to search for and seize: (1) evidence, (2) contraband, (3) instrumentalities, or (4) a person subject to arrest.
- Search warrants are only available in criminal cases and must specify the place to be searched and items to be seized.
- They may be based on affidavit or sworn testimony. Affidavits are usually sealed, particularly in early stages of investigation.
- Search warrants must be executed between 6:00am—10:00pm (absent court approval).
- Agents must provide copy of warrant at outset of search and an inventory of items seized at conclusion.

Search Warrants *(cont'd)*

- Increasingly, agents are attempting to interview employees simultaneously with execution of warrant.
- Search warrants have been used against pharmaceutical and other health care companies in recent years:
 - Columbia/HCA
 - Liberty Medical
- Search warrants increasingly are used to obtain evidence stored on company computers, including laptops and PDAs of field sales personnel.

Search Warrants: FDA vs. Other Investigative Agencies

- Because FDA conducts regulatory inspections (e.g., GMP inspections) and criminal investigations, it is important to determine quickly the nature of an FDA inquiry.
- Criminal investigations are handled by the Office of Criminal Investigations (OCI), whose investigators are authorized to carry weapons, execute warrants, and make arrests.
- Circumstances indicating an OCI investigation:
 - Credentials—OCI investigators are Series 200(e) or (f); regulatory inspectors' credentials are Series 200(d).
 - Regulatory inspectors will present company with Form 482 (notice of inspection under FDCA); OCI agents will not present such forms.
 - Regulatory inspectors may review only certain records (e.g., not authorized to review sales or pricing records); OCI has same authority and also entitled to search and seize any records as specified in search warrant.

Investigative Tools: Subpoenas & Related Demands

- Federal Grand Jury Subpoenas:
 - **Type of investigation:** Any Federal crime being investigated by grand jury
 - **Authority to issue:** Technically issued by grand jury, but process controlled in fact by prosecutor
 - **Documents/testimony:** Both
 - **Substantive scope:** No showing of relevance required
 - **Secrecy:** Rule 6(e) imposes secrecy requirements on GJ proceedings. Thus, evidence obtained cannot be shared with civil prosecutors (absent a court order). However, recipients of GJ subpoena generally are under no obligation to keep the fact of the subpoena secret; thus, government usually does not use during “covert” phase of an investigation.
 - **Practical issues:**
 - GJ subpoenas often specify that original documents (not copies) must be produced.
 - Frequently, the timing and scope of response is negotiated with the prosecutor.

Investigative Tools: Subpoenas & Related Demands

- DOJ Authorized Investigative Demands (AIDs):
 - **Type of investigation:** Federal health care fraud offenses
 - **Authority to issue:** Local US Attorneys' Office
 - **Documents/testimony:** Documents, testimony only for document authentication
 - **Substantive scope:** Materials that “may be relevant to an authorized law enforcement inquiry”—extremely broad, though scope not yet litigated
 - **Secrecy:** None, thus evidence obtained may be shared with civil prosecutors
 - **Practical issues:**
 - May be issued before, during, or after the commencement of a grand jury investigation

Investigative Tools: Subpoenas & Related Demands

- DOJ Civil Investigative Demands (CIDs):
 - **Type of investigation:** Violations of Federal Civil False Claims Act
 - **Authority to issue:** Attorney General only (prepared by trial attorneys, reviewed within Main DOJ, signed personally by Attorney General—authority not delegable)
 - **Documents/testimony:** Documents and testimony
 - **Substantive scope:** Very broad, similar to grand jury subpoena
 - **Secrecy:** None
 - **Practical issues:**
 - Due to Attorney General approval requirement, usually reserved for more serious cases
 - Usually issued only after criminal case has been declined

Investigative Tools: Subpoenas & Related Demands

- HHS IG Subpoenas:
 - **Type of investigation:** Fraud (civil or criminal) involving the delivery of or payment for health care in the US (including private insurers)
 - **Authority to issue:** HHS IG, usually after review by Office of Counsel to the HHS IG
 - **Documents/testimony:** Documents only
 - **Substantive scope:** No showing of relevance required
 - **Secrecy:** None
 - **Practical issues:**
 - Because prosecutors generally prefer to use grand jury subpoenas for criminal cases, vast majority of HHS OIG subpoenas are for civil fraud investigations

Investigative Tools: Employee Interviews

- FBI and other agencies are increasing their use of surprise, non-custodial interviews in white-collar investigations, frequently visiting employees at their homes or attempting to interview employees while executing search warrant.
- Agents not required to give Miranda warnings unless interviewee is in custody.
- Employees not required to be interviewed. If they do agree, they can request that company or personal counsel be present.
- Companies can and should advise employees of their rights and responsibilities regarding government interview—but companies should not advise employees not to cooperate, which could be construed as obstructing the investigation.
- The most important advice to employees—be truthful.



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

January 20, 2003

MEMORANDUM**TO:** Heads of Department Components
United States Attorneys**FROM:** Larry D. Thompson
Deputy Attorney General**SUBJECT:** Principles of Federal Prosecution of Business Organizations

As the Corporate Fraud Task Force has advanced in its mission, we have confronted certain issues in the principles for the federal prosecution of business organizations that require revision in order to enhance our efforts against corporate fraud. While it will be a minority of cases in which a corporation or partnership is itself subjected to criminal charges, prosecutors and investigators in every matter involving business crimes must assess the merits of seeking the conviction of the business entity itself.

Attached to this memorandum are a revised set of principles to guide Department prosecutors as they make the decision whether to seek charges against a business organization. These revisions draw heavily on the combined efforts of the Corporate Fraud Task Force and the Attorney General's Advisory Committee to put the results of more than three years of experience with the principles into practice.

The main focus of the revisions is increased emphasis on and scrutiny of the authenticity of a corporation's cooperation. Too often business organizations, while purporting to cooperate with a Department investigation, in fact take steps to impede the quick and effective exposure of the complete scope of wrongdoing under investigation. The revisions make clear that such conduct should weigh in favor of a corporate prosecution. The revisions also address the efficacy of the corporate governance mechanisms in place within a corporation, to ensure that these measures are truly effective rather than mere paper programs.

Further experience with these principles may lead to additional adjustments. I look forward to hearing comments about their operation in practice. Please forward any comments to Christopher Wray, the Principal Associate Deputy Attorney General, or to Andrew Hruska, my Senior Counsel.

Federal Prosecution of Business Organizations¹**I. Charging a Corporation: General**

A. General Principle: Corporations should not be treated leniently because of their artificial nature nor should they be subject to harsher treatment. Vigorous enforcement of the criminal laws against corporate wrongdoers, where appropriate results in great benefits for law enforcement and the public, particularly in the area of white collar crime. Indicting corporations for wrongdoing enables the government to address and be a force for positive change of corporate culture, alter corporate behavior, and prevent, discover, and punish white collar crime.

B. Comment: In all cases involving corporate wrongdoing, prosecutors should consider the factors discussed herein. First and foremost, prosecutors should be aware of the important public benefits that may flow from indicting a corporation in appropriate cases. For instance, corporations are likely to take immediate remedial steps when one is indicted for criminal conduct that is pervasive throughout a particular industry, and thus an indictment

often provides a unique opportunity for deterrence on a massive scale. In addition, a corporate indictment may result in specific deterrence by changing the culture of the indicted corporation and the behavior of its employees. Finally, certain crimes that carry with them a substantial risk of great public harm, e.g., environmental crimes or financial frauds, are by their nature most likely to be committed by businesses, and there may, therefore, be a substantial federal interest in indicting the corporation.

Charging a corporation, however, does not mean that individual directors, officers, employees, or shareholders should not also be charged. Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation. Because a corporation can act only through individuals, imposition of individual criminal liability may provide the strongest deterrent against future corporate wrongdoing. Only rarely should provable individual culpability not be pursued, even in the face of offers of corporate guilty pleas.

Corporations are "legal persons," capable of suing and being sued, and capable of committing crimes. Under the doctrine of *respondeat superior*, a corporation may be held criminally liable for the illegal acts of its directors, officers, employees, and agents. To hold a corporation liable for these actions, the government must establish that the corporate agent's actions (i) were within the scope of his duties and (ii) were intended, at least in part, to benefit the corporation. In all cases involving wrongdoing by corporate agents, prosecutors should consider the corporation, as well as the responsible individuals, as potential criminal targets.

Agents, however, may act for mixed reasons -- both for self-aggrandizement (both direct and indirect) and for the benefit of the corporation, and a corporation may be held liable as long as one motivation of its agent is to benefit the corporation. In *United States v. Automated Medical Laboratories*, 770 F.2d 399 (4th Cir. 1985), the court affirmed the corporation's conviction for the actions of a subsidiary's employee despite its claim that the employee was acting for his own benefit, namely his "ambitious nature and his desire to ascend the corporate ladder." The court stated, "*Partucci* was clearly acting in part to benefit AML since his advancement within the corporation depended on AML's well-being and its lack of difficulties with the FDA." Similarly, in *United States v. Cincotta*, 689 F.2d 238, 241-42 (1st Cir. 1982), the court held, "criminal liability may be imposed on the corporation only where the agent is acting within the scope of his employment. That, in turn, requires that the agent be performing acts of the kind which he is authorized to perform, and those acts must be motivated -- at least in part -- by an intent to benefit the corporation." Applying this test, the court upheld the corporation's conviction, notwithstanding the substantial personal benefit reaped by its miscreant agents, because the fraudulent scheme required money to pass through the corporation's treasury and the fraudulently obtained goods were resold to the corporation's customers in the corporation's name. As the court concluded, "Mystic--not the individual defendants--was making money by selling oil that it had not paid for."

Moreover, the corporation need not even necessarily profit from its agent's actions for it to be held liable. In *Automated Medical Laboratories*, the Fourth Circuit stated:

[B]enefit is not a "touchstone of criminal corporate liability; benefit at best is an evidential, not an operative, fact." Thus, whether the agent's actions ultimately redounded to the benefit of the corporation is less significant than whether the agent acted with the intent to benefit the corporation. The basic purpose of requiring that an agent have acted with the intent to benefit the corporation, however, is to insulate the corporation from criminal liability for actions of its agents which be inimical to the interests of the corporation or which may have been undertaken solely to advance the interests of that agent or of a party other than the corporation.

770 F.2d at 407 (emphasis added; quoting *Old Monastery Co. v. United States*, 147 F.2d 905, 908 (4th Cir.), cert. denied, 326 U.S. 734 (1945)).

II. Charging a Corporation: Factors to Be Considered

A. General Principle: Generally, prosecutors should apply the same factors in determining whether to charge a corporation as they do with respect to individuals. See USAM § 9-27.220, *et seq.* Thus, the prosecutor should weigh all of the factors normally considered in the sound exercise of prosecutorial judgment: the sufficiency of the evidence; the likelihood of success at trial; the probable deterrent, rehabilitative, and other consequences of conviction; and the adequacy of noncriminal approaches. See *id.* However, due to the nature of the corporate "person," some additional factors are present. In conducting an investigation, determining whether to bring

charges, and negotiating plea agreements, prosecutors should consider the following factors in reaching a decision as to the proper treatment of a corporate target:

1. the nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime (see section III, *infra*);

2. the pervasiveness of wrongdoing within the corporation, including the complicity in, or condonation of, the wrongdoing by corporate management (see section IV, *infra*);

3. the corporation's history of similar conduct, including prior criminal, civil, and regulatory enforcement actions against it (see section V, *infra*);

4. the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents, including, if necessary, the waiver of corporate attorney-client and work product protection (see section VI, *infra*);

5. the existence and adequacy of the corporation's compliance program (see section VII, *infra*);

6. the corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies (see section VIII, *infra*);

7. collateral consequences, including disproportionate harm to shareholders, pension holders and employees not proven personally culpable and impact on the public arising from the prosecution (see section IX, *infra*); and

8. the adequacy of the prosecution of individuals responsible for the corporation's malfeasance;

9. the adequacy of remedies such as civil or regulatory enforcement actions (see section X, *infra*).

B. Comment: As with the factors relevant to charging natural persons, the foregoing factors are intended to provide guidance rather than to mandate a particular result. The factors listed in this section are intended to be illustrative of those that should be considered and not a complete or exhaustive list. Some or all of these factors may or may not apply to specific cases, and in some cases one factor may override all others. The nature and seriousness of the offense may be such as to warrant prosecution regardless of the other factors. Further, national law enforcement policies in various enforcement areas may require that more or less weight be given to certain of these factors than to others.

In making a decision to charge a corporation, the prosecutor generally has wide latitude in determining when, whom, how, and even whether to prosecute for violations of Federal criminal law. In exercising that discretion, prosecutors should consider the following general statements of principles that summarize appropriate considerations to be weighed and desirable practices to be followed in discharging their prosecutorial responsibilities. In doing so, prosecutors should ensure that the general purposes of the criminal law -- assurance of warranted punishment, deterrence of further criminal conduct, protection of the public from dangerous and fraudulent conduct, rehabilitation of offenders, and restitution for victims and affected communities -- are adequately met, taking into account the special nature of the corporate "person."

III. Charging a Corporation: Special Policy Concerns

A. General Principle: The nature and seriousness of the crime, including the risk of harm to the public from the criminal conduct, are obviously primary factors in determining whether to charge a corporation. In addition, corporate conduct, particularly that of national and multi-national corporations, necessarily intersects with federal economic, taxation, and criminal law enforcement policies. In applying these principles, prosecutors must consider the practices and policies of the appropriate Division of the Department, and must comply with those policies to the extent required.

B. Comment: In determining whether to charge a corporation, prosecutors should take into account federal law enforcement priorities as discussed above. See USAM § 9-27-230. In addition, however, prosecutors must be aware of the specific policy goals and incentive programs established by the respective Divisions and regulatory agencies. Thus, whereas natural persons may be given incremental degrees of credit (ranging from immunity to lesser charges to sentencing considerations) for turning themselves in, making statements against their penal interest, and cooperating in the government's investigation of their own and others' wrongdoing, the same approach may not be appropriate in all circumstances with respect to corporations. As an example, it is entirely proper in many investigations for a prosecutor to consider the corporation's pre-indictment conduct, e.g., voluntary disclosure, cooperation, remediation or restitution, in determining whether to seek an indictment. However, this would not necessarily be appropriate in an antitrust investigation, in which antitrust violations, by definition, go to the heart of the corporation's business and for which the Antitrust Division has therefore established a firm policy, understood in the business community, that credit should not be given at the charging stage for a compliance program and that amnesty is available only to the first corporation to make full disclosure to the government. As another example, the Tax Division has a strong preference for prosecuting responsible individuals, rather than entities, for corporate tax offenses. Thus, in determining whether or not to charge a corporation, prosecutors should consult with the Criminal, Antitrust, Tax, and Environmental and Natural Resources Divisions, if appropriate or required.

IV. Charging a Corporation: Pervasiveness of Wrongdoing Within the Corporation

A. General Principle: A corporation can only act through natural persons, and it is therefore held responsible for the acts of such persons fairly attributable to it. Charging a corporation for even minor misconduct may be appropriate where the wrongdoing was pervasive and was undertaken by a large number of employees or by all the employees in a particular role within the corporation, e.g., salesmen or procurement officers, or was condoned by upper management. On the other hand, in certain limited circumstances, it may not be appropriate to impose liability upon a corporation, particularly one with a compliance program in place, under a strict *respondeat superior* theory for the single isolated act of a rogue employee. There is, of course, a wide spectrum between these two extremes, and a prosecutor should exercise sound discretion in evaluating the pervasiveness of wrongdoing within a corporation.

B. Comment: Of these factors, the most important is the role of management. Although acts of even low-level employees may result in criminal liability, a corporation is directed by its management and management is responsible for a corporate culture in which criminal conduct is either discouraged or tacitly encouraged. As stated in commentary to the Sentencing Guidelines:

Pervasiveness [is] case specific and [will] depend on the number, and degree of responsibility, of individuals [with] substantial authority ... who participated in, condoned, or were willfully ignorant of the offense. Fewer individuals need to be involved for a finding of pervasiveness if those individuals exercised a relatively high degree of authority. Pervasiveness can occur either within an organization as a whole or within a unit of an organization.

USSG §8C2.5, comment. (n. 4).

V. Charging a Corporation: The Corporation's Past History

A. General Principle: Prosecutors may consider a corporation's history of similar conduct, including prior criminal, civil, and regulatory enforcement actions against it, in determining whether to bring criminal charges.

B. Comment: A corporation, like a natural person, is expected to learn from its mistakes. A history of similar conduct may be probative of a corporate culture that encouraged, or at least condoned, such conduct, regardless of any compliance programs. Criminal prosecution of a corporation may be particularly appropriate where the corporation previously had been subject to non-criminal guidance, warnings, or sanctions, or previous criminal charges, and yet it either had not taken adequate action to prevent future unlawful conduct or had continued to engage in the conduct in spite of the warnings or enforcement actions taken against it. In making this determination, the corporate structure itself, e.g., subsidiaries or operating divisions, should be ignored, and enforcement actions taken against the corporation or any of its divisions, subsidiaries, and affiliates should be considered. See USSG § 8C2.5(c) & comment. (n. 6).

VI. Charging a Corporation: Cooperation and Voluntary Disclosure

A. General Principle: In determining whether to charge a corporation, that corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate with the government's investigation may be relevant factors. In gauging the extent of the corporation's cooperation, the prosecutor may consider the corporation's willingness to identify the culprits within the corporation, including senior executives; to make witnesses available; to disclose the complete results of its internal investigation; and to waive attorney-client and work product protection.

B. Comment: In investigating wrongdoing by or within a corporation, a prosecutor is likely to encounter several obstacles resulting from the nature of the corporation itself. It will often be difficult to determine which individual took which action on behalf of the corporation. Lines of authority and responsibility may be shared among operating divisions or departments, and records and personnel may be spread throughout the United States or even among several countries. Where the criminal conduct continued over an extended period of time, the culpable or knowledgeable personnel may have been promoted, transferred, or fired, or they may have quit or retired. Accordingly, a corporation's cooperation may be critical in identifying the culprits and locating relevant evidence.

In some circumstances, therefore, granting a corporation immunity or amnesty or pretrial diversion may be considered in the course of the government's investigation. In such circumstances, prosecutors should refer to the principles governing non-prosecution agreements generally. See USAM § 9-27.600-650. These principles permit a non prosecution agreement in exchange for cooperation when a corporation's "timely cooperation appears to be necessary to the public interest and other means of obtaining the desired cooperation are unavailable or would not be effective." Prosecutors should note that in the case of national or multi-national corporations, multi-district or global agreements may be necessary. Such agreements may only be entered into with the approval of each affected district or the appropriate Department official. See USAM §9-27.641.

In addition, the Department, in conjunction with regulatory agencies and other executive branch departments, encourages corporations, as part of their compliance programs, to conduct internal investigations and to disclose their findings to the appropriate authorities. Some agencies, such as the SEC and the EPA, as well as the Department's Environmental and Natural Resources Division, have formal voluntary disclosure programs in which self-reporting, coupled with remediation and additional criteria, may qualify the corporation for amnesty or reduced sanctions.² Even in the absence of a formal program, prosecutors may consider a corporation's timely and voluntary disclosure in evaluating the adequacy of the corporation's compliance program and its management's commitment to the compliance program. However, prosecution and economic policies specific to the industry or statute may require prosecution notwithstanding a corporation's willingness to cooperate. For example, the Antitrust Division offers amnesty only to the first corporation to agree to cooperate. This creates a strong incentive for corporations participating in anti-competitive conduct to be the first to cooperate. In addition, amnesty, immunity, or reduced sanctions may not be appropriate where the corporation's business is permeated with fraud or other crimes.

One factor the prosecutor may weigh in assessing the adequacy of a corporation's cooperation is the completeness of its disclosure including, if necessary, a waiver of the attorney-client and work product protections, both with respect to its internal investigation and with respect to communications between specific officers, directors and employees and counsel. Such waivers permit the government to obtain statements of possible witnesses, subjects, and targets, without having to negotiate individual cooperation or immunity agreements. In addition, they are often critical in enabling the government to evaluate the completeness of a corporation's voluntary disclosure and cooperation. Prosecutors may, therefore, request a waiver in appropriate circumstances.³ The Department does not, however, consider waiver of a corporation's attorney-client and work product protection an absolute requirement, and prosecutors should consider the willingness of a corporation to waive such protection when necessary to provide timely and complete information as one factor in evaluating the corporation's cooperation.

Another factor to be weighed by the prosecutor is whether the corporation appears to be protecting its culpable employees and agents. Thus, while cases will differ depending on the circumstances, a corporation's promise of support to culpable employees and agents, either through the advancing of attorneys fees,⁴ through retaining the employees without sanction for their misconduct, or through providing information to the employees about the government's investigation pursuant to a joint defense agreement, may be considered by the prosecutor in weighing the extent and value of a corporation's cooperation. By the same token, the prosecutor

should be wary of attempts to shield corporate officers and employees from liability by a willingness of the corporation to plead guilty.

Another factor to be weighed by the prosecutor is whether the corporation, while purporting to cooperate, has engaged in conduct that impedes the investigation (whether or not rising to the level of criminal obstruction). Examples of such conduct include: overly broad assertions of corporate representation of employees or former employees; inappropriate directions to employees or their counsel, such as directions not to cooperate openly and fully with the investigation including, for example, the direction to decline to be interviewed; making presentations or submissions that contain misleading assertions or omissions; incomplete or delayed production of records; and failure to promptly disclose illegal conduct known to the corporation.

Finally, a corporation's offer of cooperation does not automatically entitle it to immunity from prosecution. A corporation should not be able to escape liability merely by offering up its directors, officers, employees, or agents as in lieu of its own prosecution. Thus, a corporation's willingness to cooperate is merely one relevant factor, that needs to be considered in conjunction with the other factors, particularly those relating to the corporation's past history and the role of management in the wrongdoing.

VII. Charging a Corporation: Corporate Compliance Programs

A. General Principle: Compliance programs are established by corporate management to prevent and to detect misconduct and to ensure that corporate activities are conducted in accordance with all applicable criminal and civil laws, regulations, and rules. The Department encourages such corporate self-policing, including voluntary disclosures to the government of any problems that a corporation discovers on its own. However, the existence of a compliance program is not sufficient, in and of itself, to justify not charging a corporation for criminal conduct undertaken by its officers, directors, employees, or agents. Indeed, the commission of such crimes in the face of a compliance program may suggest that the corporate management is not adequately enforcing its program. In addition, the nature of some crimes, e.g., antitrust violations, may be such that national law enforcement policies mandate prosecutions of corporations notwithstanding the existence of a compliance program.

B. Comment: A corporate compliance program, even one specifically prohibiting the very conduct in question, does not absolve the corporation from criminal liability under the doctrine of *respondeat superior*. See *United States v. Basic Construction Co.*, 711 F.2d 570 (4th Cir. 1983) ("a corporation may be held criminally responsible for antitrust violations committed by its employees if they were acting within the scope of their authority, or apparent authority, and for the benefit of the corporation, even if... such acts were against corporate policy or express instructions."). In *United States v. Hilton Hotels Corp.*, 467 F.2d 1000 (9th Cir. 1972), *cert. denied*, 409 U.S. 1125 (1973), the Ninth Circuit affirmed antitrust liability based upon a purchasing agent for a single hotel threatening a single supplier with a boycott unless it paid dues to a local marketing association, even though the agent's actions were contrary to corporate policy and directly against express instructions from his superiors. The court reasoned that Congress, in enacting the Sherman Antitrust Act, "intended to impose liability upon business entities for the acts of those to whom they choose to delegate the conduct of their affairs, thus stimulating a maximum effort by owners and managers to assure adherence by such agents to the requirements of the Act."⁵ It concluded that "general policy statements" and even direct instructions from the agent's superiors were not sufficient; "Appellant could not gain exculpation by issuing general instructions without undertaking to enforce those instructions by means commensurate with the obvious risks." See also *United States v. Beusch*, 596 F.2d 871, 878 (9th Cir. 1979) ("[A] corporation may be liable for the acts of its employees done contrary to express instructions and policies, but ... the existence of such instructions and policies may be considered in determining whether the employee in fact acted to benefit the corporation."); *United States v. American Radiator & Standard Sanitary Corp.*, 433 F.2d 174 (3rd Cir. 1970) (affirming conviction of corporation based upon its officer's participation in price-fixing scheme, despite corporation's defense that officer's conduct violated its "rigid anti-fraternization policy" against any socialization (and exchange of price information) with its competitors; "When the act of the agent is within the scope of his employment or his apparent authority, the corporation is held legally responsible for it, although what he did may be contrary to his actual instructions and may be unlawful.").

While the Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees, the critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in

misconduct to achieve business objectives. The Department has no formal guidelines for corporate compliance programs. The fundamental questions any prosecutor should ask are: "Is the corporation's compliance program well designed?" and "Does the corporation's compliance program work?" In answering these questions, the prosecutor should consider the comprehensiveness of the compliance program; the extent and pervasiveness of the criminal conduct; the number and level of the corporate employees involved; the seriousness, duration, and frequency of the misconduct; and any remedial actions taken by the corporation, including restitution, disciplinary action, and revisions to corporate compliance programs.⁶ Prosecutors should also consider the promptness of any disclosure of wrongdoing to the government and the corporation's cooperation in the government's investigation. In evaluating compliance programs, prosecutors may consider whether the corporation has established corporate governance mechanisms that can effectively detect and prevent misconduct. For example, do the corporation's directors exercise independent review over proposed corporate actions rather than unquestioningly ratifying officers' recommendations; are the directors provided with information sufficient to enable the exercise of independent judgment, are internal audit functions conducted at a level sufficient to ensure their independence and accuracy and have the directors established an information and reporting system in the organization reasonable designed to provide management and the board of directors with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law. *In re: Caremark*, 698 A.2d 959 (Del. Ct. Chan. 1996).

Prosecutors should therefore attempt to determine whether a corporation's compliance program is merely a "paper program" or whether it was designed and implemented in an effective manner. In addition, prosecutors should determine whether the corporation has provided for a staff sufficient to audit, document, analyze, and utilize the results of the corporation's compliance efforts. In addition, prosecutors should determine whether the corporation's employees are adequately informed about the compliance program and are convinced of the corporation's commitment to it. This will enable the prosecutor to make an informed decision as to whether the corporation has adopted and implemented a truly effective compliance program that, when consistent with other federal law enforcement policies, may result in a decision to charge only the corporation's employees and agents.

Compliance programs should be designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business. Many corporations operate in complex regulatory environments outside the normal experience of criminal prosecutors. Accordingly, prosecutors should consult with relevant federal and state agencies with the expertise to evaluate the adequacy of a program's design and implementation. For instance, state and federal banking, insurance, and medical boards, the Department of Defense, the Department of Health and Human Services, the Environmental Protection Agency, and the Securities and Exchange Commission have considerable experience with compliance programs and can be very helpful to a prosecutor in evaluating such programs. In addition, the Fraud Section of the Criminal Division, the Commercial Litigation Branch of the Civil Division, and the Environmental Crimes Section of the Environment and Natural Resources Division can assist U.S. Attorneys' Offices in finding the appropriate agency office and in providing copies of compliance programs that were developed in previous cases.

VIII. Charging a Corporation: Restitution and Remediation

A. General Principle: Although neither a corporation nor an individual target may avoid prosecution merely by paying a sum of money, a prosecutor may consider the corporation's willingness to make restitution and steps already taken to do so. A prosecutor may also consider other remedial actions, such as implementing an effective corporate compliance program, improving an existing compliance program, and disciplining wrongdoers, in determining whether to charge the corporation.

B. Comment: In determining whether or not a corporation should be prosecuted, a prosecutor may consider whether meaningful remedial measures have been taken, including employee discipline and full restitution.⁷ A corporation's response to misconduct says much about its willingness to ensure that such misconduct does not recur. Thus, corporations that fully recognize the seriousness of their misconduct and accept responsibility for it should be taking steps to implement the personnel, operational, and organizational changes necessary to establish an awareness among employees that criminal conduct will not be tolerated. Among the factors prosecutors should consider and weigh are whether the corporation appropriately disciplined the wrongdoers and disclosed information concerning their illegal conduct to the government.

Employee discipline is a difficult task for many corporations because of the human element involved and sometimes because of the seniority of the employees concerned. While corporations need to be fair to their employees, they must also be unequivocally committed, at all levels of the corporation, to the highest standards of

legal and ethical behavior. Effective internal discipline can be a powerful deterrent against improper behavior by a corporation's employees. In evaluating a corporation's response to wrongdoing, prosecutors may evaluate the willingness of the corporation to discipline culpable employees of all ranks and the adequacy of the discipline imposed. The prosecutor should be satisfied that the corporation's focus is on the integrity and credibility of its remedial and disciplinary measures rather than on the protection of the wrongdoers.

In addition to employee discipline, two other factors used in evaluating a corporation's remedial efforts are restitution and reform. As with natural persons, the decision whether or not to prosecute should not depend upon the target's ability to pay restitution. A corporation's efforts to pay restitution even in advance of any court order is, however, evidence of its "acceptance of responsibility" and, consistent with the practices and policies of the appropriate Division of the Department entrusted with enforcing specific criminal laws, may be considered in determining whether to bring criminal charges. Similarly, although the inadequacy of a corporate compliance program is a factor to consider when deciding whether to charge a corporation, that corporation's quick recognition of the flaws in the program and its efforts to improve the program are also factors to consider.

IX. Charging a Corporation: Collateral Consequences

A. General Principle: Prosecutors may consider the collateral consequences of a corporate criminal conviction in determining whether to charge the corporation with a criminal offense.

B. Comment: One of the factors in determining whether to charge a natural person or a corporation is whether the likely punishment is appropriate given the nature and seriousness of the crime. In the corporate context, prosecutors may take into account the possibly substantial consequences to a corporation's officers, directors, employees, and shareholders, many of whom may, depending on the size and nature (e.g., publicly vs. closely held) of the corporation and their role in its operations, have played no role in the criminal conduct, have been completely unaware of it, or have been wholly unable to prevent it. Prosecutors should also be aware of non-penal sanctions that may accompany a criminal charge, such as potential suspension or debarment from eligibility for government contracts or federal funded programs such as health care. Whether or not such non-penal sanctions are appropriate or required in a particular case is the responsibility of the relevant agency, a decision that will be made based on the applicable statutes, regulations, and policies.

Virtually every conviction of a corporation, like virtually every conviction of an individual, will have an impact on innocent third parties, and the mere existence of such an effect is not sufficient to preclude prosecution of the corporation. Therefore, in evaluating the severity of collateral consequences, various factors already discussed, such as the pervasiveness of the criminal conduct and the adequacy of the corporation's compliance programs, should be considered in determining the weight to be given to this factor. For instance, the balance may tip in favor of prosecuting corporations in situations where the scope of the misconduct in a case is widespread and sustained within a corporate division (or spread throughout pockets of the corporate organization). In such cases, the possible unfairness of visiting punishment for the corporation's crimes upon shareholders may be of much less concern where those shareholders have substantially profited, even unknowingly, from widespread or pervasive criminal activity. Similarly, where the top layers of the corporation's management or the shareholders of a closely-held corporation were engaged in or aware of the wrongdoing and the conduct at issue was accepted as a way of doing business for an extended period, debarment may be deemed not collateral, but a direct and entirely appropriate consequence of the corporation's wrongdoing.

The appropriateness of considering such collateral consequences and the weight to be given them may depend on the special policy concerns discussed in section III, *supra*.

X. Charging a Corporation: Non-Criminal Alternatives

A. General Principle: Although non-criminal alternatives to prosecution often exist, prosecutors may consider whether such sanctions would adequately deter, punish, and rehabilitate a corporation that has engaged in wrongful conduct. In evaluating the adequacy of non-criminal alternatives to prosecution, e.g., civil or regulatory enforcement actions, the prosecutor may consider all relevant factors, including:

1. the sanctions available under the alternative means of disposition;
2. the likelihood that an effective sanction will be imposed; and

3. the effect of non-criminal disposition on Federal law enforcement interests.

B. Comment: The primary goals of criminal law are deterrence, punishment, and rehabilitation. Non-criminal sanctions may not be an appropriate response to an egregious violation, a pattern of wrongdoing, or a history of non-criminal sanctions without proper remediation. In other cases, however, these goals may be satisfied without the necessity of instituting criminal proceedings. In determining whether federal criminal charges are appropriate, the prosecutor should consider the same factors (modified appropriately for the regulatory context) considered when determining whether to leave prosecution of a natural person to another jurisdiction or to seek non-criminal alternatives to prosecution. These factors include: the strength of the regulatory authority's interest; the regulatory authority's ability and willingness to take effective enforcement action; the probable sanction if the regulatory authority's enforcement action is upheld; and the effect of a non-criminal disposition on Federal law enforcement interests. See USAM §§ 9-27.240, 9-27.250.

XI. Charging a Corporation: Selecting Charges

A. General Principle: Once a prosecutor has decided to charge a corporation, the prosecutor should charge, or should recommend that the grand jury charge, the most serious offense that is consistent with the nature of the defendant's conduct and that is likely to result in a sustainable conviction.

B. Comment: Once the decision to charge is made, the same rules as govern charging natural persons apply. These rules require "a faithful and honest application of the Sentencing Guidelines" and an "individualized assessment of the extent to which particular charges fit the specific circumstances of the case, are consistent with the purposes of the Federal criminal code, and maximize the impact of Federal resources on crime." See USAM § 9-27.300. In making this determination, "it is appropriate that the attorney for the government consider, *inter alia*, such factors as the sentencing guideline range yielded by the charge, whether the penalty yielded by such sentencing range ... is proportional to the seriousness of the defendant's conduct, and whether the charge achieves such purposes of the criminal law as punishment, protection of the public, specific and general deterrence, and rehabilitation." See Attorney General's Memorandum, dated October 12, 1993.

XII. Plea Agreements with Corporations

A. General Principle: In negotiating plea agreements with corporations, prosecutors should seek a plea to the most serious, readily provable offense charged. In addition, the terms of the plea agreement should contain appropriate provisions to ensure punishment, deterrence, rehabilitation, and compliance with the plea agreement in the corporate context. Although special circumstances may mandate a different conclusion, prosecutors generally should not agree to accept a corporate guilty plea in exchange for non-prosecution or dismissal of charges against individual officers and employees.

B. Comment: Prosecutors may enter into plea agreements with corporations for the same reasons and under the same constraints as apply to plea agreements with natural persons. See USAM §§ 9-27.400-500. This means, *inter alia*, that the corporation should be required to plead guilty to the most serious, readily provable offense charged. As is the case with individuals, the attorney making this determination should do so "on the basis of an individualized assessment of the extent to which particular charges fit the specific circumstances of the case, are consistent with the purposes of the federal criminal code, and maximize the impact of federal resources on crime. In making this determination, the attorney for the government considers, *inter alia*, such factors as the sentencing guideline range yielded by the charge, whether the penalty yielded by such sentencing range ... is proportional to the seriousness of the defendant's conduct, and whether the charge achieves such purposes of the criminal law as punishment, protection of the public, specific and general deterrence, and rehabilitation." See Attorney General's Memorandum, dated October 12, 1993. In addition, any negotiated departures from the Sentencing Guidelines must be justifiable under the Guidelines and must be disclosed to the sentencing court. A corporation should be made to realize that pleading guilty to criminal charges constitutes an admission of guilt and not merely a resolution of an inconvenient distraction from its business. As with natural persons, pleas should be structured so that the corporation may not later "proclaim lack of culpability or even complete innocence." See USAM §§ 9-27.420(b)(4), 9-27.440, 9-27.500. Thus, for instance, there should be placed upon the record a sufficient factual basis for the plea to prevent later corporate assertions of innocence.

A corporate plea agreement should also contain provisions that recognize the nature of the corporate "person" and ensure that the principles of punishment, deterrence, and rehabilitation are met. In the corporate context, punishment and deterrence are generally accomplished by substantial fines, mandatory restitution, and

institution of appropriate compliance measures, including, if necessary, continued judicial oversight or the use of special masters. See USSG §§ 8B1.1, 8C2.1, *et seq.* In addition, where the corporation is a government contractor, permanent or temporary debarment may be appropriate. Where the corporation was engaged in government contracting fraud, a prosecutor may not negotiate away an agency's right to debar or to list the corporate defendant.

In negotiating a plea agreement, prosecutors should also consider the deterrent value of prosecutions of individuals within the corporation. Therefore, one factor that a prosecutor may consider in determining whether to enter into a plea agreement is whether the corporation is seeking immunity for its employees and officers or whether the corporation is willing to cooperate in the investigation of culpable individuals. Prosecutors should rarely negotiate away individual criminal liability in a corporate plea.

Rehabilitation, of course, requires that the corporation undertake to be law-abiding in the future. It is, therefore, appropriate to require the corporation, as a condition of probation, to implement a compliance program or to reform an existing one. As discussed above, prosecutors may consult with the appropriate state and federal agencies and components of the Justice Department to ensure that a proposed compliance program is adequate and meets industry standards and best practices. See section VII, *supra*.

In plea agreements in which the corporation agrees to cooperate, the prosecutor should ensure that the cooperation is complete and truthful. To do so, the prosecutor may request that the corporation waive attorney-client and work product protection, make employees and agents available for debriefing, disclose the results of its internal investigation, file appropriate certified financial statements, agree to governmental or third-party audits, and take whatever other steps are necessary to ensure that the full scope of the corporate wrongdoing is disclosed and that the responsible culprits are identified and, if appropriate, prosecuted. See generally section VIII, *supra*.

Footnotes:

1. While these guidelines refer to corporations, they apply to the consideration of the prosecution of all types of business organizations, including partnerships, sole proprietorships, government entities, and unincorporated associations.
2. In addition, the Sentencing Guidelines reward voluntary disclosure and cooperation with a reduction in the corporation's offense level. See USSG §8C2.5(g).
3. This waiver should ordinarily be limited to the factual internal investigation and any contemporaneous advice given to the corporation concerning the conduct at issue. Except in unusual circumstances, prosecutors should not seek a waiver with respect to communications and work product related to advice concerning the government's criminal investigation.
4. Some states require corporations to pay the legal fees of officers under investigation prior to a formal determination of their guilt. Obviously, a corporation's compliance with governing law should not be considered a failure to cooperate.
5. Although this case and *Basic Construction* are both antitrust cases, their reasoning applies to other criminal violations. In the *Hilton* case, for instance, the Ninth Circuit noted that Sherman Act violations are commercial offenses "usually motivated by a desire to enhance profits," thus, bringing the case within the normal rule that a "purpose to benefit the corporation is necessary to bring the agent's acts within the scope of his employment." 467 F.2d at 1006 & n.4. In addition, in *United States v. Automated Medical Laboratories*, 770 F.2d 399, 406 n.5 (4th Cir. 1985), the Fourth Circuit stated "that *Basic Construction* states a generally applicable rule on corporate criminal liability despite the fact that it addresses violations of the antitrust laws."
6. For a detailed review of these and other factors concerning corporate compliance programs, see United States Sentencing Commission, GUIDELINES MANUAL, §8A1.2, comment. (n.3(k)) (Nov. 1997). See also USSG §8C2.5(f).
7. For example, the Antitrust Division's amnesty policy requires that "[w]here possible, the corporation [make] restitution to injured parties...."